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42

Part 482 to End

Revised as of October 1, 2010

Public Health

Containing a codification of documents of general applicability and future effect

As of October 1, 2010

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Cite this Code: CFR

To cite the regulations in this volume use title, part and section number. Thus, 42 CFR 482.1 *refers to title 42, part 482, section 1.*

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Each volume of the Code is revised at least once each calendar year and issued on a quarterly basis approximately as follows:

Title 1 through Title 16.....as of January 1
Title 17 through Title 27.....as of April 1
Title 28 through Title 41.....as of July 1
Title 42 through Title 50.....as of October 1

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An index to the text of ''Title 3—The President'' is carried within that volume.

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A List of CFR Sections Affected (LSA) is published monthly, keyed to the revision dates of the 50 CFR titles.

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RAYMOND A. MOSLEY,
Director,
Office of the Federal Register.
October 1, 2010.

THIS TITLE

Title 42—PUBLIC HEALTH is composed of five volumes. The parts in these volumes are arranged in the following order: Parts 1–399, parts 400–413, parts 414–429, parts 430 to 481, and part 482 to end. The first volume (parts 1–399) contains current regulations issued under chapter I—Public Health Service (HHS). The second, third, and fourth volumes (parts 400–413, parts 414–429, and parts 430 to 481) include regulations issued under chapter IV—Centers for Medicare & Medicaid Services (HHS) and the fifth volume (part 482 to end) contains the remaining regulations in chapter IV and the regulations issued under chapter V by the Office of Inspector General-Health Care (HHS). The contents of these volumes represent all current regulations codified under this title of the CFR as of October 1, 2010.

The OMB control numbers for the Centers for Medicare & Medicaid Services appear in § 400.310 of chapter IV. For the convenience of the user, subpart C consisting of §§ 400.300–400.310 is reprinted in the Finding Aids section of the third, fourth and fifth volumes.

For this volume, Jonn V. Lilyea was Chief Editor. The Code of Federal Regulations publication program is under the direction of Michael L. White, assisted by Ann Worley.

Title 42—Public Health

(This book contains parts 482 to End)

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CHAPTER IV—CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

EDITORIAL NOTE: Nomenclature changes to chapter IV appear at 66 FR 39452, July 31, 2001; 67 FR 36540, May 24, 2002; and 69 FR 18803, Apr. 9, 2004.

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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.

[51 FR 22042, June 17, 1986, as amended at 53 FR 6648, Mar. 2, 1988]

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 accordance 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 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.

[51 FR 22042, June 17, 1986; 51 FR 27847, Aug. 4, 1986, as amended at 53 FR 6549, Mar. 1, 1988; 53 FR 18987, May 26, 1988; 56 FR 8852, Mar. 1, 1991; 56 FR 23022, May 20, 1991; 59 FR 46514, Sept. 8, 1994; 63 FR 20130, Apr. 23, 1998; 63 FR 33874, June 22, 1998; 68 FR 53262, Sept. 9, 2003]

§ 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.

(C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

(ii) *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 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 accordance 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 adolescents 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 seclusion for the management of violent or self-destructive behavior, a physician 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 hospital 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 monitored 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 requirements must be specified in hospital policy. At a minimum, physicians and other licensed independent practitioners authorized to order restraint or

seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint or seclusion.

(12) When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes 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 independent practitioner; or

(B) Registered nurse or physician assistant who has been trained in accordance with the requirements specified in paragraph (f) of this section.

(ii) To evaluate—

(A) The patient's immediate situation;

(B) The patient's reaction to the intervention;

(C) The patient's medical and behavioral condition; and

(D) The need to continue or terminate the restraint or seclusion.

(13) States are free to have requirements 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 registered nurse or physician assistant, the trained registered nurse or physician assistant must consult the attending physician or other licensed independent 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 simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient 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 patient.

(16) When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:

(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 behavior and the intervention used;

(iii) Alternatives or other less restrictive interventions attempted (as applicable);

(iv) The patient's condition or symptom(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.

[71 FR 71426, Dec. 8, 2006]

Subpart C—Basic Hospital Functions

§ 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 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.

[68 FR 3454, Jan. 24, 2003]

§ 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: 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.

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

(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.

(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 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.

(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.

(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.

[51 FR 22042, June 17, 1986, as amended at 59 FR 64152, Dec. 13, 1994; 71 FR 68694, Nov. 27, 2006; 72 FR 66933, Nov. 27, 2007]

§ 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.

(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.* 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.

(1) 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.

(2) 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 by hospital policy and in accordance with State law, and who is responsible for the care of the patient as specified under § 482.12(c).

(i) If verbal orders are used, they are to be used infrequently.

(ii) When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law.

(3) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the personnel must have special training for this duty.

(4) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

[51 FR 22042, June 17, 1986, as amended at 67 FR 61814, Oct. 2, 2002; 71 FR 68694, Nov. 27, 2006; 72 FR 66933, Nov. 27, 2007]

§ 482.24 Condition of participation: Medical record services.

The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.

(a) *Standard: Organization and staffing.* The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.

(b) *Standard: Form and retention of record.* The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentification and protects the security of all record entries.

(1) Medical records must be retained in their original or legally reproduced form for a period of at least 5 years.

(2) The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

(3) The hospital must have a procedure for ensuring the confidentiality of patient records. In-formation from or copies of records may be released only

to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas.

(c) *Standard: Content of record.* The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.

(1) All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.

(i) All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner, except as noted in paragraph (c)(1)(ii) of this section.

(ii) For the 5 year period following January 26, 2007, all orders, including verbal orders, must be dated, timed, and authenticated by the ordering practitioner or another practitioner who is responsible for the care of the patient as specified under § 482.12(c) and authorized to write orders by hospital policy in accordance with State law.

(iii) All verbal orders must be authenticated based upon Federal and State law. If there is no State law that designates a specific timeframe for the authentication of verbal orders, verbal orders must be authenticated within 48 hours.

(2) All records must document the following, as appropriate:

(i) Evidence of—

(A) A medical history and physical examination completed and documented 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 placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

(B) An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within 30 days before admission or registration. Documentation of the updated examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

(ii) Admitting diagnosis.

(iii) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.

(iv) Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.

(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

(vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.

(vii) Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care.

(viii) Final diagnosis with completion of medical records within 30 days following discharge.

[51 FR 22042, June 17, 1986, as amended at 71 FR 68694, Nov. 27, 2006; 72 FR 66933, Nov. 27, 2007]

§ 482.25 Condition of participation: Pharmaceutical services.

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

(a) *Standard: Pharmacy management and administration.* The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

(1) A full-time, part-time, or consulting pharmacist must be responsible

for developing, supervising, and coordinating all the activities of the pharmacy services.

(2) The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

(b) *Standard: Delivery of services.* In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

(1) All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.

(2)(i) All drugs and biologicals must be kept in a secure area, and locked when appropriate.

(ii) Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.

(iii) Only authorized personnel may have access to locked areas.

(3) Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

(4) When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.

(5) Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.

(6) Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital-wide quality assurance program.

(7) Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

(8) Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.

(9) A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986; 71 FR 68694, Nov. 27, 2006]

§ 482.26 Condition of participation: Radiologic services.

The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.

(a) *Standard: Radiologic services.* The hospital must maintain, or have available, radiologic services according to needs of the patients.

(b) *Standard: Safety for patients and personnel.* The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

(1) Proper safety precutions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

(2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.

(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

(c) *Standard: Personnel.* (1) A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret

only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

(d) *Standard: Records.* Records of radiologic services must be maintained.

(1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.

(2) The hospital must maintain the following for at least 5 years:

(i) Copies of reports and printouts.

(ii) Films, scans, and other image records, as appropriate.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.27 Condition of participation: Laboratory services.

The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with part 493 of this chapter.

(a) *Standard: Adequacy of laboratory services.* The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets requirements of part 493 of this chapter.

(1) Emergency laboratory services must be available 24 hours a day.

(2) A written description of services provided must be available to the medical staff.

(3) The laboratory must make provision for proper receipt and reporting of tissue specimens.

(4) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

(b) *Standard: Potentially infectious blood and blood components*—(1) *Potentially human immunodeficiency virus (HIV) infectious blood and blood components.* Potentially HIV infectious blood and blood components are prior collections from a donor—

(i) Who tested negative at the time of donation but tests reactive for evidence of HIV infection on a later donation;

(ii) Who tests positive on the supplemental (additional, more specific) test or other follow-up testing required by FDA; and

(iii) For whom the timing of seroconversion cannot be precisely estimated.

(2) *Potentially hepatitis C virus (HCV) infectious blood and blood components.* Potentially HCV infectious blood and blood components are the blood and blood components identified in 21 CFR 610.47.

(3) *Services furnished by an outside blood collecting establishment.* If a hospital regularly uses the services of an outside blood collecting establishment, it must have an agreement with the blood collecting establishment that governs the procurement, transfer, and availability of blood and blood components. The agreement must require that the blood collecting establishment notify the hospital—

(i) Within 3 calendar days if the blood collecting establishment supplied blood and blood components collected from a donor who tested negative at the time of donation but tests reactive for evidence of HIV or HCV infection on a later donation or who is determined to be at increased risk for transmitting HIV or HCV infection;

(ii) Within 45 days of the test, of the results of the supplemental (additional, more specific) test for HIV or HCV, as relevant, or other follow-up testing required by FDA; and

(iii) Within 3 calendar days after the blood collecting establishment supplied blood and blood components collected from an infectious donor, whenever records are available, as set forth at 21 CFR 610.48(b)(3).

(4) *Quarantine and disposition of blood and blood components pending completion of testing.* If the blood collecting establishment (either internal or under an agreement) notifies the hospital of the

reactive HIV or HCV screening test results, the hospital must determine the disposition of the blood or blood product and quarantine all blood and blood components from previous donations in inventory.

(i) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is negative, absent other informative test results, the hospital may release the blood and blood components from quarantine.

(ii) If the blood collecting establishment notifies the hospital that the result of the supplemental, (additional, more specific) test or other follow-up testing required by FDA is positive, the hospital must—

(A) Dispose of the blood and blood components; and

(B) Notify the transfusion recipients as set forth in paragraph (b)(6) of this section.

(iii) If the blood collecting establishment notifies the hospital that the result of the supplemental, (additional, more specific) test or other follow-up testing required by FDA is indeterminate, the hospital must destroy or label prior collections of blood or blood components held in quarantine as set forth at 21 CFR 610.46(b)(2), 610.47(b)(2), and 610.48(c)(2).

(5) *Recordkeeping by the hospital.* The hospital must maintain—

(i) Records of the source and disposition of all units of blood and blood components for at least 10 years from the date of disposition in a manner that permits prompt retrieval; and

(ii) A fully funded plan to transfer these records to another hospital or other entity if such hospital ceases operation for any reason.

(6) *Patient notification.* If the hospital has administered potentially HIV or HCV infectious blood or blood components (either directly through its own blood collecting establishment or under an agreement) or released such blood or blood components to another entity or individual, the hospital must take the following actions:

(i) Make reasonable attempts to notify the patient, or to notify the attending physician or the physician who ordered the blood or blood component and ask the physician to notify the patient, or other individual as permitted under paragraph (b)(10) of this section, that potentially HIV or HCV infectious blood or blood components were transfused to the patient and that there may be a need for HIV or HCV testing and counseling.

(ii) If the physician is unavailable or declines to make the notification, make reasonable attempts to give this notification to the patient, legal guardian, or relative.

(iii) Document in the patient's medical record the notification or attempts to give the required notification.

(7) *Timeframe for notification*—(i) *For donors tested on or after February 20, 2008.* For notifications resulting from donors tested on or after February 20, 2008 as set forth at 21 CFR 610.46 and 21 CFR 610.47 the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HIV or HCV infectious blood and blood components. The hospital must make reasonable attempts to give notification over a period of 12 weeks unless—

(A) The patient is located and notified; or

(B) The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification timeframe to exceed 12 weeks.

(ii) For donors tested before February 20, 2008. For notifications resulting from donors tested before February 20, 2008 as set forth at 21 CFR 610.48(b) and (c), the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HCV infectious blood and blood components. The hospital must make reasonable attempts to give notification and must complete the actions within 1 year of the date on which the hospital received notification from the outside blood collecting establishment.

(8) *Content of notification.* The notification must include the following information:

(i) A basic explanation of the need for HIV or HCV testing and counseling;

(ii) Enough oral or written information so that an informed decision can

be made about whether to obtain HIV or HCV testing and counseling; and

(iii) A list of programs or places where the person can obtain HIV or HCV testing and counseling, including any requirements or restrictions the program may impose.

(9) *Policies and procedures.* The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for the confidentiality of medical records and other patient information.

(10) *Notification to legal representative or relative.* If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. For possible HIV infectious transfusion recipients that are deceased, the physician or hospital must inform the deceased patient's legal representative or relative. If the patient is a minor, the parents or legal guardian must be notified.

(11) *Applicability.* HCV notification requirements resulting from donors tested before February 20, 2008 as set forth at 21 CFR 610.48 will expire on August 24, 2015.

(c) *General blood safety issues.* For lookback activities only related to new blood safety issues that are identified after August 24, 2007, hospitals must comply with FDA regulations as they pertain to blood safety issues in the following areas:

(1) Appropriate testing and quarantining of infectious blood and blood components.

(2) Notification and counseling of recipients that may have received infectious blood and blood components.

[57 FR 7136, Feb. 28, 1992, as amended at 61 FR 47433, Sept. 9, 1996; 72 FR 48573, Aug. 24, 2007]

§ 482.28 Condition of participation: Food and dietetic services.

The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this Condition of participation if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.

(a) *Standard: Organization.* (1) The hospital must have a full-time employee who—

(i) Serves as director of the food and dietetic service;

(ii) Is responsible for the daily management of the dietary services; and

(iii) Is qualified by experience or training.

(2) There must be a qualified dietitian, full-time, part-time, or on a consultant basis.

(3) There must be administrative and technical personnel competent in their respective duties.

(b) *Standard: Diets.* Menus must meet the needs of the patients.

(1) Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients.

(2) Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients.

(3) A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.

§ 482.30 Condition of participation: Utilization review.

The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.

(a) *Applicability.* The provisions of this section apply except in either of the following circumstances:

(1) A Utilization and Quality Control Quality Improvement Organization

(QIO) has assumed binding review for the hospital.

(2) CMS has determined that the UR procedures established by the State under title XIX of the Act are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under §§ 456.50 through 456.245 of this chapter.

(b) *Standard: Composition of utilization review committee.* A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners specified in § 482.12(c)(1).

(1) Except as specified in paragraphs (b) (2) and (3) of this section, the UR committee must be one of the following:

(i) A staff committee of the institution;

(ii) A group outside the institution—

(A) Established by the local medical society and some or all of the hospitals in the locality; or

(B) Established in a manner approved by CMS.

(2) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as specified in paragraph (b)(1)(ii) of this section.

(3) The committee's or group's reviews may not be conducted by any individual who—

(i) Has a direct financial interest (for example, an ownership interest) in that hospital; or

(ii) Was professionally involved in the care of the patient whose case is being reviewed.

(c) *Standard: Scope and frequency of review.* (1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of—

(i) Admissions to the institution;

(ii) The duration of stays; and

(iii) Professional services furnished, including drugs and biologicals.

(2) Review of admissions may be performed before, at, or after hospital admission.

(3) Except as specified in paragraph (e) of this section, reviews may be conducted on a sample basis.

(4) Hospitals that are paid for inpatient hospital services under the prospective payment system set forth in Part 412 of this chapter must conduct review of duration of stays and review of professional services as follows:

(i) For duration of stays, these hospitals need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in § 412.80(a)(1)(i) of this chapter; and

(ii) For professional services, these hospitals need review only cases that they reasonably assume to be outlier cases based on extraordinarily high costs, as described in § 412.80(a)(1)(ii) of this chapter.

(d) *Standard: Determination regarding admissions or continued stays.* (1) The determination that an admission or continued stay is not medically necessary—

(i) May be made by one member of the UR committee if the practitioner or practitioners responsible for the care of the patient, as specified of § 482.12(c), concur with the determination or fail to present their views when afforded the opportunity; and

(ii) Must be made by at least two members of the UR committee in all other cases.

(2) Before making a determination that an admission or continued stay is not medically necessary, the UR committee must consult the practitioner or practitioners responsible for the care of the patient, as specified in § 482.12(c), and afford the practitioner or practitioners the opportunity to present their views.

(3) If the committee decides that admission to or continued stay in the hospital is not medically necessary, written notification must be given, no later than 2 days after the determination, to the hospital, the patient, and the practitioner or practitioners responsible for the care of the patient, as specified in § 482.12(c);

(e) *Standard: Extended stay review.* (1) In hospitals that are not paid under the prospective payment system, the UR committee must make a periodic review, as specified in the UR plan, of

each current inpatient receiving hospital services during a continuous period of extended duration. The scheduling of the periodic reviews may—

(i) Be the same for all cases; or

(ii) Differ for different classes of cases.

(2) In hospitals paid under the prospective payment system, the UR committee must review all cases reasonably assumed by the hospital to be outlier cases because the extended length of stay exceeds the threshold criteria for the diagnosis, as described in § 412.80(a)(1)(i). The hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis.

(3) The UR committee must make the periodic review no later than 7 days after the day required in the UR plan.

(f) *Standard: Review of professional services*. The committee must review professional services provided, to determine medical necessity and to promote the most efficient use of available health facilities and services.

§ 482.41 Condition of participation: Physical environment.

The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

(a) *Standard: Buildings*. The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.

(1) There must be emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.

(2) There must be facilities for emergency gas and water supply.

(b) *Standard: Life safety from fire*. (1) Except as otherwise provided in this section—

(i) The hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to hospitals.

(2) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals.

(4) Beginning March 13, 2006, a hospital must be in compliance with Chapter 19.2.9, Emergency Lighting.

(5) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to hospitals.

(6) The hospital must have procedures for the proper routine storage and prompt disposal of trash.

(7) The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.

(8) The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.

(9) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a hospital may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269; and

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

(c) *Standard: Facilities.* The hospital must maintain adequate facilities for its services.

(1) Diagnostic and therapeutic facilities must be located for the safety of patients.

(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

(3) The extent and complexity of facilities must be determined by the services offered.

(4) There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

[51 FR 22042, June 17, 1986, as amended at 53 FR 11509, Apr. 7, 1988; 68 FR 1386, Jan. 10, 2003; 69 FR 49267, Aug. 11, 2004; 70 FR 15238, Mar. 25, 2005; 71 FR 55340, Sept. 22, 2006]

§ 482.42 Condition of participation: Infection control.

The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

(a) *Standard: Organization and policies.* A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases.

(1) The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

(2) The infection control officer or officers must maintain a log of incidents related to infections and communicable diseases.

(b) *Standard: Responsibilities of chief executive officer, medical staff, and director of nursing services.* The chief executive officer, the medical staff, and the director of nursing services must—

(1) Ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers; and

(2) Be responsible for the implementation of successful corrective action plans in affected problem areas.

§ 482.43 Condition of participation: Discharge planning.

The hospital must have in effect a discharge planning process that applies to all patients. The hospital's policies and procedures must be specified in writing.

(a) *Standard: Identification of patients in need of discharge planning.* The hospital must identify at an early stage of hospitalization all patients who are

likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.

(b) *Standard: Discharge planning evaluation.* (1) The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of this section, and to other patients upon the patient's request, the request of a person acting on the patient's behalf, or the request of the physician.

(2) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, the evaluation.

(3) The discharge planning evaluation must include an evaluation of the likelihood of a patient needing post- hospital services and of the availability of the services.

(4) The discharge planning evaluation must include an evaluation of the likelihood of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the hospital.

(5) The hospital personnel must complete the evaluation on a timely basis so that appropriate arrangements for post-hospital care are made before discharge, and to avoid unnecessary delays in discharge.

(6) The hospital must include the discharge planning evaluation in the patient's medical record for use in establishing an appropriate discharge plan and must discuss the results of the evaluation with the patient or individual acting on his or her behalf.

(c) *Standard: Discharge plan.* (1) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, a discharge plan if the discharge planning evaluation indicates a need for a discharge plan.

(2) In the absence of a finding by the hospital that a patient needs a discharge plan, the patient's physician may request a discharge plan. In such a case, the hospital must develop a discharge plan for the patient.

(3) The hospital must arrange for the initial implementation of the patient's discharge plan.

(4) The hospital must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.

(5) As needed, the patient and family members or interested persons must be counseled to prepare them for post-hospital care.

(6) The hospital must include in the discharge plan a list of HHAs or SNFs that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, in the geographic area requested by the patient. HHAs must request to be listed by the hospital as available.

(i) This list must only be presented to patients for whom home health care or post-hospital extended care services are indicated and appropriate as determined by the discharge planning evaluation.

(ii) For patients enrolled in managed care organizations, the hospital must indicate the availability of home health and posthospital extended care services through individuals and entities that have a contract with the managed care organizations.

(iii) The hospital must document in the patient's medical record that the list was presented to the patient or to the individual acting on the patient's behalf.

(7) The hospital, as part of the discharge planning process, must inform the patient or the patient's family of their freedom to choose among participating Medicare providers of posthospital care services and must, when possible, respect patient and family preferences when they are expressed. The hospital must not specify or otherwise limit the qualified providers that are available to the patient.

(8) The discharge plan must identify any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare. Financial interests that are disclosable under Medicare are determined in accordance with the provisions of Part 420, Subpart C, of this chapter.

(d) *Standard: Transfer or referral.* The hospital must transfer or refer patients, along with necessary medical

information, to appropriate facilities, agencies, or outpatient services, as needed, for followup or ancillary care.

(e) *Standard: Reassessment*. The hospital must reassess its discharge planning process on an on-going basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.

[59 FR 64152, Dec. 13, 1994, as amended at 69 FR 49268, Aug. 11, 2004]

§ 482.45 Condition of participation: Organ, tissue, and eye procurement.

(a) *Standard: Organ procurement responsibilities*. The hospital must have and implement written protocols that:

(1) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose;

(2) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

(3) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues, or eyes or to decline to donate. The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

(4) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

(5) Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

(b) *Standard: Organ transplantation responsibilities*. (1) A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274) and abide by its rules. The term ''rules of the OPTN'' means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.

(2) For purposes of these standards, the term ''organ'' means a human kidney, liver, heart, lung, or pancreas.

(3) If a hospital performs any type of transplants, it must provide organ-transplant-related data, as requested by the OPTN, the Scientific Registry, and the OPOs. The hospital must also provide such data directly to the Department when requested by the Secretary.

[63 FR 33875, June 22, 1998]

Subpart D—Optional Hospital Services

§ 482.51 Condition of participation: Surgical services.

If the hospital provides surgical services, the services must be well organized and provided in accordance with

acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(a) *Standard: Organization and staffing.* The organization of the surgical services must be appropriate to the scope of the services offered.

(1) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

(2) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as ''scrub nurses'' under the supervision of a registered nurse.

(3) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the surpervision of a qualified registered nurse who is immediately available to respond to emergencies.

(4) 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.

(b) *Standard: Delivery of service.* Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

(1) Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies:

(i) A medical history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration.

(ii) An updated examination of the patient, including any changes in the patient's condition, must be completed and documented within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration.

(2) A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.

(3) The following equipment must be available to the operating room suites: call-in-system, cardiac monitor, resuscitator, defibrillator, aspirator, and tracheotomy set.

(4) There must be adequate provisions for immediate post-operative care.

(5) The operating room register must be complete and up-to-date.

(6) An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.

[51 FR 22042, June 17, 1986, as amended at 72 FR 66933, Nov. 27, 2007]

§ 482.52 Condition of participation: Anesthesia services.

If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

(a) *Standard: Organization and staffing.* The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered only by—

(1) A qualified anesthesiologist;

(2) A doctor of medicine or osteopathy (other than an anesthesiologist);

(3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

(4) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter, who, unless exempted in accordance with paragraph (c)of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or

(5) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter, who is under the supervision of an anesthesiologist who is immediately available if needed.

(b) *Standard: Delivery of services.* Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the

delineation of preanesthesia and post anesthesia responsibilities. The policies must ensure that the following are provided for each patient:

(1) A preanesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, performed within 48 hours prior to surgery or a procedure requiring anesthesia services.

(2) An intraoperative anesthesia record.

(3) A postanesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, no later than 48 hours after surgery or a procedure requiring anesthesia services. The postanesthesia evaluation for anesthesia recovery must be completed in accordance with State law and with hospital policies and procedures that have been approved by the medical staff and that reflect current standards of anesthesia care.

(c) *Standard: State exemption*. (1) A hospital may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (a)(4) of this section, if the State in which the hospital is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[51 FR 22042, June 17, 1986 as amended at 57 FR 33900, July 31, 1992; 66 FR 56769, Nov. 13, 2001; 71 FR 68694, Nov. 27, 2006; 72 FR 66934, Nov. 27, 2007]

§ 482.53 Condition of participation: Nuclear medicine services.

If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and staffing*. The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.

(1) There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.

(2) The qualifications, training, functions, and responsibilities of nuclear medicine personnel must be specified by the service director and approved by the medical staff.

(b) *Standard: Delivery of service*. Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.

(1) In-house preparation of radiopharmaceuticals is by, or under, the direct supervision of an appropriately trained registered pharmacist or a doctor of medicine or osteopathy.

(2) There is proper storage and disposal of radioactive material.

(3) If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirement for laboratory services specified in § 482.27.

(c) *Standard: Facilities*. Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance. The equipment must be—

(1) Maintained in safe operating condition; and

(2) Inspected, tested, and calibrated at least annually by qualified personnel.

(d) *Standard: Records*. The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

(1) The hospital must maintain copies of nuclear medicine reports for at least 5 years.

(2) The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.

(3) The hospital must maintain records of the receipt and disposition of radiopharmaceuticals.

(4) Nuclear medicine services must be ordered only by practitioner whose scope of Federal or State licensure and whose defined staff privileges allow such referrals.

[51 FR 22042, June 17, 1986, as amended at 57 FR 7136, Feb. 28, 1992]

§ 482.54 Condition of participation: Outpatient services.

If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Organization.* Outpatient services must be appropriately organized and integrated with inpatient services.

(b) *Standard: Personnel.* The hospitals must—

(1) Assign an individual to be responsible for outpatient services; and

(2) Have appropriate professional and nonprofessional personnel available.

§ 482.55 Condition of participation: Emergency services.

The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and direction.* If emergency services are provided at the hospital—

(1) The services must be organized under the direction of a qualified member of the medical staff;

(2) The services must be integrated with other departments of the hospital;

(3) The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff.

(b) *Standard: Personnel.* (1) The emergency services must be supervised by a qualified member of the medical staff.

(2) There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

§ 482.56 Condition of participation: Rehabilitation services.

If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.

(a) *Standard: Organization and staffing.* The organization of the service must be appropriate to the scope of the services offered.

(1) The director of the services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(2) Physical therapy, occupational therapy, speech-language pathology or audiology services, if provided, must be provided by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants, speech-language pathologists, or audiologists as defined in part 484 of this chapter.

(b) *Standard: Delivery of services.* Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and State laws.

(1) All rehabilitation services orders must be documented in the patient's medical record in accordance with the requirements at § 482.24.

(2) The provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice and must also meet the requirements of § 409.17 of this chapter.

[51 FR 22042, June 17, 1986, as amended at 72 FR 66406, Nov. 27, 2007; 75 FR 50418, Aug. 16, 2010]

§ 482.57 Condition of participation: Respiratory care services.

The hospital must meet the needs of the patients in accordance with acceptable standards of practice. The following requirements apply if the hospital provides respiratory care service.

(a) *Standard: Organization and Staffing.* The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.

(1) There must be a director of respiratory care services who is a doctor

of medicine or osteopathy with the knowledge experience, and capabilities to supervise and administer the service properly. The director may serve on either a full-time or part-time basis.

(2) There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law.

(b) *Standard: Delivery of Services.* Services must be delivered in accordance with medical staff directives.

(1) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.

(2) If blood gases or other laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for laboratory services specified in § 482.27.

(3) Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and State laws.

(4) All respiratory care services orders must be documented in the patient's medical record in accordance with the requirements at § 482.24.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986, as amended at 57 FR 7136, Feb. 28, 1992; 75 FR 50418, Aug. 16, 2010]

Subpart E—Requirements for Specialty Hospitals

SOURCE: 72 FR 15273, Mar. 30, 2007, unless otherwise noted.

§ 482.60 Special provisions applying to psychiatric hospitals.

Psychiatric hospital must—

(a) Be primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons;

(b) Meet the conditions of participation specified in §§ 482.1 through 482.23 and §§ 482.25 through 482.57;

(c) Maintain clinical records on all patients, including records sufficient to permit CMS to determine the degree and intensity of treatment furnished to Medicare beneficiaries, as specified in § 482.61; and

(d) Meet the staffing requirements specified in § 482.62.

[72 FR 60788, Oct. 26, 2007]

§ 482.61 Condition of participation: Special medical record requirements for psychiatric hospitals.

The medical records maintained by a psychiatric hospital must permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution.

(a) *Standard: Development of assessment/diagnostic data.* Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized.

(1) The identification data must include the patient's legal status.

(2) A provisional or admitting diagnosis must be made on every patient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

(3) The reasons for admission must be clearly documented as stated by the patient and/or others significantly involved.

(4) The social service records, including reports of interviews with patients, family members, and others, must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.

(5) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.

(b) *Standard: Psychiatric evaluation.* Each patient must receive a psychiatric evaluation that must—

(1) Be completed within 60 hours of admission;

(2) Include a medical history;

(3) Contain a record of mental status;

(4) Note the onset of illness and the circumstances leading to admission;

(5) Describe attitudes and behavior;

(6) Estimate intellectual functioning, memory functioning, and orientation; and

(7) Include an inventory of the patient's assets in descriptive, not interpretative, fashion.

(c) *Standard: Treatment plan.* (1) Each patient must have an individual comprehensive treatment plan that must be based on an inventory of the patient's strengths and disabilities. The written plan must include—

(i) A substantiated diagnosis;

(ii) Short-term and long-range goals;

(iii) The specific treatment modalities utilized;

(iv) The responsibilities of each member of the treatment team; and

(v) Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

(2) The treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.

(d) *Standard: Recording progress.* Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the patient as specified in § 482.12(c), nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

(e) *Standard: Discharge planning and discharge summary.* The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the patient's hospitalization and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

[72 FR 60788, Oct. 26, 2007]

§ 482.62 Condition of participation: Special staff requirements for psychiatric hospitals.

The hospital must have adequate numbers of qualified professional and supportive staff to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures, and engage in discharge planning.

(a) *Standard: Personnel.* The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:

(1) Evaluate patients;

(2) Formulate written individualized, comprehensive treatment plans;

(3) Provide active treatment measures; and

(4) Engage in discharge planning.

(b) *Standard: Director of inpatient psychiatric services; medical staff.* Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program. The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.

(1) The clinical director, service chief, or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

(2) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

(c) *Standard: Availability of medical personnel.* Doctors of medicine or osteopathy and other appropriate professional personnel must be available to provide necessary medical and surgical diagnostic and treatment services. If medical and surgical diagnostic and treatment services are not available within the institution, the institution must have an agreement with an outside source of these services to ensure that they are immediately available or a satisfactory agreement must be established for transferring patients to a general hospital that participates in the Medicare program.

(d) *Standard: Nursing services.* The hospital must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each patient's active treatment program and to maintain progress notes on each patient.

(1) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill. The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.

(2) The staffing pattern must insure the availability of a registered professional nurse 24 hours each day. There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each patient's active treatment program.

(e) *Standard: Psychological services.* The hospital must provide or have available psychological services to meet the needs of the patients.

(f) *Standard: Social services.* There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services must be furnished in accordance with accepted standards of practice and established policies and procedures.

(1) The director of the social work department or service must have a master's degree from an accredited school of social work or must be qualified by education and experience in the social services needs of the mentally ill. If the director does not hold a masters degree in social work, at least one staff member must have this qualification.

(2) Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate, information with sources outside the hospital.

(g) *Standard: Therapeutic activities.* The hospital must provide a therapeutic activities program.

(1) The program must be appropriate to the needs and interests of patients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

(2) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each patient's active treatment program.

[72 FR 60788, Oct. 26, 2007]

§ 482.66 Special requirements for hospital providers of long-term care services ("swing-beds").

A hospital that has a Medicare provider agreement must meet the following requirements in order to be granted an approval from CMS to provide post-hospital extended care services, as specified in § 409.30 of this chapter, and be reimbursed as a swing-bed hospital, as specified in § 413.114 of this chapter:

(a) *Eligibility.* A hospital must meet the following eligibility requirements:

(1) The facility has fewer than 100 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units (for eligibility of hospitals with distinct parts electing the optional reimbursement method, see § 413.24(d)(5) of this chapter).

(2) The hospital is located in a rural area. This includes all areas not delineated as ''urbanized'' areas by the Census Bureau, based on the most recent census.

(3) The hospital does not have in effect a 24-hour nursing waiver granted under § 488.54(c) of this chapter.

(4) The hospital has not had a swing-bed approval terminated within the two years previous to application.

(b) *Skilled nursing facility services.* The facility is substantially in compliance with the following skilled nursing facility requirements contained in subpart B of part 483 of this chapter.

(1) Resident rights (§ 483.10 (b)(3), (b)(4), (b)(5), (b)(6), (d), (e), (h), (i), (j)(1)(vii), (j)(1)(viii), (l), and (m)).

(2) Admission, transfer, and discharge rights (§ 483.12 (a)(1), (a)(2), (a)(3), (a)(4), (a)(5), (a)(6), and (a)(7)).

(3) Resident behavior and facility practices (§ 483.13).

(4) Patient activities (§ 483.15(f)).

(5) Social services (§ 483.15(g)).

(6) Discharge planning (§ 483.20(e)).

(7) Specialized rehabilitative services (§ 483.45).

(8) Dental services (§ 483.55).

[72 FR 60788, Oct. 26, 2007]

§ 482.68 Special requirements for transplant centers.

A transplant center located within a hospital that has a Medicare provider agreement must meet the conditions of participation specified in §§ 482.72 through 482.104 in order to be granted approval from CMS to provide transplant services.

(a) Unless specified otherwise, the conditions of participation at §§ 482.72 through 482.104 apply to heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers.

(b) In addition to meeting the conditions of participation specified in §§ 482.72 through 482.104, a transplant center must also meet the conditions of participation specified in §§ 482.1 through 482.57.

§ 482.70 Definitions.

As used in this subpart, the following definitions apply:

Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof. As applied to transplant centers, examples of adverse events include (but are not limited to) serious medical complications or death caused by living donation; unintentional transplantation of organs of mismatched blood types; transplantation of organs to unintended recipients; and unintended transmission of infectious disease to a recipient.

End-Stage Renal Disease (ESRD) means that stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

ESRD Network means all Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

Heart-Lung transplant center means a transplant center that is located in a hospital with an existing Medicare-approved heart transplant center and an existing Medicare-approved lung center that performs combined heart-lung transplants.

Intestine transplant center means a Medicare-approved liver transplant center that performs intestine transplants, combined liver-intestine transplants, or multivisceral transplants.

Network organization means the administrative governing body to the network and liaison to the Federal government.

Pancreas transplant center means a Medicare-approved kidney transplant center that performs pancreas transplants alone or subsequent to a kidney transplant as well as kidney-pancreas transplants.

Transplant center means an organ-specific transplant program (as defined in this rule) within a transplant hospital (for example, a hospital's lung transplant program may also be referred to as the hospital's lung transplant center).

Transplant hospital means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

Transplant program means a component within a transplant hospital (as defined in this rule) that provides transplantation of a particular type of organ.

General Requirements for Transplant Centers

§ 482.72 Condition of participation: OPTN membership.

A transplant center must be located in a transplant hospital that is a member of and abides by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274). The term ''rules and requirements of the

OPTN'' means those rules and requirements approved by the Secretary pursuant to § 121.4 of this title. No hospital that provides transplantation services shall be deemed to be out of compliance with section 1138(a)(1)(B) of the Act or this section unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the transplant hospital from the OPTN and also has notified the transplant hospital in writing.

§ 482.74 Condition of participation: Notification to CMS.

(a) A transplant center must notify CMS immediately of any significant changes related to the center's transplant program or changes that could affect its compliance with the conditions of participation. Instances in which CMS should receive information for follow up, as appropriate, include, but are not limited to:

(1) Change in key staff members of the transplant team, such as a change in the individual the transplant center designated to the OPTN as the center's ''primary transplant surgeon'' or ''primary transplant physician;'

(2) A decrease in the center's number of transplants or survival rates that could result in the center being out of compliance with § 482.82;

(3) Termination of an agreement between the hospital in which the transplant center is located and an OPO for the recovery and receipt of organs as required by section 482.100; and

(4) Inactivation of the transplant center.

(b) Upon receiving notification of significant changes, CMS will follow up with the transplant center as appropriate, including (but not limited to):

(1) Requesting additional information;

(2) Analyzing the information; or

(3) Conducting an on-site review.

§ 482.76 Condition of participation: Pediatric Transplants.

A transplant center that seeks Medicare approval to provide transplantation services to pediatric patients must submit to CMS a request specifically for Medicare approval to perform pediatric transplants using the procedures described at § 488.61 of this chapter.

(a) Except as specified in paragraph (d) of this section, a center requesting Medicare approval to perform pediatric transplants must meet all the conditions of participation at §§ 482.72 through 482.74 and §§ 482.80 through 482.104 with respect to its pediatric patients.

(b) A center that performs 50 percent or more of its transplants in a 12-month period on adult patients must be approved to perform adult transplants in order to be approved to perform pediatric transplants.

(1) Loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, will result in loss of the center's approval to perform pediatric transplants.

(2) Loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, may trigger a review of the center's Medicare approval to perform adult transplants.

(c) A center that performs 50 percent or more of its transplants in a 12-month period on pediatric patients must be approved to perform pediatric transplants in order to be approved to perform adult transplants.

(1) Loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, will result in loss of the center's approval to perform adult transplants.

(2) Loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, may trigger a review of the center's Medicare approval to perform pediatric transplants.

(3) A center that performs 50 percent or more of its transplants on pediatric patients in a 12-month period is not required to meet the clinical experience requirements prior to its request for approval as a pediatric transplant center.

(d) Instead of meeting all conditions of participation at §§ 482.72 through 482.74 and §§ 482.80 through 482.104, a heart transplant center that wishes to provide transplantation services to pediatric heart patients may be approved to perform pediatric heart transplants

by meeting the Omnibus Budget Reconciliation Act of 1987 criteria in section 4009(b) (Pub. L. 100–203), as follows:

(1) The center's pediatric transplant program must be operated jointly by the hospital and another facility that is Medicare-approved;

(2) The unified program shares the same transplant surgeons and quality improvement program (including oversight committee, patient protocol, and patient selection criteria); and

(3) The center demonstrates to the satisfaction of the Secretary that it is able to provide the specialized facilities, services, and personnel that are required by pediatric heart transplant patients.

TRANSPLANT CENTER DATA SUBMISSION, CLINICAL EXPERIENCE, AND OUTCOME REQUIREMENTS

§ 482.80 Condition of participation: Data submission, clinical experience, and outcome requirements for initial approval of transplant centers.

Except as specified in paragraph (d) of this section, and § 488.61 of this chapter, transplant centers must meet all data submission, clinical experience, and outcome requirements to be granted initial approval by CMS.

(a) *Standard: Data submission.* No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of required data on all transplants (deceased and living donor) it has performed. Required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow-up, and living donor registration and follow-up.

(b) *Standard: Clinical experience.* To be considered for initial approval, an organ-specific transplant center must generally perform 10 transplants over a 12-month period.

(c) *Standard: Outcome requirements.* CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants, if applicable. Except for lung transplants, CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants.

(1) CMS will compare each transplant center's observed number of patient deaths and graft failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant using the data contained in the most recent Scientific Registry of Transplant Recipients (SRTR) center-specific report.

(2) The required number of transplants must have been performed during the time frame reported in the most recent SRTR center-specific report.

(3) CMS will not consider a center's patient and graft survival rates to be acceptable if:

(i) A center's observed patient survival rate or observed graft survival rate is lower than its expected patient survival rate or expected graft survival rate; and

(ii) All three of the following thresholds are crossed over:

(A) The one-sided p-value is less than 0.05,

(B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and

(C) The number of observed events divided by the number of expected events is greater than 1.5.

(d) *Exceptions.* (1) A heart-lung transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for heart-lung transplants performed at the center.

(2) An intestine transplant center is not required to comply with the outcome performance requirements in paragraph (c) of this section for intestine, combined liver-intestine or multivisceral transplants performed at the center.

(3) A pancreas transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for pancreas transplants performed at the center.

(4) A center that is requesting initial Medicare approval to perform pediatric transplants is not required to comply

with the clinical experience requirements in paragraph (b) of this section prior to its request for approval as a pediatric transplant center.

(5) A kidney transplant center that is not Medicare-approved on the effective date of this rule is required to perform at least 3 transplants over a 12-month period prior to its request for initial approval.

§ 482.82 Condition of participation: Data submission, clinical experience, and outcome requirements for re-approval of transplant centers.

Except as specified in paragraph (d) of this section, and § 488.61 of this chapter, transplant centers must meet all data submission, clinical experience, and outcome requirements in order to be re-approved.

(a) *Standard: Data submission.* No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of the required data submissions on all transplants (deceased and living donor) it has performed over the 3-year approval period. Required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow-up, and living donor registration and follow-up.

(b) *Standard: Clinical experience.* To be considered for re-approval, an organ-specific transplant center must generally perform an average of 10 transplants per year during the re-approval period.

(c) *Standard: Outcome requirements.* CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants if applicable. Except for lung transplants, CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants.

(1) CMS will compare each transplant center's observed number of patient deaths and graft failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant using data contained in the most recent SRTR center-specific report.

(2) The required number of transplants must have been performed during the time frame reported in the most recent SRTR center-specific report.

(3) CMS will not consider a center's patient and graft survival rates to be acceptable if:

(i) A center's observed patient survival rate or observed graft survival rate is lower than its expected patient survival rate and graft survival rate; and

(ii) All three of the following thresholds are crossed over:

(A) The one-sided p-value is less than 0.05,

(B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and

(C) The number of observed events divided by the number of expected events is greater than 1.5.

(d) *Exceptions.* (1) A heart-lung transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for heart-lung transplants performed at the center.

(2) An intestine transplant center is not required to comply with the outcome requirements in paragraph (c) of this section for intestine, combined liver-intestine, and multivisceral transplants performed at the center.

(3) A pancreas transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for pancreas transplants performed at the center.

(4) A center that is approved to perform pediatric transplants is not required to comply with the clinical experience requirements in paragraph (b) of this section to be re-approved.

TRANSPLANT CENTER PROCESS REQUIREMENTS

§ 482.90 Condition of participation: Patient and living donor selection.

The transplant center must use written patient selection criteria in determining a patient's suitability for placement on the waiting list or a patient's suitability for transplantation.

If a center performs living donor transplants, the center also must use written donor selection criteria in determining the suitability of candidates for donation.

(a) *Standard: Patient selection*. Patient selection criteria must ensure fair and non-discriminatory distribution of organs.

(1) Prior to placement on the center's waiting list, a prospective transplant candidate must receive a psychosocial evaluation, if possible.

(2) Before a transplant center places a transplant candidate on its waiting list, the candidate's medical record must contain documentation that the candidate's blood type has been determined.

(3) When a patient is placed on a center's waiting list or is selected to receive a transplant, the center must document in the patient's medical record the patient selection criteria used.

(4) A transplant center must provide a copy of its patient selection criteria to a transplant patient, or a dialysis facility, as requested by a patient or a dialysis facility.

(b) *Standard: Living donor selection*. The living donor selection criteria must be consistent with the general principles of medical ethics. Transplant centers must:

(1) Ensure that a prospective living donor receives a medical and psychosocial evaluation prior to donation,

(2) Document in the living donor's medical records the living donor's suitability for donation, and

(3) Document that the living donor has given informed consent, as required under § 482.102.

§ 482.92 Condition of participation: Organ recovery and receipt.

Transplant centers must have written protocols for validation of donor-recipient blood type and other vital data for the deceased organ recovery, organ receipt, and living donor organ transplantation processes. The transplanting surgeon at the transplant center is responsible for ensuring the medical suitability of donor organs for transplantation into the intended recipient.

(a) *Standard: Organ recovery*. When the identity of an intended transplant recipient is known and the transplant center sends a team to recover the organ(s), the transplant center's recovery team must review and compare the donor data with the recipient blood type and other vital data before organ recovery takes place.

(b) *Standard: Organ receipt*. After an organ arrives at a transplant center, prior to transplantation, the transplanting surgeon and another licensed health care professional must verify that the donor's blood type and other vital data are compatible with transplantation of the intended recipient

(c) *Standard: Living donor transplantation*. If a center performs living donor transplants, the transplanting surgeon and another licensed health care professional at the center must verify that the living donor's blood type and other vital data are compatible with transplantation of the intended recipient immediately before the removal of the donor organ(s) and, if applicable, prior to the removal of the recipient's organ(s).

§ 482.94 Condition of participation: Patient and living donor management.

Transplant centers must have written patient management policies for the transplant and discharge phases of transplantation. If a transplant center performs living donor transplants, the center also must have written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation.

(a) *Standard: Patient and living donor care*. The transplant center's patient and donor management policies must ensure that:

(1) Each transplant patient is under the care of a multidisciplinary patient care team coordinated by a physician throughout the transplant and discharge phases of transplantation; and

(2) If a center performs living donor transplants, each living donor is under the care of a multidisciplinary patient care team coordinated by a physician throughout the donor evaluation, donation, and discharge phases of donation.

(b) *Standard: Waiting list management*. Transplant centers must keep their

waiting lists up to date on an ongoing basis, including:

(1) Updating of waiting list patients' clinical information;

(2) Removing patients from the center's waiting list if a patient receives a transplant or dies, or if there is any other reason the patient should no longer be on a center's waiting list; and

(3) Notifying the OPTN no later than 24 hours after a patient's removal from the center's waiting list.

(c) *Standard: Patient records.* Transplant centers must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waiting list and who is admitted for organ transplantation.

(1) For each patient who receives an evaluation for placement on a center's waiting list, the center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) has been informed of his or her transplant status, including notification of:

(i) The patient's placement on the center's waiting list;

(ii) The center's decision not to place the patient on its waiting list; or

(iii) The center's inability to make a determination regarding the patient's placement on its waiting list because further clinical testing or documentation is needed.

(2) If a patient on the waiting list is removed from the waiting list for any reason other than death or transplantation, the transplant center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) was notified no later than 10 days after the date the patient was removed from the waiting list.

(3) In the case of patients admitted for organ transplants, transplant centers must maintain written records of:

(i) Multidisciplinary patient care planning during the transplant period; and

(ii) Multidisciplinary discharge planning for post-transplant care.

(d) *Standard: Social services.* The transplant center must make social services available, furnished by qualified social workers, to transplant patients, living donors, and their families. A qualified social worker is an individual who meets licensing requirements in the State in which he or she practices; and

(1) Completed a course of study with specialization in clinical practice and holds a master's degree from a graduate school of social work accredited by the Council on Social Work Education; or

(2) Is working as a social worker in a transplant center as of the effective date of this final rule and has served for at least 2 years as a social worker, 1 year of which was in a transplantation program, and has established a consultative relationship with a social worker who is qualified under (d)(1) of this paragraph.

(e) *Standard: Nutritional services.* Transplant centers must make nutritional assessments and diet counseling services, furnished by a qualified dietitian, available to all transplant patients and living donors. A qualified dietitian is an individual who meets practice requirements in the State in which he or she practices and is a registered dietitian with the Commission on Dietetic Registration.

§ 482.96 Condition of participation: Quality assessment and performance improvement (QAPI).

Transplant centers must develop, implement, and maintain a written, comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all transplantation services, including services provided under contract or arrangement.

(a) *Standard: Components of a QAPI program.* The transplant center's QAPI program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes. Outcome measures may include, but are not limited to, patient and donor selection criteria, accuracy of the waiting list in accordance with the OPTN waiting list requirements, accuracy of donor and recipient matching, patient and donor management, techniques for organ recovery, consent practices, patient education, patient satisfaction, and patient rights. The transplant center

must take actions that result in performance improvements and track performance to ensure that improvements are sustained.

(b) *Standard: Adverse events.* A transplant center must establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case.

(1) The policies must address, at a minimum, the process for the identification, reporting, analysis, and prevention of adverse events.

(2) The transplant center must conduct a thorough analysis of and document any adverse event and must utilize the analysis to effect changes in the transplant center's policies and practices to prevent repeat incidents.

§ 482.98 Condition of participation: Human resources.

The transplant center must ensure that all individuals who provide services and/or supervise services at the center, including individuals furnishing services under contract or arrangement, are qualified to provide or supervise such services.

(a) *Standard: Director of a transplant center.* The transplant center must be under the general supervision of a qualified transplant surgeon or a qualified physician-director. The director of a transplant center need not serve full-time and may also serve as a center's primary transplant surgeon or transplant physician in accordance with § 482.98(b). The director is responsible for planning, organizing, conducting, and directing the transplant center and must devote sufficient time to carry out these responsibilities, which include but are not limited to the following:

(1) Coordinating with the hospital in which the transplant center is located to ensure adequate training of nursing staff and clinical transplant coordinators in the care of transplant patients and living donors.

(2) Ensuring that tissue typing and organ procurement services are available.

(3) Ensuring that transplantation surgery is performed by, or under the direct supervision of, a qualified transplant surgeon in accordance with § 482.98(b).

(b) *Standard: Transplant surgeon and physician.* The transplant center must identify to the OPTN a primary transplant surgeon and a transplant physician with the appropriate training and experience to provide transplantation services, who are immediately available to provide transplantation services when an organ is offered for transplantation.

(1) The transplant surgeon is responsible for providing surgical services related to transplantation.

(2) The transplant physician is responsible for providing and coordinating transplantation care.

(c) *Standard: Clinical transplant coordinator.* The transplant center must have a clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pretransplant, transplant, and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation. The clinical transplant coordinator must be a registered nurse or clinician licensed by the State in which the clinical transplant coordinator practices, who has experience and knowledge of transplantation and living donation issues. The clinical transplant coordinator's responsibilities must include, but are not limited to, the following:

(1) Ensuring the coordination of the clinical aspects of transplant patient and living donor care; and

(2) Acting as a liaison between a kidney transplant center and dialysis facilities, as applicable.

(d) *Standard: Independent living donor advocate or living donor advocate team.* The transplant center that performs living donor transplantation must identify either an independent living donor advocate or an independent living donor advocate team to ensure protection of the rights of living donors and prospective living donors.

(1) The living donor advocate or living donor advocate team must not be involved in transplantation activities on a routine basis.

(2) The independent living donor advocate or living donor advocate team must demonstrate:

(i) Knowledge of living organ donation, transplantation, medical ethics, and informed consent; and

(ii) Understanding of the potential impact of family and other external pressures on the prospective living donor's decision whether to donate and the ability to discuss these issues with the donor.

(3) The independent living donor advocate or living donor advocate team is responsible for:

(i) Representing and advising the donor;

(ii) Protecting and promoting the interests of the donor; and

(iii) Respecting the donor's decision and ensuring that the donor's decision is informed and free from coercion.

(e) *Standard: Transplant team.* The transplant center must identify a multidisciplinary transplant team and describe the responsibilities of each member of the team. The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology.

(f) *Standard: Resource commitment.* The transplant center must demonstrate availability of expertise in internal medicine, surgery, anesthesiology, immunology, infectious disease control, pathology, radiology, blood banking, and patient education as related to the provision of transplantation services.

§482.100 Condition of participation: Organ procurement.

The transplant center must ensure that the hospital in which it operates has a written agreement for the receipt of organs with an OPO designated by the Secretary that identifies specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation.

§482.102 Condition of participation: Patient and living donor rights.

In addition to meeting the condition of participation ''Patients rights'' requirements at §482.13, the transplant center must protect and promote each transplant patient's and living donor's rights.

(a) *Standard: Informed consent for transplant patients.* Transplant centers must implement written transplant patient informed consent policies that inform each patient of:

(1) The evaluation process;

(2) The surgical procedure;

(3) Alternative treatments;

(4) Potential medical or psychosocial risks;

(5) National and transplant center-specific outcomes, from the most recent SRTR center-specific report, including (but not limited to) the transplant center's observed and expected 1-year patient and graft survival, national 1-year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center;

(6) Organ donor risk factors that could affect the success of the graft or the health of the patient, including, but not limited to, the donor's history, condition or age of the organs used, or the patient's potential risk of contracting the human immunodeficiency virus and other infectious diseases if the disease cannot be detected in an infected donor;

(7) His or her right to refuse transplantation; and

(8) The fact that if his or her transplant is not provided in a Medicare-approved transplant center it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid for under Medicare Part B.

(b) *Standard: Informed consent for living donors.* Transplant centers must implement written living donor informed consent policies that inform the prospective living donor of all aspects of, and potential outcomes from, living donation. Transplant centers must ensure that the prospective living donor is fully informed about the following:

(1) The fact that communication between the donor and the transplant center will remain confidential, in accordance with the requirements at 45 CFR parts 160 and 164.

(2) The evaluation process;

(3) The surgical procedure, including post-operative treatment;

(4) The availability of alternative treatments for the transplant recipient;

(5) The potential medical or psychosocial risks to the donor;

(6) The national and transplant center-specific outcomes for recipients, and the national and center-specific outcomes for living donors, as data are available;

(7) The possibility that future health problems related to the donation may not be covered by the donor's insurance and that the donor's ability to obtain health, disability, or life insurance may be affected;

(8) The donor's right to opt out of donation at any time during the donation process; and

(9) The fact that if a transplant is not provided in a Medicare-approved transplant center it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid for under Medicare Part B.

(c) *Standard: Notification to patients.* Transplant centers must notify patients placed on the center's waiting list of information about the center that could impact the patient's ability to receive a transplant should an organ become available, and what procedures are in place to ensure the availability of a transplant team.

(1) A transplant center served by a single transplant surgeon or physician must inform patients placed on the center's waiting list of:

(i) The potential unavailability of the transplant surgeon or physician; and

(ii) Whether the center has a mechanism to provide an alternate transplant surgeon or transplant physician.

(2) At least 30 days before a center's Medicare approval is terminated, whether voluntarily or involuntarily, the center must:

(i) Inform patients on the center's waiting list and provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list; and

(ii) Inform Medicare beneficiaries on the center's waiting list that Medicare will no longer pay for transplants performed at the center after the effective date of the center's termination of approval.

(3) As soon as possible prior to a transplant center's voluntary inactivation, the center must inform patients on the center's waiting list and, as directed by the Secretary, provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list.

§ 482.104 Condition of participation: Additional requirements for kidney transplant centers.

(a) *Standard: End stage renal disease (ESRD) services.* Kidney transplant centers must directly furnish transplantation and other medical and surgical specialty services required for the care of ESRD patients. A kidney transplant center must have written policies and procedures for ongoing communications with dialysis patients' local dialysis facilities.

(b) *Standard: Dialysis services.* Kidney transplant centers must furnish inpatient dialysis services directly or under arrangement.

(c) *Standard: Participation in network activities.* Kidney transplant centers must cooperate with the ESRD Network designated for their geographic area, in fulfilling the terms of the Network's current statement of work.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A [Reserved]

Subpart B—Requirements for Long Term Care Facilities

SOURCE: 54 FR 5359, Feb. 2, 1989, unless otherwise noted.

§ 483.1 Basis and scope.

(a) *Statutory basis.* (1) Sections 1819 (a), (b), (c), and (d) of the Act provide that—

(i) Skilled nursing facilities participating in Medicare must meet certain specified requirements; and

(ii) The Secretary may impose additional requirements (see section 1819(d)(4)(B)) if they are necessary for the health and safety of individuals to whom services are furnished in the facilities.

(2) Section 1861(l) of the Act requires the facility to have in effect a transfer agreement with a hospital.

(3) Sections 1919 (a), (b), (c), and (d) of the Act provide that nursing facilities participating in Medicaid must meet certain specific requirements.

(b) *Scope.* The provisions of this part contain the requirements that an institution must meet in order to qualify to participate as a SNF in the Medicare program, and as a nursing facility in the Medicaid program. They serve as the basis for survey activities for the purpose of determining whether a facility meets the requirements for participation in Medicare and Medicaid.

[56 FR 48867, Sept. 26, 1991, as amended at 57 FR 43924, Sept. 23, 1992; 60 FR 50443, Sept. 29, 1995]

§ 483.5 Definitions.

(a) *Facility defined.* For purposes of this subpart, *facility* means a skilled nursing facility (SNF) that meets the requirements of sections 1819(a), (b), (c), and (d) of the Act, or a nursing facility (NF) that meets the requirements of sections 1919(a), (b), (c), and (d) of the Act. ''Facility'' may include a distinct part of an institution (as defined in paragraph (b) of this section and specified in § 440.40 and § 440.155 of this chapter), but does not include an institution for the mentally retarded or persons with related conditions described in § 440.150 of this chapter. For Medicare and Medicaid purposes (including eligibility, coverage, certification, and payment), the ''facility'' is always the entity that participates in the program, whether that entity is comprised of all of, or a distinct part of, a larger institution. For Medicare, an SNF (*see* section 1819(a)(1) of the Act), and for Medicaid, an NF (*see* section 1919(a)(1) of the Act) may not be an institution for mental diseases as defined in § 435.1010 of this chapter.

(b) *Distinct part*—(1) *Definition.* A distinct part SNF or NF is physically distinguishable from the larger institution or institutional complex that houses it, meets the requirements of this paragraph and of paragraph (b)(2) of this section, and meets the applicable statutory requirements for SNFs or NFs in sections 1819 or 1919 of the Act, respectively. A distinct part SNF or NF may be comprised of one or more buildings or designated parts of buildings (that is, wings, wards, or floors) that are: In the same physical area immediately adjacent to the institution's main buildings; other areas and structures that are not strictly contiguous to the main buildings but are located within close proximity of the main buildings; and any other areas that CMS determines on an individual basis, to be part of the institution's campus. A distinct part must include all of the beds within the designated area, and cannot consist of a random collection of individual rooms or beds that are scattered throughout the physical plant. The term ''distinct part'' also includes a composite distinct part that meets the additional requirements of paragraph (c) of this section.

(2) *Requirements.* In addition to meeting the participation requirements for long-term care facilities set forth elsewhere in this subpart, a distinct part SNF or NF must meet all of the following requirements:

(i) The SNF or NF must be operated under common ownership and control (that is, common governance) by the institution of which it is a distinct part, as evidenced by the following:

(A) The SNF or NF is wholly owned by the institution of which it is a distinct part.

(B) The SNF or NF is subject to the by-laws and operating decisions of a common governing body.

(C) The institution of which the SNF or NF is a distinct part has final responsibility for the distinct part's administrative decisions and personnel policies, and final approval for the distinct part's personnel actions.

(D) The SNF or NF functions as an integral and subordinate part of the institution of which it is a distinct part, with significant common resource usage of buildings, equipment, personnel, and services.

(ii) The administrator of the SNF or NF reports to and is directly accountable to the management of the institution of which the SNF or NF is a distinct part.

(iii) The SNF or NF must have a designated medical director who is responsible for implementing care policies and coordinating medical care, and who is directly accountable to the management of the institution of which it is a distinct part.

(iv) The SNF or NF is financially integrated with the institution of which it is a distinct part, as evidenced by the sharing of income and expenses with that institution, and the reporting of its costs on that institution's cost report.

(v) A single institution can have a maximum of only one distinct part SNF and one distinct part NF.

(vi) (A) An institution cannot designate a distinct part SNF or NF, but instead must submit a written request with documentation that demonstrates it meets the criteria set forth above to CMS to determine if it may be considered a distinct part.

(B) The effective date of approval of a distinct part is the date that CMS determines all requirements (including enrollment with the fiscal intermediary (FI)) are met for approval, and cannot be made retroactive.

(C) The institution must request approval from CMS for all proposed changes in the number of beds in the approved distinct part.

(c) *Composite distinct part*—(1) *Definition*. A composite distinct part is a distinct part consisting of two or more noncontiguous components that are not located within the same campus, as defined in §413.65(a)(2) of this chapter.

(2) *Requirements*. In addition to meeting the requirements of paragraph (b) of this section, a composite distinct part must meet all of the following requirements:

(i) A SNF or NF that is a composite of more than one location will be treated as a single distinct part of the institution of which it is a distinct part. As such, the composite distinct part will have only one provider agreement and only one provider number.

(ii) If two or more institutions (each with a distinct part SNF or NF) undergo a change of ownership, CMS must approve the existing SNFs or NFs as meeting the requirements before they are considered a composite distinct part of a single institution. In making such a determination, CMS considers whether its approval or disapproval of a composite distinct part promotes the effective and efficient use of public monies without sacrificing the quality of care.

(iii) If there is a change of ownership of a composite distinct part SNF or NF, the assignment of the provider agreement to the new owner will apply to all of the approved locations that comprise the composite distinct part SNF or NF.

(iv) To ensure quality of care and quality of life for all residents, the various components of a composite distinct part must meet all of the requirements for participation independently in each location.

(d) *Common area*. Common areas are dining rooms, activity rooms, meeting rooms where residents are located on a regular basis, and other areas in the facility where residents may gather together with other residents, visitors, and staff.

(e) *Fully sprinklered*. A fully sprinklered long term care facility is one that has all areas sprinklered in accordance with National Fire Protection Association 13 ''Standard for the Installation of Sprinkler Systems'' without the use of waivers or the Fire Safety Evaluation System.

[68 FR 46071, Aug. 4, 2003, as amended at 71 FR 39229, July 12, 2006; 71 FR 55340, Sept. 22, 2006]

§ 483.10 Resident rights.

The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident, including each of the following rights:

(a) *Exercise of rights.* (1) The resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States.

(2) The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights.

(3) In the case of a resident adjudged incompetent under the laws of a State by a court of competent jurisdiction, the rights of the resident are exercised by the person appointed under State law to act on the resident's behalf.

(4) In the case of a resident who has not been adjudged incompetent by the State court, any legal-surrogate designated in accordance with State law may exercise the resident's rights to the extent provided by State law.

(b) *Notice of rights and services.* (1) The facility must inform the resident both orally and in writing in a language that the resident understands of his or her rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility. The facility must also provide the resident with the notice (if any) of the State developed under section 1919(e)(6) of the Act. Such notification must be made prior to or upon admission and during the resident's stay. Receipt of such information, and any amendments to it, must be acknowledged in writing;

(2) The resident or his or her legal representative has the right—

(i) Upon an oral or written request, to access all records pertaining to himself or herself including current clinical records within 24 hours (excluding weekends and holidays); and

(ii) After receipt of his or her records for inspection, to purchase at a cost not to exceed the community standard photocopies of the records or any portions of them upon request and 2 working days advance notice to the facility.

(3) The resident has the right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition;

(4) The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (8) of this section; and

(5) The facility must—

(i) Inform each resident who is entitled to Medicaid benefits, in writing, at the time of admission to the nursing facility or, when the resident becomes eligible for Medicaid of—

(A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged;

(B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and

(ii) Inform each resident when changes are made to the items and services specified in paragraphs (5)(i)(A) and (B) of this section.

(6) The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facility's per diem rate.

(7) The facility must furnish a written description of legal rights which includes—

(i) A description of the manner of protecting personal funds, under paragraph (c) of this section;

(ii) A description of the requirements and procedures for establishing eligibility for Medicaid, including the right to request an assessment under section 1924(c) which determines the extent of a couple's non-exempt resources at the time of institutionalization and attributes to the community spouse an equitable share of resources which cannot be considered available for payment toward the cost of the institutionalized spouse's medical care in his or her process of spending down to Medicaid eligibility levels;

(iii) A posting of names, addresses, and telephone numbers of all pertinent State client advocacy groups such as the State survey and certification agency, the State licensure office, the State ombudsman program, the protection and advocacy network, and the Medicaid fraud control unit; and

(iv) A statement that the resident may file a complaint with the State survey and certification agency concerning resident abuse, neglect, misappropriation of resident property in the facility, and non-compliance with the advance directives requirements.

(8) The facility must comply with the requirements specified in subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the individual's option, formulate an advance directive. This includes a written description of the facility's policies to implement advance directives and applicable State law. Facilities are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. If an adult individual is incapacitated at the time of admission and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, the facility may give advance directive information to the individual's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. The facility is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

(9) The facility must inform each resident of the name, specialty, and way of contacting the physician responsible for his or her care.

(10) The facility must prominently display in the facility written information, and provide to residents and applicants for admission oral and written information about how to apply for and use Medicare and Medicaid benefits, and how to receive refunds for previous payments covered by such benefits.

(11) *Notification of changes.* (i) A facility must immediately inform the resident; consult with the resident's physician; and if known, notify the resident's legal respresentative or an interested family member when there is—

(A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;

(B) A significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);

(C) A need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or

(D) A decision to transfer or discharge the resident from the facility as specified in § 483.12(a).

(ii) The facility must also promptly notify the resident and, if known, the resident's legal representative or interested family member when there is—

(A) A change in room or roommate assignment as specified in § 483.15(e)(2); or

(B) A change in resident rights under Federal or State law or regulations as specified in paragraph (b)(1) of this section.

(iii) The facility must record and periodically update the address and phone number of the resident's legal representative or interested family member.

(12) *Admission to a composite distinct part.* A facility that is a composite distinct part (as defined in § 483.5(c) of this subpart) must disclose in its admission agreement its physical configuration, including the various locations that comprise the composite distinct part, and must specify the policies that

apply to room changes between its different locations under § 483.12(a)(8).

(c) *Protection of resident funds.* (1) The resident has the right to manage his or her financial affairs, and the facility may not require residents to deposit their personal funds with the facility.

(2) *Management of personal funds.* Upon written authorization of a resident, the facility must hold, safeguard, manage, and account for the personal funds of the resident deposited with the facility, as specified in paragraphs (c)(3)–(8) of this section.

(3) *Deposit of funds.* (i) *Funds in excess of $50.* The facility must deposit any residents' personal funds in excess of $50 in an interest bearing account (or accounts) that is separate from any of the facility's operating accounts, and that credits all interest earned on resident's funds to that account. (In pooled accounts, there must be a separate accounting for each resident's share.)

(ii) *Funds less than $50.* The facility must maintain a resident's personal funds that do not exceed $50 in a noninterest bearing account, interest-bearing account, or petty cash fund.

(4) *Accounting and records.* The facility must establish and maintain a system that assures a full and complete and separate accounting, according to generally accepted accounting principles, of each resident's personal funds entrusted to the facility on the resident's behalf.

(i) The system must preclude any commingling of resident funds with facility funds or with the funds of any person other than another resident.

(ii) The individual financial record must be available through quarterly statements and on request to the resident or his or her legal representative.

(5) *Notice of certain balances.* The facility must notify each resident that receives Medicaid benefits—

(i) When the amount in the resident's account reaches $200 less than the SSI resource limit for one person, specified in section 1611(a)(3)(B) of the Act; and

(ii) That, if the amount in the account, in addition to the value of the resident's other nonexempt resources, reaches the SSI resource limit for one person, the resident may lose eligibility for Medicaid or SSI.

(6) *Conveyance upon death.* Upon the death of a resident with a personal fund deposited with the facility, the facility must convey within 30 days the resident's funds, and a final accounting of those funds, to the individual or probate jurisdiction administering the resident's estate.

(7) *Assurance of financial security.* The facility must purchase a surety bond, or otherwise provide assurance satisfactory to the Secretary, to assure the security of all personal funds of residents deposited with the facility.

(8) *Limitation on charges to personal funds.* The facility may not impose a charge against the personal funds of a resident for any item or service for which payment is made under Medicaid or Medicare (except for applicable deductible and coinsurance amounts). The facility may charge the resident for requested services that are more expensive than or in excess of covered services in accordance with § 489.32 of this chapter. (This does not affect the prohibition on facility charges for items and services for which Medicaid has paid. See § 447.15, which limits participation in the Medicaid program to providers who accept, as payment in full, Medicaid payment plus any deductible, coinsurance, or copayment required by the plan to be paid by the individual.)

(i) *Services included in Medicare or Medicaid payment.* During the course of a covered Medicare or Medicaid stay, facilities may not charge a resident for the following categories of items and services:

(A) Nursing services as required at § 483.30 of this subpart.

(B) Dietary services as required at § 483.35 of this subpart.

(C) An activities program as required at § 483.15(f) of this subpart.

(D) Room/bed maintenance services.

(E) Routine personal hygiene items and services as required to meet the needs of residents, including, but not limited to, hair hygiene supplies, comb, brush, bath soap, disinfecting soaps or specialized cleansing agents when indicated to treat special skin problems or to fight infection, razor, shaving cream, toothbrush, toothpaste, denture adhesive, denture cleaner, dental floss, moisturizing lotion, tissues,

cotton balls, cotton swabs, deodorant, incontinence care and supplies, sanitary napkins and related supplies, towels, washcloths, hospital gowns, over the counter drugs, hair and nail hygiene services, bathing, and basic personal laundry.

(F) Medically-related social services as required at § 483.15(g) of this subpart.

(ii) *Items and services that may be charged to residents' funds.* Listed below are general categories and examples of items and services that the facility may charge to residents' funds if they are requested by a resident, if the facility informs the resident that there will be a charge, and if payment is not made by Medicare or Medicaid:

(A) Telephone.

(B) Television/radio for personal use.

(C) Personal comfort items, including smoking materials, notions and novelties, and confections.

(D) Cosmetic and grooming items and services in excess of those for which payment is made under Medicaid or Medicare.

(E) Personal clothing.

(F) Personal reading matter.

(G) Gifts purchased on behalf of a resident.

(H) Flowers and plants.

(I) Social events and entertainment offered outside the scope of the activities program, provided under § 483.15(f) of this subpart.

(J) Noncovered special care services such as privately hired nurses or aides.

(K) Private room, except when therapeutically required (for example, isolation for infection control).

(L) Specially prepared or alternative food requested instead of the food generally prepared by the facility, as required by § 483.35 of this subpart.

(iii) *Requests for items and services.* (A) The facility must not charge a resident (or his or her representative) for any item or service not requested by the resident.

(B) The facility must not require a resident (or his or her representative) to request any item or service as a condition of admission or continued stay.

(C) The facility must inform the resident (or his or her representative) requesting an item or service for which a charge will be made that there will be a charge for the item or service and what the charge will be.

(d) *Free choice.* The resident has the right to—

(1) Choose a personal attending physician;

(2) Be fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident's well-being; and

(3) Unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, participate in planning care and treatment or changes in care and treatment.

(e) *Privacy and confidentiality.* The resident has the right to personal privacy and confidentiality of his or her personal and clinical records.

(1) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident;

(2) Except as provided in paragraph (e)(3) of this section, the resident may approve or refuse the release of personal and clinical records to any individual outside the facility;

(3) The resident's right to refuse release of personal and clinical records does not apply when—

(i) The resident is transferred to another health care institution; or

(ii) Record release is required by law.

(f) *Grievances.* A resident has the right to—

(1) Voice grievances without discrimination or reprisal. Such grievances include those with respect to treatment which has been furnished as well as that which has not been furnished; and

(2) Prompt efforts by the facility to resolve grievances the resident may have, including those with respect to the behavior of other residents.

(g) *Examination of survey results.* A resident has the right to—

(1) Examine the results of the most recent survey of the facility conducted by Federal or State surveyors and any plan of correction in effect with respect to the facility. The facility must make the results available for examination in a place readily accessible to

residents, and must post a notice of their availability; and

(2) Receive information from agencies acting as client advocates, and be afforded the opportunity to contact these agencies.

(h) *Work*. The resident has the right to—

(1) Refuse to perform services for the facility;

(2) Perform services for the facility, if he or she chooses, when—

(i) The facility has documented the need or desire for work in the plan of care;

(ii) The plan specifies the nature of the services performed and whether the services are voluntary or paid;

(iii) Compensation for paid services is at or above prevailing rates; and

(iv) The resident agrees to the work arrangement described in the plan of care.

(i) *Mail*. The resident has the right to privacy in written communications, including the right to—

(1) Send and promptly receive mail that is unopened; and

(2) Have access to stationery, postage, and writing implements at the resident's own expense.

(j) *Access and visitation rights*. (1) The resident has the right and the facility must provide immediate access to any resident by the following:

(i) Any representative of the Secretary;

(ii) Any representative of the State:

(iii) The resident's individual physician;

(iv) The State long term care ombudsman (established under section 307(a)(12) of the Older Americans Act of 1965);

(v) The agency responsible for the protection and advocacy system for developmentally disabled individuals (established under part C of the Developmental Disabilities Assistance and Bill of Rights Act);

(vi) The agency responsible for the protection and advocacy system for mentally ill individuals (established under the Protection and Advocacy for Mentally Ill Individuals Act);

(vii) Subject to the resident's right to deny or withdraw consent at any time, immediate family or other relatives of the resident; and

(viii) Subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, others who are visiting with the consent of the resident.

(2) The facility must provide reasonable access to any resident by any entity or individual that provides health, social, legal, or other services to the resident, subject to the resident's right to deny or withdraw consent at any time.

(3) The facility must allow representatives of the State Ombudsman, described in paragraph (j)(1)(iv) of this section, to examine a resident's clinical records with the permission of the resident or the resident's legal representative, and consistent with State law.

(k) *Telephone*. The resident has the right to have reasonable access to the use of a telephone where calls can be made without being overheard.

(l) *Personal property*. The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.

(m) *Married couples*. The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.

(n) *Self-Administration of Drugs*. An individual resident may self-administer drugs if the interdisciplinary team, as defined by § 483.20(d)(2)(ii), has determined that this practice is safe.

(o) *Refusal of certain transfers*. (1) An individual has the right to refuse a transfer to another room within the institution, if the purpose of the transfer is to relocate—

(i) A resident of a SNF from the distinct part of the institution that is a SNF to a part of the institution that is not a SNF, or

(ii) A resident of a NF from the distinct part of the institution that is a NF to a distinct part of the institution that is a SNF.

(2) A resident's exercise of the right to refuse transfer under paragraph (o)(1) of this section does not affect the

individual's eligibility or entitlement to Medicare or Medicaid benefits.

[56 FR 48867, Sept. 26, 1991, as amended at 57 FR 8202, Mar. 6, 1992; 57 FR 43924, Sept. 23, 1992; 57 FR 53587, Nov. 12, 1992; 60 FR 33293, June 27, 1995; 68 FR 46072, Aug. 4, 2003]

§ 483.12 Admission, transfer and discharge rights.

(a) Transfer and discharge—

(1) *Definition:* Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.

(2) *Transfer and discharge requirements.* The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless—

(i) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;

(ii) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility;

(iii) The safety of individuals in the facility is endangered;

(iv) The health of individuals in the facility would otherwise be endangered;

(v) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid; or

(vi) The facility ceases to operate.

(3) *Documentation.* When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (a)(2)(i) through (v) of this section, the resident's clinical record must be documented. The documentation must be made by—

(i) The resident's physician when transfer or discharge is necessary under paragraph (a)(2)(i) or paragraph (a)(2)(ii) of this section; and

(ii) A physician when transfer or discharge is necessary under paragraph (a)(2)(iv) of this section.

(4) *Notice before transfer.* Before a facility transfers or discharges a resident, the facility must—

(i) Notify the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand.

(ii) Record the reasons in the resident's clinical record; and

(iii) Include in the notice the items described in paragraph (a)(6) of this section.

(5) *Timing of the notice.* (i) Except when specified in paragraph (a)(5)(ii) of this section, the notice of transfer or discharge required under paragraph (a)(4) of this section must be made by the facility at least 30 days before the resident is transferred or discharged.

(ii) Notice may be made as soon as practicable before transfer or discharge when—

(A) the safety of individuals in the facility would be endangered under paragraph (a)(2)(iii) of this section;

(B) The health of individuals in the facility would be endangered, under paragraph (a)(2)(iv) of this section;

(C) The resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (a)(2)(ii) of this section;

(D) An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (a)(2)(i) of this section; or

(E) A resident has not resided in the facility for 30 days.

(6) *Contents of the notice.* The written notice specified in paragraph (a)(4) of this section must include the following:

(i) The reason for transfer or discharge;

(ii) The effective date of transfer or discharge;

(iii) The location to which the resident is transferred or discharged;

(iv) A statement that the resident has the right to appeal the action to the State;

(v) The name, address and telephone number of the State long term care ombudsman;

(vi) For nursing facility residents with developmental disabilities, the mailing address and telephone number

of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act; and

(vii) For nursing facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy of mentally ill individuals established under the Protection and Advocacy for Mentally Ill Individuals Act.

(7) *Orientation for transfer or discharge.* A facility must provide sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility.

(8) *Room changes in a composite distinct part.* Room changes in a facility that is a composite distinct part (as defined in § 483.5(c)) must be limited to moves within the particular building in which the resident resides, unless the resident voluntarily agrees to move to another of the composite distinct part's locations.

(b) *Notice of bed-hold policy and readmission*—(1) *Notice before transfer.* Before a nursing facility transfers a resident to a hospital or allows a resident to go on therapeutic leave, the nursing facility must provide written information to the resident and a family member or legal representative that specifies—

(i) The duration of the bed-hold policy under the State plan, if any, during which the resident is permitted to return and resume residence in the nursing facility; and

(ii) The nursing facility's policies regarding bed-hold periods, which must be consistent with paragraph (b)(3) of this section, permitting a resident to return.

(2) *Bed-hold notice upon transfer.* At the time of transfer of a resident for hospitalization or therapeutic leave, a nursing facility must provide to the resident and a family member or legal representative written notice which specifies the duration of the bed-hold policy described in paragraph (b)(1) of this section.

(3) *Permitting resident to return to facility.* A nursing facility must establish and follow a written policy under which a resident, whose hospitalization or therapeutic leave exceeds the bed-hold period under the State plan, is readmitted to the facility immediately upon the first availability of a bed in a semi-private room if the resident—

(i) Requires the services provided by the facility; and

(ii) Is eligible for Medicaid nursing facility services.

(4) *Readmission to a composite distinct part.* When the nursing facility to which a resident is readmitted is a composite distinct part (as defined in § 483.5(c) of this subpart), the resident must be permitted to return to an available bed in the particular location of the composite distinct part in which he or she resided previously. If a bed is not available in that location at the time of readmission, the resident must be given the option to return to that location upon the first availability of a bed there.

(c) *Equal access to quality care.* (1) A facility must establish and maintain identical policies and practices regarding transfer, discharge, and the provision of services under the State plan for all individuals regardless of source of payment;

(2) The facility may charge any amount for services furnished to non-Medicaid residents consistent with the notice requirement in § 483.10(b)(5)(i) and (b)(6) describing the charges; and

(3) The State is not required to offer additional services on behalf of a resident other than services provided in the State plan.

(d) *Admissions policy.* (1) The facility must—

(i) Not require residents or potential residents to waive their rights to Medicare or Medicaid; and

(ii) Not require oral or written assurance that residents or potential residents are not eligible for, or will not apply for, Medicare or Medicaid benefits.

(2) The facility must not require a third party guarantee of payment to the facility as a condition of admission or expedited admission, or continued stay in the facility. However, the facility may require an individual who has legal access to a resident's income or resources available to pay for facility

care to sign a contract, without incurring personal financial liability, to provide facility payment from the resident's income or resources.

(3) In the case of a person eligible for Medicaid, a nursing facility must not charge, solicit, accept, or receive, in addition to any amount otherwise required to be paid under the State plan, any gift, money, donation, or other consideration as a precondition of admission, expedited admission or continued stay in the facility. However,—

(i) A nursing facility may charge a resident who is eligible for Medicaid for items and services the resident has requested and received, and that are not specified in the State plan as included in the term ''nursing facility services'' so long as the facility gives proper notice of the availability and cost of these services to residents and does not condition the resident's admission or continued stay on the request for and receipt of such additional services; and

(ii) A nursing facility may solicit, accept, or receive a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to a Medicaid eligible resident or potential resident, but only to the extent that the contribution is not a condition of admission, expedited admission, or continued stay in the facility for a Medicaid eligible resident.

(4) States or political subdivisions may apply stricter admissions standards under State or local laws than are specified in this section, to prohibit discrimination against individuals entitled to Medicaid.

[56 FR 48869, Sept. 26, 1991, as amended at 57 FR 43924, Sept. 23, 1992; 68 FR 46072, Aug. 4, 2003]

§ 483.13 Resident behavior and facility practices.

(a) *Restraints.* The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms.

(b) *Abuse.* The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.

(c) *Staff treatment of residents.* The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.

(1) The facility must—

(i) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;

(ii) Not employ individuals who have been—

(A) Found guilty of abusing, neglecting, or mistreating residents by a court of law; or

(B) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property; and

(iii) Report any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff to the State nurse aide registry or licensing authorities.

(2) The facility must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency).

(3) The facility must have evidence that all alleged violations are thoroughly investigated, and must prevent further potential abuse while the investigation is in progress.

(4) The results of all investigations must be reported to the administrator or his designated representative and to other officials in accordance with State law (including to the State survey and certification agency) within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.

[56 FR 48870, Sept. 26, 1991, as amended at 57 FR 43924, Sept. 23, 1992]

§ 483.15 Quality of life.

A facility must care for its residents in a manner and in an environment

that promotes maintenance or enhancement of each resident's quality of life.

(a) *Dignity*. The facility must promote care for residents in a manner and in an environment that maintains or enhances each resident's dignity and respect in full recognition of his or her individuality.

(b) *Self-determination and participation*. The resident has the right to—

(1) Choose activities, schedules, and health care consistent with his or her interests, assessments, and plans of care;

(2) Interact with members of the community both inside and outside the facility; and

(3) Make choices about aspects of his or her life in the facility that are significant to the resident.

(c) *Participation in resident and family groups*. (1) A resident has the right to organize and participate in resident groups in the facility;

(2) A resident's family has the right to meet in the facility with the families of other residents in the facility;

(3) The facility must provide a resident or family group, if one exists, with private space;

(4) Staff or visitors may attend meetings at the group's invitation;

(5) The facility must provide a designated staff person responsible for providing assistance and responding to written requests that result from group meetings;

(6) When a resident or family group exists, the facility must listen to the views and act upon the grievances and recommendations of residents and families concerning proposed policy and operational decisions affecting resident care and life in the facility.

(d) *Participation in other activities*. A resident has the right to participate in social, religious, and community activities that do not interfere with the rights of other residents in the facility.

(e) *Accommodation of needs*. A resident has the right to—

(1) Reside and receive services in the facility with reasonable accommodation of individual needs and preferences, except when the health or safety of the individual or other residents would be endangered; and

(2) Receive notice before the resident's room or roommate in the facility is changed.

(f) *Activities*. (1) The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.

(2) The activities program must be directed by a qualified professional who—

(i) Is a qualified therapeutic recreation specialist or an activities professional who—

(A) Is licensed or registered, if applicable, by the State in which practicing; and

(B) Is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or

(ii) Has 2 years of experience in a social or recreational program within the last 5 years, 1 of which was full-time in a patient activities program in a health care setting; or

(iii) Is a qualified occupational therapist or occupational therapy assistant; or

(iv) Has completed a training course approved by the State.

(g) *Social Services*. (1) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

(2) A facility with more than 120 beds must employ a qualified social worker on a full-time basis.

(3) *Qualifications of social worker*. A qualified social worker is an individual with—

(i) A bachelor's degree in social work or a bachelor's degree in a human services field including but not limited to sociology, special education, rehabilitation counseling, and psychology; and

(ii) One year of supervised social work experience in a health care setting working directly with individuals.

(h) *Environment*. The facility must provide—

(1) A safe, clean, comfortable, and homelike environment, allowing the

resident to use his or her personal belongings to the extent possible;

(2) Housekeeping and maintenance services necessary to maintain a sanitary, orderly, and comfortable interior;

(3) Clean bed and bath linens that are in good condition;

(4) Private closet space in each resident room, as specified in § 483.70(d)(2)(iv) of this part;

(5) Adequate and comfortable lighting levels in all areas;

(6) Comfortable and safe temperature levels. Facilities initially certified after October 1, 1990 must maintain a temperature range of 71–81°F; and

(7) For the maintenance of comfortable sound levels.

[56 FR 48871, Sept. 26, 1991, as amended at 57 FR 43924, Sept. 23, 1992]

§ 483.20 Resident assessment.

The facility must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity.

(a) *Admission orders.* At the time each resident is admitted, the facility must have physician orders for the resident's immediate care.

(b) *Comprehensive assessments*—(1) *Resident assessment instrument.* A facility must make a comprehensive assessment of a resident's needs, using the resident assessment instrument (RAI) specified by the State. The assessment must include at least the following:

(i) Identification and demographic information.

(ii) Customary routine.

(iii) Cognitive patterns.

(iv) Communication.

(v) Vision.

(vi) Mood and behavior patterns.

(vii) Psychosocial well-being.

(viii) Physical functioning and structural problems.

(ix) Continence.

(x) Disease diagnoses and health conditions.

(xi) Dental and nutritional status.

(xii) Skin condition.

(xiii) Activity pursuit.

(xiv) Medications.

(xv) Special treatments and procedures.

(xvi) Discharge potential.

(xvii) Documentation of summary information regarding the additional assessment performed on the care areas triggered by the completion of the Minimum Data Set (MDS).

(xviii) Documentation of participation in assessment.

The assessment process must include direct observation and communication with the resident, as well as communication with licensed and nonlicensed direct care staff members on all shifts.

(2) *When required.* Subject to the timeframes prescribed in § 413.343(b) of this chapter, a facility must conduct a comprehensive assessment of a resident in accordance with the timeframes specified in paragraphs (b)(2) (i) through (iii) of this section. The timeframes prescribed in § 413.343(b) of this chapter do not apply to CAHs.

(i) Within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or mental condition. (For purposes of this section, ''readmission'' means a return to the facility following a temporary absence for hospitalization or for therapeutic leave.)

(ii) Within 14 calendar days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition. (For purposes of this section, a ''significant change'' means a major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status, and requires interdisciplinary review or revision of the care plan, or both.)

(iii) Not less often than once every 12 months.

(c) *Quarterly review assessment.* A facility must assess a resident using the quarterly review instrument specified by the State and approved by CMS not less frequently than once every 3 months.

(d) *Use.* A facility must maintain all resident assessments completed within the previous 15 months in the resident's active record and use the results of the assessments to develop, review,

and revise the resident's comprehensive plan f care.

(e) *Coordination*. A facility must coordinate assessments with the preadmission screening and resident review program under Medicaid in part 483, subpart C to the maximum extent practicable to avoid duplicative testing and effort.

(f) *Automated data processing requirement*—(1) *Encoding data*. Within 7 days after a facility completes a resident's assessment, a facility must encode the following information for each resident in the facility:

(i) Admission assessment.

(ii) Annual assessment updates.

(iii) Significant change in status assessments.

(iv) Quarterly review assessments.

(v) A subset of items upon a resident's transfer, reentry, discharge, and death.

(vi) Background (face-sheet) information, if there is no admission assessment.

(2) *Transmitting data*. Within 7 days after a facility completes a resident's assessment, a facility must be capable of transmitting to the CMS System information for each resident contained in the MDS in a format that conforms to standard record layouts and data dictionaries, and that passes standardized edits defined by CMS and the State.

(3) *Transmittal requirements*. Within 14 days after a facility completes a resident's assessment, a facility must electronically transmit encoded, accurate, and complete MDS data to the CMS System, including the following:

(i) Admission assessment.

(ii) Annual assessment.

(iii) Significant change in status assessment.

(iv) Significant correction of prior full assessment.

(v) Significant correction of prior quarterly assessment.

(vi) Quarterly review.

(vii) A subset of items upon a resident's transfer, reentry, discharge, and death.

(viii) Background (face-sheet) information, for an initial transmission of MDS data on a resident that does not have an admission assessment.

(4) *Data format*. The facility must transmit data in the format specified by CMS or, for a State which has an alternate RAI approved by CMS, in the format specified by the State and approved by CMS.

(5) *Resident-identifiable information*. (i) A facility may not release information that is resident-identifiable to the public.

(ii) The facility may release information that is resident-identifiable to an agent only in accordance with a contract under which the agent agrees not to use or disclose the information except to the extent the facility itself is permitted to do so.

(g) *Accuracy of assessments*. The assessment must accurately reflect the resident's status.

(h) *Coordination*. A registered nurse must conduct or coordinate each assessment with the appropriate participation of health professionals.

(i) *Certification*. (1) A registered nurse must sign and certify that the assessment is completed.

(2) Each individual who completes a portion of the assessment must sign and certify the accuracy of that portion of the assessment.

(j) *Penalty for falsification*. (1) Under Medicare and Medicaid, an individual who willfully and knowingly—

(i) Certifies a material and false statement in a resident assessment is subject to a civil money penalty of not more than $1,000 for each assessment; or

(ii) Causes another individual to certify a material and false statement in a resident assessment is subject to a civil money penalty of not more than $5,000 for each assessment.

(2) Clinical disagreement does not constitute a material and false statement.

(k) *Comprehensive care plans*. (1) The facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment. The care plan must describe the following—

(i) The services that are to be furnished to attain or maintain the resident's highest practicable physical,

mental, and psychosocial well-being as required under § 483.25; and

(ii) Any services that would otherwise be required under § 483.25 but are not provided due to the resident's exercise of rights under § 483.10, including the right to refuse treatment under § 483.10(b)(4).

(2) A comprehensive care plan must be—

(i) Developed within 7 days after completion of the comprehensive assessment;

(ii) Prepared by an interdisciplinary team, that includes the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and

(iii) Periodically reviewed and revised by a team of qualified persons after each assessment.

(3) The services provided or arranged by the facility must—

(i) Meet professional standards of quality; and

(ii) Be provided by qualified persons in accordance with each resident's written plan of care.

(l) *Discharge summary*. When the facility anticipates discharge a resident must have a discharge summary that includes—

(1) A recapitulation of the resident's stay;

(2) A final summary of the resident's status to include items in paragraph (b)(2) of this section, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or legal representative; and

(3) A post-discharge plan of care that is developed with the participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.

(m) *Preadmission screening for mentally ill individuals and individuals with mental retardation*. (1) A nursing facility must not admit, on or after January 1, 1989, any new resident with—

(i) Mental illness as defined in paragraph (f)(2)(i) of this section, unless the State mental health authority has determined, based on an independent physical and mental evaluation performed by a person or entity other than the State mental health authority, prior to admission,

(A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and

(B) If the individual requires such level of services, whether the individual requires specialized services; or

(ii) Mental retardation, as defined in paragraph (f)(2)(ii) of this section, unless the State mental retardation or developmental disability authority has determined prior to admission—

(A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and

(B) If the individual requires such level of services, whether the individual requires specialized services for mental retardation.

(2) *Definition*. For purposes of this section—

(i) An individual is considered to have *mental illness* if the individual has a serious mental illness as defined in § 483.102(b)(1).

(ii) An individual is considered to be *mentally retarded* if the individual is mentally retarded as defined in § 483.102(b)(3) or is a person with a related condition as described in 42 CFR 435.1010 of this chapter.

[56 FR 48871, Sept. 26, 1991, as amended at 57 FR 43924, Sept. 23, 1992; 62 FR 67211, Dec. 23, 1997; 63 FR 53307, Oct. 5, 1998; 64 FR 41543, July 30, 1999; 68 FR 46072, Aug. 4, 2003; 71 FR 39229, July 12, 2006; 74 FR 40363, Aug.11, 2009]

§ 483.25 Quality of care.

Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

(a) *Activities of daily living*. Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident's abilities in activities of daily living do not diminish unless

circumstances of the individual's clinical condition demonstrate that diminution was unavoidable. This includes the resident's ability to—

(i) Bathe, dress, and groom;

(ii) Transfer and ambulate;

(iii) Toilet;

(iv) Eat; and

(v) Use speech, language, or other functional communication systems.

(2) A resident is given the appropriate treatment and services to maintain or improve his or her abilities specified in paragraph (a)(1) of this section; and

(3) A resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene.

(b) *Vision and hearing*. To ensure that residents receive proper treatment and assistive devices to maintain vision and hearing abilities, the facility must, if necessary, assist the resident—

(1) In making appointments, and

(2) By arranging for transportation to and from the office of a practitioner specializing in the treatment of vision or hearing impairment or the office of a professional specializing in the provision of vision or hearing assistive devices.

(c) *Pressure sores*. Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and

(2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

(d) *Urinary Incontinence*. Based on the resident's comprehensive assessment, the facility must ensure that—

(1) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary; and

(2) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

(e) *Range of motion*. Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident who enters the facility without a limited range of motion does not experience reduction in range of motion unless the resident's clinical condition demonstrates that a reduction in range of motion is unavoidable; and

(2) A resident with a limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion.

(f) *Mental and Psychosocial functioning*. Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident who displays mental or psychosocial adjustment difficulty, receives appropriate treatment and services to correct the assessed problem, and

(2) A resident whose assessment did not reveal a mental or psychosocial adjustment difficulty does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that such a pattern was unavoidable.

(g) *Naso-gastric tubes*. Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident who has been able to eat enough alone or with assistance is not fed by naso-gastric tube unless the resident's clinical condition demonstrates that use of a naso-gastric tube was unavoidable; and

(2) A resident who is fed by a naso-gastric or gastrostomy tube receives the appropriate treatment and services to prevent aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers and to restore, if possible, normal eating skills.

(h) *Accidents*. The facility must ensure that—

(1) The resident environment remains as free of accident hazards as is possible; and

(2) Each resident receives adequate supervision and assistance devices to prevent accidents.

(i) *Nutrition.* Based on a resident's comprehensive assessment, the facility must ensure that a resident—

(1) Maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible; and

(2) Receives a therapeutic diet when there is a nutritional problem.

(j) *Hydration.* The facility must provide each resident with sufficient fluid intake to maintain proper hydration and health.

(k) *Special needs.* The facility must ensure that residents receive proper treatment and care for the following special services:

(1) Injections;

(2) Parenteral and enteral fluids;

(3) Colostomy, ureterostomy, or ileostomy care;

(4) Tracheostomy care;

(5) Tracheal suctioning;

(6) Respiratory care;

(7) Foot care; and

(8) Prostheses.

(l) *Unnecessary drugs*—(1) *General.* Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

(i) In excessive dose (including duplicate drug therapy); or

(ii) For excessive duration; or

(iii) Without adequate monitoring; or

(iv) Without adequate indications for its use; or

(v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or

(vi) Any combinations of the reasons above.

(2) *Antipsychotic Drugs.* Based on a comprehensive assessment of a resident, the facility must ensure that—

(i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and

(ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

(m) *Medication Errors.* The facility must ensure that—

(1) It is free of medication error rates of five percent or greater; and

(2) Residents are free of any significant medication errors.

(n) *Influenza and pneumococcal immunizations*—(1) *Influenza.* The facility must develop policies and procedures that ensure that—

(i) Before offering the influenza immunization, each resident or the resident's legal representative receives education regarding the benefits and potential side effects of the immunization;

(ii) Each resident is offered an influenza immunization October 1 through March 31 annually, unless the immunization is medically contraindicated or the resident has already been immunized during this time period;

(iii) The resident or the resident's legal representative has the opportunity to refuse immunization; and

(iv) The resident's medical record includes documentation that indicates, at a minimum, the following:

(A) That the resident or resident's legal representative was provided education regarding the benefits and potential side effects of influenza immunization; and

(B) That the resident either received the influenza immunization or did not receive the influenza immunization due to medical contraindications or refusal.

(2) *Pneumococcal disease.* The facility must develop policies and procedures that ensure that—

(i) Before offering the pneumococcal immunization, each resident or the resident's legal representative receives education regarding the benefits and potential side effects of the immunization;

(ii) Each resident is offered a pneumococcal immunization, unless the immunization is medically contraindicated or the resident has already been immunized;

(iii) The resident or the resident's legal representative has the opportunity to refuse immunization; and

(iv) The resident's medical record includes documentation that indicates, at a minimum, the following:

(A) That the resident or resident's legal representative was provided education regarding the benefits and potential side effects of pneumococcal immunization; and

(B) That the resident either received the pneumococcal immunization or did not receive the pneumococcal immunization due to medical contraindication or refusal.

(v) *Exception*. As an alternative, based on an assessment and practitioner recommendation, a second pneumococcal immunization may be given after 5 years following the first pneumococcal immunization, unless medically contraindicated or the resident or the resident's legal representative refuses the second immunization.

[56 FR 48873, Sept. 26, 1991, as amended at 57 FR 43925, Sept. 23, 1992; 70 FR 58851, Oct. 7, 2005]

§ 483.30 Nursing services.

The facility must have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care.

(a) *Sufficient staff*. (1) The facility must provide services by sufficient numbers of each of the following types of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans:

(i) Except when waived under paragraph (c) of this section, licensed nurses; and

(ii) Other nursing personnel.

(2) Except when waived under paragraph (c) of this section, the facility must designate a licensed nurse to serve as a charge nurse on each tour of duty.

(b) *Registered nurse*. (1) Except when waived under paragraph (c) or (d) of this section, the facility must use the services of a registered nurse for at least 8 consecutive hours a day, 7 days a week.

(2) Except when waived under paragraph (c) or (d) of this section, the facility must designate a registered nurse to serve as the director of nursing on a full time basis.

(3) The director of nursing may serve as a charge nurse only when the facility has an average daily occupancy of 60 or fewer residents.

(c) *Nursing facilities: Waiver of requirement to provide licensed nurses on a 24-hour basis*. To the extent that a facility is unable to meet the requirements of paragraphs (a)(2) and (b)(1) of this section, a State may waive such requirements with respect to the facility if—

(1) The facility demonstrates to the satisfaction of the State that the facility has been unable, despite diligent efforts (including offering wages at the community prevailing rate for nursing facilities), to recruit appropriate personnel;

(2) The State determines that a waiver of the requirement will not endanger the health or safety of individuals staying in the facility;

(3) The State finds that, for any periods in which licensed nursing services are not available, a registered nurse or a physician is obligated to respond immediately to telephone calls from the facility;

(4) A waiver granted under the conditions listed in paragraph (c) of this section is subject to annual State review;

(5) In granting or renewing a waiver, a facility may be required by the State to use other qualified, licensed personnel;

(6) The State agency granting a waiver of such requirements provides notice of the waiver to the State long term care ombudsman (established under section 307(a)(12) of the Older Americans Act of 1965) and the protection and advocacy system in the State for the mentally ill and mentally retarded; and

(7) The nursing facility that is granted such a waiver by a State notifies residents of the facility (or, where appropriate, the guardians or legal representatives of such residents) and members of their immediate families of the waiver.

(d) *SNFs: Waiver of the requirement to provide services of a registered nurse for more than 40 hours a week*. (1) The Secretary may waive the requirement that a SNF provide the services of a registered nurse for more than 40 hours a week, including a director of nursing specified in paragraph (b) of this section, if the Secretary finds that—

(i) The facility is located in a rural area and the supply of skilled nursing facility services in the area is not sufficient to meet the needs of individuals residing in the area;

(ii) The facility has one full-time registered nurse who is regularly on duty at the facility 40 hours a week; and

(iii) The facility either—

(A) Has only patients whose physicians have indicated (through physicians' orders or admission notes) that they do not require the services of a registered nurse or a physician for a 48-hours period, or

(B) Has made arrangements for a registered nurse or a physician to spend time at the facility, as determined necessary by the physician, to provide necessary skilled nursing services on days when the regular full-time registered nurse is not on duty;

(iv) The Secretary provides notice of the waiver to the State long term care ombudsman (established under section 307(a)(12) of the Older Americans Act of 1965) and the protection and advocacy system in the State for the mentally ill and mentally retarded; and

(v) The facility that is granted such a waiver notifies residents of the facility (or, where appropriate, the guardians or legal representatives of such residents) and members of their immediate families of the waiver.

(2) A waiver of the registered nurse requirement under paragraph (d)(1) of this section is subject to annual renewal by the Secretary.

(e) *Nurse staffing information*—(1) *Data requirements*. The facility must post the following information on a daily basis:

(i) Facility name.

(ii) The current date.

(iii) The total number and the actual hours worked by the following categories of licensed and unlicensed nursing staff directly responsible for resident care per shift:

(A) Registered nurses.

(B) Licensed practical nurses or licensed vocational nurses (as defined under State law).

(C) Certified nurse aides.

(iv) Resident census.

(2) *Posting requirements*. (i) The facility must post the nurse staffing data specified in paragraph (e)(1) of this section on a daily basis at the beginning of each shift.

(ii) Data must be posted as follows:

(A) Clear and readable format.

(B) In a prominent place readily accessible to residents and visitors.

(3) *Public access to posted nurse staffing data*. The facility must, upon oral or written request, make nurse staffing data available to the public for review at a cost not to exceed the community standard.

(4) *Facility data retention requirements*. The facility must maintain the posted daily nurse staffing data for a minimum of 18 months, or as required by State law, whichever is greater.

[56 FR 48873, Sept. 26, 1991, as amended at 57 FR 43925, Sept. 23, 1992; 70 FR 62073, Oct. 28, 2005]

§ 483.35 Dietary services.

The facility must provide each resident with a nourishing, palatable, well-balanced diet that meets the daily nutritional and special dietary needs of each resident.

(a) *Staffing*. The facility must employ a qualified dietitian either full-time, part-time, or on a consultant basis.

(1) If a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food service who receives frequently scheduled consultation from a qualified dietitian.

(2) A qualified dietitian is one who is qualified based upon either registration by the Commission on Dietetic Registration of the American Dietetic Association, or on the basis of education, training, or experience in identification of dietary needs, planning, and implementation of dietary programs.

(b) *Sufficient staff*. The facility must employ sufficient support personnel competent to carry out the functions of the dietary service.

(c) *Menus and nutritional adequacy*. Menus must—

(1) Meet the nutritional needs of residents in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences;

(2) Be prepared in advance; and

(3) Be followed.

(d) *Food.* Each resident receives and the facility provides—

(1) Food prepared by methods that conserve nutritive value, flavor, and appearance;

(2) Food that is palatable, attractive, and at the proper temperature;

(3) Food prepared in a form designed to meet individual needs; and

(4) Substitutes offered of similar nutritive value to residents who refuse food served.

(e) *Therapeutic diets.* Therapeutic diets must be prescribed by the attending physician.

(f) *Frequency of meals.* (1) Each resident receives and the facility provides at least three meals daily, at regular times comparable to normal mealtimes in the community.

(2) There must be no more than 14 hours between a substantial evening meal and breakfast the following day, except as provided in (4) below.

(3) The facility must offer snacks at bedtime daily.

(4) When a nourishing snack is provided at bedtime, up to 16 hours may elapse between a substantial evening meal and breakfast the following day if a resident group agrees to this meal span, and a nourishing snack is served.

(g) *Assistive devices.* The facility must provide special eating equipment and utensils for residents who need them.

(h) *Paid feeding assistants*—(1) *State-approved training course.* A facility may use a paid feeding assistant, as defined in § 488.301 of this chapter, if—

(i) The feeding assistant has successfully completed a State-approved training course that meets the requirements of § 483.160 before feeding residents; and

(ii) The use of feeding assistants is consistent with State law.

(2) *Supervision.* (i) A feeding assistant must work under the supervision of a registered nurse (RN) or licensed practical nurse (LPN).

(ii) In an emergency, a feeding assistant must call a supervisory nurse for help on the resident call system.

(3) *Resident selection criteria.* (i) A facility must ensure that a feeding assistant feeds only residents who have no complicated feeding problems.

(ii) Complicated feeding problems include, but are not limited to, difficulty swallowing, recurrent lung aspirations, and tube or parenteral/IV feedings.

(iii) The facility must base resident selection on the charge nurse's assessment and the resident's latest assessment and plan of care.

(i) *Sanitary conditions.* The facility must—

(1) Procure food from sources approved or considered satisfactory by Federal, State, or local authorities;

(2) Store, prepare, distribute, and serve food under sanitary conditions; and

(3) Dispose of garbage and refuse properly.

[56 FR 48874, Sept. 26, 1991, as amended at 68 FR 55539, Sept. 26, 2003]

§ 483.40 Physician services.

A physician must personally approve in writing a recommendation that an individual be admitted to a facility. Each resident must remain under the care of a physician.

(a) *Physician supervision.* The facility must ensure that—

(1) The medical care of each resident is supervised by a physician; and

(2) Another physician supervises the medical care of residents when their attending physician is unavailable.

(b) *Physician visits.* The physician must—

(1) Review the resident's total program of care, including medications and treatments, at each visit required by paragraph (c) of this section;

(2) Write, sign, and date progress notes at each visit; and

(3) Sign and date all orders with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved facility policy after an assessment for contraindications.

(c) *Frequency of physician visits.* (1) The resident must be seen by a physician at least once every 30 days for the first 90 days after admission, and at least once every 60 days thereafter.

(2) A physician visit is considered timely if it occurs not later than 10 days after the date the visit was required.

(3) Except as provided in paragraphs (c)(4) and (f) of this section, all required physician visits must be made by the physician personally.

(4) At the option of the physician, required visits in SNFs after the initial visit may alternate between personal visits by the physician and visits by a physician assistant, nurse practitioner, or clinical nurse specialist in accordance with paragraph (e) of this section.

(d) *Availability of physicians for emergency care.* The facility must provide or arrange for the provision of physician services 24 hours a day, in case of an emergency.

(e) *Physician delegation of tasks in SNFs.* (1) Except as specified in paragraph (e)(2) of this section, a physician may delegate tasks to a physician assistant, nurse practitioner, or clinical nurse specialist who—

(i) Meets the applicable definition in § 491.2 of this chapter or, in the case of a clinical nurse specialist, is licensed as such by the State;

(ii) Is acting within the scope of practice as defined by State law; and

(iii) Is under the supervision of the physician.

(2) A physician may not delegate a task when the regulations specify that the physician must perform it personally, or when the delegation is prohibited under State law or by the facility's own policies.

(f) *Performance of physician tasks in NFs.* At the option of the State, any required physician task in a NF (including tasks which the regulations specify must be performed personally by the physician) may also be satisfied when performed by a nurse practitioner, clinical nurse specialist, or physician assistant who is not an employee of the facility but who is working in collaboration with a physician.

[56 FR 48875, Sept. 26, 1991, as amended at 67 FR 61814, Oct. 2, 2002]

§ 483.45 Specialized rehabilitative services.

(a) *Provision of services.* If specialized rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, and mental health rehabilitative services for mental illness and mental retardation, are required in the resident's comprehensive plan of care, the facility must—

(1) Provide the required services; or

(2) Obtain the required services from an outside resource (in accordance with § 483.75(h) of this part) from a provider of specialized rehabilitative services.

(b) *Qualifications.* Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.

[56 FR 48875, Sept. 26, 1991, as amended at 57 FR 43925, Sept. 23, 1992]

§ 483.55 Dental services.

The facility must assist residents in obtaining routine and 24-hour emergency dental care.

(a) *Skilled nursing facilities.* A facility (1) Must provide or obtain from an outside resource, in accordance with § 483.75(h) of this part, routine and emergency dental services to meet the needs of each resident;

(2) May charge a Medicare resident an additional amount for routine and emergency dental services;

(3) Must if necessary, assist the resident—

(i) In making appointments; and

(ii) By arranging for transportation to and from the dentist's office; and

(4) Promptly refer residents with lost or damaged dentures to a dentist.

(b) *Nursing facilities.* The facility (1) Must provide or obtain from an outside resource, in accordance with § 483.75(h) of this part, the following dental services to meet the needs of each resident:

(i) Routine dental services (to the extent covered under the State plan); and

(ii) Emergency dental services;

(2) Must, if necessary, assist the resident—

(i) In making appointments; and

(ii) By arranging for transportation to and from the dentist's office; and

(3) Must promptly refer residents with lost or damaged dentures to a dentist.

[56 FR 48875, Sept. 26, 1991]

§ 483.60 Pharmacy services.

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in § 483.75(h) of this part. The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

(a) *Procedures.* A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

(b) *Service consultation.* The facility must employ or obtain the services of a licensed pharmacist who—

(1) Provides consultation on all aspects of the provision of pharmacy services in the facility;

(2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and

(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

(c) *Drug regimen review.* (1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

(2) The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.

(d) *Labeling of drugs and biologicals.* Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

(e) *Storage of drugs and biologicals.* (1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.

(2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

[56 FR 48875, Sept. 26, 1991, as amended at 57 FR 43925, Sept. 23, 1992]

§ 483.65 Infection control.

The facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection.

(a) *Infection control program.* The facility must establish an infection control program under which it—

(1) Investigates, controls, and prevents infections in the facility;

(2) Decides what procedures, such as isolation, should be applied to an individual resident; and

(3) Maintains a record of incidents and corrective actions related to infections.

(b) *Preventing spread of infection.* (1) When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident.

(2) The facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.

(3) The facility must require staff to wash their hands after each direct resident contact for which handwashing is indicated by accepted professional practice.

(c) *Linens.* Personnel must handle, store, process, and transport linens so as to prevent the spread of infection.

[56 FR 48876, Sept. 26, 1991, as amended at 57 FR 43925, Sept. 23, 1992]

§ 483.70 Physical environment.

The facility must be designed, constructed, equipped, and maintained to protect the health and safety of residents, personnel and the public.

(a) *Life safety from fire.* (1) Except as otherwise provided in this section—

(i) The facility must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the

CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to long-term care facilities.

(2) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety ode which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of the patients.

(3) The provisions of the Life safety Code do not apply in a State where CMS finds, in accordance with applicable provisions of sections 1819(d)(2)(B)(ii) and 1919(d)(2)(B)(ii) of the Act, that a fire and safety code imposed by State law adequately protects patients, residents and personnel in long term care facilities.

(4) Beginning March 13, 2006, a long-term care facility must be in compliance with Chapter 19.2.9, Emergency Lighting.

(5) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to long-term care facilities.

(6) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a long-term care facility may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269; and

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

(7) A long term care facility must:

(i) Install, at least, battery-operated single station smoke alarms in accordance with the manufacturer's recommendations in resident sleeping rooms and common areas.

(ii) Have a program for inspection, testing, maintenance, and battery replacement that conforms to the manufacturer's recommendations and that verifies correct operation of the smoke alarms.

(iii) Exception:

(A) The facility has system-based smoke detectors in patient rooms and common areas that are installed, tested, and maintained in accordance with NFPA 72, *National Fire Alarm Code*, for system-based smoke detectors; or

(B) The facility is fully sprinklered in accordance with NFPA 13, *Standard for the Installation of Sprinkler Systems*.

(8) A long term care facility must:

(i) Install an approved, supervised automatic sprinkler system in accordance with the 1999 edition of NFPA 13, *Standard for the Installation of Sprinkler Systems,* as incorporated by reference, throughout the building by August 13, 2013. The Director of the Office of the

Federal Register has approved the NFPA 13 1999 edition of the *Standard for the Installation of Sprinkler Systems*, issued July 22, 1999 for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269.

(ii) Test, inspect, and maintain an approved, supervised automatic sprinkler system in accordance with the 1998 edition of NFPA 25, *Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems*, as incorporated by reference. The Director of the Office of the Federal Register has approved the NFPA 25, *Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems*, 1998 edition, issued January 16, 1998 for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269.

(b) *Emergency power*. (1) An emergency electrical power system must supply power adequate at least for lighting all entrances and exits; equipment to maintain the fire detection, alarm, and extinguishing systems; and life support systems in the event the normal electrical supply is interrupted.

(2) When life support systems are used, the facility must provide emergency electrical power with an emergency generator (as defined in NFPA 99, Health Care Facilities) that is located on the premises.

(c) *Space and equipment*. The facility must—

(1) Provide sufficient space and equipment in dining, health services, recreation, and program areas to enable staff to provide residents with needed services as required by these standards and as identified in each resident's plan of care; and

(2) Maintain all essential mechanical, electrical, and patient care equipment in safe operating condition.

(d) *Resident rooms*. Resident rooms must be designed and equipped for adequate nursing care, comfort, and privacy of residents.

(1) Bedrooms must—

(i) Accommodate no more than four residents;

(ii) Measure at least 80 square feet per resident in multiple resident bedrooms, and at least 100 square feet in single resident rooms;

(iii) Have direct access to an exit corridor;

(iv) Be designed or equipped to assure full visual privacy for each resident;

(v) In facilities initially certified after March 31, 1992, except in private rooms, each bed must have ceiling suspended curtains, which extend around the bed to provide total visual privacy in combination with adjacent walls and curtains;

(vi) Have at least one window to the outside; and

(vii) Have a floor at or above grade level.

(2) The facility must provide each resident with—

(i) A separate bed of proper size and height for the convenience of the resident;

(ii) A clean, comfortable mattress;

(iii) Bedding appropriate to the weather and climate; and

(iv) Functional furniture appropriate to the resident's needs, and individual closet space in the resident's bedroom with clothes racks and shelves accessible to the resident.

(3) CMS, or in the case of a nursing facility the survey agency, may permit variations in requirements specified in paragraphs (d)(1) (i) and (ii) of this section relating to rooms in individual

cases when the facility demonstrates in writing that the variations—

(i) Are in accordance with the special needs of the residents; and

(ii) Will not adversely affect residents' health and safety.

(e) *Toilet facilities.* Each resident room must be equipped with or located near toilet and bathing facilities.

(f) *Resident call system.* The nurse's station must be equipped to receive resident calls through a communication system from—

(1) Resident rooms; and

(2) Toilet and bathing facilities.

(g) *Dining and resident activities.* The facility must provide one or more rooms designated for resident dining and activities. These rooms must—

(1) Be well lighted;

(2) Be well ventilated, with nonsmoking areas identified;

(3) Be adequately furnished; and

(4) Have sufficient space to accommodate all activities.

(h) *Other environmental conditions.* The facility must provide a safe, functional, sanitary, and comfortable environment for the residents, staff and the public. The facility must—

(1) Establish procedures to ensure that water is available to essential areas when there is a loss of normal water supply;

(2) Have adequate outside ventilation by means of windows, or mechanical ventilation, or a combination of the two;

(3) Equip corridors with firmly secured handrails on each side; and

(4) Maintain an effective pest control program so that the facility is free of pests and rodents.

[56 FR 48876, Sept. 26, 1991, as amended at 57 FR 43925, Sept. 23, 1992; 68 FR 1386, Jan. 10, 2003; 69 FR 49268, Aug. 11, 2004; 70 FR 15238, Mar. 25, 2005; 71 FR 55340, Sept. 22, 2006; 73 FR 47091, Aug. 13, 2008]

§ 483.75 Administration.

A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

(a) *Licensure.* A facility must be licensed under applicable State and local law.

(b) *Compliance with Federal, State, and local laws and professional standards.* The facility must operate and provide services in compliance with all applicable Federal, State, and local laws, regulations, and codes, and with accepted professional standards and principles that apply to professionals providing services in such a facility.

(c) *Relationship to other HHS regulations.* In addition to compliance with the regulations set forth in this subpart, facilities are obliged to meet the applicable provisions of other HHS regulations, including but not limited to those pertaining to nondiscrimination on the basis of race, color, or national origin (45 CFR part 80); nondiscrimination on the basis of handicap (45 CFR part 84); nondiscrimination on the basis of age (45 CFR part 91); protection of human subjects of research (45 CFR part 46); and fraud and abuse (42 CFR part 455). Although these regulations are not in themselves considered requirements under this part, their violation may result in the termination or suspension of, or the refusal to grant or continue payment with Federal funds.

(d) *Governing body.* (1) The facility must have a governing body, or designated persons functioning as a governing body, that is legally responsible for establishing and implementing policies regarding the management and operation of the facility; and

(2) The governing body appoints the administrator who is—

(i) Licensed by the State where licensing is required; and

(ii) Responsible for management of the facility.

(e) *Required training of nursing aides*—(1) *Definitions.*

Licensed health professional means a physician; physician assistant; nurse practitioner; physical, speech, or occupational therapist; physical or occupational therapy assistant; registered professional nurse; licensed practical nurse; or licensed or certified social worker.

Nurse aide means any individual providing nursing or nursing-related services to residents in a facility who is not a licensed health professional, a registered dietitian, or someone who volunteers to provide such services without pay. Nurse aides do not include

those individuals who furnish services to residents only as paid feeding assistants as defined in § 488.301 of this chapter.

(2) *General rule.* A facility must not use any individual working in the facility as a nurse aide for more than 4 months, on a full-time basis, unless:

(i) That individual is competent to provide nursing and nursing related services; and

(ii)(A) That individual has completed a training and competency evaluation program, or a competency evaluation program approved by the State as meeting the requirements of §§ 483.151–483.154 of this part; or

(B) That individual has been deemed or determined competent as provided in § 483.150 (a) and (b).

(3) *Non-permanent employees.* A facility must not use on a temporary, per diem, leased, or any basis other than a permanent employee any individual who does not meet the requirements in paragraphs (e)(2) (i) and (ii) of this section.

(4) *Competency.* A facility must not use any individual who has worked less than 4 months as a nurse aide in that facility unless the individual—

(i) Is a full-time employee in a State-approved training and competency evaluation program;

(ii) Has demonstrated competence through satisfactory participation in a State-approved nurse aide training and competency evaluation program or competency evaluation program; or

(iii) Has been deemed or determined competent as provided in § 483.150 (a) and (b).

(5) *Registry verification.* Before allowing an individual to serve as a nurse aide, a facility must receive registry verification that the individual has met competency evaluation requirements unless—

(i) The individual is a full-time employee in a training and competency evaluation program approved by the State; or

(ii) The individual can prove that he or she has recently successfully completed a training and competency evaluation program or competency evaluation program approved by the State and has not yet been included in the registry. Facilities must follow up to ensure that such an individual actually becomes registered.

(6) *Multi-State registry verification.* Before allowing an individual to serve as a nurse aide, a facility must seek information from every State registry established under sections 1819(e)(2)(A) or 1919(e)(2)(A) of the Act the facility believes will include information on the individual.

(7) *Required retraining.* If, since an individual's most recent completion of a training and competency evaluation program, there has been a continuous period of 24 consecutive months during none of which the individual provided nursing or nursing-related services for monetary compensation, the individual must complete a new training and competency evaluation program or a new competency evaluation program.

(8) *Regular in-service education.* The facility must complete a performance review of every nurse aide at least once every 12 months, and must provide regular in-service education based on the outcome of these reviews. The in-service training must—

(i) Be sufficient to ensure the continuing competence of nurse aides, but must be no less than 12 hours per year;

(ii) Address areas of weakness as determined in nurse aides' performance reviews and may address the special needs of residents as determined by the facility staff; and

(iii) For nurse aides providing services to individuals with cognitive impairments, also address the care of the cognitively impaired.

(f) *Proficiency of Nurse aides.* The facility must ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.

(g) *Staff qualifications.* (1) The facility must employ on a full-time, part-time or consultant basis those professionals necessary to carry out the provisions of these requirements.

(2) Professional staff must be licensed, certified, or registered in accordance with applicable State laws.

(h) *Use of outside resources.* (1) If the facility does not employ a qualified professional person to furnish a specific service to be provided by the facility,

the facility must have that service furnished to residents by a person or agency outside the facility under an arrangement described in section 1861(w) of the Act or (with respect to services furnished to NF residents and dental services furnished to SNF residents) an agreement described in paragraph (h)(2) of this section.

(2) Arrangements as described in section 1861(w) of the Act or agreements pertaining to services furnished by outside resources must specify in writing that the facility assumes responsibility for—

(i) Obtaining services that meet professional standards and principles that apply to professionals providing services in such a facility; and

(ii) The timeliness of the services.

(i) *Medical director*. (1) The facility must designate a physician to serve as medical director.

(2) The medical director is responsible for—

(i) Implementation of resident care policies; and

(ii) The coordination of medical care in the facility.

(j) Laboratory services. (1) The facility must provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

(i) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter.

(ii) If the facility provides blood bank and transfusion services, it must meet the applicable requirements for laboratories specified in part 493 of this chapter.

(iii) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter.

(iv) If the facility does not provide laboratory services on site, it must have an agreement to obtain these services from a laboratory that meets the applicable requirements of part 493 of this chapter.

(2) The facility must—

(i) Provide or obtain laboratory services only when ordered by the attending physician;

(ii) Promptly notify the attending physican of the findings;

(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs asistance; and

(iv) File in the resident's clinical record laboratory reports that are dated and contain the name and address of the testing laboratory.

(k) *Radiology and other diagnostic services*. (1) The facility must provide or obtain radiology and other diagnostic services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

(i) If the facility provides its own diagnostic services, the services must meet the applicable conditions of participation for hospitals contained in § 482.26 of this subchapter.

(ii) If the facility does not provide its own diagnostic services, it must have an agreement to obtain these services from a provider or supplier that is approved to provide these services under Medicare.

(2) The facility must—

(i) Provide or obtain radiology and other diagnostic services only when ordered by the attending physician;

(ii) Promptly notify the attending physician of the findings;

(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance; and

(iv) File in the resident's clinical record signed and dated reports of x-ray and other diagnostic services.

(l) *Clinical records*. (1) The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are—

(i) Complete;

(ii) Accurately documented;

(iii) Readily accessible; and

(iv) Systematically organized.

(2) Clinical records must be retained for—

(i) The period of time required by State law; or

(ii) Five years from the date of discharge when there is no requirement in State law; or

(iii) For a minor, three years after a resident reaches legal age under State law.

(3) The facility must safeguard clinical record information against loss, destruction, or unauthorized use;

(4) The facility must keep confidential all information contained in the resident's records, regardless of the form or storage method of the records, except when release is required by—

(i) Transfer to another health care institution;

(ii) Law;

(iii) Third party payment contract; or

(iv) The resident.

(5) The clinical record must contain—

(i) Sufficient information to identify the resident;

(ii) A record of the resident's assessments;

(iii) The plan of care and services provided;

(iv) The results of any preadmission screening conducted by the State; and

(v) Progress notes.

(m) *Disaster and emergency preparedness.* (1) The facility must have detailed written plans and procedures to meet all potential emergencies and disasters, such as fire, severe weather, and missing residents.

(2) The facility must train all employees in emergency procedures when they begin to work in the facility, periodically review the procedures with existing staff, and carry out unannounced staff drills using those procedures.

(n) *Transfer agreement.* (1) In accordance with section 1861(l) of the Act, the facility (other than a nursing facility which is located in a State on an Indian reservation) must have in effect a written transfer agreement with one or more hospitals approved for participation under the Medicare and Medicaid programs that reasonably assures that—

(i) Residents will be transferred from the facility to the hospital, and ensured of timely admission to the hospital when transfer is medically appropriate as determined by the attending physician; and

(ii) Medical and other information needed for care and treatment of residents, and, when the transferring facility deems it appropriate, for determining whether such residents can be adequately cared for in a less expensive setting than either the facility or the hospital, will be exchanged between the institutions.

(2) The facility is considered to have a transfer agreement in effect if the facility has attempted in good faith to enter into an agreement with a hospital sufficiently close to the facility to make transfer feasible.

(o) *Quality assessment and assurance.* (1) A facility must maintain a quality assessment and assurance committee consisting of—

(i) The director of nursing services;

(ii) A physician designated by the facility; and

(iii) At least 3 other members of the facility's staff.

(2) The quality assessment and assurance committee—

(i) Meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary; and

(ii) Develops and implements appropriate plans of action to correct identified quality deficiencies.

(3) A State or the Secretary may not require disclosure of the records of such committee except in so far as such disclosure is related to the compliance of such committee with the requirements of this section.

(4) Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.

(p) *Disclosure of ownership.* (1) The facility must comply with the disclosure requirements of §§ 420.206 and 455.104 of this chapter.

(2) The facility must provide written notice to the State agency responsible for licensing the facility at the time of change, if a change occurs in—

(i) Persons with an ownership or control interest, as defined in §§ 420.201 and 455.101 of this chapter;

(ii) The officers, directors, agents, or managing employees;

(iii) The corporation, association, or other company responsible for the management of the facility; or

(iv) The facility's administrator or director of nursing.

(3) The notice specified in paragraph (p)(2) of this section must include the identity of each new individual or company.

(q) *Required training of feeding assistants.* A facility must not use any individual working in the facility as a paid feeding assistant unless that individual has successfully completed a State-approved training program for feeding assistants, as specified in § 483.160 of this part.

[56 FR 48877, Sept. 26, 1991, as amended at 56 FR 48918, Sept. 26, 1991; 57 FR 7136, Feb. 28, 1992; 57 FR 43925, Sept. 23, 1992; 59 FR 56237, Nov. 10, 1994; 63 FR 26311, May 12, 1998; 68 FR 55539, Sept. 26, 2003; 74 FR 40363, Aug. 11, 2009]

Subpart C—Preadmission Screening and Annual Review of Mentally Ill and Mentally Retarded Individuals

SOURCE: 57 FR 56506, Nov. 30, 1992, unless otherwise noted.

§ 483.100 Basis.

The requirements of §§ 483.100 through 483.138 governing the State's responsibility for preadmission screening and annual resident review (PASARR) of individuals with mental illness and mental retardation are based on section 1919(e)(7) of the Act.

§ 483.102 Applicability and definitions.

(a) This subpart applies to the screening or reviewing of all individuals with mental illness or mental retardation who apply to or reside in Medicaid certified NFs regardless of the source of payment for the NF services, and regardless of the individual's or resident's known diagnoses.

(b) *Definitions.* As used in this subpart—

(1) An individual is considered to have a serious mental illness (MI) if the individual meets the following requirements on diagnosis, level of impairment and duration of illness:

(i) *Diagnosis.* The individual has a major mental disorder diagnosable under the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, revised in 1987.

Incorporation of the 1987 edition of the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 that govern the use of incorporation by reference.[1]

This mental disorder is—

(A) A schizophrenic, mood, paranoid, panic or other severe anxiety disorder; somatoform disorder; personality disorder; other psychotic disorder; or another mental disorder that may lead to a chronic disability; but

(B) Not a primary diagnosis of dementia, including Alzheimer's disease or a related disorder, or a non-primary diagnosis of dementia unless the primary diagnosis is a major mental disorder as defined in paragraph (b)(1)(i)(A) of this section.

(ii) *Level of impairment.* The disorder results in functional limitations in major life activities within the past 3 to 6 months that would be appropriate for the individual's developmental stage. An individual typically has at least one of the following characteristics on a continuing or intermittent basis:

(A) *Interpersonal functioning.* The individual has serious difficulty interacting appropriately and communicating effectively with other persons, has a possible history of altercations, evictions, firing, fear of strangers, avoidance of interpersonal relationships and social isolation;

(B) *Concentration, persistence, and pace.* The individual has serious difficulty in sustaining focused attention for a long enough period to permit the completion of tasks commonly found in work settings or in work-like structured activities occurring in school or

[1] The Diagnostic and Statistical Manual of Mental Disorders is available for inspection at the Centers for Medicare & Medicaid Services, room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be obtained from the American Psychiatric Association, Division of Publications and Marketing, 1400 K Street, NW., Washington, DC 20005.

home settings, manifests difficulties in concentration, inability to complete simple tasks within an established time period, makes frequent errors, or requires assistance in the completion of these tasks; and

(C) *Adaptation to change.* The individual has serious difficulty in adapting to typical changes in circumstances associated with work, school, family, or social interaction, manifests agitation, exacerbated signs and symptoms associated with the illness, or withdrawal from the situation, or requires intervention by the mental health or judicial system.

(iii) *Recent treatment.* The treatment history indicates that the individual has experienced at least one of the following:

(A) Psychiatric treatment more intensive than outpatient care more than once in the past 2 years (e.g., partial hospitalization or inpatient hospitalization); or

(B) Within the last 2 years, due to the mental disorder, experienced an episode of significant disruption to the normal living situation, for which supportive services were required to maintain functioning at home, or in a residential treatment environment, or which resulted in intervention by housing or law enforcement officials.

(2) An individual is considered to have dementia if he or she has a primary diagnosis of dementia, as described in the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, revised in 1987, or a non-primary diagnosis of dementia unless the primary diagnosis is a major mental disorder as defined in paragraph (b)(1)(i)(A) of this section.

(3) An individual is considered to have mental retardation (MR) if he or she has—

(i) A level of retardation (mild, moderate, severe or profound) described in the American Association on Mental Retardation's Manual on Classification in Mental Retardation (1983). Incorporation by reference of the 1983 edition of the American Association on Mental Retardation's Manual on Classification in Mental Retardation was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 that govern the use of incorporations by reference;[2] or

(ii) A related condition as defined by § 435.1010 of this chapter.

[57 FR 56506, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993; 71 FR 39229, July 12, 2006]

§ 483.104 State plan requirement.

As a condition of approval of the State plan, the State must operate a preadmission screening and annual resident review program that meets the requirements of §§ 483.100 through 438.138.

§ 483.106 Basic rule.

(a) *Requirement.* The State PASARR program must require—(1) Preadmission screening of all individuals with mental illness or mental retardation who apply as new admissions to Medicaid NFs on or after January 1, 1989;

(2) Initial review, by April 1, 1990, of all current residents with mental retardation or mental illness who entered Medicaid NFs prior to January 1, 1989; and

(3) At least annual review, as of April 1, 1990, of all residents with mental illness or mental retardation, regardless of whether they were first screened under the preadmission screening or annual resident review requirements.

(b) *Admissions, readmissions and interfacility transfers*—(1) *New admission.* An individual is a new admission if he or she is admitted to any NF for the first time or does not qualify as a readmission. With the exception of certain hospital discharges described in paragraph (b)(2) of this section, new admissions are subject to preadmission screening.

[2] The American Association on Mental Retardation's Manual on Classification in Mental Retardation is available for inspection at the Centers for Medicare & Medicaid Services, Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be obtained from the American Association on Mental Retardation, 1719 Kalorama Rd., NW., Washington, DC 20009.

(2) *Exempted hospital discharge*. (i) An exempted hospital discharge means an individual—

(A) Who is admitted to any NF directly from a hospital after receiving acute inpatient care at the hospital;

(B) Who requires NF services for the condition for which he or she received care in the hospital; and

(C) Whose attending physician has certified before admission to the facility that the individual is likely to require less than 30 days nursing facility services.

(ii) If an individual who enters a NF as an exempted hospital discharge is later found to require more than 30 days of NF care, the State mental health or mental retardation authority must conduct an annual resident review within 40 calendar days of admission.

(3) *Readmissions*. An individual is a readmission if he or she was readmitted to a facility from a hospital to which he or she was transferred for the purpose of receiving care. Readmissions are subject to annual resident review rather than preadmission screening.

(4) *Interfacility transfers*—(i) An interfacility transfer occurs when an individual is transferred from one NF to another NF, with or without an intervening hospital stay. Interfacility transfers are subject to annual resident review rather than preadmission screening.

(ii) In cases of transfer of a resident with MI or MR from a NF to a hospital or to another NF, the transferring NF is responsible for ensuring that copies of the resident's most recent PASARR and resident assessment reports accompany the transferring resident.

(c) *Purpose*. The preadmission screening and annual resident review process must result in determinations based on a physical and mental evaluation of each individual with mental illness or mental retardation, that are described in §§ 483.112 and 483.114.

(d) *Responsibility for evaluations and determinations*. The PASARR determinations of whether an individual requires the level of services provided by a NF and whether specialized services are needed—

(1) For individuals with mental illness, must be made by the State mental health authority and be based on an independent physical and mental evaluation performed by a person or entity other than the State mental health authority; and

(2) For individuals with mental retardation, must be made by the State mental retardation or developmental disabilities authority.

(e) *Delegation of responsibility*—(1) The State mental health and mental retardation authorities may delegate by subcontract or otherwise the evaluation and determination functions for which they are responsible to another entity only if—

(i) The State mental health and mental retardation authorities retain ultimate control and responsibility for the performance of their statutory obligations;

(ii) The two determinations as to the need for NF services and for specialized services are made, based on a consistent analysis of the data; and

(iii) The entity to which the delegation is made is not a NF or an entity that has a direct or indirect affiliation or relationship with a NF.

(2) The State mental retardation authority has responsibility for both the evaluation and determination functions for individuals with MR whereas the State mental health authority has responsibility only for the determination function.

(3) The evaluation of individuals with MI cannot be delegated by the State mental health authority because it does not have responsibility for this function. The evaluation function must be performed by a person or entity other than the State mental health authority. In designating an independent person or entity to perform MI evaluations, the State must not use a NF or an entity that has a direct or indirect affiliation or relationship with a NF.

[57 FR 56506, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993]

§ 483.108 Relationship of PASARR to other Medicaid processes.

(a) PASARR determinations made by the State mental health or mental retardation authorities cannot be countermanded by the State Medicaid agency, either in the claims process or through other utilization control/review processes or by the State survey and certification agency. Only appeals determinations made through the system specified in subpart E of this part may overturn a PASARR determination made by the State mental health or mental retardation authorities.

(b) In making their determinations, however, the State mental health and mental retardation authorities must not use criteria relating to the need for NF care or specialized services that are inconsistent with this regulation and any supplementary criteria adopted by the State Medicaid agency under its approved State plan.

(c) To the maximum extent practicable, in order to avoid duplicative testing and effort, the PASARR must be coordinated with the routine resident assessments required by § 483.20(b).

§ 483.110 Out-of-State arrangements.

(a) *Basic rule*. The State in which the individual is a State resident (or would be a State resident at the time he or she becomes eligible for Medicaid), as defined in § 435.403 of this chapter, must pay for the PASARR and make the required determinations, in accordance with § 431.52(b).

(b) *Agreements*. A State may include arrangements for PASARR in its provider agreements with out-of-State facilities or reciprocal interstate agreements.

[57 FR 56506, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993]

§ 483.112 Preadmission screening of applicants for admission to NFs.

(a) *Determination of need for NF services*. For each NF applicant with MI or MR, the State mental health or mental retardation authority (as appropriate) must determine, in accordance with § 483.130, whether, because of the resident's physical and mental condition, the individual requires the level of services provided by a NF.

(b) *Determination of need for specialized services*. If the individual with mental illness or mental retardation is determined to require a NF level of care, the State mental health or mental retardation authority (as appropriate) must also determine, in accordance with § 483.130, whether the individual requires specialized services for the mental illness or mental retardation, as defined in § 483.120.

(c) *Timeliness*—(1) Except as specified in paragraph (c)(4) of this section, a preadmission screening determination must be made in writing within an annual average of 7 to 9 working days of referral of the individual with MI or MR by whatever agent performs the Level I identification, under § 483.128(a) of this part, to the State mental health or mental retardation authority for screening. (See § 483.128(a) for discussion of Level I evaluation.)

(2) The State may convey determinations verbally to nursing facilities and the individual and confirm them in writing.

(3) The State may compute separate annual averages for the mentally ill and the mentally retarded/developmentally disabled populations.

(4) The Secretary may grant an exception to the timeliness standard in paragraph (c)(1) of this section when the State—

(i) Exceeds the annual average; and

(ii) Provides justification satisfactory to the Secretary that a longer time period was necessary.

§ 483.114 Annual review of NF residents.

(a) *Individuals with mental illness*. For each resident of a NF who has mental illness, the State mental health authority must determine in accordance with § 483.130 whether, because of the resident's physical and mental condition, the resident requires—

(1) The level of services provided by—

(i) A NF;

(ii) An inpatient psychiatric hospital for individuals under age 21, as described in section 1905(h) of the Act; or

(iii) An institution for mental diseases providing medical assistance to individuals age 65 or older; and

(2) Specialized services for mental illness, as defined in § 483.120.

(b) *Individuals with mental retardation.* For each resident of a NF who has mental retardation, the State mental retardation or developmental disability authority must determine in accordance with §483.130 whether, because of his or her physical or mental condition, the resident requires—

(1) The level of services provided by a NF or an intermediate care facility for the mentally retarded; and

(2) Specialized services for mental retardation as defined in §483.120.

(c) *Frequency of review*—(1) A review and determination must be conducted for each resident of a Medicaid NF who has mental illness or mental retardation not less often than annually.

(2) ''Annually'' is defined as occurring within every fourth quarter after the previous preadmission screen or annual resident review.

(d) *April 1, 1990 deadline for initial reviews.* The first set of annual reviews on residents who entered the NF prior to January 1, 1989, must be completed by April 1, 1990.

§483.116 Residents and applicants determined to require NF level of services.

(a) *Individuals needing NF services.* If the State mental health or mental retardation authority determines that a resident or applicant for admission to a NF requires a NF level of services, the NF may admit or retain the individual.

(b) *Individuals needing NF services and specialized services.* If the State mental health or mental retardation authority determines that a resident or applicant for admission requires both a NF level of services and specialized services for the mental illness or mental retardation—

(1) The NF may admit or retain the individual; and

(2) The State must provide or arrange for the provision of the specialized services needed by the individual while he or she resides in the NF.

§483.118 Residents and applicants determined not to require NF level of services.

(a) *Applicants who do not require NF services.* If the State mental health or mental retardation authority determines that an applicant for admission to a NF does not require NF services, the applicant cannot be admitted. NF services are not a covered Medicaid service for that individual, and further screening is not required.

(b) *Residents who require neither NF services nor specialized services for MI or MR.* If the State mental health or mental retardation authority determines that a resident requires neither the level of services provided by a NF nor specialized services for MI or MR, regardless of the length of stay in the facility, the State must—

(1) Arrange for the safe and orderly discharge of the resident from the facility in accordance with §483.12(a); and

(2) Prepare and orient the resident for discharge.

(c) *Residents who do not require NF services but require specialized services for MI or MR*—(1) *Long term residents.* Except as otherwise may be provided in an alternative disposition plan adopted under section 1919(e)(7)(E) of the Act, for any resident who has continuously resided in a NF for at least 30 months before the date of the determination, and who requires only specialized services as defined in §483.120, the State must, in consultation with the resident's family or legal representative and caregivers—

(i) Offer the resident the choice of remaining in the facility or of receiving services in an alternative appropriate setting;

(ii) Inform the resident of the institutional and noninstitutional alternatives covered under the State Medicaid plan for the resident;

(iii) Clarify the effect on eligibility for Medicaid services under the State plan if the resident chooses to leave the facility, including its effect on readmission to the facility; and

(iv) Regardless of the resident's choice, provide for, or arrange for the provision of specialized services for the mental illness or mental retardation.

(2) *Short term residents.* Except as otherwise may be provided in an alternative disposition plan adopted under section 1919(e)(7)(E) of the Act, for any resident who requires only specialized services, as defined in §483.120, and who has not continuously resided in a NF for at least 30 months before the date of the determination, the State must,

in consultation with the resident's family or legal representative and caregivers—

(i) Arrange for the safe and orderly discharge of the resident from the facility in accordance with § 483.12(a);

(ii) Prepare and orient the resident for discharge; and

(iii) Provide for, or arrange for the provision of, specialized services for the mental illness or mental retardation.

(3) For the purpose of establishing length of stay in a NF, the 30 months of continuous residence in a NF or longer—

(i) Is calculated back from the date of the first annual resident review determination which finds that the individual is not in need of NF level of services;

(ii) May include temporary absences for hospitalization or therapeutic leave; and

(iii) May consist of consecutive residences in more than one NF.

§ 483.120 Specialized services.

(a) *Definition*—(1) For mental illness, specialized services means the services specified by the State which, combined with services provided by the NF, results in the continuous and aggressive implementation of an individualized plan of care that—

(i) Is developed and supervised by an interdisciplinary team, which includes a physician, qualified mental health professionals and, as appropriate, other professionals.

(ii) Prescribes specific therapies and activities for the treatment of persons experiencing an acute episode of serious mental illness, which necessitates supervision by trained mental health personnel; and

(iii) Is directed toward diagnosing and reducing the resident's behavioral symptoms that necessitated institutionalization, improving his or her level of independent functioning, and achieving a functioning level that permits reduction in the intensity of mental health services to below the level of specialized services at the earliest possible time.

(2) For mental retardation, specialized services means the services specified by the State which, combined with services provided by the NF or other service providers, results in treatment which meets the requirements of § 483.440(a)(1).

(b) *Who must receive specialized services.* The State must provide or arrange for the provision of specialized services, in accordance with this subpart, to all NF residents with MI or MR whose needs are such that continuous supervision, treatment and training by qualified mental health or mental retardation personnel is necessary, as identified by the screening provided in § 483.130 or §§ 483.134 and 483.136.

(c) *Services of lesser intensity than specialized services.* The NF must provide mental health or mental retardation services which are of a lesser intensity than specialized services to all residents who need such services.

§ 483.122 FFP for NF services.

(a) *Basic rule.* Except as otherwise may be provided in an alternative disposition plan adopted under section 1919(e)(7)(E) of the Act, FFP is available in State expenditures for NF services provided to a Medicaid eligible individual subject to the requirements of this part only if the individual has been determined—

(1) To need NF care under § 483.116(a) or

(2) Not to need NF services but to need specialized services, meets the requirements of § 483.118(c)(1), and elects to stay in the NF.

(b) *FFP for late reviews.* When a preadmission screening has not been performed prior to admission or an annual review is not performed timely, in accordance with § 483.114(c), but either is performed at a later date, FFP is available only for services furnished after the screening or review has been performed, subject to the provisions of paragraph (a) of this section.

§ 483.124 FFP for specialized services.

FFP is not available for specialized services furnished to NF residents as NF services.

§ 483.126 Appropriate placement.

Placement of an individual with MI or MR in a NF may be considered appropriate only when the individual's needs are such that he or she meets the

minimum standards for admission and the individual's needs for treatment do not exceed the level of services which can be delivered in the NF to which the individual is admitted either through NF services alone or, where necessary, through NF services supplemented by specialized services provided by or arranged for by the State.

§483.128 PASARR evaluation criteria.

(a) *Level I: Identification of individuals with MI or MR.* The State's PASARR program must identify all individuals who are suspected of having MI or MR as defined in §483.102. This identification function is termed Level I. Level II is the function of evaluating and determining whether NF services and specialized services are needed. The State's performance of the Level I identification function must provide at least, in the case of first time identifications, for the issuance of written notice to the individual or resident and his or her legal representative that the individual or resident is suspected of having MI or MR and is being referred to the State mental health or mental retardation authority for Level II screening.

(b) *Adaptation to culture, language, ethnic origin.* Evaluations performed under PASARR and PASARR notices must be adapted to the cultural background, language, ethnic origin and means of communication used by the individual being evaluated.

(c) *Participation by individual and family.* PASARR evaluations must involve—

(1) The individual being evaluated;

(2) The individual's legal representative, if one has been designated under State law; and

(3) The individual's family if—

(i) Available; and

(ii) The individual or the legal representative agrees to family participation.

(d) *Interdisciplinary coordination.* When parts of a PASARR evaluation are performed by more than one evaluator, the State must ensure that there is interdisciplinary coordination among the evaluators.

(e) The State's PASARR program must use at least the evaluative criteria of §483.130 (if one or both determinations can easily be made categorically as described in §483.130) or of §§483.132 and 483.134 or §483.136 (or, in the case of individuals with both MI and MR, §§483.132, 483.134 and 483.136 if a more extensive individualized evaluation is required).

(f) *Data.* In the case of individualized evaluations, information that is necessary for determining whether it is appropriate for the individual with MI or MR to be placed in an NF or in another appropriate setting should be gathered throughout all applicable portions of the PASARR evaluation (§§483.132 and 483.134 and/or §483.136). The two determinations relating to the need for NF level of care and specialized services are interrelated and must be based upon a comprehensive analysis of all data concerning the individual.

(g) *Preexisting data.* Evaluators may use relevant evaluative data, obtained prior to initiation of preadmission screening or annual resident review, if the data are considered valid and accurate and reflect the current functional status of the individual. However, in the case of individualized evaluations, to supplement and verify the currency and accuracy of existing data, the State's PASARR program may need to gather additional information necessary to assess proper placement and treatment.

(h) *Findings.* For both categorical and individualized determinations, findings of the evaluation must correspond to the person's current functional status as documented in medical and social history records.

(i) *Evaluation report: Individualized determinations.* For individualized PASARR determinations, findings must be issued in the form of a written evaluative report which—

(1) Identifies the name and professional title of person(s) who performed the evaluation(s) and the date on which each portion of the evaluation was administered;

(2) Provides a summary of the medical and social history, including the positive traits or developmental strengths and weaknesses or developmental needs of the evaluated individual;

(3) If NF services are recommended, identifies the specific services which are required to meet the evaluated individual's needs, including services required in paragraph (i)(5) of this section;

(4) If specialized services are not recommended, identifies any specific mental retardation or mental health services which are of a lesser intensity than specialized services that are required to meet the evaluated individual's needs;

(5) If specialized services are recommended, identifies the specific mental retardation or mental health services required to meet the evaluated individual's needs; and

(6) Includes the bases for the report's conclusions.

(j) *Evaluation report: Categorical determinations.* For categorical PASARR determinations, findings must be issued in the form of an abbreviated written evaluative report which—

(1) Identifies the name and professional title of the person applying the categorical determination and the data on which the application was made;

(2) Explains the categorical determination(s) that has (have) been made and, if only one of the two required determinations can be made categorically, describes the nature of any further screening which is required;

(3) Identifies, to the extent possible, based on the available data, NF services, including any mental health or specialized psychiatric rehabilitative services, that may be needed; and

(4) Includes the bases for the report's conclusions.

(k) *Interpretation of findings to individual.* For both categorical and individualized determinations, findings of the evaluation must be interpreted and explained to the individual and, where applicable, to a legal representative designated under State law.

(l) *Evaluation report.* The evaluator must send a copy of the evaluation report to the—

(1) Individual or resident and his or her legal representative;

(2) Appropriate State authority in sufficient time for the State authorities to meet the times identified in § 483.112(c) for PASs and § 483.114(c) for ARRs;

(3) Admitting or retaining NF;

(4) Individual's attending physician; and

(5) The discharging hospital if the individual is seeking NF admission from a hospital.

(m) The evaluation may be terminated if the evaluator finds at any time during the evaluation that the individual being evaluated—

(1) Does not have MI or MR; or

(2) Has—

(i) A primary diagnosis of dementia (including Alzheimer's Disease or a related disorder); or

(ii) A non-primary diagnosis of dementia without a primary diagnosis that is a serious mental illness, and does not have a diagnosis of MR or a related condition.

[57 FR 56506, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993]

§ 483.130 PASARR determination criteria.

(a) *Basis for determinations.* Determinations made by the State mental health or mental retardation authority as to whether NF level of services and specialized services are needed must be based on an evaluation of data concerning the individual, as specified in paragraph (b) of this section.

(b) *Types of determinations.* Determinations may be—

(1) Advance group determinations, in accordance with this section, by category that take into account that certain diagnoses, levels of severity of illness, or need for a particular service clearly indicate that admission to or residence in a NF is normally needed, or that the provision of specialized services is not normally needed; or

(2) Individualized determinations based on more extensive individualized evaluations as required in § 483.132, § 483.134, or § 483.136 (or, in the case of an individual having both MR and MI, §§ 483.134 and 483.136).

(c) *Group determinations by category.* Advance group determinations by category developed by the State mental health or mental retardation authorities may be made applicable to individuals by the NF or other evaluator following Level I review only if existing data on the individual appear to be current and accurate and are sufficient to

allow the evaluator readily to determine that the individual fits into the category established by the State authorities (see § 483.132(c)). Sources of existing data on the individual that could form the basis for applying a categorical determination by the State authorities would be hospital records, physician's evaluations, election of hospice status, records of community mental health centers or community mental retardation or developmental disability providers.

(d) *Examples of categories.* Examples of categories for which the State mental health or mental retardation authority may make an advance group determination that NF services are needed are—

(1) Convalescent care from an acute physical illness which—

(i) Required hospitalization; and

(ii) Does not meet all the criteria for an exempt hospital discharge, which is not subject to preadmission screening, as specified in § 483.106(b)(2).

(2) Terminal illness, as defined for hospice purposes in § 418.3 of this chapter;

(3) Severe physical illnesses such as coma, ventilator dependence, functioning at a brain stem level, or diagnoses such as chronic obstructive pulmonary disease, Parkinson's disease, Huntington's disease, amyotrophic lateral sclerosis, and congestive heart failure which result in a level of impairment so severe that the individual could not be expected to benefit from specialized services;

(4) Provisional admissions pending further assessment in cases of delirium where an accurate diagnosis cannot be made until the delirium clears;

(5) Provisional admissions pending further assessment in emergency situations requiring protective services, with placement in a nursing facility not to exceed 7 days; and

(6) Very brief and finite stays of up to a fixed number of days to provide respite to in-home caregivers to whom the individual with MI or MR is expected to return following the brief NF stay.

(e) *Time limits.* The State may specify time limits for categorical determinations that NF services are needed and in the case of paragraphs (d)(4), (5) and (6) of this section, must specify a time limit which is appropriate for provisional admissions pending further assessment and for emergency situations and respite care. If an individual is later determined to need a longer stay than the State's limit allows, the individual must be subjected to an annual resident review before continuation of the stay may be permitted and payment made for days of NF care beyond the State's time limit.

(f) The State mental health and mental retardation authorities may make categorical determinations that specialized services are not needed in the provisional, emergency and respite admission situations identified in § 483.130(d)(4)–(6). In all other cases, except for § 483.130(h), a determination that specialized services are not needed must be based on a more extensive individualized evaluation under § 483.134 or § 483.136.

(g) *Categorical determinations: No positive specialized treatment determinations.* The State mental health and mental retardation authorities must not make categorical determinations that specialized services are needed. Such a determination must be based on a more extensive individualized evaluation under § 483.134 or § 483.136 to determine the exact nature of the specialized services that are needed.

(h) *Categorical determinations: Dementia and MR.* The State mental retardation authority may make categorical determinations that individuals with dementia, which exists in combination with mental retardation or a related condition, do not need specialized services.

(i) If a State mental health or mental retardation authority determines NF needs by category, it may not waive the specialized services determination. The appropriate State authority must also determine whether specialized services are needed either by category (if permitted) or by individualized evaluations, as specified in § 483.134 or § 483.136.

(j) *Recording determinations.* All determinations made by the State mental health and mental retardation authority, regardless of how they are arrived at, must be recorded in the individual's record.

(k) *Notice of determination.* The State mental health or mental retardation authority must notify in writing the following entities of a determination made under this subpart:

(1) The evaluated individual and his or her legal representative;

(2) The admitting or retaining NF;

(3) The individual or resident's attending physician; and

(4) The discharging hospital, unless the individual is exempt from preadmission screening as provided for at § 483.106(b)(2).

(l) *Contents of notice.* Each notice of the determination made by the State mental health or mental retardation authority must include—

(1) Whether a NF level of services is needed;

(2) Whether specialized services are needed;

(3) The placement options that are available to the individual consistent with these determinations; and

(4) The rights of the individual to appeal the determination under subpart E of this part.

(m) *Placement options.* Except as otherwise may be provided in an alternative disposition plan adopted under section 1919(e)(7)(E) of the Act, the placement options and the required State actions are as follows:

(1) *Can be admitted to a NF.* Any applicant for admission to a NF who has MI or MR and who requires the level of services provided by a NF, regardless of whether specialized services are also needed, may be admitted to a NF, if the placement is appropriate, as determined in § 483.126. If specialized services are also needed, the State is responsible for providing or arranging for the provision of the specialized services.

(2) *Cannot be admitted to a NF.* Any applicant for admission to a NF who has MI or MR and who does not require the level of services provided by a NF, regardless of whether specialized services are also needed, is inappropriate for NF placement and must not be admitted.

(3) *Can be considered appropriate for continued placement in a NF.* Any NF resident with MI or MR who requires the level of services provided by a NF, regardless of the length of his or her stay or the need for specialized services, can continue to reside in the NF, if the placement is appropriate, as determined in § 483.126.

(4) *May choose to remain in the NF even though the placement would otherwise be inappropriate.* Any NF resident with MI or MR who does not require the level of services provided by a NF but does require specialized services and who has continuously resided in a NF for at least 30 consecutive months before the date of determination may choose to continue to reside in the facility or to receive covered services in an alternative appropriate institutional or noninstitutional setting. Wherever the resident chooses to reside, the State must meet his or her specialized services needs. The determination notice must provide information concerning how, when, and by whom the various placement options available to the resident will be fully explained to the resident.

(5) *Cannot be considered appropriate for continued placement in a NF and must be discharged (short-term residents).* Any NF resident with MI or MR who does not require the level of services provided by a NF but does require specialized services and who has resided in a NF for less than 30 consecutive months must be discharged in accordance with § 483.12(a) to an appropriate setting where the State must provide specialized services. The determination notice must provide information on how, when, and by whom the resident will be advised of discharge arrangements and of his/her appeal rights under both PASARR and discharge provisions.

(6) *Cannot be considered appropriate for continued placement in a NF and must be discharged (short or long-term residents).* Any NF resident with MI or MR who does not require the level of services provided by a NF and does not require specialized services regardless of his or her length of stay, must be discharged in accordance with § 483.12(a). The determination notice must provide information on how, when, and by whom the resident will be advised of discharge arrangements and of his or her appeal rights under both PASARR and discharge provisions.

(n) *Specialized services needed in a NF.* If a determination is made to admit or

allow to remain in a NF any individual who requires specialized services, the determination must be supported by assurances that the specialized services that are needed can and will be provided or arranged for by the State while the individual resides in the NF.

(o) *Record retention.* The State PASARR system must maintain records of evaluations and determinations, regardless of whether they are performed categorically or individually, in order to support its determinations and actions and to protect the appeal rights of individuals subjected to PASARR; and

(p) *Tracking system.* The State PASARR system must establish and maintain a tracking system for all individuals with MI or MR in NFs to ensure that appeals and future reviews are performed in accordance with this subpart and subpart E.

[57 FR 56506, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993]

§ 483.132 Evaluating the need for NF services and NF level of care (PASARR/NF).

(a) *Basic rule.* For each applicant for admission to a NF and each NF resident who has MI or MR, the evaluator must assess whether—

(1) The individual's total needs are such that his or her needs can be met in an appropriate community setting;

(2) The individual's total needs are such that they can be met only on an inpatient basis, which may include the option of placement in a home and community-based services waiver program, but for which the inpatient care would be required;

(3) If inpatient care is appropriate and desired, the NF is an appropriate institutional setting for meeting those needs in accordance with § 483.126; or

(4) If the inpatient care is appropriate and desired but the NF is not the appropriate setting for meeting the individual's needs in accordance with § 483.126, another setting such as an ICF/MR (including small, community-based facilities), an IMD providing services to individuals aged 65 or older, or a psychiatric hospital is an appropriate institutional setting for meeting those needs.

(b) *Determining appropriate placement.* In determining appropriate placement, the evaluator must prioritize the physical and mental needs of the individual being evaluated, taking into account the severity of each condition.

(c) *Data.* At a minimum, the data relied on to make a determination must include:

(1) Evaluation of physical status (for example, diagnoses, date of onset, medical history, and prognosis);

(2) Evaluation of mental status (for example, diagnoses, date of onset, medical history, likelihood that the individual may be a danger to himself/herself or others); and

(3) Functional assessment (activities of daily living).

(d) Based on the data compiled in § 483.132 and, as appropriate, in §§ 483.134 and 483.136, the State mental health or mental retardation authority must determine whether an NF level of services is needed.

§ 483.134 Evaluating whether an individual with mental illness requires specialized services (PASARR/MI).

(a) *Purpose.* The purpose of this section is to identify the minimum data needs and process requirements for the State mental health authority, which is responsible for determining whether or not the applicant or resident with MI, as defined in § 483.102(b)(1) of this part, needs a specialized services program for mental illness as defined in § 483.120.

(b) *Data.* Minimum data collected must include—(1) A comprehensive history and physical examination of the person. The following areas must be included (if not previously addressed):

(i) Complete medical history;

(ii) Review of all body systems;

(iii) Specific evaluation of the person's neurological system in the areas of motor functioning, sensory functioning, gait, deep tendon reflexes, cranial nerves, and abnormal reflexes; and

(iv) In case of abnormal findings which are the basis for an NF placement, additional evaluations conducted by appropriate specialists.

(2) A comprehensive drug history including current or immediate past use of medications that could mask symptoms or mimic mental illness.

(3) A psychosocial evaluation of the person, including current living arrangements and medical and support systems.

(4) A comprehensive psychiatric evaluation including a complete psychiatric history, evaluation of intellectual functioning, memory functioning, and orientation, description of current attitudes and overt behaviors, affect, suicidal or homicidal ideation, paranoia, and degree of reality testing (presence and content of delusions) and hallucinations.

(5) A functional assessment of the individual's ability to engage in activities of daily living and the level of support that would be needed to assist the individual to perform these activities while living in the community. The assessment must determine whether this level of support can be provided to the individual in an alternative community setting or whether the level of support needed is such that NF placement is required.

(6) The functional assessment must address the following areas: Self-monitoring of health status, self-administering and scheduling of medical treatment, including medication compliance, or both, self-monitoring of nutritional status, handling money, dressing appropriately, and grooming.

(c) *Personnel requirements.* (1) If the history and physical examination are not performed by a physician, then a physician must review and concur with the conclusions.

(2) The State may designate the mental health professionals who are qualified—

(i) To perform the evaluations required under paragraph (b) (2)–(6) of this section including the—

(A) Comprehensive drug history;

(B) Psychosocial evaluation;

(C) Comprehensive psychiatric evaluation;

(D) Functional assessment; and

(ii) To make the determination required in paragraph (d) of this section.

(d) *Data interpretation.* Based on the data compiled, a qualified mental health professional, as designated by the State, must validate the diagnosis of mental illness and determine whether a program of psychiatric specialized services is needed.

§ 483.136 Evaluating whether an individual with mental retardation requires specialized services (PASARR/MR).

(a) *Purpose.* The purpose of this section is to identify the minimum data needs and process requirements for the State mental retardation authority to determine whether or not the applicant or resident with mental retardation, as defined in § 483.102(b)(3) of this part, needs a continuous specialized services program, which is analogous to active treatment, as defined in § 435.1010 of this chapter and § 483.440.

(b) *Data.* Minimum data collected must include the individual's comprehensive history and physical examination results to identify the following information or, in the absence of data, must include information that permits a reviewer specifically to assess:

(1) The individual's medical problems;

(2) The level of impact these problems have on the individual's independent functioning;

(3) All current medications used by the individual and the current response of the individual to any prescribed medications in the following drug groups:

(i) Hypnotics,

(ii) Antipsychotics (neuroleptics),

(iii) Mood stabilizers and antidepressants,

(iv) Antianxiety-sedative agents, and

(v) Anti-Parkinson agents.

(4) Self-monitoring of health status;

(5) Self-administering and scheduling of medical treatments;

(6) Self-monitoring of nutritional status;

(7) Self-help development such as toileting, dressing, grooming, and eating;

(8) Sensorimotor development, such as ambulation, positioning, transfer skills, gross motor dexterity, visual motor perception, fine motor dexterity, eye-hand coordination, and extent to which prosthetic, orthotic, corrective or mechanical supportive devices can improve the individual's functional capacity;

(9) Speech and language (communication) development, such as expressive

language (verbal and nonverbal), receptive language (verbal and nonverbal), extent to which non-oral communication systems can improve the individual's function capacity, auditory functioning, and extent to which amplification devices (for example, hearing aid) or a program of amplification can improve the individual's functional capacity;

(10) Social development, such as interpersonal skills, recreation-leisure skills, and relationships with others;

(11) Academic/educational development, including functional learning skills;

(12) Independent living development such as meal preparation, budgeting and personal finances, survival skills, mobility skills (orientation to the neighborhood, town, city), laundry, housekeeping, shopping, bedmaking, care of clothing, and orientation skills (for individuals with visual impairments);

(13) Vocational development, including present vocational skills;

(14) Affective development such as interests, and skills involved with expressing emotions, making judgments, and making independent decisions; and

(15) The presence of identifiable maladaptive or inappropriate behaviors of the individual based on systematic observation (including, but not limited to, the frequency and intensity of identified maladaptive or inappropriate behaviors).

(c) *Data interpretation*—(1) The State must ensure that a licensed psychologist identifies the intellectual functioning measurement of individuals with MR or a related condition.

(2) Based on the data compiled in paragraph (b) of this section, the State mental retardation authority, using appropriate personnel, as designated by the State, must validate that the individual has MR or is a person with a related condition and must determine whether specialized services for mental retardation are needed. In making this determination, the State mental retardation authority must make a qualitative judgment on the extent to which the person's status reflects, singly and collectively, the characteristics commonly associated with the need for specialized services, including—

(i) Inability to—

(A) Take care of the most personal care needs;

(B) Understand simple commands;

(C) Communicate basic needs and wants;

(D) Be employed at a productive wage level without systematic long term supervision or support;

(E) Learn new skills without aggressive and consistent training;

(F) Apply skills learned in a training situation to other environments or settings without aggressive and consistent training;

(G) Demonstrate behavior appropriate to the time, situation or place without direct supervision; and

(H) Make decisions requiring informed consent without extreme difficulty;

(ii) Demonstration of severe maladaptive behavior(s) that place the person or others in jeopardy to health and safety; and

(iii) Presence of other skill deficits or specialized training needs that necessitate the availability of trained MR personnel, 24 hours per day, to teach the person functional skills.

[57 FR 56506, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993, as amended at 71 FR 39229, July 12, 2006]

§ 483.138 Maintenance of services and availability of FFP.

(a) *Maintenance of services*. If a NF mails a 30 day notice of its intent to transfer or discharge a resident, under § 483.12(a) of this chapter, the agency may not terminate or reduce services until—

(1) The expiration of the notice period; or

(2) A subpart E appeal, if one has been filed, has been resolved.

(b) *Availability of FFP*. FFP is available for expenditures for services provided to Medicaid recipients during—

(1) The 30 day notice period specified in § 483.12(a) of this chapter; or

(2) During the period an appeal is in progress.

Subpart D—Requirements That Must Be Met by States and State Agencies: Nurse Aide Training and Competency Evaluation, and Paid Feeding Assistants

SOURCE: 56 FR 48919, Sept. 26, 1991, unless otherwise noted.

§ 483.150 Statutory basis; Deemed meeting or waiver of requirements.

(a) *Statutory basis.* This subpart is based on sections 1819(b)(5), 1819(f)(2), 1919(b)(5), and 1919(f)(2) of the Act, which establish standards for training nurse-aides and for evaluating their competency.

(b) *Deemed meeting of requirements.* A nurse aide is deemed to satisfy the requirement of completing a training and competency evaluation approved by the State if he or she successfully completed a training and competency evaluation program before July 1, 1989 if—

(1) The aide would have satisfied this requirement if—

(i) At least 60 hours were substituted for 75 hours in sections 1819(f)(2) and 1919(f)(2) of the Act, and

(ii) The individual has made up at least the difference in the number of hours in the program he or she completed and 75 hours in supervised practical nurse aide training or in regular in-service nurse aide education;

or

(2) The individual was found to be competent (whether or not by the State) after the completion of nurse aide training of at least 100 hours duration.

(c) *Waiver of requirements.* A State may—

(1) Waive the requirement for an individual to complete a competency evaluation program approved by the State for any individual who can demonstrate to the satisfaction of the State that he or she has served as a nurse aide at one or more facilities of the same employer in the state for at least 24 consecutive months before December 19, 1989; or

(2) Deem an individual to have completed a nurse aide training and competency evaluation program approved by the State if the individual completed, before July 1, 1989, such a program that the State determines would have met the requirements for approval at the time it was offered.

[56 FR 48919, Sept. 26, 1991; 56 FR 59331, Nov. 25, 1991, as amended at 60 FR 50443, Sept. 29, 1995; 75 FR 21179, Apr. 23, 2010]

§ 483.151 State review and approval of nurse aide training and competency evaluation programs.

(a) *State review and administration.* (1) The State—

(i) Must specify any nurse aide training and competency evaluation programs that the State approves as meeting the requirements of § 483.152 and/or competency evaluations programs that the State approves as meeting the requirements of § 483.154; and

(ii) May choose to offer a nurse aide training and competency evaluation program that meets the requirements of § 483.152 and/or a competency evaluation program that meets the requirements of § 483.154.

(2) If the State does not choose to offer a nurse aide training and competency evaluation program or competency evaluation program, the State must review and approve or disapprove nurse aide training and competency evaluation programs and nurse aide competency evaluation programs upon request.

(3) The State survey agency must in the course of all surveys, determine whether the nurse aide training and competency evaluation requirements of § 483.75(e) are met.

(b) *Requirements for approval of programs.* (1) Before the State approves a nurse aide training and competency evaluation program or competency evaluation program, the State must—

(i) Determine whether the nurse aide training and competency evaluation program meets the course requirements of §§ 483.152:

(ii) Determine whether the nurse aide competency evaluation program meets the requirements of § 483.154; and

(iii) In all reviews other than the initial review, visit the entity providing the program.

(2) The State may not approve a nurse aide training and competency evaluation program or competency evaluation program offered by or in a

facility which, in the previous two years—

(i) In the case of a skilled nursing facility, has operated under a waiver under section 1819(b)(4)(C)(ii)(II) of the Act;

(ii) In the case of a nursing facility, has operated under a waiver under section 1919(b)(4)(C)(ii) of the Act that was granted on the basis of a demonstration that the facility is unable to provide nursing care required under section 1919(b)(4)(C)(i) of the Act for a period in excess of 48 hours per week;

(iii) Has been subject to an extended (or partial extended) survey under sections 1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) of the Act;

(iv) Has been assessed a civil money penalty described in section 1819(h)(2)(B)(ii) of 1919(h)(2)(A)(ii) of the Act of not less than $5,000; or

(v) Has been subject to a remedy described in sections 1819(h)(2)(B) (i) or (iii), 1819(h)(4), 1919(h)(1)(B)(i), or 1919(h)(2)(A) (i), (iii) or (iv) of the Act.

(3) A State may not, until two years since the assessment of the penalty (or penalties) has elapsed, approve a nurse aide training and competency evaluation program or competency evaluation program offered by or in a facility that, within the two-year period beginning October 1, 1988—

(i) Had its participation terminated under title XVIII of the Act or under the State plan under title XIX of the Act;

(ii) Was subject to a denial of payment under title XVIII or title XIX;

(iii) Was assessed a civil money penalty of not less than $5,000 for deficiencies in nursing facility standards;

(iv) Operated under temporary management appointed to oversee the operation of the facility and to ensure the health and safety of its residents; or

(v) Pursuant to State action, was closed or had its residents transferred.

(c) *Waiver of disapproval of nurse aide training programs.*

(1) A facility may request that CMS waive the disapproval of its nurse aide training program when the facility has been assessed a civil money penalty of not less than $5,000 if the civil money penalty was not related to the quality of care furnished to residents in the facility.

(2) For purposes of this provision, ''quality of care furnished to residents'' means the direct hands-on care and treatment that a health care professional or direct care staff furnished to a resident.

(3) Any waiver of disapproval of a nurse aide training program does not waive any requirement upon the facility to pay any civil money penalty.

(d) *Time frame for acting on a request for approval.* The State must, within 90 days of the date of a request under paragraph (a)(3) of this section or receipt of additional information from the requester—

(1) Advise the requester whether or not the program has been approved; or

(2) Request additional information form the requesting entity.

(e) *Duration of approval.* The State may not grant approval of a nurse aide training and competency evaluation program for a period longer than 2 years. A program must notify the State and the State must review that program when there are substantive changes made to that program within the 2-year period.

(f) *Withdrawal of approval.* (1) The State must withdraw approval of a nurse aide training and competency evaluation program or nurse aide competency evaluation program offered by or in a facility described in paragraph (b)(2) of this section.

(2) The State may withdraw approval of a nurse aide training and competency evaluation program or nurse aide competency evaluation program if the State determines that any of the applicable requirements of §§483.152 or 483.154 are not met by the program.

(3) The State must withdraw approval of a nurse aide training and competency evaluation program or a nurse aide competency evaluation program if the entity providing the program refuses to permit unannounced visits by the State.

(4) If a State withdraws approval of a nurse aide training and competency evaluation program or competency evaluation program—

(i) The State must notify the program in writing, indicating the reason(s) for withdrawal of approval of the program.

(ii) Students who have started a training and competency evaluation program from which approval has been withdrawn must be allowed to complete the course.

[56 FR 48919, Sept. 26, 1991, as amended at 75 FR 21179, Apr. 23, 2010]

§ 483.152 Requirements for approval of a nurse aide training and competency evaluation program.

(a) For a nurse aide training and competency evaluation program to be approved by the State, it must, at a minimum—

(1) Consist of no less than 75 clock hours of training;

(2) Include at least the subjects specified in paragraph (b) of this section;

(3) Include at least 16 hours of supervised practical training. *Supervised practical training* means training in a laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse or a licensed practical nurse;

(4) Ensure that—

(i) Students do not perform any services for which they have not trained and been found proficient by the instructor; and

(ii) Students who are providing services to residents are under the general supervision of a licensed nurse or a registered nurse;

(5) Meet the following requirements for instructors who train nurse aides;

(i) The training of nurse aides must be performed by or under the general supervision of a registered nurse who possesses a minimum of 2 years of nursing experience, at least 1 year of which must be in the provision of long term care facility services;

(ii) Instructors must have completed a course in teaching adults or have experience in teaching adults or supervising nurse aides;

(iii) In a facility-based program, the training of nurse aides may be performed under the general supervision of the director of nursing for the facility who is prohibited from performing the actual training; and

(iv) Other personnel from the health professions may supplement the instructor, including, but not limited to, registered nurses, licensed practical/vocational nurses, pharmacists, dietitians, social workers, sanitarians, fire safety experts, nursing home administrators, gerontologists, psychologists, physical and occupational therapists, activities specialists, speech/language/hearing therapists, and resident rights experts. Supplemental personnel must have at least 1 year of experience in their fields;

(6) Contain competency evaluation procedures specified in § 483.154.

(b) The curriculum of the nurse aide training program must include—

(1) At least a total of 16 hours of training in the following areas prior to any direct contact with a resident:

(i) Communication and interpersonal skills;

(ii) Infection control;

(iii) Safety/emergency procedures, including the Heimlich maneuver;

(iv) Promoting residents' independence; and

(v) Respecting residents' rights.

(2) Basic nursing skills;

(i) Taking and recording vital signs;

(ii) Measuring and recording height and weight;

(iii) Caring for the residents' environment;

(iv) Recognizing abnormal changes in body functioning and the importance of reporting such changes to a supervisor; and

(v) Caring for residents when death is imminent.

(3) Personal care skills, including, but not limited to—

(i) Bathing;

(ii) Grooming, including mouth care;

(iii) Dressing;

(iv) Toileting;

(v) Assisting with eating and hydration;

(vi) Proper feeding techniques;

(vii) Skin care; and

(viii) Transfers, positioning, and turning.

(4) Mental health and social service needs:

(i) Modifying aide's behavior in response to residents' behavior;

(ii) Awareness of developmental tasks associated with the aging process;

(iii) How to respond to resident behavior;

(iv) Allowing the resident to make personal choices, providing and reinforcing other behavior consistent with the resident's dignity; and

(v) Using the resident's family as a source of emotional support.

(5) Care of cognitively impaired residents:

(i) Techniques for addressing the unique needs and behaviors of individual with dementia (Alzheimer's and others);

(ii) Communicating with cognitively impaired residents;

(iii) Understanding the behavior of cognitively impaired residents;

(iv) Appropriate responses to the behavior of cognitively impaired residents; and

(v) Methods of reducing the effects of cognitive impairments.

(6) Basic restorative services:

(i) Training the resident in self care according to the resident's abilities;

(ii) Use of assistive devices in transferring, ambulation, eating, and dressing;

(iii) Maintenance of range of motion;

(iv) Proper turning and positioning in bed and chair;

(v) Bowel and bladder training; and

(vi) Care and use of prosthetic and orthotic devices.

(7) Residents' Rights.

(i) Providing privacy and maintenance of confidentiality;

(ii) Promoting the residents' right to make personal choices to accommodate their needs;

(iii) Giving assistance in resolving grievances and disputes;

(iv) Providing needed assistance in getting to and participating in resident and family groups and other activities;

(v) Maintaining care and security of residents' personal possessions;

(vi) Promoting the resident's right to be free from abuse, mistreatment, and neglect and the need to report any instances of such treatment to appropriate facility staff;

(vii) Avoiding the need for restraints in accordance with current professional standards.

(c) Prohibition of charges. (1) No nurse aide who is employed by, or who has received an offer of employment from, a facility on the date on which the aide begins a nurse aide training and competency evaluation program may be charged for any portion of the program (including any fees for textbooks or other required course materials).

(2) If an individual who is not employed, or does not have an offer to be employed, as a nurse aide becomes employed by, or receives an offer of employment from, a facility not later than 12 months after completing a nurse aide training and competency evaluation program, the State must provide for the reimbursement of costs incurred in completing the program on a pro rata basis during the period in which the individual is employed as a nurse aide.

§ 483.154 Nurse aide competency evaluation.

(a) *Notification to Individual.* The State must advise in advance any individual who takes the competency evaluation that a record of the successful completion of the evaluation will be included in the State's nurse aid registry.

(b) *Content of the competency evaluation program*—(1) *Written or oral examinations.* The competency evaluation must—

(i) Allow an aide to choose between a written and an oral examination;

(ii) Address each course requirement specified in § 483.152(b);

(iii) Be developed from a pool of test questions, only a portion of which is used in any one examination;

(iv) Use a system that prevents disclosure of both the pool of questions and the individual competency evaluations; and

(v) If oral, must be read from a prepared text in a neutral manner.

(2) *Demonstration of skills.* The skills demonstration must consist of a demonstration of randomly selected items drawn from a pool consisting of the tasks generally performed by nurse aides. This pool of skills must include all of the personal care skills listed in § 483.152(b)(3).

(c) *Administration of the competency evaluation.* (1) The competency examination must be administered and evaluated only by—

(i) The State directly; or

(ii) A State approved entity which is neither a skilled nursing facility that participates in Medicare nor a nursing facility that participates in Medicaid.

(2) No nurse aide who is employed by, or who has received an offer of employment from, a facility on the date on which the aide begins a nurse aide competency evaluation program may be charged for any portion of the program.

(3) If an individual who is not employed, or does not have an offer to be employed, as a nurse aide becomes employed by, or receives an offer of employment from, a facility not later than 12 months after completing a nurse aide competency evaluation program, the State must provide for the reimbursement of costs incurred in completing the program on a pro rata basis during the period in which the individual is employed as a nurse aide.

(4) The skills demonstration part of the evaluation must be—

(i) Performed in a facility or laboratory setting comparable to the setting in which the individual will function as a nurse aide; and

(ii) Administered and evaluated by a registered nurse with at least one year's experience in providing care for the elderly or the chronically ill of any age.

(d) *Facility proctoring of the competency evaluation.* (1) The competency evaluation may, at the nurse aide's option, be conducted at the facility in which the nurse aide is or will be employed unless the facility is described in § 483.151(b)(2).

(2) The State may permit the competency evaluation to be proctored by facility personnel if the State finds that the procedure adopted by the facility assures that the competency evaluation program—

(i) Is secure from tampering;

(ii) Is standardized and scored by a testing, educational, or other organization approved by the State; and

(iii) Requires no scoring by facility personnel.

(3) The State must retract the right to proctor nurse aide competency evaluations from facilities in which the State finds any evidence of impropriety, including evidence of tampering by facility staff.

(e) *Successful completion of the competency evaluation program.* (1) The State must establish a standard for satisfactory completion of the competency evaluation. To complete the competency evaluation successfully an individual must pass both the written or oral examination and the skills demonstration.

(2) A record of successful completion of the competency evaluation must be included in the nurse aide registry provided in § 483.156 within 30 days of the date if the individual is found to be competent.

(f) *Unsuccessful completion of the competency evaluation program.* (1) If the individual does not complete the evaluation satisfactorily, the individual must be advised—

(i) Of the areas which he or she; did not pass; and

(ii) That he or she has at least three opportunities to take the evaluation.

(2) The State may impose a maximum upon the number of times an individual upon the number of times an individual may attempt to complete the competency evaluation successfully, but the maximum may be no less than three.

§ 483.156 Registry of nurse aides.

(a) *Establishment of registry.* The State must establish and maintain a registry of nurse aides that meets the requirement of this section. The registry—

(1) Must include as a minimum the information contained in paragraph (c) of this section:

(2) Must be sufficiently accessible to meet the needs of the public and health care providers promptly;

(3) May include home health aides who have successfully completed a home health aide competency evaluation program approved by the State if home health aides are differentiated from nurse aides; and

(4) Must provide that any response to an inquiry that includes a finding of abuse, neglect, or misappropriation of property also include any statement disputing the finding made by the nurse aide, as provided under paragraph (c)(1)(ix) of this section.

(b) *Registry operation.* (1) The State may contract the daily operation and maintenance of the registry to a non-

State entity. However, the State must maintain accountability for overall operation of the registry and compliance with these regulations.

(2) Only the State survey and certification agency may place on the registry findings of abuse, neglect, or misappropriation of property.

(3) The State must determine which individuals who (i) have successfully completed a nurse aide training and competency evaluation program or nurse aide competency evaluation program; (ii) have been deemed as meeting these requirements; or (iii) have had these requirements waived by the State do not qualify to remain on the registry because they have performed no nursing or nursing-related services for a period of 24 consecutive months.

(4) The State may not impose any charges related to registration on individuals listed in the registry.

(5) The State must provide information on the registry promptly.

(c) *Registry Content.* (1) The registry must contain at least the following information on each individual who has successfully completed a nurse aide training and competency evaluation program which meets the requirements of §483.152 or a competency evaluation which meets the requirements of §483.154 and has been found by the State to be competent to function as a nurse aide or who may function as a nurse aide because of meeting criteria in §483.150:

(i) The individual's full name.

(ii) Information necessary to identify each individual;

(iii) The date the individual became eligible for placement in the registry through successfully completing a nurse aide training and competency evaluation program or competency evaluation program or by meeting the requirements of §483.150; and

(iv) The following information on any finding by the State survey agency of abuse, neglect, or misappropriation of property by the individual:

(A) Documentation of the State's investigation, including the nature of the allegation and the evidence that led the State to conclude that the allegation was valid;

(B) The date of the hearing, if the individual chose to have one, and its outcome; and

(C) A statement by the individual disputing the allegation, if he or she chooses to make one; and

(D) This information must be included in the registry within 10 working days of the finding and must remain in the registry permanently, unless the finding was made in error, the individual was found not guilty in a court of law, or the State is notified of the individual's death.

(2) The registry must remove entries for individuals who have performed no nursing or nursing-related services for a period of 24 consecutive months, unless the individual's registry entry includes documented findings of abuse, neglect, or misappropriation of property.

(d) *Disclosure of information.* The State must—

(1) Disclose all of the information in §483.156(c)(1) (iii) and (iv) to all requesters and may disclose additional information it deems necessary; and

(2) Promptly provide individuals with all information contained in the registry on them when adverse findings are placed on the registry and upon request. Individuals on the registry must have sufficient opportunity to correct any misstatements or inaccuracies contained in the registry.

[56 FR 48919, Sept. 26, 1991; 56 FR 59331, Nov. 25, 1991]

§483.158 FFP for nurse aide training and competency evaluation.

(a) State expenditures for nurse aide training and competency evaluation programs and competency evaluation programs are administrative costs. They are matched as indicated in §433.15(b)(8) of this chapter.

(b) FFP is available for State expenditures associated with nurse aide training and competency evaluation programs and competency evaluation programs only for—

(1) Nurse aides employed by a facility;

(2) Nurse aides who have an offer of employment from a facility;

(3) Nurse aides who become employed by a facility not later than 12 months after completing a nurse aide training

and competency evaluation program or competency evaluation program; or

(4) Nurse aides who receive an offer of employment from a facility not later than 12 months after completing a nurse aide training and competency evaluation program or competency evaluation program.

§ 483.160 Requirements for training of paid feeding assistants.

(a) Minimum training course contents. A State-approved training course for paid feeding assistants must include, at a minimum, 8 hours of training in the following:

(1) Feeding techniques.

(2) Assistance with feeding and hydration.

(3) Communication and interpersonal skills.

(4) Appropriate responses to resident behavior.

(5) Safety and emergency procedures, including the Heimlich maneuver.

(6) Infection control.

(7) Resident rights.

(8) Recognizing changes in residents that are inconsistent with their normal behavior and the importance of reporting those changes to the supervisory nurse.

(b) Maintenance of records. A facility must maintain a record of all individuals, used by the facility as feeding assistants, who have successfully completed the training course for paid feeding assistants.

[68 FR 55539, Sept. 26, 2003]

Subpart E—Appeals of Discharges, Transfers, and Preadmission Screening and Annual Resident Review (PASARR) Determinations

SOURCE: 57 FR 56514, Nov. 30, 1992, unless otherwise noted.

§ 483.200 Statutory basis.

This subpart is based on sections 1819(e)(3) and (f)(3) and 1919(e)(3) and (f)(3) of the Act, which require States to make available, to individuals who are discharged or transferred from SNFs or NFs, an appeals process that complies with guidelines issued by the Secretary.

[60 FR 50443, Sept. 29, 1995]

§ 483.202 Definitions.

For purposes of this subpart and subparts B and C—

Discharge means movement from an entity that participates in Medicare as a skilled nursing facility, a Medicare certified distinct part, an entity that participates in Medicaid as a nursing facility, or a Medicaid certified distinct part to a noninstitutional setting when the discharging facility ceases to be legally responsible for the care of the resident.

Individual means an individual or any legal representative of the individual.

Resident means a resident of a SNF or NF or any legal representative of the resident.

Transfer means movement from an entity that participates in Medicare as a skilled nursing facility, a Medicare certified distinct part, an entity that participates in Medicaid as a nursing facility or a Medicaid certified distinct part to another institutional setting when the legal responsibility for the care of the resident changes from the transferring facility to the receiving facility.

§ 483.204 Provision of a hearing and appeal system.

(a) Each State must provide a system for:

(1) A resident of a SNF or a NF to appeal a notice from the SNF or NF of intent to discharge or transfer the resident; and

(2) An individual who has been adversely affected by any PASARR determination made by the State in the context of either a preadmission screening or an annual resident review under subpart C of part 483 to appeal that determination.

(b) The State must provide an appeals system that meets the requirements of this subpart, § 483.12 of this part, and part 431 subpart E of this chapter.

[57 FR 56506, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993]

§ 483.206 Transfers, discharges and relocations subject to appeal.

(a) ''Facility'' means a certified entity, either a Medicare SNF or a Medicaid NF (see §§ 483.5 and 483.12(a)(1)).

(b) A resident has appeal rights when he or she is transferred from—

(1) A certified bed into a noncertified bed; and

(2) A bed in a certified entity to a bed in an entity which is certified as a different provider.

(c) A resident has no appeal rights when he or she is moved from one bed in the certified entity to another bed in the same certified entity.

Subpart F—Requirements That Must be Met by States and State Agencies, Resident Assessment

§ 483.315 Specification of resident assessment instrument.

(a) *Statutory basis.* Sections 1819(e)(5) and 1919(e)(5) of the Act require that a State specify the resident assessment instrument (RAI) to be used by long term care facilities in the State when conducting initial and periodic assessments of each resident's functional capacity, in accordance with § 483.20.

(b) *State options in specifying an RAI.* The RAI that the State specifies must be one of the following:

(1) The instrument designated by CMS.

(2) An alternate instrument specified by the State and approved by CMS, using the criteria specified in the State Operations Manual issued by CMS (CMS Pub. 7) which is available for purchase through the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22151.

(c) *State requirements in specifying an RAI.* (1) Within 30 days after CMS notifies the State of the CMS-designated RAI or changes to it, the State must do one of the following:

(i) Specify the CMS-designated RAI.

(ii) Notify CMS of its intent to specify an alternate instrument.

(2) Within 60 days after receiving CMS approval of an alternate RAI, the State must specify the RAI for use by all long term care facilities participating in the Medicare and Medicaid programs.

(3) After specifying an instrument, the State must provide periodic educational programs for facility staff to assist with implementation of the RAI.

(4) A State must audit implementation of the RAI through the survey process.

(5) A State must obtain approval from CMS before making any modifications to its RAI.

(6) A State must adopt revisions to the RAI that are specified by CMS.

(d) *CMS-designated RAI.* The CMS-designated RAI is published in the State Operations Manual issued by CMS (CMS Pub. 7), as updated periodically, and consists of the following:

(1) The minimum data set (MDS) and common definitions.

(2) Care area assessment (CAA) guidelines and care area triggers (CATs) that are necessary to accurately assess residents, established by CMS.

(3) The quarterly review, based on a subset of the MDS specified by CMS.

(4) The requirements for use of the RAI that appear at § 483.20.

(e) *Minimum data set (MDS).* The MDS includes assessment in the areas specified in § 483.20(b)(i) through (xviii) of this chapter, and as defined in the RAI manual published in the State Operations Manual issued by CMS (CMS Pub. 100–07).

(f) [Reserved]

(g) *Criteria for CMS approval of alternate instrument.* To receive CMS approval, a State's alternate instrument must use the standardized format, organization, item labels and definitions, and instructions specified by CMS in the latest issuance of the State Operations Manual issued by CMS (CMS Pub. 7).

(h) *State MDS system and database requirements.* As part of facility agency responsibilities, the State Survey Agency must:

(1) Support and maintain the CMS State system and database.

(2) Specify to a facility the method of transmission of data, and instruct the facility on this method.

(3) Upon receipt of facility data from CMS, ensure that a facility resolves errors.

(4) Analyze data and generate reports, as specified by CMS.

(i) *State identification of agency that receives RAI data.* The State must identify the component agency that receives RAI data, and ensure that this agency restricts access to the data except for the following:

(1) Reports that contain no resident-identifiable data.

(2) Transmission of reports to CMS.

(3) Transmission of data and reports to the State agency that conducts surveys to ensure compliance with Medicare and Medicaid participation requirements, for purposes related to this function.

(4) Transmission of data and reports to the State Medicaid agency for purposes directly related to the administration of the State Medicaid plan.

(5) Transmission of data and reports to other entities only when authorized as a routine use by CMS.

(j) *Resident-identifiable data.* (1) The State may not release information that is resident-identifiable to the public.

(2) The State may not release RAI data that is resident-identifiable except in accordance with a written agreement under which the recipient agrees to be bound by the restrictions described in paragraph (i) of this section.

[62 FR 67212, Dec. 23, 1997, as amended at 74 FR 40363, Aug. 11, 2009]

Subpart G—Condition of Participation for the Use of Restraint or Seclusion in Psychiatric Residential Treatment Facilities Providing Inpatient Psychiatric Services for Individuals Under Age 21

SOURCE: 66 FR 7161, Jan. 22, 2001, unless otherwise noted.

§ 483.350 Basis and scope.

(a) *Statutory basis.* Sections 1905(a)(16) and (h) of the Act provide that inpatient psychiatric services for individuals under age 21 include only inpatient services that are provided in an institution (or distinct part thereof) that is a psychiatric hospital as defined in section 1861(f) of the Act or in another inpatient setting that the Secretary has specified in regulations. Additionally, the Children's Health Act of 2000 (Pub. L. 106–310) imposes procedural reporting and training requirements regarding the use of restraints and involuntary seclusion in facilities, specifically including facilities that provide inpatient psychiatric services for children under the age of 21 as defined by sections 1905(a)(16) and (h) of the Act.

(b) *Scope.* This subpart imposes requirements regarding the use of restraint or seclusion in psychiatric residential treatment facilities, that are not hospitals, providing inpatient psychiatric services to individuals under age 21.

§ 483.352 Definitions.

For purposes of this subpart, the following definitions apply:

Drug used as a restraint means any drug that—

(1) Is administered to manage a resident's behavior in a way that reduces the safety risk to the resident or others;

(2) Has the temporary effect of restricting the resident's freedom of movement; and

(3) Is not a standard treatment for the resident's medical or psychiatric condition.

Emergency safety intervention means the use of restraint or seclusion as an immediate response to an emergency safety situation.

Emergency safety situation means unanticipated resident behavior that places the resident or others at serious threat of violence or injury if no intervention occurs and that calls for an emergency safety intervention as defined in this section.

Mechanical restraint means any device attached or adjacent to the resident's body that he or she cannot easily remove that restricts freedom of movement or normal access to his or her body.

Minor means a minor as defined under State law and, for the purpose of this subpart, includes a resident who has been declared legally incompetent by the applicable State court.

Personal restraint means the application of physical force without the use

of any device, for the purposes of restraining the free movement of a resident's body. The term personal restraint does not include briefly holding without undue force a resident in order to calm or comfort him or her, or holding a resident's hand to safely escort a resident from one area to another.

Psychiatric Residential Treatment Facility means a facility other than a hospital, that provides psychiatric services, as described in subpart D of part 441 of this chapter, to individuals under age 21, in an inpatient setting.

Restraint means a ''personal restraint,'' ''mechanical restraint,'' or ''drug used as a restraint'' as defined in this section.

Seclusion means the involuntary confinement of a resident alone in a room or an area from which the resident is physically prevented from leaving.

Serious injury means any significant impairment of the physical condition of the resident as determined by qualified medical personnel. This includes, but is not limited to, burns, lacerations, bone fractures, substantial hematoma, and injuries to internal organs, whether self-inflicted or inflicted by someone else.

Staff means those individuals with responsibility for managing a resident's health or participating in an emergency safety intervention and who are employed by the facility on a full-time, part-time, or contract basis.

Time out means the restriction of a resident for a period of time to a designated area from which the resident is not physically prevented from leaving, for the purpose of providing the resident an opportunity to regain self-control.

[66 FR 7161, Jan. 22, 2001, as amended at 66 FR 28116, May 22, 2001]

§ 483.354 General requirements for psychiatric residential treatment facilities.

A psychiatric residential treatment facility must meet the requirements in § 441.151 through § 441.182 of this chapter.

§ 483.356 Protection of residents.

(a) *Restraint and seclusion policy for the protection of residents.* (1) Each resident has the right to be free from restraint or seclusion, of any form, used as a means of coercion, discipline, convenience, or retaliation.

(2) An order for restraint or seclusion must not be written as a standing order or on an as-needed basis.

(3) Restraint or seclusion must not result in harm or injury to the resident and must be used only—

(i) To ensure the safety of the resident or others during an emergency safety situation; and

(ii) Until the emergency safety situation has ceased and the resident's safety and the safety of others can be ensured, even if the restraint or seclusion order has not expired.

(4) Restraint and seclusion must not be used simultaneously.

(b) *Emergency safety intervention.* An emergency safety intervention must be performed in a manner that is safe, proportionate, and appropriate to the severity of the behavior, and the resident's chronological and developmental age; size; gender; physical, medical, and psychiatric condition; and personal history (including any history of physical or sexual abuse).

(c) *Notification of facility policy.* At admission, the facility must—

(1) Inform both the incoming resident and, in the case of a minor, the resident's parent(s) or legal guardian(s) of the facility's policy regarding the use of restraint or seclusion during an emergency safety situation that may occur while the resident is in the program;

(2) Communicate its restraint and seclusion policy in a language that the resident, or his or her parent(s) or legal guardian(s) understands (including American Sign Language, if appropriate) and when necessary, the facility must provide interpreters or translators;

(3) Obtain an acknowledgment, in writing, from the resident, or in the case of a minor, from the parent(s) or legal guardian(s) that he or she has been informed of the facility's policy on the use of restraint or seclusion during an emergency safety situation. Staff must file this acknowledgment in the resident's record; and

(4) Provide a copy of the facility policy to the resident and in the case of a

minor, to the resident's parent(s) or legal guardian(s).

(d) *Contact information*. The facility's policy must provide contact information, including the phone number and mailing address, for the appropriate State Protection and Advocacy organization.

§ 483.358 Orders for the use of restraint or seclusion.

(a) Orders for restraint or seclusion must be by a physician, or other licensed practitioner permitted by the State and the facility to order restraint or seclusion and trained in the use of emergency safety interventions. Federal regulations at 42 CFR 441.151 require that inpatient psychiatric services for recipients under age 21 be provided under the direction of a physician.

(b) If the resident's treatment team physician is available, only he or she can order restraint or seclusion.

(c) A physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion must order the least restrictive emergency safety intervention that is most likely to be effective in resolving the emergency safety situation based on consultation with staff.

(d) If the order for restraint or seclusion is verbal, the verbal order must be received by a registered nurse or other licensed staff such as a licensed practical nurse, while the emergency safety intervention is being initiated by staff or immediately after the emergency safety situation ends. The physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion must verify the verbal order in a signed written form in the resident's record. The physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion must be available to staff for consultation, at least by telephone, throughout the period of the emergency safety intervention.

(e) Each order for restraint or seclusion must:

(1) Be limited to no longer than the duration of the emergency safety situation; and

(2) Under no circumstances exceed 4 hours for residents ages 18 to 21; 2 hours for residents ages 9 to 17; or 1 hour for residents under age 9.

(f) Within 1 hour of the initiation of the emergency safety intervention a physician, or other licensed practitioner trained in the use of emergency safety interventions and permitted by the state and the facility to assess the physical and psychological well being of residents, must conduct a face-to-face assessment of the physical and psychological well being of the resident, including but not limited to—

(1) The resident's physical and psychological status;

(2) The resident's behavior;

(3) The appropriateness of the intervention measures; and

(4) Any complications resulting from the intervention.

(g) Each order for restraint or seclusion must include—

(1) The name of the ordering physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion;

(2) The date and time the order was obtained; and

(3) The emergency safety intervention ordered, including the length of time for which the physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion authorized its use.

(h) Staff must document the intervention in the resident's record. That documentation must be completed by the end of the shift in which the intervention occurs. If the intervention does not end during the shift in which it began, documentation must be completed during the shift in which it ends. Documentation must include all of the following:

(1) Each order for restraint or seclusion as required in paragraph (g) of this section.

(2) The time the emergency safety intervention actually began and ended.

(3) The time and results of the 1-hour assessment required in paragraph (f) of this section.

(4) The emergency safety situation that required the resident to be restrained or put in seclusion.

(5) The name of staff involved in the emergency safety intervention.

(i) The facility must maintain a record of each emergency safety situation, the interventions used, and their outcomes.

(j) The physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion must sign the restraint or seclusion order in the resident's record as soon as possible.

[66 FR 7161, Jan. 22, 2001, as amended at 66 FR 28116, May 22, 2001]

§ 483.360 Consultation with treatment team physician.

If a physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion orders the use of restraint or seclusion, that person must contact the resident's treatment team physician, unless the ordering physician is in fact the resident's treatment team physician. The person ordering the use of restraint or seclusion must—

(a) Consult with the resident's treatment team physician as soon as possible and inform the team physician of the emergency safety situation that required the resident to be restrained or placed in seclusion; and

(b) Document in the resident's record the date and time the team physician was consulted.

[66 FR 7161, Jan. 22, 2001, as amended at 66 FR 28117, May 22, 2001]

§ 483.362 Monitoring of the resident in and immediately after restraint.

(a) Clinical staff trained in the use of emergency safety interventions must be physically present, continually assessing and monitoring the physical and psychological well-being of the resident and the safe use of restraint throughout the duration of the emergency safety intervention.

(b) If the emergency safety situation continues beyond the time limit of the order for the use of restraint, a registered nurse or other licensed staff, such as a licensed practical nurse, must immediately contact the ordering physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion to receive further instructions.

(c) A physician, or other licensed practitioner permitted by the state and the facility to evaluate the resident's well-being and trained in the use of emergency safety interventions, must evaluate the resident's well-being immediately after the restraint is removed.

[66 FR 7161, Jan. 22, 2001, as amended at 66 FR 28117, May 22, 2001]

§ 483.364 Monitoring of the resident in and immediately after seclusion.

(a) Clinical staff, trained in the use of emergency safety interventions, must be physically present in or immediately outside the seclusion room, continually assessing, monitoring, and evaluating the physical and psychological well-being of the resident in seclusion. Video monitoring does not meet this requirement.

(b) A room used for seclusion must—

(1) Allow staff full view of the resident in all areas of the room; and

(2) Be free of potentially hazardous conditions such as unprotected light fixtures and electrical outlets.

(c) If the emergency safety situation continues beyond the time limit of the order for the use of seclusion, a registered nurse or other licensed staff, such as a licensed practical nurse, must immediately contact the ordering physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion to receive further instructions.

(d) A physician, or other licensed practitioner permitted by the state and the facility to evaluate the resident's well-being and trained in the use of emergency safety interventions, must evaluate the resident's well-being immediately after the resident is removed from seclusion.

[66 FR 7161, Jan. 22, 2001, as amended at 66 FR 28117, May 22, 2001]

§ 483.366 Notification of parent(s) or legal guardian(s).

If the resident is a minor as defined in this subpart:

(a) The facility must notify the parent(s) or legal guardian(s) of the resident who has been restrained or placed in seclusion as soon as possible after the initiation of each emergency safety intervention.

(b) The facility must document in the resident's record that the parent(s) or

legal guardian(s) has been notified of the emergency safety intervention, including the date and time of notification and the name of the staff person providing the notification.

§ 483.368 Application of time out.

(a) A resident in time out must never be physically prevented from leaving the time out area.

(b) Time out may take place away from the area of activity or from other residents, such as in the resident's room (exclusionary), or in the area of activity or other residents (inclusionary).

(c) Staff must monitor the resident while he or she is in time out.

§ 483.370 Postintervention debriefings.

(a) Within 24 hours after the use of restraint or seclusion, staff involved in an emergency safety intervention and the resident must have a face-to-face discussion. This discussion must include all staff involved in the intervention except when the presence of a particular staff person may jeopardize the well-being of the resident. Other staff and the resident's parent(s) or legal guardian(s) may participate in the disussion when it is deemed appropriate by the facility. The facility must conduct such discussion in a language that is understood by the resident's parent(s) or legal guardian(s). The discussion must provide both the resident and staff the opportunity to discuss the circumstances resulting in the use of restraint or seclusion and strategies to be used by the staff, the resident, or others that could prevent the future use of restraint or seclusion.

(b) Within 24 hours after the use of restraint or seclusion, all staff involved in the emergency safety intervention, and appropriate supervisory and administrative staff, must conduct a debriefing session that includes, at a minimum, a review and discussion of—

(1) The emergency safety situation that required the intervention, including a discussion of the precipitating factors that led up to the intervention;

(2) Alternative techniques that might have prevented the use of the restraint or seclusion;

(3) The procedures, if any, that staff are to implement to prevent any recurrence of the use of restraint or seclusion; and

(4) The outcome of the intervention, including any injuries that may have resulted from the use of restraint or seclusion.

(c) Staff must document in the resident's record that both debriefing sessions took place and must include in that documentation the names of staff who were present for the debriefing, names of staff that were excused from the debriefing, and any changes to the resident's treatment plan that result from the debriefings.

§ 483.372 Medical treatment for injuries resulting from an emergency safety intervention.

(a) Staff must immediately obtain medical treatment from qualified medical personnel for a resident injured as a result of an emergency safety intervention.

(b) The psychiatric residential treatment facility must have affiliations or written transfer agreements in effect with one or more hospitals approved for participation under the Medicaid program that reasonably ensure that—

(1) A resident will be transferred from the facility to a hospital and admitted in a timely manner when a transfer is medically necessary for medical care or acute psychiatric care;

(2) Medical and other information needed for care of the resident in light of such a transfer, will be exchanged between the institutions in accordance with State medical privacy law, including any information needed to determine whether the appropriate care can be provided in a less restrictive setting; and

(3) Services are available to each resident 24 hours a day, 7 days a week.

(c) Staff must document in the resident's record, all injuries that occur as a result of an emergency safety intervention, including injuries to staff resulting from that intervention.

(d) Staff involved in an emergency safety intervention that results in an injury to a resident or staff must meet with supervisory staff and evaluate the circumstances that caused the injury and develop a plan to prevent future injuries.

§ 483.374 Facility reporting.

(a) *Attestation of facility compliance.* Each psychiatric residential treatment facility that provides inpatient psychiatric services to individuals under age 21 must attest, in writing, that the facility is in compliance with CMS's standards governing the use of restraint and seclusion. This attestation must be signed by the facility director.

(1) A facility with a current provider agreement with the Medicaid agency must provide its attestation to the State Medicaid agency by July 21, 2001.

(2) A facility enrolling as a Medicaid provider must meet this requirement at the time it executes a provider agreement with the Medicaid agency.

(b) *Reporting of serious occurrences.* The facility must report each serious occurrence to both the State Medicaid agency and, unless prohibited by State law, the State-designated Protection and Advocacy system. Serious occurrences that must be reported include a resident's death, a serious injury to a resident as defined in § 483.352 of this part, and a resident's suicide attempt.

(1) Staff must report any serious occurrence involving a resident to both the State Medicaid agency and the State-designated Protection and Advocacy system by no later than close of business the next business day after a serious occurrence. The report must include the name of the resident involved in the serious occurrence, a description of the occurrence, and the name, street address, and telephone number of the facility.

(2) In the case of a minor, the facility must notify the resident's parent(s) or legal guardian(s) as soon as possible, and in no case later than 24 hours after the serious occurrence.

(3) Staff must document in the resident's record that the serious occurrence was reported to both the State Medicaid agency and the State-designated Protection and Advocacy system, including the name of the person to whom the incident was reported. A copy of the report must be maintained in the resident's record, as well as in the incident and accident report logs kept by the facility.

(c) *Reporting of deaths.* In addition to the reporting requirements contained in paragraph (b) of this section, facilities must report the death of any resident to the Centers for Medicare & Medicaid Services (CMS) regional office.

(1) Staff must report the death of any resident to the CMS regional office by no later than close of business the next business day after the resident's death.

(2) Staff must document in the resident's record that the death was reported to the CMS regional office.

[66 FR 7161, Jan. 22, 2001, as amended at 66 FR 28117, May 22, 2001]

§ 483.376 Education and training.

(a) The facility must require staff to have ongoing education, training, and demonstrated knowledge of—

(1) Techniques to identify staff and resident behaviors, events, and environmental factors that may trigger emergency safety situations;

(2) The use of nonphysical intervention skills, such as de-escalation, mediation conflict resolution, active listening, and verbal and observational methods, to prevent emergency safety situations; and

(3) The safe use of restraint and the safe use of seclusion, including the ability to recognize and respond to signs of physical distress in residents who are restrained or in seclusion.

(b) Certification in the use of cardiopulmonary resuscitation, including periodic recertification, is required.

(c) Individuals who are qualified by education, training, and experience must provide staff training.

(d) Staff training must include training exercises in which staff members successfully demonstrate in practice the techniques they have learned for managing emergency safety situations.

(e) Staff must be trained and demonstrate competency before participating in an emergency safety intervention.

(f) Staff must demonstrate their competencies as specified in paragraph (a) of this section on a semiannual basis and their competencies as specified in paragraph (b) of this section on an annual basis.

(g) The facility must document in the staff personnel records that the training and demonstration of competency

were successfully completed. Documentation must include the date training was completed and the name of persons certifying the completion of training.

(h) All training programs and materials used by the facility must be available for review by CMS, the State Medicaid agency, and the State survey agency.

Subpart H [Reserved]

Subpart I—Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded

SOURCE: 53 FR 20496, June 3, 1988, unless otherwise noted. Redesignated at 56 FR 48918, Sept. 26, 1991.

§ 483.400 Basis and purpose.

This subpart implements section 1905 (c) and (d) of the Act which gives the Secretary authority to prescribe regulations for intermediate care facility services in facilities for the mentally retarded or persons with related conditions.

§ 483.405 Relationship to other HHS regulations.

In addition to compliance with the regulations set forth in this subpart, facilities are obliged to meet the applicable provisions of other HHS regulations, including but not limited to those pertaining to nondiscrimination on the basis of race, color, or national origin (45 CFR Part 80), nondiscrimination on the basis of handicap (45 CFR Part 84), nondiscrimination on the basis of age (45 CFR Part 91), protection of human subjects of research (45 CFR Part 46), and fraud and abuse (42 CFR Part 455). Although those regulations are not in themselves considered conditions of participation under this Part, their violation may result in the termination or suspension of, or the refusal to grant or continue, Federal financial assistance.

§ 483.410 Condition of participation: Governing body and management.

(a) *Standard: Governing body*. The facility must identify an individual or individuals to constitute the governing body of the facility. The governing body must—

(1) Exercise general policy, budget, and operating direction over the facility;

(2) Set the qualifications (in addition to those already set by State law, if any) for the administrator of the facility; and

(3) Appoint the administrator of the facility.

(b) *Standard: Compliance with Federal, State, and local laws*. The facility must be in compliance with all applicable provisions of Federal, State and local laws, regulations and codes pertaining to health, safety, and sanitation.

(c) *Standard: Client records*. (1) The facility must develop and maintain a recordkeeping system that includes a separate record for each client and that documents the client's health care, active treatment, social information, and protection of the client's rights.

(2) The facility must keep confidential all information contained in the clients' records, regardless of the form or storage method of the records.

(3) The facility must develop and implement policies and procedures governing the release of any client information, including consents necessary from the client, or parents (if the client is a minor) or legal guardian.

(4) Any individual who makes an entry in a client's record must make it legibly, date it, and sign it.

(5) The facility must provide a legend to explain any symbol or abbreviation used in a client's record.

(6) The facility must provide each identified residential living unit with appropriate aspects of each client's record.

(d) *Standard: Services provided under agreements with outside sources*. (1) If a service required under this subpart is not provided directly, the facility must have a written agreement with an outside program, resource, or service to furnish the necessary service, including emergency and other health care.

(2) The agreement must—

(i) Contain the responsibilities, functions, objectives, and other terms agreed to by both parties; and

(ii) Provide that the facility is responsible for assuring that the outside

services meet the standards for quality of services contained in this subpart.

(3) The facility must assure that outside services meet the needs of each client.

(4) If living quarters are not provided in a facility owned by the ICF/MR, the ICF/MR remains directly responsible for the standards relating to physical environment that are specified in § 483.470 (a) through (g), (j) and (k).

(e) *Standard: Licensure.* The facility must be licensed under applicable State and local law.

[53 FR 20496, June 3, 1988. Redesignated at 56 FR 48918, Sept. 26, 1991, and amended at 57 FR 43925, Sept. 23, 1992]

§ 483.420 Condition of participation: Client protections.

(a) *Standard: Protection of clients' rights.* The facility must ensure the rights of all clients. Therefore, the facility must—

(1) Inform each client, parent (if the client is a minor), or legal guardian, of the client's rights and the rules of the facility;

(2) Inform each client, parent (if the client is a minor), or legal guardian, of the client's medical condition, developmental and behavioral status, attendant risks of treatment, and of the right to refuse treatment;

(3) Allow and encourage individual clients to exercise their rights as clients of the facility, and as citizens of the United States, including the right to file complaints, and the right to due process;

(4) Allow individual clients to manage their financial affairs and teach them to do so to the extent of their capabilities;

(5) Ensure that clients are not subjected to physical, verbal, sexual or psychological abuse or punishment;

(6) Ensure that clients are free from unnecessary drugs and physical restraints and are provided active treatment to reduce dependency on drugs and physical restraints;

(7) Provide each client with the opportunity for personal privacy and ensure privacy during treatment and care of personal needs;

(8) Ensure that clients are not compelled to perform services for the facility and ensure that clients who do work for the facility are compensated for their efforts at prevailing wages and commensurate with their abilities;

(9) Ensure clients the opportunity to communicate, associate and meet privately with individuals of their choice, and to send and receive unopened mail;

(10) Ensure that clients have access to telephones with privacy for incoming and outgoing local and long distance calls except as contraindicated by factors identified within their individual program plans;

(11) Ensure clients the opportunity to participate in social, religious, and community group activities;

(12) Ensure that clients have the right to retain and use appropriate personal possessions and clothing, and ensure that each client is dressed in his or her own clothing each day; and

(13) Permit a husband and wife who both reside in the facility to share a room.

(b) *Standard: Client finances.* (1) The facility must establish and maintain a system that—

(i) Assures a full and complete accounting of clients' personal funds entrusted to the facility on behalf of clients; and

(ii) Precludes any commingling of client funds with facility funds or with the funds of any person other than another client.

(2) The client's financial record must be available on request to the client, parents (if the client is a minor) or legal guardian.

(c) *Standard: Communication with clients, parents, and guardians.* The facility must—

(1) Promote participation of parents (if the client is a minor) and legal guardians in the process of providing active treatment to a client unless their participation is unobtainable or inappropriate;

(2) Answer communications from clients' families and friends promptly and appropriately;

(3) Promote visits by individuals with a relationship to the client (such as family, close friends, legal guardians and advocates) at any reasonable hour, without prior notice, consistent with

the right of that client's and other clients' privacy, unless the interdisciplinary team determines that the visit would not be appropriate;

(4) Promote visits by parents or guardians to any area of the facility that provides direct client care services to the client, consistent with the right of that client's and other clients' privacy;

(5) Promote frequent and informal leaves from the facility for visits, trips, or vacations; and

(6) Notify promptly the client's parents or guardian of any significant incidents, or changes in the client's condition including, but not limited to, serious illness, accident, death, abuse, or unauthorized absence.

(d) *Standard: Staff treatment of clients.* (1) The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect or abuse of the client.

(i) Staff of the facility must not use physical, verbal, sexual or psychological abuse or punishment.

(ii) Staff must not punish a client by withholding food or hydration that contributes to a nutritionally adequate diet.

(iii) The facility must prohibit the employment of individuals with a conviction or prior employment history of child or client abuse, neglect or mistreatment.

(2) The facility must ensure that all allegations of mistreatment, neglect or abuse, as well as injuries of unknown source, are reported immediately to the administrator or to other officials in accordance with State law through established procedures.

(3) The facility must have evidence that all alleged violations are thoroughly investigated and must prevent further potential abuse while the investigation is in progress.

(4) The results of all investigations must be reported to the administrator or designated representative or to other officials in accordance with State law within five working days of the incident and, if the alleged violation is verified, appropriate corrective action must be taken.

§ 483.430 Condition of participation: Facility staffing.

(a) *Standard: Qualified mental retardation professional.* Each client's active treatment program must be integrated, coordinated and monitored by a qualified mental retardation professional who—

(1) Has at least one year of experience working directly with persons with mental retardation or other developmental disabilities; and

(2) Is one of the following:

(i) A doctor of medicine or osteopathy.

(ii) A registered nurse.

(iii) An individual who holds at least a bachelor's degree in a professional category specified in paragraph (b)(5) of this section.

(b) *Standard: Professional program services.* (1) Each client must receive the professional program services needed to implement the active treatment program defined by each client's individual program plan. Professional program staff must work directly with clients and with paraprofessional, nonprofessional and other professional program staff who work with clients.

(2) The facility must have available enough qualified professional staff to carry out and monitor the various professional interventions in accordance with the stated goals and objectives of every individual program plan.

(3) Professional program staff must participate as members of the interdisciplinary team in relevant aspects of the active treatment process.

(4) Professional program staff must participate in on-going staff development and training in both formal and informal settings with other professional, paraprofessional, and nonprofessional staff members.

(5) Professional program staff must be licensed, certified, or registered, as applicable, to provide professional services by the State in which he or she practices. Those professional program staff who do not fall under the jurisdiction of State licensure, certification, or registration requirements, specified in § 483.410(b), must meet the following qualifications:

(i) To be designated as an occupational therapist, an individual must be

eligible for certification as an occupational therapist by the American Occupational Therapy Association or another comparable body.

(ii) To be designated as an occupational therapy assistant, an individual must be eligible for certification as a certified occupational therapy assistant by the American Occupational Therapy Association or another comparable body.

(iii) To be designated as a physical therapist, an individual must be eligible for certification as a physical therapist by the American Physical Therapy Association or another comparable body.

(iv) To be designated as a physical therapy assistant, an individual must be eligible for registration by the American Physical Therapy Association or be a graduate of a two year college-level program approved by the American Physical Therapy Association or another comparable body.

(v) To be designated as a psychologist, an individual must have at least a master's degree in psychology from an accredited school.

(vi) To be designated as a social worker, an individual must—

(A) Hold a graduate degree from a school of social work accredited or approved by the Council on Social Work Education or another comparable body; or

(B) Hold a Bachelor of Social Work degree from a college or university accredited or approved by the Council on Social Work Education or another comparable body.

(vii) To be designated as a speech-language pathologist or audiologist, an individual must—

(A) Be eligible for a Certificate of Clinical Competence in Speech-Language Pathology or Audiology granted by the American Speech-Language-Hearing Association or another comparable body; or

(B) Meet the educational requirements for certification and be in the process of accumulating the supervised experience required for certification.

(viii) To be designated as a professional recreation staff member, an individual must have a bachelor's degree in recreation or in a specialty area such as art, dance, music or physical education.

(ix) To be designated as a professional dietitian, an individual must be eligible for registration by the American Dietetics Association.

(x) To be designated as a human services professional an individual must have at least a bachelor's degree in a human services field (including, but not limited to: sociology, special education, rehabilitation counseling, and psychology).

(xi) If the client's individual program plan is being successfully implemented by facility staff, professional program staff meeting the qualifications of paragraph (b)(5) (i) through (x) of this section are not required—

(A) Except for qualified mental retardation professionals;

(B) Except for the requirements of paragraph (b)(2) of this section concerning the facility's provision of enough qualified professional program staff; and

(C) Unless otherwise specified by State licensure and certification requirements.

(c) *Standard: Facility staffing*. (1) The facility must not depend upon clients or volunteers to perform direct care services for the facility.

(2) There must be responsible direct care staff on duty and awake on a 24-hour basis, when clients are present, to take prompt, appropriate action in case of injury, illness, fire or other emergency, in each defined residential living unit housing—

(i) Clients for whom a physician has ordered a medical care plan;

(ii) Clients who are aggressive, assaultive or security risks;

(iii) More than 16 clients; or

(iv) Fewer than 16 clients within a multi-unit building.

(3) There must be a responsible direct care staff person on duty on a 24 hour basis (when clients are present) to respond to injuries and symptoms of illness, and to handle emergencies, in each defined residential living unit housing—

(i) Clients for whom a physician has not ordered a medical care plan;

(ii) Clients who are not aggressive, assaultive or security risks; and

(iii) Sixteen or fewer clients,

(4) The facility must provide sufficient support staff so that direct care staff are not required to perform support services to the extent that these duties interfere with the exercise of their primary direct client care duties.

(d) *Standard: Direct care (residential living unit) staff.* (1) The facility must provide sufficient direct care staff to manage and supervise clients in accordance with their individual program plans.

(2) Direct care staff are defined as the present on-duty staff calculated over all shifts in a 24-hour period for each defined residential living unit.

(3) Direct care staff must be provided by the facility in the following minimum ratios of direct care staff to clients:

(i) For each defined residential living unit serving children under the age of 12, severely and profoundly retarded clients, clients with severe physical disabilities, or clients who are aggressive, assaultive, or security risks, or who manifest severely hyperactive or psychotic-like behavior, the staff to client ratio is 1 to 3.2.

(ii) For each defined residential living unit serving moderately retarded clients, the staff to client ratio is 1 to 4.

(iii) For each defined residential living unit serving clients who function within the range of mild retardation, the staff to client ratio is 1 to 6.4.

(4) When there are no clients present in the living unit, a responsible staff member must be available by telephone.

(e) *Standard: Staff training program.* (1) The facility must provide each employee with initial and continuing training that enables the employee to perform his or her duties effectively, efficiently, and competently.

(2) For employees who work with clients, training must focus on skills and competencies directed toward clients' developmental, behavioral, and health needs.

(3) Staff must be able to demonstrate the skills and techniques necessary to administer interventions to manage the inappropriate behavior of clients.

(4) Staff must be able to demonstrate the skills and techniques necessary to implement the individual program plans for each client for whom they are responsible.

§ 483.440 Condition of participation: Active treatment services.

(a) *Standard: Active treatment.* (1) Each client must receive a continuous active treatment program, which includes aggressive, consistent implementation of a program of specialized and generic training, treatment, health services and related services described in this subpart, that is directed toward—

(i) The acquisition of the behaviors necessary for the client to function with as much self determination and independence as possible; and

(ii) The prevention or deceleration of regression or loss of current optimal functional status.

(2) Active treatment does not include services to maintain generally independent clients who are able to function with little supervision or in the absence of a continuous active treatment program.

(b) *Standard: Admissions, transfers, and discharge.* (1) Clients who are admitted by the facility must be in need of and receiving active treatment services.

(2) Admission decisions must be based on a preliminary evaluation of the client that is conducted or updated by the facility or by outside sources.

(3) A preliminary evaluation must contain background information as well as currently valid assessments of functional developmental, behavioral, social, health and nutritional status to determine if the facility can provide for the client's needs and if the client is likely to benefit from placement in the facility.

(4) If a client is to be either transferred or discharged, the facility must—

(i) Have documentation in the client's record that the client was transferred or discharged for good cause; and

(ii) Provide a reasonable time to prepare the client and his or her parents or guardian for the transfer or discharge (except in emergencies).

(5) At the time of the discharge, the facility must—

(i) Develop a final summary of the client's developmental, behavioral, social, health and nutritional status and, with the consent of the client, parents (if the client is a minor) or legal guardian, provide a copy to authorized persons and agencies; and

(ii) Provide a post-discharge plan of care that will assist the client to adjust to the new living environment.

(c) *Standard: Individual program plan.* (1) Each client must have an individual program plan developed by an interdisciplinary team that represents the professions, disciplines or service areas that are relevant to—

(i) Identifying the client's needs, as described by the comprehensive functional assessments required in paragraph (c)(3) of this section; and

(ii) Designing programs that meet the client's needs.

(2) Appropriate facility staff must participate in interdisciplinary team meetings. Participation by other agencies serving the client is encouraged. Participation by the client, his or her parent (if the client is a minor), or the client's legal guardian is required unless that participation is unobtainable or inappropriate.

(3) Within 30 days after admission, the interdisciplinary team must perform accurate assessments or reassessments as needed to supplement the preliminary evaluation conducted prior to admission. The comprehensive functional assessment must take into consideration the client's age (for example, child, young adult, elderly person) and the implications for active treatment at each stage, as applicable, and must—

(i) Identify the presenting problems and disabilities and where possible, their causes;

(ii) Identify the client's specific developmental strengths;

(iii) Identify the client's specific developmental and behavioral management needs;

(iv) Identify the client's need for services without regard to the actual availability of the services needed; and

(v) Include physical development and health, nutritional status, sensorimotor development, affective development, speech and language development and auditory functioning, cognitive development, social development, adaptive behaviors or independent living skills necessary for the client to be able to function in the community, and as applicable, vocational skills.

(4) Within 30 days after admission, the interdisciplinary team must prepare for each client an individual program plan that states the specific objectives necessary to meet the client's needs, as identified by the comprehensive assessment required by paragraph (c)(3) of this section, and the planned sequence for dealing with those objectives. These objectives must—

(i) Be stated separately, in terms of a single behavioral outcome;

(ii) Be assigned projected completion dates;

(iii) Be expressed in behavioral terms that provide measurable indices of performance;

(iv) Be organized to reflect a developmental progression appropriate to the individual; and

(v) Be assigned priorities.

(5) Each written training program designed to implement the objectives in the individual program plan must specify:

(i) The methods to be used;

(ii) The schedule for use of the method;

(iii) The person responsible for the program;

(iv) The type of data and frequency of data collection necessary to be able to assess progress toward the desired objectives;

(v) The inappropriate client behavior(s), if applicable; and

(vi) Provision for the appropriate expression of behavior and the replacement of inappropriate behavior, if applicable, with behavior that is adaptive or appropriate.

(6) The individual program plan must also:

(i) Describe relevant interventions to support the individual toward independence.

(ii) Identify the location where program strategy information (which must be accessible to any person responsible for implementation) can be found.

(iii) Include, for those clients who lack them, training in personal skills

essential for privacy and independence (including, but not limited to, toilet training, personal hygiene, dental hygiene, self-feeding, bathing, dressing, grooming, and communication of basic needs), until it has been demonstrated that the client is developmentally incapable of acquiring them.

(iv) Identify mechanical supports, if needed, to achieve proper body position, balance, or alignment. The plan must specify the reason for each support, the situations in which each is to be applied, and a schedule for the use of each support.

(v) Provide that clients who have multiple disabling conditions spend a major portion of each waking day out of bed and outside the bedroom area, moving about by various methods and devices whenever possible.

(vi) Include opportunities for client choice and self-management.

(7) A copy of each client's individual program plan must be made available to all relevant staff, including staff of other agencies who work with the client, and to the client, parents (if the client is a minor) or legal guardian.

(d) *Standard: Program implementation.* (1) As soon as the interdisciplinary team has formulated a client's individual program plan, each client must receive a continuous active treatment program consisting of needed interventions and services in sufficient number and frequency to support the achievement of the objectives identified in the individual program plan.

(2) The facility must develop an active treatment schedule that outlines the current active treatment program and that is readily available for review by relevant staff.

(3) Except for those facets of the individual program plan that must be implemented only by licensed personnel, each client's individual program plan must be implemented by all staff who work with the client, including professional, paraprofessional and nonprofessional staff.

(e) *Standard: Program documentation.* (1) Data relative to accomplishment of the criteria specified in client individual program plan objectives must be documented in measureable terms.

(2) The facility must document significant events that are related to the client's individual program plan and assessments and that contribute to an overall understanding of the client's ongoing level and quality of functioning.

(f) *Standard: Program monitoring and change.* (1) The individual program plan must be reviewed at least by the qualified mental retardation professional and revised as necessary, including, but not limited to situations in which the client—

(i) Has successfully completed an objective or objectives identified in the individual program plan;

(ii) Is regressing or losing skills already gained;

(iii) Is failing to progress toward identified objectives after reasonable efforts have been made; or

(iv) Is being considered for training towards new objectives.

(2) At least annually, the comprehensive functional assessment of each client must be reviewed by the interdisciplinary team for relevancy and updated as needed, and the individual program plan must be revised, as appropriate, repeating the process set forth in paragraph (c) of this section.

(3) The facility must designate and use a specially constituted committee or committees consisting of members of facility staff, parents, legal guardians, clients (as appropriate), qualified persons who have either experience or training in contemporary practices to change inappropriate client behavior, and persons with no ownership or controlling interest in the facility to—

(i) Review, approve, and monitor individual programs designed to manage inappropriate behavior and other programs that, in the opinion of the committee, involve risks to client protection and rights;

(ii) Insure that these programs are conducted only with the written informed consent of the client, parent (if the client is a minor), or legal guardian; and

(iii) Review, monitor and make suggestions to the facility about its practices and programs as they relate to drug usage, physical restraints, time-out rooms, application of painful or noxious stimuli, control of inappropriate behavior, protection of client rights and funds, and any other area

that the committee believes need to be addressed.

(4) The provisions of paragraph (f)(3) of this section may be modified only if, in the judgment of the State survey agency, Court decrees, State law or regulations provide for equivalent client protection and consultation.

§ 483.450 Condition of participation: Client behavior and facility practices.

(a) *Standard: Facility practices—Conduct toward clients.* (1) The facility must develop and implement written policies and procedures for the management of conduct between staff and clients. These policies and procedures must—

(i) Promote the growth, development and independence of the client;

(ii) Address the extent to which client choice will be accommodated in daily decision-making, emphasizing self-determination and self-management, to the extent possible;

(iii) Specify client conduct to be allowed or not allowed; and

(iv) Be available to all staff, clients, parents of minor children, and legal guardians.

(2) To the extent possible, clients must participate in the formulation of these policies and procedures.

(3) Clients must not discipline other clients, except as part of an organized system of self-government, as set forth in facility policy.

(b) *Standard: Management of inappropriate client behavior.* (1) The facility must develop and implement written policies and procedures that govern the management of inappropriate client behavior. These policies and procedures must be consistent with the provisions of paragraph (a) of this section. These procedures must—

(i) Specify all facility approved interventions to manage inappropriate client behavior;

(ii) Designate these interventions on a hierarchy to be implemented, ranging from most positive or least intrusive, to least positive or most intrusive;

(iii) Insure, prior to the use of more restrictive techniques, that the client's record documents that programs incorporating the use of less intrusive or more positive techniques have been tried systematically and demonstrated to be ineffective; and

(iv) Address the following:

(A) The use of time-out rooms.

(B) The use of physical restraints.

(C) The use of drugs to manage inappropriate behavior.

(D) The application of painful or noxious stimuli.

(E) The staff members who may authorize the use of specified interventions.

(F) A mechanism for monitoring and controlling the use of such interventions.

(2) Interventions to manage inappropriate client behavior must be employed with sufficient safeguards and supervision to ensure that the safety, welfare and civil and human rights of clients are adequately protected.

(3) Techniques to manage inappropriate client behavior must never be used for disciplinary purposes, for the convenience of staff or as a substitute for an active treatment program.

(4) The use of systematic interventions to manage inappropriate client behavior must be incorporated into the client's individual program plan, in accordance with § 483.440(c) (4) and (5) of this subpart.

(5) Standing or as needed programs to control inappropriate behavior are not permitted.

(c) *Standard: Time-out rooms.* (1) A client may be placed in a room from which egress is prevented only if the following conditions are met:

(i) The placement is a part of an approved systematic time-out program as required by paragraph (b) of this section. (Thus, emergency placement of a client into a time-out room is not allowed.)

(ii) The client is under the direct constant visual supervision of designated staff.

(iii) The door to the room is held shut by staff or by a mechanism requiring constant physical pressure from a staff member to keep the mechanism engaged.

(2) Placement of a client in a time-out room must not exceed one hour.

(3) Clients placed in time-out rooms must be protected from hazardous conditions including, but not limited to, presence of sharp corners and objects,

uncovered light fixtures, unprotected electrical outlets.

(4) A record of time-out activities must be kept.

(d) *Standard: Physical restraints.* (1) The facility may employ physical restraint only—

(i) As an integral part of an individual program plan that is intended to lead to less restrictive means of managing and eliminating the behavior for which the restraint is applied;

(ii) As an emergency measure, but only if absolutely necessary to protect the client or others from injury; or

(iii) As a health-related protection prescribed by a physician, but only if absolutely necessary during the conduct of a specific medical or surgical procedure, or only if absolutely necessary for client protection during the time that a medical condition exists.

(2) Authorizations to use or extend restraints as an emergency must be:

(i) In effect no longer than 12 consecutive hours; and

(ii) Obtained as soon as the client is restrained or stable.

(3) The facility must not issue orders for restraint on a standing or as needed basis.

(4) A client placed in restraint must be checked at least every 30 minutes by staff trained in the use of restraints, released from the restraint as quickly as possible, and a record of these checks and usage must be kept.

(5) Restraints must be designed and used so as not to cause physical injury to the client and so as to cause the least possible discomfort.

(6) Opportunity for motion and exercise must be provided for a period of not less than 10 minutes during each two hour period in which restraint is employed, and a record of such activity must be kept.

(7) Barred enclosures must not be more than three feet in height and must not have tops.

(e) *Standard: Drug usage.* (1) The facility must not use drugs in doses that interfere with the individual client's daily living activities.

(2) Drugs used for control of inappropriate behavior must be approved by the interdisciplinary team and be used only as an integral part of the client's individual program plan that is directed specifically towards the reduction of and eventual elimination of the behaviors for which the drugs are employed.

(3) Drugs used for control of inappropriate behavior must not be used until it can be justified that the harmful effects of the behavior clearly outweigh the potentially harmful effects of the drugs.

(4) Drugs used for control of inappropriate behavior must be—

(i) Monitored closely, in conjunction with the physician and the drug regimen review requirement at § 483.460(j), for desired responses and adverse consequences by facility staff; and

(ii) Gradually withdrawn at least annually in a carefully monitored program conducted in conjunction with the interdisciplinary team, unless clinical evidence justifies that this is contraindicated.

§ 483.460 Condition of participation: Health care services.

(a) *Standard: Physician services.* (1) The facility must ensure the availability of physician services 24 hours a day.

(2) The physician must develop, in coordination with licensed nursing personnel, a medical care plan of treatment for a client if the physician determines that an individual client requires 24-hour licensed nursing care. This plan must be integrated in the individual program plan.

(3) The facility must provide or obtain preventive and general medical care as well as annual physical examinations of each client that at a minimum include the following:

(i) Evaluation of vision and hearing.

(ii) Immunizations, using as a guide the recommendations of the Public Health Service Advisory Commitee on Immunization Practices or of the Committee on the Control of Infectious Diseases of the American Academy of Pediatrics.

(iii) Routine screening laboratory examinations as determined necessary by the physician, and special studies when needed.

(iv) Tuberculosis control, appropriate to the facility's population, and in accordance with the recommendations of

the American College of Chest Physicians or the section of diseases of the chest of the American Academy of Pediatrics, or both.

(4) To the extent permitted by State law, the facility may utilize physician assistants and nurse practitioners to provide physician services as described in this section.

(b) *Standard: Physician participation in the individual program plan.* A physician must participate in—

(1) The establishment of each newly admitted client's initial individual program plan as required by §456.380 of this chapter that specified plan of care requirements for ICFs; and

(2) If appropriate, physicians must participate in the review and update of an individual program plan as part of the interdisciplinary team process either in person or through written report to the interdisciplinary team.

(c) *Standard: Nursing services.* The facility must provide clients with nursing services in accordance with their needs. These services must include—

(1) Participation as appropriate in the development, review, and update of an individual program plan as part of the interdisciplinary team process;

(2) The development, with a physician, of a medical care plan of treatment for a client when the physician has determined that an individual client requires such a plan;

(3) For those clients certified as not needing a medical care plan, a review of their health status which must—

(i) Be by a direct physical examination;

(ii) Be by a licensed nurse;

(iii) Be on a quarterly or more frequent basis depending on client need;

(iv) Be recorded in the client's record; and

(v) Result in any necessary action (including referral to a physician to address client health problems).

(4) Other nursing care as prescribed by the physician or as identified by client needs; and

(5) Implementing, with other members of the interdisciplinary team, appropriate protective and preventive health measures that include, but are not limited to—

(i) Training clients and staff as needed in appropriate health and hygiene methods;

(ii) Control of communicable diseases and infections, including the instruction of other personnel in methods of infection control; and

(iii) Training direct care staff in detecting signs and symptoms of illness or dysfunction, first aid for accidents or illness, and basic skills required to meet the health needs of the clients.

(d) *Standard: Nursing staff.* (1) Nurses providing services in the facility must have a current license to practice in the State.

(2) The facility must employ or arrange for licensed nursing services sufficient to care for clients health needs including those clients with medical care plans.

(3) The facility must utilize registered nurses as appropriate and required by State law to perform the health services specified in this section.

(4) If the facility utilizes only licensed practical or vocational nurses to provide health services, it must have a formal arrangement with a registered nurse to be available for verbal or on-site consultation to the licensed practical or vocational nurse.

(5) Non-licensed nursing personnel who work with clients under a medical care plan must do so under the supervision of licensed persons.

(e) *Standard: Dental services.* (1) The facility must provide or make arrangements for comprehensive diagnostic and treatment services for each client from qualified personnel, including licensed dentists and dental hygienists either through organized dental services in-house or through arrangement.

(2) If appropriate, dental professionals must participate, in the development, review and update of an individual program plan as part of the interdisciplinary process either in person or through written report to the interdisciplinary team.

(3) The facility must provide education and training in the maintenance of oral health.

(f) *Standard: Comprehensive dental diagnostic services.* Comprehensive dental diagnostic services include—

(1) A complete extraoral and intraoral examination, using all diagnostic aids necessary to properly evaluate the client's oral condition, not later than one month after admission to the facility (unless the examination was completed within twelve months before admission);

(2) Periodic examination and diagnosis performed at least annually, including radiographs when indicated and detection of manifestations of systemic disease; and

(3) A review of the results of examination and entry of the results in the client's dental record.

(g) *Standard: Comprehensive dental treatment*. The facility must ensure comprehensive dental treatment services that include—

(1) The availability for emergency dental treatment on a 24-hour-a-day basis by a licensed dentist; and

(2) Dental care needed for relief of pain and infections, restoration of teeth, and maintenance of dental health.

(h) *Standard: Documentation of dental services*. (1) If the facility maintains an in-house dental service, the facility must keep a permanent dental record for each client, with a dental summary maintained in the client's living unit.

(2) If the facility does not maintain an in-house dental service, the facility must obtain a dental summary of the results of dental visits and maintain the summary in the client's living unit.

(i) *Standard: Pharmacy services*. The facility must provide or make arrangements for the provision of routine and emergency drugs and biologicals to its clients. Drugs and biologicals may be obtained from community or contract pharmacists or the facility may maintain a licensed pharmacy.

(j) *Standard: Drug regimen review*. (1) A pharmacist with input from the interdisciplinary team must review the drug regimen of each client at least quarterly.

(2) The pharmacist must report any irregularities in clients' drug regimens to the prescribing physician and interdisciplinary team.

(3) The pharmacist must prepare a record of each client's drug regimen reviews and the facility must maintain that record.

(4) An individual medication administration record must be maintained for each client.

(5) As appropriate the pharmacist must participate in the development, implementation, and review of each client's individual program plan either in person or through written report to the interdisciplinary team.

(k) *Standard: Drug administration*. The facility must have an organized system for drug administration that identifies each drug up to the point of administration. The system must assure that—

(1) All drugs are administered in compliance with the physician's orders;

(2) All drugs, including those that are self-administered, are administered without error;

(3) Unlicensed personnel are allowed to administer drugs only if State law permits;

(4) Clients are taught how to administer their own medications if the interdisciplinary team determines that self administration of medications is an appropriate objective, and if the physician does not specify otherwise;

(5) The client's physician is informed of the interdisciplinary team's decision that self-administration of medications is an objective for the client;

(6) No client self-administers medications until he or she demonstrates the competency to do so;

(7) Drugs used by clients while not under the direct care of the facility are packaged and labeled in accordance with State law; and

(8) Drug administration errors and adverse drug reactions are recorded and reported immediately to a physician.

(l) *Standard: Drug storage and recordkeeping*. (1) The facility must store drugs under proper conditions of sanitation, temperature, light, humidity, and security.

(2) The facility must keep all drugs and biologicals locked except when being prepared for administration. Only authorized persons may have access to the keys to the drug storage area. Clients who have been trained to self administer drugs in accordance with § 483.460(k)(4) may have access to keys to their individual drug supply.

(3) The facility must maintain records of the receipt and disposition of all controlled drugs.

(4) The facility must, on a sample basis, periodically reconcile the receipt and disposition of all controlled drugs in schedules II through IV (drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 801 *et seq.*, as implemented by 21 CFR part 308).

(5) If the facility maintains a licensed pharmacy, the facility must comply with the regulations for controlled drugs.

(m) *Standard: Drug labeling.* (1) Labeling of drugs and biologicals must—

(i) Be based on currently accepted professional principles and practices; and

(ii) Include the appropriate accessory and cautionary instructions, as well as the expiration date, if applicable.

(2) The facility must remove from use—

(i) Outdated drugs; and

(ii) Drug containers with worn, illegible, or missing labels.

(3) Drugs and biologicals packaged in containers designated for a particular client must be immediately removed from the client's current medication supply if discontinued by the physician.

(n) *Standard: Laboratory services.* (1) If a facility chooses to provide laboratory services, the laboratory must meet the requirements specified in part 493 of this chapter.

(2) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialities of service in accordance with the requirements of part 493 of this chapter.

[53 FR 20496, June 3, 1988, as amended at 57 FR 7136, Feb. 28, 1992]

§ 483.470 Condition of participation: Physical environment.

(a) *Standard: Client living environment.* (1) The facility must not house clients of grossly different ages, developmental levels, and social needs in close physical or social proximity unless the housing is planned to promote the growth and development of all those housed together.

(2) The facility must not segregate clients solely on the basis of their physical disabilities. It must integrate clients who have ambulation deficits or who are deaf, blind, or have seizure disorders, etc., with others of comparable social and intellectual development.

(b) *Standard: Client bedrooms.* (1) Bedrooms must—

(i) Be rooms that have at least one outside wall;

(ii) Be equipped with or located near toilet and bathing facilities;

(iii) Accommodate no more than four clients unless granted a variance under paragraph (b)(3) of this section;

(iv) Measure at least 60 square feet per client in multiple client bedrooms and at least 80 square feet in single client bedrooms; and

(v) In all facilities initially certified, or in buildings constructed or with major renovations or conversions on or after October 3, 1988, have walls that extend from floor to ceiling.

(2) If a bedroom is below grade level, it must have a window that—

(i) Is usable as a second means of escape by the client(s) occupying the room; and

(ii) Is no more than 44 inches (measured to the window sill) above the floor unless the facility is surveyed under the Health Care Occupancy Chapter of the Life Safety Code, in which case the window must be no more than 36 inches (measured to the window sill) above the floor.

(3) The survey agency may grant a variance from the limit of four clients per room only if a physician who is a member of the interdisciplinary team and who is a qualified mental retardation professional—

(i) Certifies that each client to be placed in a bedroom housing more than four persons is so severely medically impaired as to require direct and continuous monitoring during sleeping hours; and

(ii) Documents the reasons why housing in a room of only four or fewer persons would not be medically feasible.

(4) The facility must provide each client with—

(i) A separate bed of proper size and height for the convenience of the client;

(ii) A clean, comfortable, mattress;

(iii) Bedding appropriate to the weather and climate; and

(iv) Functional furniture appropriate to the client's needs, and individual closet space in the client's bedroom with clothes racks and shelves accessible to the client.

(c) *Standard: Storage space in bedroom.* The facility must provide—

(1) Space and equipment for daily out-of-bed activity for all clients who are not yet mobile, except those who have a short-term illness or those few clients for whom out-of-bed activity is a threat to health and safety; and

(2) Suitable storage space, accessible to clients, for personal possessions, such as TVs, radios, prosthetic equipment and clothing.

(d) *Standard: Client bathrooms.* The facility must—

(1) Provide toilet and bathing facilities appropriate in number, size, and design to meet the needs of the clients;

(2) Provide for individual privacy in toilets, bathtubs, and showers; and

(3) In areas of the facility where clients who have not been trained to regulate water temperature are exposed to hot water, ensure that the temperature of the water does not exceed 110 °Fahrenheit.

(e) *Standard: Heating and ventilation.* (1) Each client bedroom in the facility must have—

(i) At least one window to the outside; and

(ii) Direct outside ventilation by means of windows, air conditioning, or mechanical ventilation.

(2) The facility must—

(i) Maintain the temperature and humidity within a normal comfort range by heating, air conditioning or other means; and

(ii) Ensure that the heating apparatus does not constitute a burn or smoke hazard to clients.

(f) *Standard: Floors.* The facility must have—

(1) Floors that have a resilient, nonabrasive, and slip-resistant surface;

(2) Nonabrasive carpeting, if the area used by clients is carpeted and serves clients who lie on the floor or ambulate with parts of their bodies, other than feet, touching the floor; and

(3) Exposed floor surfaces and floor coverings that promote mobility in areas used by clients, and promote maintenance of sanitary conditions.

(g) *Standard: Space and equipment.* The facility must—

(1) Provide sufficient space and equipment in dining, living, health services, recreation, and program areas (including adequately equipped and sound treated areas for hearing and other evaluations if they are conducted in the facility) to enable staff to provide clients with needed services as required by this subpart and as identified in each client's individual program plan.

(2) Furnish, maintain in good repair, and teach clients to use and to make informed choices about the use of dentures, eyeglasses, hearing and other communications aids, braces, and other devices identified by the interdisciplinary team as needed by the client.

(3) Provide adequate clean linen and dirty linen storage areas.

(h) *Standard: Emergency plan and procedures.* (1) The facility must develop and implement detailed written plans and procedures to meet all potential emergencies and disasters such as fire, severe weather, and missing clients.

(2) The facility must communicate, periodically review, make the plan available, and provide training to the staff.

(i) *Standard: Evacuation drills.* (1) The facility must hold evacuation drills at least quarterly for each shift of personnel and under varied conditions to—

(i) Ensure that all personnel on all shifts are trained to perform assigned tasks;

(ii) Ensure that all personnel on all shifts are familiar with the use of the facility's fire protection features; and

(iii) Evaluate the effectiveness of emergency and disaster plans and procedures.

(2) The facility must—

(i) Actually evacuate clients during at least one drill each year on each shift;

(ii) Make special provisions for the evacuation of clients with physical disabilities;

(iii) File a report and evaluation on each evacuation drill;

(iv) Investigate all problems with evacuation drills, including accidents, and take corrective action; and

(v) During fire drills, clients may be evacuated to a safe area in facilities certified under the Health Care Occupancies Chapter of the Life Safety Code.

(3) Facilities must meet the requirements of paragraphs (i)(1) and (2) of this section for any live-in and relief staff they utilize.

(j) *Standard: Fire protection*—(1) *General*. Except as otherwise provided in this section—

(i) The facility must meet the applicable provisions of either the Health Care Occupancies Chapters or the Residential Board and Care Occupancies Chapter of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted LSC does not apply to a facility.

(2) The State survey agency may apply a single chapter of the LSC to the entire facility or may apply different chapters to different buildings or parts of buildings as permitted by the LSC.

(3) A facility that meets the LSC definition of a residential board and care occupancy must have its evacuation capability evaluated in accordance with the Evacuation Difficulty Index of the Fire Safety Evaluation System for Board and Care facilities (FSES/BC).

(4) If CMS finds that the State has a fire and safety code imposed by State law that adequately protects a facility's clients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the LSC.

(5) Beginning March 13, 2006, a facility must be in compliance with Chapter 19.2.9, Emergency Lighting.

(6) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to a facility.

(7) *Facilities that meet the LSC definition of a health care occupancy*. (i) After consideration of State survey agency recommendations, CMS may waive, for appropriate periods, specific provisions of the Life Safety Code if the following requirements are met:

(A) The waiver would not adversely affect the health and safety of the clients.

(B) Rigid application of specific provisions would result in an unreasonable hardship for the facility.

(ii) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a facility may install alcohol-based hand rub dispensers if—

(A) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(B) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(C) The dispensers are installed in a manner that adequately protects against inappropriate access;

(D) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the

Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269; and

(E) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

(k) *Standard: Paint.* The facility must—

(1) Use lead-free paint inside the facility; and

(2) Remove or cover interior paint or plaster containing lead so that it is not accessible to clients.

(l) *Standard: Infection control.* (1) The facility must provide a sanitary environment to avoid sources and transmission of infections. There must be an active program for the prevention, control, and investigation of infection and communicable diseases.

(2) The facility must implement successful corrective action in affected problem areas.

(3) The facility must maintain a record of incidents and corrective actions related to infections.

(4) The facility must prohibit employees with symptoms or signs of a communicable disease from direct contact with clients and their food.

[53 FR 20496, June 3, 1988. Redesignated at 56 FR 48918, Sept. 26, 1991, as amended at 68 FR 1387, Jan. 10, 2003; 69 FR 49271, Aug. 11, 2004; 70 FR 15239, Mar. 25, 2005; 71 FR 55340, Sept. 22, 2006]

§ 483.480 Condition of participation: Dietetic services.

(a) *Standard: Food and nutrition services.* (1) Each client must receive a nourishing, well-balanced diet including modified and specially-prescribed diets.

(2) A qualified dietitian must be employed either full-time, part-time, or on a consultant basis at the facility's discretion.

(3) If a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food services.

(4) The client's interdisciplinary team, including a qualified dietitian and physician, must prescribe all modified and special diets including those used as a part of a program to manage inappropriate client behavior.

(5) Foods proposed for use as a primary reinforcement of adaptive behavior are evaluated in light of the client's nutritional status and needs.

(6) Unless otherwise specified by medical needs, the diet must be prepared at least in accordance with the latest edition of the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences, adjusted for age, sex, disability and activity.

(b) *Standard: Meal services.* (1) Each client must receive at least three meals daily, at regular times comparable to normal mealtimes in the community with—

(i) Not more than 14 hours between a substantial evening meal and breakfast of the following day, except on weekends and holidays when a nourishing snack is provided at bedtime, 16 hours may elapse between a substantial evening meal and breakfast; and

(ii) Not less than 10 hours between breakfast and the evening meal of the same day, except as provided under paragraph (b)(1)(i) of this section.

(2) Food must be served—

(i) In appropriate quantity;

(ii) At appropriate temperature;

(iii) In a form consistent with the developmental level of the client; and

(iv) With appropriate utensils.

(3) Food served to clients individually and uneaten must be discarded.

(c) *Standard: Menus.* (1) Menus must—

(i) Be prepared in advance;

(ii) Provide a variety of foods at each meal;

(iii) Be different for the same days of each week and adjusted for seasonal changes; and

(iv) Include the average portion sizes for menu items.

(2) Menus for food actually served must be kept on file for 30 days.

(d) *Standard: Dining areas and service.* The facility must—

(1) Serve meals for all clients, including persons with ambulation deficits, in dining areas, unless otherwise specified by the interdisciplinary team or a physician;

(2) Provide table service for all clients who can and will eat at a table, including clients in wheelchairs;

(3) Equip areas with tables, chairs, eating utensils, and dishes designed to meet the developmental needs of each client;

(4) Supervise and staff dining rooms adequately to direct self-help dining procedure, to assure that each client receives enough food and to assure that each client eats in a manner consistent with his or her developmental level: and

(5) Ensure that each client eats in an upright position, unless otherwise specified by the interdisciplinary team or a physician.

PART 484—HOME HEALTH SERVICES

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

SOURCE: 54 FR 33367, Aug. 14, 1989, unless otherwise noted.

Subpart A—General Provisions

§ 484.1 Basis and scope.

(a) *Basis and scope.* This part is based on the indicated provisions of the following sections of the Act:

(1) Sections 1861(o) and 1891 establish the conditions that an HHA must meet in order to participate in Medicare.

(2) Section 1861(z) specifies the Institutional planning standards that HHAs must meet.

(3) Section 1895 provides for the establishment of a prospective payment system for home health services covered under Medicare.

(b) This part also sets forth additional requirements that are considered necessary to ensure the health and safety of patients.

[60 FR 50443, Sept. 29, 1995, as amended at 65 FR 41211, July 3, 2000]

§ 484.2 Definitions.

As used in this part, unless the context indicates otherwise—*Bylaws or equivalent* means a set of rules adopted by an HHA for governing the agency's operation.

Branch office means a location or site from which a home health agency provides services within a portion of the total geographic area served by the parent agency. The branch office is part of the home health agency and is located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the branch independently to meet the conditions of participation as a home health agency.

Clinical note means a notation of a contact with a patient that is written and dated by a member of the health team, and that describes signs and symptoms, treatment and drugs administered and the patient's reaction, and any changes in physical or emotional condition.

HHA stands for home health agency.

Nonprofit agency means an agency exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1954.

Parent home health agency means the agency that develops and maintains administrative controls of subunits and/or branch offices.

Primary home health agency means the agency that is responsible for the services furnished to patients and for implementation of the plan of care.

Progress note means a written notation, dated and signed by a member of the health team, that summarizes facts about care furnished and the patient's response during a given period of time.

Proprietary agency means a private profit-making agency licensed by the State.

Public agency means an agency operated by a State or local government.

Subdivision means a component of a multi-function health agency, such as the home care department of a hospital or the nursing division of a health department, which independently meets the conditions of participation for HHAs. A subdivision that has subunits or branch offices is considered a parent agency.

Subunit means a semi-autonomous organization that—

(1) Serves patients in a geographic area different from that of the parent agency; and

(2) Must independently meet the conditions of participation for HHAs because it is too far from the parent agency to share administration, supervision, and services on a daily basis.

Summary report means the compilation of the pertinent factors of a patient's clinical notes and progress notes that is submitted to the patient's physician.

Supervision means authoritative procedural guidance by a qualified person for the accomplishment of a function or activity. Unless otherwise specified in this part, the supervisor must be on the premises to supervise an individual who does not meet the qualifications specified in § 484.4.

§ 484.4 Personnel qualifications.

Staff required to meet the conditions set forth in this part are staff who meet the qualifications specified in this section.

Administrator, home health agency. A person who:

(a) Is a licensed physician; or

(b) Is a registered nurse; or

(c) Has training and experience in health service administration and at least 1 year of supervisory or administrative experience in home health care or related health programs.

Audiologist. A person who:

(a) Meets the education and experience requirements for a Certificate of Clinical Competence in audiology granted by the American Speech-Language-Hearing Association; or

(b) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

Home health aide. Effective for services furnished after August 14, 1990, a person who has successfully completed a State-established or other training program that meets the requirements

of §484.36(a) and a competency evaluation program or State licensure program that meets the requirements of §484.36 (b) or (e), or a competency evaluation program or State licensure program that meets the requirements of §484.36 (b) or (e). An individual is not considered to have completed a training and competency evaluation program, or a competency evaluation program if, since the individual's most recent completion of this program(s), there has been a continuous period of 24 consecutive months during none of which the individual furnished services described in §409.40 of this chapter for compensation.

Occupational therapist. A person who—

(a)(1) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing, unless licensure does not apply;

(2) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA), or successor organizations of ACOTE; and

(3) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(b) On or before December 31, 2009—

(1) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing; or

(2) When licensure or other regulation does not apply—

(i) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or successor organizations of ACOTE; and

(ii) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc., (NBCOT).

(c) On or before January 1, 2008—

(1) Graduated after successful completion of an occupational therapy program accredited jointly by the committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or

(2) Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for Certification in Occupational Therapy.

(d) On or before December 31, 1977—

(1) Had 2 years of appropriate experience as an occupational therapist; and

(2) Had achieved a satisfactory grade on an occupational therapist proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(e) If educated outside the United States, must meet all of the following:

(1) Graduated after successful completion of an occupational therapist education program accredited as substantially equivalent to occupational therapist entry level education in the United States by one of the following:

(i) The Accreditation Council for Occupational Therapy Education (ACOTE).

(ii) Successor organizations of ACOTE.

(iii) The World Federation of Occupational Therapists.

(iv) A credentialing body approved by the American Occupational Therapy Association.

(2) Successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(3) On or before December 31, 2009, is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing.

Occupational therapy assistant. A person who—

(a) Meets all of the following:

(1) Is licensed, unless licensure does not apply, or otherwise regulated, if applicable, as an occupational therapy assistant by the State in which practicing.

(2) Graduated after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education, (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or its successor organizations.

(3) Is eligible to take or successfully completed the entry-level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(b) On or before December 31, 2009—

(1) Is licensed or otherwise regulated as an occupational therapy assistant, if applicable, by the State in which practicing; or any qualifications defined by the State in which practicing, unless licensure does not apply; or

(2) Must meet both of the following:

(i) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association.

(ii) After January 1, 2010, meets the requirements in paragraph (a) of this section.

(c) After December 31, 1977 and on or before December 31, 2007—

(1) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association; or

(2) Completed the requirements to practice as an occupational therapy assistant applicable in the State in which practicing.

(d) On or before December 31, 1977—

(1) Had 2 years of appropriate experience as an occupational therapy assistant; and

(2) Had achieved a satisfactory grade on an occupational therapy assistant proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(e) If educated outside the United States, on or after January 1, 2008—

(1) Graduated after successful completion of an occupational therapy assistant education program that is accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by—

(i) The Accreditation Council for Occupational Therapy Education (ACOTE).

(ii) Its successor organizations.

(iii) The World Federation of Occupational Therapists.

(iv) By a credentialing body approved by the American Occupational Therapy Association; and

(2) Successfully completed the entry-level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

Physical therapist. A person who is licensed, if applicable, by the State in which practicing, unless licensure does not apply and meets one of the following requirements:

(a)(1) Graduated after successful completion of a physical therapist education program approved by one of the following:

(i) The Commission on Accreditation in Physical Therapy Education (CAPTE).

(ii) Successor organizations of CAPTE.

(iii) An education program outside the United States determined to be substantially equivalent to physical therapist entry-level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or an organization identified in 8 CFR 212.15(e) as it relates to physical therapists; and

(2) Passed an examination for physical therapists approved by the State in which physical therapy services are provided.

(b) On or before December 31, 2009—

(1) Graduated after successful completion of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); or

(2) Meets both of the following:

(i) Graduated after successful completion of an education program determined to be substantially equivalent to

physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified in 8 CFR 212.15(e) as it relates to physical therapists.

(ii) Passed an examination for physical therapists approved by the State in which physical therapy services are provided.

(c) Before January 1, 2008—

(1) Graduated from a physical therapy curriculum approved by one of the following:

(i) The American Physical Therapy Association.

(ii) The Committee on Allied Health Education and Accreditation of the American Medical Association.

(iii) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association.

(d) On or before December 31, 1977 was licensed or qualified as a physical therapist and meets both of the following:

(1) Has 2 years of appropriate experience as a physical therapist.

(2) Has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(e) Before January 1, 1966—

(1) Was admitted to membership by the American Physical Therapy Association; or

(2) Was admitted to registration by the American Registry of Physical Therapists; or

(3) Has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education.

(f) Before January 1, 1966 was licensed or registered, and before January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy.

(g) If trained outside the United States before January 1, 2008, meets the following requirements:

(1) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.

(2) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

Physical therapist assistant. A person who is licensed, unless licensure does not apply, registered, or certified as a physical therapist assistant, if applicable, by the State in which practicing, and meets one of the following requirements:

(a)(1) Graduated from a physical therapist assistant curriculum approved by the Commission on Accreditation in Physical Therapy Education of the American Physical Therapy Association; or if educated outside the United States or trained in the United States military, graduated from an education program determined to be substantially equivalent to physical therapist assistant entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified at 8 CFR 212.15(e); and

(2) Passed a national examination for physical therapist assistants.

(b) On or before December 31, 2009, meets one of the following:

(1) Is licensed, or otherwise regulated in the State in which practicing.

(2) In States where licensure or other regulations do not apply, graduated on or before December 31, 2009, from a 2-year college-level program approved by the American Physical Therapy Association and, effective January 1, 2010 meets the requirements of paragraph (a) of this definition.

(c) Before January 1, 2008, where licensure or other regulation does not apply, graduated from a 2-year college-level program approved by the American Physical Therapy Association.

(d) On or before December 31, 1977, was licensed or qualified as a physical therapist assistant and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

Physician. A doctor of medicine, osteophathy or podiatry legally authorized to practice medicine and surgery by the State in which such function or action is performed.

Practical (vocational) nurse. A person who is licensed as a practical (vocational) nurse by the State in which practicing.

Public health nurse. A registered nurse who has completed a baccalaureate degree program approved by the National League for Nursing for public health nursing preparation or postregistered nurse study that includes content aproved by the National League for Nursing for public health nursing preparation.

Registered nurse (RN). A graduate of an approved school of professional nursing, who is licensed as a registered nurse by the State in which practicing.

Social work assistant. A person who:

(1) Has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has had at least 1 year of social work experience in a health care setting; or

(2) Has 2 years of appropriate experience as a social work assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a social work assistant after December 31, 1977.

Social worker. A person who has a master's degree from a school of social work accredited by the Council on Social Work Education, and has 1 year of social work experience in a health care setting.

Speech-language pathologist. A person who meets either of the following requirements:

(a) The education and experience requirements for a Certificate of Clinical Competence in speech-language pathology granted by the American Speech-Language-Hearing Association.

(b) The educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32973, July 18, 1991; 69 FR 66426, Nov. 15, 2004; 72 FR 66406, Nov. 27, 2007; 73 FR 2433, Jan. 15, 2008]

Subpart B—Administration

§ 484.10 Condition of participation: Patient rights.

The patient has the right to be informed of his or her rights. The HHA must protect and promote the exercise of these rights.

(a) *Standard: Notice of rights*. (1) The HHA must provide the patient with a written notice of the patient's rights in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of treatment.

(2) The HHA must maintain documentation showing that it has complied with the requirements of this section.

(b) *Standard: Exercise of rights and respect for property and person*. (1) The patient has the right to exercise his or her rights as a patient of the HHA.

(2) The patient's family or guardian may exercise the patient's rights when the patient has been judged incompetent.

(3) The patient has the right to have his or her property treated with respect.

(4) The patient has the right to voice grievances regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for property by anyone who is furnishing services on behalf of the HHA and must not be subjected to discrimination or reprisal for doing so.

(5) The HHA must investigate complaints made by a patient or the patient's family or guardian regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for the patient's property by anyone furnishing services on behalf of the HHA, and must document both the existence of the complaint and the resolution of the complaint.

(c) *Standard: Right to be informed and to participate in planning care and treatment*. (1) The patient has the right to be informed, in advance about the care

to be furnished, and of any changes in the care to be furnished.

(i) The HHA must advise the patient in advance of the disciplines that will furnish care, and the frequency of visits proposed to be furnished.

(ii) The HHA must advise the patient in advance of any change in the plan of care before the change is made.

(2) The patient has the right to participate in the planning of the care.

(i) The HHA must advise the patient in advance of the right to participate in planning the care or treatment and in planning changes in the care or treatment.

(ii) The HHA complies with the requirements of subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. The HHA must inform and distribute written information to the patient, in advance, concerning its policies on advance directives, including a description of applicable State law. The HHA may furnish advance directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.

(d) *Standard: Confidentiality of medical records.* The patient has the right to confidentiality of the clinical records maintained by the HHA. The HHA must advise the patient of the agency's policies and procedures regarding disclosure of clinical records.

(e) *Standard: Patient liability for payment.* (1) The patient has the right to be advised, before care is initiated, of the extent to which payment for the HHA services may be expected from Medicare or other sources, and the extent to which payment may be required from the patient. Before the care is initiated, the HHA must inform the patient, orally and in writing, of—

(i) The extent to which payment may be expected from Medicare, Medicaid, or any other Federally funded or aided program known to the HHA;

(ii) The charges for services that will not be covered by Medicare; and

(iii) The charges that the individual may have to pay.

(2) The patient has the right to be advised orally and in writing of any changes in the information provided in accordance with paragraph (e)(1) of this section when they occur. The HHA must advise the patient of these changes orally and in writing as soon as possible, but no later than 30 calendar days from the date that the HHA becomes aware of a change.

(f) *Standard: Home health hotline.* The patient has the right to be advised of the availability of the toll-free HHA hotline in the State. When the agency accepts the patient for treatment or care, the HHA must advise the patient in writing of the telephone number of the home health hotline established by the State, the hours of its operation, and that the purpose of the hotline is to receive complaints or questions about local HHAs. The patient also has the right to use this hotline to lodge complaints concerning the implementation of the advance directives requirements.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32973, July 18, 1991; 57 FR 8203, Mar. 6, 1992; 60 FR 33293, June 27, 1995]

§ 484.11 Condition of participation: Release of patient identifiable OASIS information.

The HHA and agent acting on behalf of the HHA in accordance with a written contract must ensure the confidentiality of all patient identifiable information contained in the clinical record, including OASIS data, and may not release patient identifiable OASIS information to the public.

[64 FR 3763, Jan. 25, 1999]

§ 484.12 Condition of participation: Compliance with Federal, State, and local laws, disclosure and ownership information, and accepted professional standards and principles.

(a) *Standard: Compliance with Federal, State, and local laws and regulations.* The HHA and its staff must operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations. If State or applicable local law provides for the licensure of HHAs, an agency not subject to licensure is approved by the licensing authority as meeting the standards established for licensure.

(b) *Standard: Disclosure of ownership and management information.* The HHA must comply with the requirements of

Part 420, Subpart C of this chapter. The HHA also must disclose the following information to the State survey agency at the time of the HHA's initial request for certification, for each survey, and at the time of any change in ownership or management:

(1) The name and address of all persons with an ownership or control interest in the HHA as defined in §§ 420.201, 420.202, and 420.206 of this chapter.

(2) The name and address of each person who is an officer, a director, an agent or a managing employee of the HHA as defined in §§ 420.201, 420.202, and 420.206 of this chapter.

(3) The name and address of the corporation, association, or other company that is responsible for the management of the HHA, and the name and address of the chief executive officer and the chairman of the board of directors of that corporation, association, or other company responsible for the management of the HHA.

(c) *Standard: Compliance with accepted professional standards and principles.* The HHA and its staff must comply with accepted professional standards and principles that apply to professionals furnishing services in an HHA.

§ 484.14 Condition of participation: Organization, services, and administration.

Organization, services furnished, administrative control, and lines of authority for the delegation of responsibility down to the patient care level are clearly set forth in writing and are readily identifiable. Administrative and supervisory functions are not delegated to another agency or organization and all services not furnished directly, including services provided through subunits are monitored and controlled by the parent agency. If an agency has subunits, appropriate administrative records are maintained for each subunit.

(a) *Standard: Services furnished.* Part-time or intermittent skilled nursing services and at least one other therapeutic service (physical, speech, or occupational therapy; medical social services; or home health aide services) are made available on a visiting basis, in a place of residence used as a patient's home. An HHA must provide at least one of the qualifying services directly through agency employees, but may provide the second qualifying service and additional services under arrangements with another agency or organization.

(b) *Standard: Governing body.* A governing body (or designated persons so functioning) assumes full legal authority and responsibility for the operation of the agency. The governing body appoints a qualified administrator, arranges for professional advice as required under § 484.16, adopts and periodically reviews written bylaws or an acceptable equivalent, and oversees the management and fiscal affairs of the agency.

(c) *Standard: Administrator.* The administrator, who may also be the supervising physician or registered nurse required under paragraph (d) of this section, organizes and directs the agency's ongoing functions; maintains ongoing liaison among the governing body, the group of professional personnel, and the staff; employs qualified personnel and ensures adequate staff education and evaluations; ensures the accuracy of public information materials and activities; and implements an effective budgeting and accounting system. A qualified person is authorized in writing to act in the absence of the administrator.

(d) *Standard: Supervising physician or registered nurse.* The skilled nursing and other therapeutic services furnished are under the supervision and direction of a physician or a registered nurse (who preferably has at least 1 year of nursing experience and is a public health nurse). This person, or similarly qualified alternate, is available at all times during operating hours and participates in all activities relevant to the professional services furnished, including the development of qualifications and the assignment of personnel.

(e) *Standard: Personnel policies.* Personnel practices and patient care are supported by appropriate, written personnel policies. Personnel records include qualifications and licensure that are kept current.

(f) *Standard: Personnel under hourly or per visit contracts.* If personnel under hourly or per visit contracts are used

by the HHA, there is a written contract between those personnel and the agency that specifies the following:

(1) Patients are accepted for care only by the primary HHA.

(2) The services to be furnished.

(3) The necessity to conform to all applicable agency policies, including personnel qualifications.

(4) The responsibility for participating in developing plans of care.

(5) The manner in which services will be controlled, coordinated, and evaluated by the primary HHA.

(6) The procedures for submitting clinical and progress notes, scheduling of visits, periodic patient evaluation.

(7) The procedures for payment for services furnished under the contract.

(g) *Standard: Coordination of patient services.* All personnel furnishing services maintain liaison to ensure that their efforts are coordinated effectively and support the objectives outlined in the plan of care. The clinical record or minutes of case conferences establish that effective interchange, reporting, and coordination of patient care does occur. A written summary report for each patient is sent to the attending physician at least every 60 days.

(h) *Standard: Services under arrangements.* Services furnished under arrangements are subject to a written contract conforming with the requirements specified in paragraph (f) of this section and with the requirements of section 1861(w) of the Act (42 U.S.C. 1495x(w)).

(i) *Standard: Institutional planning.* The HHA, under the direction of the governing body, prepares an overall plan and a budget that includes an annual operating budget and capital expenditure plan.

(1) *Annual operating budget.* There is an annual operating budget that includes all anticipated income and expenses related to items that would, under generally accepted accounting principles, be considered income and expense items. However, it is not required that there be prepared, in connection with any budget, an item by item identification of the components of each type of anticipated income or expense.

(2) *Capital expenditure plan.* (i) There is a capital expenditure plan for at least a 3-year period, including the operating budget year. The plan includes and identifies in detail the anticipated sources of financing for, and the objectives of, each anticipated expenditure of more than $600,000 for items that would under generally accepted accounting principles, be considered capital items. In determining if a single capital expenditure exceeds $600,000, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition, improvement, modernization, expansion, or replacement of land, plant, building, and equipment are included. Expenditures directly or indirectly related to capital expenditures, such as grading, paving, broker commissions, taxes assessed during the construction period, and costs involved in demolishing or razing structures on land are also included. Transactions that are separated in time, but are components of an overall plan or patient care objective, are viewed in their entirety without regard to their timing. Other costs related to capital expenditures include title fees, permit and license fees, broker commissions, architect, legal, accounting, and appraisal fees; interest, finance, or carrying charges on bonds, notes and other costs incurred for borrowing funds.

(ii) If the anticipated source of financing is, in any part, the anticipated payment from title V (Maternal and Child Health and Crippled Children's Services) or title XVIII (Medicare) or title XIX (Medicaid) of the Social Security Act, the plan specifies the following:

(A) Whether the proposed capital expenditure is required to comform, or is likely to be required to conform, to current standards, criteria, or plans developed in accordance with the Public Health Service Act or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963.

(B) Whether a capital expenditure proposal has been submitted to the designated planning agency for approval in accordance with section 1122 of the Act (42 U.S.C. 1320a–1) and implementing regulations.

(C) Whether the designated planning agency has approved or disapproved the proposed capital expenditure if it was presented to that agency.

(3) *Preparation of plan and budget.* The overall plan and budget is prepared under the direction of the governing body of the HHA by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the HHA.

(4) *Annual review of plan and budget.* The overall plan and budget is reviewed and updated at least annually by the committee referred to in paragraph (i)(3) of this section under the direction of the governing body of the HHA.

(j) *Standard: Laboratory services.* (1) If the HHA engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the FDA, such testing must be in compliance with all applicable requirements of part 493 of this chapter.

(2) If the HHA chooses to refer specimens for laboratory testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32973, July 18, 1991; 56 FR 51334, Oct. 11, 1991; 57 FR 7136, Feb. 28, 1992; 66 FR 32778, June 18, 2001]

§ 484.16 Condition of participation: Group of professional personnel.

A group of professional personnel, which includes at least one physician and one registered nurse (preferably a public health nurse), and with appropriate representation from other professional disciplines, establishes and annually reviews the agency's policies governing scope of services offered, admission and discharge policies, medical supervision and plans of care, emergency care, clinical records, personnel qualifications, and program evaluation. At least one member of the group is neither an owner nor an employee of the agency.

(a) *Standard: Advisory and evaluation function.* The group of professional personnel meets frequently to advise the agency on professional issues, to participate in the evaluation of the agency's program, and to assist the agency in maintaining liaison with other health care providers in the community and in the agency's community information program. The meetings are documented by dated minutes.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32974, July 18, 1991]

§ 484.18 Condition of participation: Acceptance of patients, plan of care, and medical supervision.

Patients are accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the agency in the patient's place of residence. Care follows a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine.

(a) *Standard: Plan of care.* The plan of care developed in consultation with the agency staff covers all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items. If a physician refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modifications to the original plan. Orders for therapy services include the specific procedures and modalities to be used and the amount, frequency, and duration. The therapist and other agency personnel participate in developing the plan of care.

(b) *Standard: Periodic review of plan of care.* The total plan of care is reviewed by the attending physician and HHA personnel as often as the severity of the patient's condition requires, but at least once every 60 days or more frequently when there is a beneficiary elected transfer; a significant change in condition resulting in a change in

the case-mix assignment; or a discharge and return to the same HHA during the 60-day episode. Agency professional staff promptly alert the physician to any changes that suggest a need to alter the plan of care.

(c) *Standard: Conformance with physician orders.* Drugs and treatments are administered by agency staff only as ordered by the physician with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per agency policy developed in consultation with a physician, and after an assessment for contraindications. Verbal orders are put in writing and signed and dated with the date of receipt by the registered nurse or qualified therapist (as defined in § 484.4 of this chapter) responsible for furnishing or supervising the ordered services. Verbal orders are only accepted by personnel authorized to do so by applicable State and Federal laws and regulations as well as by the HHA's internal policies.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32974, July 18, 1991; 64 FR 3784, Jan. 25, 1999; 65 FR 41211, July 3, 2000; 67 FR 61814, Oct. 2, 2002]

§ 484.20 Condition of participation: Reporting OASIS information.

HHAs must electronically report all OASIS data collected in accordance with § 484.55.

(a) *Standard: Encoding and transmitting OASIS data.* An HHA must encode and electronically transmit each completed OASIS assessment to the State agency or the CMS OASIS contractor, regarding each beneficiary with respect to which such information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the beneficiary.

(b) *Standard: Accuracy of encoded OASIS data.* The encoded OASIS data must accurately reflect the patient's status at the time of assessment.

(c) *Standard: Transmittal of OASIS data.* An HHA must—

(1) For all completed assessments, transmit OASIS data in a format that meets the requirements of paragraph (d) of this section.

(2) Successfully transmit test data to the State agency or CMS OASIS contractor.

(3) Transmit data using electronics communications software that provides a direct telephone connection from the HHA to the State agency or CMS OASIS contractor.

(4) Transmit data that includes the CMS-assigned branch identification number, as applicable.

(d) *Standard: Data Format.* The HHA must encode and transmit data using the software available from CMS or software that conforms to CMS standard electronic record layout, edit specifications, and data dictionary, and that includes the required OASIS data set.

[64 FR 3763, Jan. 25, 1999, as amended at 70 FR 76208, Dec. 23, 2005]

Subpart C—Furnishing of Services

§ 484.30 Condition of participation: Skilled nursing services.

The HHA furnishes skilled nursing services by or under the supervision of a registered nurse and in accordance with the plan of care.

(a) *Standard: Duties of the registered nurse.* The registered nurse makes the initial evaluation visit, regularly reevaluates the patient's nursing needs, initiates the plan of care and necessary revisions, furnishes those services requiring substantial and specialized nursing skill, initiates appropriate preventive and rehabilitative nursing procedures, prepares clinical and progress notes, coordinates services, informs the physician and other personnel of changes in the patient's condition and needs, counsels the patient and family in meeting nursing and related needs, participates in in-service programs, and supervises and teaches other nursing personnel.

(b) *Standard: Duties of the licensed practical nurse.* The licensed practical nurse furnishes services in accordance with agency policies, prepares clinical and progress notes, assists the physician and registered nurse in performing specialized procedures, prepares equipment and materials for treatments observing aseptic technique as required,

and assists the patient in learning appropriate self-care techniques.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32974, July 18, 1991]

§ 484.32 Condition of participation: Therapy services.

Any therapy services offered by the HHA directly or under arrangement are given by a qualified therapist or by a qualified therapy assistant under the supervision of a qualified therapist and in accordance with the plan of care. The qualified therapist assists the physician in evaluating level of function, helps develop the plan of care (revising it as necessary), prepares clinical and progress notes, advises and consults with the family and other agency personnel, and participates in in-service programs.

(a) *Standard: Supervision of physical therapy assistant and occupational therapy assistant.* Services furnished by a qualified physical therapy assistant or qualified occupational therapy assistant may be furnished under the supervision of a qualified physical or occupational therapist. A physical therapy assistant or occupational therapy assistant performs services planned, delegated, and supervised by the therapist, assists in preparing clinical notes and progress reports, and participates in educating the patient and family, and in in-service programs.

(b) *Standard: Supervision of speech therapy services.* Speech therapy services are furnished only by or under supervision of a qualified speech pathologist or audiologist.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32974, July 18, 1991]

§ 484.34 Condition of participation: Medical social services.

If the agency furnishes medical social services, those services are given by a qualified social worker or by a qualified social work assistant under the supervision of a qualified social worker, and in accordance with the plan of care. The social worker assists the physician and other team members in understanding the significant social and emotional factors related to the health problems, participates in the development of the plan of care, prepares clinical and progress notes, works with the family, uses appropriate community resources, participates in discharge planning and in-service programs, and acts as a consultant to other agency personnel.

§ 484.36 Condition of participation: Home health aide services.

Home health aides are selected on the basis of such factors as a sympathetic attitude toward the care of the sick, ability to read, write, and carry out directions, and maturity and ability to deal effectively with the demands of the job. They are closely supervised to ensure their competence in providing care. For home health services furnished (either directly or through arrangements with other organizations) after August 14, 1990, the HHA must use individuals who meet the personnel qualifications specified in § 484.4 for ''home health aide''.

(a) *Standard: Home health aide training*—(1) *Content and duration of training.* The aide training program must address each of the following subject areas through classroom and supervised practical training totalling at least 75 hours, with at least 16 hours devoted to supervised practical training. The individual being trained must complete at least 16 hours of classroom training before beginning the supervisied practical training.

(i) Communications skills.

(ii) Observation, reporting and documentation of patient status and the care or service furnished.

(iii) Reading and recording temperature, pulse, and respiration.

(iv) Basic infection control procedures.

(v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.

(vi) Maintenance of a clean, safe, and healthy environment.

(vii) Recognizing emergencies and knowledge of emergency procedures.

(viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the HHA, including the need for respect for the patient, his or her privacy and his or her property.

(ix) Appropriate and safe techniques in personal hygiene and grooming that include—

(A) Bed bath.

(B) Sponge, tub, or shower bath.

(C) Shampoo, sink, tub, or bed.

(D) Nail and skin care.

(E) Oral hygiene.

(F) Toileting and elimination.

(x) Safe transfer techniques and ambulation.

(xi) Normal range of motion and positioning.

(xii) Adequate nutrition and fluid intake.

(xiii) Any other task that the HHA may choose to have the home health aide perform.

''Supervised practical training'' means training in a laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse or licensed practical nurse.

(2) *Conduct of training*—(i) *Organizations*. A home health aide training program may be offered by any organization except an HHA that, within the previous 2 years has been found—

(A) Out of compliance with requirements of this paragraph (a) or paragraph (b) of this section;

(B) To permit an individual that does not meet the definition of ''home health aide'' as specified in § 484.4 to furnish home health aide services (with the exception of licensed health professionals and volunteers);

(C) Has been subject to an extended (or partial extended) survey as a result of having been found to have furnished substandard care (or for other reasons at the discretion of the CMS or the State);

(D) Has been assessed a civil monetary penalty of not less than $5,000 as an intermediate sanction;

(E) Has been found to have compliance deficiencies that endanger the health and safety of the HHA's patients and has had a temporary management appointed to oversee the management of the HHA;

(F) Has had all or part of its Medicare payments suspended; or

(G) Under any Federal or State law within the 2-year period beginning on October 1, 1988—

(*1*) Has had its participation in the Medicare program terminated;

(*2*) Has been assessed a penalty of not less than $5,000 for deficiencies in Federal or State standards for HHAs;

(*3*) Was subject to a suspension of Medicare payments to which it otherwise would have been entitled;

(*4*) Had operated under a temporary management that was appointed to oversee the operation of the HHA and to ensure the health and safety of the HHA's patients; or

(*5*) Was closed or had it's residents transferred by the State.

(ii) *Qualifications for instructors*. The training of home health aides and the supervision of home health aides during the supervised practical portion of the training must be performed by or under the general supervision of a registered nurse who possesses a minimum of 2 years of nursing experience, at least 1 year of which must be in the provision of home health care. Other individuals may be used to provide instruction under the supervision of a qualified registered nurse.

(3) *Documentation of training*. The HHA must maintain sufficient documentation to demonstrate that the requirements of this standard are met.

(b) *Standard: Competency evaluation and in-service training*—(1) *Applicability*. An individual may furnish home health aide services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this paragraph. The HHA is responsible for ensuring that the individuals who furnish home health aide services on its behalf meet the competency evaluation requirements of this section.

(2) *Content and frequency of evaluations and amount of in-service training*. (i) The competency evaluation must address each of the subjects listed in paragraph (a)(1) (ii) through (xiii) of this section.

(ii) The HHA must complete a performance review of each home health aide no less frequently than every 12 months.

(iii) The home health aide must receive at least 12 hours of in-service training during each 12-month period.

The in-service training may be furnished while the aide is furnishing care to the patient.

(3) *Conduct of evaluation and training*—(i) *Organizations*. A home health aide competency evaluation program may be offered by any organization except as specified in paragraph (a)(2)(i) of this section.

The in-service training may be offered by any organization.

(ii) *Evaluators and instructors*. The competency evaluation must be performed by a registered nurse. The in-service training generally must be supervised by a registered nurse who possesses a minimum of 2 years of nursing experience at least 1 year of which must be in the provision of home health care.

(iii) *Subject areas*. The subject areas listed at paragraphs (a)(1) (iii), (ix), (x), and (xi) of this section must be evaluated after observation of the aide's performance of the tasks with a patient. The other subject areas in paragraph (a)(1) of this section may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient.

(4) *Competency determination*. (i) A home health aide is not considered competent in any task for which he or she is evaluated as ''unsatisfactory''. The aide must not perform that task without direct supervision by a licensed nurse until after he or she receives training in the task for which he or she was evaluated as ''unsatisfactory'' and passes a subsequent evaluation with ''satisfactory''.

(ii) A home health aide is not considered to have successfully passed a competency evaluation if the aide has an ''unsatisfactory'' rating in more than one of the required areas.

(5) *Documentation of competency evaluation*. The HHA must maintain documentation which demonstrates that the requirements of this standard are met.

(6) *Effective date*. The HHA must implement a competency evaluation program that meets the requirements of this paragraph before February 14, 1990. The HHA must provide the preparation necessary for the individual to successfully complete the competency evaluation program. After August 14, 1990, the HHA may use only those aides that have been found to be competent in accordance with § 484.36(b).

(c) *Standard: Assignment and duties of the home health aide*—(1) *Assignment*. The home health aide is assigned to a specific patient by the registered nurse. Written patient care instructions for the home health aide must be prepared by the registered nurse or other appropriate professional who is responsible for the supervision of the home health aide under paragraph (d) of this section.

(2) *Duties*. The home health aide provides services that are ordered by the physician in the plan of care and that the aide is permitted to perform under State law. The duties of a home health aide include the provision of hands-on personal care, performance of simple procedures as an extension of therapy or nursing services, assistance in ambulation or exercises, and assistance in administering medications that are ordinarily self-administered. Any home health aide services offered by an HHA must be provided by a qualified home health aide.

(d) *Standard: Supervision*. (1) If the patient receives skilled nursing care, the registered nurse must perform the supervisory visit required by paragraph (d)(2) of this section. If the patient is not receiving skilled nursing care, but is receiving another skilled service (that is, physical therapy, occupational therapy, or speech-language pathology services), supervision may be provided by the appropriate therapist.

(2) The registered nurse (or another professional described in paragraph (d)(1) of this section) must make an on-site visit to the patient's home no less frequently than every 2 weeks.

(3) If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy or speech-language pathology services, the registered nurse must make a supervisory visit to the patient's home no less frequently than every 60 days. In these cases, to ensure that the aide is properly caring for the patient, each supervisory visit must occur while the home health aide is providing patient care.

(4) If home health aide services are provided by an individual who is not

employed directly by the HHA (or hospice), the services of the home health aide must be provided under arrangements, as defined in section 1861(w)(1) of the Act. If the HHA (or hospice) chooses to provide home health aide services under arrangements with another organization, the HHA's (or hospice's) responsibilities include, but are not limited to—

(i) Ensuring the overall quality of the care provided by the aide;

(ii) Supervision of the aide's services as described in paragraphs (d)(1) and (d)(2) of this section; and

(iii) Ensuring that home health aides providing services under arrangements have met the training requirements of paragraphs (a) and (b) of this section.

(e) *Personal care attendant: Evaluation requirements*—(1) *Applicability*. This paragraph applies to individuals who are employed by HHAs exclusively to furnish personal care attendant services under a Medicaid personal care benefit.

(2) *Rule*. An individual may furnish personal care services, as defined in § 440.170 of this chapter, on behalf of an HHA after the individual has been found competent by the State to furnish those services for which a competency evaluation is required by paragraph (b) of this section and which the individual is required to perform. The individual need not be determined competent in those services listed in paragraph (a) of this section that the individual is not required to furnish.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32974, July 18, 1991; 56 FR 51334, Oct. 11, 1991; 59 FR 65498, Dec. 20, 1994; 60 FR 39123, Aug. 1, 1995; 66 FR 32778, June 18, 2001]

§ 484.38 Condition of participation: Qualifying to furnish outpatient physical therapy or speech pathology services.

An HHA that wishes to furnish outpatient physical therapy or speech pathology services must meet all the pertinent conditions of this part and also meet the additional health and safety requirements set forth in §§ 485.711, 485.713, 485.715, 485.719, 485.723, and 485.727 of this chapter to implement section 1861(p) of the Act.

[54 FR 33367, Aug. 14, 1989, as amended at 60 FR 2329, Jan. 9, 1995; 60 FR 11632, Mar. 2, 1995]

§ 484.48 Condition of participation: Clinical records.

A clinical record containing pertinent past and current findings in accordance with accepted professional standards is maintained for every patient receiving home health services. In addition to the plan of care, the record contains appropriate identifying information; name of physician; drug, dietary, treatment, and activity orders; signed and dated clinical and progress notes; copies of summary reports sent to the attending physician; and a discharge summary. The HHA must inform the attending physician of the availability of a discharge summary. The discharge summary must be sent to the attending physician upon request and must include the patient's medical and health status at discharge.

(a) *Standards: Retention of records*. Clinical records are retained for 5 years after the month the cost report to which the records apply is filed with the intermediary, unless State law stipulates a longer period of time. Policies provide for retention even if the HHA discontinues operations. If a patient is transferred to another health facility, a copy of the record or abstract is sent with the patient.

(b) *Standards: Protection of records*. Clinical record information is safeguarded against loss or unauthorized use. Written procedures govern use and removal of records and the conditions for release of information. Patient's written consent is required for release of information not authorized by law.

[54 FR 33367, Aug. 14, 1989, as amended at 60 FR 65498, Dec. 20, 1994]

§ 484.52 Condition of participation: Evaluation of the agency's program.

The HHA has written policies requiring an overall evaluation of the agency's total program at least once a year by the group of professional personnel (or a committee of this group), HHA staff, and consumers, or by professional people outside the agency working in conjunction with consumers. The evaluation consists of an overall policy and administrative review and a clinical record review. The evaluation assesses

the extent to which the agency's program is appropriate, adequate, effective, and efficient. Results of the evaluation are reported to and acted upon by those responsible for the operation of the agency and are maintained separately as administrative records.

(a) *Standard: Policy and administrative review.* As a part of the evaluation process the policies and administrative practices of the agency are reviewed to determine the extent to which they promote patient care that is appropriate, adequate, effective, and efficient. Mechanisms are established in writing for the collection of pertinent data to assist in evaluation.

(b) *Standard: Clinical record review.* At least quarterly, appropriate health professionals, representing at least the scope of the program, review a sample of both active and closed clinical records to determine whether established policies are followed in furnishing services directly or under arrangement. There is a continuing review of clinical records for each 60-day period that a patient receives home health services to determine adequacy of the plan of care and appropriateness of continuation of care.

[54 FR 33367, Aug. 14, 1989; 66 FR 32778, June 18, 2001]

§ 484.55 Condition of participation: Comprehensive assessment of patients.

Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward achievement of desired outcomes. The comprehensive assessment must identify the patient's continuing need for home care and meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs. For Medicare beneficiaries, the HHA must verify the patient's eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment. The comprehensive assessment must also incorporate the use of the current version of the Outcome and Assessment Information Set (OASIS) items, using the language and groupings of the OASIS items, as specified by the Secretary.

(a) *Standard: Initial assessment visit.* (1) A registered nurse must conduct an initial assessment visit to determine the immediate care and support needs of the patient; and, for Medicare patients, to determine eligibility for the Medicare home health benefit, including homebound status. The initial assessment visit must be held either within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician-ordered start of care date.

(2) When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled professional.

(b) *Standard: Completion of the comprehensive assessment.* (1) The comprehensive assessment must be completed in a timely manner, consistent with the patient's immediate needs, but no later than 5 calendar days after the start of care.

(2) Except as provided in paragraph (b)(3) of this section, a registered nurse must complete the comprehensive assessment and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status.

(3) When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by the physician, a physical therapist, speech-language pathologist or occupational therapist may complete the comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status. The occupational therapist may complete the comprehensive assessment if the need for occupational therapy establishes program eligibility.

(c) *Standard: Drug regimen review.* The comprehensive assessment must include a review of all medications the patient is currently using in order to identify any potential adverse effects

and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.

(d) *Standard: Update of the comprehensive assessment.* The comprehensive assessment must be updated and revised (including the administration of the OASIS) as frequently as the patient's condition warrants due to a major decline or improvement in the patient's health status, but not less frequently than—

(1) The last five days of every 60 days beginning with the start-of-care date, unless there is a—

(i) Beneficiary elected transfer;

(ii) Significant change in condition; or

(iii) Discharge and return to the same HHA during the 60-day episode.

(2) Within 48 hours of the patient's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests;

(3) At discharge.

(e) *Standard: Incorporation of OASIS data items.* The OASIS data items determined by the Secretary must be incorporated into the HHA's own assessment and must include: clinical record items, demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status, neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and data items collected at inpatient facility admission or discharge only.

[64 FR 3784, Jan. 25, 1999, as amended at 65 FR 41211, July 3, 2000; 74 FR 58134, Nov. 10, 2009]

Subpart D [Reserved]

Subpart E—Prospective Payment System for Home Health Agencies

SOURCE: 65 FR 41212, July 3, 2000, unless otherwise noted.

§ 484.200 Basis and scope.

(a) *Basis.* This subpart implements section 1895 of the Act, which provides for the implementation of a prospective payment system (PPS) for HHAs for portions of cost reporting periods occurring on or after October 1, 2000.

(b) *Scope.* This subpart sets forth the framework for the HHA PPS, including the methodology used for the development of the payment rates, associated adjustments, and related rules.

§ 484.202 Definitions.

As used in this subpart—

Case-mix index means a scale that measures the relative difference in resource intensity among different groups in the clinical model.

Discipline means one of the six home health disciplines covered under the Medicare home health benefit (skilled nursing services, home health aide services, physical therapy services, occupational therapy services, speech-language pathology services, and medical social services).

Home health market basket index means an index that reflects changes over time in the prices of an appropriate mix of goods and services included in home health services.

Rural area means, with respect to home health episodes ending on or after January 1, 2006, an area defined in § 412.64(b)(1)(ii)(C) of this chapter.

Urban area means, with respect to home health episodes ending on or after January 1, 2006, an area defined in § 412.64(b)(1)(ii)(A) and (B) of this chapter.

[70 FR 68142, Nov. 9, 2005]

§ 484.205 Basis of payment.

(a) *Method of payment.* An HHA receives a national prospective 60-day episode payment of a predetermined rate for a home health service previously paid on a reasonable cost basis (except the osteoporosis drug defined in section 1861(kk) of the Act) as of August 5, 1997. The national 60-day episode payment is determined in accordance with § 484.215. The national prospective 60-day episode payment is subject to the following adjustments and additional payments:

(1) A low-utilization payment adjustment (LUPA) of a predetermined per-visit rate as specified in § 484.230.

(2) A partial episode payment (PEP) adjustment due to an intervening event

defined as a beneficiary elected transfer or a discharge and return to the same HHA during the 60-day episode, that warrants a new 60-day episode payment during an existing 60-day episode, that initiates the start of a new 60-day episode payment and a new physician certification of the new plan of care. The PEP adjustment is determined in accordance with § 484.235.

(3) An outlier payment is determined in accordance with § 484.240.

(b) *Episode payment.* The national prospective 60-day episode payment represents payment in full for all costs associated with furnishing home health services previously paid on a reasonable cost basis (except the osteoporosis drug listed in section 1861(m) of the Act as defined in section 1861(kk) of the Act) as of August 5, 1997 unless the national 60-day episode payment is subject to a low-utilization payment adjustment set forth in § 484.230, a partial episode payment adjustment set forth at § 484.235, or an additional outlier payment set forth in § 484.240. All payments under this system may be subject to a medical review adjustment reflecting beneficiary eligibility, medical necessity determinations, and HHRG assignment. DME provided as a home health service as defined in section 1861(m) of the Act continues to be paid the fee schedule amount.

(1) *Split percentage payment for initial episodes.* The initial percentage payment for initial episodes is paid to an HHA at 60 percent of the case-mix and wage adjusted 60-day episode rate. The residual final payment for initial episodes is paid at 40 percent of the case-mix and wage adjusted 60-day episode rate. Split percentage payments are made in accordance with requirements at § 409.43(c) of this chapter.

(2) *Split percentage payment for subsequent episodes.* The initial percentage payment for subsequent episodes is paid to an HHA at 50 percent of the case-mix and wage adjusted 60-day episode rate. The residual final payment for subsequent episodes is paid at 50 percent of the case-mix and wage adjusted 60-day episode rate. Split percentage payments are made in accordance with requirements at § 409.43(c) of this chapter.

(c) *Low-utilization payment.* An HHA receives a national 60-day episode payment of a predetermined rate for home health services previously paid on a reasonable cost basis as of August 5, 1997, unless CMS determines at the end of the 60-day episode that the HHA furnished minimal services to a patient during the 60-day episode. A low- utilization payment adjustment is determined in accordance with § 484.230.

(d) *Partial episode payment adjustment.* An HHA receives a national 60-day episode payment of a predetermined rate for home health services previously paid on a reasonable cost basis as of August 5, 1997, unless CMS determines an intervening event, defined as a beneficiary elected transfer, or discharge and return to the same HHA during a 60-day episode, warrants a new 60-day episode payment. The PEP adjustment would not apply in situations of transfers among HHAs of common ownership as defined in § 424.22 of this chapter. Those situations would be considered services provided under arrangement on behalf of the originating HHA by the receiving HHA with the common ownership interest for the balance of the 60-day episode. The common ownership exception to the transfer PEP adjustment does not apply if the beneficiary moves to a different MSA or Non-MSA during the 60-day episode before the transfer to the receiving HHA. The transferring HHA in situations of common ownership not only serves as a billing agent, but must also exercise professional responsibility over the arranged-for services in order for services provided under arrangements to be paid. The discharge and return to the same HHA during the 60-day episode is only recognized in those circumstances when a beneficiary reached the goals in the original plan of care. The original plan of care must have been terminated with no anticipated need for additional home health services for the balance of the 60-day episode. If the intervening event warrants a new 60-day episode payment and the new physician certification of a new plan of care, the initial HHA receives a partial episode payment adjustment reflecting the length of time the patient remained under its

care. A partial episode payment adjustment is determined in accordance with § 484.235.

(e) *Outlier payment.* An HHA receives a national 60-day episode payment of a predetermined rate for a home health service paid on a reasonable cost basis as of August 5, 1997, unless the imputed cost of the 60-day episode exceeds a threshold amount. The outlier payment is defined to be a proportion of the imputed costs beyond the threshold. An outlier payment is a payment in addition to the national 60-day episode payment. The total of all outlier payments is limited to 5 percent of total outlays under the HHA PPS. An outlier payment is determined in accordance with § 484.240.

[65 FR 41212, July 3, 2000, as amended at 72 FR 49878]

§ 484.210 Data used for the calculation of the national prospective 60-day episode payment.

To calculate the national prospective 60-day episode payment, CMS uses the following:

(a) Medicare cost data on the most recent audited cost report data available.

(b) Utilization data based on Medicare claims.

(c) An appropriate wage index to adjust for area wage differences.

(d) The most recent projections of increases in costs from the HHA market basket index.

(e) OASIS assessment data and other data that account for the relative resource utilization for different HHA Medicare patient case-mix. An HHA must submit to CMS the OASIS data described at § 484.55(b)(1) and (d)(1) in order for CMS to administer the payment rate methodologies described in §§ 484.215, 484.230 and 484.235.

[65 FR 41212, July 3, 2000, as amended at 74 FR 58134, Nov. 10, 2009]

§ 484.215 Initial establishment of the calculation of the national 60-day episode payment.

(a) *Determining an HHA's costs.* In calculating the initial unadjusted national 60-day episode payment applicable for a service furnished by an HHA using data on the most recent available audited cost reports, CMS determines each HHA's costs by summing its allowable costs for the period. CMS determines the national mean cost per visit.

(b) *Determining HHA utilization.* In calculating the initial unadjusted national 60-day episode payment, CMS determines the national mean utilization for each of the six disciplines using home health claims data.

(c) *Use of the market basket index.* CMS uses the HHA market basket index to adjust the HHA cost data to reflect cost increases occurring between October 1, 1996 through September 30, 2001.

(d) *Calculation of the unadjusted national average prospective payment amount for the 60-day episode.* CMS calculates the unadjusted national 60-day episode payment in the following manner:

(1) By computing the mean national cost per visit.

(2) By computing the national mean utilization for each discipline.

(3) By multiplying the mean national cost per visit by the national mean utilization summed in the aggregate for the six disciplines.

(4) By adding to the amount derived in paragraph (d)(3) of this section, amounts for nonroutine medical supplies, an OASIS adjustment for estimated ongoing reporting costs, an OASIS adjustment for the one time implementation costs associated with assessment scheduling form changes and amounts for Part B therapies that could have been unbundled to Part B prior to October 1, 2000. The resulting amount is the unadjusted national 60-day episode rate.

(e) *Standardization of the data for variation in area wage levels and case-mix.* CMS standardizes—

(1) The cost data described in paragraph (a) of this section to remove the effects of geographic variation in wage levels and variation in case-mix;

(2) The cost data for geographic variation in wage levels using the hospital wage index; and

(3) The cost data for HHA variation in case-mix using the case-mix indices and other data that indicate HHA case-mix.

§ 484.220 Calculation of the adjusted national prospective 60-day episode payment rate for case-mix and area wage levels.

CMS adjusts the national prospective 60-day episode payment rate to account for the following:

(a) HHA case-mix using a case-mix index to explain the relative resource utilization of different patients. To address changes to the case-mix that are a result of changes in the coding or classification of different units of service that do not reflect real changes in case-mix, the national prospective 60-day episode payment rate will be adjusted downward as follows:

(1) For CY 2008, the adjustment is 2.75 percent.

(2) For CY 2009 and CY 2010, the adjustment is 2.75 percent in each year.

(3) For CY 2011, the adjustment is 2.71 percent.

(b) Geographic differences in wage levels using an appropriate wage index based on the site of service of the beneficiary.

[72 FR 49879, Aug. 29, 2007]

§ 484.225 Annual update of the unadjusted national prospective 60-day episode payment rate.

(a) CMS updates the unadjusted national 60-day episode payment rate on a fiscal year basis.

(b) For fiscal year 2001, the unadjusted national 60-day episode payment rate is adjusted using the latest available home health market basket index factors.

(c) For fiscal years 2002 and 2003, the unadjusted national prospective 60-day episode payment rate is updated by a factor equal to the applicable home health market basket minus 1.1 percentage points.

(d) For the last calendar quarter of 2003 and the first calendar quarter of 2004, the unadjusted national prospective 60-day episode payment rate is equal to the rate from the previous fiscal year (FY 2003) increased by the applicable home health market basket index amount.

(e) For the last the 3 calendar quarters of 2004, the unadjusted national prospective 60-day episode payment rate is equal to the rate from the previous fiscal year (FY 2003) increased by the applicable home health market basket minus 0.8 percentage points.

(f) For calendar year 2005, the unadjusted national prospective 60-day episode payment rate is equal to the rate from the previous calendar year, increased by the applicable home health market basket minus 0.8 percentage points.

(g) For calendar year 2006, the unadjusted national prospective 60-day episode payment rate is equal to the rate from calendar year 2005.

(h) For 2007 and subsequent calendar years, in the case of a home health agency that submits home health quality data, as specified by the Secretary, the unadjusted national prospective 60-day episode rate is equal to the rate for the previous calendar year increased by the applicable home health market basket index amount.

(i) For 2007 and subsequent calendar years, in the case of a home health agency that does not submit home health quality data, as specified by the Secretary, the unadjusted national prospective 60-day episode rate is equal to the rate for the previous calendar year increased by the applicable home health market basket index amount minus 2 percentage points. Any reduction of the percentage change will apply only to the calendar year involved and will not be taken into account in computing the prospective payment amount for a subsequent calendar year.

[65 FR 41212, July 3, 2000, as amended at 69 FR 62138, Oct. 22, 2004; 71 FR 65935, Nov. 9, 2006]

§ 484.230 Methodology used for the calculation of the low-utilization payment adjustment.

An episode with four or fewer visits is paid the national per-visit amount by discipline updated annually by the applicable market basket for each visit type. The national per-visit amount is determined by using cost data set forth in § 484.210(a) and adjusting by the appropriate wage index based on the site of service for the beneficiary. For 2008 and subsequent calendar years, an amount will be added to low-utilization payment adjustments for low-utilization episodes that occur as the beneficiary's only episode or initial episode

in a sequence of adjacent episodes. For purposes of the home health PPS, a sequence of adjacent episodes for a beneficiary is a series of claims with no more than 60 days without home care between the end of one episode, which is the 60th day (except for episodes that have been PEP-adjusted), and the beginning of the next episode. This additional amount will be updated annually after 2008 by a factor equal to the applicable home health market basket percentage.

[65 FR 41212, July 3, 2000, as amended at 72 FR 69879, Aug. 29, 2007]

§ 484.235 Methodology used for the calculation of the partial episode payment adjustment.

(a) CMS makes a PEP adjustment to the original 60-day episode payment that is interrupted by an intervening event described in § 484.205(d).

(b) The original 60-day episode payment is adjusted to reflect the length of time the beneficiary remained under the care of the original HHA based on the first billable visit date through and including the last billable visit date.

(c) The partial episode payment is calculated by determining the actual days served by the original HHA as a proportion of 60 multiplied by the initial 60-day episode payment.

§ 484.240 Methodology used for the calculation of the outlier payment.

(a) CMS makes an outlier payment for an episode whose estimated cost exceeds a threshold amount for each case-mix group.

(b) The outlier threshold for each case-mix group is the episode payment amount for that group, the PEP adjustment amount for the episode plus a fixed dollar loss amount that is the same for all case-mix groups.

(c) The outlier payment is a proportion of the amount of estimated cost beyond the threshold.

(d) CMS imputes the cost for each episode by multiplying the national per-visit amount of each discipline by the number of visits in the discipline and computing the total imputed cost for all disciplines.

(e) The fixed dollar loss amount and the loss sharing proportion are chosen so that the estimated total outlier payment is no more than 5 percent of total payment under home health PPS.

[65 FR 41212, July 3, 2000, as amended at 72 FR 69879, Aug. 29, 2007]

§ 484.245 Accelerated payments for home health agencies.

(a) *General rule.* Upon request, an accelerated payment may be made to an HHA that is receiving payment under the home health prospective payment system if the HHA is experiencing financial difficulties because there is a delay by the intermediary in making payment to the HHA.

(b) *Approval of payment.* An HHA's request for an accelerated payment must be approved by the intermediary and CMS.

(c) *Amount of payment.* The amount of the accelerated payment is computed as a percentage of the net payment for unbilled or unpaid covered services.

(d) *Recovery of payment.* Recovery of the accelerated payment is made by recoupment as HHA bills are processed or by direct payment by the HHA.

§ 484.250 Patient assessment data.

An HHA must submit to CMS the OASIS data described at § 484.55(b)(1) and (d)(1) in order for CMS to administer the payment rate methodologies described in §§ 484.215, 484.230, and 484.235.

[74 FR 58134, Nov. 10, 2009]

§ 484.260 Limitation on review.

An HHA is not entitled to judicial or administrative review under sections 1869 or 1878 of the Act, or otherwise, with regard to the establishment of the payment unit, including the national 60-day prospective episode payment rate, adjustments and outlier payments. An HHA is not entitled to the review regarding the establishment of the transition period, definition and application of the unit of payments, the computation of initial standard prospective payment amounts, the establishment of the adjustment for outliers, and the establishment of case-mix and area wage adjustment factors.

§ 484.265 Additional payment.

QIO photocopy and mailing costs. An additional payment is made to a home

health agency in accordance with § 476.78 of this chapter for the costs of photocopying and mailing medical records requested by a QIO.

[68 FR 67960, Dec. 5, 2003]

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

SOURCE: 48 FR 56293, Dec. 15, 1982, unless otherwise noted. Redesignated at 50 FR 33034, Aug. 16, 1985.

Subpart A [Reserved]

Subpart B—Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities

§ 485.50 Basis and scope.

This subpart sets forth the conditions that facilities must meet to be certified as comprehensive outpatient rehabilitation facilities (CORFs) under section 1861(cc)(2) of the Social Security Act and be accepted for participation in Medicare in accordance with part 489 of this chapter.

§ 485.51 Definition.

As used in this subpart, unless the context indicates otherwise, *''comprehensive outpatient rehabilitation facility''*, *''CORF''*, or *''facility''* means a nonresidential facility that—

(a) Is established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons, at a single fixed location, by or under the supervision of a physician except as provided in paragraph (c) of this section;

(b) Meets all the requirements of this subpart.

(c) *Exception*. May provide influenza, pneumococcal and Hepatitis B vaccines provided the applicable conditions of coverage under § 410.58 and § 410.63 of this chapter are met.

[48 FR 56293, Dec. 15, 1982, as amended at 72 FR 66408, Nov. 27, 2007]

§ 485.54 Condition of participation: Compliance with State and local laws.

The facility and all personnel who provide services must be in compliance with applicable State and local laws and regulations.

(a) *Standard: Licensure of facility*. If State or local law provides for licensing, the facility must be currently licensed or approved as meeting the standards established for licensure.

(b) *Standard: Licensure of personnel*. Personnel that provide service must be licensed, certified, or registered in accordance with applicable State and local laws.

§ 485.56 Condition of participation: Governing body and administration.

The facility must have a governing body that assumes full legal responsibility for establishing and implementing policies regarding the management and operation of the facility.

(a) *Standard: Disclosure of ownership*. The facility must comply with the provisions of part 420, subpart C of this chapter that require health care providers and fiscal agents to disclose certain information about ownership and control.

(b) *Standard: Administrator*. The governing body must appoint an administrator who—

(1) Is responsible for the overall management of the facility under the authority delegated by the governing body;

(2) Implements and enforces the facility's policies and procedures;

(3) Designates, in writing, an individual who, in the absence of the administrator, acts on behalf of the administrator; and

(4) Retains professional and administrative responsibility for all personnel providing facility services.

(c) *Standard: Group of professional personnel*. The facility must have a group of professional personnel associated with the facility that—

(1) Develops and periodically reviews policies to govern the services provided by the facility; and

(2) Consists of at least one physician and one professional representing each of the services provided by the facility.

(d) *Standard: Institutional budget plan*. The facility must have an institutional budget plan that meets the following conditions:

(1) It is prepared, under the direction of the governing body, by a committee consisting of representatives of the governing body and the administrative staff.

(2) It provides for—

(i) An annual operating budget prepared according to generally accepted accounting principles;

(ii) A 3-year capital expenditure plan if expenditures in excess of $100,000 are anticipated, for that period, for the acquisition of land; the improvement of land, buildings, and equipment; and the

replacement, modernization, and expansion of buildings and equipment; and

(iii) Annual review and updating by the governing body.

(e) *Standard: Patient care policies.* The facility must have written patient care policies that govern the services it furnishes. The patient care policies must include the following:

(1) A description of the services the facility furnishes through employees and those furnished under arrangements.

(2) Rules for and personnel responsibilities in handling medical emergencies.

(3) Rules for the storage, handling, and administration of drugs and biologicals.

(4) Criteria for patient admission, continuing care, and discharge.

(5) Procedures for preparing and maintaining clinical records on all patients.

(6) A procedure for explaining to the patient and the patient's family the extent and purpose of the services to be provided.

(7) A procedure to assist the referring physician in locating another level of care for—patients whose treatment has terminated and who are discharged.

(8) A requirement that patients accepted by the facility must be under the care of a physician.

(9) A requirement that there be a plan of treatment established by a physician for each patient.

(10) A procedure to ensure that the group of professional personnel reviews and takes appropriate action on recommendations from the utilization review committee regarding patient care policies.

(f) *Standard: Delegation of authority.* The responsibility for overall administration, management, and operation must be retained by the facility itself and not delegated to others.

(1) The facility may enter into a contract for purposes of assistance in financial management and may delegate to others the following and similar services:

(i) Bookkeeping.

(ii) Assistance in the development of procedures for billing and accounting systems.

(iii) Assistance in the development of an operating budget.

(iv) Purchase of supplies in bulk form.

(v) The preparation of financial statements.

(2) When the services listed in paragraph (f)(1) of this section are delegated, a contract must be in effect and:

(i) May not be for a term of more than 5 years;

(ii) Must be subject to termination within 60 days of written notice by either party;

(iii) Must contain a clause requiring renegotiation of any provision that CMS finds to be in contravention to any new, revised or amended Federal regulation or law;

(iv) Must state that only the facility may bill the Medicare program; and

(v) May not include clauses that state or imply that the contractor has power and authority to act on behalf of the facility, or clauses that give the contractor rights, duties, discretions, or responsibilities that enable it to dictate the administration, mangement, or operations of the facility.

§ 485.58 Condition of participation: Comprehensive rehabilitation program.

The facility must provide a coordinated rehabilitation program that includes, at a minimum, physicians' services, physical therapy services, and social or psychological services. These services must be furnished by personnel that meet the qualifications set forth in §§ 485.70 and 484.4 of this chapter and must be consistent with the plan of treatment and the results of comprehensive patient assessments.

(a) *Standard: Physician services.* (1) A facility physician must be present in the facility for a sufficient time to—

(i) Provide, in accordance with accepted principles of medical practice, medical direction, medical care services, consultation, and medical supervision of nonphysician staff;

(ii) Establish the plan of treatment in cases where a plan has not been established by the referring physician;

(iii) Assist in establishing and implementing the facility's patient care policies; and

(iv) Participate in plan of treatment reviews, patient case review conferences, comprehensive patient assessment and reassessments, and utilization review.

(2) The facility must provide for emergency physician services during the facility operating hours.

(b) *Standard: Plan of treatment.* For each patient, a physician must establish a plan of treatment before the facility initiates treatment. The plan of treatment must meet the following requirements:

(1) It must delineate anticipated goals and specify the type, amount, frequency and duration of services to be provided.

(2) It must be promptly evaluated after changes in the patient's condition and revised when necessary.

(3) It must, if appropriate, be developed in consultation with the facility physician and the appropriate facility professional personnel.

(4) It must be reviewed at least every 60 days by a facility physician who, when appropriate, consults with the professional personnel providing services. The results of this review must be communicated to the patient's referring physician for concurrence before treatment is continued or discontinued.

(5) It must be revised if the comprehensive reassessment of the patient's status or the results of the patient case review conference indicate the need for revision.

(c) *Standard: Coordination of services.* The facility must designate, in writing, a qualified professional to ensure that professional personnel coordinate their related activities and exchange information about each patient under their care. Mechanisms to assist in the coordination of services must include—

(1) Providing to all personnel associated with the facility, a schedule indicating the frequency and type of services provided at the facility;

(2) A procedure for communicating to all patient care personnel pertinent information concerning significant changes in the patient's status;

(3) Periodic clinical record entries, noting at least the patient's status in relationship to goal attainment; and

(4) Scheduling patient case review conferences for purposes of determining appropriateness of treatment, when indicated by the results of the initial comprehensive patient assessment, reassessment(s), the recommendation of the facility physician (or other physician who established the plan of treatment), or upon the recommendation of one of the professionals providing services.

(d) *Standard: Provision of services.* (1) All patients must be referred to the facility by a physician who provides the following information to the facility before treatment is initiated:

(i) The patient's significant medical history.

(ii) Current medical findings.

(iii) Diagnosis(es) and contraindications to any treatment modality.

(iv) Rehabilitation goals, if determined.

(2) Services may be provided by facility employees or by others under arrangements made by the facility.

(3) The facility must have on its premises the necessary equipment to implement the plan of treatment and sufficient space to allow adequate care.

(4) The services must be furnished by personnel that meet the qualifications of § 485.70 and the number of qualified personnel must be adequate for the volume and diversity of services offered. Personnel that do not meet the qualifications specified in § 485.70 may be used by the facility in assisting qualified staff. When a qualified individual is assisted by these personnel, the qualified individual must be on the premises, and must instruct these personnel in appropriate patient care service techniques and retain responsibility for their activities.

(5) A qualified professional must initiate and coordinate the appropriate portions of the plan of treatment, monitor the patient's progress, and recommend changes, in the plan, if necessary.

(6) A qualified professional representing each service made available at the facility must be either on the premises of the facility or must be available through direct telecommunication for consultation and assistance during the facility's operating hours. At least one qualified professional

must be on the premises during the facility's operating hours.

(7) All services must be provided consistent with accepted professional standards and practice.

(e) *Standard: Scope and site of services*—(1) *Basic requirements*. The facility must provide all the CORF services required in the plan of treatment and, except as provided in paragraph (e)(2) of this section, must provide the services on its premises.

(2) *Exceptions*. Physical therapy, occupational therapy, and speech-language pathology services may be furnished away from the premises of the CORF including the individual's home when payment is not otherwise made under Title XVIII of the Act. In addition, a single home environment evaluation is covered if there is a need to evaluate the potential impact of the home environment on the rehabilitation goals. The single home environment evaluation requires the presence of the patient and the physical therapist, occupational therapist, or speech-language pathologist, as appropriate.

(f) *Standard: Patient assessment*. Each qualified professional involved in the patient's care, as specified in the plan of treatment, must—

(1) Carry out an initial patient assessment; and

(2) In order to identify whether or not the current plan of treatment is appropriate, perform a patient reassessment after significant changes in the patient's status.

(g) *Standard: Laboratory services*. (1) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter.

(2) If the facility chooses to refer specimens for laboratory testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter.

[48 FR 56293, Dec. 15, 1982, as amended at 56 FR 8852, Mar. 1, 1991; 57 FR 7137, Feb. 28, 1992; 73 FR 69941, Nov. 19, 2008]

§ 485.60 Condition of participation: Clinical records.

The facility must maintain clinical records on all patients in accordance with accepted professional standards and practice. The clinical records must be completely, promptly, and accurately documented, readily accessible, and systematically organized to facilitate retrieval and compilation of information.

(a) *Standard: Content*. Each clinical record must contain sufficient information to identify the patient clearly and to justify the diagnosis and treatment. Entries in the clinical record must be made as frequently as is necessary to insure effective treatment and must be signed by personnel providing services. All entries made by assistant level personnel must be countersigned by the corresponding professional. Documentation on each patient must be consolidated into one clinical record that must contain—

(1) The initial assessment and subsequent reassessments of the patient's needs;

(2) Current plan of treatment;

(3) Identification data and consent or authorization forms;

(4) Pertinent medical history, past and present;

(5) A report of pertinent physical examinations if any;

(6) Progress notes or other documentation that reflect patient reaction to treatment, tests, or injury, or the need to change the established plan of treatment; and

(7) Upon discharge, a discharge summary including patient status relative to goal achievement, prognosis, and future treatment considerations.

(b) *Standard: Protection of clinical record information*. The facility must safeguard clinical record information against loss, destruction, or unauthorized use. The facility must have procedures that govern the use and removal of records and the conditions for release of information. The facility must obtain the patient's written consent before releasing information not required to be released by law.

(c) *Standard: Retention and preservation*. The facility must retain clinical

record information for 5 years after patient discharge and must make provision for the maintenance of such records in the event that it is no longer able to treat patients.

§ 485.62 Condition of participation: Physical environment.

The facility must provide a physical environment that protects the health and safety or patients, personnel, and the public.

(a) *Standard: Safety and comfort of patients.* The physical premises of the facility and those areas of its surrounding physical structure that are used by the patients (including at least all stairwells, corridors and passageways) must meet the following requirements:

(1) Applicable Federal, State, and local building, fire, and safety codes must be met.

(2) Fire extinguishers must be easily accessible and fire regulations must be prominently posted.

(3) A fire alarm system with local (in-house) capability must be functional, and where power is generated by electricity, an alternate power source with automatic triggering must be present.

(4) Lights, supported by an emergency power source, must be placed at exits.

(5) A sufficient number of staff to evacuate patients during a disaster must be on the premises of the facility whenever patients are being treated.

(6) Lighting must be sufficient to carry out services safely; room temperature must be maintained at comfortable levels; and ventilation through windows, mechanical means, or a combination of both must be provided.

(7) Safe and sufficient space must be available for the scope of services offered.

(b) *Standard: Sanitary environment.* The facility must maintain a sanitary environment and establish a program to identify, investigate, prevent, and control the cause of patient infections.

(1) The facility must establish written policies and procedures designed to control and prevent infection in the facility and to investigate and identify possible causes of infection.

(2) The facility must monitor the infection control program to ensure that the staff implement the policies and procedures and that the policies and procedures are consistent with current practices in the field.

(3) The facility must make available at all times a quantity of laundered linen adequate for proper care and comfort of patients. Linens must be handled, stored, and processed in a mannner that prevents the spread of infection.

(4) Provisions must be in effect to ensure that the facility's premises are maintained free of rodent and insect infestation.

(c) *Standard: Maintenance of equipment, physical location, and grounds.* The facility must establish a written preventive maintenance program to ensure that—

(1) All equipment is properly maintained and equipment needing periodic calibration is calibrated consistent with the manufacturer's recommendations; and

(2) The interior of the facility, the exterior of the physical structure housing the facility, and the exterior walkways and parking areas are clean and orderly and maintained free of any defects that are a hazard to patients, personnel, and the public.

(d) *Standard: Access for the physically impaired.* The facility must ensure the following:

(1) Doorways, stairwells, corridors, and passageways used by patients are—

(i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs); and

(ii) In the case of stairwells, equipped with firmly attached handrails on at least one side.

(2) At least one toilet facility is accessible and constructed to allow utilization by ambulatory and non-ambulatory individuals.

(3) At least one entrance is usable by individuals in wheelchairs.

(4) In multi-story buildings, elevators are accessible to and usable by the physically impaired on the level that they use to enter the building and all levels normally used by the patients of the facility.

(5) Parking spaces are large enough and close enough to the facility to

allow safe access by the physically impaired.

§ 485.64 Condition of participation: Disaster procedures.

The facility must have written policies and procedures that specifically define the handling of patients, personnel, records, and the public during disasters. All personnel associated with the facility must be knowledgeable with respect to these procedures, be trained in their application, and be assigned specific responsibilities.

(a) *Standard: Disaster plan.* The facility's written disaster plan must be developed and maintained with assistance of qualified fire, safety, and other appropriate experts. The plan must include—

(1) Procedures for prompt transfer of casualties and records;

(2) Procedures for notifying community emergency personnel (for example, fire department, ambulance, etc.);

(3) Instructions regarding the location and use of alarm systems and signals and fire fighting equipment; and

(4) Specification of evacuation routes and procedures for leaving the facility.

(b) *Standard: Drills and staff training.* (1) The facility must provide ongoing training and drills for all personnel associated with the facility in all aspects of disaster preparedness.

(2) All new personnel must be oriented and assigned specific responsibilities regarding the facility's disaster plan within two weeks of their first workday.

§ 485.66 Condition of participation: Utilization review plan.

The facility must have in effect a written utilization review plan that is implemented at least each quarter, to assess the necessity of services and promotes the most efficient use of services provided by the facility.

(a) *Standard: Utilization review committee.* The utilization review committee, consisting of the group of professional personnel specified in § 485.56(c), a committee of this group, or a group of similar composition, comprised by professional personnel not associated with the facility, must carry out the utilization review plan.

(b) *Standard: Utilization review plan.* The utilization review plan must contain written procedures for evaluating—

(1) Admissions, continued care, and discharges using, at a minimum, the criteria established in the patient care policies;

(2) The applicability of the plan of treatment to established goals; and

(3) The adequacy of clinical records with regard to—

(i) Assessing the quality of services provided; and

(ii) Determining whether the facility's policies and clinical practices are compatible and promote appropriate and efficient utilization of services.

§ 485.70 Personnel qualifications.

This section sets forth the qualifications that must be met, as a condition of participation, under § 485.58, and as a condition of coverage of services under § 410.100 of this chapter.

(a) A facility physician must be a doctor of medicine or osteopathy who—

(1) Is licensed under State law to practice medicine or surgery; and

(2) Has had, subsequent to completing a 1-year hospital internship, at least 1 year of training in the medical management of patients requiring rehabilitation services; or

(3) Has had at least 1 year of full-time or part-time experience in a rehabilitation setting providing physicians' services similar to those required in this subpart.

(b) A licensed practical nurse must be licensed as a practical or vocational nurse by the State in which practicing, if applicable.

(c) An occupational therapist and an occupational therapy assistant must meet the qualifications in § 484.4 of this chapter.

(d) An orthotist must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program in orthotics that is jointly recognized by the American Council on Education and the American Board for Certification in Orthotics and Prosthetics; and

(3) Be eligible to take that Board's certification examination in orthotics.

(e) A physical therapist and a physical therapist assistant must meet the qualifications in § 484.4 of this chapter.

(f) A *prosthetist* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program in prosthetics that is jointly recognized by the American Council on Education and the American Board for Certification in Orthotics and Prosthetics; and

(3) Be eligible to take that Board's certification examination in prosthetics.

(g) A *psychologist* must be certified or licensed by the State in which he or she is practicing, if that State requires certification or licensing, and must hold a masters degree in psychology from and educational institution approved by the State in which the institution is located.

(h) A *registered nurse* must be a graduate of an approved school of nursing and be licensed as a registered nurse by the State in which practicing, if applicable.

(i) A *rehabilitation counselor* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Hold at least a bachelor's degree; and

(3) Be eligible to take the certification examination administered by the Commission on Rehabilitation Counselor Certification.

(j) A respiratory therapist must complete one the following criteria:

(1) *Criterion 1.* All of the following must be completed:

(i) Be licensed by the State in which practicing, if applicable.

(ii) Have successfully completed a nationally-accredited educational program for respiratory therapists.

(iii)(A) Be eligible to take the registry examination administered by the National Board for Respiratory Care for respiratory therapists; or

(B) Have passed the registry examination administered by the National Board for Respiratory Care for respiratory therapists.

(2) *Criterion 2:* All of the following must be completed:

(i) Be licensed by the State in which practicing, if applicable.

(ii) Have equivalent training and experience as determined by the National Board for Respiratory Care.

(k) A *respiratory therapy technician* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program accredited by the Committees on Allied Health Education and Accreditation (CAHEA) in collaboration with the Joint Review Committee for Respiratory Therapy Education; and

(3) Either—

(i) Be eligible to take the certification examination for respiratory therapy technicians administered by the National Board for Respiratory Therapy, Inc,; or

(ii) Have equivalent training and experience as determined by the National Board for Respiratory Therapy, Inc.

(l) A *social worker* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Hold at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education; and

(3) Have 1 year of social work experience in a health care setting.

(m) A speech-language pathologist must meet the qualifications set forth in part 484 of this chapter.

[48 FR 56293, Dec. 15, 1982. Redesignated and amended at 50 FR 33034, Aug. 16, 1985; 51 FR 41352, Nov. 14, 1986; 60 FR 2327, Jan. 9, 1995; 72 FR 66408, Nov. 27, 2007; 73 FR 69941, Nov. 19, 2008; 74 FR 62014, Nov. 25, 2009]

§ 485.74 Appeal rights.

The appeal provisions set forth in part 498 of this chapter, for providers, are applicable to any entity that is participating or seeks to participate in the Medicare program as a CORF.

[48 FR 56293, Dec. 15, 1982, as amended at 52 FR 22454, June 12, 1987]

Subparts C–E [Reserved]

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

SOURCE: 58 FR 30671, May 26, 1993, unless otherwise noted.

§ 485.601 Basis and scope.

(a) *Statutory basis.* This subpart is based on section 1820 of the Act which sets forth the conditions for designating certain hospitals as CAHs.

(b) *Scope.* This subpart sets forth the conditions that a hospital must meet to be designated as a CAH.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.602 Definitions.

As used in this subpart, unless the context indicates otherwise:

Direct services means services provided by employed staff of the CAH, not services provided through arrangements or agreements.

[59 FR 45403, Sept. 1, 1994, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.603 Rural health network.

A rural health network is an organization that meets the following specifications:

(a) It includes—

(1) At least one hospital that the State has designated or plans to designate as a CAH; and

(2) At least one hospital that furnishes acute care services.

(b) The members of the organization have entered into agreements regarding—

(1) Patient referral and transfer;

(2) The development and use of communications systems, including, where feasible, telemetry systems and systems for electronic sharing of patient data; and

(3) The provision of emergency and nonemergency transportation among members.

(c) Each CAH has an agreement with respect to credentialing and quality assurance with at least—

(1) One hospital that is a member of the network when applicable;

(2) One QIO or equivalent entity; or

(3) One other appropriate and qualified entity identified in the State rural health care plan.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46035, Aug. 29, 1997; 63 FR 26359, May 12, 1998]

§ 485.604 Personnel qualifications.

Staff that furnish services in a CAH must meet the applicable requirements of this section.

(a) *Clinical nurse specialist.* A clinical nurse specialist must be a person who performs the services of a clinical nurse specialist as authorized by the State, in accordance with State law or the State regulatory mechanism provided by State law.

(b) *Nurse practitioner.* A nurse practitioner must be a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualification of nurse practitioners, and who meets one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates.

(2) Has successfully completed a 1 academic year program that—

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program.

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (a)(2) of this section, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

(c) *Physician assistant.* A physician assistant must be a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians.

(2) Has satisfactorily completed a program for preparing physician assistants that—

(i) Was at least one academic year in length;

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation.

(3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (c)(2) of this section and has been assisting primary care physicians for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.606 Designation and certification of CAHs.

(a) *Criteria for State designation.* (1) A State that has established a Medicare rural hospital flexibility program described in section 1820(c) of the Act may designate one or more facilities as CAHs if each facility meets the CAH conditions of participation in this subpart F.

(2) The State must not deny any hospital that is otherwise eligible for designation as a CAH under this paragraph (a) solely because the hospital has entered into an agreement under which the hospital may provide posthospital SNF care as described in § 482.66 of this chapter.

(b) Criteria for CMS certification. CMS certifies a facility as a CAH if—

(1) The facility is designated as a CAH by the State in which it is located and has been surveyed by the State survey agency or by CMS and found to meet all conditions of participation in this Part and all other applicable requirements for participation in Part 489 of this chapter.

(2) The facility is a medical assistance facility operating in Montana or a rural primary care hospital designated by CMS before August 5, 1997, and is otherwise eligible to be designated as a CAH by the State under the rules in this subpart.

[62 FR 46036, Aug. 29, 1997, as amended at 63 FR 26359, May 12, 1998]

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

The CAH and its staff are in compliance with applicable Federal, State and local laws and regulations.

(a) *Standard: Compliance with Federal laws and regulations.* The CAH is in compliance with applicable Federal laws and regulations related to the health and safety of patients.

(b) *Standard: Compliance with State and local laws and regulations.* All patient care services are furnished in accordance with applicable State and local laws and regulations.

(c) *Standard: Licensure of CAH.* The CAH is licensed in accordance with applicable Federal, State and local laws and regulations.

(d) *Standard: Licensure, certification or registration of personnel.* Staff of the CAH are licensed, certified, or registered in accordance with applicable Federal, State, and local laws and regulations.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.610 Condition of participation: Status and location.

(a) *Standard:* Status. The facility is—

(1) A currently participating hospital that meets all conditions of participation set forth in this subpart;

(2) A recently closed facility, provided that the facility—

(i) Was a hospital that ceased operations on or after the date that is 10 years before November 29, 1999; and

(ii) Meets the criteria for designation under this subpart as of the effective date of its designation; or

(3) A health clinic or a health center (as defined by the State) that—

(i) Is licensed by the State as a health clinic or a health center;

(ii) Was a hospital that was downsized to a health clinic or a health center; and

(iii) As of the effective date of its designation, meets the criteria for designation set forth in this subpart.

(b) *Standard: Location in a rural area or treatment as rural.* The CAH meets the requirements of either paragraph (b)(1) or (b)(2) of this section or the requirements of either (b)(3) or (b)(4) of this section.

(1) The CAH meets the following requirements:

(i) The CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or that has been recognized as urban under § 412.64(b), excluding paragraph (b)(3) of this chapter;

(ii) The CAH has not been classified as an urban hospital for purposes of the standardized payment amount by CMS or the Medicare Geographic Classification Review Board under § 412.230(e) of this chapter, and is not among a group of hospitals that have been redesignated to an adjacent urban area under § 412.232 of this chapter.

(2) The CAH is located within a Metropolitan Statistical Area, as defined by the Office of Management and Budget, but is being treated as being located in a rural area in accordance with § 412.103 of this chapter.

(3) Effective for October 1, 2004 through September 30, 2006, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2004, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but as of FY 2005 was included as part of such a Metropolitan Statistical Area as a result of the most recent census data and implementation of the new Metropolitan Statistical Area definitions announced by the Office of Management and Budget on June 3, 2003.

(4) Effective for October 1, 2009 through September 30, 2011, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2009, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but, as of FY 2010, was included as part of such a Metropolitan Statistical Area as a result of the most recent census data and implementation of the new Metropolitan Statistical Area definitions announced by the Office of Management and Budget on November 20, 2008.

(c) *Standard: Location relative to other facilities or necessary provider certification.* The CAH is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or before January 1, 2006, the CAH is certified by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a necessary provider on or before December 31, 2005, will maintain its necessary provider designation after January 1, 2006.

(d) *Standard: Relocation of CAHs with a necessary provider designation.* A CAH that has a necessary provider designation from the State that was in effect prior to January 1, 2006, and relocates its facility after January 1, 2006, can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the relocated facility meets the requirements as specified in paragraph (d)(1) of this section.

(1) If a necessary provider CAH relocates its facility and begins providing services in a new location, the CAH can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the CAH in its new location—

(i) Serves at least 75 percent of the same service area that it served prior to its relocation;

(ii) Provides at least 75 percent of the same services that it provided prior to the relocation; and

(iii) Is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees) that were on staff at the original location.

(2) If a CAH that has been designated as a necessary provider by the State begins providing services at another location after January 1, 2006, and does not meet the requirements in paragraph (d)(1) of this section, the action will be considered a cessation of business as described in § 489.52(b)(3).

(e) *Standard: Off-campus and co-location requirements for CAHs.* A CAH may

continue to meet the location requirements of paragraph (c) of this section only if the CAH meets the following:

(1) If a CAH with a necessary provider designation is co-located (that is, it shares a campus, as defined in §413.65(a)(2) of this chapter, with another hospital or CAH), the necessary provider CAH can continue to meet the location requirement of paragraph (c) of this section only if the co-location arrangement was in effect before January 1, 2008, and the type and scope of services offered by the facility co-located with the necessary provider CAH do not change. A change of ownership of any of the facilities with a co-location arrangement that was in effect before January 1, 2008, will not be considered to be a new co-location arrangement.

(2) If a CAH or a necessary provider CAH operates an off-campus provider-based location, excluding an RHC as defined in §405.2401(b) of this chapter, but including a department or remote location, as defined in §413.65(a)(2) of this chapter, or an off-campus distinct part psychiatric or rehabilitation unit, as defined in §485.647, that was created or acquired by the CAH on or after January 1, 2008, the CAH can continue to meet the location requirement of paragraph (c) of this section only if the off-campus provider-based location or off-campus distinct part unit is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH.

(3) If either a CAH or a CAH that has been designated as a necessary provider by the State does not meet the requirements in paragraph (e)(1) of this section, by co-locating with another hospital or CAH on or after January 1, 2008, or creates or acquires an off-campus provider-based location or off-campus distinct part unit on or after January 1, 2008, that does not meet the requirements in paragraph (e)(2) of this section, the CAH's provider agreement will be subject to termination in accordance with the provisions of §489.53(a)(3) of this subchapter, unless the CAH terminates the off-campus arrangement or the co-location arrangement, or both.

[62 FR 46036, Aug. 29, 1997, as amended at 65 FR 47052, Aug. 1, 2000; 66 FR 39938, Aug. 1, 2001; 69 FR 49271, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004; 70 FR 47490, Aug. 12, 2005; 71 FR 48143, Aug. 18, 2006; 72 FR 66934, Nov. 27, 2007; 73 FR 9862, Feb. 22, 2008; 74 FR 44001, Aug. 27, 2009; 75 FR 50418, Aug. 16, 2010]

§485.612 Condition of participation: Compliance with hospital requirements at the time of application.

Except for recently closed facilities as described in §485.610(a)(2), or health clinics or health centers as described in §485.610(a)(3), the facility is a hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.

[66 FR 32196, June 13, 2001]

§485.616 Condition of participation: Agreements.

(a) *Standard: Agreements with network hospitals.* In the case of a CAH that is a member of a rural health network as defined in §485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for—

(1) Patient referral and transfer;

(2) The development and use of communications systems of the network, including the network's system for the electronic sharing of patient data, and telemetry and medical records, if the network has in operation such a system; and

(3) The provision of emergency and nonemergency transportation between the facility and the hospital.

(b) *Standard: Agreements for credentialing and quality assurance.* Each CAH that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least—

(1) One hospital that is a member of the network;

(2) One QIO or equivalent entity; or

(3) One other appropriate and qualified entity identified in the State rural health care plan.

[62 FR 46036, Aug. 29, 1997]

§ 485.618 Condition of participation: Emergency services.

The CAH provides emergency care necessary to meet the needs of its inpatients and outpatients.

(a) *Standard: Availability.* Emergency services are available on a 24-hours a day basis.

(b) *Standard: Equipment, supplies, and medication.* Equipment, supplies, and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency cases. The items available must include the following:

(1) *Drugs and biologicals* commonly used in life-saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions.

(2) *Equipment and supplies* commonly used in life-saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters.

(c) *Standard: Blood and blood products.* The facility provides, either directly or under arrangements, the following:

(1) Services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis.

(2) Blood storage facilities that meet the requirements of 42 CFR part 493, subpart K, and are under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy. If blood banking services are provided under an arrangement, the arrangement is approved by the facility's medical staff and by the persons directly responsible for the operation of the facility.

(d) *Standard: Personnel.* (1) Except as specified in paragraph (d)(3) of this section, there must be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care, on call and immediately available by telephone or radio contact, and available on site within the following timeframes:

(i) Within 30 minutes, on a 24-hour a day basis, if the CAH is located in an area other than an area described in paragraph (d)(1)(ii) of this section; or

(ii) Within 60 minutes, on a 24-hour a day basis, if all of the following requirements are met:

(A) The CAH is located in an area designated as a frontier area (that is, an area with fewer than six residents per square mile based on the latest population data published by the Bureau of the Census) or in an area that meets the criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS, under section 1820(b) of the Act.

(B) The State has determined, under criteria in its rural health care plan, that allowing an emergency response time longer than 30 minutes is the only feasible method of providing emergency care to residents of the area served by the CAH.

(C) The State maintains documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency.

(2) A registered nurse with training and experience in emergency care can be utilized to conduct specific medical screening examinations only if—

(i) The registered nurse is on site and immediately available at the CAH when a patient requests medical care; and

(ii) The nature of the patient's request for medical care is within the scope of practice of a registered nurse and consistent with applicable State laws and the CAH's bylaws or rules and regulations.

(3) A registered nurse satisfies the personnel requirement specified in paragraph (d)(1) of this section for a temporary period if—

(i) The CAH has no greater than 10 beds;

(ii) The CAH is located in an area designated as a frontier area or remote location as described in paragraph (d)(1)(ii)(A) of this section;

(iii) The State in which the CAH is located submits a letter to CMS signed

by the Governor, following consultation on the issue of using RNs on a temporary basis as part of their State rural healthcare plan with the State Boards of Medicine and Nursing, and in accordance with State law, requesting that a registered nurse with training and experience in emergency care be included in the list of personnel specified in paragraph (d)(1) of this section. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of emergency services in the States. The letter from the Governor must also describe the circumstances and duration of the temporary request to include the registered nurses on the list of personnel specified in paragraph (d)(1) of this section;

(iv) Once a Governor submits a letter, as specified in paragraph (d)(3)(iii) of this section, a CAH must submit documentation to the State survey agency demonstrating that it has been unable, due to the shortage of such personnel in the area, to provide adequate coverage as specified in this paragraph (d).

(4) The request, as specified in paragraph (d)(3)(iii) of this section, and the withdrawal of the request, may be submitted to us at any time, and are effective upon submission.

(e) *Standard: Coordination with emergency response systems.* The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hours a day basis to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 64 FR 41544, July 30, 1999; 67 FR 80041, Dec. 31, 2002; 69 FR 49271, Aug. 11, 2004; 71 FR 68230, Nov. 24, 2006]

§ 485.620 Condition of participation: Number of beds and length of stay.

(a) *Standard: Number of beds.* Except as permitted for CAHs having distinct part units under § 485.647, the CAH maintains no more than 25 inpatient beds after January 1, 2004, that can be used for either inpatient or swing-bed services.

(b) *Standard: Length of stay.* The CAH provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient.

[62 FR 46036, Aug. 29, 1997, as amended at 65 FR 47052, Aug. 1, 2000; 69 FR 49271, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004]

§ 485.623 Condition of participation: Physical plant and environment.

(a) *Standard: Construction.* The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of direct services.

(b) *Standard: Maintenance.* The CAH has housekeeping and preventive maintenance programs to ensure that—

(1) All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition;

(2) There is proper routine storage and prompt disposal of trash;

(3) Drugs and biologicals are appropriately stored;

(4) The premises are clean and orderly; and

(5) There is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.

(c) *Standard: Emergency procedures.* The CAH assures the safety of patients in non-medical emergencies by—

(1) Training staff in handling emergencies, including prompt reporting of fires, extinguishing of fires, protection and, where necessary, evacuation of patients, personnel, and guests, and cooperation with fire fighting and disaster authorities;

(2) Providing for emergency power and lighting in the emergency room and for battery lamps and flashlights in other areas;

(3) Providing for an emergency fuel and water supply; and

(4) Taking other appropriate measures that are consistent with the particular conditions of the area in which the CAH is located.

(d) *Standard: Life safety from fire.* (1) Except as otherwise provided in this section—

(i) The CAH must meet the applicable provisions of the 2000 edition of the

Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the Life Safety Code does not apply to a CAH.

(2) If CMS finds that the State has a fire and safety code imposed by State law that adequately protects patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the LSC.

(3) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the CAH, but only if the waiver does not adversely affect the health and safety of patients.

(4) The CAH maintains written evidence of regular inspection and approval by State or local fire control agencies.

(5) Beginning March 13, 2006, a critical access hospital must be in compliance with Chapter 9.2.9, Emergency Lighting.

(6) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to critical access hospitals.

(7) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a critical access hospital may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269; and

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46036, 46037, Aug. 29, 1997; 68 FR 1387, Jan. 10, 2003; 69 FR 49271, Aug. 11, 2004; 70 FR 15239, Mar. 25, 2005; 71 FR 55341, Sept. 22, 2006]

§ 485.627 Condition of participation: Organizational structure.

(a) *Standard: Governing body or responsible individual*. The CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the CAH's total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment.

(b) *Standard: Disclosure*. The CAH discloses the names and addresses of—

(1) Its owners, or those with a controlling interest in the CAH or in any

subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest, in accordance with subpart C of part 420 of this chapter;

(2) The person principally responsible for the operation of the CAH; and

(3) The person responsible for medical direction.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.631 Condition of participation: Staffing and staff responsibilities.

(a) *Standard: Staffing*—(1) The CAH has a professional health care staff that includes one or more doctors of medicine or osteopathy, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.

(2) Any ancillary personnel are supervised by the professional staff.

(3) The staff is sufficient to provide the services essential to the operation of the CAH.

(4) A doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates.

(5) A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the CAH has one or more inpatients.

(b) *Standard: Responsibilities of the doctor of medicine or osteopathy*. (1) The doctor of medicine or osteopathy—

(i) Provides medical direction for the CAH's health care activities and consultation for, and medical supervision of, the health care staff;

(ii) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH's written policies governing the services it furnishes.

(iii) In conjunction with the physician assistant and/or nurse practitioner members, periodically reviews the CAH's patient records, provides medical orders, and provides medical care services to the patients of the CAH; and

(iv) Periodically reviews and signs the records of all inpatients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants.

(v) Periodically, but not less than every 2 weeks, reviews and signs a sample of outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants according to the policies of the CAH and according to current standards of practice where State law requires record reviews or co-signatures, or both, by a collaborating physician.

(vi) Is not required to review and sign outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants where State law does not require record reviews or co-signatures, or both, by a collaborating physician.

(2) A doctor of medicine or osteopathy is present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances) to provide the medical direction, medical care services, consultation, and supervision described in this paragraph, and is available through direct radio or telephone communication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the CAH. A site visit is not required if no patients have been treated since the latest site visit.

(c) *Standard: Physician assistant, nurse practitioner, and clinical nurse specialist responsibilities*. (1) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH's staff—

(i) Participate in the development, execution and periodic review of the written policies governing the services the CAH furnishes; and

(ii) Participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records.

(2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy:

(i) Provides services in accordance with the CAH's policies.

(ii) Arranges for, or refers patients to, needed services that cannot be furnished at the CAH, and assures that adequate patient health records are maintained and transferred as required when patients are referred.

(3) Whenever a patient is admitted to the CAH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the CAH is notified of the admission.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 70 FR 68728, Nov. 10, 2005]

§ 485.635 Condition of participation: Provision of services.

(a) *Standard: Patient care policies.* (1) The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

(2) The policies are developed with the advice of a group of professional personnel that includes one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of § 485.631(a)(1); at least one member is not a member of the CAH staff.

(3) The policies include the following:

(i) A description of the services the CAH furnishes directly and those furnished through agreement or arrangement.

(ii) Policies and procedures for emergency medical services.

(iii) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH.

(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.

(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.

(vi) A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

(vii) If the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of § 483.25(i) is met with respect to inpatients receiving posthospital SNF care.

(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.

(b) *Standard: Direct services*—(1) *General.* The CAH staff furnishes, as direct services, those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

(2) *Laboratory services.* The CAH provides, as direct services, basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include:

(i) Chemical examination of urine by stick or tablet method or both (including urine ketones);

(ii) Hemoglobin or hematocrit;

(iii) Blood glucose:

(iv) Examination of stool specimens for occult blood;

(v) Pregnancy tests; and

(vi) Primary culturing for transmittal to a certified laboratory.

(3) *Radiology services.* Radiology services furnished at the CAH are provided as direct services by staff qualified under State law, and do not expose

CAH patients or staff to radiation hazards.

(4) *Emergency procedures*. In accordance with the requirements of § 485.618, the CAH provides as direct services medical emergency procedures as a first response to common life-threatening injuries and acute illness.

(c) *Standard: Services provided through agreements or arrangements*. (1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including—

(i) Inpatient hospital care;

(ii) Services of doctors of medicine or osteopathy; and

(iii) Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH.

(iv) Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.

(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.

(3) The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.

(4) The person principally responsible for the operation of the CAH under § 485.627(b)(2) of this chapter is also responsible for the following:

(i) Services furnished in the CAH whether or not they are furnished under arrangements or agreements.

(ii) Ensuring that a contractor of services (including one for shared services and joint ventures) furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services.

(d) *Standard: Nursing services*. Nursing services must meet the needs of patients.

(1) A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available.

(2) A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH.

(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or, where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.

(4) A nursing care plan must be developed and kept current for each inpatient.

(e) *Standard: Rehabilitation Therapy Services*. Physical therapy, occupational therapy, and speech-language pathology services furnished at the CAH, if provided, are provided by staff qualified under State law, and consistent with the requirements for therapy services in § 409.17 of this subpart.

[58 FR 30671, May 26, 1993; 58 FR 49935, Sept. 24, 1993, as amended at 59 FR 45403, Sept. 1, 1994; 62 FR 46037, Aug. 29, 1997; 72 FR 66408, Nov. 27, 2007; 73 FR 69941, Nov. 19, 2008]

§ 485.638 Conditions of participation: Clinical records.

(a) *Standard: Records system*—(1) The CAH maintains a clinical records system in accordance with written policies and procedures.

(2) The records are legible, complete, accurately documented, readily accessible, and systematically organized.

(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

(4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable—

(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

(ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment; and

(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.

(b) *Standard: Protection of record information*—(1) The CAH maintains the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.

(2) Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information.

(3) The patient's written consent is required for release of information not required by law.

(c) *Standard: Retention of records.* The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending proceeding.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.639 Condition of participation: Surgical services.

Surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.

(a) *Designation of qualified practitioners.* The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by—

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(2) A doctor of dental surgery or dental medicine; or

(3) A doctor of podiatric medicine.

(b) *Anesthetic risk and evaluation.* (1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

(2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section.

(c) *Administration of anesthesia.* The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope-of-practice laws.

(1) Anesthesia must be administered by only—

(i) A qualified anesthesiologist;

(ii) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(iii) A doctor of dental surgery or dental medicine;

(iv) A doctor of podiatric medicine;

(v) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter;

(vi) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter; or

(vii) A supervised trainee in an approved educational program, as described in §§ 413.85 or 413.86 of this chapter.

(2) In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

(d) *Discharge.* All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

(e) *Standard: State exemption*. (1) A CAH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (c)(2) of this section, if the State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[60 FR 45851, Sept. 1, 1995, as amended at 62 FR 46037, Aug. 29, 1997; 66 FR 39938, Aug. 1, 2001; 66 FR 56769, Nov. 13, 2001]

§ 485.641 Condition of participation: Periodic evaluation and quality assurance review.

(a) *Standard: Periodic evaluation*—(1) The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of—

(i) The utilization of CAH services, including at least the number of patients served and the volume of services;

(ii) A representative sample of both active and closed clinical records; and

(iii) The CAH's health care policies.

(2) The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.

(b) *Standard: Quality assurance*. The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that—

(1) All patient care services and other services affecting patient health and safety, are evaluated;

(2) Nosocomial infections and medication therapy are evaluated;

(3) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH;

(4) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by—

(i) One hospital that is a member of the network, when applicable;

(ii) One QIO or equivalent entity; or

(iii) One other appropriate and qualified entity identified in the State rural health care plan; and

(5)(i) The CAH staff considers the findings of the evaluations, including any findings or recommendations of the QIO, and takes corrective action if necessary.

(ii) The CAH also takes appropriate remedial action to address deficiencies found through the quality assurance program.

(iii) The CAH documents the outcome of all remedial action.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 63 FR 26359, May 12, 1998]

§ 485.643 Condition of participation: Organ, tissue, and eye procurement.

The CAH must have and implement written protocols that:

(a) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the CAH. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye

banks identified by the CAH for this purpose;

(b) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

(c) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its option to either donate or not donate organs, tissues, or eyes. The individual designated by the CAH to initiate the request to the family must be a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

(d) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

(e) Ensure that the CAH works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

(f) For purposes of these standards, the term ''organ'' means a human kidney, liver, heart, lung, pancreas, or intestines (or multivisceral organs).

[65 FR 47110, Aug. 1, 2000, as amended at 66 FR 39938, Aug. 1, 2001]

§ 485.645 Special requirements for CAH providers of long-term care services (“swing-beds”)

A CAH must meet the following requirements in order to be granted an approval from CMS to provided post-hospital SNF care, as specified in § 409.30 of this chapter, and to be paid for SNF-level services, in accordance with paragraph (c) of this section.

(a) *Eligibility*. A CAH must meet the following eligibility requirements:

(1) The facility has been certified as a CAH by CMS under § 485.606(b) of this subpart; and

(2) The facility provides not more than 25 inpatient beds. Any bed of a unit of the facility that is licensed as a distinct-part SNF at the time the facility applies to the State for designation as a CAH is not counted under paragraph (a) of this section.

(b) *Facilities participating as rural primary care hospitals (RPCHs) on September 30, 1997*. These facilities must meet the following requirements:

(1) Notwithstanding paragraph (a) of this section, a CAH that participated in Medicare as a RPCH on September 30, 1997, and on that date had in effect an approval from CMS to use its inpatient facilities to provide post-hospital SNF care may continue in that status under the same terms, conditions and limitations that were applicable at the time those approvals were granted.

(2) A CAH that was granted swing-bed approval under paragraph (b)(1) of this section may request that its application to be a CAH and swing-bed provider be reevaluated under paragraph (a) of this section. If this request is approved, the approval is effective not earlier than October 1, 1997. As of the date of approval, the CAH no longer has any status under paragraph (b)(1) of this section and may not request reinstatement under paragraph (b)(1) of this section.

(c) *Payment*. Payment for inpatient RPCH services to a CAH that has qualified as a CAH under the provisions in paragraph (a) of this section is made in accordance with § 413.70 of this chapter. Payment for post-hospital SNF-level of care services is made in accordance with the payment provisions in § 413.114 of this chapter.

(d) *SNF services*. The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:

(1) Residents rights (§ 483.10(b)(3) through (b)(6), (d) (e), (h), (i), (j)(1)(vii) and (viii), (l), and (m) of this chapter).

(2) Admission, transfer, and discharge rights (§ 483.12(a) of this chapter).

(3) Resident behavior and facility practices (§ 483.13 of this chapter).

(4) Patient activities (§ 483.15(f) of this chapter), except that the services

may be directed either by a qualified professional meeting the requirements of § 485.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

(5) Social services (§ 483.15(g) of this chapter).

(6) Comprehensive assessment, comprehensive care plan, and discharge planning (§ 483.20(b), (k), and (l) of this chapter, except that the CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under § 483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in § 413.343(b) of this chapter).

(7) Specialized rehabilitative services (§ 483.45 of this chapter).

(8) Dental services (§ 483.55 of this chapter).

(9) Nutrition (§ 483.25(i) of this chapter).

[63 FR 26359, May 12, 1998 as amended at 64 FR 41544, July 30, 1999; 67 FR 50120, Aug. 1, 2002; 69 FR 49272, Aug. 11, 2004]

§ 485.647 Condition of participation: psychiatric and rehabilitation distinct part units.

(a) *Conditions.* (1) If a CAH provides inpatient psychiatric services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482 of this subchapter, the common requirements of § 412.25(a)(2) through (f) of Part 412 of this chapter for hospital units excluded from the prospective payment systems, and the additional requirements of § 412.27 of Part 412 of this chapter for excluded psychiatric units.

(2) If a CAH provides inpatient rehabilitation services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482 of this subchapter, the common requirements of § 412.25(a)(2) through (f) of Part 412 of this chapter for hospital units excluded from the prospective payments systems, and the additional requirements of §§ 412.29 and § 412.30 of Part 412 of this chapter related specifically to rehabilitation units.

(b) *Eligibility requirements.* (1) To be eligible to receive Medicare payments for psychiatric or rehabilitation services as a distinct part unit, the facility provides no more than 10 beds in the distinct part unit.

(2) The beds in the distinct part are excluded from the 25 inpatient-bed count limit specified in § 485.620(a).

(3) The average annual 96-hour length of stay requirement specified under § 485.620(b) does not apply to the 10 beds in the distinct part units specified in paragraph (b)(1) of this section, and admissions and days of inpatient care in the distinct part units are not taken into account in determining the CAH's compliance with the limits on the number of beds and length of stay in § 485.620.

[69 FR 49272, Aug. 11, 2004]

Subpart G [Reserved]

Subpart H—Conditions of Participation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services

§ 485.701 Basis and scope.

This subpart implements section 1861(p)(4) of the Act, which—

(a) Defines outpatient physical therapy and speech pathology services;

(b) Imposes requirements with respect to adequate program, facilities, policies, staffing, and clinical records; and

(c) Authorizes the Secretary to establish by regulation other health and safety requirements.

[60 FR 2327, Jan. 9, 1995]

§ 485.703 Definitions.

Clinic. A facility that is established primarily to furnish outpatient physician services and that meets the following tests of physician involvement:

(1) The medical services are furnished by a group of three or more physicians practicing medicine together.

(2) A physician is present during all hours of operation of the clinic to furnish medical services, as distinguished from purely administrative services.

Extension location. A location or site from which a rehabilitation agency provides services within a portion of the total geographic area served by the primary site. The extension location is part of the rehabilitation agency. The extension location should be located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the extension location to independently meet the conditions of participation as a rehabilitation agency.

Organization. A clinic, rehabilitation agency, or public health agency.

Public health agency. An official agency established by a State or local government, the primary function of which is to maintain the health of the population served by performing environmental health services, preventive medical services, and in certain cases, therapeutic services.

Rehabilitation agency. An agency that—

(1) Provides an integrated interdisciplinary rehabilitation program designed to upgrade the physical functioning of handicapped disabled individuals by bringing specialized rehabilitation staff together to perform as a team; and

(2) Provides at least physical therapy or speech-language pathology services.

Supervision. Authoritative procedural guidance that is for the accomplishment of a function or activity and that—

(1) Includes initial direction and periodic observation of the actual performance of the function or activity; and

(2) Is furnished by a qualified person—

(i) Whose sphere of competence encompasses the particular function or activity; and

(ii) Who (unless otherwise provided in this subpart) is on the premises if the person performing the function or activity does not meet the assistant-level practitioner qualifications specified in § 485.705.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988; 54 FR 38679, Sept. 20, 1989. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995; 73 FR 69941, Nov. 19, 2008]

§ 485.705 Personnel qualifications.

(a) *General qualification requirements.* Except as specified in paragraphs (b) and (c) of this section, all personnel who are involved in the furnishing of outpatient physical therapy, occupational therapy, and speech-language pathology services directly by or under arrangements with an organization must be legally authorized (licensed or, if applicable, certified or registered) to practice by the State in which they perform the functions or actions, and must act only within the scope of their State license or State certification or registration.

(b) *Exception for Federally defined qualifications.* The following Federally defined qualifications must be met:

(1) For a physician, the qualifications and conditions as defined in section 1861(r) of the Act and the requirements in part 484 of this chapter.

(2) *For a speech-language pathologist,* the qualifications specified in section 1861(11)(1) of the Act and the requirements in part 484 of this chapter.

(c) *Exceptions when no State Licensing laws or State certification or registration requirements exist.* If no State licensing laws or State certification or registration requirements exist for the profession, the following requirements must be met—

(1) An *administrator* is a person who has a bachelor's degree and:

(i) Has experience or specialized training in the administration of health institutions or agencies; or

(ii) Is qualified and has experience in one of the professional health disciplines.

(2) An *occupational therapist* must meet the requirements in part 484 of this chapter.

(3) *An occupational therapy assistant* must meet the requirements in part 484 of this chapter.

(4) A *physical therapist* must meet the requirements in part 484 of this chapter.

(5) A *physical therapist assistant* must meet the requirements in part 484 of this chapter.

(6) A *social worker* must meet the requirements in part 484 of this chapter.

(7) A *vocational specialist* is a person who has a baccalaureate degree and—

(i) Two years experience in vocational counseling in a rehabilitation setting such as a sheltered workshop, State employment service agency, etc.; or

(ii) At least 18 semester hours in vocational rehabilitation, educational or vocational guidance, psychology, social work, special education or personnel administration, and 1 year of experience in vocational counseling in a rehabilitation setting; or

(iii) A master's degree in vocational counseling.

(8) A nurse practitioner is a person who must:

(i) Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law; *and*

(ii) Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners; *or*

(iii) Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law and have been granted a Medicare billing number as a nurse practitioner by December 31, 2000; *or*

(iv) Be a nurse practitioner who on or after January 1, 2001, applies for a Medicare billing number for the first time and meets the standards for nurse practitioners in paragraphs (c)(8)(i) and (c)(8)(ii) of this section; *or*

(v) Be a nurse practitioner who on or after January 1, 2003, applies for a Medicare billing number for the first time and possesses a master's degree in nursing and meets the standards for nurse practitioners in paragraphs (b)(1)(i) and (b)(1)(ii) of this section.

(9) *A clinical nurse specialist* is a person who must:

(i) Be a registered nurse who is currently licensed to practice in the State where he or she practices and be authorized to perform the services of a clinical nurse specialist in accordance with State law;

(ii) Have a master's degree in a defined clinical area of nursing from an accredited educational institution; and,

(iii) Be certified as a clinical nurse specialist by the American Nurses Credentialing Center.

(10) *A physician assistant* is a person who:

(i) Has graduated from a physician assistant educational program that is accredited by the Commission on Accreditation of Allied Health Education Programs; or

(ii) Has passed the national certification examination that is administered by the National Commission on Certification of Physician Assistants; and

(iii) Is licensed by the State to practice as a physician assistant.

[63 FR 58912, Nov. 2, 1998; 64 FR 25457, May 12, 1999; 64 FR 59442, Nov. 2, 1999]

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

The organization and its staff are in compliance with all applicable Federal, State, and local laws and regulations.

(a) *Standard: Licensure of organization.* In any State in which State or applicable local law provides for the licensing of organizations, a clinic, rehabilitation agency, or public health agency is licensed in accordance with applicable laws.

(b) *Standard: Licensure or registration of personnel.* Staff of the organization are licensed or registered in accordance with applicable laws.

[41 FR 20865, May 21, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995]

§ 485.709 Condition of participation: Administrative management.

The clinic or rehabilitation agency has an effective governing body that is legally responsible for the conduct of the clinic or rehabilitation agency. The

governing body designates an administrator, and establishes administrative policies.

(a) *Standard: Governing body*. There is a governing body (or designated person(s) so functioning) which assumes full legal responsibility for the overall conduct of the clinic or rehabilitation agency and for compliance with applicable laws and regulations. The name of the owner(s) of the clinic or rehabilitation agency is fully disclosed to the State agency. In the case of corporations, the names of the corporate officers are made known.

(b) *Standard: Administrator*. The governing body—

(1) Appoints a qualified full-time administrator;

(2) Delegates to the administrator the internal operation of the clinic or rehabilitation agency in accordance with written policies;

(3) Defines clearly the administrator's responsibilities for procurement and direction of personnel; and

(4) Designates a competent individual to act during temporary absence of the administrator.

(c) *Standard: Personnel policies*. Personnel practices are supported by appropriate written personnel policies that are kept current. Personnel records include the qualifications of all professional and assistant level personnel, as well as evidence of State licensure if applicable.

(d) *Standard: Patient care policies*. Patient care practices and procedures are supported by written policies established by a group of professional personnel including one or more physicians associated with the clinic or rehabilitation agency, one or more qualified physical therapists (if physical therapy services are provided), and one or more qualified speech pathologists (if speech pathology services are provided). The policies govern the outpatient physical therapy and/or speech pathology services and related services that are provided. These policies are evaluated at least annually by the group of professional personnel, and revised as necessary based upon this evaluation.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.711 Condition of participation: Plan of care and physician involvement.

For each patient in need of outpatient physical therapy or speech pathology services, there is a written plan of care established and periodically reviewed by a physician, or by a physical therapist or speech pathologist respectively.

(a) *Standard: Medical history and prior treatment*. The following are obtained by the organization before or at the time of initiation of treatment:

(1) The patient's significant past history.

(2) Current medical findings, if any.

(3) Diagnosis(es), if established.

(4) Physician's orders, if any.

(5) Rehabilitation goals, if determined.

(6) Contraindications, if any.

(7) The extent to which the patient is aware of the diagnosis(es) and prognosis.

(8) If appropriate, the summary of treatment furnished and results achieved during previous periods of rehabilitation services or institutionalization.

(b) *Standard: Plan of care*. (1) For each patient there is a written plan of care established by the physician or by the physical therapist or speech-language pathologist who furnishes the services.

(2) The plan of care for physical therapy or speech pathology services indicates anticipated goals and specifies for those services the—

(i) Type;

(ii) Amount;

(iii) Frequency; and

(iv) Duration.

(3) The plan of care and results of treatment are reviewed by the physician or by the individual who established the plan at least as often as the patient's condition requires, and the indicated action is taken.

(4) Changes in the plan of care are noted in the clinical record. If the patient has an attending physician, the therapist or speech-language pathologist who furnishes the services promptly notifies him or her of any change in the patient's condition or in the plan of care.

(c) *Standard: Emergency care.* The rehabilitation agency must establish procedures to be followed by personnel in an emergency, which cover immediate care of the patient, persons to be notified, and reports to be prepared.

[54 FR 38679, Sept. 20, 1989. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 63 FR 58913, Nov. 2, 1998; 73 FR 69941, Nov. 19, 2008]

§485.713 Condition of participation: Physical therapy services.

If the organization offers physical therapy services, it provides an adequate program of physical therapy and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

(a) *Standard: Adequate program.* (1) The organization is considered to have an adequate outpatient physical therapy program if it can:

(i) Provide services using therapeutic exercise and the modalities of heat, cold, water, and electricity;

(ii) Conduct patient evaluations; and

(iii) Administer tests and measurements of strength, balance, endurance, range of motion, and activities of daily living.

(2) A qualified physical therapist is present or readily available to offer supervision when a physical therapist assistant furnishes services.

(i) If a qualified physical therapist is not on the premises during all hours of operation, patients are scheduled so as to ensure that the therapist is present when special skills are needed, for example, for evaluation and reevaluation.

(ii) When a physical therapist assistant furnishes services off the organization's premises, those services are supervised by a qualified physical therapist who makes an onsite supervisory visit at least once every 30 days.

(b) *Standard: Facilities and equipment.* The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of disabilities it accepts for service.

(c) *Standard: Personnel qualified to provide physical therapy services.* Physical therapy services are provided by, or under the supervision of, a qualified physical therapist. The number of qualified physical therapists and qualified physical therapist assistants is adequate for the volume and diversity of physical therapy services offered. A qualified physical therapist is on the premises or readily available during the operating hours of the organization.

(d) *Standard: Supportive personnel.* If personnel are available to assist qualified physical therapists by performing services incident to physical therapy that do not require professional knowledge and skill, these personnel are instructed in appropriate patient care services by qualified physical therapists who retain responsibility for the treatment prescribed by the attending physician.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§485.715 Condition of participation: Speech pathology services.

If speech pathology services are offered, the organization provides an adequate program of speech pathology and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

(a) *Standard: Adequate program.* The organization is considered to have an adequate outpatient speech pathology program if it can provide the diagnostic and treatment services to effectively treat speech disorders.

(b) *Standard: Facilities and equipment.* The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of speech disorders it accepts for service.

(c) *Standard: Personnel qualified to provide speech pathology services.* Speech pathology services are given or supervised by a qualified speech pathologist and the number of qualified speech pathologists is adequate for the volume

and diversity of speech pathology services offered. At least one qualified speech pathologist is present at all times when speech pathology services are furnished.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326–2328, Jan. 9, 1995]

§ 485.717 Condition of participation: Rehabilitation program.

This condition and standards apply only to a rehabilitation agency's own patients, not to patients of hospitals, skilled nursing facilities (SNFs), or Medicaid nursing facilities (NFs) to which the agency furnishes services. The hospital, SNF, or NF is responsible for ensuring that qualified staff furnish services for which they arrange or contract for their patients. The rehabilitation agency provides physical therapy and speech-language pathology services to all of its patients who need them.

(a) *Standard: Qualification of staff.* The agency's therapy services are furnished by qualified individuals as direct services and/or services provided under contract.

(b) *Standard: Arrangements for services.* If services are provided under contract, the contract must specify the term of the contract, the manner of termination or renewal and provide that the agency retains responsibility for the control and supervision of the services.

[73 FR 69942, Nov. 19, 2008]

§ 485.719 Condition of participation: Arrangements for physical therapy and speech pathology services to be performed by other than salaried organization personnel.

(a) *Conditions.* If an organization provides outpatient physical therapy or speech pathology services under an arrangement with others, the services are to be furnished in accordance with the terms of a written contract, which provides that the organization retains of professional and administrative responsibility for, and control and supervision of, the services.

(b) *Standard: Contract provisions.* The contract—

(1) Specifies the term of the contract and the manner of termination or renewal;

(2) Requires that personnel who furnish the services meet the requirements that are set forth in this subpart for salaried personnel; and

(3) Provides that the contracting outside resource may not bill the patient or Medicare for the services. This limitation is based on section 1861(w)(1) of the Act, which provides that—

(i) Only the provider may bill the beneficiary for covered services furnished under arrangements; and

(ii) Receipt of Medicare payment by the provider, on behalf of an entitled individual, discharges the liability of the individual or any other person to pay for those services.

[56 FR 46562, Sept. 13, 1991. Redesignated and amended at 60 FR 2326, 2328, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.721 Condition of participation: Clinical records.

The organization maintains clinical records on all patients in accordance with accepted professional standards, and practices. The clinical records are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.

(a) *Standard: Protection of clinical record information.* The organization recognizes the confidentiality of clinical record information and provides safeguards against loss, destruction, or unauthorized use. Written procedures govern the use and removal of records and the conditions for release of information. The patient's written consent is required for release of information not authorized by law.

(b) *Standard: Content.* The clinical record contains sufficient information to identify the patient clearly, to justify the diagnosis(es) and treatment, and to document the results accurately. All clinical records contain the following general categories of data:

(1) Documented evidence of the assessment of the needs of the patient, of an appropriate plan of care, and of the care and services furnished.

(2) Identification data and consent forms.

(3) Medical history.

(4) Report of physical examinations, if any.

(5) Observations and progress notes.

(6) Reports of treatments and clinical findings.

(7) Discharge summary including final diagnosis(es) and prognosis.

(c) *Standard: Completion of records and centralization of reports.* Current clinical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's clinical record. Each physician signs the entries that he or she makes in the clinical record.

(d) *Standard: Retention and preservation.* Clinical records are retained for at least:

(1) The period determined by the respective State statute, or the statute of limitations in the State; or

(2) In the absence of a State statute—

(i) Five years after the date of discharge; or

(ii) In the case of a minor, 3 years after the patient becomes of age under State law or 5 years after the date of discharge, whichever is longer.

(e) *Standard: Indexes.* Clinical records are indexed at least according to name of patient to facilitate acquisition of statistical medical information and retrieval of records for research or administrative action.

(f) *Standard: Location and facilities.* The organization maintains adequate facilities and equipment, conveniently located, to provide efficient processing of clinical records (reviewing, indexing, filing, and prompt retrieval).

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326–2328, Jan. 9, 1995]

§ 485.723 Condition of participation: Physical environment.

The building housing the organization is constructed, equipped, and maintained to protect the health and safety of patients, personnel, and the public and provides a functional, sanitary, and comfortable environment.

(a) *Standard: Safety of patients.* The organization satisfies the following requirements:

(1) It complies with all applicable State and local building, fire, and safety codes.

(2) Permanently attached automatic fire-extinguishing systems of adequate capacity are installed in all areas of the premises considered to have special fire hazards. Fire extinguishers are conveniently located on each floor of the premises. Fire regulations are prominently posted.

(3) Doorways, passageways and stairwells negotiated by patients are:

(i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs), (ii) free from obstruction at all times, and (iii) in the case of stairwells, equipped with firmly attached handrails on at least one side.

(4) Lights are placed at exits and in corridors used by patients and are supported by an emergency power source.

(5) A fire alarm system with local alarm capability and, where applicable, an emergency power source, is functional.

(6) At least two persons are on duty on the premises of the organization whenever a patient is being treated.

(7) No occupancies or activities undesirable or injurious to the health and safety of patients are located in the building.

(b) *Standard: Maintenance of equipment, building, and grounds.* The organization establishes a written preventive-maintenance program to ensure that—

(1) The equipment is operative, and is properly calibrated; and

(2) The interior and exterior of the building are clean and orderly and maintained free of any defects that are a potential hazard to patients, personnel, and the public.

(c) *Standard: Other environmental considerations.* The organization provides a functional, sanitary, and comfortable environment for patients, personnel, and the public.

(1) Provision is made for adequate and comfortable lighting levels in all areas; limitation of sounds at comfort levels; a comfortable room temperature; and adequate ventilation through windows, mechanical means, or a combination of both.

(2) Toilet rooms, toilet stalls, and lavatories are accessible and constructed so as to allow use by nonambulatory and semiambulatory individuals.

(3) Whatever the size of the building, there is an adequate amount of space

for the services provided and disabilities treated, including reception area, staff space, examining room, treatment areas, and storage.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326–2328, Jan. 9, 1995]

§ 485.725 Condition of participation: Infection control.

The organization that provides outpatient physical therapy services establishes an infection-control committee of representative professional staff with responsibility for overall infection control. All necessary housekeeping and maintenance services are provided to maintain a sanitary and comfortable environment and to help prevent the development and transmission of infection.

(a) *Standard: Infection-control committee.* The infection-control committee establishes policies and procedures for investigating, controlling, and preventing infections in the organization and monitors staff performance to ensure that the policies and procedures are executed.

(b) All personnel follow written procedures for effective aseptic techniques. The procedures are reviewed annually and revised if necessary to improve them.

(c) *Standard: Housekeeping.* (1) The organization employs sufficient housekeeping personnel and provides all necessary equipment to maintain a safe, clean, and orderly interior. A full-time employee is designated as the one responsible for the housekeeping services and for supervision and training of housekeeping personnel.

(2) An organization that has a contract with an outside resource for housekeeping services may be found to be in compliance with this standard provided the organization or outside resource or both meet the requirements of the standard.

(d) *Standard: Linen.* The organization has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

(e) *Standard: Pest control.* The organization's premises are maintained free from insects and rodents through operation of a pest-control program.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2328, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.727 Condition of participation: Disaster preparedness.

The organization has a written plan, periodically rehearsed, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from a disaster.

(a) *Standard: Disaster plan.* The organization has a written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster. The plan is developed and maintained with the assistance of qualified fire, safety, and other appropriate experts, and includes:

(1) Transfer of casualties and records;

(2) The location and use of alarm systems and signals;

(3) Methods of containing fire;

(4) Notification of appropriate persons; and

(5) Evacuation routes and procedures.

(b) *Standard: Staff training and drills.* All employees are trained, as part of their employment orientation, in all aspects of preparedness for any disaster. The disaster program includes orientation and ongoing training and drills for all personnel in all procedures so that each employee promptly and correctly carries out his assigned role in case of a disaster.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988. Redesignated and amended at 60 FR 2326–2327, 2329, Jan. 9, 1995]

§ 485.729 Condition of participation: Program evaluation.

The organization has procedures that provide for a systematic evaluation of its total program to ensure appropriate utilization of services and to determine whether the organization's policies are followed in providing services to patients through employees or under arrangements with others.

(a) *Standard: Clinical-record review.* A sample of active and closed clinical records is reviewed quarterly by the

appropriate health professionals to ensure that established policies are followed in providing services.

(b) *Standard: Annual statistical evaluation.* An evaluation is conducted annually of statistical data such as number of different patients treated, number of patient visits, condition on admission and discharge, number of new patients, number of patients by diagnosis(es), sources of referral, number and cost of units of service by treatment given, and total staff days or work hours by discipline.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326–2327, 2329, Jan. 9, 1995]

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

Subpart A—General Provisions

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Subpart C—Conditions for Coverage: Portable X-Ray Services

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REQUIREMENTS FOR CERTIFICATION AND DESIGNATION

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ORGAN PROCUREMENT ORGANIZATION PROCESS PERFORMANCE MEASURES

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AUTHORITY: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b-8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C 273).

Subpart A—General Provisions

§486.1 Basis and scope.

(a) *Statutory basis.* This part is based on the following sections of the Act:

1102 and 1138(b), 1871 of the Social Security Act, section 371(b) of the Public Health Service Act—for coverage of organ procurement services.

1861(p)—for coverage of outpatient physical therapy services furnished by physical therapists in independent practice.

1861(s) (3), (15), and (17)—for coverage of portable X-ray services.

(b) *Scope.* (1) This part sets forth the conditions for coverage of certain specialized services that are furnished by

suppliers and that are not specified in other portions of this chapter.

(2) The conditions for coverage of other specialized services furnished by suppliers are set forth in the following regulations which, unless otherwise indicated, are part of this chapter:

(i) Ambulatory surgical center (ASC) services—Part 416.

(ii) Ambulance services—Part 410, subpart B.

(iii) ESRD services—Part 405, subpart U.

(iv) Laboratory services—Part 493.

(v) Mammography services—Part 410, subpart B (§ 410.34) and 21 CFR Part 900, subpart B, of the Food and Drug Administration regulations.

(vi) Rural health clinic and Federally qualified health center services—Part 491, subpart A.

[60 FR 50447, Sept. 29, 1995, as amended at 71 FR 31046, May 31, 2006]

Subpart B [Reserved]

Subpart C—Conditions for Coverage: Portable X-Ray Services

AUTHORITY: Secs. 1102, 1861(s) (3), (11) and (12), 1864, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x(s) (3), (11), and (12), 1395aa and 1395hh).

SOURCE: 34 FR 388, Jan. 10, 1969, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977, and further redesignated and amended at 60 FR 2326, Jan. 9, 1995.

§ 486.100 Condition for coverage: Compliance with Federal, State, and local laws and regulations.

The supplier of portable X-ray services is in conformity with all applicable Federal, State, and local laws and regulations.

(a) *Standard—licensure or registration of supplier.* In any State in which State or applicable local law provides for the licensure or registration of suppliers of X-ray services, the supplier is (1) licensed or registered pursuant to such law, or (2) approved by the agency of the State or locality responsible for licensure or registration as meeting the standards established for such licensure or registration.

(b) *Standard—licensure or registration of personnel.* All personnel engaged in operating portable X-ray equipment are currently licensed or registered in accordance with all applicable State and local laws.

(c) *Standard—licensure or registration of equipment.* All portable X-ray equipment used in providing portable X-ray services is licensed or registered in accordance with all applicable State and local laws.

(d) *Standard—conformity with other Federal, State, and local laws and regulations.* The supplier of portable X-ray services agrees to render such services in conformity with Federal, State, and local laws relating to safety standards.

[34 FR 388, Jan. 10, 1969. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995; 60 FR 45086, Aug. 30, 1995]

§ 486.102 Condition for coverage: Supervision by a qualified physician.

Portable X-ray services are provided under the supervision of a qualified physician.

(a) *Standard—physician supervision.* The performance of the roentgenologic procedures is subject to the supervision of a physician who meets the requirements of paragraph (b) of this section and one of the following requirements is met:

(1) The supervising physician owns the equipment and it is operated only by his employees, or

(2) The supervising physician certifies annually that he periodically checks the procedural manuals and observes the operators' performance, that he has verified that equipment and personnel meet applicable Federal, State, and local licensure and registration requirements and that safe operating procedures are used.

(b) *Standard—qualifications of the physician supervisor.* Portable X-ray services are provided under the supervision of a licensed doctor of medicine or licensed doctor of osteopathy who is qualified by advanced training and experience in the use of X-rays for diagnostic purposes, i.e., he (1) is certified in radiology by the American Board of Radiology or by the American Osteopathic Board of Radiology or possesses qualifications which are equivalent to those required for such certification, or

(2) is certified or meets the requirements for certification in a medical specialty in which he has become qualified by experience and training in the use of X-rays for diagnostic purposes, or (3) specializes in radiology and is recognized by the medical community as a specialist in radiology.

[34 FR 388, Jan. 10, 1969. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995; 60 FR 45086, Aug. 30, 1995]

§ 486.104 Condition for coverage: Qualifications, orientation and health of technical personnel.

Portable X-ray services are provided by qualified technologists.

(a) *Standard-qualifications of technologists.* All operators of the portable X-ray equipment meet the requirements of paragraphs (a)(1), (2), (3), or (4) of this section:

(1) Successful completion of a program of formal training in X-ray technology in a school approved by the Joint Review Committee on Education in Radiologic Technology (JRCERT), or have earned a bachelor's or associate degree in radiologic technology from an accredited college or university.

(2) For those whose training was completed prior to July 1, 1966, but on or after July 1, 1960: Successful completion of 24 full months of training and/or experience under the direct supervision of a physician who is certified in radiology by the American College of Radiology or who possesses qualifications which are equivalent to those required for such certification, and at least 12 full months of pertinent portable X-ray equipment operation experience in the 5 years prior to January 1, 1968.

(3) For those whose training was completed prior to July 1, 1960: Successful completion of 24 full months of training and/or experience of which at least 12 full months were under the direct supervision of a physician who is certified in radiology by the American College of Radiology or who possesses qualifications which are equivalent to those required for such certification, and at least 12 full months of pertinent portable X-ray equipment operation experience in the 5 years prior to January 1, 1968.

(4) For those whose training was completed prior to January 1, 1993, successful completion of a program of formal training in X-ray technology in a school approved by the Council on Education of the American Medical Association, or by the American Osteopathic Association is acceptable.

(b) *Standard—personnel orientation.* The supplier of portable X-ray services has an orientation program for personnel, based on a procedural manual which is: Available to all members of the staff, incorporates relevant portions of professionally recognized documents, and includes instruction in all of the following:

(1) Precautions to be followed to protect the patient from unnecessary exposure to radiation;

(2) Precautions to be followed to protect an individual supporting the patient during X-ray procedures from unnecessary exposure to radiation;

(3) Precautions to be followed to protect other individuals in the surrounding environment from exposure to radiation;

(4) Precautions to be followed to protect the operator of portable X-ray equipment from unnecessary exposure to radiation;

(5) Considerations in determining the area which will receive the primary beam;

(6) Determination of the time interval at which to check personnel radiation monitors;

(7) Use of the personnel radiation monitor in providing an additional check on safety of equipment;

(8) Proper use and maintenance of equipment;

(9) Proper maintenance of records;

(10) Technical problems which may arise and methods of solution;

(11) Protection against electrical hazards;

(12) Hazards of excessive exposure to radiation.

(c) *Standard: Employee records.* Records are maintained and include evidence that—

(1) Each employee is qualified for his or her position by means of training and experience; and

(2) Employees receive adequate health supervision.

[34 FR 388, Jan. 10, 1969. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988; 60 FR 45086, Aug. 30, 1995; 73 FR 69942, Nov. 19, 2008]

§ 486.106 Condition for coverage: Referral for service and preservation of records.

All portable X-ray services performed for Medicare beneficiaries are ordered by a doctor of medicine or doctor of osteopathy and records are properly preserved.

(a) *Standard—referral by a physician.* Portable X-ray examinations are performed only on the order of a doctor of medicine or doctor of osteopathy licensed to practice in the State. The supplier's records show that:

(1) The X-ray test was ordered by a licensed doctor of medicine or doctor of osteopathy, and

(2) Such physician's written, signed order specifies the reason an X-ray test is required, the area of the body to be exposed, the number of radiographs to be obtained, and the views needed; it also includes a statement concerning the condition of the patient which indicates why portable X-ray services are necessary.

(b) *Standard—records of examinations performed.* The supplier makes for each patient a record of the date of the X-ray examination, the name of the patient, a description of the procedures ordered and performed, the referring physician, the operator(s) of the portable X-ray equipment who performed the examination, the physician to whom the radiograph was sent, and the date it was sent.

(c) *Standard—preservation of records.* Such reports are maintained for a period of at least 2 years, or for the period of time required by State law for such records (as distinguished from requirements as to the radiograph itself), whichever is longer.

[34 FR 388, Jan. 10, 1969. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995; 60 FR 45086, Aug. 30, 1995]

§ 486.108 Condition for coverage: Safety standards.

X-ray examinations are conducted through the use of equipment which is free of unnecessary hazards for patients, personnel, and other persons in the immediate environment, and through operating procedures which provide minimum radiation exposure to patients, personnel, and other persons in the immediate environment.

(a) *Standard—tube housing and devices to restrict the useful beam.* The tube housing is of diagnostic type. Diaphragms, cones, or adjustable collimators capable of restricting the useful beam to the area of clinical interest are used and provide the same degree of protection as is required of the housing.

(b) *Standard—total filtration.* (1) The aluminum equivalent of the total filtration in the primary beam is not less than that shown in the following table except when contraindicated for a particular diagnostic procedure.

Operating kVp	Total filtration (inherent plus added)
Below 50 kVp	0.5 millimeters aluminum.
50–70 kVp	1.5 millimeters aluminum.
Above 70 kVp	2.5 millimeters aluminum.

(2) If the filter in the machine is not accessible for examination or the total filtration is unknown, it can be assumed that the requirements are met if the half-value layer is not less than that shown in the following table:

Operating kVp	Half-value layer
50 kVp	0.6 millimeters aluminum.
70 kVp	1.6 millimeters aluminum.
90 kVp	2.6 millimeters aluminum.
100 kVp	2.8 millimeters aluminum.
110 kVp	3.0 millimeters aluminum.
120 kVp	3.3 millimeters aluminum.

(c) *Standard—termination of exposure.* A device is provided to terminate the exposure after a preset time or exposure.

(d) *Standard—control panel.* The control panel provides a device (usually a milliammeter or a means for an audible signal to give positive indication of the production of X-rays whenever the X-ray tube is energized. The control panel includes appropriate indicators (labelled control settings and/or meters) which show the physical factors

(such as kVp, mA, exposure time or whether timing is automatic) used for the exposure.

(e) *Standard—exposure control switch.* The exposure control switch is of the dead-man type and is so arranged that the operator can stand at least 6 feet from the patient and well away from the useful beam.

(f) *Standard—protection against electrical hazards.* Only shockproof equipment is used. All electrical equipment is grounded.

(g) *Standard—mechanical supporting or restraining devices.* Mechanical supporting or restraining devices are provided so that such devices can be used when a patient must be held in position for radiography.

(h) *Standard—protective gloves and aprons.* Protective gloves and aprons are provided so that when the patient must be held by an individual, that individual is protected with these shielding devices.

(i) *Standard—restriction of the useful beam.* Diaphragms, cones, or adjustable collimators are used to restrict the useful beam to the area of clinical interest.

(j) *Standard—personnel monitoring.* A device which can be worn to monitor radiation exposure (e.g., a film badge) is provided to each individual who operates portable X-ray equipment. The device is evaluated for radiation exposure to the operator at least monthly and appropriate records are maintained by the supplier of portable X-ray services of radiation exposure measured by such a device for each individual.

(k) *Standard—personnel and public protection.* No individual occupationally exposed to radiation is permitted to hold patients during exposures except during emergencies, nor is any other individual regularly used for this service. Care is taken to assure that pregnant women do not assist in portable X-ray examinations.

[34 FR 388, Jan. 10, 1969. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995; 60 FR 45086, Aug. 30, 1995]

§486.110 Condition for coverage: Inspection of equipment.

Inspections of all X-ray equipment and shielding are made by qualified individuals at intervals not greater than every 24 months.

(a) *Standard—qualified inspectors.* Inspections are made at least every 24 months by a radiation health specialist who is on the staff of or approved by an appropriate State or local government agency.

(b) *Standard—records of inspection and scope of inspection.* The supplier maintains records of current inspections which include the extent to which equipment and shielding are in compliance with the safety standards outlined in §486.108.

[34 FR 388, Jan. 10, 1969. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995; 60 FR 45086, Aug. 30, 1995; 60 FR 50447, Sept. 29, 1995]

Subparts D–F [Reserved]

Subpart G—Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations

SOURCE: 71 FR 31046, May 31, 2006, unless otherwise noted.

§486.301 Basis and scope.

(a) *Statutory basis.* (1) Section 1138(b) of the Act sets forth the requirements that an organ procurement organization (OPO) must meet to have its organ procurement services to hospitals covered under Medicare and Medicaid. These include certification as a ''qualified'' OPO and designation as the OPO for a particular service area.

(2) Section 371(b) of the Public Health Service Act sets forth the requirements for certification and the functions that a qualified OPO is expected to perform.

(3) Section 1102 of the Act authorizes the Secretary of Health and Human Services to make and publish rules and regulations necessary to the efficient administration of the functions that are assigned to the Secretary under the Act.

(4) Section 1871 of the Act authorizes the Secretary to prescribe regulations as may be necessary to carry out the administration of the Medicare program under title XVIII.

(b) *Scope.* This subpart sets forth—

(1) The conditions and requirements that an OPO must meet;

(2) The procedures for certification and designation of OPOs; and

(3) The terms of the agreement with CMS and the basis for and the effect of de-certification.

(4) The requirements for an OPO to be re-certified.

§ 486.302 Definitions.

As used in this subpart, the following definitions apply:

Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof. As applied to OPOs, adverse events include but are not limited to transmission of disease from a donor to a recipient, avoidable loss of a medically suitable potential donor for whom consent for donation has been obtained, or delivery to a transplant center of the wrong organ or an organ whose blood type does not match the blood type of the intended recipient.

Agreement cycle refers to the time period of at least 4 years when an agreement is in effect between CMS and an OPO.

Certification means a CMS determination that an OPO meets the requirements for certification at § 486.303.

Death record review means an assessment of the medical chart of a deceased patient to evaluate potential for organ donation.

Decertification means a CMS determination that an OPO no longer meets the requirements for certification at § 486.303.

Designated requestor or effective requestor is an individual (generally employed by a hospital), who is trained to handle or participate in the donation consent process. The designated requestor may request consent for donation from the family of a potential donor or from the individual(s) responsible for making the donation decision in circumstances permitted under State law, provide information about donation to the family or decision-maker(s), or provide support to or collaborate with the OPO in the donation consent process.

Designation means CMS assignment of a geographic service area to an OPO. Once an OPO is certified and assigned a geographic service area, organ procurement costs of the OPO are eligible for Medicare and Medicaid payment under section 1138(b)(1)(F) of the Act.

Donation service area (DSA) means a geographical area of sufficient size to ensure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire metropolitan statistical area or does not include any part of such an area and that meets the standards of this subpart.

Donor means a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is recovered for the purpose of transplantation.

Donor after cardiac death (DCD) means an individual who donates after his or her heart has irreversibly stopped beating. A donor after cardiac death may be termed a non-heartbeating or asystolic donor.

Donor document is any documented indication of an individual's choice in regard to donation that meets the requirements of the governing state law.

Eligible death for organ donation means the death of a patient 70 years old or younger, who ultimately is legally declared brain dead according to hospital policy independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in the case, and independent of local acceptance criteria or transplant center practice, who exhibits none of the following:

(1) Active infections (specific diagnoses).

(i) Bacterial:

(A) Tuberculosis.

(B) Gangrenous bowel or perforated bowel and/or intra-abdominal sepsis.

(ii) Viral:

(A) HIV infection by serologic or molecular detection.

(B) Rabies.

(C) Reactive Hepatitis B Surface Antigen.

(D) Retroviral infections including HTLV I/II.

(E) Viral Encephalitis or Meningitis.

(F) Active Herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia.

(G) Acute Epstein Barr Virus (mononucleosis).

(H) West Nile Virus infection.

(I) Severe acute respiratory syndrome (SARS).

(iii) Fungal:

(A) Active infection with Cryptococcus, Aspergillus, Histoplasma, Coccidioides.

(B) Active candidemia or invasive yeast infection.

(iv) Parasites: active infection with Trypanosoma cruzi (Chagas'), Leishmania, Strongyloides, or Malaria (Plasmodium sp.).

(v) Prion: Creutzfeldt-Jacob Disease.

(2) General:

(i) Aplastic Anemia.

(ii) Agranulocytosis.

(iii) Extreme Immaturity (<500 grams or gestational age of <32 weeks).

(iv) Current malignant neoplasms except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease.

(v) Previous malignant neoplasms with current evident metastatic disease.

(vi) A history of melanoma.

(vii) Hematologic malignancies: Leukemia, Hodgkin's Disease, Lymphoma, Multiple Myeloma.

(viii) Multi-system organ failure (MSOF) due to overwhelming sepsis or MSOF without sepsis defined as 3 or more systems in simultaneous failure for a period of 24 hours or more without response to treatment or resuscitation.

(ix) Active Fungal, Parasitic, viral, or Bacterial Meningitis or encephalitis.

(3) The number of eligible deaths is the denominator for the donation rate outcome performance measure as described at § 486.318(a)(1).

Eligible donor means any donor that meets the eligible death criteria. The number of eligible donors is the numerator of the donation rate outcome performance measure.

Entire metropolitan statistical area means a metropolitan statistical area (MSA), a consolidated metropolitan statistical area (CMSA), or a primary metropolitan statistical area (PMSA) listed in the State and Metropolitan Area Data Book published by the U.S. Bureau of the Census. CMS does not recognize a CMSA as a metropolitan area for the purposes of establishing a geographical area for an OPO.

Expected donation rate means the donation rate expected for an OPO based on the national experience for OPOs serving similar hospitals and donation service areas. This rate is adjusted for the following hospital characteristics: Level I or Level II trauma center, Metropolitan Statistical Area size, MS Case Mix Index, total bed size, number of intensive care unit (ICU) beds, primary service, presence of a neurosurgery unit, and hospital control/ownership.

Observed donation rate is the number of donors meeting the eligibility criteria per 100 deaths.

Open area means an OPO service area for which CMS has notified the public that it is accepting applications for designation.

Organ means a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine).

Organ procurement organization (OPO) means an organization that performs or coordinates the procurement, preservation, and transport of organs and maintains a system for locating prospective recipients for available organs.

Re-certification cycle means the 4-year cycle during which an OPO is certified.

Standard criteria donor (SCD) means a donor that meets the eligibility criteria for an eligible donor and does not meet the criteria to be a donor after cardiac death or expanded criteria donor.

Transplant hospital means a hospital that provides organ transplants and other medical and surgical specialty services required for the care of transplant patients. There may be one or more types of organ transplant centers operating within the same transplant hospital.

Urgent need occurs when an OPO's noncompliance with one or more conditions for coverage has caused, or is likely to cause, serious injury, harm, impairment, or death to a potential or actual donor or an organ recipient.

REQUIREMENTS FOR CERTIFICATION AND DESIGNATION

§ 486.303 Requirements for certification.

In order to be certified as a qualified organ procurement organization, an organ procurement organization must:

(a) Have received a grant under 42 U.S.C. 273(a) or have been certified or re-certified by the Secretary within the previous 4 years as being a qualified OPO.

(b) Be a non-profit entity that is exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1986.

(c) Have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to transplant hospitals.

(d) Have an agreement with CMS, as the Secretary's designated representative, to be reimbursed under title XVIII for the procurement of kidneys.

(e) Have been re-certified as an OPO under the Medicare program from January 1, 2002 through December 31, 2005.

(f) Have procedures to obtain payment for non-renal organs provided to transplant centers.

(g) Agree to enter into an agreement with any hospital or critical access hospital in the OPO's service area, including a transplant hospital that requests an agreement.

(h) Meet the conditions for coverage for organ procurement organizations, which include both outcome and process performance measures.

(i) Meet the provisions of titles XI, XVIII, and XIX of the Act, section 371(b) of the Public Health Services Act, and any other applicable Federal regulations.

§ 486.304 Requirements for designation.

(a) Designation is a condition for payment. Payment may be made under the Medicare and Medicaid programs for organ procurement costs attributable to payments made to an OPO by a hospital only if the OPO has been designated by CMS as an OPO.

(b) An OPO must be certified as a qualified OPO by CMS under 42 U.S.C. 273(b) and § 486.303 to be eligible for designation.

(c) An OPO must enter into an agreement with CMS in order for the organ procurement costs attributable to the OPO to be reimbursed under Medicare and Medicaid.

§ 486.306 OPO service area size designation and documentation requirements.

(a) *General documentation requirement.* An OPO must make available to CMS documentation verifying that the OPO meets the requirements of paragraphs (b) through (d) of this section at the time of application and throughout the period of its designation.

(b) *Service area designation.* The defined service area either includes an entire metropolitan statistical area or a New England county metropolitan statistical area as specified by the Director of the Office of Management and Budget or does not include any part of such an area.

(c) *Service area location and characteristics.* An OPO must define and document a proposed service area's location through the following information:

(1) The names of counties (or parishes in Louisiana) served or, if the service area includes an entire State, the name of the State.

(2) Geographic boundaries of the service area.

(3) The number and the names of all hospitals and critical access hospitals in the service area that have both a ventilator and an operating room.

§ 486.308 Designation of one OPO for each service area.

(a) CMS designates only one OPO per service area. A service area is open for competition when the OPO for the service area is de-certified and all administrative appeals under § 486.314 are exhausted.

(b) Designation periods—

(1) *General.* An OPO is normally designated for a 4-year agreement cycle. The period may be shorter, for example, if an OPO has voluntarily terminated its agreement with CMS and CMS selects a successor OPO for the balance of the 4-year agreement cycle. In rare situations, a designation period

may be longer, for example, a designation may be extended if additional time is needed to select a successor OPO to an OPO that has been de-certified.

(2) *Re-Certification*. Re-certification must occur not more frequently than once every 4 years.

(c) Unless CMS has granted a hospital a waiver under paragraphs

(d) through (f) of this section, the hospital must enter into an agreement only with the OPO designated to serve the area in which the hospital is located.

(d) If CMS changes the OPO designated for an area, hospitals located in that area must enter into agreements with the newly designated OPO or submit a request for a waiver in accordance with paragraph (e) of this section within 30 days of notice of the change in designation.

(e) A hospital may request and CMS may grant a waiver permitting the hospital to have an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located. To qualify for a waiver, the hospital must submit data to CMS establishing that—

(1) The waiver is expected to increase organ donations; and

(2) The waiver will ensure equitable treatment of patients listed for transplants within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement.

(f) In making a determination on waiver requests, CMS considers—

(1) Cost effectiveness;

(2) Improvements in quality;

(3) Changes in a hospital's designated OPO due to changes in the definitions of metropolitan statistical areas, if applicable; and

(4) The length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO.

(g) A hospital may continue to operate under its existing agreement with an out-of-area OPO while CMS is processing the waiver request. If a waiver request is denied, a hospital must enter into an agreement with the designated OPO within 30 days of notification of the final determination.

§486.309 Re-certification from August 1, 2006 through July 31, 2010.

An OPO will be considered to be re-certified for the period of August 1, 2006 through July 31, 2010 if an OPO met the standards to be a qualified OPO within a 4-year period ending December 31, 2001 and has an agreement with the Secretary that is scheduled to terminate on July 31, 2006. Agreements based on the August 1, 2006 through July 31, 2010 re-certification cycle will end on January 31, 2011.

§486.310 Changes in control or ownership or service area.

(a) *OPO requirements*. (1) A designated OPO considering a change in control (see §413.17(b)(3)) or ownership or in its service area must notify CMS before putting it into effect. This notification is required to ensure that the OPO, if changed, will continue to satisfy Medicare and Medicaid requirements. The merger of one OPO into another or the consolidation of one OPO with another is considered a change in control or ownership.

(2) A designated OPO considering a change in its service area must obtain prior CMS approval. In the case of a service area change that results from a change of control or ownership due to merger or consolidation, the OPOs must resubmit the information required in an application for designation. The OPO must provide information specific to the board structure of the new organization, as well as operating budgets, financial information, and other written documentation CMS determines to be necessary for designation.

(b) *CMS requirements*. (1) If CMS finds that the OPO has changed to such an extent that it no longer satisfies the requirements for OPO designation, CMS may de-certify the OPO and declare the OPO's service area to be an open area. An OPO may appeal such a de-certification as set forth in §486.314. The OPO's service area is not opened for competition until the conclusion of the administrative appeals process.

(2) If CMS finds that the changed OPO continues to satisfy the requirements for OPO designation, the period of designation of the changed OPO is the remaining portion of the 4-year term of the OPO that was reorganized. If more than one designated OPO is involved in the reorganization, the remaining designation term is the longest of the remaining periods unless CMS determines that a shorter period is in the best interest of the Medicare and Medicaid programs. The changed OPO must continue to meet the requirements for certification at § 486.303 throughout the remaining period.

RE-CERTIFICATION AND DE-CERTIFICATION

§ 486.312 De-certification.

(a) *Voluntary termination of agreement.* If an OPO wishes to terminate its agreement, the OPO must send CMS written notice of its intention to terminate its agreement and the proposed effective date. CMS may approve the proposed date, set a different date no later than 6 months after the proposed effective date, or set a date less than 6 months after the proposed effective date if it determines that a different date would not disrupt services to the service area. If CMS determines that a designated OPO has ceased to furnish organ procurement services to its service area, the cessation of services is deemed to constitute a voluntary termination by the OPO, effective on a date determined by CMS. CMS will de-certify the OPO as of the effective date of the voluntary termination.

(b) *Involuntary termination of agreement.* During the term of the agreement, CMS may terminate an agreement with an OPO if the OPO no longer meets the requirements for certification at § 486.303. CMS may also terminate an agreement immediately in cases of urgent need, such as the discovery of unsound medical practices. CMS will de-certify the OPO as of the effective date of the involuntary termination.

(c) *Non-renewal of agreement.* CMS will not voluntarily renew its agreement with an OPO if the OPO fails to meet the requirements for certification at § 486.318, based on findings from the most recent re-certification cycle, or the other requirements for certification at § 486.303. CMS will de-certify the OPO as of the ending date of the agreement.

(d) *Notice to OPO.* Except in cases of urgent need, CMS gives written notice of de-certification to an OPO at least 90 days before the effective date of the de-certification. In cases of urgent need, CMS gives written notice of de-certification to an OPO at least 3 calendar days prior to the effective date of the de-certification. The notice of de-certification states the reasons for de-certification and the effective date.

(e) *Public notice.* Once CMS approves the date for a voluntary termination, the OPO must provide prompt public notice of the date of de-certification and such other information as CMS may require through publication in local newspapers in the service area. In the case of involuntary termination or non-renewal of an agreement, CMS provides public notice of the date of de-certification through publication in local newspapers in the service area. No payment under titles XVIII or XIX of the Act will be made with respect to organ procurement costs attributable to the OPO on or after the effective date of de-certification.

§ 486.314 Appeals.

If an OPO's de-certification is due to involuntary termination or non-renewal of its agreement with CMS, the OPO may appeal the de-certification on substantive and procedural grounds.

(a) *Notice of initial determination.* CMS mails notice to the OPO of an initial de-certification determination. The notice contains the reasons for the determination, the effect of the determination, and the OPO's right to seek reconsideration.

(b) *Reconsideration.* (1) Filing request. If the OPO is dissatisfied with the de-certification determination, it has 15 business days from receipt of the notice of de-certification to seek reconsideration from CMS. The request for reconsideration must state the issues or findings of fact with which the OPO disagrees and the reasons for disagreement.

(2) An OPO must seek reconsideration before it is entitled to seek a

hearing before a hearing officer. If an OPO does not request reconsideration or its request is not made timely, the OPO has no right to further administrative review.

(3) *Reconsideration determination.* CMS makes a written reconsidered determination within 10 business days of receipt of the request for reconsideration, affirming, reversing, or modifying the initial determination and the findings on which it was based. CMS augments the administrative record to include any additional materials submitted by the OPO, and a copy of the reconsideration decision and sends the supplemented administrative record to the CMS hearing officer.

(c) *Request for hearing.* An OPO dissatisfied with the CMS reconsideration decision, must file a request for a hearing before a CMS hearing officer within 40 business days of receipt of the notice of the reconsideration determination. If an OPO does not request a hearing or its request is not received timely, the OPO has no right to further administrative review.

(d) *Administrative record.* The hearing officer sends the administrative record to both parties within 10 business days of receipt of the request for a hearing.

(1) The administrative record consists of, but is not limited to, the following:

(i) Factual findings from the survey(s) on the OPO conditions for coverage.

(ii) Data from the outcome measures.

(iii) Rankings of OPOs based on the outcome data.

(iv) Correspondence between CMS and the affected OPO.

(2) The administrative record will not include any privileged information.

(e) *Pre-Hearing conference.* At any time before the hearing, the CMS hearing officer may call a pre-hearing conference if he or she believes that a conference would more clearly define the issues. At the pre-hearing conference, the hearing officer may establish the briefing schedule, sets the hearing date, and addresses other administrative matters. The hearing officer will issue an order reflecting the results of the pre-hearing conference.

(f) *Date of hearing.* The hearing officer sets a date for the hearing that is no more than 60 calendar days following the receipt of the request for a hearing.

(g) *Conduct of hearing.* (1) The hearing is open to both parties, CMS and the OPO.

(2) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(3) The hearing officer provides the parties with an opportunity to enter an objection to the inclusion of any document. The hearing officer will consider the objection and will rule on the document's admissibility.

(4) The hearing officer decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

(5) The hearing officer rules on the admissibility of evidence and may admit evidence that would be inadmissible under rules applicable to court procedures.

(6) The hearing officer rules on motions and other procedural items.

(7) The hearing officer regulates the course of the hearing and conduct of counsel.

(8) The hearing officer may examine witnesses.

(9) The hearing officer takes any action authorized by the rules in this subpart.

(h) Parties' rights. CMS and the OPO may:

(1) Appear by counsel or other authorized representative, in all hearing proceedings.

(2) Participate in any pre-hearing conference held by the hearing officer.

(3) Agree to stipulations as to facts which will be made a part of the record.

(4) Make opening statements at the hearing.

(5) Present relevant evidence on the issues at the hearing.

(6) Present witnesses, who then must be available for cross-examination, and cross-examine witnesses presented by the other party.

(7) Present oral arguments at the hearing.

(i) Hearing officer's decision. The hearing officer renders a decision on

the appeal of the notice of de-certification within 20 business days of the hearing.

(1) *Reversal of de-certification.* If the hearing officer reverses CMS' determination to de-certify an OPO in a case involving the involuntary termination of the OPO's agreement, CMS will not terminate the OPO's agreement and will not de-certify the OPO.

(2) *De-certification is upheld.* If the de-certification determination is upheld by the hearing officer, the OPO is de-certified and it has no further administrative appeal rights.

(j) *Extension of agreement.* If there is insufficient time prior to expiration of an agreement with CMS to allow for competition of the service area and, if necessary, transition of the service area to a successor OPO, CMS may choose to extend the OPO's agreement with CMS.

(k) *Effects of de-certification.* Medicare and Medicaid payments may not be made for organ procurement services the OPO furnishes on or after the effective date of de-certification. CMS will then open the de-certified OPO's service area for competition as set forth in § 486.316(c).

§ 486.316 Re-certification and competition processes.

(a) *Re-Certification of OPOs.* An OPO is re-certified for an additional 4 years and its service area is not opened for competition when the OPO:

(1) Meets all 3 outcome measure requirements at § 486.318; and

(2) Has been shown by survey to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at § 486.320 through § 486.348.

(b) *De-certification and competition.* If an OPO does not meet all 3 outcome measures as described in paragraph (a)(1) of this section or the requirements described in paragraph (a)(2) of this section, the OPO is de-certified. If the OPO does not appeal or the OPO appeals and the reconsideration official and CMS hearing officer uphold the de-certification, the OPO's service area is opened for competition from other OPOs. The de-certified OPO is not permitted to compete for its open area or any other open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

(c) *Criteria to compete.* To compete for an open service area, an OPO must meet the criteria in paragraph (a) of this section and the following additional criteria:

(1) The OPO's performance on the donation rate outcome measure and yield outcome measure is at or above 100 percent of the mean national rate averaged over the 4 years of the re-certification cycle; and

(2) The OPO's donation rate is at least 15 percentage points higher than the donation rate of the OPO currently designated for the service area.

(3) The OPO must compete for the entire service area.

(d) *Criteria for selection.* CMS will designate an OPO for an open service area based on the following criteria:

(1) Performance on the outcome measures at § 486.318;

(2) Relative success in meeting the process performance measures and other conditions at §§ 486.320 through 486.348;

(3) Contiguity to the open service area.

(4) Success in identifying and overcoming barriers to donation within its own service area and the relevance of those barriers to barriers in the open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

(e) *No OPO applies.* If no OPO applies to compete for a de-certified OPO's open area, CMS may select a single OPO to take over the entire open area or may adjust the service area boundaries of two or more contiguous OPOs to incorporate the open area. CMS will make its decision based on the criteria in paragraph (d) of this section.

ORGAN PROCUREMENT ORGANIZATION OUTCOME REQUIREMENTS

§ 486.318 Condition: Outcome measures.

(a) With the exception of OPOs operating exclusively in non-contiguous U.S. states, commonwealths, territories, or possessions, an OPO must meet all 3 of the following outcome measures:

(1) The OPO's donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the mean national donation rate of eligible donors as a percentage of eligible deaths, averaged over the 4 years of the re-certification cycle. Both the numerator and denominator of an individual OPO's donation rate ratio are adjusted by adding a 1 for each donation after cardiac death donor and each donor over the age of 70;

(2) The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re-certification, as calculated by the SRTR;

(3) At least 2 out of the 3 following yield measures are no more than 1 standard deviation below the national mean, averaged over the 4 years of the re-certification cycle:

(i) The number of organs transplanted per standard criteria donor, including pancreata used for islet cell transplantation;

(ii) The number of organs transplanted per expanded criteria donor, including pancreata used for islet cell transplantation; and

(iii) The number of organs used for research per donor, including pancreata used for islet cell research.

(b) For OPOs operating exclusively in non-contiguous U.S. states, commonwealths, territories, and possessions, the OPO outcome measures are as follows:

(1) The OPO's donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the mean national donation rate of eligible donors as a percentage of eligible deaths, averaged over the 4 years of the re-certification cycle. Both the numerator and denominator of an individual OPO's donation rate ratio are adjusted by adding a 1 for each donation after cardiac death donor and each donor over the age of 70;

(2) The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re-certification, as calculated by the SRTR;

(3) At least 2 out of the 3 following are no more than 1 standard deviation below the national mean:

(i) The number of kidneys transplanted per standard criteria donor;

(ii) The number of kidneys transplanted per expanded criteria donor; and

(iii) The number of organs used for research per donor, including pancreata recovered for islet cell transplantation.

(c) Data for the outcome measures.

(1) An OPO's performance on the outcome measures is based on 36 months of data, beginning with January 1 of the first full year of the re-certification cycle and ending 36 months later on December 31, 7 months prior to the end of the re-certification cycle.

(2) If an OPO takes over another OPO's service area on a date later than January 1 of the first full year of the re-certification cycle so that 36 months of data are not available to evaluate the OPO's performance in its new service area, we will not hold the OPO accountable for its performance in the new area until the end of the following re-certification cycle when 36 months of data are available.

ORGAN PROCUREMENT ORGANIZATION PROCESS PERFORMANCE MEASURES

§ 486.320 Condition: Participation in Organ Procurement and Transplantation Network.

After being designated, an OPO must become a member of, participate in, and abide by the rules and requirements of the OPTN established and operated in accordance with section 372 of the Public Health Service Act (42 U.S.C. 274). The term ''rules and requirements of the OPTN'' means those rules and requirements approved by the Secretary. No OPO is considered out of compliance with section 1138(b)(1)(D) of the Act or this section until the Secretary approves a determination that

the OPO failed to comply with the rules and requirements of the OPTN. The Secretary may impose sanctions under section 1138 only after such noncompliance has been determined in this manner.

§ 486.322 Condition: Relationships with hospitals, critical access hospitals, and tissue banks.

(a) *Standard:* Hospital agreements. An OPO must have a written agreement with 95 percent of the Medicare and Medicaid participating hospitals and critical access hospitals in its service area that have both a ventilator and an operating room and have not been granted a waiver by CMS to work with another OPO. The agreement must describe the responsibilities of both the OPO and hospital or critical access hospital in regard to donation after cardiac death (if the OPO has a protocol for donation after cardiac death) and the requirements for hospitals at § 482.45 or § 485.643. The agreement must specify the meaning of the terms ''timely referral'' and ''imminent death.''

(b) *Standard:* Designated requestor training for hospital staff. The OPO must offer to provide designated requestor training on at least an annual basis for hospital and critical access hospital staff.

(c) *Standard:* Cooperation with tissue banks.

(1) The OPO must have arrangements to cooperate with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements. The OPO must cooperate in the following activities, as may be appropriate, to ensure that all usable tissues are obtained from potential donors:

(i) Screening and referral of potential tissue donors.

(ii) Obtaining informed consent from families of potential tissue donors.

(iii) Retrieval, processing, preservation, storage, and distribution of tissues.

(iv) Providing designated requestor training.

(2) An OPO is not required to have an arrangement with a tissue bank that is unwilling to have an arrangement with the OPO.

§ 486.324 Condition: Administration and governing body.

(a) While an OPO may have more than one board, the OPO must have an advisory board that has both the authority described in paragraph (b) of this section and the following membership:

(1) Members who represent hospital administrators, either intensive care or emergency room personnel, tissue banks, and voluntary health associations in the OPO's service area.

(2) Individuals who represent the public residing in the OPO's service area.

(3) A physician with knowledge, experience, or skill in the field of human histocompatibility, or an individual with a doctorate degree in a biological science and with knowledge, experience, or skills in the field of human histocompatibility.

(4) A neurosurgeon or other physician with knowledge or skills in the neurosciences.

(5) A transplant surgeon representing each transplant hospital in the service area with which the OPO has arrangements to coordinate its activities. The transplant surgeon must have practicing privileges and perform transplants in the transplant hospital represented.

(6) An organ donor family member.

(b) The OPO board described in paragraph (a) of this section has the authority to recommend policies for the following:

(1) Procurement of organs.

(2) Effective agreements to identify potential organ donors with a substantial majority of hospitals in its service area that have facilities for organ donation.

(3) Systematic efforts, including professional education, to acquire all useable organs from potential donors.

(4) Arrangements for the acquisition and preservation of donated organs and provision of quality standards for the acquisition of organs that are consistent with the standards adopted by the OPTN, including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immunodeficiency syndrome (AIDS).

(5) Appropriate tissue typing of organs.

(6) A system for allocation of organs among transplant patients that is consistent with the rules and requirements of the OPTN, as defined in §486.320 of this part.

(7) Transportation of organs to transplant hospitals.

(8) Coordination of activities with transplant hospitals in the OPO's service area.

(9) Participation in the OPTN.

(10) Arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all useable tissues are obtained from potential donors.

(11) Annual evaluation of the effectiveness of the OPO in acquiring organs.

(12) Assistance to hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.

(c) The advisory board described in paragraph (a) of this section has no authority over any other activity of the OPO and may not serve as the OPO's governing body or board of directors. Members of the advisory board described in paragraph (a) of this section are prohibited from serving on any other OPO board.

(d) The OPO must have bylaws for each of its board(s) that address potential conflicts of interest, length of terms, and criteria for selecting and removing members. (e) A governing body must have full legal authority and responsibility for the management and provision of all OPO services and must develop and oversee implementation of policies and procedures considered necessary for the effective administration of the OPO, including fiscal operations, the OPO's quality assessment and performance improvement (QAPI) program, and services furnished under contract or arrangement, including agreements for these services. The governing body must appoint an individual to be responsible for the day-to-day operation of the OPO.

(e) A governing body must have full legal authority and responsibility for the management and provision of all OPO services and must develop and oversee implementation of policies and procedures considered necessary for the effective administration of the OPO, including fiscal operations, the OPO's quality assessment and performance improvement (QAPI) program, and services furnished under contract or arrangement, including agreements for these services. The governing body must appoint an individual to be responsible for the day-to-day operation of the OPO.

(f) The OPO must have procedures to address potential conflicts of interest for the governing body described in paragraph (d) of this section.

(g) The OPO's policies must state whether the OPO recovers organs from donors after cardiac death.

§486.326 Condition: Human resources.

All OPOs must have a sufficient number of qualified staff, including a director, a medical director, organ procurement coordinators, and hospital development staff to obtain all usable organs from potential donors, and to ensure that required services are provided to families of potential donors, hospitals, tissue banks, and individuals and facilities that use organs for research.

(a) *Standard: Qualifications.* (1) The OPO must ensure that all individuals who provide services and/or supervise services, including services furnished under contract or arrangement, are qualified to provide or supervise the services.

(2) The OPO must develop and implement a written policy that addresses potential conflicts of interest for the OPO's director, medical director, senior management, and procurement coordinators.

(3) The OPO must have credentialing records for physicians and other practitioners who routinely recover organs in hospitals under contract or arrangement with the OPO and ensure that all physicians and other practitioners who recover organs in hospitals with which the OPO has agreements are qualified and trained.

(b) *Standard: Staffing.* (1) The OPO must provide sufficient coverage, either by its own staff or under contract or arrangement, to assure both that hospital referral calls are screened for

donor potential and that potential donors are evaluated for medical suitability for organ and/or tissue donation in a timely manner.

(2) The OPO must have a sufficient number of qualified staff to provide information and support to potential organ donor families; request consent for donation; ensure optimal maintenance of the donor, efficient placement of organs, and adequate oversight of organ recovery; and conduct QAPI activities, such as death record reviews and hospital development.

(3) The OPO must provide a sufficient number of recovery personnel, either from its own staff or under contract or arrangement, to ensure that all usable organs are recovered in a manner that, to the extent possible, preserves them for transplantation.

(c) *Standard: Education, training, and performance evaluation*. The OPO must provide its staff with the education, training, and supervision necessary to furnish required services. Training must include but is not limited to performance expectations for staff, applicable organizational policies and procedures, and QAPI activities. OPOs must evaluate the performance of their staffs and provide training, as needed, to improve individual and overall staff performance and effectiveness.

(d) *Standard: Medical director*. The OPO's medical director is a physician licensed in at least one of the States or territories within the OPO's service area or as required by State or territory law or by the jurisdiction in which the OPO is located. The medical director is responsible for implementation of the OPO's protocols for donor evaluation and management and organ recovery and placement. The medical director is responsible for oversight of the clinical management of potential donors, including providing assistance in managing a donor case when the surgeon on call is unavailable.

§ 486.328 Condition: Reporting of data.

(a) An OPO must provide individually-identifiable, hospital-specific organ donation and transplantation data and other information to the Organ Procurement and Transplantation Network, the Scientific Registry of Transplant Recipients, and DHHS, as requested by the Secretary. The data may include, but are not limited to:

(1) Number of hospital deaths;

(2) Results of death record reviews;

(3) Number and timeliness of referral calls from hospitals;

(4) Number of eligible deaths;

(5) Data related to non-recovery of organs;

(6) Data about consents for donation;

(7) Number of eligible donors;

(8) Number of organs recovered, by type of organ; and

(9) Number of organs transplanted, by type of organ.

(b) An OPO must provide hospital-specific organ donation data annually to the transplant hospitals with which it has agreements.

(c) Data to be used for OPO re-certification purposes must be reported to the OPTN and must include data for all deaths in all hospitals and critical access hospitals in the OPO's donation service area, unless a hospital or critical access hospital has been granted a waiver to work with a different OPO.

(d) Data reported by the OPO to the OPTN must be reported within 30 days after the end of the month in which a death occurred. If an OPO determines through death record review or other means that the data it reported to the OPTN was incorrect, it must report the corrected data to the OPTN within 30 days of the end of the month in which the error is identified.

(e) For the purpose of determining the information to be collected under paragraph (a) of this section, the following definitions apply:

(1) *Kidneys procured*. Each kidney recovered will be counted individually. En bloc kidneys recovered will count as two kidneys procured.

(2) *Kidneys transplanted*. Each kidney transplanted will be counted individually. En bloc kidney transplants will be counted as two kidneys transplanted.

(3) *Extra-renal organs procured*. Each organ recovered is counted individually.

(4) *Extra-renal organs transplanted*. Each organ or part thereof transplanted will be counted individually. For example, a single liver is counted as one organ procured and each portion

that is transplanted will count as one transplant. Further, a heart and double lung transplant will be counted as three organs transplanted. A kidney/pancreas transplant will count as one kidney transplanted and one extra-renal organ transplanted.

§ 486.330 Condition: Information management.

An OPO must establish and use an electronic information management system to maintain the required medical, social and identifying information for every donor and transplant recipient and develop and follow procedures to ensure the confidentiality and security of the information.

(a) *Donor information.* The OPO must maintain a record for every donor. The record must include, at a minimum, information identifying the donor (for example, name, address, date of birth, social security number or other unique identifier, such as Medicare health insurance claim number), organs and (when applicable) tissues recovered, date of the organ recovery, donor management data, all test results, current hospital history, past medical and social history, the pronouncement of death, and consent and next-of-kin information.

(b) *Disposition of organs.* The OPO must maintain records showing the disposition of each organ recovered for the purpose of transplantation, including information identifying transplant recipients.

(c) *Data retention.* Donor and transplant recipient records must be maintained in a human readable and reproducible paper or electronic format for 7 years.

(d) *Format of records.* The OPO must maintain data in a format that can readily be transferred to a successor OPO and in the event of a transfer must provide to CMS copies of all records, data, and software necessary to ensure uninterrupted service by a successor OPO. Records and data subject to this requirement include donor and transplant recipient records and procedural manuals and other materials used in conducting OPO operations.

§ 486.342 Condition: Requesting consent.

An OPO must encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of potential donor families.

(a) An OPO must have a written protocol to ensure that, in the absence of a donor document, the individual(s) responsible for making the donation decision are informed of their options to donate organs or tissues (when the OPO is making a request for tissues) or to decline to donate. The OPO must provide to the individual(s) responsible for making the donation decision, at a minimum, the following:

(1) A list of the organs and/or tissues that may be recovered.

(2) The most likely uses for the donated organs or tissues.

(3) A description of the screening and recovery processes.

(4) Information about the organizations that will recover, process, and distribute the tissue.

(5) Information regarding access to and release of the donor's medical records.

(6) An explanation of the impact the donation process will have on burial arrangements and the appearance of the donor's body.

(7) Contact information for individual(s) with questions or concerns.

(8) A copy of the signed consent form if a donation is made.

(b) If an OPO does not request consent to donation because a potential donor consented to donation before his or her death in a manner that satisfied applicable State law requirements in the potential donor's State of residence, the OPO must provide information about the donation to the family of the potential donor, as requested.

§ 486.344 Condition: Evaluation and management of potential donors and organ placement and recovery.

The OPO must have written protocols for donor evaluation and management and organ placement and recovery that meet current standards of practice and are designed to maximize organ quality and optimize the number of donors and the number of organs recovered and transplanted per donor.

(a) *Potential donor protocol management.* (1) The medical director is responsible for ensuring that potential donor evaluation and management protocols are implemented correctly and appropriately to ensure that potential donors are thoroughly assessed for medical suitability for organ donation and clinically managed to optimize organ viability and function.

(2) The OPO must implement a system that ensures that a qualified physician or other qualified individual is available to assist in the medical management of a potential donor when the surgeon on call is unavailable.

(b) *Potential donor evaluation.* The OPO must do the following:

(1) Verify that death has been pronounced according to applicable local, State, and Federal laws.

(2) Determine whether there are conditions that may influence donor acceptance.

(3) If possible, obtain the potential donor's medical and social history.

(4) Review the potential donor's medical chart and perform a physical examination of the donor.

(5) Obtain the potential donor's vital signs and perform all pertinent tests.

(c) *Testing.* The OPO must do the following:

(1) Arrange for screening and testing of the potential donor for infectious disease according to current standards of practice, including testing for the human immunodeficiency virus.

(2) Ensure that screening and testing of the potential donor (including point-of-care testing and blood typing) are conducted by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 of this chapter.

(3) Ensure that the potential donor's blood is typed using two separate blood samples.

(4) Document potential donor's record with all test results, including blood type, before organ recovery.

(d) *Standard: Collaboration with transplant programs.* (1) The OPO must establish protocols in collaboration with transplant programs that define the roles and responsibilities of the OPO and the transplant program for all activities associated with the evaluation and management of potential donors, organ recovery, and organ placement, including donation after cardiac death, if the OPO has implemented a protocol for donation after cardiac death.

(2) The protocol must ensure that:

(i) The OPO is responsible for two separate determinations of the donor's blood type;

(ii) If the identify of the intended recipient is known, the OPO has a procedure to ensure that prior to organ recovery, an individual from the OPO's staff compares the blood type of the donor with the blood type of the intended recipient, and the accuracy of the comparison is verified by a different individual;

(iii) Documentation of the donor's blood type accompanies the organ to the hospital where the transplant will take place.

(3) The established protocols must be reviewed regularly with the transplant programs to incorporate practices that have been shown to maximize organ donation and transplantation.

(e) *Documentation of recipient information.* If the intended recipient has been identified prior to recovery of an organ for transplantation, the OPO must have written documentation from the OPTN showing, at a minimum, the intended organ recipient's ranking in relation to other suitable candidates and the recipient's OPTN identification number and blood type.

(f) *Donation after cardiac death.* If an OPO recovers organs from donors after cardiac death, the OPO must have protocols that address the following:

(1) Criteria for evaluating patients for donation after cardiac death;

(2) Withdrawal of support, including the relationship between the time of consent to donation and the withdrawal of support;

(3) Use of medications and interventions not related to withdrawal of support;

(4) Involvement of family members prior to organ recovery;

(5) Criteria for declaration of death and the time period that must elapse prior to organ recovery.

(g) *Organ allocation.* The OPO must have a system to allocate donated organs among transplant patients that is

consistent with the rules and requirements of the OPTN, as defined in § 486.320 of this part.

(h) *Organ placement*. The OPO must develop and implement a protocol to maximize placement of organs for transplantation.

§ 486.346 Condition: Organ preparation and transport.

(a) The OPO must arrange for testing of organs for infectious disease and tissue typing of organs according to current standards of practice. The OPO must ensure that testing and tissue typing of organs are conducted by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 of this chapter.

(b) The OPO must send complete documentation of donor information to the transplant center with the organ, including donor evaluation, the complete record of the donor's management, documentation of consent, documentation of the pronouncement of death, and documentation for determining organ quality. Two individuals, one of whom must be an OPO employee, must verify that the documentation that accompanies an organ to a transplant center is correct.

(c) The OPO must develop and follow a written protocol for packaging, labeling, handling, and shipping organs in a manner that ensures their arrival without compromise to the quality of the organ. The protocol must include procedures to check the accuracy and integrity of labels, packaging, and contents prior to transport, including verification by two individuals, one of whom must be an OPO employee, that information listed on the labels is correct.

(d) All packaging in which an organ is transported must be marked with the identification number, specific contents, and donor's blood type.

§ 486.348 Condition: Quality assessment and performance improvement (QAPI).

The OPO must develop, implement, and maintain a comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all donation services, including services provided under contract or arrangement.

(a) *Standard: Components of a QAPI program*. The OPO's QAPI program must include objective measures to evaluate and demonstrate improved performance with regard to OPO activities, such as hospital development, designated requestor training, donor management, timeliness of on-site response to hospital referrals, consent practices, organ recovery and placement, and organ packaging and transport. The OPO must take actions that result in performance improvements and track performance to ensure that improvements are sustained.

(b) *Standard: Death record reviews*. As part of its ongoing QAPI efforts, an OPO must conduct at least monthly death record reviews in every Medicare and Medicaid participating hospital in its service area that has a Level I or Level II trauma center or 150 or more beds, a ventilator, and an intensive care unit (unless the hospital has a waiver to work with another OPO), with the exception of psychiatric and rehabilitation hospitals. When missed opportunities for donation are identified, the OPO must implement actions to improve performance.

(c) *Standard: Adverse events*. (1) An OPO must establish written policies to address, at a minimum, the process for identification, reporting, analysis, and prevention of adverse events that occur during the organ donation process.

(2) The OPO must conduct a thorough analysis of any adverse event and must use the analysis to affect changes in the OPO's policies and practices to prevent repeat incidents.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

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Subpart G [Reserved]

Subpart H—Termination of Medicare Coverage and Alternative Sanctions for End-Stage Renal Disease (ESRD) Facilities

488.604 Termination of Medicare coverage.
488.606 Alternative sanctions.
488.608 Notice of alternative sanction and appeal rights: Termination of coverage.
488.610 Notice of appeal rights: Alternative sanctions.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302 and 1395(hh)); Continuing Resolution Pub. L. 110–149 H.J. Res. 72.

SOURCE: 53 FR 22859, June 17, 1988, unless otherwise noted.

Subpart A—General Provisions

§ 488.1 Definitions.

As used in this part—

Accredited provider or supplier means a provider or supplier that has voluntarily applied for and has been accredited by a national accreditation program meeting the requirements of and approved by CMS in accordance with § 488.5 or § 488.6.

Act means the Social Security Act.

AOA stands for the American Osteopathic Association.

Certification is a recommendation made by the State survey agency on the compliance of providers and suppliers with the conditions of participation, requirements (for SNFs and NFs), and conditions of coverage.

Conditions for coverage means the requirements suppliers must meet to participate in the Medicare program.

Conditions of participation means the requirements providers other than skilled nursing facilities must meet to participate in the Medicare program and includes conditions of certification for rural health clinics.

Full review means a survey of a hospital for compliance with all conditions of participation for hospitals.

JCAHO stands for the Joint Commission on Accreditation of Healthcare Organizations.

Medicare condition means any condition of participation or for coverage, including any long term care requirements.

Provider of services or *provider* means a hospital, critical access hospital, skilled nursing facility, nursing facility, home health agency, hospice, comprehensive outpatient rehabilitation facility, or provider of outpatient physical therapy or speech pathology services.

Rate of disparity means the percentage of all sample validation surveys for which a State survey agency finds noncompliance with one or more Medicare conditions and no comparable condition level deficiency was cited by the accreditation organization, where it is reasonable to conclude that the deficiencies were present at the time of the accreditation organization's most recent surveys of providers or suppliers of the same type.

Example: Assume that during a validation review period State survey agencies perform validation surveys at 200 facilities of the same type (for example, ambulatory surgical centers, home health agencies) accredited by the same accreditation organization. The State survey agencies find 60 of the facilities out of compliance with one or more Medicare conditions, and it is reasonable to conclude that these deficiencies were present at the time of the most recent survey by an accreditation organization. The accreditation organization, however, has found deficiencies comparable to the condition level deficiencies at only 22 of the 60 facilities. These validation results would yield ((60–22)/200) a rate of disparity of 19 percent.

Reasonable assurance means that an accreditation organization has demonstrated to CMS's satisfaction that its requirements, taken as a whole, are at least as stringent as those established by CMS, taken as a whole.

State includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

State survey agency means the State health agency or other appropriate State or local agency used by HFCA to perform survey and review functions for Medicare.

Substantial allegation of noncompliance means a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that, if substantiated, would affect the health and safety of patients and raises doubts as to a provider's or supplier's noncompliance with any Medicare condition.

Supplier means any of the following: Independent laboratory; portable X-ray services; physical therapist in independent practice; ESRD facility; rural health clinic; Federally qualified health center; chiropractor; or ambulatory surgical center.

Validation review period means the one year period during which CMS conducts a review of the validation surveys and evaluates the results of the most recent surveys performed by the accreditation organization.

[53 FR 22859, June 17, 1988, as amended at 54 FR 5373, Feb. 2, 1989; 56 FR 48879, Sept. 26, 1991; 57 FR 24982, June 12, 1992; 58 FR 30676, May 26, 1993; 58 FR 61838, Nov. 23, 1993; 62 FR 46037, Aug. 29, 1997; 71 FR 68230, Nov. 24, 2006]

§ 488.2 Statutory basis.

This part is based on the indicated provisions of the following sections of the Act:

1128—Exclusion of entities from participation in Medicare.
1128A—Civil money penalties.
1814—Conditions for, and limitations on, payment for Part A services.
1819—Requirements for SNFs.
1861(f)—Requirements for psychiatric hospitals.
1861(z)—Institutional planning standards that hospitals and SNFs must meet.
1861(ee)—Discharge planning guidelines for hospitals.
1861(ss)(2)—Accreditation of religious nonmedical health care institutions.
1864—Use of State survey agencies.
1865—Effect of accreditation.
1880—Requirements for hospitals and SNFs of the Indian Health Service.
1883—Requirements for hospitals that provide SNF care.
1902—Requirements for participation in the Medicaid program.
1913—Medicaid requirements for hospitals that provide NF care.
1919—Medicaid requirements for NFs.

[60 FR 50443, Sept. 29, 1995, as amended at 64 FR 67052, Nov. 30, 1999]

§ 488.3 Conditions of participation; conditions for coverage; and long-term care requirements.

(a) *Basic rules.* In order to be approved for participation in or coverage under the Medicare program, a prospective provider or supplier must:

(1) Meet the applicable statutory definition in section 1138(b), 1819, 1832(a)(2)(F), 1861, 1881, or 1919 of the Act; and

(2) Be in compliance with the applicable conditions or long-term care requirements prescribed in subpart N, Q or U of part 405, part 416, subpart C of part 418, part 482, part 483, part 484, part 485, subpart A of part 491, or part 494 of this chapter.

(b) *Special Conditions.* (1) The Secretary, after consultation with the JCAHO or AOA, may issue conditions of participation for hospitals higher or more precise than those of either those accrediting bodies.

(2) The Secretary may, at a State's request, approve health and safety requirements for providers and suppliers in that State, which are higher than those otherwise applied in the Medicare program.

(3) If a State or political subdivision imposes higher requirements on institutions as a condition for the purchase of health services under a State Medicaid Plan approved under Title XIX of the Act, (or if Guam, Puerto Rico, or the Virgin Islands does so under a State plan for Old Age Assistance under Title I of the Act, or for Aid to the Aged, Blind, and Disabled under the original Title XVI of the Act), the Secretary is required to impose similar requirements as a condition for payment under Medicare in that State or political subdivision.

[53 FR 22859, June 17, 1988, as amended at 58 FR 61838, Nov. 23, 1993]

§ 488.4 Application and reapplication procedures for accreditation organizations.

(a) A national accreditation organization applying for approval of deeming authority for Medicare requirements under § 488.5 or 488.6 of this subpart must furnish to CMS the information and materials specified in paragraphs (a)(1) through (10) of this section. A national accreditation organization reapplying for approval must furnish to CMS whatever information and materials from paragraphs (a)(1) through (10) of this section that CMS requests. The materials and information are—

(1) The types of providers and suppliers for which the organization is requesting approval;

(2) A detailed comparison of the organization's accreditation requirements and standards with the applicable Medicare requirements (for example, a crosswalk);

(3) A detailed description of the organization's survey process, including—

(i) Frequency of the surveys performed;

(ii) Copies of the organization's survey forms, guidelines and instructions to surveyors;

(iii) Accreditation survey review process and the accreditation status decision-making process;

(iv) Procedures used to notify accredited facilities of deficiencies and the procedures used to monitor the correction of deficiencies in accredited facilities; and

(v) Whether surveys are announced or unannounced;

(4) Detailed information about the individuals who perform surveys for the accreditation organization, including—

(i) The size and composition of accreditation survey teams for each type of provider and supplier accredited;

(ii) The education and experience requirements surveyors must meet;

(iii) The content and frequency of the in-service training provided to survey personnel;

(iv) The evaluation systems used to monitor the performance of individual surveyors and survey teams; and

(v) Policies and procedures with respect to an individual's participation in the survey or accreditation decision process of any facility with which the individual is professionally or financially affiliated;

(5) A description of the organization's data management and analysis system with respect to its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system;

(6) The organization's procedures for responding to and for the investigation of complaints against accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs;

(7) The organization's policies and procedures with respect to the withholding or removal of accreditation status for facilities that fail to meet the accreditation organization's standards or requirements, and other actions taken by the organization in response to noncompliance with its standards and requirements;

(8) A description of all types (for example, full, partial, type of facility, etc.) and categories (provisional, conditional, temporary, etc.) of accreditation offered by the organization, the duration of each type and category of accreditation and a statement specifying the types and categories of accreditation for which approval of deeming authority is sought;

(9) A list of all currently accredited facilities, the type and category of accreditation currently held by each facility, and the expiration date of each facility's current accreditation; and

(10) A list of all full and partial accreditation surveys scheduled to be performed by the organization.

(b) The accreditation organization must also submit the following supporting documentation—

(1) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data in ASCII comparable code;

(2) A resource analysis that demonstrates that the organization's staffing, funding and other resources are adequate to perform the required surveys and related activities; and

(3) A statement acknowledging that as a condition for approval of deeming authority, the organization will agree to—

(i) Notify CMS in writing of any facility that has had its accreditation revoked, withdrawn, or revised, or that has had any other remedial or adverse action taken against it by the accreditation organization within 30 days of any such action taken;

(ii) Notify all accredited facilities within 10 days of CMS's withdrawal of the organization's approval of deeming authority;

(iii) Notify CMS in writing at least 30 days in advance of the effective date of any proposed changes in accreditation requirements;

(iv) Within 30 days of a change in CMS requirements, submit to CMS an acknowledgement of CMS's notification of the change as well as a revised crosswalk reflecting the new requirements and inform CMS about how the organization plans to alter its requirements to conform to CMS's new requirements;

(v) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings;

(vi) [Reserved]

(vii) Notify CMS in writing within ten days of a deficiency identified in any accreditation entity where the deficiency poses an immediate jeopardy to the entity's patients or residents or a hazard to the general public; and

(viii) Conform accreditation requirements to changes in Medicare requirements.

(c) If CMS determines that additional information is necessary to make a determination for approval or denial of the accreditation organization's application for deeming authority, the organization will be notified and afforded an opportunity to provide the additional information.

(d) CMS may visit the organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents and interviews with the organization's staff.

(e) The accreditation organization will receive a formal notice from CMS stating whether the request for deeming authority has been approved or denied, the rationale for any denial, and reconsideration and reapplication procedures.

(f) An accreditation organization may withdraw its application for approval of deeming authority at any time before the formal notice provided for in paragraph (e) of this section is received.

(g) Except as provided in paragraph (i) of this section, an accreditation organization that has been notified that its request for deeming authority has been denied may request a reconsideration of that determination in accordance with subpart D of this part.

(h) Except as provided in paragraph (i) of this section, any accreditation organization whose request for approval of deeming authority has been denied may resubmit its application if the organization—

(1) Has revised its accreditation program to address the rationale for denial of its previous request;

(2) Can demonstrate that it can provide reasonable assurance that its accredited facilities meet applicable Medicare requirements; and

(3) Resubmits the application in its entirety.

(i) If an accreditation organization has requested, in accordance with part 488, subpart D of this chapter, a reconsideration of CMS's determination that its request for deeming approval is denied, it may not submit a new application for deeming authority for the type of provider or supplier that is at issue in the reconsideration until the reconsideration is administratively final.

[58 FR 61838, Nov. 23, 1993]

§ 488.5 Effect of JCAHO or AOA accreditation of hospitals.

(a) *Deemed to meet.* Institutions accredited as hospitals by the JCAHO or AOA are deemed to meet all of the Medicare conditions of participation for hospitals, except—

(1) The requirement for utilization review as specified in section 1861(e)(6) of the Act and in § 482.30 of this chapter;

(2) The additional special staffing and medical records requirements that are considered necessary for the provision of active treatment in psychiatric hospitals (section 1861(f) of the Act) and implementing regulations; and

(3) Any requirements under section 1861(e) of the Act and implementing

regulations that CMS, after consulting with JCAHO or AOA, identifies as being higher or more precise than the requirements for accreditation (section 1865(a)(4) of the Act).

(b) *Deemed status for providers and suppliers that participate in the Medicaid program.* Eligibility for Medicaid participation can be established through Medicare deemed status for providers and suppliers that are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements for that provider r supplier type.

(c) *Release and use of hospital accreditation surveys.* (1) A hospital deemed to meet program requirements must authorize its accreditation organization to release to CMS and the State survey agency a copy of its most current accreditation survey together with any other information related to the survey that CMS may require (including corrective action plans).

(2) CMS may use a validation survey, an accreditation survey or other information related to the survey to determine that a hospital does not meet the Medicare conditions of participation.

(3) CMS may disclose the survey and information related to the survey to the extent that the accreditation survey and related survey information are related to an enforcement action taken by CMS.

[58 FR 61840, Nov. 23, 1993]

§ 488.6 Other national accreditation programs for hospitals and other providers and suppliers.

(a) In accordance with the requirements of this subpart, a national accreditation program for hospitals; psychiatric hospitals; transplant centers, except for kidney transplant centers; SNFs; HHAs; ASCs; RHCs; CORFs; hospices; religious nonmedical health care institutions; screening mammography services; critical access hospitals; or clinic, rehabilitation agency, or public health agency providers of outpatient physical therapy, occupational therapy or speech pathology services may provide reasonable assurance to CMS that it requires the providers or suppliers it accredits to meet requirements that are at least as stringent as the Medicare conditions when taken as a whole. In such a case, CMS may deem the providers or suppliers the program accredits to be in compliance with the appropriate Medicare conditions. These providers and suppliers are subject to validation surveys under § 488.7 of this subpart. CMS will publish notices in the FEDERAL REGISTER in accordance with § 488.8(b) identifying the programs and deeming authority of any national accreditation program and the providers or suppliers it accredits. The notice will describe how the accreditation organization's accreditation program provides reasonable assurance that entities accredited by the organization meet Medicare requirements. (See § 488.5 for requirements concerning hospitals accredited by JCAHO or AOA.)

(b) Eligibility for Medicaid participation can be established through Medicare deemed status for providers and suppliers that are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements for that provider or supplier type.

(c)(1) A provider or supplier deemed to meet program requirements under paragraph (a) of this section must authorize its accreditation organization to release to CMS and the State survey agency a copy of its most current accreditation survey, together with any information related to the survey that CMS may require (including corrective action plans).

(2) CMS may determine that a provider or supplier does not meet the Medicare conditions on the basis of its own investigation of the accreditation survey or any other information related to the survey.

(3) Upon written request, CMS may disclose the survey and information related to the survey—

(i) Of any HHA; or

(ii) Of any other provider or supplier specified at paragraph (a) of this section if the accreditation survey and related survey information relate to an enforcement action taken by CMS.

[58 FR 61840, Nov. 23, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 64 FR 67052, Nov. 30, 1999; 72 FR 15278, Mar. 30, 2007]

§ 488.7 Validation survey.

(a) *Basis for survey.* CMS may require a survey of an accredited provider or

supplier to validate its organization's accreditation process. These surveys will be conducted on a representative sample basis, or in response to substantial allegations of noncompliance.

(1) When conducted on a representative sample basis, the survey is comprehensive and addresses all Medicare conditions or is focused on a specific condition or conditions.

(2) When conducted in response to a substantial allegation, the State survey agency surveys for any condition that CMS determines is related to the allegations.

(3) If the State survey agency substantiates a deficiency and CMS determines that the provider or supplier is out of compliance with any Medicare condition, the State survey agency conducts a full Medicare survey.

(b) *Effect of selection for survey*. A provider or supplier selected for a validation survey must—

(1) Authorize the validation survey to take place; and

(2) Authorize the State survey agency to monitor the correction of any deficiencies found through the validation survey.

(c) *Refusal to cooperate with survey*. If a provider or supplier selected for a validation survey fails to comply with the requirements specified in paragraph (b) of this section, it will no longer be deemed to meet the Medicare conditions but will be subject to full review by the State survey agency in accordance with § 488.11 and may be subject to termination of its provider agreement under § 489.53 of this chapter.

(d) *Consequences of finding of noncompliance*. If a validation survey results in a finding that the provider or supplier is out of compliance with one or more Medicare conditions, the provider or supplier will no longer be deemed to meet any Medicare conditions. Specifically, the provider or supplier will be subject to the participation and enforcement requirements applied to all providers or suppliers that are found out of compliance following a State agency survey under § 488.24 and to full review by a State agency survey in accordance with § 488.11 and may be subject to termination of the provider agreement under § 439.53 of this chapter and any other applicable intermediate sanctions and remedies.

(e) *Reinstating effect of accreditation*. An accredited provider or supplier will again be deemed to meet the Medicare conditions in accordance with this section if—

(1) It withdraws any prior refusal to authorize its accreditation organization to release a copy of the provider's or supplier's current accreditation survey;

(2) It withdraws any prior refusal to allow a validation survey; and

(3) CMS finds that the provider or supplier meets all the applicable Medicare conditions. If CMS finds that an accredited facility meets the Life Safety Code Standard by virtue of a plan of correction, the State survey agency will continue to monitor the facility until it is in compliance with the Life Safety Code Standard.

[58 FR 61840, Nov. 23, 1993]

§ 488.8 Federal review of accreditation organizations.

(a) *Review and approval of national accreditation organization*. CMS's review and evaluation of a national accreditation organization will be conducted in accordance with, but will not necessarily be limited to, the following general criteria—

(1) The equivalency of an accreditation organization's accreditation requirements of an entity to the comparable CMS requirements for the entity;

(2) The organization's survey process to determine—

(i) The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training;

(ii) The comparability of survey procedures to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities;

(iii) The organization's procedures for monitoring providers or suppliers found by the organization to be out of compliance with program requirements. These monitoring procedures

are to be used only when the organization identifies noncompliance. If noncompliance is identified through validation surveys, the State survey agency monitors corrections as specified at §488.7(b)(3);

(iv) The ability of the organization to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner;

(v) The ability of the organization to provide CMS with electronic data in ASCII comparable code and reports necessary for effective validation and assessment of the organization survey process;

(vi) The adequacy of staff and other resources;

(vii) The organization's ability to provide adequate funding for performing required surveys; and

(viii) The organization's policies with respect to whether surveys are announced or unannounced; and

(3) The accreditation organization's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS may require (including corrective action plans).

(b) *Notice and comment.* (1) CMS will publish a proposed notice in the FEDERAL REGISTER whenever it contemplates approving an accreditation organization's application for deeming authority. The proposed notice will specify the basis for granting approval of deeming authority and the types of providers and suppliers accredited by the organization for which deeming authority would be approved. The proposed notice will also describe how the accreditation organization's accreditation program provides reasonable assurance that entities accredited by the organization meet Medicare requirements. The proposed notice will also provide opportunity for public comment.

(2) CMS will publish a final notice in the FEDERAL REGISTER whenever it grants deeming authority to a national accreditation organization. Publication of the final notice will follow publication of the proposed notice by at least six months. The final notice will specify the effective date of the approval of deeming authority and the term of approval (which will not exceed six years).

(c) *Effects of approval of an accreditation organization.* CMS will deem providers and suppliers accredited by an approved accreditation organization to meet the Medicare conditions for which the approval of deeming authority has specifically been granted. The deeming authority will take effect 90 days following the publication of the final notice.

(d) *Continuing Federal oversight of equivalency of an accreditation organization and removal of deeming authority.* This paragraph establishes specific criteria and procedures for continuing oversight and for removing the approval of deeming authority of a national accreditation organization.

(1) *Comparability review.* CMS will compare the equivalency of an accreditation organization's accreditation requirements to the comparable CMS requirements if—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new requirements or change its survey process. An accreditation organization must provide written notification to CMS at least 30 days in advance of the effective date of any proposed changes in its accreditation requirements or survey process; and

(iii) An accreditation organization's approval has been in effect for the maximum term specified by CMS in the final notice.

(2) *Validation review.* Following the end of a validation review period, CMS will identify any accreditation programs for which—

(i) Validation survey results indicate a rate of disparity between certifications of the accreditation organization and certification of the State agency of 20 percent or more; or

(ii) Validation survey results, irrespective of the rate of disparity, indicate widespread or systematic problems in an organization's accreditation process that provide evidence that there is no longer reasonable assurance that accredited entities meet Medicare requirements.

(3) *Reapplication procedures.* (i) Every six years, or sooner as determined by

CMS, an approved accreditation organization must reapply for continued approval of deeming authority. CMS will notify the organization of the materials the organization must submit as part of the reapplication procedure.

(ii) An accreditation organization that is not meeting the requirements of this subpart, as determined through a comparability review, must furnish CMS, upon request and at any time, with the reapplication materials CMS requests. CMS will establish a deadline by which the materials are to be submitted.

(e) *Notice*. If a comparability or validation review reveals documentation that an accreditation organization is not meeting the requirements of this subpart, CMS will provide written notice to the organization indicating that its deeming authority approval may be in jeopardy and that a deeming authority review is being initiated. The notice provides the following information—

(1) A statement of the requirements, instances, rates or patterns of discrepancies that were found as well as other related documentation;

(2) An explanation of CMS's deeming authority review on which the final determination is based;

(3) A description of the process available if the accreditation organization wishes an opportunity to explain or justify the findings made during the comparability or validation review;

(4) A description of the possible actions that may be imposed by CMS based on the findings from the validation review; and

(5) The reapplication materials the organization must submit and the deadline for their submission.

(f) *Deeming authority review*. (1) CMS will conduct a review of an accreditation organization's accreditation program if the comparability or validation review produces findings as described at paragraph (d)(1) or (2), respectively, of this section. CMS will review as appropriate either or both—

(i) The requirements of the accreditation organization; or

(ii) The criteria described in paragraph (a)(1) of this section to reevaluate whether the accreditation organization continues to meet all these criteria.

(2) If CMS determines, following the deeming authority review, that the accreditation organization has failed to adopt requirements comparable to CMS's or submit new requirements timely, the accreditation organization may be given a conditional approval of its deeming authority for a probationary period of up to 180 days to adopt comparable requirements.

(3) If CMS determines, following the deeming authority review, that the rate of disparity identified during the validation review meets either of the criteria set forth in paragraph (d)(2) of this section CMS—

(i) May give the accreditation organization conditional approval of its deeming authority during a probationary period of up to one year (whether or not there are also noncomparable requirements) that will be effective 30 days following the date of this determination;

(ii) Will require the accreditation organization to release to CMS upon its request any facility-specific data that is required by CMS for continued monitoring:

(iii) Will require the accreditation organization to provide CMS with a survey schedule for the purpose of intermittent onsite monitoring by CMS staff, State surveyors, or both; and

(iv) Will publish in the Medicare Annual Report to Congress the name of any accreditation organization given a probationary period by CMS.

(4) Within 60 days after the end of any probationary period, CMS will make a final determination as to whether or not an accreditation program continues to meet the criteria described at paragraph (a)(1) of this section and will issue an appropriate notice (including reasons for the determination) to the accreditation organization and affected providers or suppliers. This determination will be based on any of the following—

(i) The evaluation of the most current validation survey and review findings. The evaluation must indicate an acceptable rate of disparity of less than 20 percent between the certifications of the accreditation organization and the certifications of the State agency as

described at paragraph (d)(2)(i) of this section in order for the accreditation organization to retain its approval;

(ii) The evaluation of facility-specific data, as necessary, as well as other related information;

(iii) The evaluation of an accreditation organization's surveyors in terms of qualifications, ongoing training composition of survey team, etc.;

(iv) The evaluation of survey procedures; or

(v) The accreditation requirements.

(5) If the accreditation program has not made improvements acceptable to CMS during the probationary period, CMS may remove recognition of deemed authority effective 30 days from the date that it provides written notice to the organization that its deeming authority will be removed.

(6) The existence of any validation review, deeming authority review, probationary period, or any other action by CMS, does not affect or limit the conducting of any validation survey.

(7) CMS will publish a notice in the FEDERAL REGISTER containing a justification of the basis for removing the deeming authority from an accreditation organization. The notice will provide the reasons the accreditation organization's accreditation program no longer meets Medicare requirements.

(8) After CMS removes approval of an accreditation organization's deeming authority, an affected provider's or supplier's deemed status continues in effect 60 days after the removal of approval. CMS may extend the period for an additional 60 days for a provider or supplier if it determines that the provider or supplier submitted an application within the initial 60 day timeframe to another approved accreditation organization or to CMS so that a certification of compliance with Medicare conditions can be determined.

(9) Failure to comply with the timeframe requirements specified in paragraph (f)(8) of this section will jeopardize a provider's or supplier's participation in the Medicare program and where applicable in the Medicaid program.

(g) If at any time CMS determines that the continued approval of deeming authority of any accreditation organization poses an immediate jeopardy to the patients of the entities accredited by that organization, or such continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of deeming authority of that accreditation organization.

(h) Any accreditation organization dissatisfied with a determination to remove its deeming authority may request a reconsideration of that determination in accordance with subpart D of this part.

[58 FR 61841, Nov. 23, 1993]

§ 488.9 Onsite observation of accreditation organization operations.

As part of the application review process, the validation review process, or the continuing oversight of an accreditation organization's performance, CMS may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and to assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, the review of documents, auditing meetings concerning the accreditation process, the evaluation of survey results or the accreditation decision-making process, and interviews with the organization's staff.

[58 FR 61842, Nov. 23, 1993]

§ 488.10 State survey agency review: Statutory provisions.

(a) Section 1864(a) of the Act requires the Secretary to enter into an agreement with any State that is able and willing to do so, under which appropriate State or local survey agencies will determine whether:

(1) Providers or prospective providers meet the Medicare conditions of participation or requirements (for SNFs and NFs);

(2) Suppliers meet the conditions for coverage; and

(3) Rural health clinics meet the conditions of certification.

(b) Section 1865(a) of the Act provides that if an institution is accredited as a hospital by the JCAHO, it will be deemed to meet the conditions of participation:

(1) Except those specified in § 488.5;

(2) Provided that such hospital, if it is included within a validation survey, authorizes the JCAHO to release to CMS (on a confidential basis) upon request a copy of the most current JCAHO accreditation survey.

(c) Section 1864(c) of the Act authorizes the Secretary to enter into agreements with State survey agencies for the purpose of conducting validation surveys in hospitals accredited by the JCAHO. Section 1865(b) provides that an accredited hospital which is found after a validation survey to have significant deficiencies related to the health and safety of patients will no longer be deemed to meet the conditions of participation.

(d) Section 1865(a) of the Act also provides that if CMS finds that accreditation of a hospital; psychiatric hospital; SNF; HHA; hospice; ASC; RHC; CORF; laboratory; screening mammography service; critical access hospital; or clinic, rehabilitation agency, or public health agency provider of outpatient physical therapy, occupational therapy, or speech pathology services by any national accreditation organization provides reasonable assurance that any or all Medicare conditions are met, CMS may treat the provider or supplier as meeting the conditions.

[53 FR 22859, June 17, 1988, as amended at 56 FR 48879, Sept. 26, 1991; 58 FR 61842, Nov. 23, 1993; 62 FR 46037, Aug. 29, 1997]

§ 488.11 State survey agency functions.

State and local agencies that have agreements under section 1864(a) of the Act perform the following functions:

(a) Survey and make recommendations regarding the issues listed in § 488.10.

(b) Conduct validation surveys of accredited facilities as provided in § 488.7.

(c) Perform other surveys and carry out other appropriate activities and certify their findings to CMS.

(d) Make recommendations regarding the effective dates of provider agreements and supplier approvals in accordance with § 489.13 of this chapter.

[62 FR 43936, Aug. 18, 1997]

§ 488.12 Effect of survey agency certification.

Certifications by the State survey agency represent recommendations to CMS.

(a) On the basis of these recommendations, CMS will determine whether:

(1) A provider or supplier is eligible to participate in or be covered under the Medicare program; or

(2) An accredited hospital is deemed to meet the Medicare conditions of participation or is subject to full review by the State survey agency.

(b) Notice of CMS's determination will be sent to the provider or supplier.

§ 488.14 Effect of QIO review.

When a QIO is conducting review activities under section 1154 of the Act and part 466 of this chapter, its activities are in lieu of the utilization review and evaluation activities required of health care institutions under sections 1861(e)(6), and 1861(k) of the Act.

[59 FR 56237, Nov. 10, 1994]

§ 488.18 Documentation of findings.

(a) The findings of the State agency with respect to each of the conditions of participation, requirements (for SNFs and NFs), or conditions for coverage must be adequately documented. When the State agency certifies to the Secretary that a provider or supplier is not in compliance with the conditions or requirements (for SNFs and NFs), and therefore not eligible to participate in the program, such documentation includes, in addition to the description of the specific deficiencies which resulted in the agency's recommendation, any provider or supplier response.

(b) If a provider or supplier is certified by the State agency as in compliance with the conditions or participation requirements (for SNFs and NFs) or as meeting the requirements for special certification (see § 488.54), with deficiencies not adversely affecting the health and safety of patients, the following information will be incorporated into the finding:

(1) A statement of the deficiencies that were found.

(2) A description of further action that is required to remove the deficiencies.

(3) A time-phased plan of correction developed by the provider and supplier and concurred with by the State agency.

(4) A scheduled time for a resurvey of the institution or agency to be conducted by the State agency within 90 days following the completion of the survey.

(c) If, on the basis of the State certification, the Secretary determines that the provider or supplier is eligible to participate, the information described in paragraph (b) of this section will be incorporated into a notice of eligibility to the provider or supplier.

(d) If the State agency receives information to the effect that a hospital or a critical access hospital (as defined in section 1861(mm)(1) of the Act) has violated § 489.24 of this chapter, the State agency is to report the information to CMS promptly.

[39 FR 2251, Jan. 17, 1974. Redesignated at 39 FR 11419, Mar. 28, 1974, and further redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 53 FR 23100, June 17, 1988; 59 FR 32120, June 22, 1994; 59 FR 56237, Nov. 10, 1994; 62 FR 46037, Aug. 29, 1997]

EFFECTIVE DATE NOTE: At 59 FR 32120, June 22, 1994, in § 488.18, paragraph (d) was added. The amendment contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 488.20 Periodic review of compliance and approval.

(a) Determinations by CMS to the effect that a provider or supplier is in compliance with the conditions of participation, or requirements (for SNFs and NFs), or the conditions for coverage are made as often as CMS deems necessary and may be more or less than a 12-month period, except for SNFs, NFs and HHAs. (See § 488.308 for special rules for SNFs and NFs.)

(b) The responsibilities of State survey agencies in the review and certification of compliance are as follows:

(1) Resurvey providers or suppliers as frequently as necessary to ascertain compliance and confirm the correction of deficiencies;

(2) Review reports prepared by a Professional Standards Review Organization (authorized under Part B Title XI of the Act) or a State inspection of care team (authorized under Title XIX of the Act) regarding the quality of a facility's care;

(3) Evaluate reports that may pertain to the health and safety of patients; and

(4) Take appropriate actions that may be necessary to achieve compliance or certify noncompliance to CMS.

(c) A State survey agency certification to CMS that a provider or supplier is no longer in compliance with the conditions of participation or requirements (for SNFs and NFs) or conditions for coverage will supersede the State survey agency's previous certification.

(Secs. 1102, 1814, 1861, 1863 through 1866, 1871, and 1881; 42 U.S.C. 1302, 1395f, 1395x, 1395z through 1395cc, 1395hh, and 1395rr)

[45 FR 74833, Nov. 12, 1981. Redesignated and amended at 53 FR 23100, June 17, 1988, and further amended at 54 FR 5373, Feb. 2, 1989; 56 FR 48879, Sept. 26, 1991; 59 FR 56237, Nov. 10, 1994]

§ 488.24 Certification of noncompliance.

(a) Special rules for certification of noncompliance for SNFs and NFs are set forth in § 488.330.

(b) The State agency will certify that a provider or supplier is not or is no longer in compliance with the conditions of participation or conditions for coverage where the deficiencies are of such character as to substantially limit the provider's or supplier's capacity to furnish adequate care or which adversely affect the health and safety of patients; or

(c) If CMS determines that an institution or agency does not qualify for participation or coverage because it is not in compliance with the conditions of participation or conditions for coverage, or if a provider's agreement is terminated for that reason, the institution or agency has the right to request that the determination be reviewed. (Appeals procedures are set forth in Part 498 of this chapter.)

[59 FR 56237, Nov. 10, 1994]

§ 488.26 Determining compliance.

(a) Additional rules for certification of compliance for SNFs and NFs are set forth in § 488.330.

(b) The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition. Evaluation of a provider's or supplier's performance against these standards enables the State survey agency to document the nature and extent of deficiencies, if any, with respect to a particular function, and to assess the need for improvement in relation to the prescribed conditions.

(c) The State survey agency must adhere to the following principles in determining compliance with participation requirements:

(1) The survey process is the means to assess compliance with Federal health, safety and quality standards;

(2) The survey process uses resident outcomes as the primary means to establish the compliance status of facilities. Specifically surveyors will directly observe the actual provision of care and services to residents, and the effects of that care, to assess whether the care provided meets the needs of individual residents;

(3) Surveyors are professionals who use their judgment, in concert with Federal forms and procedures, to determine compliance;

(4) Federal procedures are used by all surveyors to ensure uniform and consistent application and interpretation of Federal requirements;

(5) Federal forms are used by all surveyors to ensure proper recording of findings and to document the basis for the findings.

(d) The State survey agency must use the survey methods, procedures, and forms that are prescribed by CMS.

(e) The State survey agency must ensure that a facility's actual provision of care and services to residents and the effects of that care on residents are assessed in a systematic manner.

[59 FR 56237, Nov. 10, 1994]

§ 488.28 Providers or suppliers, other than SNFs and NFs, with deficiencies.

(a) If a provider or supplier is found to be deficient with respect to one or more of the standards in the conditions of participation or conditions for coverage, it may participate in or be covered under the Health Insurance for the Aged and Disabled Program only if the facility has submitted an acceptable plan of correction for achieving compliance within a reasonable period of time acceptable to the Secretary.

(b) The existing deficiencies noted either individually or in combination neither jeopardize the health and safety of patients nor are of such character as to seriously limit the provider's capacity to render adequate care.

(c)(1) If it is determined during a survey that a provider or supplier is not in compliance with one or more of the standards, it is granted a reasonable time to achieve compliance.

(2) The amount of time depends upon the—

(i) Nature of the deficiency; and

(ii) State survey agency's judgment as to the capabilities of the facility to provide adequate and safe care.

(d) Ordinarily a provider or supplier is expected to take the steps needed to achieve compliance within 60 days of being notified of the deficiencies but the State survey agency may recommend that additional time be granted by the Secretary in individual situations, if in its judgment, it is not reasonable to expect compliance within 60 days, for example, a facility must obtain the approval of its governing body, or engage in competitive bidding.

[59 FR 56237, Nov. 10, 1994]

§ 488.30 Revisit user fee for revisit surveys.

(a) *Definitions.* As used in this section, the following definitions apply:

Certification (both initial and recertification) means those activities as defined in § 488.1.

Complaint surveys means those surveys conducted on the basis of a substantial allegation of noncompliance, as defined in § 488.1.

Provider of services, provider, or supplier has the meaning defined in § 488.1, and ambulatory surgical centers,

transplant centers, and religious nonmedical health care institutions subject to § 416.2, § 482.70, and § 403.702 [C8] of this chapter, respectively, will be subject to user fees unless otherwise exempted.

Revisit survey means a survey performed with respect to a provider or supplier cited for deficiencies during an initial certification, recertification, or substantiated complaint survey and that is designed to evaluate the extent to which previously-cited deficiencies have been corrected and the provider or supplier is in substantial compliance with applicable conditions of participation, requirements, or conditions for coverage. Revisit surveys include both offsite and onsite review.

Substantiated complaint survey means a complaint survey that results in the proof or finding of noncompliance at the time of the survey, a finding that noncompliance was proven to exist, but was corrected prior to the survey, and includes any deficiency that is cited during a complaint survey, whether or not the cited deficiency was the original subject of the complaint.

(b) *Criteria for determining the fee.* (1) The provider or supplier will be assessed a revisit user fee based upon one or more of the following:

(i) The average cost per provider or supplier type.

(ii) The type of revisit survey conducted (onsite or offsite).

(iii) The size of the provider or supplier.

(iv) The number of follow-up revisits resulting from uncorrected deficiencies.

(v) The seriousness and number of deficiencies.

(2) CMS may adjust the fees to account for any regional differences in cost.

(c) *Fee schedule.* CMS must publish in the FEDERAL REGISTER the proposed and final notices of a uniform fee schedule before it assesses revised revisit user fees. The notices must set forth which criteria will be used and how, as well as the amounts of the assessed fees based on the criteria as identified in paragraph (b) of this subpart.

(d) *Collection of fees.* (1) Fees for revisit surveys under this section may be deducted from amounts otherwise payable to the provider or supplier. As they are collected, fees will be deposited as an offset collection to be used exclusively for survey and certification activities conducted by State survey agencies pursuant to section 1864 of the Act or by CMS, and will be available for CMS until expended. CMS may devise other collection methods as it deems appropriate. In determining these methods, CMS will consider efficiency, effectiveness, and convenience for the providers, suppliers, and CMS. CMS may consider any method allowed by law, including: Credit card; electronic fund transfer; check; money order; and offset collections from claims submitted.

(2) Fees for revisit surveys under this section are not allowable items on a cost report, as identified in part 413, subpart B of this chapter, under title XVIII of the Act.

(3) Fees for revisit surveys will be due for any revisit surveys conducted during the time period for which authority to levy a revisit user fee exists.

(e) *Reconsideration process for revisit user fees.* (1) CMS will review a request for reconsideration of an assessed revisit user fee—

(i) If a provider or supplier believes an error of fact has been made in the application of the revisit user fee, such as clerical errors, billing for a fee already paid, or assessment of a fee when there was no revisit conducted, and

(ii) If the request for reconsideration is received by CMS within 14 calendar days from the date identified on the revisit user fee assessment notice.

(2) CMS will issue a credit toward any future revisit surveys conducted, if the provider or supplier has remitted an assessed revisit user fee and for which a reconsideration request is found in favor of the provider or supplier. If in the event that CMS judges that a significant amount of time has elapsed before such a credit is used, CMS will refund the assessed revisit user fee amount paid to the provider or supplier.

(3) CMS will not reconsider the assessment of revisit user fees that request reconsideration of the survey findings or deficiency citations that may have given rise to the revisit, the

revisit findings, the need for the revisit itself, or other similarly identified basis for the assessment of the revisit user fee.

(f) *Enforcement.* If the full revisit user fee payment is not received within 30 calendar days from the date identified on the revisit user fee assessment notice, CMS may terminate the facility's provider agreement (pursuant to § 489.53(a)(16) of this chapter) and enrollment in the Medicare program or the supplier's enrollment and participation in the Medicare program (pursuant to § 424.535(a)(1) of this chapter).

[72 FR 53648, Sept. 19, 2007]

Subpart B—Special Requirements

§ 488.52 [Reserved]

§ 488.54 Temporary waivers applicable to hospitals.

(a) *General provisions.* If a hospital is found to be out of compliance with one or more conditions of participation for hospitals, as specified in part 482 of this chapter, a temporary waiver may be granted by CMS. CMS may extend a temporary waiver only if such a waiver would not jeopardize or adversely affect the health and safety of patients. The waiver may be issued for any one year period or less under certain circumstances. The waiver may be withdrawn earlier if CMS determines this action is necessary to protect the health and safety of patients. A waiver may be granted only if:

(1) The hospital is located in a rural area. This includes all areas not delineated as ''urban'' by the Bureau of the Census, based on the most recent census;

(2) The hospital has 50 or fewer inpatient hospital beds;

(3) The character and seriousness of the deficiencies do not adversely affect the health and safety of patients; and

(4) The hospital has made and continues to make a good faith effort to comply with personnel requirements consistent with any waiver.

(b) *Minimum compliance requirements.* Each case will have to be decided on its individual merits, and while the degree and extent of compliance will vary, the institution must, as a minimum, meet all of the statutory conditions in section 1861(e)(1)–(8), in addition to meeting such other requirements as the Secretary finds necessary under section 1861(e)(9). (For further information relating to the exception in section 1861(e)(5) of the Act, see paragraph (c) of this section.)

(c) *Temporary waiver of 24-hour nursing requirement of 24-hour registered nurse requirement.* CMS may waive the requirement contained in section 1861(e)(5) that a hospital must provide 24-hour nursing service furnished or supervised by a registered nurse. Such a waiver may be granted when the following criteria are met:

(1) The hospital's failure to comply fully with the 24-hour nursing requirement is attributable to a temporary shortage of qualified nursing personnel in the area in which the hospital is located.

(2) A registered nurse is present on the premises to furnish or supervise the nursing services during at least the daytime shift, 7 days a week.

(3) The hospital has in charge, on all tours of duty not covered by a registered nurse, a licensed practical (vocational) nurse.

(4) The hospital complies with all requirements specified in paragraph (a) of this section.

(d) *Temporary waiver for technical personnel.* CMS may waive technical personnel requirements, issued under section 1861(e)(9) of the Act, contained in the Conditions of Participation; Hospitals (part 482 of this chapter). Such a waiver must take into account the availability of technical personnel and the educational opportunities for technical personnel in the area in which the hospital is located. CMS may also limit the scope of services furnished by a hospital in conjunction with the waiver in order not to adversely affect the health and safety of the patients. In addition, the hospital must also comply with all requirements specified in paragraph (a) of this section.

[39 FR 2251, Jan. 17, 1974. Redesignated at 39 FR 11419, Mar. 28, 1974, and amended at 41 FR 27962, July 8, 1976. Further redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 47 FR 31531, July 20, 1982; 51 FR 22041, June 17, 1986. Redesignated at 53 FR 23100, June 17, 1988]

§ 488.56 Temporary waivers applicable to skilled nursing facilities.

(a) *Waiver of 7-day registered nurse requirement.* To the extent that § 483.30 of this chapter requires any skilled nursing facility to engage the services of a registered nurse more than 40 hours a week, the Secretary may waive such requirement for such periods as he deems appropriate if, based upon documented findings of the State agency, he determines that:

(1) Such facility is located in a rural area and the supply of skilled nursing facility services in such area is not sufficient to meet the needs of individual patients therein,

(2) Such facility has at least one fulltime registered nurse who is regularly on duty at such facility 40 hours a week, and

(3) Such facility (i) has only patients whose attending physicians have indicated (through physicians' orders or admission notes) that each such patient does not require the services of a registered nurse for a 48-hour period, or (ii) has made arrangements for a registered nurse or a physician to spend such time at the facility as is determined necessary by the patient's attending physician to provide necessary services on days when the regular fulltime registered nurse is not on duty.

(4) Such facility has made and continues to make a good faith effort to comply with the more than 40-hour registered nurse requirement, but such compliance is impeded by the unavailability of registered nurses in the area.

(b) *Waiver of medical director requirement.* To the extent that § 488.75(i) of this chapter requires any skilled nursing facility to engage the services of a medical director either part-time or full-time, the Secretary may waive such requirement for such periods as he deems appropriate if, based upon documented findings of the State agency, he determines that:

(1) Such facility is located in an area where the supply of physicians is not sufficient to permit compliance with this requirement without seriously reducing the availability of physician services within the area, and

(2) Such facility has made and continues to make a good faith effort to comply with § 488.75(i) of this chapter, but such compliance is impeded by the unavailability of physicians in the area.

[39 FR 35777, Oct. 3, 1974. Redesignated and amended at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 53 FR 23100, June 17, 1988, and further amended at 56 FR 48879, Sept. 26, 1991; 57 FR 43925, Sept. 23, 1992]

§ 488.60 Special procedures for approving end stage renal disease facilities.

(a) *Consideration for approval.* An ESRD facility that wishes to be approved or that wishes an expansion of dialysis services to be approved for coverage, in accordance with part 494 of this chapter, must secure a determination by the Secretary. To secure a determination, the facility must submit the following documents and data for consideration by the Secretary:

(1) Certification by the State agency referred to in § 488.12 of this part.

(2) Data furnished by ESRD network organizations and recommendations of the Public Health Service concerning the facility's contribution to the ESRD services of the network.

(3) Data concerning the facility's compliance with professional norms and standards.

(4) Data pertaining to the facility's qualifications for approval or for any expansion of services.

(b) *Determining compliance with minimal utilization rates: Time limitations*—(1) *Unconditional status.* A facility which meets minimal utilization requirements will be assigned this status as long as it continues to meet these requirements.

(2) *Conditional status.* A conditional status may be granted to a facility for not more than four consecutive calendar years and will not be renewable (see § 405.2122(b) of this chapter). Its status may be examined each calendar year to ascertain its compliance with Subpart U.

(3) *Exception status.* Under unusual circumstances (see § 405.2122 (b) of this chapter) the Secretary may grant a time-limited exception to a facility which is not in compliance with the minimal utilization rate(s) for either unconditional status or conditional

status. This exception status may be granted, and may be renewed on an annual basis, under circumstances where rigid application of minimal utilization rate requirements would adversely affect the achievement of ESRD program objectives.

(c) *New applicant.* A facility which has not previously participated in the ESRD program must submit a plan detailing how it expects to meet the conditional minimal utilization rate status by the end of the second calendar year of its operation under the program and meet the unconditional minimal utilization rate status by the end of the fourth calendar year of its operation under the program.

(d) *Notification.* The Secretary will notify each facility and its network coordinating council of its initial and its subsequent minimal utilization rate classification.

(e) *Failure to meet minimal utilization rate.* A facility failing to meet standards for unconditional status or conditional status, or if applicable, for exception status, will be so notified at the time of such classification.

(f) *Interim regulations participant.* A facility previously participating under the interim regulations will not be approved under the program established by subpart U until it has demonstrated that it meets all the applicable requirements of this subpart, including the appropriate minimal utilization rate. It may continue under the interim program only for a period not to exceed 1 year from the effective date of these amendments (see § 405.2100(c) of this chapter). During this period it may demonstrate its ability to meet the appropriate minimal utilization rate. Failure to qualify under this subpart will automatically terminate coverage of such facility's services under the ESRD program at the end of such year.

[41 FR 22510, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and further amended at 45 FR 58124, Sept. 2, 1980. Redesignated and amended at 53 FR 23100, June 17, 1988; 73 FR 20474, Apr. 15, 2008]

§ 488.61 Special procedures for approval and re-approval of organ transplant centers.

For the purposes of this subpart, the survey, certification, and enforcement procedures described at 42 CFR part 488, subpart A apply to transplant centers, including the periodic review of compliance and approval described at § 488.20.

(a) *Initial approval procedures for transplant centers that are not Medicare-approved as of June 28, 2007.* A transplant center, including a kidney transplant center, may submit a request to CMS for Medicare approval at any time.

(1) The request, signed by a person authorized to represent the center (for example, a chief executive officer), must include:

(i) The hospital's Medicare provider I.D. number;

(ii) Name(s) of the designated primary transplant surgeon and primary transplant physician; and,

(iii) A statement from the OPTN that the center has complied with all data submission requirements.

(2) To determine compliance with the clinical experience and outcome requirements at §§ 482.80(b) and 482.80(c), CMS will review the data contained in the most recent OPTN Data Report and 1-year patient and graft survival data contained in the most recent Scientific Registry of Transplant Recipient (SRTR) center-specific report.

(3) If CMS determines that a transplant center has not met the data submission, clinical experience, or outcome requirements, CMS may deny the request for approval or may review the center's compliance with the conditions of participation at §§ 482.72 through 482.76 and §§ 482.90 through 482.104 of this chapter, using the procedures described at 42 CFR part 488, subpart A, to determine whether the center's request will be approved. CMS will notify the transplant center in writing whether it is approved and, if approved, of the effective date of its approval.

(4) CMS will consider mitigating factors, including (but not limited to) the following in considering initial approval of a transplant center that does not meet the data submission, clinical

experience, outcome requirements and other conditions of participation:

(i) The extent to which outcome measures are met or exceeded;

(ii) Availability of Medicare-approved transplant centers in the area; and

(iii) Extenuating circumstances (e.g., natural disaster) that may have a temporary effect on meeting the conditions of participation.

(iv) CMS will not approve any program with a condition-level deficiency. However, CMS may approve a program with a standard-level deficiency upon receipt of an acceptable plan of correction.

(5) If CMS determines that a transplant center has met the data submission, clinical experience, and outcome requirements, CMS will review the center's compliance with the conditions of participation contained at §§ 482.72 through 482.76 and §§ 482.90 through 482.104 of this chapter using the procedures described at 42 CFR part 488, subpart A. If the transplant center is found to be in compliance with all the conditions of participation at §§ 482.72 through 482.104, except for § 482.82 of this chapter (Re-approval Requirements), CMS will notify the transplant center in writing of the effective date of its Medicare-approval. CMS will notify the transplant center in writing if it is not Medicare-approved.

(6) A kidney transplant center may submit a request for initial approval after performing at least 3 transplants over a 12-month period.

(7) Transplant centers will be approved for 3 years.

(b) *Initial approval procedures for transplant centers, including kidney transplant centers, that are Medicare approved as of June 28, 2007.* (1) A transplant center that wants to continue to be Medicare approved must be in compliance with the conditions of participation at §§ 482.72 through 482.104 as of June 28, 2007 and submit a request to CMS for Medicare approval under the conditions of participation no later than December 26, 2007, using the process described in paragraph (a)(1) of the section.

(2) CMS will determine whether to approve the transplant center, using the procedures described in paragraphs (a)(2) through (a)(5) of this section. Until CMS makes a determination whether to approve the transplant center under the conditions of participation at §§ 482.72 through 482.104, the transplant center will continue to be Medicare approved under the end stage renal disease (ESRD) conditions for coverage (CfCs) in part 405, subpart U of this chapter for kidney transplant centers or the pertinent national coverage decisions (NCDs) for extra-renal organ transplant centers, as applicable, and the transplant center will continue to be reimbursed for services provided to Medicare beneficiaries.

(3) Once CMS approves a kidney transplant center under the conditions of participation, the ESRD CfCs no longer apply to the center as of the date of its approval. Once CMS approves an extra-renal organ transplant center under the conditions of participation, the NCDs no longer apply to the center as of the date of its approval.

(4) If a transplant center that is Medicare approved as of June 28, 2007 submits a request for approval under the CoPs at §§ 482.72 through 482.104 of this chapter but CMS does not approve the transplant center, or if the transplant center does not submit its request to CMS for Medicare approval under the CoPs by December 26, 2007, CMS will revoke the transplant center's approval under the conditions for coverage for kidney transplant centers or the national coverage decisions for extra-renal transplant centers, as applicable, and the transplant center will no longer be reimbursed for services provided to Medicare beneficiaries. CMS will notify the transplant center in writing of the effective date of its loss of Medicare approval.

(c) *Re-approval procedures.* Once Medicare-approved, transplant centers, including kidney transplant centers, must be in compliance with all the conditions of participation for transplant centers at §§ 482.72 through 482.104 of this chapter, except for § 482.80 (initial approval requirements) throughout the 3-year approval period.

(1) Prior to the end of the 3-year approval period, CMS will review the transplant center's data in making re-approval determinations.

(i) To determine compliance with the data submission requirements at § 482.82(a) of this chapter, CMS will request data submission data from the OPTN for the previous 3 calendar years.

(ii) To determine compliance with the clinical experience and outcome requirements at § 482.82(b) and § 482.82(c) of this chapter, CMS will review the data contained in the most recent OPTN Data Report and 1-year patient and graft survival data contained in the most recent SRTR center-specific reports.

(2) If CMS determines that a transplant center has not met the data submission, clinical experience, or outcome requirements at § 482.82, the transplant center will be reviewed for compliance with §§ 482.72 through 482.76 and §§ 482.90 through 482.104 of this chapter, using the procedures described at 42 CFR part 488, subpart A.

(3) If CMS determines that a transplant center has met the data submission, clinical experience, and outcome requirements at § 482.82, CMS may choose to review the transplant center for compliance with §§ 482.72 through 482.76 and §§ 482.90 through 482.104 of this chapter, using the procedures described at 42 CFR part 488, subpart A.

(4) CMS will consider mitigating factors, including (but not limited to) the following in considering re-approval of a transplant center that does not meet the data submission, clinical experience, outcome requirements and other conditions of participation:

(i) The extent to which outcome measures are met or exceeded;

(ii) Availability of Medicare-approved transplant centers in the area; and

(iii) Extenuating circumstances (*e.g.*, natural disaster) that may have a temporary effect on meeting the conditions of participation.

(iv) CMS will not approve any program with a condition-level deficiency. However, CMS may re-approve a program with a standard-level deficiency upon receipt of an acceptable plan of correction.

(5) CMS will notify the transplant center in writing if its approval is being revoked and of the effective date of the revocation.

(d) *Loss of Medicare Approval.* Centers that have lost their Medicare approval may seek re-entry into the Medicare program at any time. A center that has lost its Medicare approval must:

(1) Request initial approval using the procedures described in § 488.61(a);

(2) Be in compliance with §§ 482.72 through 482.104 of this chapter, except for § 482.82 (Re-approval Requirements), at the time of the request for Medicare approval; and

(3) Submit a report to CMS documenting any changes or corrective actions taken by the center as a result of the loss of its Medicare approval status.

(e) *Transplant Center Inactivity.* A transplant center may remain inactive and retain its Medicare approval for a period not to exceed 12 months during the 3-year approval cycle. A transplant center must notify CMS upon its voluntary inactivation as required by § 482.74(d) of this chapter.

[72 FR 15278, Mar. 30, 2007]

§ 488.64 Remote facility variances for utilization review requirements.

(a) As used in this section:

(1) An ''available'' individual is one who:

(i) Possesses the necessary professional qualifications;

(ii) Is not precluded from participating by reason of financial interest in any such facility or direct responsibility for the care of the patients being reviewed or, in the case of a skilled nursing facility, employment by the facility; and

(iii) Is not precluded from effective participation by the distance between the facility and his residence, office, or other place of work. An individual whose residence, office, or other place of work is more than approximately one hour's travel time from the facility shall be considered precluded from effective participation.

(2) ''Adjacent facility'' means a health care facility located within a 50-mile radius of the facility which requests a variance.

(b) The Secretary may grant a requesting facility a variance from the time frames set forth in §§ 405.1137(d) of this chapter and 482.30 as applicable, within which reviews all of cases must

be commenced and completed, upon a showing satisfactory to the Secretary that the requesting facility has been unable to meet one or more of the requirements of § 405.1137 of this chapter or § 482.30 of this chapter, as applicable, by reason of insufficient medical and other professional personnel available to conduct the utilization review required by § 405.1137 of this chapter or § 482.30 of this chapter, as applicable.

(c) The request for variance shall document the requesting facility's inability to meet the requirements for which a variance is requested and the facility's good faith efforts to comply with the requirements contained in § 405.1137 of this chapter or § 482.30 of this chapter, as applicable.

(d) The request shall include an assurance by the requesting facility that it will continue its good faith efforts to meet the requirements contained in § 405.1137 of this chapter or § 482.30 of this chapter, as applicable.

(e) A revised utilization review plan for the requesting facility shall be submitted concurrently with the request for a variance. The revised plan shall specify the methods and procedures which the requesting facility will use, if a variance is granted, to assure:

(1) That effective and timely control will be maintained over the utilization of services; and

(2) That reviews will be conducted so as to improve the quality of care provided to patients.

(f) The request for a variance shall include:

(1) The name, location, and type (e.g., hospital, skilled nursing facility) of the facility for which the variance is requested;

(2) The total number of patient admissions and average daily patient census at the facility within the previous six months;

(3) The total number of title XVIII and title XIX patient admissions and the average daily patient census of title XVIII and title XIX patients in the facility within the previous six months;

(4) As relevant to the request, the names of all physicians on the active staff of the facility and the names of all other professional personnel on the staff of the facility, or both;

(5) The name, location, and type of each adjacent facility (e.g., hospital, skilled nursing facility);

(6) The distance and average travel time between the facility and each adjacent facility;

(7) As relevant to the request, the location of practice of available physicians and the estimated number of other available professional personnel, or both (see paragraph (a)(1)(iii) of this section);

(8) Documentation by the facility of its attempt to obtain the services of available physicians or other professional personnel, or both; and

(9) A statement of whether a QIO exists in the area where the facility is located.

(g) The Secretary shall promptly notify the facility of the action taken on the request. Where a variance is in effect, the validation of utilization review pursuant to § 405.1137 of this chapter or § 482.30 shall be made with reference to the revised utilization review plan submitted with the request for variance.

(h) The Secretary, in granting a variance, will specify the period for which the variance has been granted; such period will not exceed one year. A request for a renewal shall be submitted not later than 30 days prior to the expiration of the variance and shall contain all information required by paragraphs (c), (d), and (f) of this section. Renewal of the variance will be contingent upon the facility's continuing to meet the provisions of this section.

[40 FR 30818, July 23, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977; 51 FR 22041, June 17, 1986; 51 FR 27847, Aug. 4, 1986; 51 FR 43197, Dec. 1, 1986. Redesignated and amended at 53 FR 23100, June 17, 1988]

§ 488.68 State Agency responsibilities for OASIS collection and data base requirements.

As part of State agency survey responsibilities, the State agency or other entity designated by CMS has overall responsibility for fulfilling the following requirements for operating the OASIS system:

(a) *Establish and maintain an OASIS database*. The State agency or other entity designated by CMS must—

(1) Use a standard system developed or approved by CMS to collect, store, and analyze data;

(2) Conduct basic system management activities including hardware and software maintenance, system back-up, and monitoring the status of the database; and

(3) Obtain CMS approval before modifying any parts of the CMS standard system including, but not limited to, standard CMS-approved—

(i) OASIS data items;

(ii) Record formats and validation edits; and

(iii) Agency encoding and transmission methods.

(b) *Analyze and edit OASIS data.* The State agency or other entity designated by CMS must—

(1) Upon receipt of data from an HHA, edit the data as specified by CMS and ensure that the HHA resolves errors within the limits specified by CMS;

(2) At least monthly, make available for retrieval by CMS all edited OASIS records received during that period, according to formats specified by CMS, and correct and retransmit previously rejected data as needed; and

(3) Analyze data and generate reports as specified by CMS.

(c) *Ensure accuracy of OASIS data.* The State agency must audit the accuracy of the OASIS data through the survey process.

(d) *Restrict access to OASIS data.* The State agency or other entity designated by CMS must do the following:

(1) Ensure that access to data is restricted except for the transmission of data and reports to—

(i) CMS;

(ii) The State agency component that conducts surveys for purposes related to this function; and

(iii) Other entities if authorized by CMS.

(2) Ensure that patient identifiable OASIS data is released only to the extent that it is permitted under the Privacy Act of 1974.

(e) *Provide training and technical support for HHAs.* The State agency or other entity designated by CMS must—

(1) Instruct each HHA on the administration of the data set, privacy/confidentiality of the data set, and integration of the OASIS data set into the facility's own record keeping system;

(2) Instruct each HHA on the use of software to encode and transmit OASIS data to the State;

(3) Specify to a facility the method of transmission of data to the State, and instruct the facility on this method.

(4) Monitor each HHA's ability to transmit OASIS data.

(5) Provide ongoing technical assistance and general support to HHAs in implementing the OASIS reporting requirements specified in the conditions of participation for home health agencies; and

(6) Carry out any other functions as designated by CMS necessary to maintain OASIS data on the standard State system.

[64 FR 3763, Jan. 25, 1999]

SUBPART C—SURVEY FORMS AND PROCEDURES

§ 488.100 Long term care survey forms, Part A.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

PART A — ADMINISTRATIVE AND PROCEDURAL REQUIREMENTS

MEDICARE / MEDICAID SKILLED NURSING FACILITY AND INTERMEDIATE CARE FACILITY SURVEY REPORT

PROVIDER NUMBER	FACILITY NAME AND ADDRESS (*City, State, Zip Code*)
VENDOR NUMBER	
SURVEY DATE	

SURVEYORS' NAMES	TITLES

Form HCFA-525 (2-86)

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NAME OF FACILITY

CODE	COMPLIANCE WITH STATE AND LOCAL LAWS	YES	NO	N/A	EXPLANATORY STATEMENT
	Compliance with State and Local Laws *(Condition of Participation)*				
F500	SNF (405.1120) ☐ MET ☐ NOT MET				
	A. **Licensure**				
F501	SNF (405.1120(a)) (Standard) ☐ MET ☐ NOT MET				
F502	ICF (442.251) (Standard) ☐ MET ☐ NOT MET				
F503	The facility has a current State License (Number _____)				
	B. **Personnel Licensure**				
F504	SNF (405.1120(b)) (Standard) ☐ MET ☐ NOT MET				
F505	ICF (442.302) (Standard) ☐ MET ☐ NOT MET				
F506	Staff of the facility are licensed or registered in accordance with applicable State laws.				
	C. **Compliance with Other Laws**				
F507	SNF (405.1120(c)) (Standard) ☐ MET ☐ NOT MET				
F508	ICF (442.252) (Standard) ☐ MET ☐ NOT MET				
F509	ICF (442.315) (Standard) ☐ MET ☐ NOT MET				
F510	The facility is in compliance with applicable Federal, State and local laws and regulations relating to fire and safety, sanitation, communicable and reportable diseases, postmortem procedures and other relevant health and safety requirements.				

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NAME OF FACILITY

CODE	COMPLIANCE WITH STATE AND LOCAL LAWS/ GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	The facility is in compliance with applicable regulations pertaining to:				
F511	Buying, dispensing, safeguarding, administering, and disposing of medications and controlled substances. **Exception: Not applicable to SNFs.**				
F512	Construction, maintenance and equipment. **Exception: Not applicable to SNFs.**				
F513	Current reports from all responsible governmental agencies are retained at the facility.				
	Governing Body and Management ***(Condition of Participation)***				
F514	SNF (405.1121) ☐ MET ☐ NOT MET The facility has a governing body with full legal authority and responsibility for operation of the facility.				
	A. **Disclosure**				
F515	SNF (405.1121(a)) (Standard) ☐ MET ☐ NOT MET Full disclosure of ownership has been made in accordance with requirements at 42 CFR 420.206.				
	B. **Administration**				
F516	SNF (405.1121(c)) (Standard) ☐ MET ☐ NOT MET				
F517	1. Written bylaws address the operation of the facility.				
F518	2. Written bylaws and policies address effective resident care.				
F519	3. Bylaws are reviewed and revised as necessary.				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F520	ICF (442.301) (Standard) ☐ MET ☐ NOT MET				
	C. **Independent Medical Review**				
F521	SNF (405.1121(d)) (Standard) ☐ MET ☐ NOT MET The facility has policies which ensure that the facility cooperates in an effective program for regular independent medical evaluation and audit of residents in the facility to the extent required by the programs in which the facility participates.				
	D. **Administrator**				
F522	SNF (405.1121(e)) (Standard) ☐ MET ☐ NOT MET				
F523	ICF (442.303) (Standard) ☐ MET ☐ NOT MET				
F524	The facility has a licensed administrator who has authority for the overall operation of the facility. (Administrator's license or registration number _____).				
	E. **Resident Care Director**				
F525	ICF (442.304) (Standard) ☐ MET ☐ NOT MET				
F526	1. The administrator or another professional staff member is the resident care director (RSD).				
F527	2. The RSD coordinates and monitors each resident's care.				

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NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	F. Institutional Planning				
F528	SNF (405.1121(f)) (Standard) ☐ MET ☐ NOT MET				
F529	1. The facility has an overall plan and budget prepared by a committee of representatives from the governing body, administrative staff, and the organized medical staff (if any).				
F530	2. The overall plan and budget is reviewed and updated at least annually.				
F531	3. The plan includes a capital expenditures plan, if necessary.				
	G. Personnel Policies and Procedures				
F532	SNF (405.1121(g)) (Standard) ☐ MET ☐ NOT MET				
	1. The facility has written policies and procedures that support sound resident care and personnel practices and address, at least:				
F533	a. Control of communicable disease;				
F534	b. The review of employee incidents and accidents to identify health and safety hazards; and				
F535	c. The existence of a safe and sanitary environment.				
F536	2. Personnel records are current, available to each employee, and contain sufficient information to support placement in the position to which assigned.				
F537	3. Referral or provision for periodic health examinations to ensure freedom from communicable disease.				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	H. **Outside Resources/Consultant Agreements**				
F538	SNF (405.1121(i)) (Standard) ☐ MET ☐ NOT MET				
F539	ICF (442.317) (Standard) ☐ MET ☐ NOT MET				
F540	The facility has written agreements with qualified persons to render a service (if it does not employ a qualified professional person to do so). The agreements:				
F541	1. Address the responsibilities, functions, objectives, and terms (including financial arrangements and charges);				
F542	2. Are signed by an authorized representative of the facility and the outside resource; and				
F543	3. Specify that the facility retains ultimate responsibility for the services rendered.				
	I. **Notification of Change in Resident Status**				
F544	SNF (405.1121(j)) (Standard) ☐ MET ☐ NOT MET				
F545	The facility has policies and procedures to notify physicians and other responsible persons in the event of an accident involving the resident, or resident's physical, mental or emotional status, or resident charges, billings or related administrative matter.				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	J. Resident Rights				
F546	SNF (405.1121(k)) (Standard) ☐ MET ☐ NOT MET **Indicators 1 thru 12 apply to SNFs.**				
F547	ICF (442.311) (Standard) ☐ MET ☐ NOT MET				
	1. Information				
F548	a. The facility informs each resident, before or at the time of admission, of his rights and responsibilities.				
F549	b. The facility informs each resident, before or at the time of admission, of all rules governing resident conduct.				
F550	c. The facility informs each resident of amendments to their policies on residents' rights and responsibilities and rules governing conduct.				
F551	d. Each resident acknowledges in writing receipt of residents' rights information and any amendment to it.				
F552	e. The resident must be informed in writing of all services and charges for services.				
F553	f. The resident must be informed in writing of all changes in services and charges before or at the time of admission and on a continuing basis.				
F554	g. The resident must be informed of services not covered by Medicare or Medicaid in the basic rate.				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	2. **Medical Condition and Treatment**				
F555	a. Each resident is informed by a physician of his health and medical condition unless the physician decides that informing the resident is medically contraindicated.				
F556	b. Each resident is given an opportunity to participate in planning his total care and medical treatment.				
F557	c. Each resident is given an opportunity to refuse treatment.				
F558	d. Each resident gives informed, written consent before participating in experimental research.				
F559	e. If the physician decides that informing the resident of his health and medical condition is medically contraindicated, the physician has documented this decision in the resident's medical record.				
	3. **Transfer and Discharge**				
	Each resident is transferred or discharged only for:				
F560	a. Medical reasons.				
F561	b. His/her welfare or that of other residents.				
F562	c. Nonpayment except as prohibited by the Medicare or Medicaid program.				
	4. **Exercising Rights**				
F563	a. Each resident is encouraged and assisted to exercise his/her rights as a resident of the facility and as a citizen.				
F564	b. Each resident is allowed to submit complaints and recommendations concerning the policies and services of the facility to staff or to outside representatives of the resident's choice or both.				
F565	c. Such complaints are submitted free from restraint, coercion, discrimination, or reprisal.				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	5. **Financial Affairs**				
F566	a. Residents are allowed to manage their own personal financial affairs.				
F567	b. The facility establishes and maintains a system that assures full and complete accounting of residents' personal funds. An accounting report is made to residents in skilled nursing facilities at least on a quarterly basis.				
F568	c. The facility does not commingle resident funds with any other funds other than resident funds.				
F569	d. If a resident requests assistance from the facility in managing his personal financial affairs, resident's delegation is in writing.				
	e. The facility system of accounting includes written receipts for:				
F570	1. All personal possessions and funds received by or deposited with the facility.				
F571	2. All disbursement made to or for the resident.				
F572	f. The financial record must be available to the resident and his/her family.				
	6. **Freedom from Abuse and Restraints**				
F573	a. Each resident is free from mental and physical abuse.				
F574	b. Chemical and physical restraints are only used when authorized by a physician in writing for a specified period of time or in emergencies.				
F575	c. If used in emergencies, they are necessary to protect the resident from injury to himself or others.				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F576	d. The use is authorized by a professional staff member identified in the written policies and procedures of the facility.				
F577	e. The use is reported promptly to the resident's physician by the staff member.				
	7. **Privacy**				
F578	a. Each resident is treated with respect, consideration and full recognition of his/her dignity and individuality.				
F579	b. Each resident is given privacy during treatment and care of personal needs.				
F580	c. Each resident's records, including information in an automated data bank, are treated confidentially.				
F581	d. Each resident must give written consent before the facility releases information from his/her record to someone not otherwise authorized to receive it.				
F582	e. Married residents are given privacy during visits by their spouses.				
F583	f. Married residents are permitted to share a room.				
	8. **Work**				
F584	No resident may be required to perform services for the facility.				
	9. **Freedom of Association and Correspondence**				
F585	a. Each resident is allowed to communicate, associate and meet privately with individuals of his choice unless this infringes upon the rights of another resident.				
F586	b. Each resident is allowed to send and receive personal mail unopened.				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	10. **Activities**				
F587	Each resident is allowed to participate in social, religious, and community group activities.				
	11. **Personal Possessions**				
F588	Each resident is allowed to retain and use his personal possessions and clothing as space permits.				
	12. **Written Policies and Procedures: Delegation of Rights and Responsibilities**				
F589	ICF (442.312) (Standard) ☐ MET ☐ NOT MET				
F590	a. The facility has written policies and procedures that provide that all the rights and responsibilities of a resident pass to the resident's guardian, next of kin or sponsoring agency or agencies if the resident is adjudicated incompetent under State law or is determined by his physician to be incapable of understanding his rights and responsibilities.				
F591	b. Physician determinations of incapability and the specific reasons thereof are recorded by the physician in the resident's record.				
	K. **Resident Care Policies**				
F592	SNF (405.1121(l)) (Standard) ☐ MET ☐ NOT MET				
F593	1. The facility has written policies to govern the continuing skilled nursing care and related medical or other services provided.				
F594	2. These policies reflect awareness of and provision for meeting the total medical and psychosocial needs of residents including admission, transfer, discharge planning, and the range of services available to residents; and				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F595	3. The protection of residents' personal and property rights.				
F596	4. The policies are developed by a group of professional personnel, including the Medical Director or the organized medical staff, and are periodically reviewed and revised (if necessary).				
F597	5. These policies are available to admitting physicians, sponsoring agencies, residents, and the public.				
F598	6. The Medical Director or a registered nurse is designated as responsible for the execution of the policies.				
	L. **Public Availability**				
F599	ICF (442.305) (Standard) ☐ MET ☐ NOT MET				
F600	1. The facility has written policies and procedures governing all the services it provides.				
F601	2. The policies and procedures are available to the staff and residents, members of the family, the public, and legal representatives of residents.				
	M. **Admissions**				
F602	ICF (442.306) (Standard) ☐ MET ☐ NOT MET				
	The facility has written policies and procedures that ensure that it admits as residents only those residents whose needs can be met by:				
F603	1. the facility itself.				
F604	2. the facility in cooperation with community resources.				
F605	3. the facility in cooperation with other providers of care affiliated with or under contract to the facility.				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	N. Transfers				
F606	ICF (442.307) (Standard) ☐ MET ☐ NOT MET				
F607	1. The facility has written policies and procedures to ensure that residents are transferred promptly to a hospital, SNF or other appropriate facility when a change is necessary.				
F608	2. Except in emergencies, the facility consults the resident, his next of kin, the attending physician, and the responsible agency, if any, at least five days before discharge.				
F609	3. The facility uses casework services and other means to ensure that adequate arrangements are made to meet resident's needs through other resources.				
	O. Restraints				
F610	ICF (442.308) (Standard) ☐ MET ☐ NOT MET				
	The facilty has written policies and procedures that:				
F611	1. Define the uses of chemical and physical restraints.				
F612	2. Identify the professional personnel who may authorize the use of restraints in emergencies under 442.311(f).				
F613	3. Describe procedures for monitoring and controlling the use of these restraints.				
	P. Complaints				
F614	ICF (442.309) (Standard) ☐ MET ☐ NOT MET				
	The facility has written policies and procedures that:				
F615	1. Describe the procedures the facility uses to receive complaints and recommendations from residents.				
F616	2. Ensure that the facility responds to complaints and recommendations.				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	Q. Staff Development				
F617	SNF (405.1121(h)) (Standard) ☐ MET ☐ NOT MET				
F618	ICF (442.314) (Standard) ☐ MET ☐ NOT MET				
F619	1. The facility conducts an orientation program for all new employees that includes a review of all its policies.				
F620	2. The facility plans and conducts an inservice staff development program for all personnel to assist them in developing and improving their skills.				
F621	3. The facility maintains a record of the orientation and staff development programs it conducts.				
F622	4. The record includes the content of the program and the names of participants.				
F623	5. Inservice training includes at least prevention and control of infections, fire prevention and safety, confidentiality of resident information, and preservation of resident dignity including protection of resident's privacy and personal and property rights.				

NAME OF FACILITY

CODE	MEDICAL DIRECTION	YES	NO	N/A	EXPLANATORY STATEMENT
	Medical Direction *(Condition of Participation)*				
F624	SNF (405.1122) ☐ MET ☐ NOT MET The facility has a written agreement with a licensed physician to serve as Medical Director on a part-time or full-time basis as is appropriate to the needs of the residents and the facility. (See 405.1911(b) regarding waiver of this requirement.)				
	A. **Coordination of Medical Care**				
F625	SNF (405.1122(a)) (Standard) ☐ MET ☐ NOT MET				
F626	1. Medical direction and coordination of medical care in the facility are provided by a Medical Director.				
F627	2. The Medical Director is responsible for development of policies approved by the governing body.				
F628	3. Coordination of medical care includes liaison with attending physicians to ensure their writing orders promptly upon admission of a resident, and periodic evaluation of the adequacy and appropriateness of health professional and supportive staff and services.				
	B. **Responsibilities to the Facility**				
F629	SNF (405.1122(b)) (Standard) ☐ MET ☐ NOT MET				
F630	1. The Medical Director is responsible for surveillance of the health status of the facility's employees.				
F631	2. Incidents and accidents that occur on the premises are reviewed by the Medical Director to identify hazards to health and safety.				

NAME OF FACILITY

CODE	PHYSICIAN SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	Physician Services *(Condition of Participation)*				
F632	SNF (405.1123) ☐ MET ☐ NOT MET Residents in need of skilled or rehabilitative care are admitted to the facility only upon the recommendation of, and remain under the care of, a physician. To the extent feasible, each resident designates a personal physician.				
	A. **Physician Supervision**				
F633	SNF (405.1123(b)) (Standard) ☐ MET ☐ NOT MET				
F634	ICF (442.346) (Standard) ☐ MET ☐ NOT MET				
F635	1. The facility has a policy that the health care of every resident must be under the supervision of a physician.				
F636	2. All attending physicians must make arrangements for the medical care of their residents in their absence.				
	B. **Emergency Services**				
F637	SNF (405.1123(c)) (Standard) ☐ MET ☐ NOT MET The facility has written procedures available at each nurses' station, that provide for having a physician available to furnish necessary medical care in case of emergency.				

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NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	Nursing Services *(Condition of Participation)*				
F638	SNF (405.1124) ☐ MET ☐ NOT MET The facility provides 24-hour service by licensed nurses, including the services of a registered nurse at least during the day tour of duty, 7 days a week. There is an organized nursing service with a sufficient number of qualified nursing personnel to meet the total nursing needs of all residents (See 405.1911(a) regarding waiver of the 7-day registered nurse requirement).				
F639	ICF (442.342) (Standard) ☐ MET ☐ NOT MET The facility provides nursing care as needed including restorative nursing care.				
	A. **Director of Nursing Services**				
F640	SNF (405.1124(a)) (Standard) ☐ MET ☐ NOT MET				
F641	1. The director of nursing services is a qualified registered nurse employed full-time.				
F642	2. The director of nursing services has, in writing, administrative authority, responsibility, and accountability for the functions, activities, and training of the nursing services staff, and serves only one facility in this capacity.				
F643	3. If the director of nursing services has other institutional responsibilities, a qualified registered nurse serves as assistant so that there is the equivalent of a full-time director of nursing services on duty.				

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	B. **Health Services Supervision**				
F644	ICF (442.339) (Standard) ☐ MET ☐ NOT MET				
F645	1. The facility has a full-time registered nurse, or a licensed practical or vocational nurse to supervise the health services 7 days a week on the day shift.				
F646	2. The nurse has a current State license.				
F647	3. If the supervisor of health services is a licensed practical or vocational nurse, the facilty has a formal contract with a registered nurse to serve as a consultant no less than 4 hours a week.				
F648	4. To qualify to serve as a health services supervisor, a licensed practical or vocational nurse must: a. Have graduated from a State-approved school of practical nursing, or				
F649	b. Have education or other training that the State authority responsible for licensing practical nurses considered equal to graduation from a State-approved school of practical nursing, or				
F650	c. Have passed the Public Health Service examination for waivered licensed practical or vocational nurses.				
F651	5. If the nurse in charge is licensed by the State in a category other than registered nurse or licensed practical or vocational nurse: a. The individual has completed a training program to get the license that includes at least the same number of classroom and practice hours in all nursing subjects as in the program of a State-approved school of practical or vocational nursing, and				

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NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F652	b. The State agency responsible for licensing the individual submits a report to the Medicaid agency comparing State-licensed practical nurse or vocational nurse course requirements with those for the program completed by the individual.				
	C. **Twenty-four Hour Nursing Service**				
F653	SNF (405.1124(c)) (Standard) ☐ MET ☐ NOT MET				
F654	ICF (442.338) (Standard) ☐ MET ☐ NOT MET				
F655	1. 24-Hour Nursing Nursing policies and procedures address the total nursing needs of the residents.				
F656	The policies are designed to ensure that each resident receives: Treatment.				
F657	Medications as prescribed.				
F658	Diet as prescribed.				
F659	Rehabilitative nursing care as needed.				
F660	Proper care to prevent decubitus ulcers and deformities.				
F661	Proper care to ensure that residents are clean, well-groomed and comfortable.				
F662	Protection from accident and injury.				
F663	Protection from infection.				
F664	Encouragement, assistance, and training in self-care and group activities.				

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F665	2. Weekly time schedules are maintained and indicate the number and classifications of nursing personnel including relief personnel, who worked on each unit for each tour of duty.				
	D. **Rehabilitative Nursing Care**				
F666	SNF (405.1124(e)) (Standard) ☐ MET ☐ NOT MET				
F667	Nursing personnel are trained in rehabilitative nursing.				
	E. **Supervision of Resident Nutrition**				
F668	SNF (405.1124(f)) (Standard) ☐ MET ☐ NOT MET				
F669	A procedure is established to inform dietetic service of physicians' diet orders and of residents' dietetic problems.				
	F. **Administration of Drugs**				
F670	SNF (405.1124(g)) (Standard) ☐ MET ☐ NOT MET				
F671	Procedures are established by the Pharmaceutical Services Committee (see 405.1127(d)) to ensure that drugs are checked against physicians' orders.				
	G. **Conformance with Physicians' Drug Orders**				
F672	SNF (405.1124(h)) (Standard) ☐ MET ☐ NOT MET **Indicators 1 thru 4 apply to SNFs.**				
F673	ICF (442.335) (Standard) ☐ MET ☐ NOT MET				
F674	1. Drugs not specifically limited as to time or number of doses when ordered are controlled by automatic stop orders or other methods in accordance with written policies.				

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NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F675	2. The attending physician is notified of an automatic stop order prior to the last dose so that the physician may decide if the administration of the drug or biological is to be continued or altered.				
F676	ICF (442.334) (Standard) ☐ MET ☐ NOT MET				
F677	3. Physicians' verbal orders for drugs are given only to a licensed nurse, pharmacist, or physician and are immediately recorded and signed by the person receiving the order. (Verbal orders for Schedule II drugs are permitted only in the case of a bona fide emergency situation.)				
F678	4. Such orders are countersigned by the attending physician within a reasonable time.				
	H. **Storage of Drugs and Biologicals**				
F679	SNF (405.1124(i)) (Standard) ☐ MET ☐ NOT MET				
F680	1. Procedures for storing and disposing of drugs and biologicals are established by the pharmaceutical services committee.				
F681	2. In accordance with State and Federal laws, all drugs and biologicals are stored in locked compartments under proper temperature controls.				
F682	3. Only authorized personnel have access to the keys.				
F683	4. Separately locked, permanently affixed compartments are provided for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention & Control Act of 1970 and other drugs subject to abuse, except under single unit dosage distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.				
F684	5. An emergency medication kit approved by the pharmaceutical services committee is kept readily available.				

NAME OF FACILITY

CODE	DIETETIC SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	Dietetic Services *(Condition of Participation)*				
F685	SNF (405.1125) ☐ MET ☐ NOT MET The facility provides a hygienic dietetic service that meets the daily nutritional needs of patients, ensures that special dietary needs are met, and provides palatable and attractive meals. A facility that has a contract with an outside food management company may be found to be in compliance with this condition provided the facility and/or company meets the standards listed herein.				
	A. **Staffing**				
F686	SNF (405.1125(a)) (Standard) ☐ MET ☐ NOT MET				
F687	1. Overall supervisory responsibility for the dietetic service is assigned to a full-time qualified dietetic service supervisor.				
F688	2. If the dietetic service supervisor is not a qualified dietitian, the dietetic service supervisor functions with frequent, regularly scheduled consultation from a person so qualified. (§405.1101(e).)				
F689	3. In addition, the facility employs sufficient supportive personnel competent to carry out the functions of the dietetic service.				
F690	4. If consultant dietetic services are used, the consultant's visits are at appropriate times, and of sufficient duration and frequency to provide continuing liaison with medical and nursing staffs, advice to the administrator, resident counseling, guidance to the supervisor and staff of the dietetic service, approval of all menus, and participation in the development or revisions of dietetic policies and procedures. (See §405.1121(i).)				

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NAME OF FACILITY

CODE	DIETETIC SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	B. **Staffing**				
F691	ICF (442.332) (Standard) ☐ MET ☐ NOT MET				
F692	1. The facility has a staff member trained or experienced in food management or nutrition who is responsible for: a. Planning meals that meet the nutritional needs of each resident.				
F693	b. Following the orders of the resident's physician.				
F694	c. To the extent medically possible, following the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences (Recommended Dietary Allowances, 8th Ed., 1974).				
F695	d. Supervising the meal preparation and service to ensure that the menu plan is followed.				
F696	2. For residents who required medically prescribed special diets, the facility: a. Has menus for those residents planned by a professionally qualified dietitian or reviewed and approved by the attending physician; and				
F697	b. Supervises the preparation and serving of meals to ensure that the resident accepts the special diet.				
F698	3. The facility keeps for 30 days a record of each menu as served.				

NAME OF FACILITY

CODE	DIETETIC SERVICES/ SPECIALIZED REHABILITATION SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	C. **Hygiene of Staff**				
F699	SNF (405.1125(f)) (Standard) ☐ MET ☐ NOT MET				
F700	In the event food service employees are assigned duties outside the dietetic service, these duties do not interfere with the sanitation, safety, or the time required for dietetic work assignments. (See §405.1121(g).)				
	D. **Sanitary Conditions**				
F701	SNF (405.1125(g)) (Standard) ☐ MET ☐ NOT MET				
F702	Written reports of inspections by State and local health authorities are on file at the facility, with notation made of action taken by the facility to comply with any recommendations.				
	Specialized Rehabilitation Services *(Condition of Participation)*				
F703	SNF (405.1126) ☐ MET ☐ NOT MET The facility provides, or arranges for, under written agreement, specialized rehabilitative services by qualified personnel (i.e., physical therapy, speech pathology and audiology, and occupational therapy) as needed by residents to improve and maintain functioning. Safe and adequate space and equipment are available, commensurate with the services offered. If the facility does not offer such services directly, it does not admit nor retain residents in need of this care unless provision is made for such services under arrangement with qualified outside resources under which the facility assumes professional responsibility for the services rendered. (See §405.1121(i).)				

NAME OF FACILITY

CODE	SPECIALIZED REHABILITATION SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	A. Staffing and Organization				
F704	SNF (405.1126(a)) (Standard) ☐ MET ☐ NOT MET **Indicators 1 thru 3 apply to SNFs**				
F705	ICF (442.343) (Standard) ☐ MET ☐ NOT MET				
F706	1. Specialized rehabilitative services are provided, in accordance with accepted professional practices, by qualified therapists or by qualified assistants or other supportive personnel under the supervision of qualified therapists.				
F707	2. Other rehabilitative services also may be provided, but must be in a facility where all rehabilitative services are provided through an organized rehabilitative service under the supervision of a physician qualified in physical medicine who determines the goals and limitations of these services and assigns duties appropriate to the training and experience of those providing such services. **Exception: Does not apply to ICFs.**				
F708	3. Written administrative and resident care policies and procedures are developed for rehabilitative services by appropriate therapists and representatives of the medical, administrative, and nursing staffs. **Exception: Does not apply to ICF's** **See General Requirements 442.305**				

NAME OF FACILITY

CODE	SPECIALIZED REHABILITATION SERVICES/ PHARMACEUTICAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	B. **Documentation of Services**				
F709	SNF (405.1126(c)) (Standard) ☐ MET ☐ NOT MET The physician's order, the plan of rehabilitative care, services rendered, evaluations of progress, and other pertinent information are recorded in the patient's medical record, and are dated and signed by the physician ordering the service and the person who provided the service.				
	C. **Qualifying to Provide Outpatient Physical Therapy Services**				
F710	SNF (405.1126(d)) (Standard) ☐ MET ☐ NOT MET If the facility provides outpatient physical therapy services, it meets the applicable health and safety regulations pertaining to such services as are included in Subpart Q of this part. (See §405.1719, 405.1720, 405.1722(a) and (b)(1)(2)(3)(i), (4), (5), (6), (7), and (8); and 405.1725.)				
	Pharmaceutical Services *(Condition of Participation)*				
F711	SNF (405.1127) ☐ MET ☐ NOT MET The facility has appropriate methods and procedures for the dispensing and administering of drugs and biologicals. The facility is responsible for providing such drugs and biologicals for its residents, insofar as they are covered under the programs, and for ensuring that pharmaceutical services are provided in accordance with accepted professional principles.				

NAME OF FACILITY

CODE	PHARMACEUTICAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	A. **Supervision of Services**				
F712	SNF (405.1127(a)) (Standard) ☐ MET ☐ NOT MET				
F713	1. The pharmaceutical services are under the general supervision of a qualified pharmacist.				
F714	2. The pharmacist is responsible to the administrative staff for developing coordinating, and supervising all pharmaceutical services.				
F715	3. The pharmacist (if not a full-time employee) devotes a sufficient number of hours, based upon the needs of the facility, during regularly scheduled visits to carry out these responsibilities.				
F716	ICF (442.333) (Standard) ☐ MET ☐ NOT MET				
F717	1. The facility employs a licensed pharmacist, or				
F718	2. The facility has formal arrangements with a licensed pharmacist to advise the facility on ordering, storage, administration, disposal and recordkeeping of drugs and biologicals.				
	B. **Control and Accountability**				
F719	SNF (405.1127(b)) (Standard) ☐ MET ☐ NOT MET				
F720	1. The pharmaceutical service has procedures for control and accountability of all drugs and biologicals throughout the facility.				
F721	2. Only approved drugs and biologicals are used in the facility.				
F722	3. Records of receipt and disposition of all controlled drugs are maintained in sufficient detail to enable an accurate reconciliation.				

NAME OF FACILITY

CODE	PHARMACEUTICAL SERVICES/ LABORATORY AND RADIOLOGIC SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	C. **Pharmaceutical Services Committee**				
F723	SNF (405.1127(d)) (Standard) ☐ MET ☐ NOT MET				
F724	1. A pharmaceutical services committee or its equivalent develops written policies and procedures for safe and effective drug therapy, distribution, control and use.				
F725	2. The committee is comprised of at least the pharmacist, the director of nursing services, the administrator, and one physician.				
F726	3. The committee oversees pharmaceutical services in the facility, makes recommendations for improvement, and monitors the service to ensure its accuracy and adequacy.				
	Laboratory and Radiologic Services *(Condition of Participation)*				
F727	SNF (405.1128) ☐ MET ☐ NOT MET The facility has provision for promptly obtaining required laboratory, X-ray, and other diagnostic services.				
	A. **Provision for Services**				
F728	SNF (405.1128(a)) (Standard) ☐ MET ☐ NOT MET				
F729	1. If the facility provides its own laboratory and X-ray services, these meet the applicable conditions established for certification of hospitals that are contained in 405.1028 and 405.1029, respectively.				

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NAME OF FACILITY

CODE	LABORATORY AND RADIOLOGIC SERVICES/ DENTAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F730	2. If the facility itself does not provide such services, arrangements are made for obtaining these services from a physician's office, a participating hospital or skilled nursing facility, or a portable X-ray supplier or independent laboratory which is approved to provide these services under the program.				
F731	3. The facility assists the resident, if necessary, in arranging for transportation to and from the source of service.				
	B. **Blood and Blood Products**				
F732	SNF (405.1128(b)) (Standard) ☐ MET ☐ NOT MET				
F733	1. Blood handling and storage facilities are safe, adequate, and properly supervised.				
F734	2. If the facility provides for maintaining and transfusing blood and blood products, it meets the conditions established for certification of hospitals that are contained in §405.1028(j).				
F735	3. If the facility does not provide its own facility but does provide transfusion services alone, it meets at least the requirements of §405.1028(j)(1), (3), (4), (6), and (9).				
	Dental Services *(Condition of Participation)*				
F736	SNF (405.1129) ☐ MET ☐ NOT MET The facility has satisfactory arrangements to assist residents to obtain routine and emergency dental care (See §405.1121(i). (The basic Hospital Insurance Program does not cover the services of a dentist in a skilled nursing facility in connection with the care, treatment, filling, removal, or replacement of teeth or structures supporting the teeth; and only certain oral surgery is included in the Supplemental Medical Insurance Program.)				

NAME OF FACILITY

CODE	DENTAL SERVICES/SOCIAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	A. **Advisory Dentist**				
F737	SNF (405.1129(a)) (Standard) ☐ MET ☐ NOT MET				
F738	A dentist recommends oral hygiene policies and practices for the care of residents. (§405.1121(h).				
	B. **Arrangements of Outside Services**				
F739	SNF (405.1129(b)) (Standard) ☐ MET ☐ NOT MET				
F740	1. The facility has a cooperative agreement with a dentist, and				
F741	2. Maintains a list of dentists in the community for residents who do not have a private dentist.				
F742	3. The facility assists the resident, if necessary, in arranging for transportation to and from the dentist's office.				
	Social Services ***(Condition of Participation)***				
F743	SNF (405.1130) ☐ MET ☐ NOT MET The facility has satisfactory arrangements for identifying the medically related social and emotional needs of the resident. It is not mandatory that the skilled nursing facility itself provide social services in order to participate in the program. If the facility does not provide social services, it has written procedures for referring residents in need of social services to appropriate social agencies. If social services are offered by the facility, they are provided under a clearly defined plan, by qualified persons, to assist each resident to adjust to the social and emotional aspects of the resident's illness, treatment, and stay in the facility.				

NAME OF FACILITY

CODE	SOCIAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	A. **Social Service Functions**				
F744	SNF (405.1130(a)) (Standard) ☐ MET ☐ NOT MET				
F745	Services are provided to meet the social and emotional needs of residents by qualified staff of the facility, or by referral, based on established procedures, to appropriate social agencies.				
F746	ICF (442.344(b)) ☐ MET ☐ NOT MET The facility either provides these services itself or arranges for them with qualified outside resources.				
	B. **Staffing**				
F747	SNF (405.1130(b)) (Standard) ☐ MET ☐ NOT MET				
F748	1. If the facility offers social services, a member of the staff of the facility is designated as responsible for social services.				
F749	2. If the designated person is not a qualified social worker, the facility has a written agreement with a qualified social worker or recognized social agency for consultation and assistance on a regularly scheduled basis. (See §405.1101(s).)				
F750	3. The social service also has sufficient supportive personnel to meet resident needs.				
F751	4. Facilities are adequate for social service personnel, easily accessible to residents and medical and other staff, and ensure privacy for interviews.				

NAME OF FACILITY

CODE	SOCIAL SERVICES/ACTIVITIES	YES	NO	N/A	EXPLANATORY STATEMENT
F752	ICF (442.344(c)) ☐ MET ☐ NOT MET				
F753	The facility designates one staff member, qualified by training or experience, to be responsible for: a. Arranging for social services; and				
F754	b. Integrating social services with other elements of the plan of care.				
	C. **Records and Confidentiality**				
F755	SNF (405.1130(c)) (Standard) ☐ MET ☐ NOT MET				
F756	Records of pertinent social data about personal and family problems medically related to the resident's illness and care, and of action taken to meet the resident's needs, are maintained in the resident's medical records.				
F757	If social services are provided by an outside resource, a record is maintained of each referral to such resource.				
	Activities *(Condition of Participation)*				
F758	SNF (405.1131) ☐ MET ☐ NOT MET The facility provides for an activities program, appropriate to the needs and interests of each resident, to encourage self care, resumption of normal activities, and maintenance of an optimal level of psychosocial functioning.				

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NAME OF FACILITY

CODE	ACTIVITIES/MEDICAL RECORDS	YES	NO	N/A	EXPLANATORY STATEMENT
	A. **Staffing**				
F759	SNF (405.1131(a)) (Standard) ☐ MET ☐ NOT MET				
F760	A member of the facility's staff is designated as responsible for the activities program.				
F761	If not a qualified activities coordinator, this staff member functions with frequent, regularly scheduled consultation from a person so qualified. (See §405.1101(o).)				
F762	ICF (442.345(b)) ☐ MET ☐ NOT MET The facility designates one staff member, qualified by training or experience in directing group activity, to be responsible for activity service.				
	Medical Records *(Condition of Participation)*				
F763	SNF (405.1132) ☐ MET ☐ NOT MET The facility maintains clinical (medical) records on all residents in accordance with accepted professional standards and practices. The medical record service has sufficient staff, facilities, and equipment to provide medical records that are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.				
F764	ICF (442.318(a)) ☐ MET ☐ NOT MET The facility maintains an organized resident record system that contains a record for each resident.				

NAME OF FACILITY

CODE	MEDICAL RECORDS	YES	NO	N/A	EXPLANATORY STATEMENT
	A. Staffing				
F765	SNF (405.1132(a)) (Standard) ☐ MET ☐ NOT MET				
F766	1. Overall supervisory responsibility for the medical record service is assigned to a full-time employee of the facility.				
F767	2. The facility also employs sufficient supportive personnel competent to carry out the functions of the medical record service.				
F768	3. If the medical record supervisor is not a qualified medical record practitioner, this person functions with consultation from a person qualified. (See §405.1101(l).)				
	B. Protection of Medical Record Information				
F769	SNF (405.1132(b)) (Standard) ☐ MET ☐ NOT MET				
F770	ICF (442.318(d)) ☐ MET ☐ NOT MET				
F771	The facility safeguards medical record information against loss, destruction, or unauthorized use.				
	C. Physician Documentation				
F772	SNF (405.1132(d)) (Standard) ☐ MET ☐ NOT MET				
F773	1. Only physicians enter or authenticate in medical records opinions that require medical judgment (in accordance with medical staff bylaws, rules, and regulations, if applicable).				
F774	2. All physicians sign their entries into the medical record.				

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NAME OF FACILITY

CODE	MEDICAL RECORDS	YES	NO	N/A	EXPLANATORY STATEMENT
	D. Completion of Records and Centralization of Reports				
F775	SNF (405.1132(e)) (Standard) ☐ MET ☐ NOT MET				
F776	1. Current medical records and those of discharged residents are completed promptly.				
F777	2. All clinical information pertaining to a resident's stay is centralized in the resident's medical record.				
	E. Retention and Preservation				
F778	SNF (405.1132(f)) (Standard) ☐ MET ☐ NOT MET Medical records are retained for a period of time not less than that determined by the respective State statute, the statue of limitations in the State, or 5 years from the date of discharge in the absence of a State statute, or, in the case of a minor, 3 years after the resident becomes of age under State law.				
F779	ICF (442.318(e)) ☐ MET ☐ NOT MET The facility must keep a resident's record for at least 3 years after the resident is discharged.				
	F. Location and Facilities				
F780	SNF (405.1132(h)) (Standard) ☐ MET ☐ NOT MET The facility maintains adequate facilities and equipment, conveniently located to provide efficient processing of medical records (reviewing, indexing, filing, and prompt retrieval).				

NAME OF FACILITY

CODE	TRANSFER AGREEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	Transfer Agreement *(Condition of Participation)*				
F781	SNF (405.1133) ☐ MET ☐ NOT MET				
F782	ICF (442.316) (Standard) ☐ MET ☐ NOT MET				
F783	The facility has in effect a transfer agreement with one or more hospitals approved for participation under the programs, which provides the basis for effective working arrangements under which inpatient hospital care or other hospital services are available promptly to the facility's residents when needed. (A facility that has been unable to establish a transfer agreement with the hospital(s) in the community or service area after documented attempts to do so is considered to have such an agreement in effect.) Exception: A facility that has been unable to establish a written agreement after documented attempts to do so, is considered to have such an agreement.				
	Resident Transfer				
F784	SNF (405.1133(a)) (Standard) ☐ MET ☐ NOT MET				
F785	A hospital and a skilled nursing facility shall be considered to have a transfer agreement in effect if, by reason of a written agreement between them or (in case of two institutions are under common control) by resaon of a written undertaking by the person or body which controls them, there is reasonable assurance that: 1. Transfer of patients will be effected between the hospital and the skilled nursing facility, ensuring timely admission, whenever such transfer is medically appropriate as determined by the attending physician.				

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NAME OF FACILITY

CODE	TRANSFER AGREEMENT/PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F786	2. There will be interchange of medical and other information necessary or useful in the care and treatment of individuals transferred between institutions, or in determining whether such individuals can be adequately cared for otherwise than in either of such institutions.				
F787	3. Security and accountability for residents' personal effects are provided on transfer.				
	Physical Environment ***(Condition of Participation)***				
F788	SNF (405.1134) ☐ MET ☐ NOT MET The facility is constructed, equipped, and maintained to protect the health and safety or residents, personnel, and the public.				
	A. **Life Safety from Fire** SNF (405.1134(a)) (Standard) ☐ MET ☐ NOT MET				
	ICF (442.321) (Standard) ☐ MET ☐ NOT MET				
	(See appropriate HCFA Fire Safety survey form.)				
	B. **Maintenance of Equipment, Building, and Grounds**				
F789	SNF (405.1134(i)) (Standard) ☐ MET ☐ NOT MET				
F790	The facility establishes a written preventative maintenance program to ensure that all equipment is operative.				

NAME OF FACILITY

CODE	INFECTION CONTROL	YES	NO	N/A	EXPLANATORY STATEMENT
	Infection Control ***(Condition of Participation)***				
F791	SNF (405.1135) ☐ MET ☐ NOT MET The facility establishes an infection control committee of representative professional staff with responsibility for overall infection control in the facility. All necessary housekeeping and maintenance services are provided to maintain a sanitary and comfortable environment and to help prevent the development and transmission of infection.				
	A. **Infection Control Committee**				
F792	SNF (405.1135(a)) (Standard) ☐ MET ☐ NOT MET				
F793	1. The infection control committee is composed of members of the medical and nursing staffs, administration, and the dietetic, pharmacy, housekeeping, maintenance, and other services.				
F794	2. The committee establishes policies and procedures for investigating, controlling, and preventing infection in the facility.				
F795	3. The committee monitors staff performance to ensure that the policies and procedures are executed.				
	B. **Aseptic and Isolation Techniques**				
F796	SNF (405.1135(b)) (Standard) ☐ MET ☐ NOT MET				
F797	1. The facility has written procedures for aseptic and isolation techniques.				
F798	2. These procedures are reviewed and revised for effectiveness and improvement as necessary.				

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NAME OF FACILITY

CODE	INFECTION CONTROL	YES	NO	N/A	EXPLANATORY STATEMENT
	C. **Housekeeping**				
F799	SNF (405.1135(c)) (Standard) ☐ MET ☐ NOT MET				
F800	1. The facility employs sufficient housekeeping personnel.				
F801	2. Provides all necessary equipment to maintain a safe, clean and orderly interior.				
F802	3. A full-time employee is designated responsible for the services and for supervision and training of personnel.				
F803	4. If a facility has a contract with an outside resource for housekeeping services, the facility and/or outside resource meets the requirements of the standards.				
	D. **Pest Control**				
F804	SNF (405.1135(e)) (Standard) ☐ MET ☐ NOT MET The facility has an ongoing pest control program.				

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NAME OF FACILITY

CODE	DISASTER PREPAREDNESS	YES	NO	N/A	EXPLANATORY STATEMENT
	Disaster Preparedness *(Condition of Participation)*				
F805	SNF (405.1136) ☐ MET ☐ NOT MET The facility has a written plan, periodically rehearsed, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (residents and personnel) arising from such disasters.				
	A. **Plan**				
F806	ICF (442.313) (Standard) ☐ MET ☐ NOT MET				
F807	1. The facility has a written plan for staff and residents to follow in case of emergencies such as fire or explosion.				
F808	2. The facility rehearses the plan regularly.				
F809	3. The facility has written procedures for the staff to follow in case of an emergency involving an individual resident.				
F810	4. These procedures include: a. Caring for the resident.				
F811	b. Notifying the attending physician and other individuals responsible for the resident.				
F812	c. Arranging for transportation, hospitalization, and other appropriate services.				
F813	SNF (405.1136(a)) (Standard) ☐ MET ☐ NOT MET				
F814	1. The facility has an acceptable written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster.				
F815	2. The plan is developed and maintained with the assistance of qualified fire, safety, and other appropriate experts.				

NAME OF FACILITY

CODE	DISASTER PREPAREDNESS/UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F816	3. Includes procedures for prompt transfer of casualties and records.				
F817	4. Instructions regarding the location and use of alarm systems and signals and of fire-fighting equipment.				
F818	5. Information regarding methods of containing fire.				
F819	6. Procedures for notification of appropriate persons.				
F820	7. Specifications of evacuation routes and procedures. (See §405.1134(a).)				
	B. **Orientation and training**				
F821	SNF (405.1136(b)) (Standard) ☐ MET ☐ NOT MET				
F822	The disaster program includes orientation and ongoing training and drills for all personnel in all procedures so that each employee promptly and correctly carries out a specific role in case of a disaster (See §405.1121(h).)				
	Utilization Review *(Condition of Participation)*				
F823	SNF (405.1137) ☐ MET ☐ NOT MET The facility carries out utilization review of the services provided in the facility to residents who are entitled to benefits under the program(s). Utilization review assures the maintenance of high quality care and appropriate and efficient utilization of facility services. There are two elements to utilization review: medical care evaluation studies and review of extended duration cases.				

NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
	A. **Plan**				
F824	SNF (405.1137(a)) (Standard) ☐ MET ☐ NOT MET				
F825	1. The facility has a currently applicable written description of its utilization review plan.				
F826	2. Such description includes: a. The organization and composition of the committee or group which will be responsible for the utilization review function.				
F827	b. Methods of criteria (including norms where available) to be used to define periods of continuous extended duration and to assign or select subsequent dates for continued stay review.				
F828	c. Methods for selection and conduct of medical care evaluation studies.				
	B. **Organization and Composition of Utilization Review Committees**				
F829	SNF (405.1137(b)) (Standard) ☐ MET ☐ NOT MET				
F830	1. The utilization review (UR) function is conducted by: a. A staff committee of the skilled nursing facility which is composed of two or more physicians, with participation of other professional personnel; or,				

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CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F831	b. A group outside the facility which is similarly composed and which is established by the local medical or osteopathic society and some or all of the hospitals and skilled nursing facilities in the locality; or (indicate name of the outside group and briefly describe the organization.)				
F832	c. A group established and organized in a manner approved by the Secretary that is capable of performing such function.				
F833	2. The medical care evaluation studies, educational duties of the review program, and the review of admissions and long-stay cases are performed by: a. the same committee or group;				
F834	b. or more committees or groups. Briefly explain who performs these functions.				
	C. **Medical Care Evaluation Studies**				
F835	SNF (405.1137(c)) (Standard) ☐ MET ☐ NOT MET				
F836	1. Medical care evaluation studies are performed to promote the most effective and efficient use of available health facilities and services consistent with resident needs and professionally recognized standards of health care.				
F837	2. Studies emphasize identification and analysis of patterns of resident care and suggest, where appropriate, possible changes for maintaining consistently high quality care and effective and efficient use of services.				

NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F838	3. Each medical care evaluation study identifies and analyzes factors related to the care rendered in the facility and where indicated, results in recommendations for change beneficial to residents, staff, the facility, and the community.				
F839	4. Studies, on a sample or other basis, include, but need not be limited to, admissions, durations of stay, ancillary services furnished (including drugs and biologicals), and professional services performed on premises.				
F840	At least one study was completed during the last year. Type of study last completed: _____				
	D. **Extended Stay Review**				
F841	SNF (405.1137(d)) (Standard) ☐ MET ☐ NOT MET				
F842	1. Periodic review is made of each current inpatient skilled nursing facility beneficiary case of continuous extended duration, and the length of which is defined in the utilization review plan to determine whether further inpatient stay is necessary.				
F843	2. The review is based on the attending physician's reasons for and plan for continued stay and any other documentation the committee or group deems appropriate.				
F844	3. Cases are screened by: a. A qualified non-physician representative of the committee.				
F845	b. The group.				
F846	c. The reviewer uses criteria established by the physician members of the committee.				

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NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F847	4. In instances when non-physician members are utilized, those cases are referred to a physician member for further review when it appears that the resident no longer requires further inpatient care.				
F848	5. Non-physician representatives used to screen extended stay review cases, have experience in such screening or appropriate training in the application of the screening criteria used, or both.				
F849	6. Before the expiration of each new period, the case must be reviewed again in like manner with such reviews being repeated as long as the stay continues beyond the scheduled review dates and notice has not been given pursuant to paragraph (e) of this section.				
	E. **Further Stay Not Medically Necessary**				
F850	SNF (405.1137(e)) (Standard) ☐ MET ☐ NOT MET				
F851	1. A final determination of the committee or group that continued stay is not medically necessary is made by at least two physician members of the committee or group, except that the final determination may be made by one physician where the attending physician, when given an opportunity to express his views, does not do so, or does not contest the finding that the continued stay is not medically necessary.				
F852	2. If the committee or group, or its nonphysician representative where a physician member concurs, has reason to believe from the review of an extended duration case or a case reviewed as part of a medical care evaluation study that further stay is no longer medically necessary, the committee or group shall notify the individual's attending physician and afford him an opportunity to present his views before it makes a final determination.				

NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F853	3. If the final determination of the committee or group is that further stay is no longer medically necessary, written notification of the finding is given to the facility, the attending physician, and the individual (or where appropriate, his next of kin) no later than 2 days after such final determination is made and, in no event in the case of an extended duration case, later than 3 working days after the end of the extended duration period specified pursuant to paragraph (d) of this section.				
	F. **Administrative Responsibilities**				
F854	SNF (405.1137(f)) (Standard) ☐ MET ☐ NOT MET				
F855	The administrative staff of the facility is kept directly and fully informed of committee activities to facilitate support and assistance. (Explain)				
	G. **Utilization Review Records**				
F856	SNF (405.1137(g)) (Standard) ☐ MET ☐ NOT MET				
F857	1. Written records of committee activities are maintained.				
F858	2. Appropriate reports, signed by the committee chairman, are made regularly to the medical staff, administrative staff, governing body, and sponsors (if any).				
F859	3. Minutes of each committee meeting is maintained and include at least: a. Name of committee.				
F860	b. Date and duration of meeting.				
F861	c. Names of committee members present and absent.				

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NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F862	4. Description of activities presently in progress to satisfy the requirements for medical care evaluation studies, including the subject, reason for study, dates of commencement and expected completion, summary of studies completed since the last meeting, conclusions and follow-up on implementation of recommendations made from previous studies.				
F863	5. Summary of extended duration cases reviewed including the number of cases, identification number, admission and review dates, and decision reached, including the basis for each determination and action taken for each case not approved for extended care.				
	H. **Discharge Planning**				
F864	SNF (405.1137(h)) (Standard) ☐ MET ☐ NOT MET The facility maintains a centralized, coordinated program to ensure that each resident has a planned program of continuing care which meets his postdischarge needs.				
F865	1. The facility has in operation an organized discharge planning program.				
F866	The utilization review committee, in its evaluation of the current status of each extended duration case, has available to it the results of such discharge planning and information on alternative available community resources to which the resident may be referred.				
F867	2. The facility maintains written discharge planning procedures which describe: a. How the discharge coordinator will function, and his authority and relationships with the facility's staff.				
F868	b. The maximum time period after which reevaluation of each resident's discharge plan is made.				

NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F869	c. Local resources available to the facility, the resident, and the attending physician to assist in developing and implementing individual discharge plans; and				
F870	d. Provisions for periodic review and reevaluation of the facility's discharge planning program.				
F871	3. At the time of discharge, the facility provides those responsible for the resident's post discharge care with appropriate summary of information about the discharged resident to ensure the optimal continuity of care.				
	The discharge summary includes at least the following:				
F872	a. Current information relative to diagnoses.				
F873	b. Rehabilitation potential.				
F874	c. A summary of the course of prior treatment.				
F875	d. Physician orders for the immediate care of the resident.				
F876	e. Pertinent social information.				

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§ 488.105 Long term care survey forms, Part B.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

PART B

MEDICARE / MEDICAID SKILLED NURSING FACILITY AND INTERMEDIATE CARE FACILITY SURVEY REPORT

LONG TERM CARE SURVEY

PROVIDER NUMBER	FACILITY NAME AND ADDRESS (*City, State, Zip*)
VENDOR NUMBER	
SURVEY DATE	

SURVEYORS' NAMES	TITLES

SURVEY TEAM COMPOSITION

F1 Indicate the Number of Surveyors According to Discipline:

A.		Administrator	H.		Life Safety Code Specialist
B.		Nurse	I.		Laboratorian
C.		Dietitian	J.		Sanitarian
D.		Pharmacist	K.		Therapist
E.		Records Administrator	L.		Physician
F.		Social Worker	M.		National Institute of Mental Health
G.		Qualified Mental Retardation Professional	N.		Other

Note: More than one discipline may be marked for surveyors qualified in multiple disciplines.

F2 Indicate the Total Number of Surveyors Onsite: _____

Form HCFA-519 (2-86)

(CONTINUED ON REVERSE)

RESIDENT CENSUS AND CONDITIONS OF RESIDENTS

PROVIDER NO. _____ ☐ F3 MEDICARE _____ ☐ F4 MEDICAID _____ ☐ F5 OTHER _____ F6 TOTAL RESIDENTS _____

CODE	
	BATHING
F7	___ Number of residents requiring assistance in bathing more than one part of body—or does not bathe self.
F8	___ Number of residents requiring assistance in bathing only a single part (as back or disabled extremity) or bathes self completely.
F9	___ **TOTAL***
	DRESSING
F10	___ Number of residents totally dressed by another person.
F11	___ Number of residents needing assistance to dress self or remain partly dressed. (Exclude those residents totally dressed.)
F12	___ Number of residents able to get clothes from closets and drawers-puts on clothes, outer garments, braces-manages fasteners. Act of tying shoes is excluded.
F13	___ **TOTAL***
	TOILETING
F14	___ Number of residents not toileted. (Use protective padding, catheter.)
F15	___ Number of residents who must use a bedpan or commode and/or receive assistance in getting to and using a toilet.
F16	___ Number of residents able to get to toilet—gets on and off toilet—cleans self—arranges clothes.
F17	___ **TOTAL***
	TRANSFERRING
F18	___ Number of residents needing assistance in all transfers (moving in or out of bed and/or chair, toilet, tub transfers).
F19	___ Number of residents needing assistance in transferring to toilet and tub only.
F20	___ Number of residents able to complete all transfers independently (may or may not be using mechanical supports).
F21	___ Total*

CODE	
	CONTINENCE
F22	___ Number of residents with indwelling or external catheters.
F23	___ Number of residents with partial or total incontinence in urination or defecation—partial or total control by suppositories or enemas, regulated use of urinals and/or bedpans.
F24	___ Number of residents with urination and defecation entirely self-controlled.
F25	___ **TOTAL***
	FEEDING
F26	___ Number of residents who receive enteral/parenteral feedings.
F27	___ Number of residents who receive NG tube feedings.
F28	___ Number of residents who require assistance in act of eating.
F29	___ Number of residents who get food from plate or its equivalent into mouth—(pre-cutting of meat and preparation of food, buttering bread, opening cartons, removing plate covers, etc., are *excluded* from evaluation).
F30	___ **TOTAL***
F31	___ Number of completely bedfast residents.
F32	___ Number of chairbound residents.
F33	___ Number of ambulatory residents (may use cane, walker, or crutches).
F34	___ Number of physically restrained residents (belt, vest, cuffs).
F35	___ Number of residents receiving psychotropic drugs.
F36	___ Number of confused or disoriented residents.
F37	___ Number of residents with decubiti.
F38	___ Number of residents on individually written bowel and bladder retraining program.
F39	___ Number of residents receiving special skin care.
F40	___ Number of residents receiving intravenous therapy and/or blood transfusion.
F41	___ Number of residents requiring no assistance in ADLs.
F42	___ Number of residents on self-administration of drugs.
F43	___ Number of residents with contractures.
F44	___ Number of residents receiving respiratory care.
F45	___ Number of residents receiving tracheostomy care.
F46	___ Number of residents receiving suctioning.
F47	___ Number of residents receiving rehabilitative services (physical therapy, speech pathology and audiology, occupational therapy)
F48	___ Number of residents receiving injections.
F49	___ Number of residents receiving colostomy care.

Form HCFA-519 (2-86) *MUST EQUAL TOTAL NUMBER OF RESIDENTS IN FACILITY Page 2

NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
	GOVERNING BODY *(CONDITION OF PARTICIPATION)*				
F50	SNF (405.1121) ☐ MET ☐ NOT MET				
	RESIDENT RIGHTS				
F51	SNF (405.1121(k)) (Standard) ☐ MET ☐ NOT MET Indicators A thru K apply to this standard for SNFs.				
F52	ICF (442.311) (Standard) ☐ MET ☐ NOT MET Indicators A thru K apply to this standard for ICFs.				
	A. Information				
F53	1. The facility informs each resident, before or at the time of admission, of his/her rights and responsibilities.				
F54	2. The facility informs each resident, before or at the time of admission, of all rules governing resident conduct.				
F55	3. The facility informs each resident of amendments to their policies on residents' rights and responsibilities and rules governing conduct.				
F56	4. Each resident acknowledges in writing receipt of residents' rights information and any amendment to it.				
F57	5. The resident must be informed in writing of all services and charges for services.				
F58	6. The resident must be informed in writing of all changes in services and charges before or at the time of admission and on a continuing basis.				
F59	7. The resident must be informed of services not covered by Medicare or Medicaid and not covered in the basic rate.				

NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
	B. Medical Condition and Treatment				
F60	1. Each resident is informed by a physician of his/her health and medical condition unless the physician decides that informing the resident is medically contraindicated.				
F61	2. Each resident is given an opportunity to participate in planning his/her total care and medical treatment.				
F62	3. Each resident is given an opportunity to refuse treatment.				
F63	4. Each resident gives informed, written consent before participating in experimental research.				
F64	5. If the physician decides that informing the resident of his/her health and medical condition is medically contraindicated, the physician has documented this decision in the resident's medical record.				
	C. Transfer and Discharge				
	Each resident is transferred or discharged only for:				
F65	1. Medical reasons.				
F66	2. His/her welfare or that of other residents.				
F67	3. Nonpayment except as prohibited by the Medicare or Medicaid program.				
F68	4. Each resident is given reasonable advance notice to ensure orderly transfer or discharge. EXCEPTION: Not required for ICF residents.				
	D. Exercising Rights				
F69	1. Each resident is encouraged and assisted to exercise his/her rights as a resident of the facility and as a citizen.				
F70	2. Each resident is allowed to submit complaints and recommendations concerning the policies and services of the facility to staff or to outside representatives of the resident's choice or both.				

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NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
F71	3. Such complaints are submitted free from restraint, coercion, discrimination, or reprisal.				
	E. **Financial Affairs**				
F72	1. Residents are allowed to manage their own personal financial affairs.				
F73	2. The facility establishes and maintains a system that assures full and complete accounting of residents' personal funds. An accounting report is made to each resident in a skilled nursing facility at least on a quarterly basis.				
F74	3. The facility does not commingle resident funds with any other funds.				
F75	4. If a resident requests assistance from the facility in managing his/her personal financial affairs, resident's delegation is in writing.				
	5. The facility system of accounting includes written receipts for:				
F76	All personal possessions and funds received by or deposited with the facility.				
F77	All disbursements made to or for the resident.				
F78	6. The financial record must be available to the resident and his/her family.				
	F. **Freedom from Abuse and Restraints**				
F79	1. Each resident is free from mental and physical abuse.				
F80	2. Chemical and physical restraints are only used when authorized by a physician in writing for a specified period of time or in emergencies.				

NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
F81	3. If used in emergencies, they are necessary to protect the resident from injury to himself/herself or others.				
F82	4. The emergency use is authorized by a professional staff member identified in the written policies and procedures of the facility.				
F83	5. The emergency use is reported promptly to the resident's physician by the staff member.				
	G. **Privacy**				
F84	1. Each resident is treated with respect, consideration and full recognition of his/her dignity and individuality.				
F85	2. Each resident is given privacy during treatment and care of personal needs.				
F86	3. Each resident's records, including information in an automated data bank, are treated confidentially.				
F87	4. Each resident must give written consent before the facility releases information from his/her record to someone not otherwise authorized to receive it.				
F88	5. Married residents are given privacy during visits by their spouses.				
F89	6. Married residents are permitted to share a room.				
	H. **Work**				
F90	No resident may be required to perform services for the facility.				

NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
	I. Freedom of Association and Correspondence				
F91	1. Each resident is allowed to communicate, associate and meet privately with individuals of his/her choice unless this infringes upon the rights of another resident.				
F92	2. Each resident is allowed to send and receive personal mail unopened.				
	J. Activities				
F93	Each resident is allowed to participate in social, religious, and community group activities.				
	K. Personal Possessions				
F94	Each resident is allowed to retain and use his/her personal possessions and clothing as space permits.				
	L. Delegation of Rights and Responsibilities				
F95	ICF (442.312) (Standard) ☐ MET ☐ NOT MET				
F96	1. All the rights and responsibilities of a resident pass to the resident's guardian, next of kin or sponsoring agency or agencies if the resident is adjudicated incompetent under State law or is determined by his/her physician to be incapable of understanding his/her rights and responsibilities.				
F97	2. Physician determinations of incapability and the specific reasons thereof are recorded by the physician in the resident's record.				

NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
	STAFF DEVELOPMENT				
F98	SNF (405.1121(h)) (Standard) ☐ MET ☐ NOT MET				
F99	ICF (442.314) (Standard) ☐ MET ☐ NOT MET				
F100	1. Facility staff are knowledgeable about the problems and needs of the aged, ill, and disabled.				
F101	2. Facility staff practices proper techniques in providing care to the aged, ill, and disabled.				
F102	3. Facility staff practice proper technique for prevention and control of infection, fire prevention and safety, accident prevention, confidentiality of resident information, and preservation of resident dignity, including protection of privacy and personal and property rights.				
	STATUS CHANGE NOTIFICATIONS				
F103	SNF (405.1121(j)) (Standard) ☐ MET ☐ NOT MET				
F104	ICF (442.307) (Standard) ☐ Met ☐ Not Met				
F105	1. The facility notifies the resident's attending physician and other responsible persons in the event of an accident involving the resident, or other significant change in the resident's physical, mental, or emotional status, or resident charges, billings, and related administrative matters.				
F106	2. Except in a medical emergency, a resident is not transferred or discharged, nor is treatment altered radically, without consultation with the resident or, if the resident is incompetent, without prior notification of next of kin or sponsor.				

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NAME OF FACILITY

CODE	PHYSICIANS' SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	PHYSICIANS' SERVICES *(CONDITION OF PARTICIPATION)*				
F107	SNF (405.1123) ☐ MET ☐ NOT MET				
	A. Medical Findings and Orders at Time of Admission				
F108	SNF (405.1123(a)) (Standard) ☐ MET ☐ NOT MET				
F109	1. There is made available to the facility prior to or at the time of admission, resident information which includes current medical findings, diagnoses, and orders from a physician for immediate care of the resident.				
F110	2. Information about the rehabilitation potential of the resident and a summary of prior treatment are made available to the facility at the time of admission or within 48 hours thereafter.				

NAME OF FACILITY

CODE	PHYSICIANS' SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	B. **Resident Supervision by Physician**				
F111	SNF (405.1123(b)) (Standard) ☐ MET ☐ NOT MET				
F112	ICF (442.346) (Standard) ☐ MET ☐ NOT MET **Indicators B and C apply to** this standard for ICFS.				
F113	1. Every resident must be under the supervision of a physician.				
F114	2. A physician prescribes a planned regimen of care based on a medical evaluation of each resident's immediate and long-term care needs. **Exception: Not required for ICF residents**				
F115	3. A physician is available to provide care in the absence of any resident's attending physician.				
F116	4. Medical evaluation is done within 48 hours of admission unless done within 5 days prior to admission. **Exception: Not required for ICF residents.**				
F117	5. Each resident is seen by their attending physician at least once every 30 days for the first 90 days after admission. **Exception: ICF residents must be seen every 60 days unless otherwise justified and documented by the attending physician.**				
F118	6. Each resident's total program of care including medications and treatments is reviewed during a visit by the attending physician at least once every 30 days for the first 90 days and revised as necessary. **Exception: Only medications must be reviewed quarterly for ICF residents.**				

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NAME OF FACILITY

CODE	PHYSICIANS' SERVICES/NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F119	7. Progress notes are written and signed by the physician at the time of each visit, and all orders are signed by the physician.				
F120	8. Alternate physician visit schedules that exceed a 30-day schedule adopted after the 90th day following admission are justified by the attending physician in the medical record. These visits cannot exceed 60 days or apply to residents who require specialized rehabilitation schedules. EXCEPTION: Not required for ICF residents.				
	C. **Emergency Services**				
F121	SNF (405.1123(c)) (Standard) ☐ MET ☐ NOT MET				
F122	Emergency services from a physician are available and provided to each resident who requires emergency care.				
	NURSING SERVICES *(CONDITION OF PARTICIPATION)*				
F123	SNF (405.1124) ☐ MET ☐ NOT MET				
F124	SNF (405.1124(c)) (Standard) ☐ Met ☐ Not Met Indicators A and B apply to this standard for SNFs.				
F125	ICF (442.338) ☐ Met ☐ Not Met Indicators A thru E apply to this standard for ICFs except where noted.				
F126	A. The facility provides nursing services which are sufficient to meet nursing needs of all residents all hours of each day. 1. Each resident receives all treatments, medications and diet as prescribed. Deviations are reported and appropriate action is taken.				

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F127	2. Each resident receives daily personal hygiene as needed to assure cleanliness, good skin care, good grooming, and oral hygiene taking into account individual preferences. Residents are encouraged to engage in self care activity.				
F128	3. Each resident receives care necessary to prevent skin breakdown.				
F129	4. Each resident with a decubitus receives care necessary to promote the healing of the decubitus including proper dressing.				
F130	5. When residents require restraints the application is ordered by the physician, applied properly, and released at least every 2 hours.				
F131	6. Each resident with incontinence is provided with care necessary to encourage continence including frequent toileting and opportunities for rehabilitative training.				
F132	7. Each resident with a urinary catheter receives proper routine care including periodic evaluation.				
F133	8. Each resident receives proper care for the following needs: Injections Parenteral Fluids Colostomy/Ileostomy Respiratory Care Tracheostomy Care Suctioning Tube Feeding				
F134	9. Infection Control Techniques are properly carried out in the provision of care to each resident.				

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NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F135	10. Proper nursing and sanitary procedures and techniques are used when medications are given to residents.				
F136	11. Adequate resident care supplies are available for providing treatments.				
	B. **Twenty-Four Hour Nursing Service**				
F137	1. Nursing personnel,including registered nurses, licensed practical (vocational) nurses, nurse aides, orderlies, and ward clerks, are assigned duties consistent with their education and experience, and based on the characteristics of the resident load. EXCEPTION: Not required for ICFs.				
F138	2. Weekly time schedules are maintained and indicate the number and classifications of nursing personnel including relief personnel, who worked on each unit for each tour of duty. (If a distinct part certification, show the staffing for the DP and, if appropriate, any nonparticipating remainder and explain any sharing of nursing personnel.) **Exception: Not required for Freestanding ICFs.**				
F139	3. There is a sufficient number of nursing staff available to meet the total needs of all residents.				
F140	4. There is a registered nurse on the day tour of duty 7 days a week. **Exception: Not required for ICF residents.**				

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	C. **Charge Nurse**				
F141	SNF (405.1124(b)) (Standard) ☐ MET ☐ NOT MET				
F142	1. A registered nurse or a qualified licensed practical (or vocational) nurse is designated as charge nurse by the director of nursing for each tour of duty. **Exception: Not required for ICFs.**				
F143	2. The director of nursing services does not serve as charge nurse in a facility with an average daily total occupancy of 60 or more residents. **Exception: Not required for ICFs.**				
F144	3. The ICF must have a registered nurse, or a licensed practical or vocational nurse full-time, 7 days a week, on the day shift. **Exception: Not required for SNFs.**				

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NAME OF FACILITY

List the number of full-time equivalents of RN's, LPN's, Aides/Orderlies assigned to nursing duty from the last 3 complete weeks. (Note only actual staff on duty.)

Shift		CODE	Day 1			Day 2			Day 3			Day 4			Day 5			Day 6			Day 7		
			RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A
DAY	DP	F145																					
	Entire Facility	F146																					
EVENING	DP	F147																					
	Entire Facility	F148																					
NIGHT	DP	F149																					
	Entire Facility	F150																					

Shift		CODE	Day 1			Day 2			Day 3			Day 4			Day 5			Day 6			Day 7		
			RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A
DAY	DP																						
	Entire Facility																						
EVENING	DP																						
	Entire Facility																						
NIGHT	DP																						
	Entire Facility																						

NAME OF FACILITY

Shift		CODE	Day 1			Day 2			Day 3			Day 4			Day 5			Day 6			Day 7		
			RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A
DAY	DP	F151																					
	Entire Facility	F152																					
EVENING	DP	F153																					
	Entire Facility	F154																					
NIGHT	DP	F155																					
	Entire Facility	F156																					

STAFFING PATTERN WORKSHEETS DAY OF SURVEY (OPTIONAL)

ENTIRE FACILITY STAFFING PATTERN (DAY OF SURVEY)

	CODE		RN	PN	A
DAY	F157	REPORT			
	F158	ACTUAL			
EVENING	F159	REPORT			
	F160	ACTUAL			
NIGHT	F161	REPORT			
	F162	ACTUAL			

UNIT STAFFING PATTERN WORKSHEET (DAY OF SURVEY)

	CODE	Unit			Unit			Unit			Unit			Unit			Unit			Unit		
		RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A
DAY	F163																					
EVENING	F164																					
NIGHT	F165																					
CENSUS	F166																					

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	D PATIENT CARE MANAGEMENT				
F167	SNF (405.1124(d)) (Standard) ☐ MET ☐ NOT MET				
F168	ICF (442.341) (Standard) ☐ MET ☐ NOT MET				
F169	1 Each resident's needs are addressed in a written plan of care which demonstrates that the plans of all services are integrated, consonant with the physician's plan of medical care, and implemented shortly after admission.				
F170	2 Each professional service identifies needs, goals, plans, and evaluates the effectiveness of interventions, plus institutes changes in the plan of care in a timely manner.				
	E. **Rehabilitative Nursing Services are performed daily, and recorded for those residents who require such service.**				
F171	SNF (405.1124(e)) (Standard) ☐ MET ☐ NOT MET				
F172	ICF (442.342) (Standard) ☐ Met ☐ Not Met				
F173	1. Each resident receives rehabilitative nursing care to promote maximum physical functioning to prevent immobility, deformities, and contractures.				
F174	2. There is an ongoing evaluation of each resident's rehabilitative nursing needs. This may include;				
F175	(a) Range of motion, ambulation, turning and positioning and other activities;				
F176	(b) Assistance and instruction in the activities of daily living such as feeding, dressing, grooming, oral hygiene and toilet activities;				
F177	(c) Remotivation therapy and/or reality orientation when appropriate.				
F178	3. These activities are coordinated with other resident care services.				

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	F. The facility has an awareness of nutritional needs and fluid intake of residents and provides prompt assistance where necessary in feeding residents.				
F179	SNF (405.1124(f)) (Standard) ☐ MET ☐ NOT MET				
F180	1. Each resident is provided with the amount of food and fluid on a daily basis necessary to maintain their appropriate minimum average weight. Between meal feedings are offered and the amount consumed is observed. Daily food and fluid intake is observed and encouraged.				
F181	2. Each resident needing assistance in eating or drinking is provided prompt assistance. Specific self-help devices are available when necessary.				
F182	3. Deviations from normal food and fluid intake are recorded and reported to the charge nurse and the attending physician.				

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	G. **Administration of Drugs**				
F183	SNF (405.1124(g)) (Standard) ☐ MET ☐ NOT MET				
F184	ICF (442.337) (Standard) ☐ MET ☐ NOT MET				
F185	1. The resident is identified prior to administration of a drug.				
F186	2. Drugs and biologicals are administered as soon as possible after doses are prepared.				
F187	3. Administered by same person who prepared the doses for administration except under single unit dose package distribution systems.				
F188	**Exception: ICF residents may self administer medication only with their physician's permission.**				
	H. **Conformance with Physician Drug Orders**				
F189	SNF (405.1124(h)) (Standard) ☐ MET ☐ NOT MET				
F190	ICF (442.334) (Standard) ☐ MET ☐ NOT MET				
F191	Drugs are administered in accordance with written orders of the attending physician.				
F192	Drug Error Rate _____% (See Form HCFA-522)				

NAME OF FACILITY

CODE	DIETETIC SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	DIETETIC SERVICES *(CONDITION OF PARTICIPATION)*				
F193	SNF (405.1125) ☐ MET ☐ NOT MET				
F194	ICF (442.332) (Standard) ☐ MET ☐ NOT MET Indicators A and B apply to this standard for ICFS.				
	A. **Menus and Nutritional Adequacy**				
F195	SNF (405.1125(b)) (Standard) ☐ MET ☐ NOT MET				
F196	Menus are planned and followed to meet the nutritional needs of each resident in accordance with physicians' orders and, to the extent medically possible, based on the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences.				
	B. **Therapeutic Diets**				
F197	SNF (405.1125(c)) (Standard) ☐ MET ☐ NOT MET				
F198	1. Therapeutic diets are prescribed by the attending physician.				
F199	2. Therapeutic menus are planned in writing, prepared, and served as ordered with supervision from the dietitian and advice from the physician whenever necessary.				
F200	Number of Regular Diets_____				
F201	Number of Therapeutic Diets_____				
F202	Number of Mechanically Altered Diets _____				
F203	Number of Tube Feedings_____				

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NAME OF FACILITY

CODE	DIETETIC SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	C. Preparation				
F204	SNF (405.1125(e)) (Standard) ☐ MET ☐ NOT MET				
F205	1. Food is prepared by methods that conserve its nutritive value and flavor.				
F206	2. Meals are palatable, served at proper temperatures. They are cut, ground, chopped, pureed or in a form which meets individual resident needs.				
F207	3. If a resident refuses food served, appropriate substitutes of similar nutritive value are offered.				
	D. Frequency				
F208	SNF (405.1125(d)) (Standard) ☐ MET ☐ NOT MET				
F209	ICF (442.331) (Standard) ☐ MET ☐ NOT MET				
F210	1. At least three meals are served daily at regular hours with not more than a 14-hour span between a substantial evening meal and breakfast.				
F211	2. To the extent medically possible, bedtime nourishments are offered to all residents. **Exception: Not required for ICF Residents.**				
	E. Staffing				
F212	SNF (405.1125.(a)) (Standard) ☐ MET ☐ NOT MET				
F213	1. Food service personnel are on duty daily over a period of 12 or more hours.				

NAME OF FACILITY

CODE	SPECIALIZED REHABILITATIVE SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	SPECIALIZED REHABILITATIVE SERVICES *(CONDITION OF PARTICIPATION)*				
F214	SNF (405.1126) ☐ MET ☐ NOT MET				
F215	SNF (405.1126(b)) (Standard) ☐ MET ☐ NOT MET				
F216	ICF (442.343) (Standard) ☐ MET ☐ NOT MET				
	A. Plan of Care				
F217	Rehabilitative services are provided under a written plan of care, initiated by the attending physician and developed in consultation with appropriate therapists(s) and the nursing service.				
	B. Therapy				
F218	Therapy is provided according to orders of the attending physician in accordance with accepted professional practices by qualified therapists or qualified assistants.				
	C. Progress				
F219	1. A report of the resident's progress is communicated to the attending physician within 2 weeks of the initiation of specialized rehabilitative services. **Exception: ICF resident's progress must be reviewed regularly.**				

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NAME OF FACILITY

CODE	SPECIALIZED REHABILITATIVE SERVICES/PHARMACEUTICAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F220	2. The resident's progress is thereafter reviewed regularly, and the plan of rehabilitative care is reevaluated as necessary, but at least every 30 days, by the physician and the therapist. **Exceptions: ICF residents' plans must be revised as necessary.**				
	PHARMACEUTICAL SERVICES *(CONDITION OF PARTICIPATION)*				
F221	SNF (405.1127) ☐ MET ☐ NOT MET				
	A. Supervision				
F222	SNF (405.1127(a)) (Standard) ☐ MET ☐ NOT MET				
F223	ICF (442.336) (Standard) ☐ MET ☐ NOT MET				
F224	The pharmacist reviews the drug regimen of each resident at least monthly and reports any irregularities to the medical director and administrator.				

NAME OF FACILITY

CODE	PHARMACEUTICAL SERVICES LABORATORY AND RADIOLOGIC SERVICES/SOCIAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	B. **Labeling of Drugs and Biologicals**				
F225	SNF (405.1127(c)) (Standard) ☐ MET ☐ NOT MET				
F226	ICF (442.333) (Standard) ☐ MET ☐ NOT MET				
F227	The labeling of drugs and biologicals is based on currently accepted professional principles and includes the appropriate accessary and cautionary instructions as well as an expiration date when applicable.				
	LABORATORY AND RADIOLOGIC SERVICES *(CONDITION OF PARTICIPATION)*				
F228	SNF (405.1128) ☐ MET ☐ NOT MET				
F229	SNF (405.1128(a)) (Standard) ☐ MET ☐ NOT MET				
	Provision of Services				
F230	1. All services are provided only on the orders of a physician.				
F231	2. The attending physician is notified promptly of diagnostic findings.				
F232	3. Signed and dated reports of a clinical laboratory, X-ray and other diagnostic services are filed with the resident's medical record.				

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NAME OF FACILITY

CODE	SOCIAL SERVICES/ACTIVITIES	YES	NO	N/A	EXPLANATORY STATEMENT
	SOCIAL SERVICES *(CONDITION OF PARTICIPATION)*				
F233	SNF (405.1130) ☐ MET ☐ NOT MET				
F234	SNF (405.1130(a)) (Standard) ☐ MET ☐ NOT MET				
F235	ICF (442.344) (Standard) ☐ MET ☐ NOT MET				
	A. **Plan**				
F236	The medically related social and emotional needs of the resident are identified.				
	B. **Provision of Services**				
F237	1. Services are provided to meet the social and emotional needs by the facility or by referral to an appropriate social agency.				
F238	2. If financial assistance is indicated, arrangements are made promptly for referral to an appropriate agency.				
	ACTIVITIES *(CONDITION OF PARTICIPATION)*				
F239	SNF(405.1131) ☐ MET ☐ NOT MET				
	Provision of Services				
F240	SNF (405.1131(b)) (Standard) ☐ MET ☐ NOT MET				

Form HCFA-519 (2-86)

NAME OF FACILITY

CODE	ACTIVITIES	YES	NO	N/A	EXPLANATORY STATEMENT
F241	ICF (442.345) (Standard) ☐ MET ☐ NOT MET				
F242	1. An ongoing program of meaningful activities is provided based on identified needs and interests of each resident. It is designed to promote opportunities for engaging in normal pursuits, including religious activities of their choice, if any.				
F243	2. Unless contraindicated by the attending physicians each resident is encouraged to participate in the activities program.				
F244	3. The activities promote the physical, social and mental well-being of the resident.				
F245	4. Equipment is maintained in good working order.				
F246	5. Supplies and equipment are available.				

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NAME OF FACILITY

CODE	MEDICAL RECORDS	YES	NO	N/A	EXPLANATORY STATEMENT
	MEDICAL RECORDS *(CONDITION OF PARTICIPATION)*				
F247	SNF (405.1132) ☐ MET ☐ NOT MET				
	Content				
F248	SNF (405.1132(c)) (Standard) ☐ MET ☐ NOT MET				
F249	ICF (442.318) (Standard) ☐ MET ☐ NOT MET				
F250	1. The medical record contains sufficient information to identify the resident clearly, to justify diagnoses and treatment, and to document results accurately.				

NAME OF FACILITY

CODE	MEDICAL RECORDS	YES	NO	N/A	EXPLANATORY STATEMENT
	2. The medical record contains the following information:				
F251	a. Identification information				
F252	b. Admission data including past medical and social history				
F253	c. Transfer form, discharge summary from any transferring facility				
F254	d. Report of resident's attending physician				
F255	e. Report of physical examinations				
F256	f. Reports of physicians' periodic evaluations and progress notes				
F257	g. Diagnostic reports and therapeutic orders				
F258	h. Reports of treatments				
F259	i. Medications administered				
F260	j. An overall plan of care setting forth goals to be accomplished through each service's designed activities, therapies and treatments.				
F261	k. Assessments and goals of each service's plan of care				
F262	l. Treatments and services rendered				
F263	m. Progress notes				
F264	n. All symptoms and other indications of illness or injury including date, time and action taken regarding each problem.				

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NAME OF FACILITY

CODE		YES	NO	N/A	EXPLANATORY STATEMENT
	TRANSFER AGREEMENT *(CONDITION OF PARTICIPATION)*				
F265	SNF (405.1133) ☐ MET ☐ NOT MET				
F266	SNF (405.1133(a)) (Standard) ☐ MET ☐ NOT MET				
F267	ICF (442.316) (Standard) ☐ MET ☐ NOT MET				
F268	A. Whenever the attending physician determines that a transfer is medically appropriate between a hospital or a facility providing more specialized care and the nursing facility, admission to the new facility shall be effected in a timely manner.				
F269	B. Information necessary for providing care and treatment to transferred individuals is provided.				

NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	PHYSICAL ENVIRONMENT ***(CONDITION OF PARTICIPATION)***				
F270	SNF (405.1134) ☐ MET ☐ NOT MET				
	A. **Nursing Unit**				
F271	SNF (405.1134(d)) (Standard) ☐ MET ☐ NOT MET				
F272	1. The unit is properly equipped for preparation and storage of drugs and biologicals.				
F273	2. Utility and storage rooms are adequate in size.				
F274	3. The unit is equipped to register resident calls with a functioning communication system from resident areas including resident rooms and toilet and bathing facilities.				
	B. **Dining and Activities Area**				
F275	SNF (405.1134(g) (Standard) ☐ MET ☐ NOT MET				
F276	ICF (442.329) (Standard) ☐ MET ☐ NOT MET				
F277	1. The facility provides one or more clean, orderly and appropriately furnished rooms of adequate size, designated for resident dining and resident activities.				
F278	2. Dining and activity rooms are well lighted and ventilated.				
F279	3. Any multipurpose room used for dining and resident activities has sufficient space to accommodate all activities and prevent their interference with each other.				

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NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F280	SNF (405.1134(e)) (Standard) ☐ MET ☐ NOT MET				
	INDICATORS C AND D APPLY TO THIS STANDARD FOR SNF				
	C. Resident Rooms				
F281	ICF (442.325) (Standard) ☐ MET ☐ NOT MET				
F282	1. Single resident rooms have at least 100 square feet.				
F283	2. Multiple resident rooms have no more than four residents and at least 80 square feet per resident.				
F284	3. Each room is equipped with or conveniently located near toilet and bathing facilities.				
F285	4. There is capability of maintaining privacy in each.				
F286	5. There is adequate storage space for each resident.				
F287	6. There is a comfortable and functioning bed and chair plus a functional cabinet and light.				
F288	7. The resident call system functions in resident rooms.				
F289	8. Each room is designed and equipped for adequate nursing care and the comfort and privacy of the residents.				
F290	9. Each room is at or above grade level.				
F291	10. Each room has direct access to a corridor and outside exposure. **Exception: Not required for ICF residents.**				

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NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	D. Toilet and Bath Facilities				
F292	ICF (442.326) (Standard) ☐ MET ☐ NOT MET				
F293	1. Facilities are clean, sanitary and free of odors.				
F294	2. Facilities have safe and comfortable hot water temperatures.				
F295	3. Facilities maintain privacy.				
F296	4. Facilities have grab bars and other safeguards against slipping.				
F297	5. Facilities have fixtures in good condition.				
F298	6. The resident call system functions in toilet and bath facilities.				
	E. Social Service Area				
F299	SNF (405.1130(b)) (Standard) ☐ MET ☐ NOT MET				
F300	1. Ensures privacy for social service interviewing.				
F301	2. Adequate space for clerical and interviewing functions is provided.				
F302	3. Facilities are easily acessible to residents and staff.				

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NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	F. Therapy Areas				
F303	SNF (405.1126(a)) (Standard) ☐ MET ☐ NOT MET				
F304	ICF (442.328(a)) ☐ MET ☐ NOT MET				
F305	1. Space is adequate for proper use of equipment by all residents receiving treatments.				
F306	2. Equipment is safe and in proper working condition.				
	G. Facilities for Special Care				
F307	SNF (405.1134(f)) (Standard) ☐ MET ☐ NOT MET				
F308	ICF (442.328(b)) ☐ MET ☐ NOT MET				
F309	1. Single rooms with private toilet and handwashing facilities are available for isolating residents.				
F310	2. Precautionary signs are used to identify these rooms when in use.				
	H. Common Resident Areas				
F311	SNF (405.1134(j)) (Standard) ☐ MET ☐ NOT MET				
F312	ICF (442.324) (Standard) ☐ MET ☐ NOT MET				
F313	1. All common resident areas are clean, sanitary and free of odors.				
F314	2. Provision is made for adequate and comfortable lighting levels in all areas.				
F315	3. There is limitation of sounds at comfort levels.				

NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F316	4. A comfortable room temperature is maintained.				
F317	5. There is adequate ventilation through windows or mechanical means or a combination of both.				
F318	6. Corridors are equipped with firmly secured handrails on each side.				
F319	7. Staff are aware of procedures to ensure water to all essential areas in the event of loss of normal supply.				
	I. **Maintenance of Building and Equipment**				
F320	SNF (405.1134(i)) (Standard) ☐ MET ☐ NOT MET				
F321	1. The interior and exterior of the building are clean and orderly.				
F322	2. All essential mechanical and electrical equipment is maintained in safe operating condition.				
F323	3. Sufficient storage space is available and used for equipment to ensure that the facility is orderly and safe.				
F324	4. Resident care equipment is clean and maintained in safe operating condition.				
F325	ICF (442.331(b)) ☐ MET ☐ NOT MET Indicators J thru L apply to ICFs.				
	J. **Dietetic Service Area**				
F326	SNF (405.1134(h)) (Standard) ☐ MET ☐ NOT MET				
F327	1. Kitchen and dietetic service areas are adequate to insure proper, timely food services for all residents				
F328	2. Kitchen areas are properly ventilated, arranged, and equipped for storage and preparation of food as well as for dish and utensil cleaning, and refuse storage and removal.				

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NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT/INFECTION CONTROL	YES	NO	N/A	EXPLANATORY STATEMENT
F329	K. HYGIENE OF DIETARY STAFF SNF (405.1125(f)) (Standard) ☐ Met ☐ Not Met				
F330	Dietetic service personnel practice hygienic food handling techniques.				
F331	L. DIETARY SANITARY CONDITIONS SNF (405.1125(g)) (Standard) ☐ Met ☐ Not Met				
F332	1. Food is stored, refrigerated, prepared, distributed, and served under sanitary conditions.				
F333	2. Waste is disposed of properly.				
F334	M. **Emergency Power** SNF (405.1134(b)) (Standard) ☐ MET ☐ NOT MET				
F335	1. An emergency source of electrical power necessary to protect the health and safety of residents is available in the event the normal electrical supply is interrupted.				
F336	2. Emergency power is adequate at least for lighting in all means of egress; equipment to maintain fire detection, alarm, and extinguishing systems; and life safety support systems.				
F337	3. Emergency power is provided by an emergency electrical generator located on the premises where life support systems are used.				
F338	**INFECTION CONTROL *(CONDITION OF PARTICIPATION)*** SNF (405.1135) ☐ MET ☐ NOT MET				
F339	**A. Infection Control** SNF (405.1135(b)) (Standard) ☐ MET ☐ NOT MET				
F340	Aseptic and isolation techniques are followed by all personnel.				

NAME OF FACILITY

CODE	INFECTION CONTROL/DISASTER PREPAREDNESS	YES	NO	N/A	EXPLANATORY STATEMENT
	B. Sanitation				
F341	SNF (405.1135(c)) (Standard) ☐ MET ☐ NOT MET				
F342	The facility maintains a safe, clean, and orderly interior.				
	C. Linen				
F343	SNF (405.1135(d) (Standard) ☐ MET ☐ NOT MET				
F344	ICF (442.327) (Standard) ☐ MET ☐ NOT MET				
F345	1. The facility has available at all times a quantity of linen essential for proper care and comfort of residents.				
F346	2. Linens are handled; stored, processed, and transported in such a manner as to prevent the spread of infection.				
	D. PEST CONTROL				
F347	SNF (405.1135(e)) (Standard) ☐ Met ☐ Not Met				
F348	ICF (442.315(c)) (Standard) ☐ Met ☐ Not Met				
F349	The facility is maintained free from insects and rodents.				
	DISASTER PREPAREDNESS *(CONDITION OF PARTICIPATION)*				
F350	SNF (405.1136) ☐ MET ☐ NOT MET				
F351	SNF (405.1136(a)) (Standard) ☐ MET ☐ NOT MET				
F352	ICF (442.313) (Standard) ☐ MET ☐ NOT MET Indicators A and B apply to this standard for ICFS.				
	A. Disaster Plan				
F353	1. Facility staff are aware of plans, procedures to be followed for fire, explosion or other disaster.				

NAME OF FACILITY

CODE	DISASTER PREPAREDNESS	YES	NO	N/A	EXPLANATORY STATEMENT
F354	2. Facility staff are knowledgeable about evacuation routes.				
F355	3. Facility staff are aware of their specific responsibilities in regard to evaluation and protection of residents.				
F356	4. Facility staff are aware of methods of containing fire.				
	B. **Drills**				
F357	SNF (405.1136(b)) (Standard) ☐ MET ☐ NOT MET				
F358	1. All employees are trained, as part of their employment orientation in all aspects of preparedness for any disaster.				
F359	2. Facility staff participate in ongoing training and drills in all procedures so that each employee promptly and correctly carries out a specific role in case of a disaster.				

SKILLED NURSING FACILITY & INTERMEDIATE CARE FACILITY

SURVEY REPORT — PART B
CRUCIAL DATA EXTRACT
(To be used with 2-86 Revision of Form HCFA-519)

PROVIDER NO.	FACILITY NAME	SURVEY DATE

SURVEY TEAM COMPOSITION

*F1: INDICATE THE NUMBER OF SURVEYORS ACCORDING TO DISCIPLINE:

A.	_____	ADMINISTRATOR	H.	_____	LIFE SAFETY CODE SPECIALIST
B.	_____	NURSE	I.	_____	LABORATORIAN
C.	_____	DIETITIAN	J.	_____	SANITARIAN
D.	_____	PHARMACIST	K.	_____	THERAPIST
E.	_____	RECORDS ADMINISTRATOR	L.	_____	PHYSICIAN
F.	_____	SOCIAL WORKER	M.	_____	NATIONAL INSTITUTE OF MENTAL HEALTH
G.	_____	QUALIFIED MENTAL RETARDATION PROFESSIONAL	N.	_____	OTHER

NOTE: MORE THAN ONE DISCIPLINE MAY BE MARKED FOR SURVEYORS QUALIFIED IN MULTIPLE DISCIPLINES.

*F2: INDICATE THE TOTAL NUMBER OF SURVEYORS ONSITE: ____

*F193 DRUG ERROR RATE: _____% (Round % to nearest whole number.)

*SF5 Survey Form Indicator (Check one)

Traditional Survey (1) ☐ New LTC Survey (2) ☐

NOTE: PLEASE ATTACH COPY OF PAGES 2, 14 AND 15.

*Mandatory

Form HCFA-519E (2-86)

☆U.S. GOVERNMENT PRINTING OFFICE : 1986 O - 153-203 : QL 3

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

RESIDENTS SELECTED FOR INDEPTH REVIEW

PROVIDER NUMBER	SURVEY DATE

	RESIDENT NAME (TARGETED)*	ROOM NUMBER	REASON FOR SELECTION
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			
16.			
17.			
18.			
19.			
20.			

FORM HCFA-520 (2-86) * NOTE IF ICF OR SNF RESIDENT

★U.S.GPO:1986-0-181-264/53839

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

TOUR NOTES WORKSHEET

PROVIDER NUMBER	SURVEY DATE

INSTRUCTIONS

1. *Note care and problems in care on all units.*
2. *Report deficiencies directly to survey report form or evaluate further during indepth sample review.*
3. *Select residents for indepth review.*
4. *Select a proportionate number from each section.*

INDEPTH SAMPLE

Facility Census	0–60	61–120	121–200	200+
Sample Size	25% (Min10)	20% (Min15)	15% (Min24)	10% (Min30) (Max50)

OBSERVE RESIDENTS FOR THE FOLLOWING CARE PROBLEMS

GROOMING/PERSONAL HYGIENE

POSITIONING

ASSISTIVE DEVICES

AMBULATION

RESTRAINTS

HYDRATION

INFECTION CONTROL

PATIENT RIGHTS

OTHER

FORM HCFA-521 (2-86)

*U.S. GPO 1986 O-181-284/53827

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

OBSERVATION / INTERVIEW RECORD REVIEW WORKSHEET

PROVIDER NUMBER	SURVEY DATE	OBSERVATION/INTERVIEW OF: (RESIDENT IDENTIFIER)

INSTRUCTIONS

1. Observe each resident in sample to identify ADL needs and potential problems. Check appropriate blocks.
2. Interview only residents in sample who are capable and willing.
3. Review each resident's record to ensure assessments, plans, interventions and evaluations are appropriate and current.
4. Note deficiencies on survey report form after reviewing all residents in sample.

RESIDENT NEEDS

ADL's
- ☐ Bathing
- ☐ Dressing
- ☐ Toileting
- ☐ Transferring
- ☐ Continence
- ☐ Feeding

SKIN
- ☐ Tears/Wounds
- ☐ Ulcers
- ☐ Rashes
- ☐ Flaking
- ☐ Scaling
- ☐ Red Area

DECUBITUS
- ☐ Grade
- ☐ Foul Odor
- ☐ Draining
- ☐ Dressing
- ☐ Unclean
- ☐ Not Dry
- ☐ Not Intact
- ☐ Poor Technique

GROOMING/HYGIENE
- ☐ Eyes/Ears/Mouth
- ☐ Oral/Dental Hygiene
- ☐ Foot Care
- ☐ Facial Hair
- ☐ Hair/Scalp
- ☐ Nails
- ☐ Clothing
- ☐ Shoes/Slippers
- ☐ Odors

POSITIONING
- ☐ Need Present
- ☐ Contracted Extremities
- ☐ Improper Position
- ☐ No Protective Device
- ☐ ROM Improper
- ☐ Lack of Turning as Needed
- ☐ Schedule Not Present
- ☐ Improper Techniques
- ☐ Aseptic/Other

DRESSINGS
- ☐ Present
- ☐ Unclean
- ☐ Not Dry
- ☐ Not Intact
- ☐ Foul Odor
- ☐ Poor Technique

RESTRAINTS
- ☐ Type
- ☐ Inappropriate Application
- ☐ Improper Body Alignment/Support
- ☐ Not Released/Exercised Every 2 Hours
- ☐ Chemically Restrained

BOWEL/BLADDER
- ☐ Incontinent
- ☐ Not Routinely Toileted
- ☐ Commode Not Available
- ☐ Schedule Not Available

CATHETER
- ☐ Present
- ☐ Inappropriate
- ☐ Poor Drainage
- ☐ Drainage System Open
- ☐ No Urine in Bag
- ☐ Urine Leaking
- ☐ Abdomen Distended
- ☐ Tubing Not Clean
- ☐ No I/O Recording
- ☐ Supply Storage Unclean

INJECTIONS
- ☐ Receives Injections
- ☐ Site Red/Swollen
- ☐ Improper Technique
- ☐ Resident Reacts

COLOSTOMY/ILEOSTOMY
- ☐ Present
- ☐ Not Well Regulated
- ☐ Odors
- ☐ Diarrhea/Constipation
- ☐ Site Red/Irritated

PARENTERAL FLUID/IV'S
- ☐ Present
- ☐ Rate Incorrect/Stopped
- ☐ Site Red/Swollen
- ☐ Dressing Unclean
- ☐ Unsafe Splint
- ☐ Improper Label
- ☐ Outdated Solution
- ☐ No I/O Recording

TRACHEOSOTOMY
- ☐ Present
- ☐ Site Red/Swollen
- ☐ Obstructed
- ☐ Unclean
- ☐ Improper Suctioning
- ☐ Equipment Not Available

SUCTIONING
- ☐ Need Present
- ☐ Audible Rales
- ☐ Labored Breathing
- ☐ Drainage
- ☐ Equipment Not Available

RESPIRATORY
- ☐ Congested/Short Breath
- ☐ IPPB Not Available
- ☐ Oxygen Not Available
- ☐ Improper Equipment Use

DIETARY NEEDS
- ☐ Over/Underweight
- ☐ Dehydrated
- ☐ Edema
- ☐ Emaciated
- ☐ Dull/Dry Hair
- ☐ Swollen/Red Tongue
- ☐ Bleeding Gums
- ☐ Cracked Lips
- ☐ Inability to Chew
- ☐ Swallowing Prob.
- ☐ Pallor

TUBE FEEDING
- ☐ Present
- ☐ Nutrition Inadequate
- ☐ Poorly Tolerated
- ☐ Vomits
- ☐ Dehydrated
- ☐ Over/Underweight
- ☐ Diarrhea/Constipation
- ☐ Poor Skin Condition
- ☐ Poor Mouth Condition
- ☐ Improper Technique

REHABILITATION NEEDS
- ☐ Cannot Communicate
- ☐ Ineffective Use of Assistive Device
- ☐ Improper Equipment Use
- ☐ Improper Technique
- ☐ Equipment Inadequate

SOCIAL SERVICE NEEDS
- ☐ Not Oriented
- ☐ Not Able to Converse
- ☐ Uncooperative/Disrupts
- ☐ Withdrawn
- ☐ Anxious
- ☐ Confused
- ☐ Lonely
- ☐ Vision/Hearing Needs
- ☐ Mentally Retarded

OTHER
- ☐
- ☐
- ☐
- ☐
- ☐

ACTIVITY NEEDS
- ☐ Not Participating
- ☐ Vision/Hearing
- ☐ Chair/Bedfast
- ☐ **Dependence ≥ 4 ADL's**

PATIENT RIGHTS
- ☐ Privacy Not Maintained
- ☐ Staff Not Courteous
- ☐ Not Informed of Rights
- ☐ Mental/Physical Abuse
- ☐ Cannot Exercise Rights
- ☐ Cannot Manage Affairs

NOTES:

Form HCFA 524 (2-86)

SEE REVERSE

RECORD REVIEW

☐ Drug Regimen Review (See SOM Appendix N Part 1): ☐ Satisfactory ☐ Unsatisfactory

ROUTINE REPORTS: ☐ Weights ☐ Lab ☐ X-ray ☐ Other

ASSESSMENT	PLAN	INTERVENTION	EVALUATION

PHYSICIAN SERVICES

☐ Admission Information

☐ Rehabilitation Information

☐ Physical Exam

☐ Written Care Plan

☐ Signs Orders/Notes

☐ Required Visits

☐ Emergency Availability

☐ Review of Care

★ U.S. GPO: 1986-0-181-264/53835

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

DRUG PASS WORKSHEET

PROVIDER NUMBER	SURVEY DATE	ERROR RATE ☐

INSTRUCTIONS	DEFICIENCY FORMULA
1. Perform Drug Pass Observations on 20 Residents. *2. Record Observation of each Opportunity.* *3. Compare Observation Notes with Physician Orders.* *4. Calculate and Note Error Rate.* *5. Note Deficiencies on Survey Report Form.*	*1. One or more Significant Errors = Deficiency* *2.* $\frac{\text{Significant + Non-significant}}{\text{Doses Given + Doses Ordered But Not Given}}$ *X 100* $\geq 5\%$ *= Deficiency*

IDENTIFIER	POUR	PASS	RECORD
RESIDENT'S FULL NAME, ROOM NUMBER, TIME	DRUG PRESCRIPTION NAME, DOSE AND FORM	OBSERVATION OF ADMINISTRATION	DRUG ORDER WRITTEN AS: *(IF DIFFERS FROM ADMINIS ONLY)*

FORM HCFA-522 (2-86)

SEE REVERSE

DRUG ERROR CALCULATION
(SEE SOM Appendix N Part 2)

How to Calculate a Medication Error Rate—In calculating the percentage of errors, the numerator in the ratio is the total number of errors that you observe, both significant and non-significant. The denominator is all the doses observed being administered **plus** the doses ordered but not administered. The equation for calculating a medication error rate is as follows:

$$\text{Medication Error Rate} = \frac{\text{Number of errors observed}}{\text{Opportunities for errors}} \times 100$$

Where: Opportunities for errors equals the number of doses administered **plus** the number of doses ordered but not administered.

Comments

For example, you observed the administration of drugs to 20 patients. There were a total of 47 drugs administered (47 opportunities for errors). At the completion of the reconciliation of your Observations with the physicians' orders, you find that three medication errors were made in administration and one medication was omitted (ordered but not administered). The omitted dose is included in both the numerator and the denominator. Therefore, following the above formula, your equation would be as follows:

$$\frac{3 + 1}{47 + 1} \times 100 = 8.3\%$$

★U.S.GPO:1986-0-181-264/53836

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

DINING AREA & EATING ASSISTANCE WORKSHEET

PROVIDER NUMBER	SURVEY DATE

INSTRUCTIONS

TASKS 1. Observe Dining Area.
2. Note Meals Served/Review Physicians Orders.
3. Note Assistance Provided.
4. Note Deficiencies on Survey Summary Form.

➡ *SAMPLE A MINIMUM OF FIVE (5) RESIDENTS ⬅

1. DINING AREA AND MEALS

a. Size does not restrict movement.

b. Accommodates all residents.

c. Cleanliness.

d. Adequate/comfortable lighting.

e. Adequate/comfortable ventilation.

2. SERVING OF MEALS *

a. Number of meals/time span between meal.

b. Conformance to physicians order.

c. Nutritional adequacy.

d. Adequacy of portions.

e. Residents eat approximately 75% of meals.

f. Puree dishes served individually.

g. Food cut, chopped or ground for individual resident needs.

h. Acceptable taste.

i. Proper temperature.

j. Plates covered.

FORM HCFA-523 (2-86)

SEE REVERSE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO 0938-0400

2. SERVING OF MEALS * *(continued)*

k. Served promptly.

l. Residents ready for meal when served.

m. Attractive.

n. Utensils available.

o. Functional trays for bedfast residents.

p. Salt, pepper, sugar, other condiments on resident's trays unless contraindicated.

q. Medically able residents eating in dining area.

r. Bedtime nourishment offered.

3. SUPERVISION OF RESIDENT NUTRITION

a. Prompt assistance.

b. Proper assistance (spoon-feeding; supervision or instruction to develop eating skills).

c. Courteous and unhurried assistance.

d. Self-help devices present (straws, easy grip utensils, special cup, etc.).

e. Intake recorded/deviations from normal are reported.

FORM HCFA-523 (2-86)

*U.S.GPO 1986 0 181 264/53834

§ 488.110 Procedural guidelines.

SNF/ICF Survey Process. The purpose for implementing a new SNF/ICF survey process is to assess whether the quality of care, as intended by the law and regulations, and as needed by the resident, is actually being provided in nursing homes. Although the onsite review procedures have been changed, facilities must continue to meet all applicable Conditions/Standards, in order to participate in Medicare/Medicaid programs. That is, the methods used to

compile information about compliance with law and regulations are changed; the law and regulations themselves are not changed. The new process differs from the traditional process, principally in terms of its emphasis on resident outcomes. In ascertaining whether residents grooming and personal hygiene needs are met, for example, surveyors will no longer routinely evaluate a facility's written policies and procedures. Instead, surveyors will observe residents in order to make that determination. In addition, surveyors will confirm, through interviews with residents and staff, that such needs are indeed met on a regular basis. In most reviews, then, surveyors will ascertain whether the facility is actually providing the required and needed care and services, rather than whether the facility is capable of providing the care and services.

THE OUTCOME-ORIENTED SURVEY PROCESS—SKILLED NURSING FACILITIES (SNFS) AND INTERMEDIATE CARE FACILITIES (ICFS)

(a) General.
(b) The Survey Tasks.
(c) Task 1—Entrance Conference.
(d) Task 2—Resident Sample—Selection Methodology.
(e) Task 3—Tour of the Facility.
(f) Task 4—Observation/Interview/Medical Record Review (including drug regimen review).
(g) Task 5—Drug Pass Observation.
(h) Task 6—Dining Area and Eating Assistance Observation.
(i) Task 7—Forming the Deficiency Statement.
(j) Task 8—Exit Conference.
(k) Plan of Correction.
(l) Followup Surveys.
(m) Role of Surveyor.
(n) Confidentiality and Respect for Resident Privacy.
(o) Team Composition.
(p) Type of Facility-Application of SNF or ICF Regulations.
(q) Use of Part A and Part B of the Survey Report.

(a) *General.* A complete SNF/ICF facility survey consists of three components:

- Life Safety Code requirements;
- Administrative and structural requirements (Part A of the Survey Report, Form CMS–525); and
- Direct resident care requirements (Part B of the Survey Report, Form CMS–519), along with the related worksheets (CMS–520 through 524).

Use this survey process for all surveys of SNFs and ICFs—whether freestanding, distinct parts, or dually certified. Do not use this process for surveys of Intermediate Care Facilities for Mentally Retarded (ICFs/MR), swingbed hospitals or skilled nursing sections of hospitals that are not separately certified as SNF distinct parts. Do not announce SNF/ICF surveys ahead of time.

(b) *The Survey Tasks.* Listed below are the survey tasks for easy reference:

- Task 1. Entrance Conference.
- Task 2. Resident Sample—Selection Methodology.
- Task 3. Tour of the Facility. Resident Needs. Physical Environment. Meeting with Resident Council Representatives. Tour Summation and Focus of Remaining Survey Activity.
- Task 4. Observation/Interview/Medical Record. Review of Each Individual in the Resident Sample (including drug regimen review).
- Task 5. Drug Pass Observation.
- Task 6. Dining Area and Eating Assistance Observation.
- Task 7. Forming the Deficiency Statement (if necessary).
- Task 8. Exit Conference.

(c) *Task 1—Entrance Conference.* Perform these activities during the entrance conference in every certification and recertification survey:

- Introduce all members of the team to the facility staff, if possible, even though the whole team may not be present for the entire entrance conference. (All surveyors wear identification tags.)
- Explain the SNF/ICF survey process as resident centered in focus, and outline the basic steps.
- Ask the facility for a list showing names of residents by room number with each of the following care needs/treatments identified for each resident to whom they apply:

—Decubitus care
—Restraints
—Catheters
—Injections
—Parenteral fluids
—Rehabilitation service
—Colostomy/ileostomy care
—Respiratory care

—Tracheostomy care
—Suctioning
—Tube feeding

Use this list for selecting the resident sample.

• Ask the facility to complete page 2 of Form CMS–519 (Resident Census) as soon as possible, so that the information can further orient you to the facility's population. In a survey of a SNF with a distinct part ICF, you may collect two sets of census data. However, consolidate the information when submitting it to the regional office. You may modify the Resident Census Form to include the numbers of licensed and certified beds, if necessary.

• Ask the facility to post signs on readily viewed areas (at least one on each floor) announcing that State surveyors are in the facility performing an ''inspection,'' and are available to meet with residents in private. Also indicate the name and telephone number of the State agency. Hand-printed signs with legible, large letters are acceptable.

• If the facility has a Resident Council, make mutually agreeable arrangements to meet privately with the president and officers and other individuals they might invite.

• Inform the facility that interviews with residents and Resident Councils are conducted privately, unless they independently request otherwise, in order to enhance the development of rapport as well as to allay any resident anxiety. Tell the facility that information is gathered from interviews, the tour, observations, discussions, record review, and facility officials. Point out that the facility will be given an opportunity to respond to all findings.

(d) *Task 2—Resident Sample—Selection Methodology*. This methodology is aimed at formulating a sample that reflects the actual distribution of care needs/treatments in the facility population.

Primarily performed on a random basis, it also ensures representation in the sample of certain care needs and treatments that are assessed during the survey.

(1) *Sample Size*. Calculate the size of the sample according to the following guide:

Number of residents in facility	Number of residents in sample [1]
0–60 residents.	25% of residents (minimum—10).
61–120 residents.	20% of residents (minimum—15).
121–200 residents.	15% of residents (minimum—24).
201+ residents.	10% of residents (minimum—30).

[1] Maximum—50.

Note that the calculation is based on the resident census, not beds. After determining the appropriate sample size, select residents for the sample in a random manner. You may, for example, select every fifth resident from the resident census, beginning at a random position on the list. For surveys of dually certified facilities or distinct part SNFs/ICFs, first use the combined SNF/ICF population to calculate the size of the sample, and then select a sample that reflects the proportions of SNF and ICF residents in the facility's overall population.

(2) *Special Care Needs/Treatments*. The survey form specifies several care needs/treatments that must always be reviewed when they apply to any facility residents. These include:

• Decubitus Care
• Restraints
• Catheters
• Injections, Parenteral Fluids, Colostomy/Ileostomy, Respiratory Care, Tracheostomy Care, Suctioning, Tube Feeding
• Rehabilitative Services (physical therapy, speech pathology and audiology services, occupational therapy)

Due to the relatively low prevalence of these care needs/treatments, appropriate residents may be either underrepresented or entirely omitted from the sample. Therefore, determine during the tour how many residents in the random selection fall into each of these care categories. Then, compare the number of such residents in the random selection with the total number of residents in the facility with each specified care need/treatment (based on either the resident census or other information provided by the facility).

Review no less than 25 percent of the residents in each of these special care needs/treatments categories. For example, if the facility has 10 residents with

decubitus ulcers, but only one of these residents is selected randomly, review two more residents with decubitis ulcers (25% of 10 equals 2.5, so review a total of 3). Or, if the facility has two residents who require tube feeding, neither of whom is in the random selection, review the care of at least one of the these residents. This can be accomplished in the following manner:

Conduct in-depth reviews of the randomly selected residents and then perform limited reviews of additional residents as needed to cover the specified care categories. Such reviews are limited to the care and services related to the pertinent care areas only, e.g., catheters, restraints, or colostomy. Utilize those worksheets or portions of worksheets which are appropriate to the limited review. Refer to the Care Guidelines, as a resource document, when appropriate.

Always keep in mind that neither the random selection approach nor the review of residents within the specified care categories precludes investigation of other resident care situations that you believe might pose a serious threat to a resident's health or safety. Add to the sample, as appropriate.

(e) *Task 3—Tour of the Facility*—(1) *Purpose*. Conduct the tour in order to:

- Develop an overall picture of the types and patterns of care delivery present within the facility;
- View the physical environment; and
- Ascertain whether randomly selected residents are communicative and willing to be interviewed.

(2) *Protocol*. You may tour the entire facility as a team or separately, as long as all areas of the facility are examined by at least one team member. Success of the latter approach, however, is largely dependent on open intra-team communication and the ability of each team member to identify situations for further review by the team member of the appropriate discipline. You may conduct the tour with or without facility staff accompanying you, as you prefer. Facilities, however, vary in staff member availability. Record your notes on the Tour Notes Worksheet, Form CMS–521.

Allow approximately three hours for the tour. Converse with residents, family members/significant others (if present), and staff, asking open-ended questions in order to confirm observations, obtain additional information, or corroborate information, (e.g., accidents, odors, apparent inappropriate dress, adequacy and appropriateness of activities). Converse sufficiently with residents selected for in-depth review to ascertain whether they are willing to be interviewed and are communicative. Observe staff interactions with other staff members as well as with residents for insight into matters such as resident rights and assignments of staff responsibilities.

Always knock and/or get permission before entering a room or interrupting privacy. If you wish to inspect a resident's skin, observe a treatment procedure, or observe a resident who is exposed, courteously ask permission from the resident if she/he comprehends, or ask permission from the staff nurse if the resident cannot communicate. Do not do ''hands-on'' monitoring such as removal of dressings; ask staff to remove a dressing or handle a resident.

(3) *Resident Needs*. While touring, focus on the residents' needs—physical, emotional, psychosocial, or spiritual—and whether those needs are being met. Refer to the following list as needed:

—Personal hygiene, grooming, and appropriate dress
—Position
—Assistive and other restorative devices
—Rehabilitation issues
—Functional limitations in ADL
—Functional limitations in gait, balance and coordination
—Hydration and nutritional status
—Resident rights
—Activity for time of day (appropriate or inappropriate)
—Emotional status
—Level of orientation
—Awareness of surroundings
—Behaviors
—Cleanliness of immediate environment (wheelchair, bed, bedside table, etc.)
—Odors
—Adequate clothing and care supplies as well as maintenance and cleanliness of same

(4) *Review of the Physical Environment*. As you tour each resident's room and

auxiliary rooms, also examine them in connection with the physical environment requirements. You need not document physical environment on the Tour Notes Worksheet. Instead, you may note any negative findings directly on the Survey Report Form in the remarks section.

(5) *Meeting With Resident Council Representatives.* If a facility has a Resident Council, one or more surveyors meet with the respresentatives in a private area. Facility staff members do not attend unless specifically requested by the Council. Explain the purpose of the survey and briefly outline the steps in the survey process, i.e., entrance conference * * * exit conference. Indicate your interest in learning about the strengths of the facility in addition to any complaints or shortcomings. State that this meeting is one part of the information gathering; the findings have not yet been completed nor the conclusions formulated. Explain further, however, that the official survey findings are usually available within three months after the completion of the survey, and give the telephone number of the State agency office.

Use this meeting to ascertain strengths and/or problems, if any, from the consumer's perspective, as well as to develop additional information about aspects of care and services gleaned during the tour that were possibly substandard.

Conduct the meeting in a manner that allows for comments about any aspect of the facility. (See the section on Interview Procedures.) Use open-ended questions such as:

- ''What is best about this home?''
- ''What is worst?''
- ''What would you like to change?''

In order to get more detail, use questions such as:

- ''Can you be more specific?''
- ''Can you give me an example?''
- ''What can anyone else tell me about this?''

If you wish to obtain information about a topic not raised by the residents, use an approach like the following:

- ''Tell me what you think about the food/staff/cleanliness here.''
- ''What would make it better?''
- ''What don't you like? What do you like?''

(6) *Tour Summation and Focus of Remaining Survey Activity.* When the tour is completed, review the resident census data provided by the facility. Determine if the care categories specified in the section on Resident Sample are sufficiently represented in the random selection, make adjustments as needed, and complete the listing of residents on the worksheet labeled ''Residents Selected for In-depth Review'', Form CMS–520.

Transcribe notes of a negative nature onto the SRF in the ''Remarks'' column under the appropriate rule. Findings from a later segment in the survey or gathered by another surveyor may combine to substantiate a deficiency. You need not check ''met'' or ''not met'' at this point in the survey. Discuss significant impressions/conclusions at the completion of each subsequent survey task, and transfer any negative findings onto the Survey Report Form in the Remarks section.

(f) *Task 4—Observation/Interview/Medical Record Review (including drug regimen review).* Perform the in-depth review of each individual in the resident sample in order to ascertain whether the facility is meeting resident needs. Evaluate specific indicators for each resident, utilizing the front and back of the ''Observation/Interview/Record Review (OIRR)'' worksheet, Form CMS–524. You may prefer to perform the record review first, complete resident/staff/family observations and interviews, and finally, return to the record for any final unresolved issues. On the other hand, you may prefer to do the interviews first. Either method is acceptable. Whenever possible, however, complete one resident's observation/interview/medical record review and document the OIRR before moving onto another resident. If because of the facility layout, it is more efficient to do more than one record review at a time, limit such record review to two or three residents so your familiarity with the particular resident and continuity of the OIRR are not compromised.

(1) *Observation.* Conduct observations concurrently with interviews of residents, family/significant others, and

discussions with direct care staff [of the various disciplines involved. In multi-facility operations, whenever possible, observe staff that is regularly assigned to the facility in order to gain an understanding of the care and services usually provided.] Maintain respect for resident privacy. Minimize disruption of the operations of the facility or impositions upon any resident as much as possible. Based upon your observations of the residents' needs, gather information about any of the following areas, as appropriate:

Bowel and bladder training
Catheter care
Restraints
Injections
Parenteral fluids
Tube feeding/gastrostomy
Colostomy/ileostomy
Respiratory therapy
Tracheostomy care
Suctioning

(2) *Interviews*. Interview each resident in private unless he/she independently requests that a facility staff member or other individual be present. Conduct the in-depth interview in a nonthreatening and noninvasive fashion so as to decrease anxiety and defensiveness. The open-ended approach described in the section on the Resident Council is also appropriate for the in-depth interview. While prolonged time expenditure is not usually a worthwhile use of resources or the resident's time, do allow time initially to establish rapport.

At each interview:

- Introduce yourself.
- Address the resident by name.
- Explain in simple terms the reason for your visit (e.g., to assure that the care and services are adequate and appropriate for each resident).
- Briefly outline the process—entrance conference, tour, interviews, observations, review of medical records, resident interviews, and exit conference.
- Mention that the selection of a particular resident for an interview is not meant to imply that his/her care is substandard or that the facility provides substandard care. Also mention that most of those interviewed are selected randomly.
- Assure that you will strive for anonymity for the resident and that the interview is used in addition to medical records, observations, discussions, etc., to capture an accurate picture of the treatment and care provided by the facility. Explain that the official findings of the survey are usually available to the public about three months after completion of the survey, but resident names are not given to the public.
- When residents experience difficulty expressing themselves:

—Avoid pressuring residents to verbalize
—Accept and respond to all communication
—Ignore mistakes in word choice
—Allow time for recollection of words
—Encourage self-expression through any means available

- When interviewing residents with decreased receptive capacity:

—Speak slowly and distinctly
—Speak at conversational voice level
—Sit within the resident's line of vision

- Listen to all resident information/allegations without judgment. Information gathered subsequently may substantiate or repudiate an allegation.

The length of the interview varies, depending on the condition and wishes of the resident and the amount of information supplied. Expect the average interview, however, to last approximately 15 minutes. Courteously terminate an interview whenever the resident is unable or unwilling to continue, or is too confused or disoriented to continue. Do, however, perform the other activities of this task (observation and record review). If, in spite of your conversing during the tour, you find that less than 40 percent of the residents in your sample are sufficiently alert and willing to be interviewed, try to select replacements so that a complete OIRR is performed for a group this size, if possible. There may be situations, however, where the resident population has a high percentage of confused individuals and this percentage is not achievable. Expect that the information from confused individuals can be, but is not necessarily, less

reliable than that from more alert individuals.

Include the following areas in the interview of each resident in the sample:

Activities of daily living
Grooming/hygiene
Nutrition/dietary
Restorative/rehabilitation care and services
Activities
Social services
Resident rights

Refer to the Care Guidelines ''evaluation factors'' as a resource for possible elements to consider when focusing on particular aspects of care and resident needs.

Document information obtained from the interviews/observations on the OIRR Worksheet. Record in the ''Notes'' section any additional information you may need in connection with substandard care or services. Unless the resident specifically requests that he/she be identified, do not reveal the source of the information gleaned from the interview.

(3) *Medical Record Review*. The medical record review is a three-part process, which involves first reconciling the observation/interview findings with the record, then reconciling the record against itself, and lastly performing the drug regimen review.

Document your findings on the OIRR Worksheet, as appropriate, and summarize on the Survey Report Form the findings that are indicative of problematic or substandard care. Be alert for repeated similar instances of substandard care developing as the number of completed OIRR Worksheets increases.

NOTE: The problems related to a particular standard or condition could range from identical (e.g., meals not in accordance with dietary plan) to different but related (e.g., nursing services—lapse in care provided to residents with catheters, to residents with contractures, to residents needing assistance for personal hygiene and residents with improperly applied restraints).

(i) *Reconciling the observation/interview findings with the record*. Determine if:

- An assessment has been performed.
- A plan with goals has been developed.
- The interventions have been carried out.
- The resident has been evaluated to determine the effectiveness of the interventions.

For example, if a resident has developed a decubitus ulcer while in the facility, record review can validate staff and resident interviews regarding the facility's attempts at prevention. Use your own judgment; review as much of the record(s) as necessary to evaluate the care planning. Note that facilities need not establish specific areas in the record stating ''Assessment,'' ''Plan,'' ''Intervention,'' or ''Evaluation'' in order for the documentation to be considered adequate.

(ii) *Reconciling the record with itself*. Determine:

- If the resident has been properly assessed for all his/her needs.
- That normal and routine nursing practices such as periodic weights, temperatures, blood pressures, etc., are performed as required by the resident's conditions.

(iii) *Performing the drug regimen review*. The purpose of the drug regimen review is to determine if the pharmacist has reviewed the drug regimen on a monthly basis. Follow the procedures in Part One of Appendix N, Surveyor Procedures for Pharmaceutical Service Requirements in Long-Term Care Facilities. Fill in the appropriate boxes on the top left hand corner of the reverse side of the OIRR Worksheet, Form CMS–524. Appendix N lists many irregularities that can occur. Review at least six different indicators on each survey. However, the same six indicators need not be reviewed on every survey.

NOTE: If you detect irregularities and the documentation demonstrates that the pharmacist has notified the attending physician, do not cite a deficiency. Do, however, bring the irregularity to the attention of the medical director or other facility official, and note the official's name and date of notification on the Survey Report Form.

(g) *Task 5—Drug Pass Observation*. The purpose of the drug pass observation is to observe the actual preparation and administration of medications to residents. With this approach, there is no doubt that the errors detected, if any, are errors in drug administration, not

documentation. Follow the procedure in Part Two of Appendix N, Surveyor Procedures for Pharmaceutical Service Requirements in Long-Term Care Facilities, and complete the Drug Pass Worksheet, Form CMS–522. Be as neutral and unobtrusive as possible during the drug pass observation. Whenever possible, select one surveyor, who is a Registered Nurse or a pharmacist, to observe the drug pass of approximately 20 residents. In facilities where fewer than 20 residents are receiving medications, review as many residents receiving medications as possible. Residents selected for the in-depth review need not be included in the group chosen for the drug pass; however, their whole or partial inclusion is acceptable. In order to get a balanced view of a facility's practices, observe more than one person administering a drug pass, if feasible. This might involve observing the morning pass one day in Wing A, for example, and the morning pass the next day in Wing B.

Transfer findings noted on the ''Drug Pass'' worksheet to the SRF under the appropriate rule. If your team concludes that the facility's medication error rate is 5 percent or more, cite the deficiency under Nursing Services/Administration of Drugs. Report the error rate under F209. If the deficiency is at the standard level, cite it in Nursing Services, rather than Pharmacy.

(h) *Task 6—Dining Area and Eating Assistance Observation.* The purpose of this task is to ascertain the extent to which the facility meets dietary needs, particularly for those who require eating assistance. This task also yields information about staff interaction with residents, promptness and appropriateness of assistance, adaptive equipment usage and availability, as well as appropriateness of dress and hygiene for meals.

For this task, use the worksheet entitled ''Dining Area and Eating Assistance Observation'' (Form CMS–523). Observe two meals; for a balanced view, try to observe meals at different times of the day. For example, try to observe a breakfast and a dinner rather than two breakfasts. Give particular care to performing observations as unobtrusively as possible. Chatting with residents and sitting down nearby may help alleviate resident anxiety over the observation process.

Select a minimum of five residents for each meal observation and include residents who have their meals in their rooms. Residents selected for the in-depth review need not be included in the dining and eating assistance observation; however, their whole or partial inclusion is acceptable. Ascertain the extent to which the facility assesses, plans, and evaluates the nutritional care of residents and eating assistance needs by reviewing the sample of 10 or more residents. If you are unable to determine whether the facility meets the standards from the sample reviewed, expand the sample and focus on the specific area(s) in question, until you can formulate a conclusion about the extent of compliance. As with the other survey tasks, transfer the findings noted on the ''Dining & Eating Assistance Observation'' worksheet to the Survey Report Form.

(i) *Task 7—Forming the Deficiency Statement*—(1) *General.* The Survey Report Form contains information about all of the negative findings of the survey. Be sure to transfer to the Survey Report Form data from the tour, drug pass observation, dining area and eating assistance observation, as well as in-depth review of the sample of residents. Transfer only those findings which could possibly contribute to a determination that the facility is deficient in a certain area.

Meet as a group in a pre-exit conference to discuss the findings and make conclusions about the deficiencies, subject to information provided by facility officials that may further explain the situation. Review the summaries/conclusions from each task and decide whether any further information and/or documentation is necessary to substantiate a deficiency. As the facility for additional information for clarification about particular findings, if necessary. Always consider information provided by the facility. If the facility considers as acceptable, practices which you believe are not acceptable, ask the facility to backup its contention with suitable reference material or sources and submit them for your consideration.

(2) *Analysis.* Analyze the findings on the Survey Report Form for the degree of severity, frequency of occurrence and impact on delivery of care or quality of life. The threshold at which the frequency of occurrences amounts to a deficiency varies from situation to situation. One occurrence directly related to a life-threatening or fatal outcome can be cited as a deficiency. On the other hand, a few sporadic occurrences may have so slight an impact on delivery of care or quality of life that they do not warrant a deficiency citation. Review carefully all the information gathered. What may appear during observation as a pattern, may or may not be corroborated by records, staff, and residents. For example, six of the 32 residents in the sample are dressed in mismatched, poorly buttoned clothes. A few of the six are wearing slippers without socks. A few others are wearing worn clothes. Six occurrences might well be indicative of a pattern of susbstandard care. Close scrutiny of records, discussions with staff, and interviews reveal, however, that the six residents are participating in dressing retraining programs. Those residents who are without socks, chose to do so. The worn clothing items were also chosen—they are favorites.

Combinations of substandard care such as poor grooming of a number of residents, lack of ambulation of a number of residents, lack of attention to positioning, poor skin care, etc., can yield a deficiency in nursing services just as 10 out of 10 residents receiving substandard care for decubiti yields a deficiency.

(3) *Deficiencies Alleged by Staff or Residents.* If staff or residents allege deficiencies, but records, interviews, and observation fail to confirm the situation, it is unlikely that a deficiency exists. Care and services that are indeed confirmed by the survey to be in compliance with the regulatory requirements, but considered deficient by residents or staff, cannot be cited as deficient for certification purposes. On the other hand, if an allegation is of a very serious nature (e.g., resident abuse) and the tools of record review and observation are not effective because the problem is concealed, obtain as much information as possible or necessary to ascertain compliance, and cite accordingly. Residents, family, or former employees may be helpful for information gathering.

(4) *Composing the Deficiency Statement.* Write the deficiency statement in terms specific enough to allow a reasonably knowledgeable person to understand the aspect(s) of the requirement(s) that is (are) not met. Do not delve into the facility's policies and procedures to determine or speculate on the root cause of a deficiency, or sift through various alternatives in an effort to prescribe an acceptable remedy. Indicate the data prefix tag and regulatory citation, followed by a summary of the deficiency and supporting findings using resident identifiers, not resident names, as in the following example.

F102 SNF 405.1123(b).—Each resident has not had a physician's visit at least once every 30 days for the first 90 days after admission. Resident #1602 has not been seen by a physician since she was admitted 50 days ago. Her condition has deteriorated since that time (formulation of decubiti, infections).

When the data prefix tag does not repeat the regulations, also include a short phrase that describes the prefix tag (e.g., F117 decubitus ulcer care). List the data tags in numerical order, whenever possible.

(j) *Task 8—Exit Conference.* The purpose of the exit conference is to inform the facility of survey findings and to arrange for a plan of correction, if needed. Keep the tone of the exit conference consistent with the character of the survey process—inspection and enforcement. Tactful, business-like, professional presentation of the findings is of paramount importance. Recognize that the facility may wish to respond to various findings. Although deficiency statements continue to depend, in part, on surveyor professional judgment, support your conclusions with resident-specific examples (identifiers other than names) whenever you can do so without compromising confidentiality. Before formally citing deficiencies, discuss any allegations or findings that could not be substantiated during earlier tasks in the process. For example, if information is gathered that suggests a newly hired

R.N. is not currently licensed, ask the facility officials to present current licensure information for the nurse in question. Identify residents when the substandard care is readily observed or discerned through record review. Ensure that the facility improves the care provided to all affected residents, not only the identified residents. Make clear to the facility that during a follow-up visit the surveyors may review residents other than those with significant problems from the original sample, in order to see that the facility has corrected the problems overall. Do not disclose the source of information provided during interviews, unless the resident has specifically requested you to inform the facility of his/her comments or complaints. In accordance with your Agency's policy, present the Statement of Deficiencies, form CMS–2567, on site or after supervisory review, no later than 10 calendar days following the survey.

(k) *Plan of Correction*. Explain to the facility that your role is to identify care and services which are not consistent with the regulatory requirements, rather than to ascertain the root causes of deficiencies. Each facility is expected to review its own care delivery. Subsequent to the exit conference, each facility is required to submit a plan of correction that identifies necessary changes in operation that will assure correction of the cited deficiencies. In reviewing and accepting a proposed plan of correction, apply these criteria:

- Does the facility have a reasonable approach for correcting the deficiencies?
- Is there a high probability that the planned action will result in compliance?
- Is compliance expected timely?

Plans of correction specific to residents identified on the deficiency statement are acceptable only where the deficiency is determined to be unique to that resident and not indicative of a possible systemic problem. For example, as a result of an aide being absent, two residents are not ambulated three times that day as called for in their care plans. A plan of correction that says ''Ambulate John Jones and Mary Smith three times per day,'' is not acceptable. An acceptable plan of correction would explain changes made to the facility's staffing and scheduling in order to gurantee that staff is available to provide all necessary services for all residents.

Acceptance of the plan of correction does not absolve the facility of the responsibility for compliance should the implementation not result in correction and compliance. Acceptance indicates the State agency's acknowledgement that the facility indicated a willingness and ability to make corrections adequately and timely.

Allow the facility up to 10 days to prepare and submit the plan of correction to the State agency, however, follow your SA policy if the timeframe is shorter. Retain the various survey worksheets as well as the Survey Report Form at the State agency. Forward the deficiency statement to the CMS regional office.

(l) *Follow-up Surveys*. The purpose of the follow-up survey is to re-evaluate the specific types of care or care delivery patterns that were cited as deficient during the original survey. Ascertain the corrective status of all deficiencies cited on the CMS–2567. Because this survey process focuses on the actual provision of care and services, revisits are almost always necessary to ascertain whether the deficienicies have indeed been corrected. The nature of the deficiencies dictates the scope of the follow-up visit. Use as many tasks or portions of the Survey Report Form(s) as needed to ascertain compliance status. For example, you need not perform another drug pass if no drug related deficiencies were cited on the initial survey. Similarly, you need not repeat the dining area and eating assistance observations if no related problems were identified. All or some of the aspects of the observation/interview/medical record review, however, are likely to be appropriate for the follow-up survey.

When selecting the resident sample for the follow-up, determine the sample size using the same formula as used earlier in the survey, with the following exceptions:

- The maximum sample size is 30 residents, rather than 50.

• The minimum sample size of 10 residents does not apply if only one care category was cited as deficient and the total number of residents in the facility in that category was less than 10 (e.g., deficiency cited under catheter care and only five residents have catheters).

Include in the sample those residents who, in your judgment, are appropriate for reviewing vis-a-vis the cited substandard care. If possible, include some residents identified as receiving substandard care during the initial survey. If after completing the follow-up activities you determine that the cited deficiencies were not corrected, initiate adverse action procedures, as appropriate.

(m) *Role of Surveyor*. The survey and certification process is intended to determine whether providers and suppliers meet program participation requirements. The primary role of the surveyor, then, is to assess the quality of care and services and to relate those findings to statutory and regulatory requirements for program participation.

When you find substandard care or services in the course of a survey, carefully document your findings. Explain the deficiency in sufficient detail so that the facility officials understand your rationale. If the cause of the deficiency is obvious, share the information with the provider. For example, if you cite a deficiency for restraints (F118), indicate that restraints were applied backwards on residents 1621, 1634, 1646, etc.

In those instances where the cause is not obvious, do not delve into the facility's policies and procedures to determine the root cause of any deficiency. Do not recommend or prescribe an acceptable remedy. The provider is responsible for deciding on and implementing the action(s) necessary for achieving compliance. For the restraint situation in the example above, you would not ascertain whether the improper application was due to improper training or lack of training, nor would you attempt to identify the staff member who applied the restraints. It is the provider's responsibility to make the necessary changes or corrections to ensure that the restriants are applied properly.

A secondary role for the surveyor is to provide general consultation to the provider/consumer community. This includes meeting with provider/consumer associations and other groups as well as participating in seminars. It also includes informational activities, whereby you respond to oral or written inquiries about required outcomes in care and services.

(n) *Confidentiality and Respect for Resident Privacy*. Conduct the survey in a manner that allows for the greatest degree of confidentiality for residents, particularly regarding the information gathered during the in-depth interviews. When recording observations about care and resident conditions, protect the privacy of all residents. Use a code such as resident identifier number rather than names on worksheets whenever possible. Never use a resident's name on the Deficiency Statement, Form CMS–2567. Block out resident names, if any, from any document that is disclosed to the facility, individual or organization.

When communicating to the facility about substandard care, fully identify the resident(s) by name if the situation was identified through observation or record review. Improperly applied restraints, expired medication, cold food, gloves not worn for a sterile procedure, and diet inconsistent with order, are examples of problems which can be identified to the facility by resident name. Information about injuries due to broken equipment, prolonged use of restraints, and opened mail is less likely to be obtained through observation or record review. Do not reveal the source of information unless actually observed, discovered in the record review, or requested by the resident or family.

(o) *Team Composition*. Whenever possible, use the following survey team model:

SNF/ICF SURVEY TEAM MODEL

In facilities with 200 beds or less, the team size may range from 2 to 4 members. If the team size is:

• *2 members:* The team has at least one RN plus another RN or a dietitian or a pharmacist.

• *3–4 member:* In addition to the composition described above, the team has one or two members of any discipline such as a social worker, sanitarian, etc.

If the facility has over 200 beds *and* the survey will last more than 2 days, the team size may be greater than 4 members. Select additional disciplines as appropriate to the facility's compliance history.

Average onsite time per survey: 60 person hours (Number of surveyors multiplied by the number of hours on site)

Preferably, team members have gerontological training and experience. Any member may serve as the team leader, consistent with State agency procedures. In followup surveys, select disciplines based on major areas of correction. Include a social worker, for example, if the survey revealed major psychosocial problems. This model does not consider integrated survey and Inspection of Care review teams, which typically would be larger.

(p) *Type of Facility—Application of SNF or ICF Regulations.* Apply the regulations to the various types of facilities in the following manner:

• Freestanding Skilled Nursing Facility (SNF)	Apply SNF regulations.
• Freestanding Intermediate Care Facility (ICF)	Apply ICF regulations.
• SNF Distinct Part of a Hospital	Apply SNF regulations.
• ICF Distinct Part of a Hospital	Apply ICF regulations.
• Dually Certified SNF/ICF	Apply SNF regulations and 442.346(b).
• Freestanding SNF with ICF Distinct Part (Regardless of the proportion of SNF and ICF beds, the facility type is determined by the higher level of care. Therefore, LTC facilities with distinct parts are defined as SNFs with ICF distinct parts.)	Apply SNF regulations for SNF unit. Apply ICF regulations for ICF distinct part. Apply both SNF and ICF regulations for shared services (e.g., dietary). If the same deficiency occurs in both the SNF and ICF components of the facility, cite both SNF and ICF regulations. If the deficiency occurs in the SNF part only, cite only the SNF regulation. If the deficiency occurs in the ICF part only, cite only the ICF regulation.

(q) *Use of Part A and Part B of the Survey Report*—(1) *Use of Part A (CMS–525).* Use Part A for initial certification surveys only, except under the following circumstances:

• When a terminated facility requests program participation 60 days or more after termination. Treat this situation as a request for initial certification and complete Part A of the survey report in addition to Part B.

• If an ICF with a favorable compliance history requests to covert a number of beds to SNF level, complete both Part A and Part B for compliance with the SNF requirements. If distinct part status is at issue, also examine whether it meets the criteria for certification as a distinct part.

(i) *Addendum for Outpatient Physical Therapy (OPT) or Speech Pathology Services.* Use the Outpatient Physical Therapy—Speech Pathology SRF (CMS–1893) as an addendum to Part A.

(ii) *Resurvey of Participating Facilities.* Do not use Part A for resurveys of participating SNFs and ICFs. A determination of compliance, based on documented examination of the written policies and procedures and other pertinent documents during the initial survey, establishes the facility's compliance status with Part A requirements. This does not preclude citing deficiencies if they pertain to administrative or structural requirements from Part A that are uncovered incidental to a Part B survey. As an assurance measure, however, each facility at the time of recertification must complete an affidavit (on the CMS–1516) attesting that no substantive changes have occurred that would affect compliance. Each facility must also agree to notify the State agency immediately of any upcoming changes in its organization or management which may affect its compliance status. If a new administrator is unable to complete the affidavit, proceed with the survey using the Part B form and worksheets; do not use the Part A form. The survey cannot be considered complete, however, until the affidavit is signed. If the facility fails to complete the affidavit, it cannot participate in the program.

(iii) *Substantial Changes in a Facility's Organization and Management.* If you receive such information, review the changes to ensure compliance with the regulations. Request copies of the appropriate documents (e.g., written policies and procedures, personnel qualifications, or agreements) if they were

not submitted. If the changes have made continued compliance seem doubtful, determine through a Part B survey whether deficiencies have resulted. Cite any deficiencies on the CMS–2567 and follow the usual procedures.

(2) *Use of Part B (CMS–519).* Use Part B and the worksheets for all types of SNF and ICF surveys—initials, recertifications, followup, complaints, etc.

The worksheets are:

- CMS–520—Residents Selected for In-depth Review
- CMS–521—Tour Notes Worksheet
- CMS–522—Drug Pass Worksheet
- CMS–523—Dining Area and Eating Assistance Worksheet
- CMS–5245—Observation/Interview/Record Review Worksheet

For complaint investigations, perform a full or partial Part B survey based on the extent of the allegations. If the complaint alleges substandard care in a general fashion or in a variety of services and care areas, perform several tasks or a full Part B survey, as needed. If the complaint is of a more specific nature, such as an allegation of improper medications, perform an appropriate partial Part B survey, such as a drug pass review and a review of selected medical records.

§488.115 Care guidelines.

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Resident Rights F53 SNF 405.1121(k)(1) ICF 442.311(a) F54 SNF 405.1121(h)(1) ICF 442.311(a)(1) A. Information* F55 SNF 405.1121(h)(1) ICF 442.311(a)(2) 1. Rights and Responsibilities F56 SNF 405.1121(k)(1) ICF 442.311(a)(3) 2. Rules of Resident Conduct F57 SNF 405.1121(h)(2) ICF 442.311(a)(4) 3. Resident Acknowledgement	Where is information concerning resident rights and responsibilities available in the facility?	Ask Resident: - Did you receive a copy of the Resident's Bill of Rights? Was it explained to you? - Were you told of any responsibilities you have in living here? - Were you given a chance to ask questions? - Did he/she receive a written copy of services provided by the facility and any additional costs for these services?	Looked for signed acknowledgement of receipt of resident rights information. Residents unable to sign name may have their "mark" witnessed. Look for written statement of charges services. Social Work records may idicate patient rights information discussed with resident.	Because of the confusion surrounding admission to a new facility and the large amount of information given to a resident or resident's family on admission, information given at this time is often forgotten. Therefore, surveyor should verify resident's recollection with staff interviews and record checks. Written information on services and costs must be given to the resident, as well as copies of residents rights and responsibilities. Copies of residents' rights should also be available to patients and visitors, e.g., in resident lounges, lobbies, or other area where residents and visitors could easily see and read them.	Notification of Change in Status 405.1121(j) 442.307 Patient Care Policies 405.1121(e) 442.308 442.309 442.310 442.305 Medical Direction 405.1122(a) Medical Records 405.1132(b)(d) 442.310

INTENT
To assure that the resident maintains, in so far as possible, those personal rights that are a part of normal, adult life, and including the right to personal dignity.

*Information concerning incompetent residents is given in L. Delegation of Rights and Responsibilities.

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F58 SNF 405.1121(k)(2) ICF 442.311(a)(4) 4. Resident informed in writing of changes in services and charges for services. F59 SNF 405.1121(k)(2) ICF 442.311(a)(4) 5. Information to resident of services not covered by Medicare or Medicaid and not covered in the basic rate.		Ask Resident: - If there are changes in services or costs does someone explain these? Ask Administrative Staff: - How do residents learn what is expected of them? - How do they learn about any changes in the facility's procedures and/or costs?			

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
B. Medical Condition & Treatment F60-64 SNF 405.1121(k)(2) ICF 442.311(b)		Ask Resident: - Has your doctor discussed your health with you, how is it, what's wrong, and what you can expect in the future? - Have you had the opportunity to help plan what you need and how you are taken care of? - Do you know that you can refuse treatment or medication? - Have you ever refused medication or treatment? - What happened when you did? Ask Staff: - Is the facility participating in any experimental research? If yes, ask what residents are involved. Interview a sample of these residents. Ask Resident (or Guardian): - Are you participating in the _____ study? - Was this explained to you well enough so that you understand what the study is about and any risks that may be involved?	If the resident has not been informed of his/her medical condition, physician notes should document that the resident was not informed because it was medically contraindicated. Do care plans or other documentation reflect resident participation in care planning? If resident states he/she has refused treatment or medication does documentation indicate adherence to/violation of resident rights. Review records of residents identified as participating in a clinical research study. Are informed consent forms signed? Do these signed forms list all known risks for the resident? All needed informed consent statements are present and properly signed.	Unless there is documentation that the residents medical condition should not be discussed with him/her resident interviews/record reviews should indicate that the resident and physician have discussed his/her medical condition.* If you cannot confirm that this has occurred, interview staff to get further clarification. Almost all residents who are able to participate to some extent in their care planning do so. You should find evidence of this for the majority of the residents (e.g., care planning interview, nurses notes, social worker progress notes). Residents do have the right to refuse medication or other treatment, but you would expect that the facility would discuss the implications of this refusal with the resident and possibly do some "gentle persuasion".*	Patient Care Management 405.1124(d) 442.319 442.341

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F60–64 (cont'd)				However, except in an emergency situation force should never be used to compel a resident to accept medication or treatment. Deceit is also a violation of resident rights, except in the case of therapeutically indicated placebos ordered by the physician. Any resident participating in research studies should fully understand the implication of the study. The facility is not in compliance with the resident rights regulation if the resident consents to participate in a clinical study without full knowledge of the study. (Record review only as other nonclinical studies may not require informed consent).	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
C. Transfer and Discharge F65-68 SNF 405.1121(k)(4) ICF 442.311(c)	Look for residents that may be inappropriately placed physically - an alert resident rooming with a confused, noisy resident; very ill resident placed far from the nurses station; residents not compatible with each other, (e.g., different life-styles, habits, etc.).	Ask Resident: - How well do you get along with your roommate? - Have you ever been moved from one room to another? If yes, why? - How were you involved in the decision to move? - How much time was there between the time they told you you were to be moved, and when you were moved? - Have you asked for your room to be changed? Ask Direct Care and Other Staff: - What are some of the reasons residents rooms are changed? - What are some of the reasons for discharge of residents or transfer to a hospital or LTC facility? - How are residents involved in the decision to move? - If a resident requests a room change, how is this handled? - When a resident requests a room change are the following areas of consideration presented and discussed:	Nursing, physician, and/or social service progress notes should indicate reason for transfer and discussion with resident and/or family/guardian. If staff interviews give you cause to feel that transfers and discharges may be in violation of these regulations, review a sample of closed records for transfer information on how it was handled. If residents are transferred between facilities with common ownership and similar levels of care, transfers must be reviewed to determine reasons for transfer. Efforts to maintain the census is not an acceptable reason for transfer. Do discharge records review: - reason for discharge, medical non-payment or need for different level of care?	To be in compliance with transfer and discharge regulations the facility must be able to confirm that all discharges/ transfers were for medical or resident welfare reasons, or non-payment. Welfare reasons include physical, emotional, social issues. Transfers and discharges made solely for the convenvience of the facility are unacceptable. (Relocation to accommodate contagious or other disorders requiring isolation procedures are not for the convenvience of the facility).	Status Change Notification 405.1121(j) Medical Records 405.1132(c)(e) 442.318(c)(4) Transfer Agreement 405.1133(a)(2) 442.307(b)(1)(2)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F65-68 (cont'd)		+ cost factors + resident welfare + resident's reason for requesting the move + facility's assessment of whether the move would be beneficial or not for the resident.			

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
D. Exercising Rights F69 SNF 405.1121(k)(5) ICF 442.311(d)	Do residents appear comfortable when speaking to the surveyors as opposed to being afraid that someone may see them or overhear their conversation?	Ask Resident: - Do you belong to, or have representation on the resident council? - Are you informed of changes in the facility that will affect you? - Are you given a chance to express views on these changes prior to their implementation? - Does the facility assist in arranging for you to vote either at the polls or via absentee ballot? - Are you assisted in obtaining legal or Social Services if needed? - Do you feel comfortable in expressing yourself freely or are you concerned about retaliation? - Is staff/administration responsive to complaints? Do you know who to complain to? Ask Staff: - What arrangements are made for residents to vote? - How do you handle it if someone needs a lawyer or other service that you don't provide?	Review resident council documentation, as available, to determine level of activity. Review social work or progress notes for legal referrals. Is there documentation in progress notes or elsewhere, of resident complaints and disposition of complaints?	Compliance determinations will be made based primarily on resident/staff interviews and the correlation of interview information with documentation in the Medical record. If residents ask, they should be allowed to speak to the surveyor without facility personnel being present. However the resident has the right to have a third party of their choosing present during an interview.	Social Services 405.1130 442.344

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
E. Financial Affairs F72-78 SNF 405.1121(k)(6) 405.1121(m) ICF 442.311(e) 442.320		Ask Residents: - Are you able to take care of your own financial affairs? - Does the facility keep some money for you that you can have when you request it? - When you ask for this money, how quickly do you get it? - Do you know the amount of money you have available at this time? - If the facility pays bills for you do they periodically provide an itemized listing of the transactions they have made? - When did you receive the last itemized statement? - Are you comfortable that your funds are taken care of correctly? - If you deposit money or valuables with the facility, do you receive a receipt for this deposit? - Are you or your family able to review your financial records when you request to do so? - Have you ever had money or anything else stolen? If so, what was done about it?	A copy of the statement should be in the residents financial record and given to the resident at least quarterly. Receipts, account logs showing deposits/withdrawals, authorization/reasons for withdrawals, and interest earned should be reviewed. If resident indicates there may be a problem, an in-depth interview should be conducted. Resident records indicate separate financial records from facility records.	Residents should have reasonable access to their funds (may not be available at 2 A.M.) and should have at least a quarterly accounting of their funds. If questions arise they should be resolved. Personal possessions and funds received from the residents should be protected from theft and other loss. If losses do occur there should be: 1. a procedure which is implemented to investigate the loss, and 2. a plan to prevent recurrence. Resident funds must not be appropriated for facility furnishings, linen direct care supplies, etc	Social Services 405.1130(a)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F72-78 (cont'd)		- Does the home provide safe-keeping for valuables? - Have they ever lost anything of yours? <u>Ask Staff</u>: - What is the procedure when residents lose personal belongings? Valuables? - How are resident personal funds handled? - What is your procedure when a resident asks to get an accounting of their funds? * The special needs of residents with Alzheimer's disease who "lose" personal possessions should be noted. Individuals in stages 2 and 3 of Alzheimer's disease sometimes believe their personal possessions were stolen.			

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F. Freedom From Abuse and Restraints F79-83 SNF 405.1121(k)(7) ICF 442.311(f)	- How many residents are physically restrained? - What type or restraints are used? - Are they applied correctly? - What is the apparent physical/mental condition of those residents restrained? - Do you observe the release of restraints every 2 hours and the provision of at least 10 minutes exercise for the resident? - Do staff respond to request for water, assistance to bathroom, etc., from a resident who is restrained? What is the interval between request and response?	Ask Resident: - Why are you wearing this? - How often is this worn? - Do you know what would happen if it were removed? - How often is it removed? - What is done for you when the restraint is removed? - For nonrestrained resident-- + Have you ever been restrained? + For what reason? + What explanation was given for the restraint? - Do you ever feel that you receive medication when you don't need it?	Look for a physician's order for the restraint. Review nurses', physicians' progress notes re: reason for restraints and resident reaction to them. Also any alternative methods tried. What time of day are restraints most often applied? Review schedule of releasing restraints. Care plans: - When restraint is to be used. - For how long. - What are plans for alternative measures. - Is the resident periodically re-evaluated? If appropriate are the Social Service or activities departments involved in providing different directions for resident attention?	There must be a physician's order for all restraints, including "safety devices" which are defined in some State laws. Progress notes should show evidence that methods other than restraints were initially used to protect the resident from injury, and that restraints were used only when other methods were not adequate If used in an "emergency" the reason for use must be documented and show that: a. Its use was necessary to protect the resident from injury. b. Its use was necessary to protect others from injury. The resident must be observed by a staff member at least every 30 mins. while restrained. The restraints must be released and the resident exercised, toileted, etc. at least every 2 hours.	Nursing Services 405.1124(c)(5) Rehab Nursing 405.1124(e) Patient Care Management 405.1124(d)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F79-83 (cont'd)	- How often are restrained residents observed by staff? - Observe effect on residents. Do you see what may be signs of over-medication? - How often is this observed? - Residents should be free from mental and physical abuse. -Observe interaction of staff and residents for any sign of harassment, humiliation or threats. - Do residents appear comfortable with staff? - Look for numbers of residents with bruises or other injuries (skin of the elderly bruises easily, so do not automatically assume abuse or injury). - Observe resident to resident interactions and staff response to any physical or mental abuse of one resident to another.	Ask Staff: - What is the facility policy regarding re: restraints? - What is considered an "emergency" need for restraints? - What is the most common reason for use of restraints? - Do you try any alternative measures before using restraints? - What information do you give the physician to help him make the decision to order restraints? - What do you routinely do for the resident when you periodically release the restraints? - Does use of restraints increase on evenings or nights when there are fewer staff members? - Have you had any accidents or incidents in the last year while residents were restrained? - How do you define the difference between a "safety device" and a "restraint"? - How do your policies differ in regard to "safety devices" and restraints?	Who authorizes the use of restraints in an emergency? Do progress notes indicate that a professional staff member authorized the use of "emergency" restraints? There should be documentation that the use of "emergency" restraint has been promptly reported to the residents physician. Review incident and accident reports to identify any problematic trends. Does the drug regimen review indicate appropriate use of psychoactive drugs? Are there resident complaints documented? What is the resolution of these complaints?	The restraint must be applied correctly. If the use of restraints increased during evening and night hours review progress notes, nurses notes and staffing to make a determination as to whether the restraints are justified or if they are for staff convenience. Care plans should plan not only for care while the resident is restrained but should show effort to find alternative treatments to restraints, or there should be documentation in the medical record that no alternative is appropriate. An appropriate drug regimen reviews should be conducted on the resident. Your observations should show interaction between residents and staff to be, except in unusual situations, free from tension and hostility. Staff should step into situation where one resident may be abusing another.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCI
F79–83 (cont'd)	- Observe for evidence of resident neglect, residents left in urine/feces without cleaning.	Ask Resident: - Do you feel safe in the facility? - Do you ever feel intimidated, harassed, or otherwise abused? - How are confused residents treated? - Is anyone ever hit or treated roughly? - Do you feel as if you are treated with respect /dignity? - Is the staff/administration responsive to complaints? - Do you know who to complain to?		Resident should feel free to voice complaints. If no complaints are noted in records or on record review, why not? Residents should seem comfortable in relating how they are treated?	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
G. Privacy F84-89 SNF 405.1121(k)(8) (9)(14) ICF 442.311(g)	- Observe interactions between staff and residents for indications of respect, consideration, dignity and individuality. - How do staff members enter a residents room or go behind a privacy curtain? - Are privacy curtains used or doors shut when personal care needs and/or treatments are rendered? - Are there areas for residents to be alone or meet in private with visitors?	Ask Resident: - Do you feel that you are treated as a worthwhile, adult individual? - - When you are being cared for, are you comfortable? - What is the degree of privacy and respect you receive? - Do you feel comforatable that if the door to your room is closed staff will knock or otherwise make their presence known before entry? - Do you have a private place to make telephone calls? - - Can you see your record if/when you ask? - Has any information about your condition been given to someone outside of the facility without your permission?	Review progress notes for indications that staff see resident as an individual-i.e., resident eats breakfast in bed because he/she enjoys it. Signed consent for release of information. Do maintenance of and content of medical records indicate that confidentiality is practiced?	Observations and interviews will give you information to determine if residents are respected and treated as individuals. Is privacy available--e.g., access to a private place to meet or make phone calls, ability to shut door when having visitors, etc. Medical records should not be left where unauthorized personnel can read them and there should be identification codes needed to access computerized records. Married residents should be sharing rooms if they desire to do so unless there are appropriate contradictions.	Medical Records 405.1132(b) 442.318(d)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F84-89 (cont'd)	- Are medical records kept in their assigned spots not carelessly left for nonauthorized persons to view? - Are married residents sharing rooms? - Observe for negative attitudes toward aging-infantilization and patronizing of residents. - If residents undress in public area, how does staff handle this? - Listen to staff conversation in public places (elevator, lobby). Are resident issues being discussed?	For Married Residents: - When your husband/wife visits can you shut your door and be assured of privacy? - Can you ask that you not be disturbed and have that request respected? Ask Staff: - What is done to assure that each resident maintains his/her dignity and individuality? - How are medical records kept secure? Who has access? - Do you have married couples here? - Do they share rooms? - If not, why? - What arrangements do you make for spouses or significant others to visit? - Do you allow their door to be closed? - Can you adhere to a request that they not be disturbed? - How are residents' medical records and conditions kept confidential?			

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
H. Work F90 SNF 405.1121(k)(10) ICF 442.311(h)	- Are residents doing any type of work such as picking up dirty trays, pushing laundry hampers, etc.? - What about clerical work?	Ask Resident: - Are you ever asked to help out in the facility such as pick up dirty trays or stamp mail? - If yes, do you do this? - Do you want to, or do you feel it is expected of you? - Do you feel you can say "no"? Ask Staff: - Are residents asked to help with facility staff if you are shorthanded? - What is their reaction? - What useful work is available for residents who want/need to be usefully "employed"?	If residents are performing services for the facility, is that included in their care plan with specific therapeutic goals defined? If appropriate does the family concur? Are results documented in progress notes? What service (activities, nursing, etc.) is responsible for planning reevaluating and adjusting work activity? Look for physician's orders for approval or disapproval of work activity or restrictions on this activity. Look for evidence that the resident is given opportunities to refuse to do the work. The resident, however, is not restricted from doing the amount and type of work they desire unless it is in conflict with the plan of care.	Services performed by a resident should be part of the resident's plan of care and should be done only if the resident is in full agreement. Service rewards are specifically identified and not obtained using the residents own funds.	405.1124(d) 442.341

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
I. Freedom of Association and Correspondence F91-92 SNF 405.1121(k)(11) (12) ICF 442.311(i)	- Are there areas in the facility-e.g., small lounges, etc., where residents can and do meet privately? - Is mail delivered opened or unopened? - Are facility personnel assisting residents, if needed, in opening and/or reading mail?	Ask Residents: - Can you have visits from anyone? - Can you find a private place to visit? - Do you receive your mail unopened unless you request otherwise? - Are there telephones you have access to? - Does the staff or volunteers assist you in reading or sending mail, if needed? - How timely is your mail delivered? - How do you receive incoming calls? Ask Staff: - Where do residents go when they want privacy? - What telephones are available to residents? - What is the facility visiting policy?	Physician orders and care plans for indications of restrictions on visitors and/or receiving and sending mail.	All residents may have access to and maintain contact with the community and members of that community have access to them. Subject to reasonable scheduling restrictions, residents may receive visits from anyone they wish. A particular visitor may be restricted by the facility for one of the following reasons: - The resident refuses to see the visitor. - The resident's physician documents specific reasons why such a visit would be harmful to the resident's health. - The visitor's behavior is unreasonably disruptive of the functioning of the facility (reasons are documented and kept on file). Decisions to restrict a visitor are reviewed and reevaluated each time the resident's plan of care and medical orders are reviewed by the physician and nursing staff or at the resident's request.	Resident Rights 405.1121(k)(8) 442.311(g)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F91-92 (cont'd)	Do the available telephones accomodate the physically handicapped (e.g., wheelchair bound, hearing impaired, etc.).			Space is provided for residents to receive visitors in reasonable comfort and privacy. Telephones, consistent with ANSI standards (45.1134(c)), are made available and accessible for residents to make and receive calls with privacy. Residents who need help are assisted in using the phone. The fact that telephone communication is possible, as well as any restrictions, is made known to residents. Arrangements are made to provide assistance to residents who require help in reading or sending mail.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
J. Activities F93 SNF 405.1121(k)(12) ICF 442.311(j)	- What planned activities are occurring? - What unplanned activities are occurring--individual, 2 or 3 persons or a larger group. - If there is a facility chapel, is it open? - Are activities posted at wheelchair level and kept up to date? - Are residents lined up in front of a T.V. in a common room for hours? - Are activities offered during the evening and on weekends.	Ask Residents: - What do you like to do? - What did you do yesterday? (compare answers) - Is participation in activities optional? - Are you encouraged to participate? - Is pressure exerted on you to attend specific activities? - Which ones? (Surveyors should be aware of special encouragement--"gentle persuasion", which might be important for the depressed or withdrawn resident.) - Are residents notified of community activities? - Are arrangements made for transportation, etc. so that residents can participate? - Can residents go to religious services if they wish? - What opportunities are you given to make choices in your life within the facility? (eg. are all residents "put to bed" at the same time?). Ask Staff: - Are arrangements ever made to take residents to community activities? - Do friends and relatives ever take them to community activities? - Do your residents attend religious service of their choice? - How are residents kept informed/notified of activities?	Care plans or other documentation should indicate resident preferences for both facility and non-facility planned activities. Progress notes of responses to activities.	Compliance with this element is determined by evidence that residents are given the opportunity to participate in available activities they choose unless medically contraindicated. Residents must not be forced to participate against their wishes.	Patient Activities 405.1131(b) 442.345(a)(c)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
K. Personal Possessions F94 SNF 405.1121(k)(13) ICF 442.311(k)	- Are residents wearing their own clothing or facility nightgowns, robes, etc.? - In resident rooms observe for personal belongings. - Ask residents if you can look in the closet-is personal clothing in there? - Ask residents if belongings such as clothing are identified with name tags or other identifying methods? - Is there enough space to store clothing?	Ask Residents: - What clothing and personal belongings can you have? - Is there a place that you can secure any valuables that you may not want to keep in your room? Ask Staff: - What personal belongings may residents have? - What do you do to secure valuables and other personal property? - What provisions are made for the care of personal clothing?	Admission notes on personal property inventory (e.g., the record should indicate a list of any personal property secured by the facility). The record should indicate how personal clothing will be laundered.	Residents are permitted to keep reasonable amounts of personal clothing and possessions for their use while in the facility and such personal property is kept in a safe location which is convenient to the resident. The amount that is reasonable will be dependent on space available in the facility. Patients are advised, prior to or at admission, of the kinds and amounts of clothing and possessions permitted for personal use, and whether the facility will accept responsibility for maintaining these items (e.g., cleaning and laundry). Any personal clothing or possessions retained by the facility for the patient during his stay is identified. The facility is responsible for secure storage of such items, and they are returned to the patient promptly upon request or upon discharge from the facility.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
L. Delegation of Rights and Responsibilities F95-97 SNF 405.1121(k) ICF 442.312		Ask Administrative Staff: - When do you have relatives make decisions for residents-i.e., how do you decide when the resident isn't capable of making decisions himself? - Have any legal steps been taken? Ask Resident and/or Guardian: - Do you feel that you are given all pertinent information? - What opportunities do you have to make decisions regarding clothing, meals, bathing schedules, etc.? - For guardian: are you notified/informed in a timely manner as appropriate?	Review physician progress notes--incapability must be documented. Is there clear documentation as to whom rights and responsibilities have been assigned? Are pertinent consents/documents signed by appointed guardian?	The fact that a resident has been judged incompetent, is medically incapable of understanding, or exhibits a communication barrier, does not absolve the facility from advising the resident of their rights to the extent the patient is able to understand them. If the resident is incapable of understanding their rights, the facility advises the guardian or sponsor and acquires a statement indicating an understanding of resident's rights. The surveyor reviews records of residents selected for indepth review who are classified either incompetent, medically incapable of understanding their rights, or have a communication barrier to verify documented evidence (signed acknowledgment) that the guardian or other sponsor has been advised of these resident rights and understand their role in acting on behalf of the resident.	Resident Rights 405.1121(k)(1) 442.311(a)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
STAFF DEVELOPMENT F98 SNF 405.1121 F99 ICF 442.314 F100 1. Facility staff are knowledgeable about the problems and needs of the aged, ill, and disabled. F101 2. Facility staff practices proper techniques in providing care to the aged, ill and diseased. F102 3. Facility staff practice proper technique for prevention and control of infection, fire prevention	How do staff relate to residents? Does the facility reflect adaptations for the elderly, i.e., information given in large print, floors covered with materials that allow for ease of movement with walkers, wheel chairs, etc.? Is resident care given using accepted professional standards? Is privacy maintained during bathing treatment, toileting? Are housekeeping staff courteous and responsive to resident needs?	Ask Residents - Does staff know how to take care of you? - What things do they do to help you accommodate your (poor vision, unsteady walking, arthritis, etc.)? Ask Staff - What, if any, training have you had here to learn about unique problems and needs of the aged? - What training have you had during the last 12 months? - How have you learned about facility policies and procedures? - Does the facility ask your needs when they develop a training program? - In what areas would you like to have training?	Care plans reflect staff's knowledge of the problems and needs of the residents and special adaptations that are needed. Progress notes indicate that the special needs are considered in implementing planned care.	Facility staff adjusts care to needs/problems of resident. Staff is knowledgeable concerning facility policies and procedures. Staff practices correct techniques, i.e., infection control rehabilitation nursing techniques, etc. Staff interacts and treats residents in a kind, caring way.	Residents Rights SNF 405.1121(k) ICF 442.311 Infection Control 405.1135(a)(b)(c)(d)(e) 442.327(b) Physical Environment 405.1134(a) 442.315(b)(c) 442.326(a)(c) Nursing Services 405.1124(a)(c)(e) 442.338(a)(2) Social Services 405.1130(a)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F102 (cont'd) and safety, accident prevention, confidentiality of resident information, and preservation of resident dignity including protection of privacy and personal and property rights. INTENT To assure that facility provides ongoing training to staff so that they will be knowledgeable in current practices, use proper techniques, and interact with residents in a kind, caring way.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Status Change Notifications F103-104 SNF 405.1121(j) ICF 442.307 F105 1. The facility notifies the resident's attending physician and other responsible persons in the event of an accident involving the resident, or other significant change in the resident's physical, mental, or emotional status, or patient charges, billings, and related administrative matters.	Note residents condition: - Clean - Well groomed - Well adjusted - Casts - Bruises - Decubitus Ulcer - Multiple sites of edema - Aberrant behavior, e.g., abusive, disruptive, not reasonable, etc.	Ask Resident: - Have you been injured since you have been in the facility? - If you are injured or become ill, is your physician called? - Are your relatives notified? - Do you know who is notified if administrative changes such as changes in charges, billings, etc. occur? Ask Staff: - Who do you notify if a resident is injured or has a change in condition? - When would they be notified? Does the facility have a policy regarding how soon a relative or responsible party would be notified? - Do you notify them of actual changes in resident condition and also if resident's condition is getting progressively worse?	- Progress note should document injury/change in condition plus notification of physician and appropriate family member/guardian. - Changes in charges should be documented. Ask facility where this is located. - Review accident and incident reports for indepth sample.	- All injuries and changes in condition must be documented. The resident's physician and family must be notified of signicant changes. This should be documented, but this notification should be confirmed by the resident if possible.	Resident Supervision by Physician 405.1123(b)(3) Emergency Services 405.1123(c)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F106 2. Except in a medical emergency, a resident is not transferred or discharged, nor is treatment altered radically, without consultation with the resident or, if the resident is incompetent, without prior notification of next of kin or sponsor. INTENT To assure that: - the resident receives proper treatment in the event of an accident or change of condition. - resident and/or next of kin or responsible party is aware in advance of any changes. - resident is not discharged to gain a higher source payment for that bed or facility convenience.		Ask Resident: - Have you ever been or do you know if others have been transferred or discharged without discussing it with you first?	- Nursing, physician and social work progress notes should be reviewed for evidence of discussion of transfer/discharge with resident or other designated person.	- Except in an emergency, all transfers or discharges are first discussed with the resident or next of kin as evidenced by documentation in the medical record or confirmed by asking resident.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Physician's Services F107 SNF 405.1123 A. Medical Findings and Orders at Time of Admission F108 SNF 405.1123(a) F109 1. There is made available to the facility prior to or at the time of admission, resident information which includes current medical findings diagnoses, and orders from a physician for immediate care of the resident. F110 2. Information about the rehabilitation potential of		Ask Staff: - Interview nursing staff to determine if they receive transfer information and admission orders on day of admission. - Ask Administrator and Director of Nursing to explain procedure if a resident arrives without sufficient medical information and/or orders.	Review records of residents selected for indepth review to ascertain that: - There is a referral form from the transferring facility that was received in advance of admission or on date of admission that includes current medical findings, diagnosis and orders from a physician for the immediate care of the residents. - If the medical orders were not obtained from the residents attending physician, there are temporary orders from the emergency care physician. - Information on the rehabilitation potential (prognosis) of the resident and a summary of the course of treatment followed in the transferring facility were transmitted within 48 hours of admission. - The summary of treatment should include discharge summaries from therapies or special services when appropriate. - for residents admitted directly from the	Examine medical records of the residents selected for indepth review to determine if date of orders, medical data and other required information is the date of admission or within 48 hours of admission. The facility should receive sufficient information and orders to provide continuity of care of all residents.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F110 (cont'd) the resident and a summary of prior treatments are made available to the facility at the time of admission, or within 48 hours thereafter.			community, the attending physician provided current medical findings, diagnosis, prognosis, and orders. - The order should cover: + Medications and treatments + Diet + Therapies (P.T., O.T., Speech) + Activities (bedrest, ambulatory, able to participate with any specific limitations on activity).		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Resident Supervision by Physician F111 SNF 405.1123(b) F112 ICF 442.346 B. Resident Supervision by Physician F113 1. Every resident must be under the supervision of a physician F114 2. A physician prescribes a planned regimen of care based on a medical evaluation of each resident's immediate and long-term care needs.	Observe resident for any problem/conditions that should be addressed by physician, e.g., edema, loss of appetite, weight loss, etc.	Ask Resident: - How often physician visits. - If physician has discussed plan of care and medical treatment. - If resident feels treatment and/or plan of care meets his/her needs. - What kinds of questions do you ask the physician about your health problems? (Cite examples). Ask Licensed Nursing Staff - How often physician visits and is it often enough to meet resident's need? - Does physician participate in evaluation and reevaluation of resident's plan of care? - Does plan of care meet resident's needs? - Is physician available in an emergency? - Is physician available to disucss residents treatment and care? Ask Administrator - Facility's policy regarding a physician to provide care in the absence of the resident's own physician. - Facility's policy on physician visits.	Review medical records of selected for indepth review for: - A current plan of care that is based upon physician's orders and resident needs. - Evidence that the plan is reviewed and revised as needed. - Evidence through physician's progress notes, nurses notes, physician's orders, that the physician participates in the resident's overall plan of care. - Evidence that rehabilitation potential is addressed. - Long range plans include an estimate of the length of time for skilled nursing care and a discharge plan. - Physician's orders for medications and treatments on admission and during stay. - A medical evaluation completed within 48 hours of admission unless done within 5 days prior to admission that includes attention to needs such as diet, vision, hearing, speech	Medical records should provide evidence that the residents are under the supervision of a physician by the coordination of physician's orders and progress notes with the resident's plan of care and observations of residents needs. There is evidence that the physician reviews and revises the plan of care as needed. There is evidence that physician services are available to the residents when the residents need such services. An alternate schedule for physician visits may be established if the attending physician determines that the resident need not be seen every 30 days. Justification for the decision is placed in the resident's medical record and is reviewed by the U.R. Committee and State medical review team. Where there is a change in the resident's condition and the physician has failed to document his findings or evaluation of the condition, the physician has failed to provide	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F114 (cont'd)			level of activity, emotional adjustment. - Evidence in care plans and treatment records that physician's orders are being implemented. - Discrepancies in medication record, diet order, intake and output records. - Evidence that an alternate physician provided care if applicable. - Progress notes by physician at least every 30 days for first 90 days (ICF-at least every 60 days). - Review of medications and treatments every 30 days or 60 days if an alternate schedule of visits has been approved. - Documentation of physician observations, actions and plans for treatment. - Justification for alternate schedule of visits.	evidence of his evaluation of resident needs and supervised care.	
F115 3. A physician is available to provide care in the absence of any resident's attending physician.				A physician is available to respond within a reasonable time when a resident needs medical attention.	
F116 4. Medical evaluation is done within 48 hours of admission unless done within 5 days prior to admissions. NOT ICFs.					
F117 5. Each SNF resident is seen by their attending physician at least once every 30 days for the first 90 days after admission.			A few closed records should be reviewed to determine if residents were appropriately discharged by an order written by the attending physician. Also review	Although medical evaluation can be noted as a revision of the previous H&P A statement such as "no change" when in conflict with the status of the	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F117 (cont'd) Exception: ICF residents must be seen every 60 days unless otherwise justified and documented by the attending physician. F118 6. Each resident's total program of care including medications and treatments is reviewed during a visit by the attending physician at least once every 30 days for the first 90 days and revised as necessary.			discharge plans to assure that they were adequate and implemented. Verbal medication orders are countersigned by a physician. Physician is reviewing all medication orders every quarter.	resident on this admission to the facility, does not constitute a medical evaluation. Verbal medication orders must be countersigned with 48 hours.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Exception: Only medications must be reviewed quarterly for ICF residents.					
F119 7. Progress notes are written and signed by the physician at the time of each visit, and all orders are signed by the physician.					
F120 8. Alternate physician visit schedules that exceed a 30-day schedule adopted after the 90th day following admission are justified by the attending physician in					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F120 (cont'd) the medical record. These visits cannot exceed 60 days or apply to patients who require specialized rehabilitation schedules. Exception ICF residents must be seen every 60 days unless justified otherwise documented by the attending physician.					
C. Emergency Services F121 SNF 405.1123(c) F122 Emergency services from a physician are available and provided to each resident who requires emergency care		Ask Staff: - Are you aware of physician reporting procedures and medical protocols to be followed during a fire emergency? - Do you know where names and telephone numbers are of physicians to be called in case of emergency?	- If records document an accident or a medical emergency, was the patient seen by a physician or was the physician notified promptly of the emergency? - Review physician's orders to see if specific medications or treatments were ordered to treat emergency situation if applicable.	- Surveyor verifies that there are readily available written procedures for securing a physician in case of emergency. - Names and telephone numbers are posted or on rolodex. - An alternate physician is designated.	Status Change Notification 405.1121(j)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F122 (cont'd) INTENT: To assure that a physician has overall responsibility for the managment and supervision of the residents care.			- Review physicians progress notes to see if emergency situation was addressed.	- There is provision for: + Notification of attending physician/ emergency and other responsible person. + Arrangements for transportation. + Preparation of reports. + There is evidence in the medical records that proper procedures have been carried out. + Residents with sudden changes in condition have been evaluated by the physician.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Nursing Services F123 SNF 405.1124					
F124 SNF 405.1124(c) F125 F126 ICF 442.1124(c) A facility provides nursing services sufficient to meet nursing needs of all residents all hours of each day. F127 Grooming and Personal Hygiene SNF 405.1124(c)	Basic care provided to residents: Surveyors should observe the basic care provided by staff to the residents. Listed below are suggested areas of attention which may provide evidence of the quality of personal care: - Eyes/Ears/Mouth Presence/absence of: + Secretions forming around eyelids, redness or irritation of eyes. + Eyeglasses worn when appropriate are clean, in good repair and fit properly. + Backs of ears scaly, obvious wax build-up, discharge, odor. + Hearing aid worn when appropriate, is in good repair and working. + Dried food particles or drool, etc. around mouth.	Ask Resident: - If the resident's clothing is inappropr-ate, ask: + Did you choose your clothing today? + Is this what you want to wear? + Do you have other clothing available? - If the resident is not clean, poorly groomed, or inappropriately groomed, ask the resident: + Have you had any help in caring for yourself today (e.g., washing your face, brushing your teeth, etc.)? + How often do you have a bath/shower? + How often is your hair washed? + How often do you brush your teeth/ clean your dentures? + Were there extenuating cicumstances (e.g.,	Nursing notes, flow sheets or bathing records should indicate that the care plan for grooming and personal hygiene is being followed. For example: - Bathing schedules are being followed (including the use of any soaps or special lotions). - Assistance instruction and/or supervision is being provided as identified for each activity. Nursing documentation should also indicate resident response or any changes in the resident's behavior, reaction to an activity, or the ability to carry out grooming and personal hygiene activities. Look for indications of progress toward a goal or further deterioration of resident functioning.	Refer to information on observation. A pattern of evidence of poor personal care indicates non-compliance unless the care plan specifically deals with this and appropriate planning and implementation is occurring. The regulations require that individual preferences are taken into account when providing for grooming and personal hygiene and that residents are encouraged in self-care activity. Do your patient interviews substantiate compliance with the regulations?	Resident Rights 405.1121(k)(8)(13) 442.311 (g)(k) Social Services 405.1130(a) 442.344 Activities 405.1131 442.345(a)(c) Patient Care Management 405.1124(d) 442.341 Training 405.1121(h) 442.314

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F127 (cont'd)	+ Dentures worn when appropriate and in good repair. + Oral hygiene. - Odors presence/absence of: + Body odors - Hair/Scalp + Clean and free of rashes + Hair combed - Nails are clean and appropriate length - Clothing is appropriate, clean, and in good repair. + Extremities elevated as necessary while in chair or wheelchair. + Appropriate techniques to prevent infection. + Use of whirlpool as a treatment modality as available and appropriate. - With resident's permission check: + heels, feet and toes + lateral hip + scapular area + sacrum + buttocks + bony prominences in contact with braces + condition of stump (especially diabetic	resident is participating in dressing retraining program)? - Special consideration might be given to the demented patient who frequently "borrows" clothes and for whom removal may elicit catastrophic reaction—whether clothing "matches" may not be the most important issue in the care of these patients. Ask Direct Care Staff: - How do you choose what clothing each of your residents wear each day? - Do you have a specific schedule for washing residents' hair? - How did you learn to bathe resident? - How did you learn to wash residents hair? - How did you learn to shave residents? - How do you handle situations when residents want to wear dirty clothes, or mismatched clothes? - How much care do you let the residents do on their own?			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F127 (cont'd)	amputees with elastic bandage or sock removed).				
Skin Condition F128-129 SNF 405.1124(c)	Observe with residents' permission: - General condition of skin + Redness + Blanching + Soft/dry/rough etc. + Rashes/irritation + Bruises + Scabs + Free of above - Measures taken to prevent skin breakdown. - Pressure sores - Pressure sores Rx - Factors contributing to prevention of pressure sores + Overall cleanliness and maintenance of dry and aerated skin (uncompromised by urine/feces/perspiration) + Padding for pressure points and bony prominences including padding on bed/chair + Proper gentle massage to bony areas several times a day.	Ask Resident: - Are your feet usually swollen? - Do you know what causes the swelling? - What do you do to alleviate it? - Is this discoloration normal for you? - How did this wound/bruise develop? - Are the treatments done about the same time every day? - What staff person has looked at your skin recently?	Look at nursing notes and P.O.C. for evidence of: - Planned preventive measures - Treatments/Intervention including nutrition - Routine assessment/evaluation of skin condition - Documentation of specific skin problems with location number, severity, measurements as appropriate, and cause - Progress or lack of progress in healing - Assessment/Reevaluation of interventions with alterations in plan - Appropriate nutritional plan - Methods to control edema of lower extremities	Preventable pressure sores are not occurring. Ulcers present are treated on a routine basis according to P.O.C. Is skin clean? Is resident dry? Is turning schedule adhered to? Are linens clean and smooth? Do personnel know preventive measures and practice these? Has a nutritional assessment been done, and if appropriate, recommendations implemented?	Dietetic Services 405.1125(i)(c)(e) 442.332(a)(1)(b)(1) Activities 405.1131(b) 442.345(a) Patient Care Management 405.1124(d) 442.341 Training 405.1121(h) 442.314 Rehabilitative Nursing 405.1124(e) 442.342 Supervision of Patient Nutrition 405.1124(f) 442.332(b)(2)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F128-129 (cont'd)	+ Regular assistance for resident to turn or shift weight (bed-rails, footboards, trapeze). + Bed linens, clothing, underpads smooth and free from wrinkles. + Elastic bandages or hose are smooth and wrinkle free. + Elastic bandages wrapped smooth with appropriate overlap. + Dietary/nutritional support for skin integrity. (See Guidelines for Dietary/Nutrition + Prevention of shearing force when resident's position altered by staff. + Turning and reposi-tioning as needed. - Care and Treatment: + Turning and reposi-tioning every two hours or as needed (e.g., alternative approach that is justified by the facility.) + Positioning of the ulcer site or protec-tion of affected areas. + Use of effective pressure relief devices.	Ask Direct Care Staff: - What can you tell me about Mr./Mrs._____ swollen feet/wounds/ brusises/etc.? - What do you do for them? Ask Charge Nurse: - How did _____ get cuts, bruises, etc.? - What is being done to prevent further occur-ance? - What treatment is he/she receiving?			Resident Super-vision by Physician 405.1123(b)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Wounds/Wound Dressings F126 SNF 405.1124(c)	- Condition of dressing - i.e., clean, firmly secured unless contra-indicated. - Observe, if possible, and with resident's permission, a dressing change + Pre-dressing Removal Equipment and supplies organized Hands washed Residents provided with privacy - Dressing Is: + Old dressing observed for drainage? + Wound examined + Appropriate technique used + Proper disposal of old dressing? + Post dressing + Does staff member wash hands? + Return resident to comfortable position or previous activity?	Ask Resident: - How often is the dressing changed? - By whom is the dressing changed? - Does it seem dressing changes are frequent enough? - Are there any odors from the dressing? - Is the dressing change always done in a similar way? - If not, what are the differences? - Do you feel confident that the wound is being well cared for? - Is the area/wound healing? - What caused the ulcer, wound, etc.? Is it healing? Does the staff keep you informed of its status? Ask Staff: - Specific treatment and schedule for each resident?	- Physician orders for wound care - Progress notes detailing condition of wound - i.e., size, drainage, surrounding tissue, odor - Treatment provided - Progress/change - Plan of Care (POC) + The plan of care should address: - Area in need of treatment, treatment to be performed, frequency, and responsible staff. - All necessary solutions, ointments, irrigations, types of dressings, and materials. - Any necessary precautions, drains, if present, sutures and tubing. - Specific goals of treatment as well as any problems or limitations imposed as a result of treatment.	Physician orders, your observations, progress notes and POC should reflect the same information. Treatment provided over a period of time with no improvement and no re-evaluation also would represent non-compliance, unless nursing/physician progress notes address the "no improvement" problem. Compliance is evidenced by: - treatment given according to doctor's orders and POC. - use of appropriate technique when caring for wound/changing dressing (e.g., follows facility's written procedures). - periodic evaluation of healing process and revision of care plan as needed.	Physician Services 405.1123 442.346 Infection Control 405.1135(b) Pt. Care Management 405.1124 442.341 Dietetic Services 405.1125(b)(c)(e) 442.332(a)(1)(b)(1) Medical Records 405.1132 442.318

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Restraints F130 When residents require restraints the application is ordered by the physician, applied properly, and released at least every two hours. (See also information under Resident rights-freedom from abuse & restraints)	Direct to evidence of: - Proper application - Proper use - Maintenance of good body alignment - Resident observation, release and exercise Observe frequently throughout your visit to validate care. Specific observations should include the following items: - Type of restraint: belts, wrist or ankle cuffs, blanket restraints, vests, bed nets, locked, etc., (When locked restraints are used can you readily find the key and/or scissors?) as well as geriatric chair or geri-table/ tray in place for prolonged periods. - Protective devices and/or safety devices that are used as restraints must be evaluated as restraints. - Appropriate application: skin protected from injury (restraint neither too loose nor too tight to prevent	Use of restraints may be precipitated by an "emergency" situation in which there is a threat to the resident's health or safety, or a threat to the health and safety of others due to the resident's behavior. Restrained residents may not be coherent or rational enough to respond to questions and caution in interviewing therefore, must be exercised. However, observation of a resident in a geri-chair with table in place or a resident in a wheelchair (with vest restraint) for several hours would warrant appropriate questions as to when the staff last assisted him or her to move about or whether the resident would like to get out of the chair. Staff interviews focus on the reason why the resident is restrained. <u>Ask Direct Care Staff and Charge Nurse</u>: - When, why, and how to release and apply restraints? - Why is the resident	- Physician orders for restraint: reason, length of time, type - Progress notes - Describe the resident's status/behavior which prompted the use of the restraint. - If a chemical restraint, the order should indicate a specific time period for its use as well as a stop date. - Plan of Care should + Identify other methods or therapies that are being used in conjunction with restraints. + What alternatives to restraints have been considered. + Identify staff responsible for observing the resident (every 30 minutes), and releasing and exercising the resident (every 2 hours for at least 10 minutes). Time intervals should be identified. + Indicate involvement and input of other disciplines necessary to overcome the problem. + Indicate a specific period of time for	- Is there a physician's order, including the circumstances in which they will be used, the length of use, and the type of restraint? - Is the restraint applied properly? - Is it released at least every two hours and the resident provided with exercise and toilet facilities if needed? - Does the staff observe the resident frequently while he/she is restrained? - Are chemical restraints administered in accordance with physician's orders? - Is the order for restraints renewed only after a reassessment of the patient?	<u>Patient Rights</u> 405.1121(k)(1)(7) 442.311(f)(2)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F130 (cont'd)	rubbing and blistering or impeded circulation) - Body alignment and support: use of pillows, footboards, and wheelchair footrests to maintain appropriate posture, circulation, and to prevent skin injury or breakdown. - Periodic release and exercise: exercise may include ambulation, range of motion, massage, or other opportunities for motion (at least 10 minutes every 2 hours during day and evening hours). - Chemical restraints: residents appear drowsy throughout the day (may indicate tranquilizers or other drgus are being used to limit or control behavior for staff convenience).	restrained? - Was the resident given an option of restraint? - When were you taught the use of restraints? By whom? - If chemically restrained (excessively sedated) + Why is this done? + Whether alternate means of restraint have been attempted, for how long this will continue, etc. This should elucidate from staff whether the chemical restraint is necessary, or whether it is done for staff convience by controlling resident behavior - Do you ask the resident for permission before using restraints? - How does the restrained resident summon assistance? - What is the usual time-frame for assistance to reach the restrained resident? <u>Ask Resident:</u> + Why are you restrained? + What would happen if the restraint were removed? + When do you use bed rails? + What purpose do they serve? + How do you gain assistance?	using the restraint. - Indication of assessment of factors which precipitate residents behavior which has warrented restraints and plans to intervene early enough to prevent occurence. - Type, duration and frequency of exercise should be documented. - An assessment of why restraints are continued should be documented.		

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Bowel and Bladder F131 SNF 405.1124(c) Each resident with incontinence is provided with care necessary to encourage continence including frequent toileting and opportunities for rehabilitative training.	- There should be a chart/record in the resident's room on which the program is documented accurately. - If the room is located a distance from the toileting room or for residents with problems ambulating, a commode may be present in the room. - Verify that a call light is available to the resident if non-ambulatory or restrained. - Are fluids available at bedside? - Is there roughage on meal tray? - Diet is appropriate to enhance elimination?	Both the resident and direct care staff should be interviewed and should exhibit a good understanding of the importance of maintaining a regular schedule of elimination. If neither are aware of the intake and toileting schedule, then determine whether they are appropriately panning the resident or carrying out a retraining program. - Verify that the resident is aware that he/she is on a retraining program and knows the content of the program. Ask Resident: Suggested questions are: - How do you deal with constipation/diarrhea? - Are you involved in a special bowel/bladder training program? - If so, how does your program work? - Any problems with it? - Any successes to date? - What does the staff do for you in this matter? - Are they consistent and timely? - How long do you have to wait to be taken to the toilet?	- Physician orders if required by facility policy - Nursing notes for + Assessment + Documentation of techniques and progress, reevaluation - Plan of care The plan of care should clearly address: + Goals that resident will aim for. + Methods to accomplish the goals. + Schedule for fluid intake. + Schedule for toileting. + Responsible staff + Any limitations the resident may encounter as a result of either incontinence or the training program. - Progress notes/physician orders for cause of incontinence. - Laboratory tests of kidney function when available - Treatment for diarrhea/constipation - Residents preference for treatment of constipation. - Recently admitted and newly incontinent residents should be thoroughly assessed for at	- Are all incontinent patients assessed for cause of incontinence and ability to be helped by a bowel/bladder rehabilitative training program or an incontinence management program? - Are all appropriate residents involved in bladder/bowel training programs or, incontinence management and there is a schedule that shows when the program will be started? - Is there evidence of follow through on all shifts? - For residents not on bowel/bladder retraining programs the plan of care should address specific measures for managing incontinence with a view to prevention of skin and other problems and maintenance of resident dignity.	Nursing Services 405.1124(e) Dietetic Services 405.1125(c)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F131 (cont'd)	- When a resident puts on his/her call bell for toileting assistance, how long is it before assistance is given/ - Observe pre-meal toileting. - Privacy provided. - Schedule for toileting should allow for resident's normal sleep pattern, to avoid disrupted sleep.	Ask Nurses Aides and Charge Nurse: + Will you describe this resident's bowel/ bladder (B/B) training program? + How long has it been in effect? + When will you evaluate the results? + If this program is not successful - What assessment was done to determine B/B status - For residents not on B/B retraining programs what is the facility program for managing incontinence?	at least 7 days for the cause of incontinence and when appropriate an intensive bowel and bladder B/B training program should be instituted. - A trial B/B training program is suggested for all residents with incontinance problems. - I & O		
Catheter Care F132 SNF 405.1124(c) Each resident with a urinary catheter receives proper routine care including periodic evaluation	The indwelling catheter should promote a continuous flow of urine unless ordered otherwise. The surveyor should also observe for the following: - Ample supplies for catheter insertion and care. - Proper positioning of the tubing and drainage bag. - Cleaniness of the	Ask Resident: - What is the tubing/ cathetor for? - Why do you have one? - Does it cause any discomfort? - If it does, what is done about it? - How do you feel about having the catheter? - Is any special care given in relation to the catheter?	The surveyor should verify that there is a physicians order for an indwelling catheter, including the type and frequency of catheter care. If irrigation is ordered, the order should include type of solution and frequency of irrigation. The record should also indicate the color, consistency, and amount of urinary drainage.	*The facility should follow accepted professional standards in their catheter care. There should be medical reasons for catheter insertion - staff convenience cannot be justification. Direct care staff should know signs and symtoms of urinary tract	Infection Control 405.1135(b)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F132 (cont'd)	tubing and drainage bag. - Color and consistency of urine in bag. - Availability and accuracy of documentation on the I&O sheet if ordered or policy. - Proper equipment for ambulation - leg bag if resident is ambulating. (if ordered) - Availability of fluids. - When indicated monitor intake to ensure adequate intake and output or conformance with physician orders. - How many observed residents are on catheter care?	Ask Nursing Aide and Charge Nurse: - How do you routinely position and secure catheters and drainage bags? - How often is each part of the system changed? - What are the indications for insertion of the catheter? - What is the facility's procedure for routine catheter care? - How do you observe for U.T.I.'s in residents with indwelling catheters? - What is the facility's procedure for the cleansing and storage of reusable catheter equipment and drainage receptacles? - How do you care for catheter tubing?	- Assessment should address: + Need for an indwelling catheter. + Resultant problems or limitations. - Plan of Care should address: + Type of catheter and type and frequency of care. + For irrigation, the rationale, the type of solution, amount, and frequency of irrigation. + Frequency of symptoms which would precipitate catheter change. + Time frames of catheter change and responsible staff. + Appropriate increase in oral fluid intake. - Intervention The record must reflect: + When and by whom the catheter was inserted and for what reason. + Any special care provided + New problems or changes + Only appropriately trained staff should deliver catheter care. + Only licensed staff should insert	infections (U.T.I.s) and these should be reported and treated promptly. *The Center for Disease Control has developed standards for catheter care which may be used but it is not a requirement.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F132 (cont'd)			indwelling catheter. + The specific type and size of equipment used should be noted. + Signs and symptoms of urinary tract infections (UTI) should be acted upon and documented as to follow-up. - Evaluation/Reevaluation The record should reflect that the resident: + Is assessed for UTI. + Has no abdominal distention. - Notes should also include: + The color and odor of urine and the development of any problems after insertion of indwelling catheter. + Verify that catheter is patent.		

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCES
Injections F133 SNF 1124(c)	- Observe for preparation of injection - i.e maintenence of sterility; correct dilution, handwashing, before preparation, etc. - Observe injection site for: + Redness + Discoloration + Swelling + Lesions - Observe for proper technique when injection is given + correct site + correct needle size + correct volume of drug + sterility maintained - Resident is observed for any adverse reaction - What is the disposal method for used needles or syringes?	Ask Nurse: - What is your plan for alternating injection sites? Show me. - What is the medication for and what are potential adverse reactions? - Is there nonspecific pain at the injection site or shooting pains down a limb? - Is there skin irritations or lumps under the skin? - If adverse reaction occur, how soon are they reported? - Could this be given by any other route? Ask Resident: Suggested questions are: 1. What kind of medicine do you receive by injection/shot? Why do you need that medicine? 2. Do you have pain or numbness at or around your injection site? 3. Who gives the injection? 4. Do you receive your injection according to a schedule?	- Physician order sheet - Nursing notes for: + Resident response to medication if appropriate + Any problems noted at injection site + Any other adverse reactions + Site of injection - Plan of care + Rotation of injection site + Care for any special problems related to the injection. - Infection Control: reports for any infections connected with injections.	- Is the medication administered according to the physicians order? - Is proper technique used in preparation and administration including site rotation? - Does the nurse administering the medication know the expected action of the drug? - If infection control reports show infections at injection sites. - Is the resident's response to the medication noted in the progress notes?	Staff Development 405.1121(h) 442.314 Infection Control 405.1135(b)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCES
Parenteral Fluids F133 SNF 405.1124(c)	The surveyor should observe that parenteral fluids are administered with safe, aseptic technique providing fluids as ordered by the physician. Safety and comfort measures are to be taken insuring maximum protection and optimum hydration of the resident. The surveyor should note the following items: - Labeling of the solution bottle/bag. - Rate of infusion/cc/ml per hour. - Date and time started --additives, if any. - Any signs of swelling or redness at site. - Site dressing is clean, dry and dated. - Accurate I&O of parental and P.O. fluids - If splint (armboard) is used, it is applied to prevent movement but not impede circulation. - Positioning of I.V. tubing. - Comfort of restraint used to allow for maximum resident freedom while preventing movement of I.V. site.	Ask Resident: - Why do you have this tube in your (arm)(leg)? - Is it comfortable? - Is there a way it would be more comfortable? - How long has it been in? - How much longer will it stay in? Ask Appropriate Staff: - Why the resident is receiving I.V. therapy? - What the drip rate is (the amount of fluid to be received per hour). - How often the dressing is changed. - How often the tubing is changed. - What are possible side effects? - How often is the site changed? - How often is the infusion checked for drip rate and the remaining volume to be administered? Ask Nursing Aide - What are your responsibilities when caring for a resident receiving IV fluids? - What training have you had?	- Physician's order for parental therapy specifying type of fluid, rate of infusion/hour, and additives, if any, is available and current. - Twenty-four hour I&O record. - Nursing documentation indicates physician's orders are being followed. - Any adverse reactions are noted in the medical record. - Record indicates: + Infusion started by whom; cite time, rate of flow + Note is made of observation of pain or swelling at infusion site. + The need or reason for parenteral fluids. + Response to the therapy. + Problems and limitations encountered by the resident as a result of receiving parenteral fluids. - Plan of Care* The plan of care should include + Type, rate of infusion /hour, and additives (if ordered).	- Is the parenteral fluid administered according to the physician's order and in accordance with accepted nursing practice? - Are infiltrations noted in a timely manner before a large amount of fluid infiltrates? - Is the facility procedure for care of the IV site and tubing changes followed for all patients unless contraindicated? - Does documentation reflect what the patient received, any problems, and his/her response to the parenteral fluid? - Have any adverse effects been caused by administration of IV fluid? - If yes, were these preventable?	Resident Care Policies 405.1121(1) Infection Control 405.1135(b) Patient Care Management 405.1124(d) 442.341

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F133 (cont'd)			specified goals for correction, time frames, and responsible staff. - Documentation must include time administered and by whom, the amount of fluid infused, and any other special care administered as a result of IV therapy (i.e., mouth care, assistance with ADLs, etc.). - The record must reflect: + Conditions of site and any infiltrations, phlebitis, necrosis, etc. noted, along with measures taken to correct these. + The resident's response to therapy + Changes in laboratory studies *Plan of care would not be modified for a one-time IV infusion.		
Colostomy/Ileostomy F133 SNF 405.1124(c)	The surveyor should ascertain that the facility is providing appropriate nursing care to those residents who have had bowel surgery resulting in a colostomy or ileostomy. It is recommended that the surveyor, with the resi-	Ask Resident: - Why was the ostomy performed? - How do you feel about the ostomy? - Does it ever cause you problems (e.i., pain, skin problems, odors accidents)? If so, what	The surveyor should determine that: - Colostomy irrigations, if ordered, are documented as performed by the resident or appropriately trained staff. - In the case of sigmoid colostomy regular patterns of bowel elimination are	Compliance would be indicated if residents are physically and emotionally comfortable with the ostomy with minimal or no skin problems. If residents are not comfortable with the ostomy, are having skin or other problems, the facility	Patient Care Management 405.1124(d)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Colostomy/Ileostomy F133 (cont'd)	dents permission, observe care being given to determine that proper techniques are being used. The following steps should be taken to assure that proper ostomy care is being provided. - The ostomy dressing should be changed or the bag emptied and thoroughly cleaned promptly after each bowel evacuation or more frequently, if drainage continues. - The peristomal skin should be cleansed and dried, and appropriate measures taken to prevent excoriation and infection. - The resident's privacy should be considered while providing care. - The resident should be provided with information and instruction in self-care at the appropriate level of understanding. - The resident should be observed for signs of withdrawal, disgust anxiety, or other emotional responses which may be related to his/	does staff do about it? - What does the staff generally do with or for the ostomy? Are they consistent and timely? - Has staff talked to you about doing some of the care for this? If so, what was the outcome? If not, is this something you'd be interested in learning more about? <u>Ask Staff</u>: - If nurses aid: + How did you learn to take care of colostomies? + What do you do if the skin around the colostomy becomes red or sore? + Do you ever teach the residents to care for their own colostomies? - If nurse (RN or LPN) + What is the procedure if the resident becomes constipated? <u>Ask Other Nursing Staff</u>: - Is there a facility procedure for ostomy care? - Do you have skin problems with your	documented as established through management of diet, fluid intake, exercise, and the use of prescribed laxatives, suppositories, and/or irrigations. - Ostomy care is documented in the resident's record along with a description of the excreta. - Problems in irregularity, skin breakdown, or other observable concerns are documented and reported to the physician. - Documentation indicates that nursing measures are taken to assist the resident who is experiencing problems in understanding and/or accepting the presence of the ostomy. - Documentation of nursing measures to maintain skin integrity. - Assessment The assessment should indicate: + Needs, problems, and limitations as a result of an ostomy. + Specific degree of	should be responding to these and correcting them as reasonable. Care plans should indicate specific goals in relation to problems and specific interventions for reaching these goals. When available an enterostomal therapy nurse should be involved in developing the care plan for residents with urinary and intestinal stomas.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Colostomy/Ileostomy F133 (cont'd)	her acceptance of the colostomy/ileostomy. - The surveyor should observe the staff giving ostomy care to verify that proper technique is used.	ostomy residents? - What do you do when skin becomes excoreated? - What teaching do you do with the residents? - What in general is the response to this teaching?	self-care performed or assistance needed. + Special skin care needs. + Special dietary needs. + Emotional support. + Medications and treatments if needed. - Plan of Care The plan of care should clearly address: + Specific goals to overcome or improve the problems(s) identified. + Methods to accomplish the goal (training, assistance, supervision, treatments, emotional support). + Services necessary and who will perform the services. + Time frame for accomplishing goals.		Social Services 405.1130(a) 442.334(a)(b)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Respiratory Therapy F133 SNF 405.1124(c)	- Aerosol Compressor or IPPB (Intermittent Positive Pressure Breathing Machine) The surveyor must determine that the facility is providing respiratory therapy as ordered by the physician. Observation for this indicator should focus on the necessary equipment as well as on the resident. In order to determine that the necessary equipment is available, the surveyor must look for the following: + Aerosol compressor or IPPB Machine. Check that the machine is clean and operable. + Tubing - If tubing is not attached to the machine, ask to see it. Check that it is stored dry and with consideration for cleanliness. + Nebulizer Cup - should be attached to tubing. It is filled with either the prescribed medicine or distilled water only if about to be used. It should not be	While interviewing the resident, observe for sounds of congestion. Note color of lips and nail beds. Ask Resident: - Do you ever feel short of breath? - If yes, what is done when this occurs? - Is the therapy helping you to feel better? - Are there any problems with it? - If so, how does the staff respond? - Is the therapy consistently performed - both concerning time and method of providing it. Ask Staff: - What is the reason the resident is getting this therapy? - What are the expected results? - Can you demonstrate how you use the equipment? - How often is the equipment cleaned? - What are the infection control procedures in regard to use of res-	The surveyor should determine that: - Respiratory/oxygen therapy is performed or administered by appropriately trained staff. - There is a physician's order for therapy, and it is specific as to rate of delivery, etc. - If the physician's order is for prn therapy, it should specify for what symptoms. - Any information gained from resident or staff is verified in the record. - Assessment + The assessment should address both the need or reason for therapy and any problems or limitations which result from the need for therapy. - Plan of Care The surveyor should note: + The kind, amount, frequency, and/or duration of therapy based on the physician's order. + Specific goals to overcome to improve any identified	Only qualified (trained) personnel should administer/assist with respiratory therapy. Therapy must be provided as ordered. The effectiveness of the therapy must be periodically evaluated and therapy revised as appropriate. Effective infection control measures must be practiced. Needed safety precaution for the use of oxygen must be practiced. Equipment should be available and in working order.	Staff Development 405.1121 (h) 442.314 Infection Control 405.1135(b) Patient Care Management 405.1124(d) 442.341

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Respiratory Therapy F133 (cont'd)	stored wet. If it is not attached to the tubing, ask to see it. The mouthpiece is connected to the nebulizer cup. The surveyor should also check that all involved equipment is clean. - Oxygen Therapy The surveyor must establish that the facility is meeting the oxygen needs of the resident. When the facility does not have wall units, check that: + There are enough cylinders for oxygen delivery. + There should be flow meters and regulators for tanks in use. + A wrench should be attached or stored close by. + If using large cylinders (size G or H), look for a carrier since these tanks cannot be transported without it. + The cylinder at the resident's bedside should either be on	piratory equipment? - What training was given you in the use of this equipment? - Where is the emergency oxygen supply?	problems and/or limitations. + Specific methods to accomplish the goals (observation, supervision, training, etc.). + Who is responsible to perform therapy or assist in accomplishment of goal. - Intervention - The record should display evidence that: + The plan of care is functional + The therapy was admin-administered in accordance with physician's order for the specified reason(s) by an appropriately trained staff member + Change in condition is tion is documented and acted upon promptly. - Evaluation/Reevaluation The record should reflect: + The resident's response to therapy. + If response was undesirable, evidence of further intervention. + Any progress, deterioration, or development of new problems.		Physical Envionment 405.1134 (i) Medical Records 405.1132 442.318

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Respiratory Therapy F133 (cont'd)	the carrier, sitting on a metal skirt, or otherwise secured. + There should be other necessary equipment available such as humidifiers, nebulizers, masks, nasal cannulas, T-pieces, etc., all should be dry and clean when stored. + Check to see that non bed-bound residents are not limited to their own chair/room when using oxygen (portable units will prevent social isolation. + Water reservoir is appropriately filled per manufacturers instructions. + Check to make certain the tank is not empty and that any tank is labeled as such. + Check for good oral hygiene of resident. + The room should be posted with a "No Smoking" sign. - Residents on respirators: + Are alarm systems turned on?	<u>Residents on Respirators Ask Staff (all levels)</u>: - What training have you had in caring for	+ Based on the above information, possible modification of goals.		

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Respiratory Therapy F133 (cont'd)	+ Is sufficient Oxygen supply available? + Is the ventilator accessible to an emergency outlet? + Is the resident in a location that allows for frequent observation by staff? + How does the resident communicate with staff? + What level of staff (aide, LPN, RN) caring for the resident? + Is such equipment at bedside? + Is there reserve back-up equipment? + What is the condition of the residents skin around intubation tube/tracheostomy. + Does the care given use appropriate technique in caring of the patient?	residents on respirators? - Can you show me how the alarm system works? - What is your procedure for pulmonary care? - What is your procedure for changing tubing and the water reservoir? - What happens if the power goes off?			

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Tracheostomy Care F133 SNF 405.1124(c)	Satisfactory tracheostomy care is a procedure which promotes a clean, unobstructed air passageway and maintains the skin integrity surrounding the tracheostomy site. The surveyor should determine whether: - Adequate supplies are available for the care of the tracheostomy such as tracheostomy kits, hydrogen peroxide, normal saline or sterile water, suction machine, catheter, sterile gloves, and clean dressings. - The resident is breathing without difficulty and is comfortable. - The dressing is clean, dry, and intact; the cannula is clean, in the proper position, and secured. - The skin surrounding trach is clean and dry with no redness or inflammation. - The resident has adequate oral hygiene. - An extra tube, the same size as the one in	Resident interviews must be guided by the resident's communication ability. Ask Resident: - How long will you have it? - What care can you do for yourself? - What do you need help with? - Who helps you? - Is someone always available to suction him/her when needed? - Is the suction equipment always available in working order? - Is the dressing kept clean and comfortable? - Is the tube kept clean and changed as needed? - How often are the tubes and dressings changed? - Does he/she feel confident in the personnel caring for his trach- - What is communicating with staff and other residents like? - Are staff patient and do they allow you enough time to express your needs/thoughts/feelings? [- May I observe your tracheostomy care?] Ask Staff: - Why does resident have	- The surveyor should determine that tracheostomy care is done as scheduled and as needed following the proper procedure. - Any special solutions that are needed should be addressed in the physician's orders. - Assessment - The record should reflect that the need for tracheostomy care was assessed in terms of: + Frequency + Skin integrity surrounding the tracheostomy, noting redness, inflammation, and/or excoriations. - Plan of Care should include: + Specific times of trach care and the responsible, appropriate trained person performing this task. + Specific problems relating to skin and breathing as well as the goals set to overcome these problems listing the appropriate personnel responsible. + Time frames for resolving problems	Stoma and surrounding skin should be in good condition and if not, there should be treatment directed to resolving this problem. All staff caring for the tracheostomy must be trained and emergency procedures must be known. All needed equipment must be available and in working order. Resident must at all times have readily available a means of communicating with the staff in an emergency.	Infection Control 405.1135 (b) Training 405.1121(h) 442.314 Patient Care Management 405.1124(d) Physicians Services 405.1123(b) Social Services 405.1130(a)

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Tracheostomy Care F133 (cont'd)	place, is available at bedside. - Does resident have an adequate method of communicating with the staff? - Does staff allow enough time for residents to communicate?	tracheostomy? - What training were you given to enable you to care for tracheostomies? - What is the procedure for tracheostomy care? - How often is the tube changed? - What do you do if the tube comes out? - May I watch you do a dressing change? - If not convenient, describe what you do. [- How do you communicate with a tracheostomized resident?]	listed in goals. + Plan for periodic assessment of appropriateness of residents own self care re: teaching or nursing assuming more responsibility as appropriate. - Intervention - The surveyor should look for documentation of: + Trach care and oral hygiene administration, including responsible personnel, time and date, and effects. + Any problems or changes noted in resident condition (e.g., redness, swelling, tracheal obstruction). + Emotional response to tracheostomy. - Evaluation/Reevaluation + Resident is or is not benefiting from trach care and skin care. + If problems are noted, the progress notes and plans for care should indicate changes in treatment. + Resident's emotional response to care of the tracheostomy should be evaluated,		

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Trachoestomy Care F133 (cont'd)			since this may require additional care planning.		
Suctioning F133 SNF 405.1124(c)	Suctioning is necessary for any resident who is unable to cough up secretions that are obstructing his airway. Suctioning may occur via the oral or nasal route, or stoma route with sterile technique. Attempts should be made to observe a resident being suctioned should such an opportunity arise. If so, observe that a clean/aseptic technique is observed throughout and that the resident tolerated the procedure. There should not be bloody aspirant, cyanosis, or bronchospasm. Check that equipment is in good working order, frequency of procedure, etc. Resident observations which indicate need for intervention include: - Secretions are draining from a resident's mouth or trach and the resident is unable to	Ask Resident: - How are you feeling now after the suctioning? Does the suctioning seem to help? - Has staff explained to you the need for suctioning? Why do you need to be suctioned? How often? - Who performs the suctioning (i.e., nurses or nurses aides)? Do you feel safe with the staff performing the suctioning? - Does everyone do it about the same way? Ask Staff: - When and where did you learn to suction? - Tell me what procedure you use when you suction a resident. - Do you always have enough suction machines and catheters? - How frequently is suction tubing changed? - What provisions do you have for suctioning if the electricity is lost?	- Assessment - The record should reflect that: + The resident is frequently observed for suctioning needs. + Any limitations a resident has as a result of his suctioniong needs should be specifically noted. + Any problems resulting must be specified. - Plan of Care should include: + Awareness of the resident's suctioning needs, goals, approaches, and responsible staff needed to improve the problem or at least to maintain the resident at his present status without further deterioration. The plan must clearly indicate specific approaches towards: - Prevention of skin problems around the trach if one exists. - Correction of any existing skin pro-	- All equipment must be available and in working order. - All staff caring for the resident must know what to do in an emergency. - Current professionally accepted standards of care must be maintained.	Infection Control 405.1135(b) Patient Care Management 405.1124(d)

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Suctioning F133 (cont'd)	cough or clear himself. - There are audible crackles or wheezes and/or diminished breath sounds. - The resident is dyspneic. - Restlessness or agitation may also be an indication that suctioning is needed. Upon completion of suctioning above symptoms should, in most cases, be relieved. The surveyor should observe that the resident is positioned to facilitate breathing (usually at a 45 degree angle). Check to see that the facility has an ample supply of suction machines and suction catheters to meet the needs of residents requiring them and that they are clean and properly stored.	- Where are your emergency electrical outlets? - What is your procedure for disposing of the secretions from suctioning? - How often does Mrs./Mr. need to be suctioned? - May I observe you when you suction Mrs./Mr.?	blems. - Provision of good oral hygiene including a rigid schedule for mouth care, schedules, or procedures for maintaining clean equipment at bedside, as well as disposal of used (dirty) equipment. - Route of suctioning (i.e., oral/nasal/trach). - Intervention - The record should indicate clearly that: + The plan of care is being implemented. Documentation should reflect: + The number of times the resident required suctioning, for what specific reason, and by whom the resident was suctioned. + Any special treatment the resident received in conjunction with suctioning		

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Suctioning F133 (cont'd)			(i.e., oral hygiene, skin care, etc.). - Evaluation/Reeevaluation The record should reflect: + How well the resident tolerates suctioning procedures. + Any bloody aspirant, cardiac arrhythmia, cyanosis, or broncho-spasm. + Further interventions utilized to overcome or improve these. + The amount of sputum as well as its color and consistency. + Any progress or lack of progress, deterior-ation, and/or the de-velopment of new problems. + The evaluation should determine whether goals are being reach-ed or if new goals must be addressed.		
Tube Feedings F133 SNF 405.1124(c)	- Staff use proper tech-nique in administering feedings and medica-tions. Check to see that staff checks for location of tube before feeding and that tubing	If the resident is able to be interviewed, sug-gested questions may be: Do you feel comfortable/ safe with all the staff who perform the feeding?	Tube Feeding Review: - Plan of care - Must document tube placement and formula potency prior to each feeding.	- Has the feeding been ordered by a physician? - Is tube feeding nutri-tionally adequate? - Have attempts been made to discontinue tube feeding if indicated?	Nursing Services 405.1124(d)(f) 442.338(a)(2) Meal Service 442.331(c)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Tube Feedings F133 (cont'd)	is irrigated before and after addition of medication. - The tube is clean and formula flows freely. - The equipment is clean and protected. If dressings are ordered, they are in place, clean, and dry. - The nasal tube is securely but comfortably secured on the face with skin maintained intact and without irritation. - The skin around the gastrostomy is kept clean and free from irritation or infection. It should be checked carefully for leakage of gastric contents. - A resident who has a N/G tube for a prolonged period of time should be observed for possible complications, such as nasal erosion, sinusitis, esophagitis, gastric ulceration, and pulmonary infection. - Resident is fed slowly with head elevated to 45° during feeding and at least 1 hour post-feeding.	If not, what happens? Are you losing or gaining weight? What is your goal? Ask Staff: - Please describe how you would carry out a resident's tube feeding.	- In the case of continuous feeding, tube placement must be documented at least every 4 hours. - Naso gastric tube must be secured in a manner that avoids creating pressure on the nose and nasopharynx. - Identify frequency, amt. of feeding based on the physician's order and time span over which each feeding is accomplished. - Medication and treatment records. - Fluid intake records. - Number of calories as well as amount of additional water. - Documentation present regarding removal and reinsertion of tubes. - Record should indicate measures taken to prevent diarrhea and constipation and to treat if they have developed.	- Is skin free from irritation; mouth care is given several times daily? (More frequent mouth care in the case of continuous feeding.) - Have changes in resident condition been noted and addressed (weight loss, constipation, diarrhea, skin condition)? - Have observed problems been coordinated with other departments and resolved? - Is feeding being monitored to ensure that feeding is occurring at the ordered/appropriate rate? - Varied supplements as preferences allow?	Dietetic Services 405.1125(c)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Tube Feedings F133 (cont'd)	- Supplies for mouth care are in evidence, observe if possible for technique; mouth shows evidence of good care (i.e., moist, clean.)				
Nursing Services F137 SNF (405.1124) ICF (442.338) B. Twenty-four hour nursing. F137 1. Assigned duties consistent with their education and experience/ based on the characteristics of the resident load. F138 2. Weekly time schedules are maintained. F139 3. There is a sufficient number of nursing staff	Are personnel performing duties that are allowed under the State Nurse Practice Act? Do you observe care being rendered in an appropriate, competent manner? Does the time schedule posted indicate that at least the minimum required personnel are scheduled and actually on duty? What is the usual response time before a call bell is answered? In SNF's is an RN on duty during the day? Are licensed staff and aide staff functioning in appropriate roles? Where are staff spending their time?	Ask Resident: - Do residents generally feel that people taking care of them know what they are doing? - If no, explain. - Are your treatments done in a consistent manner? - If no, explain. - Do you feel that there are enough people here to take care of you? - If no, explain. - How long do you usually wait for help when you put your call light on? - Is there anything that doesn't get done as often as it should? Ask Staff: - Do you feel qualified to do all the work you are assigned to do? - If no, explain. - Do you feel you have enough training to keep up with the care the residents require?	- Review progress notes to determine who is giving care. - Review care plan to determine who the facility has assigned to care responsibility to. - Check staffing sheets for minimal requirements and time and attendance for actual staffing. - Review charts maintained for ADL medications, I & O, restraints, etc., to assure that sufficient staff are available for carrying out responsibilities as specified in patient care plans.	All nursing personnel must function within their State Nursing Practice Act. Levels of staffing meet at least minimum requirements. Nursing care needs must be identified by the facility & documentation, resident and staff interviews should determine if these needs are met. All nursing staff should have education or training to prepare them for the care they perform.	Patient Rights 405.1121(k)(g) Patient Care Policies 405.1121(l) Medical Records 405.1132(c) 442.318(a)(c) Patient Care Management 405.1124(d) 442.341 Staff Development 405.1121(h) 442.314

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F139 (cont'd) available to meet the total needs of all residents.	Check for staff who are actually on duty.	- If no, what else do you need?			
F140 4. There is a registered nurse on the day tour of duty 7 days a week (for SNF only).					
Intent That all residents are cared for by personnel qualified to provide the care & that sufficient numbers & classifications of personnel are available.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Patient Care Management F167 SNF 405.1124(d) F168 ICF 442.341 F169 A. Each resident's needs are addressed in a written plan of care which demonstrates that the plans of all services are integrated, consonant with the physician's plan of medical care, and is implemented shortly after admission. F170 B. Each professional service identifies needs,	Observe resident level of physical, mental, emotional and social functioning. Note problems, potential problems, needs, using observation/interview/record review work sheet.	Ask Resident: - Are you aware that you have a plan of care? - Did you participate in developing a plan of care? - Do you/your family know what the plan is and details? (e.g., diet, ambulation, dressing, etc.) - Do you attend and participate in plan of care meetings? - Who else attends the plan of care meetings? - When did you last attend the meeting for your plan of care? - Does the staff assist you in achieving the goals on the plan of care? If not, who does or why not? - Do you have all necessary assistive devices and equipment? - Is there anything that is not part of your plan of care that you think should be included? - What happens if you question any treatment or procedure? Can you give an example?	Review: - Plan of care The content of the plan of care is of primary importance rather than the format. Separate care plans are not required for each discipline, but may be accepted if there is evidence that the various disciplines coordinate their planning. - Nursing assessment/reassessments and notes. - Physician orders. - Physician notes. - Assessments/evaluations and progress notes from all professional disciplines as appropriate. - Medication and treatment records as applicable. - Lab reports, as applicable.	- Are all resident's needs/problems identified? - Is the plan developed to meet these needs? - Does the plan demonstrate an interdisciplinary approach, and include: + Goals stated in measurable/observable terms? + Approaches (staff action) to meet the resident action goals? + Responsible disciplines/staff responsible for approachs to assist resident in achieving goal/goals? + Is plan being reassessed and changed as needed to reflect current status? + Does plan of care accurately reflect information gained from observation, interview and record review?	Physician Services 405.1123 442.346 Medical Records 405.1132 442.318 Resident Rights 405.1121(k) 442.311 24 Hour Nursing Service 405.1124 442.338 Specialized Rehabilitation Services 405.1126 442.343 Training 405.1121(h) 442.314 Resident Rooms 405.1134(e) 442.325 442.326 Infection Control 405.1135 442.328 442.324

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F 170 (cont'd) goals, plans, and evaluates the effectiveness of interventions plus institutes changes in the plan of care in a timely manner. INTENT The intent is to assure that the facility identifies the resident's (with residents/family input if applicable) needs through the coordinated efforts of all disciplines.		Ask Staff: - What is your input into resident's plan of care? - What aspect of the resident plan of care are you carrying out? - What is this particular resident's plan of care? - How do you assist the resident in carrying out the plan of care? - Who attends the care planning meeting? - Is the plan of care useful to you in caring for the resident? - Is there anything the resident needs that is not addressed in the plan of care? - How often is it reassessed?			Social Services 405.1130 405.1130(a) 442.344(d) Activities 405.1131 442.345 Dietetic Services 442.1135 442.332

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Restorative Nursing Activities of Daily Living F171-176 SNF 405.1124(e) ICF 442.342 442.343(a)(c) INTENT To assist the resident to attain or maintain his/her maximum level of independence and function?	A. Observe residents in need of assistance. 1. Is needed assistance provided? 2. Is resident provided assistance and instruction, as appropriate, in all ADL's to increase his/her level of independence? 3. Does staff minimize pain/discomfort while assisting resident? 4. Is resident taught transfer techniques? 5. Is resident assisted to toilet in timely manner? 6. Resident personal equipment available & within reach? Glasses Hearing aids Dentures [Artificial larynx]	Ask Resident: - What assistance do you need with bathing and/or dressing? Who helps you? - Does the staff plan with you your dressing/bathing schedule? - Do the nursing and activities staff coordinate your schedule so that you have the opportunity to participate in favorite activities? - Are you able to dress/bathe at times convenient for you? - Are you bathed consistently? (i.e., on the day(s) scheduled does the bath get performed?) - Where are you bathed? (bed, shower, tub?) - Are there adequate clothes available for you to wear? - Do they come back from laundry in appropriate condition? - How do you get in and out of bed? - If staff assists you, do they seem to be able to do their job appropriately? Do you always feel safe when	Review: - Plan of care + Reflects assessment, goals, methods to reach goals, service providers, evaluation, and achievement . + Addresses restorative nursing assessment, program initiation, implementation and evaluation of the progress over a reasonable time period. Professional judgement determines the assessment of appropriate time frames. + Identifies planning for potential discharge for all residents to determine a disposition on home care or an alternate level of care. - Nursing Notes + Demonstrate evidence of assessment, intervention, response to treatments/teaching and their progress toward independence, a maintenance level or a deterioration. + Provide evidence of interdisciplinary conferences.	Are patient needs identified? Verify that the plan of care addresses resident needs and is implemented as scheduled and that all appropriate information is documented. If goals are not reached, has a reevaluation been performed and goals revised? Does restorative nursing assist the resident to acquire a higher level of independence? Is sufficient time allowed to resident for learning to increase his/her level of independence? Are assistive devices used regularly as per plan and are they in good repair? Is there an assessment, and if appropriate, a plan for each ADL that the resident needs to gain independece in? Maintenance goals should be noted as appropriate.	Physicians Services 405.1124(a)(b) Nursing Services 405.1124(a)(b)(c) 442.342 Dietetic Services 405.1125(a) 442.331(c) Activities 405.1131(a)(b) 442.345(a)(b) Specialized Rehab. Services 405.1126 442.343(e)(1)(2)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F171-176 (cont'd) ADL's (cont'd)	Prosthetic devices (eg. braces, artificial extremities). Adaptive equipment (e.g., built-up spoon, reachers). Orthotic devices (eg. splints, AFO's). Restraints (eg. vest, waist, wrist, ankle, mitts, nets, geri-chairs). Grooming items (eg. comb, brush, shaver). Oral hygiene (eg. toothbrush, toothpaste, mouthwash, denture cup). Self-feeding devices. Assistive devices for special sensory loss needs (eg. communication boards, large print books, magnifiers, writing tablets, picture cards, talking books). <u>Training/re-training</u> Prosthetic management Stroke adapted ADL's Self-injections of medications Bowel/Bladder Self-feeding Self grooming Ambulation	being helped? - Are staff members encouraging you to do things for yourself? - Do you have any problems getting to the bathroom on time? - Do you have any problems with leakage when you sneeze, laugh or at any other particular time? - How does the staff help you with these problems? - Are they aware of the problems? - Do you bowels move regularly? - If not, what do you/staff do about this? Are you able to feed yourself? - Are you able to get to the dining room by yourself? If not, why? In that case, what does staff do about this? - How long have you been up today? - Do you usually lie down for a rest? - If you need help getting into or out of bed, is staff available to help you when you need it? - Where do you spend most of your time - in your chair, wheelchair or in bed?			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F171-176 (cont'd)	Colostomy/Ileostomy Care Respiratory Care (oxygen inhalation) Speech Mobility Upper extremity dressing Lower extremity dressing Observe at mealtime whether staff encourages/guides residents in self-feeding or <u>feeds</u> the residents.	Does anyone move your arms or legs or help you with exercises? - Have your sleeping habits changed since you came to the nursing home? If yes, in what way? - Are you able to get help during the night if needed? + What kind of help is needed? + Is staff response timely? - Do you feel there are adequate care supplies at this facility? - If not, can you give me an example of why you feel this way? - Is your family involved in assisting you or if learning to help you? - Do you feel there is adequate staff at this facility? - If not, can you give me an example of why you feel this way? - Does staff assist and/or encourage activities (e.g., R.O.M., ambulation ADL, communication programs, feeding)? - How often does staff assist in activities? - Is there anything resident would like to do			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F171-176 (cont'd)		for himself/herself that staff is doing? - Is resident comfortable (e.g. free from pain)? - Is your cane/walker/crutches comfortable for you to use? - Did anyone measure you so you have the right size cane/walker/crutches? - Did anyone show you the correct way to use your cane/walker/crutches? - If the facility arranged so that you can get around easily? Ask Activities Staff Do you provide information to nursing staff about time and place of activities, plus names of residents who are to attend or those who might be interested in attending? Chair-bound Resident Ask Resident: - Does he/she know why he/she is in a chair? - Is resident assisted to use bathroom? - Is resident comfortable? - Does he/she see therapist? (O.T., Speech, P.T.) and how often? - Does resident go to a			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F171-176 (cont'd)		therapy area or does therapist come to resident? - Is able to reach items needed? Ask Nurses Aide -Who give you information about the time and place of activities and which residents are to attend? How are you given this information? -How do you encourage a resident to do the most for themself? Wheelchair Resident Ask Resident: - Does he/she know why he/she needs a wheelchair? - Is resident trained and/or encouraged in independent W/C ambulation and activity? - Does resident know how to lock and unlock wheelchair? Ask Staff: - How is a resident set up for independent W/C ambulation? - Nurse Aide - has resident received instruction in transfer techniques? For Bed Bound Resident In addition to appropriate interview questions above:			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F171-176 (cont'd)		Ask Resident: - How do you spend your day? - Can you do some things for yourself? - Does the staff give you a chance to learn self-care skills? Ask Nurse: - If the resident had access to a recliner chair, would he/she be able to be out of bed? - Is the time out of bed coordinated with the activity schedule and necessary care? Ask Nurses Aide: - Does this resident do any self-care? Why not? - If no, has anyone tried to teach him/her to do some care?			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Positioning F175 SNF 405.1124(e) Intent To assure that the resident is positioned at all times to promote maximum therapeutic benefit and comfort, as well as safety.	Observe residents in bed, chairs, restrained, or in "protective devices" for - body alignment - positioning - contractures (when did they occur and what is being done)? - ROM program (observe extent & technique of provider) - Assistive devices (overhead pulleys, slings, splints, etc.) - Turning/repositioning schedule and adherence to the schedule. - Devices to maintain positioning, i.e., sandbags, extra pillows, etc. Specific Observations for the Bed Resident (as appropriate to condition). Positioning/body alignment Resting splints & correct application Foot positioning boards Trapeze Hand rolls Elbow/leg splints & correct application Restraints Siderails (padded) Special mattresses	Ask Resident: - How often are you turned/repositioned by the staff? - Is that often enough? - Are you comfortable now? Do you have any pain or discomfort? Where? - How long have you had joint stiffness (contractures)? - What kinds of exercise do you do every day, including range of motion (ROM)? How long does the exercise last and how frequently do you exercise each week? - Do you wear special devices? How often? - Consistently? - Are they always applied and removed appropriately and promptly? How Often? - By whom? Bed Rest Resident Ask Resident: - Why do you have to stay in bed? - How often does staff get you OOB? - Do they know how to get you up? - Who sets you up and/or assists you in bedside ADL's? - Does staff, therapist check positioning, supportive devices?	- MD orders for non-nsq interventions/treatments. - Plan of care should include at a minimum: + Restorative goals + specific joints to be exercised + devices to be used in positioning + frequency of treatment or repositioning + resident teaching information + resident teaching information + services responsible for carrying out the procedures + time frames for reaching goals - Nursing progress notes indicate: + Plan has been implemented + Progress toward goals + Response to information from reevaluation - Look for actual turning/repositioning schedule	Plan of care should be complete (addressing resident positioning needs) and plan is implemented on a daily basis. Care givers are knowledgeable re plan content Residents are turned as scheduled. In good body alignment with proper assistive devices & equipment. Contractures are prevented and/or treated. Plan is reviewed, reevaluated and revised at least quarterly, but must be done as often as patient condition dictates. Ask aide assigned to demonstrate the hand holds he/she uses for ROM. If aide doesn't know, ROM is probably not being done. Do it "at bath time" is not sufficient.	Rehabilitative Services 405.1126(h) 442.343(c)(2) MD Orders Activities Resident Rights Nursing-Staffing Inservice Social Service Dietary

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F175 (cont'd)	Blankets/pillows Clean, smooth linen Clean, appropriate bed wear Turning schedules ROM schedule O.O.B. (as tolerated) Water available All adaptive devices are clean and in good repair. All assistive supportive devices are clean and in good repair. <u>Specific Observation for the OOB Resident in Chair</u> (geri-chair, lounge chair in room, as appropriate to condition) Arrangement of room facilitates residents optimal independence (e.g., independent eating, grooming, T.V., radio, water). Positioning/body alignment. Blankets/lap robe, pillows, foot stool. Hand rolls, splints. Clean, dry attire. Pressure relief device. Restraints, with release & activity schedule. Call bell available.	- When? - Does staff answer call bells propmtly? How soon? - Is resident able to reach items (e.g., water call bell, urinal, emesis basin, tissues)? - How much confidence do you have when the nurses are helping you transfer, or turn and so on? - Does resident go to therapy area or does therapist come to resident? <u>Bed Rest Resident</u> <u>Ask Staff</u>: - How often is position changed? - What activity is done at the time (e.g., R.O.M., toileting, OOB, grooming? - What can resident do independently? - Is equipment available? - Who maintains and cleans the equipment? - What is the schedule for this? - What training have you had to learn to position patients correctly?			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F175 (cont'd)	Specific Observation for the Wheel Chair Resident (as appropriate to condition, including deliberate alterations made to equipment for specific reasons.) - Proper fit - Good working condition - Appropriate arm rest, footrest, leg support, lap tray - Proper positioning - Pressure relief aids, (e.g., gel flotation pads, egg crate mattress, sheepskin) - Set up for independent W/C ambulation - Functional adapted toilet area - Transfer techniques Observe how staff wheel the resident (e.g., do they inform before starting movement)? Are patients moved wheeling forward and facing elevator doors? Observe staff for: - verbal cues - physical support - body mechanics Specific Observation for the Ambulatory Resident (as appropriate to condition) - Gait (steady/unsteady) - Appropriate devices for	- Was there any part of your orientation when you first came to work here that addressed positioning? - Do you have any periodic reviews/updates on positioning? Chair Bound Resident Ask Staff: - How often is resident repositioned/taken out of chair? - What is the activity at time of repositioning and/or release of the restraint? - What can resident do independently? Ambulatory Resident Ask Staff: Is resident encouraged to independently ambulate to and from activities and dining room (with or without personal assistance)? - Does resident do as much as he/she can independently? - What does resident do? - How do you know that resident is maximally independent? - If it is not working independently, how do			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F175 (cont'd)	ambulation (e.g., cane, crutches, hemi-sling - Posture - Appropriate staff assistance in ambulation - Grab bars (halls, bath/shower area) - Functionally adapted toilet area	you deal with it? - Is there something resident would like to do that he/she is not allowed to do (e.g., shave self, apply make-up, style own hair)? - What training have you had in learning to position residents and do range of motion? - What opportunity do you have for ongoing training? - Who does the actual training? Check question placement under Interviewing. May be more appropriate for resident's rights section. Observe wheeling technique used by staff.			
Nursing Services G. Administration of Drugs F183–184 SNF 405.1124(g) ICF 442.337 F186 1. The patient is identified prior to administration of a drug.	Observe a drug pass with at least 20 residents receiving medication. See SOM Appendix N. Transmittal No. 174 for details of the Surveyor Methodology for Detecting Medication Errors. - Observe medication administration techniques (e.g., hand-	Ask Resident - Do you always receive your medication on time? - If not, what is the problem? - Do you receive the correct medication? - What does it look like? - Who explained your medications to you? - What reactions do you have? - What happens if you have a question or refuse to take your medication? - Who gives you your medication? - Do your medications change in appearance?	Review the medication administration record. (as appropriate) See S.O.M. Appendix N, Transmittal No. 174 for details of the record review.	If the combined total of significant & non-significant errors is 5% or above, a deficiency is present. Any significant error is cause for a deficiency. See Appendix N for details.	Physician Services 405.1124(b)(7) Pharmaceutical Services Supervision 405.1127(a) 442.336(a)(b)

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F187 2. Drugs and biologicals are administered as soon after doses are prepared. F188 b. Administered by same person who prepared the doses for administration except under single unit dose packet distribution system. Exception: ICF residents may self administer medications with their physician's permission.	washing, pouring of dosage, position of resident).	- Do the nurses stay with you when you take your medication? - Do any of the medications bother you? Ask Staff: - Do you generally have available the medications you need? - Are there any problems in administering medications? Note drug doses refused by resident and how handled by staff.			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
H. Conformance with Physician Drug Orders F189 F190 F191 SNF 405.1124(h) ICF 442.334(a) Drugs are administered in accordance with written orders of the attending physician. Intent All residents receive medications as ordered by the physician.	Combine with observation of drug pass.		- Review the latest recap of the physicians orders - Review the medication administration record (as appropriate) - See S.O.M. Appendix N, Transmittal No. 174 for details of the record review.	See Appendix N for details	Physician Services 405.1123(b)(7)

LONG TERM CARE SURVEY

SURVEY AREA CROSS REFERENCE	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	
DIETETIC SERVICES (Condition of Participation) F193 SNF (405.1125) A. Menus and Nutritional Adequacy F194 SNF (405.1125(b)) F194 ICF 442.332(a)(1) F196 Menus are planned and followed to meet the nutritional needs of each resident in accordance with physicians' orders and, to the extent medically possible, based on the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences.	o <u>Specific Observations which might be indicative of possible nutrition problems:</u> Clinical - underweight/ overweight - dehydration - edema - cracked lips - pallor - dull or dry hair - swollen or red tongue - bleeding gums - decubitus ulcers - infections o Physiologic factors which may affect intake: - Swallowing difficulties - Vomiting - Food intolerance - Poor dentition - Sore mouth - Constipation - Diarrhea - Inability to feed slef - Decreased visual and olfactory acuity - Unable to communicate - Loss of appetite o Psychological/Social - Confusion	Ask dietary manager to explain the procedure for making substitutions and recording the changes. - Is menu usually followed? <u>Ask Resident</u>: 1. How are your meals? 2. Are there foods you are not allowed to have? 3. Are you on a special diet? 4. Do you receive foods that are not appropriate for your diet? If so, what do you and the staff do about that? 5. What time do you receive breakfast, lunch and supper? Do you always receive a meal at mealtime? If not, why? What happens then? 6. Do you like the taste of the food? 7. Is the temperature appropriate (i.e., milk chilled, coffee hot, etc.)? 8. Do you get enough to eat? What do you do if you're still hungry after a meal?	<u>Review Nutrition assessment for the following documentation</u>: o Usual/ideal body weight/ height o Dietary allergies/ sensitivities, ability to chew and swallow regular foods without difficulty. o Full or partial dentures o Mental and emotional condition o Physical appearance, skin condition o Appetite and food preference. o Vitamin and mineral supplements. o Food and fluid intake in measurable terms and frequency of meals. o Degree of assistance needed in eating, related mobility, vision, or other identified problems. o Medications (e.g., diuretics, insulin, antibiotics, etc.) o Related laboratory findings (e.g., fasting blood sugar, cholesterol, sodium, potassium, hemoglobin, BUN, serum albumin, transferrin or creatinine-height index if available).	o Were physician diet orders followed? o Did nursing plan for feeding and assistance at mealtime? o Is there rehabilitative use of assistive devices, if appropriate? o Is modification of consistency of meals made if resident has a problem or change in condition? o Are between meal and bedtime snacks provided as needed? o Is socialization at meals provided? o Has dietitian provided counseling of resident and family as needed (related to diet)? o Usual body weight is maintained/supported? o Is there evidence that the plan is being carried out (e.g., documentation in the resident's chart, observation by the surveyor, and resident/staff interviews)? If the resident refuses meals or does not respond to intervention, the notes in the chart should indicate efforts to intervene or provide counseling.	<u>Physician Services</u> 405.1123 442.346 <u>Medical Records</u> 405.1132 442.318 <u>Nursing Services</u> 405.1124(e)(f) <u>Specialized Rehabilitative Services</u> 405.1126 <u>Patient Care Management</u> 405.1124(d)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196(cont'd) Intent Ensures that each resident receives food in the amount, kind, and consistency to support optimal nutritional status.	- Excessive food likes and dislikes - Refusal to eat o Selected biochemical changes which might indication changes in nutritional stutus: - Visceral protein status o serum albumin o transferrin o BUN o Serum electrolytes During mealtime observe the resident for: - adherence to food preferences - adequate space for eating - self-feeding skills - proper position for eating - ability to eat foods served - use of adaptive feeding devices - amount of food actually eaten - protection of resident's clothes - amount of time resident is allowed to chew and swallow - Assistance provided as needed to and from dining area - All beverages are covered]	9. Do you receive nourishment in the evening? Do you have a choice about what you want to eat? 10. Do you receive medicines during meals? If yes, do you know what it is or what it is for? 11. Do you get food from outside of facility that you buy or family brings? How often? What kind of food? 12. How often does anyone from the kitchen come to ascertain your feelings and opinions on the food service, your portion size, etc.? 13. Where do you eat (e.g., dining room, your room, etc.)? Is this your choice? Do you have a choice of where you eat? 14. How often have you seen a therapist for your swallowing difficulties?" "How has the therapist instructed you/staff/family on methods to improve your swallowing? Ask Dietician - Describe the meal planning input you receive from residents.	o Food/drug interactions o Mental/emotional assessment as it relates to resident's food habits. Review: o Plan of Care o Nursing Notes Review: o Physicians orders o Progress notes o Notes from other professional disciplines as appropriate. Nutritional status depends not only on adequacy of menu planning but also whether the resident eats the food and how the body uses it. While the surveyor is not responsible for individual nutritional assessments of residents, when specific information is needed during the survey to make a compliance decision, the surveyor will utilize the following minimum assessment guideline: Menu Evaluation o Adequate in energy and nutrients - Protein - Calories	Is there evidence that the resident's progress is regularly observed (e.g., awareness of food and fluid intake such as acceptance of foods, food consumed, and resident's appetite)? o Is fluid intake for resident encouraged, Foley catheter, problem feeders monitored? o Is there general evidence as to whether poor resident conditions are due to poor care or whether the facility has taken appropriate measures to prevent or resolve problems. o Is there indication of progress toward desired outcomes? If not, is the evidence of re-evaluation available within specified time frames? o When the antropometric and clinical data do not correlate with dietary data, (food intake, dietary supplements) the surveyor should take note that the problem may not be nutritional.	Nursing Services -405.1124(f)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196(cont'd)	Assistance being provided in case of choking, incontinence, falling, or other emergencies. Nursing Staff supervision of dining areas including residents' rooms during meal times.		- Vitamin C - Calcium Selected evaluation of residents for in depth review: A check list can be used to evaluate daily menus for basic foods: (use standard serving protions) Daily food plan should include: MILK GROUP 1 pt milk MEAT GROUP 5 equivalents:* 1 equivalent equals 1 oz. of meat (edible portion) weighed after cooking (this includes eggs, dried peas, beans, nuts, and all meat, fish and poultry). VEGETABLE AND FRUIT GROUP 5 services or more, including a dark green or deep yellow vegetable for vitamin A value every other day and a citrus fruit or other fruit rich in Vitamin C daily.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196 (cont'd)	Observe serving portions sizes on all menu items: MILK GROUP - 1 pint daily Source of: Protein Calcium Phosphorus B Complex MEAT GROUP - 5 lean meat equivalents (1 meat equivalent = 1 oz meat, poultry, fish, cheese & eggs; also dried peas, beans, and nuts). Source of: Protein Iron Vitamin B12 VEGETABLE AND FRUIT GROUP - 5 servings or more (1/2 cup = 1 serving) Source of: Vitamin A,C, B6, Folacin, Fiber BREAD-CEREAL-POTATO-LEGUME-PASTA GROUP - 7 servings (1 serving = 1 slice bread; 1/2 cup other; 3/4 cup flake-type cereal).		BREAD-CEREAL-POTATO-LEGUME-PASTA GROUP 7 servings FATS AND SWEETS (Without this group the diet contains 1,415 Kcal) Diets should be adapted from facility's currently approved diet manual. Menus are dated and contain minimum portion sizes. Are substitutions noted on the file copy? Are substitutions made within the same food group i.e., meat for another source of protein in the meat group, or vegetable of similar nutritional value?		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196 (cont'd)	FATS AND SWEETS (to increase caloric intake) IODIZED SALT (unless contraindicated) Adequate fiber in diet		o Documentation of decision to withdraw or begin artificial feeding and hydration. Check menus for variety Are they specific (i.e., states kinds of fruit, juice, vegetable)? DIETARY SERVICES SELECTED NUTRITIONAL REQUIREMENT RECORD REVIEW N.B. The basal energy expenditure (BEE) and calorie requirement using Harris-Benedic formula recognizes the variation in energy needs for individuals. 1. Anthropometry- Weight /Height NOTE: The following sample formulas and guidelines are not the only acceptable guides available. The surveyor should ask to use the assessment guidelines used by the facility before using the ones provided here. o Important indicator of nutritional outcomes. o Disease state can have adverse effect on desired body weight.		

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196 (cont'd)			2. <u>Weight for Height Calculation</u> Females: Allow 100 lbs. for first 5 ft. of height plus 5 lbs. for each additional inch Males: Allow 106 lbs. for first 5 ft. of height plus 6 lbs. for each additional inch <u>Estimating Caloric Needs</u> 1. FORMULA: Harris-Benedict Equation Men: 66 + (13.7 x Wt. in Kg) + (5 x Ht. in cm) - (6.8 x Age)=BEE Women: 65.5 + 9.6 X Wt. in Kg.) + (1.7 x Ht. in cm) - (4.7 x Age)=BEE Parenteral Anabolic: 1.75 x BEE Oral Anabolic: 1.5 x BEE (Kcals)		

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196 (cont'd)			Oral Maintenance: 1.20 x BEE (Kcals) Metric Conversions (Approx) pounds (lb.) x 0.45 = kilograms (Kg) inches (in.) x 2.5 = centimeters (cm) Estimating Protein Needs 1. Allow 0.8 gram protein per kilogram of ideal body weight. 2. Increase to 1.2 - 1.5 gm/kg for patients with depleted protein stores (decubitus, draining wounds, fractures, etc.). Fluid Requirement Based on actual body weight: Over 55 years with no major cardiac or renal diseases: (NOTE: 2.2 lbs. equals 1 kg of body weight)		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196 (cont'd)			Example: 120 lbs/2.2 lbs. = 54.5 kg (55 kgs) 55 kg x 30 cc - 1,650 cc/day Note: Isotonic Standard Tube Feeding = Approximately 80% water. Amputation % of Body Weight Leg 20% Below Knees 10% Arm 6% At Elbow 3.6% Suggested Standards for Evaluating Significance of Weight Loss % of body weight loss Interval / Significant Loss / Severe Loss 1 week 1-2% 2% 1 month 5% 5% 3 months 7 1/2% 7 1/2% 6 months 10% 10% From Blackburn, et al: "Nutritional and Metabolic Assessment of the Hospitalized Patient: JPEN vol. 1, 1977.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS			CROSS REFERENCE
F196 (cont'd)			Lab Indices for Visceral Proteins				
				Mild Deficiency	Moderate Deficiency	Severe Deficiency	
			Albumin g/dl	3.5-3.2	3.2-2.8	2.8	
			Total Lumphocyte Count (cu/mm)	1800-1500	1500-900	900	
			Transferrin (If Available)	200-180	180-160	160	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
B. Therapeutic Diets F197 SNF 405.1125(c) F198 ICF 442.332(b)(1)(2) F199 1. Therapeutic diets are prescribed by the attending physician. F182 2. Therapeutic menus are planned in writing, prepared, and served as ordered with supervision from the dietician and advice from the attending physician whenever necessary.	System for the provision of diets: o Dietetic service Kardex or file o Therapeutic menus o Nourishment preparation and service o Adequacy of nourishment o Individual menus or diet cards SPECIAL FEEDINGS: The surveyor should also attempt to observe that: o Staff use proper technique in administering feedings and medications. Check to see that staff checks for location of tube before feeding and that tubing is irrigated before and after addition of medication. o Unused milk-based tube feeding should be discarded in a timely manner	Ask Staff: o Number, type of therapeutic diets? o Time of nourishment activity, who's responsible? o Nourishment provided for day of survey? The surveyor should interview staff regarding their knowledge of the feeding schedule and training in administering tube feedings. Some residents having difficulty in speaking or swallowing with the tube in place (i.e., poor toleration). The surveyor should inquire if mouth feeding was attempted. Ask Resident: If the resident is able to be interviewed, suggested questions may be: 1. How long have you been fed by this tube? 2. When was the last time you tried to eat by mouth? What happened? 3. How often do you receive the feeding? Is this consistent?	Review: - Physician diet orders in medical record - Nurses' Kardex - Dietary Kardex - Therapeutic diet menu - Diet cards Note: - Consider appropriateness of special diet-updated and reviewed since admission. - Progress notes reflect reevaluation of resident's progress on diet. Selected number of residents on therapeutic diets should be considered for indepth reviews. Tube Feeding Review: - Plan of Care - Identify frequency, amt. of feeding based on the physician's order and the time span over which each feeding is accomplished. - Medication and treatment records - Fluid intake records - Number of calories as	On Pureed diets: o Ordered by physician o Prepared fresh daily o Same calories and/or food groups as if served whole. Pureed foods are coordinated with general/regular menu. On Tube Feeding: o Has the feeding been ordered by physician? o Is tube feeding nutritionally adequate? o Have attempts been made to progress tube feeding if indicated? o Have changes in resident condition been noted and addressed.	Nursing Services 405.1124 405.1124(c) (d.) Patient care plan (f.) Supervision of patient nutrition

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F197-199 (cont'd)		4. Does the staff help you in feeding? Do you feel comfortable/safe with all the staff who perform the feeding? If not, what happens? 5. Are you losing or gaining weight? What is your goal? 6. How often is the tube changed? Who does this? Do you feel comfortable/safe with all staff who perform this procedure?	well as amount of additional water - Periodic reassessment of ability to swallow - Record should indicate measures taken to prevent diarrhea and constipation and to treat if they have developed.	weight loss, constipation, diarrhea, skin condition)? o Have observed problems been coordinated with other departments and resolved? o Is feeding being monitored to ensure that feeding is occurring at the ordered/appropriate rate? o Varied nourishments as preferences allow?	
		Interview staff regarding knowledge of diabetic diets. o What nourishment does the diabetic patient receive? o If diabetic patient refuses the meal, what is done to supplement the meal? If resident is able to be interviewed, suggested questions: 1. How long have you been on your diabetic diet? 2. Do your know some of foods you must avoid? What are they?	Diabetic Diets Review: o Pertinent Laboratory data: - urinary glucose - serum glucose o Wt. gain/losses	On Diabetic Diets and Other Therapeutic Diets o Ordered by Physician o Varied, nutritionally adequate o Individualized to suit resident o Re-evaluation indicates diet meets objectives. If not appropriate, documentation is provided o Laboratory results support diagnosis o Between meals nourishment provided as needed and recorded in measurable amounts.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F197-199 (cont'd) F198 Therapeutic diets prescribed by the attending physician	Observe tray/meal service: o Low sodium diets are platable (taste) o Sugar sources on diabetic diet trays o Salt sources on sodium restricted diet trays.	3. Do you receive a nourishment between meals or before going go bed?			
F199		FOR THE RESIDENT WITH DECUBITUS ULCERS			
Therapeutic menus are planned in writing, prepared and served as ordered with supervision from the dietician and advice from the physician whenever necessary.	Functioning system to provide the needed nutrients: - Resident's general appearance - Meal service + Food acceptance + Adherence to food preferences - Food supplement + Type to support + Method of service + Assistance provided + Timely provision as ordered - Portion sizes - Conforms to physicians orders	Ask Staff: 1. Regarding knowledge of dietary needs. 2. What do you do when this resident refuses milk, meats, bread, etc.? 3. What nourishments are provided to this resident? How often? 4. What happens when a weight loss is noticed with this resident? Ask Resident: 1. Has anyone talked with you about the importance of eating your meals? 2. Do you get foods that you don't eat on your tray? 3. When do you feel hungry? 4. Do you get between meal nourishments?	1. Identify residents with conditions that immobilize or prevent voluntary body movement. 2. Identify location, number, size and depth of decubitus ulcers. 3. Calculations of kilocaloric and protein levels as needed. 4. Micronutrient need assessment and recommendation. 5. Progress notes + monitor weight + monitor healing of decubitus ulcers. 6. Pertinent Laboratory Data + Hemoglobin/Hematocrit + Serum Albumin + Total Lymphocyte Count 7. Fluid Intake + sufficient to maintain hydration	A system is in place to provide the type and amount of nutritional support needed by the residents who have developed decubitus ulcers. Food and supplementation are provided in a method to ensure intake of nutrients needed by residents with decubitus ulcers. Nutritional intervention is assessed and reassessed to ensure appropriate intervention for acceptable health care outcome.	Nursing Service 405.1124 (d) Patient Care Plan (f) Supervision of Patient Nutrition

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F197-199 (cont'd) F198 Therapeutic diets prescribed by the attending physician F199 Therapeutic menus are planned in writing, prepared and served as ordered with supervision from the dietician and advice from the physician whenever necessary.	RENAL REVIEW System in place for the the correct provision of renal diets. - Individualized menu - Dietary Staff Utilize menu when serving diets.	Interview Staff regarding knowledge of renal diets: 1. What foods should be restricted when a patient has kidney problems? 2. What nourishments are given to these patients? 3. Are fluids restricted? Ask Resident: 1. Are you on a special diet? 2. What foods must you avoid? 3. Do you feel hungry? 4. Do you eat everything at mealtimes? 5. Are the foods the kitchen sends you the correct ones for your diet? 6. Has the dietitian explained your diet to you?	Renal Patient Diet Review - Pertinent Laboratory Data + Serum Sodium + BUN + Serum Potassium + Albumin + Hematocrit + Creatinine - Pertinent Medications + Vitamin/Mineral + Supplements - Weight gains/losses	On Renal Diets - Ordered by physician - Written menu nutritionally complete in so far as medically possible, including calories - Individualized to suit resident - Laboratory testing as needed - Coordination with dialysis unit to determine effectiveness of diet	Nursing Service 405.1124 (d) Patient Care Plan (f) Supervision of Patient Nutrition

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
C. Preparation F204 SNF 405.1125(e) F205 1. Food is prepared by methods that conserve its nutritive value and flavor. F206 2. Meals are palatable, served at proper temperatures. They are cut, ground, chopped, pureed or in a form which meets individual resident needs. F207 3. If a resident refuses food served, appropriate substitutes of similar nutritive value are offered.	Observe: o Feeding assistance is provided or not provided by staff o Length of time residents sit and wait for meal service o Food is served soon after cooking or refrigerated o Trays are free of spillage of foods or liquids o Foods are appropriately covered and kept at a proper temperature o Cooking and service utensils are clean, sanitary and greaseless o Refrigerated foods must be covered o Leftover and pre-cooked foods must be dated and labeled o All cooked food stored above raw meats in refrigerator o Temperature gauge on or in refrigerator to record temperature o Shelving to allow air circulation o Food not stored in refrigerator must be stored off the floor (This is applicable to food stored in walk-in refrigerator and freezer.)		Review: o Plan of Care o Progress notes o Notes from other professional disciplines to determine rehabilitation potential to self feed, use of assistance devices. o Record of food substitution to determine alternate choice provided o Standardized recipes	The facility has kitchen and dietetic service areas adequate to meet the food service needs. These areas are properly ventilated, arranged, and equipped for sanitary refrigeration, storage, and preparation of food. Equipment and storage areas are clean, well maintained, within proper temperatures ranges, and safe Proper temperatures: (Fahrenheit) Frozen food storage -- 0 or below Cold food storage -- 40-45 degrees Hot food holding equipment -- 140 degress minimum Dishwasher wash cycle -- 150 - 160 degrees Dishwasher rinse cycle -- 160-180 degrees or a color change in thermopaper; or adherence to manufacturers recommendations	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F207 (Cont'd) INTENT To provide foods that are safe and nutritious SNF 495.1125(e)	- No rust on shelves - No dripping or spillage on shelves and floors - Degree to which diet modification is commensurate with residents tolerance and capability - Residents for meal satisfaction - Observe appearance of food color, texture, aroma, and flavor - Less than 75% of meal is consumed - Type of substitutions provided		- Progress notes - Diet card - Day's menu substitute record	Dietary personnel are clean and free of infectious disease. They practice acceptable techniques and procedures to keep foods at proper temperatures and protected against contamination. Is dietary information pertinent to dietary modification? Has resident been assessed for eating program to maintain independence? The food substitute is of similar nutritive value as the refused item (e.g., milk refused, alternate of calcium rich food should be provided.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
D. Frequency F208 SNF 405.1124(d) F209 ICF 442.331(a) F210 1. At least three meals are served daily at regular hours with not more than a 14-hour span between a substantial evening meal and breakfast. F211 2. To the extent medically possible, bedtime nourishments are offered to all residents	o Menus as under A on page 63 o Who serves nourishments o Nourishment list and schedule	Interview various residents about the nourishment service: o Are nourishments offered routinely? o At what time are they offered? o By whom? o What kind of nourishments are offered?	Review o Menu as under A o Nourishment List	Three meals or their equivalent are served daily with not more than a 14-hour span between the evening meal and breakfast. The nourishment service is more difficult to evaluate: must find evidence that patients are offered nourishments on a planned basis and documented.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
E. Staffing F212 SNF 405.1125 (a) F213 1. Food service personnel are on duty daily over a period of 12 or more hours. Intent Persons are providing services commensurate with their level of training; and at the level of sophistication needed by the residents.	- Food service personnel are on duty for all defined dietary responsibilities: - Supervision - Food Preparation - Dishwashing - Cleaning - Duty Schedules	- Interview personnel to verify that they are aware of their responsibilities and job descriptions.		- From an assessment of the total dietetic service operation: + The dietetic supervisor is capable of the overall management and supervision of the dietetic service. + There are dietetic personnel on duty over a 12-hour period who demonstrate ability to perform tasks adequately. + Dietetic personnel receive appropriate orientation and training consistent with their duties and responsibilities. There is evidence that the dietetic staff are knowledgeable about food service policies and procedures and apply these accepted professionals practices in their daily work. + Services provided are consistent with the size, scope and facilities available.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
SPECIALIZED REHABILITATIVE SERVICES F214 SNF 405.1126 F215 SNF 405.1126(b) F216 ICF 442.343 A. PLAN OF CARE ICF442.343(e)(1)(2) F217 Rehabilitative services are provided under a written plan of care, initiated by the attending physician and developed in consultation with appropriate therapist(s) and the nursing service. B. THERAPY F218 ICF442.343(a)(c)(d) Therapy is provided according to orders of the attending physican in accordance with accepted	OBSERVE RESIDENTS As per "Restorative Nursing Activities of Daily Living" SNF 405.1124(e)2(b) ALSO: OBSERVE RESIDENTS IN THERAPY AREAS: - Is privacy provided during treatment, as applicable (e.g., cubicle curtains, room dividers, one to one area)? - Is there appropriate, courteous resident/staff interaction? - Are therapy areas appropriate to treatment given (e.g., small, quiet area for speech/language/ hearing test and sessions, large for P.T., exercise and therapy groups, O.T. perceptual testing/splinting, A.D.L. adaptations area, as applicable)? - Is equipment clean and in good working condition? Is it operating as per manufacturer instructions (e.g., hydrocollator temp., parafin, whirlpool, etc.)?	ASK RESIDENT: (or ask staff, if resident has severe communication problem): - Are you receiving any kind of therapy? P.T.? O.P.? Speech? - What kinds of therapist(s) are working with you on your swallowing problem? - What kinds of therapists have instructed you on how to improve your swallowing? - How do the methods to improve swallowing help you? - How often do you see the therapist? - What happens if the therapist is absent for scheduled treatments? - Where do you receive your therapy? - How long have you been receiving therapy? - Do other staff members assist with therapy? Who and in what way? - Are you in a comfortable environment (room temperature, privacy, etc.)? - Do you have input into developing or revising your therapy treatments? -What things did you do immediately before entering this facility, that you are unable to do now? ASK THERAPY STAFF: - How many days/hours per week do you provide therapy? - Do you participate in the development of the resident's overall plan of care? In what way? - Do you utilize P.T.	REVIEW: - Plan of care - Doctors' orders - Nursing assessment and progress notes - Aide assignment sheets - Therapy assessments/evaluations (includes a minimum of): + name, age, date, diagnoses + referring physician and reason for referral + history, precautions, limitations + objective documentation (e.g., tests, measurements) + rehabilitation potential - Treatment plan (includes a minimum of): + specific rehabilitation needs and objectives + treatment to meet specific measureable rehabilitative goals + Type, amount, frequency, duration, modalities + name of therapist(s) who will provide treatment + restorative nursing follow-thru (recommendations for plan of care)	- Are rehabilitation services integrated with restorative nursing? - Do therapists participate in development of resident plan of care? - Do observations and interview indicate that services are provided in conjunction with 24 hour nursing, and in accordance with the overall plan of care regarding restorative nursing and specialized rehabilitation services?	Nursing Services 405.1124 442.338 442.319 442.341 Physician Services 405.1123 442.346 Medical Records 405.1132 442.318 Activities Program 405.1131 442.345 Resident Rights 405.1121(k) 442.311 Training 405.1121(h) 442.311 Infection Control 405.1135 442.315 442.327 442.328

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F218 (cont'd) professional practices by qualified therapists or qualified assistants. C. PROGRESS ICF 442.343(f) F219 1. A report of the resident's progress is communicated to the attending physician within 2 weeks of the initiation of specialized rehabilitative services. EXCEPTION: ICF resident's progress must be reviewed regularly.	- Are assistive devices being provided as needed? - Do assistive devices fit well, function and are used properly (e.g., wheelchairs, crutches, braces, glasses, hearing aids, canes, artificial limbs assistive eating devices)? - Is staff responsive to resident expressions of discomfort? - How are the prescribed treatments and training meeting the needs of the resident? - Are parallel bars sturdy and well secured to floor? Are systems designed for weight lifting sturdy and well secured; if attached to wall with rigging and hand grips in good conditions? - Are nonverbal residents provided with means of communication (e.g., writing tablets and utensils, picture cards)? - Are visually impaired residents provided with	"aides" In what way (if interviewing the registered physical therapist)? - How do you assure carry-over of therapeutics in your absence? - How often do you provide inservice to staff? What topics are covered? - Do you have opportunities to attend inservices? - How do you communicate patient progress/regression, etc. with physician, nursing personnel, family, other disciplines? - How many residents currently are receiving P.T., O.T., Speech-language pathology and audiology therapy (SLP/AT) . - Do you utilize the services of a certified occupational/therapy assistant (if interviewing the registered occupational therapist)? If so, in what way? - Is space available for the conduction of your therapy? - Is equipment readily available to meet resident needs? - Is there a coordinated interdisciplinary	+ identifies modalities that will be delegated to non-skill staff - Progress notes indicate that plan of rehabilitation care has been re-evaluated by the physician and therapist as necessary but at least every 30 days. - Communication with physician: + 2 week progress after initiation + monthly progress + discharge summary - Treatment documentation: + frequency + summary		Physical Environment 405.1134 442.324 442.325 442.326 442.328 442.329 442.330 Dietetic Services 405.1125(e) 442.329 442.331(c)

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	magnifiers and large print books? - Is equipment such as whirlpool cleaned between patients?	approach toward rehabilitation of the geriatric resident evident in your facility? In what way do you see this?			
F220 2. The resident's progress is thereafter reviewed regularly and the plan of rehabilitative care is re-evaluated as necessary, But at least every 30 days by the physician and therapist. EXCEPTION ICF resident's plan must be revised as necessary INTENT Therapy services are provided that will assist the resident to attain his/her optimal level of function.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Pharmaceutical Services F221 SNF 405.1127 F222 A. Supervision F223 ICF 442.336(a)(b) F224 SNF 405.1127(a) The pharmacist reviews the drug regimen of each resident at least monthly & reports any irregularities to the medical director and administrator. A registered nurse may be utilized to perform this monthly review for ICF residents. Also the attending or staff physician must review medication quarterly.	- Observe residents for excess sedation or adverse effects: + drooling + shuffling gait + involuntary movements of limbs, tongue, facial muscles + loss of affect + drowsiness + postural abnormalities + pill rolling movement - Observe for depression aggitation	Ask Resident: - Are you aware of the medications you are taking--use, frequency, contraindictions? - Has your physician discussed the medications you are taking, with you? - How many medications are you taking? - How do you feel the medcation helps you? - How do medications bother you? (e.g., make you feel nauseated or dizzy) - Have you told anyone about this? Ask Staff: - How often does the pharmacist review the resident's medications? - To whom does he report any irregularities? - When the pharmacist reports irregularities, what is done about it? - To whom do you report any problems about medication? - Do you feel the residents are receiving the proper medications, amount and kind? - Is the pharmacist available to you for consultation?	Review medical record: - to see if pharmacist or nurse has reviewed a drug regimen on a monthly basis. - for evidence that the reviewer has reported irregularities to the physician or other who has authority to correct the irregularities for evidence that the irregularities have been evaluated. - review nurses notes, progress notes, care plan, etc. for any adverse reaction to medication and indication that corrective action was taken. - screen the drug therapy of the residents included in the sample using the indicators (forms if prepared) outlined in SOM Appendix N Transmittal #174. - review pharmacists drug regimen monthly reports to determine if pharmacist has commented on potential irregularities, screened out through this process (need full year).	Reviews were performed in the facility. There was evidence of a review performed on every resident whose record was reviewed indepth. In records reviewed, the average prescription utilization was not substantially over 6.1 If it is, review for appropriateness. Apparent irregularities were identified and reported. * Refer to SOM Appendix N in 174 for further information on drug regimen review.	Physicians Services 405.1123(b) 442.346 Nursing Services 405.1124 442.338

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F224 (cont'd)		- Where does the pharmacist perform his drug regimen review?			
B. Labeling of Drugs and Biologicals F225 SNF 405.1127(c) F226 ICF 442.333 F227 The labeling of drugs and biologicals is based on currently accepted professional principles and includes the appropriate accessory and cautionary instructions as well as an expiration date when applicable. INTENT To assure that residents receive medications as ordered and that they are monitored for possible side effects.	Observe labels of medications for residents observed on drug pass tour for: - name of drug - dosage form - strength of drug - quantity of drug - expiration date - presence of a control number - appropriate accessory or cautionary statement				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Laboratory and Radiological Services F228 SNF 405.1128 F229 SNF 405.1128 (a) A. Provision of Services F230 1. All services are provided only on the orders of a physician. F231 2. The attending physician is notified promptly of findings.	Observe symptoms of targeted residents, e.g., drainage, odors, jaundice, fevers, edema, etc.	Ask Nursing/Rehabilitative Staff: - What do you do when you think a resident needs laboratory work done - blood work, cultures, etc.? - How long does it take to get lab results back? - What do you do with the results when they do come back? - Do you have any problems with your laboratory services? - How are lab specimens stored? - Do you have any instruction from the lab regarding collection and storage of specimens?	Review the physician's order sheet to see if: - orders for lab services are signed - that there are orders for tests that have been done. Nursing progress notes are reviewed for documentation of physician notification of lab results. Physician progress notes or other documentation indicating that the physician is aware of lab results. There are lab reports on the medical record for all tests ordered (except if just performed).	There must be signed physician orders for all lab/radiology services performed. Record results of all testing in the medical record. There is documentation in nursing or physician notes to indicate the results of lab tests were promptly communicated to the physician. When lab tests are performed the resident should be informed of significant findings and the possible therapeutic alternatives.	Nursing Services 405.1124(a)(b)(c) 442.343 Physician Services 405.1123(b)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F232 3. Signed and dated reports of a clinical laboratory, x-ray and other diagnostic services are filled with the patient's medical record. INTENT To assure that lab tests are performed as ordered and findings are reported to physicians are made aware of symptoms that may require lab tests.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Social Services F233 SNF 405.1130 F234 SNF 405.1130(a) F235 ICF 442.344(d) A. Plan F236 The medically related social and emotional needs of the residents are identified. B. Provision of Services F237 1. Services are provided to meet the social and emotional needs by the facility or by referral to an appropriate social agency.	Observe resident for: - level of alertness - behavior exhibited (disoriented, confused, uncooperative, disruptive, aggressive, anxious, withdrawn, isolated, lonely). - personal appearance - apparent disabilities - apparent vision and/or hearing problems they exhibit as you talk to them - interaction to staff, other residents, family, visitors - participation in group activities - independence in activities, decision making - Therapeutic staff intervention: constructive reaction to resident's behavior - resident's participation on policy making bodies and committees of facility, e.g., resident councils.	- How long have you been in the facility? - Can you explain to me why you are here? - Have you had any problem adjusting to the facility i.e., loss of independence? - Have you had any other problems? - Has staff been helpful, e.g., financial? - Do you have any family or any other visitors? - Do they have any problems with which this facility has not been helpful? - If exhibiting disruptive depressed, agitated, anxious, etc. behavior- I noticed that you are upset (quiet, nervous, unhappy) today, Can you tell me what has bothered you? - Does staff respond to your suggestions about your own care? - Did you participate in planning what care you will get and who will give it to you? - Do you make use of the dining, activity, community room, and/or outdoor area?	Review medical records of residents selected for in-depth review to determine that: - Assessment and plan of care identifies residents medically related social and emotional needs and/or problems. - Resident's family and home situation, information related to medical and nursing requirements, and community resources are considered in making decisions regarding the residents care. - Medical records contain current specific information signed and dated which highlights the social and emotional needs of the resident and significant findings and actions are entered promptly in the medical record. - Social service notes address the following, if applicable: + losses due to aging + relationship with staff and other residents + mental status + behavior problems + adjustment to the facility + illness	The residents social and emotional needs are identified. The plan of care addresses those needs. The plan of care is being followed, reviewed and revised as necessary. The family's needs and concerns are addressed if applicable. There is referral to appropriate agencies if necessary. Sufficient space is provided for private meetings and discussions. While it is not a program requirement a social worker or other staff may contribute to the resident's care plans by indicating personal strengths that can be used to build upon.	Nursing Services SNF 405.1124 ICF 442.338 Activities SNF 405.1131 ICF 442.345(a)(c)(d) Physicians Services SNF 405.1123(b) ICF 442.346 Patient Care Management SNF 1124(d) ICF 442.346 Physical Environment SNF 405.1130(b) ICF 442.344(c)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F233-238 (cont'd) F238 2. If financial assistance is indicated, arrangements are made promptly for referral to an appropriate agency.		- Can you tell me about your life here? What do you do in a usual day? - Are things like getting up, bathing, dressing, eating, done at the same time for everyone? - If you could change some things about living here, what would you change? <u>Ask Social Worker/Nurse</u> -When the social worker is readily available, delete "ask the nurse". -How often is the resident seen by a social worker?" - Who is responsible for identifying the resident's: + social and emotional needs + family and home situation + problems and needs + financial needs - How are needs identified and reported? - Does resident participate in the development of his/her care plan? - Ask nursing how often the social worker sees resident. - Does the social worker discuss residents needs/problems with nursing staff if there is a need for nursing to be involved?	- Plan of care, social service notes, reflect the current status of the resident. - There is evidence that the residents mental status has been considered when plan of care was developed. - Vision and hearing problems have been addressed. - Plan of care addresses residents needs as observed by the surveyor and stated by the resident. - Notes and plan indicate that needs have been re-evaluated and care plan changed as necessary. - There is evidence that the problems and needs of the family have been addressed. - There are indications that a referral has been made to the appropriate agency and a statement describing why. - There is documentation from the outside agency indicating what actions were taken and any plan for follow-up.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F233-238 (cont'd)		- How is physician notified and involved in plan of care? - Ask social service staff their role, function, and what services they provide. - Ask staff what referral services are available. - If services are being provided by outside resource, are resources documented work service? - Ask social service staff about their background and education. - If there is a consultant ask staff: + How often does the person come? + How long do they stay? + What does the person do while in the facility? + What assistance, consultation is being provided? + Ask social service staff if adequate space is provided for them by the facility to conduct private interviews and meetings.	- The time period between date of referral and date of services is reasonable and if not, there is evidence of follow-thru by staff. - The outside agency has documented their involvement and activities. - Plan of care demonstrates awareness of behavior, articulates the reasons for it, and indicates in the plan of care an approach to the behavior. - Assessment should contain: + a flexible approach to each resident (should be individualized). + awareness of a mental status evaluation. + resident history. + family availability for planning, resident support, etc. + identification of problems resulting from placement. + recent social adjustment. + discharge planning. - The record reflects	- There is documentation of collaboration between nursing and social work for meeting emotional needs.	Patient Care Management 405.1124(d)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F233–238 (cont'd)			Social Service intervention with family and resident, i.e., grief and bereavement counseling. - Review integrated plan of care for: + Plan for concerted social services. + Plan for supportive services for adjustment. - Adjustment goals. - Interventions for specific conditions.		
Activities F239 SNF 405.1131 F240 SNF 405.1131(b) F241 ICF 442.345 F242 1. An ongoing program of meaningful activities is provided based on identified needs and	General level of activities throughout the facility, as well as in specifically designated areas. How many residents are lying on their beds or sitting in chairs staring at the walls during waking hours? What is the level of residents interest in activities they are doing? Are residents positioned correctly for activity?	- How does he/she spend the day? - Of the activities resident has during the week, what does he/she enjoy most/least? - If has none, why? - Has staff asked about his/her interests? Suggested specific activities or people to get acquainted with in response to interests? - What organized activities has he/she participated in this past week? - How does resident find out about upcoming programs or happenings?	Activities Assessment Interests of the resident (past and present) are identified as to resident's current capabilities and necessary adaptations to pursue their interests. Documentation that information about social history, medical problems and limitations impacting residents' activities have been communicated to activities personnel and used in assessment and development of activities portion of care plan.	Are each resident's personal interests known? If not, what actions are being taken to identify them? Residents in facility 60 days should not be without some identified interests. Are each resident's needs identified? If not, what actions are being taken to identify them? Have medical contraindications been identified in the care plans? Needs and contraindications of residents in the facility more than 30 days should be known and/or have a plan of action.	Nursing Services 405.1124 442.319 Social Services 405.1130 442.344 Special Rehabilitative Services 405.1126 442.363 Physician Services 405.1123 442.329

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F242-(cont'd) interests of each resident. It is designed to promote opportunities for engaging in normal pursuits, including religious activities of their choice, if any. F243 2. Unless contraindicated by the attending physician, all residents are encouraged to participate in activities. F244 3. The activities promote the physical, social and mental well being of the residents.	Are needed personal equipment (e.g., splints, glasses) and adaptations for limitations and safety (e.g., cardholder, goggles, footrests) used in activities?	- Does resident get out of facility to activities? - Does resident have problems getting to activities? If so, does the staff assist? - Does the staff encourage residents to go to activities? - Does resident participate in Resident Council? - Does resident have free choice of activities? - What kind of activities do bedfast residents engage in? Ask Resident: - Hove you ever had difficulty in having private visits? Give examples.	- Needs of the resident in the following areas are identified: + social interaction + creative expression + work and service opportunities + intellectual stimulation or activities adaptation + physical exercise + spiritual or religious expression - Plan of care Used all available information about: + interests + needs + indications and contraindications for activities from other assessments + physician orders and progress notes	Does each resident's activities promote his . physical, social and mental well-being?	Physical Environment 405.1134 442.329 Infection Control 405.1135 442.328 Resident Rights 405.1121(k) 405.311 Medical Records 405.1132 405.318 Patient Care Management 405.1124(d) 442.341

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F245 4. Equipment is maintained in good working order. F246 5. Supplies and equipment for activities of interest are available. INTENT Each resident has individual and/or group activities to meet activities needs through his interests daily.	Is lighting adequate throughout the facility for activities in which residents are engaged? Do men and women have activities of interest to them? Do residents communicate with each other in activities? Are methods of communicating upcoming activities appropriate to the resident populations? Specific observation for physically impaired/alert residents: Activities adapted to meet specific needs of the resident. Alert residents have activities of interest and at their cognitive functional level. Specific observations for confused/disoriented, emotionally disturbed and mentally retarded residents: There are current calendars, clocks and patients	Ask Nursing/Activity Staff - Do they know the interests of residents under their care? TV programs they like? Activities they want to participate in today/this week? - Do they know the personal equipment needed (e.g., glasses, hearing aids, reacher)? - Do they know the adaptive equipment used by residents for specific activities (e.g., talking books, built up tools)? - Do they talk to residents to identify new interests and report these and "dislikes" to activities personnel? How? - What is staff's involvement with individual and group activities of residents in their care? - How do they determine interests of residents who have difficulty communicating? - What activities does resident participate in regularly? Which activities does he/she enjoy most/least?	Activities notes spell out implementation of plan, resident's reactions to specific activities, approaches, and people. Residents' participation in individual and group self-started and organized structured and unstructured activities timespent. Evaluation of plan of care for: changes in interests; changes in precautions, changes in needs, new problems, approaches, etc. Plans are revised as needed.	Are equipment and supplies to meet residents interests available and maintained in good working order? Are residents evaluated periodically with emphasis on participation levels and desire for new activities? Are plans readjusted if they do not reach desired outcomes? Residents in the facility more than 60 days should have at least two activities per week of interest to them personally.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F246 (cont'd)	and patients names or symbols visible to all the residents. Staff consistently use techniques such as reality orientation, empathy, and/or validation therapy as per each individual's needs. Resident has familiar items if available in room (e.g., family pictures, artwork, afghan, chair from home). Residents in restraints have activities of interest geared to their abilities when restrained (e.g., table-top activity, music, radio, reading and writing material; when out of restraints (e.g., walks, exercise, group, toileting). Small group and one-on-one involvement with staff reinforcing appropriate responses. Staff reaction to resident behavior during activities (e.g., crying, whining, demanding, nonverbal, agression,	- If he/she does not participate, why? - Which activities appear to relax/calm the resident? Excite him/her? - How does staff manage maladaptive behavior (e.g., abusive, disruptive, combative)? - Is direct care staff involved in resident activities? How? When (weekends, evenings)? - Does resident have one-to-one assistance in activities? - How many residents have few activities a day of interest to them as individuals? - Why do these residents have so little interest? - What is your plan to find more activities of interest to them that will meet their needs? - What types of residents seem not to be interested in activities? - How many (who) residents have only passive activities?			

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F 246 (cont'd.)	loudness). Specific observation for comatose or teminally ill resident: - Appropriate items for sensory enrichment in room (e.g., TV, radio, adequate lighting) - Resident placed in supportive living environment (e.g., around people, in hall, activities room, sunshine, fresh air), when appropriate to the resident needs and consistent with the resident's choice. Specific observation of environment for conducting activity program: - Adequate lighting. - Functional area is appropriate for activities of interest (e.g., religious services, arts and crafts, cooking, reading, TV watching, card playing, parties, discussion groups, gardening).	- How do you adapt activities for needs of residents who are: - confused/disoriented - emotionally disturbed - mentally retarded - physically impaired but alert - terminally ill? - Are community volunteers utilized in the activities program? In what way? - Are the residents encouraged to offer suggestions for new activities? If so, what activities have been instituted as a result? - How they manage maladaptive behavior (e.g., abusive, disruptive, combative)? - How do they help depressed residents (e.g., tearful, emotionally labile)?		Resident may refuse to participate in activity. However if the activities are part of a diagnostic or therapeutic program, the resident is responsible for assisting in the selection of mutually acceptable alternative activities.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE

F246 (cont'd)	- Multi-purpose room use and timing of activities does not conflict.
	- Outdoor activity area.
	- Functional furniture, indoors and outdoors.
	- Evidence of free choice activities:
	  - newspapers
	  - magazines
	  - record player
	  - radios
	  - games
	  - TV's
	  - reading
	  - sewing
	  - personal visits
	  - church services
	- Activities, equipment and supplies are appropriate and sufficient to meet interest of residents.
	- Activities equipment and supplies sufficient for conducting activities.
	- Activities equipment clean, safe, and in working order.
	- Residents rooms contain independent project materials, as appropriate.
	- Residents have access to the total activity environment (e.g., lobby, sunroom, dayroom, porch, dining room).				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
MEDICAL RECORDS F247 SNF 405.1132				All information required is present in the record. Does the record document all observable resident needs/problems?	
Content F248 SNF 405.1132(c)					
F249 ICF 442.318(a)(c)					
F250 1. The medical record contains sufficient information to identify the resident clearly to justify diagnoses and treatment and to document results accurately. F251 2. The medical record contains the following information.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F251 (cont'd) a. Identification information.					
F252 b. Admission data including past medical social history.					
F253 c. Transfer form, discharge summary from any transferring facility.					
F254 d. Report of resident's attending physician.					
F255 e. Report of physical examinations.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F256 f. Reports of physicians' periodic evaluations and progress notes.					
F257 g. Diagnostic reports and therapeutic orders.					
F258 h. Reports of treatments.					
F259 i. Medications administered.					
F260 j. An overall plan of care setting forth goals to be accomplished through each service's designed activities, therapies and treatments.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F261 k. Assessments and goals of each service's plan of care.					
F262 l. Treatments and services rendered.					
F263 m. Progress notes.					
F264 n. All symptoms and other indications of illness or injury including date, time and action taken regarding each problem.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F264 (cont'd) INTENT Brings together all resident information. Reflects the care being given to the residents and helps all care givers to make decisions on care needed.					
TRANSFER AGREEMENT F265 SNF 405.1133		Ask Staff: - What is the routine information you provide to a new facility when you transfer a resident? - Who provides this?	Review information on medical record of resident who was temporarily transferred and is again back in the facility.	All pertinent resident information must be documented on the medical record at the time of transfer.	Patient Rights 404.1121(k) 442.311
F266 SNF 405.1133(a)			Look at physician and nursing progress notes of above residents to determine if the timeliness of transfer was consistent with accepted standards of care.	The resident was not injured in any way by a delay in the transfer process.	
F267 ICF 442.316					
F268 A. Whenever the physician determines that a transfer is medically appropriate between a			Does facility have an agreement with a hospital? Not required if hospital under same ownership, direction and in same campus.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F 268 (cont'd) hospital or a facility providing more specialized care and the nursing facility, admission to the new facility shall be effected in a timely manner.			Is transfer form complete with all data, with appropriate signatures? Does the medical record indicate that adequate and pertinent aspects of the discharge planning portion of the patient care plan accompany the patient on transfer?		
F269 B. Information necessary for providing care and treatment to transferred individuals is provided.					
PHYSICAL ENVIRONMENT F270 SNF 405.1134					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F271 A. Nursing Unit SNF 405.1134(d)				Medication preparation and storage areas provide adequate space and light to prepare medication and to store medication and needed supplies.	Nursing Service 405.1124(g) 442.337
F272 1. Unit properly equipped for preparation and storage of drugs and biologicals.	There is adequate light to prepare medications. There is sufficient space to prepare medications for administration in a safe and effective manner.	Ask Nursing Staff: - What do you use the medication room (area) for? - Where is the handwashing sink? - Do you have enough, convenient storage area for I.V. fluids and medications needing refrigeration. - Where are the keys for the medication room and unit dose carts? - Do you feel you have adequate storage space for supplies and equipment? - If no, what problems does that cause? - Does the resident call system function properly?		Light is available when and where the medication cart is in use. A medication refrigerator is available and does not contain patient or employee snacks. Juice, etc., used in administering medication is allowed.	Infection Control 405.1135
F273 2. Utility and storage rooms are adequate size.	There is sufficient space for storage of medications. Unit dose carts are protected from tampering and theft.			Clean and dirty areas must be separated, preferably in separate rooms.	Governing Body 442.325
F274 3. The unit is equipped to register resident calls with a functioning communications system from resident areas including rooms and toilets and bathing facility.	Medications are stored in a locked area. Refrigeration facilities are available for medications. There is sufficient storage space for I.V. fluids. Handwashing facilities are readily accessible either in the medication preparation area or adjacent to it.	Ask Residents: - Do the call bells in your room and in the toilets and bathing areas always work?		Storage space must be available for bulky items and supplies so that they can be stored without blocking corridors and exits. Medications are protected from unauthorized use. Call bells must be in working order and must be present in all resident bedrooms, toilets and	Resident Rooms 405.1134(e) 442.325

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F274 (cont'd)	Audible call system is on and working. Long cords are available for chair bound patients.	- If no: - How often is it that they do not work? - How long does it take to get them fixed?		bathing areas. Audible signals, if in the system, must be in working order and turned on.	
B. Dining and activities area F275 SNF 405.1134(g) F276 ICF 442.329 F277 1. The facility provides one or more clean, orderly, and appropriately furnished rooms of adequate size, designed for resident dining and resident activities.	Area is clean and well maintained. There is sufficient space between tables to allow for safe passage of wheelchairs and residents with walkers, canes and other assistive devices. Table height or design allows residents in wheelchairs to sit a normal distance from the table. Lighting and ventilation in the dining/activity areas is provided according to recommended standards. A multi-purpose room should not be used for storage of items such as beds, mattresses, boxes, etc.	Ask Residents: - Is there enough room between tables to allow you to feel safe in getting to your table? - Can you sit comfortably in your wheelchair at the table? - How is the lighting and ventilation level for you? - Are sitting preferences permitted? - Do you go to the dining room for meals?		Regulations clearly set out conditions for compliance. Refer to the regulations.	Dietetic Services 405.1125 442.331 Patient Activities 405.1131 442.345

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F278 2. Dining and activity rooms are well lighted and ventilated.	Are dining areas utilized at meal service?				
F279 3. Any multi-purpose room used for dining and resident activities has sufficient space to accommodate all activities and prevent their interference with each other.					
F280 SNF 405.1134(e) Indicators C&D apply to SNFs					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
C. Resident Rooms F281 ICF 442.325 F282 1. Single rooms have at least 100 sq. ft. F283 2. Multiple resident rooms have no more that 4 residents and at least 80 sq. feet per resident. F284 3. Each room is equipped with or conveniently located near toilet and bathing facilities.	Observe rooms and furnishings for maintenance, cleanliness and safety. Look for dust/dirt on lights, high surfaces, under heating units, and in corners. Use a flashlight. Are beds, lights, plumbing all in working order? Observe for all regulatory requirements as noted to the left. Are privacy curtains present, and appropriate to maintain resident privacy? Test several call lights. Are call lights within reach, including emergency lights in toilets and bathing areas? Are toilet and bathing facilities appropriate in number, size, and design to meet resident needs? What personal belongings do residents have in their rooms? Is there	Ask Residents: - Is your room kept clean? Who cleans it? When, and how often? - Is your bed, chair, and other furniture and fixtures kept in good repair? - Do you feel you have enough privacy? - What personal belongings are you allowed to have? - Is the lighting in your room sufficient for you? - Is your chair comfortable? - When do you permit staff to clean you room? - When do you ask staff not to clean you room?		Refer to the regulations.	Resident Rights 405.1121(k)(1)(5) (9)(13) 442.311(a)(d)(2) (g)(1)(2) (6)(k) Physical Environment 405.1134(d)(e) 442.326

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F285 4. There is a capability of maintaining privacy in each.	sufficient storage and security for their belongings?				
F286 5. There is adequate storage space for each resident.					
F287 6. There is a comfortable and functioning bed and chair, plus a functional cabinet and light.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F288 7. The resident call system functions in resident rooms.					
F289 8. Each room is designed and equipped for adequate nursing care and the comfort and privacy of residents.					
F290 9. Each room is at or above grade level.					
F291 10. Each room has direct access to a corridor and outside exposure. Exception: Not required for ICF residents.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
D. Toilet and bath facilities F292 ICF 442.326 F293 1. Facilities are clean, sanitary and free of odors. F294 2. Facilities have safe and comfortable hot water temperatures. F295 3. Facilities maintain privacy. F296 4. Facilities have grab bars and other safe guards against slipping.	Are there adequate numbers of toilets, baths, and showers for the residents that are accessible to, and functional for all residents? Are these conveniently located in or near resident rooms? Check for water on floors of bath and shower rooms. Is privacy provided? Are facilities clean, sanitary and free of unpleasant odors? Are bathrooms equipped with soap, toilet tissue, towels, etc.? Hot water is between 110–120 degrees or the acceptable State level. Hot water temperature control must be maintained. Single use, disposable towels should be available for handwashing purposes. Note also condition of grab bars, plumbing and fixtures. Bath areas are not used for storage.	Ask Residents: - When was your last bath? The one before? - What safety precautions are used for getting in and out of the bathtub? - What equipment is needed to get in and out of the tub, and how do you feel about it? - How do you get your wheelchair into the toilet or bathroom? - When, if ever, do you refuse to be bathed?	Bathing schedule for patients in your indepth review.	Privacy is maintained for residents in toilet and bathing areas. Toilet and bathing areas are clean. Water is removed from floors immediately upon completion of bathing. Hot water is within the acceptable temperature range. Soap, toilet paper and towels are available in the bathrooms. Grab bars are present and securely fastened to the wall. Ventilation and lighting systems are correctly functioning. Plumbing and other fixtures are in good condition.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F297 5. Facilities have fixtures in good condition.					
F298 6. The resident call system functions in toilet and bath facilities.			Facility has appropriate arrangements for providing social services, either using: - outside resources (contract or consultant services) - qualified facility personnel under a clearly defined plan.		
E. Social Service Area F299 SNF 405.1130(b) ICF 442.344 F300 1. Ensures privacy for social service interviewing.	Does the social worker have a locked file available? Where are social service interviews and clerical functions performed? Are rooms in areas easily accessible to residents?	Ask Resident: - Does the social worker see you in a private room or in your own room? - If in your own room, do you feel that you have enough privacy?		Refer to regulations.	
F301 2. Adequate space for clerical and interviewing functions is provided. F302 3. Facilities are easily accessible to residents and staff.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F. Therapy areas F303 SNF 405.1126(a) F304 ICF 442.328(a) F305 1. Space is adequate for proper use of equipment by all residents receiving treatment	Therapy areas are accessible to all residents needing the facilities. Space allows for safe maneuvering of residents and equipment and staff. All residents are able to be observed and supervised during therapy. Equipment has labels (stickers, etc.) to indicate proper maintenance. All equipment fastened to floor and walls is secure.	Ask Resident: - Do you feel that the equipment you use is safe? - Do you have enough room for your treatment? Ask Therapy Staff: - Is your equipment adequately maintained? - Do you have enough room to safely and adequately provide treatment?	Refer to regulations.		
G. Facilities for Special care F307 SNF 405.1134(f) F308 ICF 442.328(b)	Are therapy areas properly ventilated to effectively reduce heat, moisture and odors? Are private rooms available that meet regulatory criteria. If a resident is infected and in isolation, are precautionary signs posted, and are they legible and understandable?	Ask Supervisory personnel: - What room(s) do you use for isolation? - What is your procedure if the room is already occupied when you need it for isolation? - Will you show me the signs you use to identify the isolation room?		Rooms meeting the regulatory requirements are available in the facility. There is a procedure that is implemented when an isolation is needed, but it is already occupied. Isolation signs are visable and clearly convey their intended message.	Resident Rights 405.1121(k)(4) 442.311(c)(2) Infection Control 405.1135(b)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F309 1. Single rooms with private toilet and handwashing facilities are available for isolating residents.					
F310 2. Precautionary signs are used to identify these rooms when in use.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
H. Common Resident Areas F311 SNF 405.1134(j) F312 ICF 442.324 F313 1. All common resident areas are clean, sanitary and free of odors. F314 2. Provision is made for adequate and comfortable lighting levels in all areas. F315 3. There is limitation of sounds at comfort levels.	Use senses – sight, hearing, olfactory when surveying common areas as lounges, lobby, corridors. Note levels of lighting for both reading and non-reading areas. Is it bright enough but without glare? Are areas clean and without offensive odors? Do background sound levels allow for ease of communication and comfort for residents/visitors? Do residents seem comfortable with the room temperature – note the use of several layers of clothing, many residents fanning themselves, etc. Are handrails on each side of the corridor and are they secure? Are smoking/no smoking areas designated?	Ask Residents: – Do you think that the lounges and corridors are usually clean? – Do they have any unpleasant odors? – Is the lighting level comfortable for you to read? Is it adequate for you to feel safe walking? – Do you have any difficulty with the noise level? – Is the temperature usually comfortable for you? – Do you feel there is adequate ventilation? – Are there handrails in all of the corridors? – Are they securely fastened to the wall? Ask Supervisory Staff: – If there is a water main break or other interruption in the water supply, how do you obtain water for essential areas and duties?		– Floors and furniture should appear clean – free of gross contamination. – Residents should have lighting bright enough to safely negotiate corridors, lounges, etc., and in reading area, be bright enough to read. But the brightness should be free of glare. Remember, the elderly need a higher level of lighting as their sight diminishes. – Except for times when a louder level of sound is necessary for communication, sounds should be unobtrusive and "comfortable". – Room temperature comfort levels vary widely, and in general the elderly will require a higher temperature for comfort than younger people. Use information from resident interviews and your observations to determine if the temperature is "comfortable" for most residents. – All corridors in	Infection Control 405.1135(c)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F316 4. A comfortable room temperature is maintained.				resident-used areas are equipped with handrails on each side. These rails securely fastened provide the residents with a firm support. - Supervisory staff are able to tell you how they will obtain water for drinking, cleaning/bathing of residents, and other essential functions if their normal water supply is interrupted.	
F317 5. There is adequate ventilation thru windows or mechanical measures or a combination of both.					
F318 6. Corridors are equipped with firmly secured handrails on each side.					
F319 7. Staff are aware of procedures to ensure water to all essential areas in the event of loss of normal supply.					Disaster Preparedness 405.1136 442.313

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
I. Maintenance of Building and Equipment F320 SNF 405.1134(i) F321 1. The interior and exterior of the building are clean and orderly. F322 2. All essential mechanical and electrical equipment is maintained in safe operating condition. F323 3. Sufficient storage space is available and used for equipment to ensure that the facility is orderly and safe.	- Ceiling and floor tile in good condition - Paint in good repair - No holes in walls - Look for rat and other rodent trails outside and inside - Preventive maintenance program for all equipment is followed - Wheelchairs not stored in hallways, bathrooms, etc. - Window screens are in good repair - Check overbed tables, wheelchairs, etc., for cleanliness and operation	Ask Staff: - How many housekeeping staff are available? - How late are housekeepers on duty during the week? - How is weekend coverage different? Ask Resident: - What if any problems have you had with special equipment you need to use?			Physical Environment 405.1134(d)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F324 4. Resident care equipment is clean and maintained in safe operating condition.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Indicator J applies to ICFs. J. Dietetic Service Area F326 SNF 405.1134(h) F327 1. Kitchen and dietetic service areas are adequate to insure proper, timely service for all patients. F328 2. Kitchen areas are properly ventilated, arranged, and equipped for storage and preparation of food as well as for dish and utensil cleaning, and refuse storage and removal.	Observe for - needed space to carry out routine operations - maintenance of working surfaces equipment, utensils, and serving dishes - operable dish washer machine. - 3-sink method of pot/dish washing properly carried out/or written procedure posted - operable and clean exhaust fan - stored dishes and pots are free of baked-on food particles and chipped/cracked surfaces - food stored off floor - protective covers for fluorescent lights - handwashing sink readily accessible	Ask Staff: - What have you been trained to do? - What type of dishwasher machine do you have? How does it operate?	The proper temperature for the Dishwasher wash cycle is 150–160 degrees Fahrenheit. The dishwasher rinse cycle is acceptable at temperature of 180 degrees Fahrenheit or when there is a change in the temperature-sensitive tape (thermolabel). The individual manufacturers' specifications may countermand these instructions, particulary in the case of chemical sanitization.		Dietetic Services 405.1125(g) 442.331(b)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Indicator K applies to ICF K. Dieteary Staff Hygiene F329 SNF 405.1125(f) F330 1. Dietetic service personnel practice hygenic food handling techniques. Indicator L applies to ICF L. Dietary Sanitary Conditions F331 SNF 405.1125(g) F332 1. Food is stored, refrigerated, prepared, distributed, and served under sanitary conditions. F333 2. Waste is disposed of properly.	Observe the following: - cleanliness of hands, fingernails, hair, clothing - use of hair restraint - whether employees wash hands with soap and water after using the toilet, smoking, blowing their nose, touching raw meat, poultry or eggs - employees using hands to mix food when utentils could be used - employees using the same spoon more than once for tasting food while preparing, cooking, or serving. Verify that: - hot foods are 140 degrees or above - cold foods are 45 degrees or lower (*note: food held for more than 2-3 hours between 60 and 125 degrees may not be safe to eat) - cooked meats held longer than 72 hours are used, discarded or put in the freezer	Ask Staff: - What happens when you report to work with a cold, a cut or sore on your hand? - Where is handwashing sink for dietary staff? - Do you use disposable plastic hand covers? If so, when? - Where are your serving utensils located? - What are temperatures for the refrigerators and freezers? Who is responsible for checking temperatures? - Do you have thermometers to check water and food temperatures? (ask them to demonstrate how they take temperatures)			Dietetic Services 405.1125(e)(f)(g)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F333 (cont'd)	- check that the refrigerators are equipped with an accurate thermometer - food does not have an "off" or bad odor - cracked eggs are discarded - foods are dated and then stored as to their preparation date. Observe that waste is in covered containers, bagged and tied for disposal, and that dumpsters are covered.				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
L. Emergency Power F334 SNF 405.1134(b)	Is an emergency generator available? Test generator under full load conditions.			As per regulations and covered by the Life Safety Code surveyor	
F335 1. An emergency source of electrical power necessary to protect the health and safety of residents is available.	Check items of emergency power: - lighting - fire detection - alarms - extinguishing systems - life support systems Transfer time from normal power to emergency power to occur within 10 seconds.				
F336 2. Emergency power is adequate at least for lighting in all means of egress; equipment to maintain fire detection, alarm, and extinguishing systems; and life support systems.	Check for gounded extension cords at nurses stations. Where are emergency outlets?				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F337 3. Emergency power is provided by an emergency generator located on the premises where life support systems are used.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Infection Control F338 SNF 405.1135 A. Infection Control F339 SNF 405.1135(b) F340 Aseptic and isolation techniques are followed by all personnel. B. Sanitation F341 SNF 405.1135(c) F342 The facility maintains a safe, clean, and orderly interior. C. Linen F343 SNF 405.1135(d)	- Observation of dressing technique to identify if infection control principles are being adhered to: - sterile technique - sterile/clean field - disposal of dressing - handwashing - use of gloves - Observation of isolation precautions: - signs - linen, double bagged - soiled linen, double bagged - gowns/masks - gloves - handwashing - disposable dishes - information for visitors - Procedures followed by: - Laundry - Housekeeping How is dirty linen transported to laundry or holding area? Do aides wash hands after cleaning dirty linen? How do aides handle clean/dirty linen while changing beds?	Ask Staff: - What type of dressing changes are you performing? - How often are dressings changed? - Why is resident on isolation/precautions? - Do laundry/housekeeping personnel/aides know procedures? Ask Resident: - Do you know why you have dressings? - Do you know why you are on isolation/precautions? - Do you have clean linen when you need it?	Review records of residents selected for indepth review for infection.	Compliance will be based mainly on your observations. Deficiencies will be cited if you see: - breaks in aseptic or isolation technique - clutter or unclean conditions that would cause unsafe conditions - inadequate supplies of linen to provide proper care and comfort for residents - inadequate techniques for handling clean and dirty linen - evidence of insect or rodent infestation - use flash light to check for roaches in closets, cabinets.	Nursing Services 405.1124 442.338

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F344 ICF 442.327					
F345 1. The facility has available at all times a quantity of linen essential for proper care and comfort of residents.					
F346 2. Linens are handled: stored, processed, and transported in such a manner as to prevent the spread of infection.					
D. Pest Control F347 SNF 405.1135(e)	Look for evidence of insect or rodent presence (mouse or rat droppings, roaches, ants, flies around trash) - Screen doors closed - Windows that can be opened have screens that are in good repair	Ask Staff: - Have you seen insects (roaches, ants, flies, etc.)? - Have you seen rodents and/or droppings? - What foods are residents permitted to keep in their rooms?			
F348 ICF 442.315(c)					
F349 The facility is maintained free from insects and rodents.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
DISASTER PREPAREDNESS F350 SNF 405.1136 F351 SNF 405.1136(a) F352 ICF 442.313 Indicators A and B apply to ICFs. A. Disaster Plan F353 1. Facility staff are aware of plans, procedures to be followed for fire, explosion or other disaster. F354 2. Facility staff are knowledgeable about evacuation routes.	- Disaster plan is located at each nursing station. - Evacuation plans posted in each smoke compartment.	Ask Residents: - Do you know what to do in case of fire? - How often do you rehearse it? Ask Staff: - What are your responsibilities at a fire drill? - What is the facilities disaster plan? (Specify types, [(e.g., fire, flood, etc.)] - How you undergone disaster training? - Have you participated in a fire disaster drill? When? - How frequently are drills held? - Have you been trained/instructed in the use of fire equipment, fire containment methods? - Have you been trained in transfer or casualties and routes? - How would staff meet emotional needs of residents during/following a "disaster", e.g., fire		A disaster plan is available and facility staff know their roles.	Physical Environment 405.1134(a)(b) 442.321

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F355 3. Facility staff are aware of their specific responsibilities in regard to evaluation and protection of residents.					
F356 4. Facility staff are aware of methods of containing fire.					
B. Drills F357 SNF 405.1136(b)					
F358 1. All employees are trained as part of their employment orientation in all aspects of preparedness for any disaster.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F359 2. Facility staff participate in ongoing training and drills in all procedures so that each employee promtly and correctly carries out a specific role in case of a disaster. INTENT To ensure a clean, safe environment for residents.					

Subpart D—Reconsideration of Adverse Determinations—Deeming Authority for Accreditation Organizations and CLIA Exemption of Laboratories Under State Programs

SOURCE: 57 FR 34012, July 31, 1992, unless otherwise noted.

§ 488.201 Reconsideration.

(a) *Right to reconsideration.* (1) A national accreditation organization dissatisfied with a determination that its accreditation requirements do not provide (or do not continue to provide) reasonable assurance that the entities accredited by the accreditation organization meet the applicable long-term care requirements, conditions for coverage, conditions of certification, conditions of participation, or CLIA condition level requirements is entitled to a reconsideration as provided in this subpart.

(2) A State dissatisfied with a determination that the requirements it imposes on laboratories in that State and under the laws of that State do not provide (or do not continue to provide) reasonable assurance that laboratories licensed or approved by the State meet applicable CLIA requirements is entitled to a reconsideration as provided in this subpart.

(b) *Eligibility for reconsideration.* CMS will reconsider any determination to deny, remove or not renew the approval of deeming authority to private accreditation organizations, or any determination to deny, remove or not renew the approval of a State laboratory program for the purpose of exempting the State's laboratories from CLIA requirements, if the accreditation organization or State files a written request for a reconsideration in accordance with paragraphs (c) and (d) of this section.

(c) *Manner and timing of request for reconsideration.* (1) A national accreditation organization or a State laboratory program described in paragraph (b), dissatisfied with a determination with respect to its deeming authority, or, in the case of a State, a determination with respect to the exemption of the laboratories in the State from CLIA requirements, may request a reconsideration of the determination by filing a request with CMS either directly by its authorized officials or through its legal representative. The request must be filed within 60 days of the receipt of notice of an adverse determination or nonrenewal as provided in subpart A of part 488 or subpart E of part 493, as applicable.

(2) Reconsideration procedures are available after the effective date of the decision to deny, remove, or not renew the approval of an accreditation organization or State laboratory program.

(d) *Content of request.* The request for reconsideration must specify the findings or issues with which the accreditation organization or State disagrees and the reasons for the disagreement.

[57 FR 34012, July 31, 1992, as amended at 58 FR 61843, Nov. 23, 1993]

§ 488.203 Withdrawal of request for reconsideration.

A requestor may withdraw its request for reconsideration at any time before the issuance of a reconsideration determination.

§ 488.205 Right to informal hearing.

In response to a request for reconsideration, CMS will provide the accreditation organization or the State laboratory program the opportunity for an informal hearing as described in § 488.207 that will—

(a) Be conducted by a hearing officer appointed by the Administrator of CMS; and

(b) Provide the accreditation organization or State laboratory program the opportunity to present, in writing or in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew deeming authority or the exemption of a State's laboratories from CLIA requirements.

§ 488.207 Informal hearing procedures.

(a) CMS will provide written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(b) The informal reconsideration hearing will be conducted in accordance with the following procedures—

(1) The hearing is open to CMS and the organization requesting the reconsideration, including—

(i) Authorized representatives;

(ii) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts); and

(iii) Legal counsel;

(2) The hearing is conducted by the hearing officer who receives testimony and documents related to the proposed action;

(3) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissable under the usual rules of court procedures;

(4) Either party may call witnesses from among those individuals specified in paragraph (b)(1) of this section; and

(5) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

§ 488.209 Hearing officer's findings.

(a) Within 30 days of the close of the hearing, the hearing officer will present the findings and recommendations to the accreditation organization or State laboratory program that requested the reconsideration.

(b) The written report of the hearing officer will include—

(1) Separate numbered findings of fact; and

(2) The legal conclusions of the hearing officer.

§ 488.211 Final reconsideration determination.

(a) The hearing officer's decision is final unless the Administrator, within 30 days of the hearing officer's decision, chooses to review that decision.

(b) The Administrator may accept, reject or modify the hearing officer's findings.

(c) Should the Administrator choose to review the hearing officer's decision, the Administrator will issue a final reconsideration determination to the accreditation organization or State laboratory program on the basis of the hearing officer's findings and recommendations and other relevant information.

(d) The reconsideration determination of the Administrator is final.

(e) A final reconsideration determination against an accreditation organization or State laboratory program will be published by CMS in the FEDERAL REGISTER.

Subpart E—Survey and Certification of Long-Term Care Facilities

SOURCE: 59 FR 56238, Nov. 10, 1994, unless otherwise noted.

§ 488.300 Statutory basis.

Sections 1819 and 1919 of the Act establish requirements for surveying SNFs and NFs to determine whether they meet the requirements for participation in the Medicare and Medicaid programs.

§ 488.301 Definitions.

As used in this subpart—

Abbreviated standard survey means a survey other than a standard survey that gathers information primarily through resident-centered techniques on facility compliance with the requirements for participation. An abbreviated standard survey may be premised on complaints received; a change of ownership, management, or director of nursing; or other indicators of specific concern.

Abuse means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish.

Deficiency means a SNF's or NF's failure to meet a participation requirement specified in the Act or in part 483, subpart B of this chapter.

Dually participating facility means a facility that has a provider agreement in both the Medicare and Medicaid programs.

Extended survey means a survey that evaluates additional participation requirements subsequent to finding substandard quality of care during a standard survey.

Facility means a SNF or NF, or a distinct part SNF or NF, in accordance with § 483.5 of this chapter.

Immediate family means husband or wife; natural or adoptive parent, child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild.

Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.

Misappropriation of resident property means the deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a resident's belongings or money without the resident's consent.

Neglect means failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness.

Noncompliance means any deficiency that causes a facility to not be in substantial compliance.

Nurse aide means an individual, as defined in § 483.75(e)(1) of this chapter.

Nursing facility (NF) means a Medicaid nursing facility.

Paid feeding assistant means an individual who meets the requirements specified in § 483.35(h)(2) of this chapter and who is paid to feed residents by a facility, or who is used under an arrangement with another agency or organization.

Partial extended survey means a survey that evaluates additional participation requirements subsequent to finding substandard quality of care during an abbreviated standard survey.

Skilled nursing facility (SNF) means a Medicare nursing facility.

Standard survey means a periodic, resident-centered inspection which gathers information about the quality of service furnished in a facility to determine compliance with the requirements for participation.

Substandard quality of care means one or more deficiencies related to participation requirements under § 483.13, Resident behavior and facility practices, § 483.15, Quality of life, or § 483.25, Quality of care of this chapter, which constitute either immediate jeopardy to resident health or safety; a pattern of or widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm.

Substantial compliance means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm.

Validation survey means a survey conducted by the Secretary within 2 months following a standard survey, abbreviated standard survey, partial extended survey, or extended survey for the purpose of monitoring State survey agency performance.

[59 FR 56238, Nov. 10, 1994, as amended at 68 FR 55539, Sept. 26, 2003]

§ 488.303 State plan requirement.

(a) A State plan must provide that the requirements of this subpart and subpart F of this part are met, to the extent that those requirements apply to the Medicaid program.

(b) A State may establish a program to reward, through public recognition, incentive payments, or both, nursing facilities that provide the highest quality care to Medicaid residents. For purposes of section 1903(a)(7) of the Social Security Act, proper expenses incurred by a State in carrying out such a program are considered to be expenses necessary for the proper and efficient administration of the State plan.

(c) A State must conduct periodic educational programs for the staff and residents (and their representatives) of NFs in order to present current regulations, procedures, and policies under this subpart and subpart F of this part.

(d) Required remedies for a non-State operated NF. A State must establish, in addition to termination of the provider agreement, the following remedies or an approved alternative to the following remedies for imposition against a non-State operated NF:

(1) Temporary management.

(2) Denial of payment for new admissions.

(3) Civil money penalties.

(4) Transfer of residents.

(5) Closure of the facility and transfer of residents.

(6) State monitoring.

(e) Optional remedies for a non-State operated NF. A State may establish the following remedies for imposition against a non-State operated NF:

(1) Directed plan of correction.

(2) Directed in-service training.

(3) Alternative or additional State remedies.

(f) Alternative or additional State remedies. If a State uses remedies that are in addition to those specified in paragraph (d) or (e) of this section, or alternative to those specified in paragraph (d) of this section (other than termination of participation), it must—

(1) Specify those remedies in the State plan; and

(2) Demonstrate to CMS's satisfaction that those alternative remedies are as effective in deterring noncompliance and correcting deficiencies as the remedies listed in paragraphs (d) and (e) of this section.

[59 FR 56238, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.305 Standard surveys.

(a) For each SNF and NF, the State survey agency must conduct standard surveys that include all of the following:

(1) A case-mix stratified sample of residents;

(2) A survey of the quality of care furnished, as measured by indicators of medical, nursing, and rehabilitative care, dietary and nutrition services, activities and social participation, and sanitation, infection control, and the physical environment;

(3) An audit of written plans of care and residents' assessments to determine the accuracy of such assessments and the adequacy of such plans of care; and

(4) A review of compliance with residents' rights requirements set forth in sections 1819(c) and 1919(c) of the Act.

(b) The State survey agency's failure to follow the procedures set forth in this section will not invalidate otherwise legitimate determinations that a facility's deficiencies exist.

§ 488.307 Unannounced surveys.

(a) *Basic rule.* All standard surveys must be unannounced.

(b) *Review of survey agency's scheduling and surveying procedures.* (1) CMS reviews on an annual basis each State survey agency's scheduling and surveying procedures and practices to ensure that survey agencies avoid giving notice of a survey through the scheduling procedures and the conduct of the surveys.

(2) CMS takes corrective action in accordance with the nature and complexity of the problem when survey agencies are found to have notified a SNF or NF through their scheduling or procedural policies. Sanctions for inadequate survey performance are in accordance with § 488.320.

(c) *Civil money penalties.* An individual who notifies a SNF or NF, or causes a SNF or NF to be notified, of the time or date on which a standard survey is scheduled to be conducted is subject to a Federal civil money penalty not to exceed $2,000.

§ 488.308 Survey frequency.

(a) *Basic period.* The survey agency must conduct a standard survey of each SNF and NF not later than 15 months after the last day of the previous standard survey.

(b) *Statewide average interval.* (1) The statewide average interval between standard surveys must be 12 months or less, computed in accordance with paragraph (d) of this section.

(2) CMS takes corrective action in accordance with the nature of the State survey agency's failure to ensure that the 12-month statewide average interval requirement is met. CMS's corrective action is in accordance with § 488.320.

(c) *Other surveys.* The survey agency may conduct a survey as frequently as necessary to—

(1) Determine whether a facility complies with the participation requirements; and

(2) Confirm that the facility has corrected deficiencies previously cited.

(d) *Computation of statewide average interval.* The statewide average interval is computed at the end of each Federal fiscal year by comparing the last day of the most recent standard survey for each participating facility to the last day of each facility's previous standard survey.

(e) *Special surveys.* (1) The survey agency may conduct a standard or an abbreviated standard survey to determine whether certain changes have caused a decline in the quality of care furnished by a SNF or a NF, within 60 days of a change in the following:

(i) Ownership;

(ii) Entity responsible for management of a facility (management firm);

(iii) Nursing home administrator; or

(iv) Director of nursing.

(2) The survey agency must review all complaint allegations and conduct a standard or an abbreviated standard survey to investigate complaints of violations of requirements by SNFs and NFs if its review of the allegation concludes that—

(i) A deficiency in one or more of the requirements may have occurred; and

(ii) Only a survey can determine whether a deficiency or deficiencies exist.

(3) The survey agency does not conduct a survey if the complaint raises issues that are outside the purview of Federal participation requirements.

§ 488.310 Extended survey.

(a) *Purpose of survey.* The purpose of an extended survey is to identify the policies and procedures that caused the facility to furnish substandard quality of care.

(b) *Scope of extended survey.* An extended survey includes all of the following:

(1) Review of a larger sample of resident assessments than the sample used in a standard survey.

(2) Review of the staffing and in-service training.

(3) If appropriate, examination of the contracts with consultants.

(4) A review of the policies and procedures related to the requirements for which deficiencies exist.

(5) Investigation of any participation requirement at the discretion of the survey agency.

(c) *Timing and basis for survey.* The survey agency must conduct an extended survey not later than 14 calendar days after completion of a standard survey which found that the facility had furnished substandard quality of care.

§ 488.312 Consistency of survey results.

CMS does and the survey agency must implement programs to measure accuracy and improve consistency in the application of survey results and enforcement remedies.

§ 488.314 Survey teams.

(a) *Team composition.* (1) Surveys must be conducted by an interdisciplinary team of professionals, which must include a registered nurse.

(2) Examples of professionals include, but are not limited to, physicians, physician assistants, nurse practitioners, physical, speech, or occupational therapists, registered professional nurses, dieticians, sanitarians, engineers, licensed practical nurses, or social workers.

(3) The State determines what constitutes a professional, subject to CMS approval.

(4) Any of the following circumstances disqualifies a surveyor for surveying a particular facility:

(i) The surveyor currently works, or, within the past two years, has worked as an employee, as employment agency staff at the facility, or as an officer, consultant, or agent for the facility to be surveyed.

(ii) The surveyor has any financial interest or any ownership interest in the facility.

(iii) The surveyor has an immediate family member who has a relationship with a facility described in paragraphs (a)(4)(i) or paragraph (a)(4)(ii) of this section.

(iv) The surveyor has an immediate family member who is a resident in the facility to be surveyed. For purposes of this section, an immediate family member is defined at § 488.301 of this part.

(b) *CMS training.* CMS provides comprehensive training to surveyors, including at least the following:

(1) Application and interpretation of regulations for SNFs and NFs.

(2) Techniques and survey procedures for conducting standard and extended surveys.

(3) Techniques for auditing resident assessments and plans of care.

(c) *Required surveyor training.* (1) Except as specified in paragraph (c)(3) of

this section, the survey agency may not permit an individual to serve as a member of a survey team unless the individual has successfully completed a training and testing program prescribed by the Secretary.

(2) The survey agency must have a mechanism to identify and respond to in-service training needs of the surveyors.

(3) The survey agency may permit an individual who has not completed a training program to participate in a survey as a trainee if accompanied onsite by a surveyor who has successfully completed the required training and testing program.

[59 FR 56238, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.318 Inadequate survey performance.

(a) CMS considers survey performance to be inadequate if the State survey agency—

(1) Indicates a pattern of failure to—

(i) Identify deficiencies and the failure cannot be explained by changed conditions in the facility or other case specific factors;

(ii) Cite only valid deficiencies;

(iii) Conduct surveys in accordance with the requirements of this subpart; or

(iv) Use Federal standards, protocols, and the forms, methods and procedures specified by CMS in manual instructions; or

(2) Fails to identify an immediate jeopardy situation.

(b) Inadequate survey performance does not—

(1) Relieve a SNF or NF of its obligation to meet all requirements for program participation; or

(2) Invalidate adequately documented deficiencies.

§ 488.320 Sanctions for inadequate survey performance.

(a) *Annual assessment of survey performance.* CMS assesses the performance of the State's survey and certification program annually.

(b) *Sanctions for inadequate survey performance.* When a State demonstrates inadequate survey performance, as specified in § 488.318, CMS notifies the survey agency of the inadequacy and takes action in accordance with paragraphs (c) and (d) of this section.

(c) *Medicaid facilities.* (1) For a pattern of failure to identify deficiencies in Medicaid facilities, CMS—

(i) Reduces FFP, as specified in paragraph (e) of this section, and if appropriate;

(ii) Provides for training of survey teams.

(2) For other survey inadequacies in Medicaid facilities, CMS provides for training of survey teams.

(d) *Medicare facilities.* For all survey inadequacies in Medicare facilities, CMS—

(1) Requires that the State survey agency submit a plan of correction;

(2) Provides for training of survey teams;

(3) Provides technical assistance on scheduling and procedural policies;

(4) Provides CMS-directed scheduling; or

(5) Initiates action to terminate the agreement between the Secretary and the State under section 1864 of the Act, either in whole or in part.

(e) *Reduction of FFP.* In reducing FFP for inadequate survey performance, CMS uses the formula specified in section 1919(g)(3)(C) of the Act, that is 33 percent multiplied by a fraction—

(1) The numerator of which is equal to the total number of residents in the NFs that CMS found to be noncompliant during validation surveys for that quarter; and

(2) The denominator of which is equal to the total number of residents in the NFs in which CMS conducted validation surveys during that quarter.

(f) *Appeal of FFP reduction.* When a State is dissatisfied with CMS's determination to reduce FFP, the State may appeal the determination to the Departmental Appeals Board, using the procedures specified in 45 CFR part 16.

§ 488.325 Disclosure of results of surveys and activities.

(a) *Information which must be provided to public.* As provided in sections 1819(g)(5) and 1919(g)(5) of the Act, the following information must be made available to the public, upon the public's request, by the State or CMS for all surveys and certifications of SNFs and NFs:

(1) Statements of deficiencies and providers' comments.

(2) A list of isolated deficiencies that constitute no actual harm, with the potential for minimal harm.

(3) Approved plans of correction.

(4) Statements that the facility did not submit an acceptable plan of correction or failed to comply with the conditions of imposed remedies.

(5) Final appeal results.

(6) Notice of termination of a facility.

(7) Medicare and Medicaid cost reports.

(8) Names of individuals with direct or indirect ownership interest in a SNF or NF, as defined in § 420.201 of this chapter.

(9) Names of individuals with direct or indirect ownership interest in a SNF or NF, as defined in § 420.201 of this chapter, who have been found guilty by a court of law of a criminal offense in violation of Medicare or Medicaid law.

(b) *Charge to public for information.* CMS and the State may charge the public for specified services with respect to requests for information in accordance with—

(1) Section 401.140 of this chapter, for Medicare; or

(2) State procedures, for Medicaid.

(c) *How public can request information.* The public may request information in accordance with disclosure procedures specified in 45 CFR part 5.

(d) *When information must be disclosed.* The disclosing agency must make available to the public, upon the public's request, information concerning all surveys and certifications of SNFs and NFs, including statements of deficiencies, separate listings of any isolated deficiencies that constitute no actual harm, with the potential for minimal harm, and plans of correction (which contain any provider response to the deficiency statement) within 14 calendar days after each item is made available to the facility.

(e) *Procedures for responding to requests.* The procedures and time periods for responding to requests are in accordance with—

(1) Section 401.136 of this chapter for documents maintained by CMS; and

(2) State procedures for documents maintained by the State.

(f) *Information that must be provided to the State's long-term care ombudsman.* The State must provide the State's long-term care ombudsman with the following:

(1) A statement of deficiencies reflecting facility noncompliance, including a separate list of isolated deficiencies that constitute no harm with the potential for minimal harm.

(2) Reports of adverse actions specified at § 488.406 imposed on a facility.

(3) Written response by the provider.

(4) A provider's request for an appeal and the results of any appeal.

(g) *Information which must be provided to State by a facility with substandard quality of care.* (1) To provide for the notice to physicians required under sections 1819(g)(5)(C) and 1919(g)(5)(C) of the Act, not later than 10 working days after receiving a notice of substandard quality of care, a SNF or NF must provide the State with a list of—

(i) Each resident in the facility with respect to which such finding was made; and

(ii) The name and address of his or her attending physician.

(2) Failure to disclose the information timely will result in termination of participation or imposition of alternative remedies.

(h) *Information the State must provide to attending physician and State board.* Not later than 20 calendar days after a SNF or NF complies with paragraph (g) of this section, the State must provide written notice of the noncompliance to—

(1) The attending physician of each resident in the facility with respect to which a finding of substandard quality of care was made; and

(2) The State board responsible for licensing the facility's administrator.

(i) *Access to information by State Medicaid fraud control unit.* The State must provide access to any survey and certification information incidental to a SNF's or NF's participation in Medicare or Medicaid upon written request by the State Medicaid fraud control unit established under part 1007, of this title, consistent with current State laws.

[59 FR 56238, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.330 Certification of compliance or noncompliance.

(a) *General rules*—(1) *Responsibility for certification.* (i) The State survey agency surveys all facilities for compliance or noncompliance with requirements for long term care facilities. The survey by the State survey agency may be followed by a Federal validation survey.

(A) The State certifies the compliance or noncompliance of non-State operated NFs. Regardless of the State entity doing the certification, it is final, except in the case of a complaint or validation survey conducted by CMS, or CMS review of the State's findings.

(B) CMS certifies the compliance or noncompliance of all State-operated facilities.

(C) The State survey agency certifies the compliance or noncompliance of a non-State operated SNF, subject to the approval of CMS.

(D) The State survey agency certifies compliance or noncompliance for a dually participating SNF/NF. In the case of a disagreement between CMS and the State survey agency, a finding of noncompliance takes precedence over that of compliance.

(ii) In the case of a validation survey, the Secretary's determination as to the facility's noncompliance is binding, and takes precedence over a certification of compliance resulting from the State survey.

(2) *Basis for certification.* (i) Certification by the State is based on the survey agency findings.

(ii) Certification by CMS is based on either the survey agency findings (in the case of State-operated facilities), or, in the case of a validation survey, on CMS's own survey findings.

(b) *Effect of certification*—(1) *Certification of compliance.* A certification of compliance constitutes a determination that the facility is in substantial compliance and is eligible to participate in Medicaid as a NF, or in Medicare as a SNF, or in Medicare and Medicaid as a dually participating facility.

(2) *Certification of noncompliance.* A certification of noncompliance requires denial of participation for prospective providers and enforcement action for current providers in accordance with subpart F of this part. Enforcement action must include one of the following:

(i) Termination of any Medicare or Medicaid provider agreements that are in effect.

(ii) Application of alternative remedies instead of, or in addition to, termination procedures.

(c) *Notice of certification of noncompliance and resulting action.* The notice of certification of noncompliance is sent in accordance with the timeframes specified in § 488.402(f), and resulting action is issued by CMS, except when the State is taking the action for a non-State operated NF.

(d) *Content of notice of certification of noncompliance.* The notice of certification of noncompliance is sent in accordance with the timeframes specified in § 488.402(f) and includes information on all of the following:

(1) Nature of noncompliance.

(2) Any alternative remedies to be imposed under subpart F of this part.

(3) Any termination or denial of participation action to be taken under this part.

(4) The appeal rights available to the facility under this part.

(5) Timeframes to be met by the provider and certifying agency with regard to each of the enforcement actions or appeal procedures addressed in the notice.

(e) *Appeals.* (1) Notwithstanding any provision of State law, the State must impose remedies promptly on any provider of services participating in the Medicaid program—

(i) After promptly notifying the facility of the deficiencies and impending remedy or remedies; and

(ii) Except for civil money penalties, during any pending hearing that may be requested by the provider of services.

(2) CMS imposes remedies promptly on any provider of services participating in the Medicare or Medicaid program or any provider of services participating in both the Medicare and Medicaid programs—

(i) After promptly notifying the facility of the deficiencies and impending remedy or remedies; and

(ii) Except for civil money penalties, during any pending hearing that may

be requested by the provider of services.

(3) The provisions of part 498 of this chapter apply when the following providers request a hearing on a denial of participation, or certification of noncompliance leading to an enforcement remedy (including termination of the provider agreement), except State monitoring:

(i) All State-operated facilities;

(ii) SNFs and dually participating SNF/NFs; and

(iii) Any other facilities subject to a CMS validation survey or CMS review of the State's findings.

(4) The provisions of part 431 of this chapter apply when a non-State operated Medicaid NF, which has not received a CMS validation survey or CMS review of the State's findings, requests a hearing on the State's denial of participation, termination of provider agreement, or certification of noncompliance leading to an alternative remedy, except State monitoring.

(f) *Provider agreements.* CMS or the Medicaid agency may execute a provider agreement when a prospective provider is in substantial compliance with all the requirements for participation for a SNF or NF, respectively.

(g) *Special rules for Federal validation surveys.* (1) CMS may make independent certifications of a NF's, SNF's, or dually participating facility's noncompliance based on a CMS validation survey.

(2) CMS issues the notice of actions affecting facilities for which CMS did validation surveys.

(3) For non-State-operated NFs and non-State-operated dually participating facilities, any disagreement between CMS and the State regarding the timing and choice of remedies is resolved in accordance with § 488.452.

(4) Either CMS or the survey agency, at CMS's option, may revisit the facility to ensure that corrections are made.

[59 FR 56238, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.331 Informal dispute resolution.

(a) *Opportunity to refute survey findings.* (1) For non-Federal surveys, the State must offer a facility an informal opportunity, at the facility's request, to dispute survey findings upon the facility's receipt of the official statement of deficiencies.

(2) For Federal surveys, CMS offers a facility an informal opportunity, at the facility's request, to dispute survey findings upon the facility's receipt of the official statement of deficiencies.

(b)(1) Failure of the State or CMS, as appropriate, to complete informal dispute resolution timely cannot delay the effective date of any enforcement action against the facility.

(2) A facility may not seek a delay of any enforcement action against it on the grounds that informal dispute resolution has not been completed before the effective date of the enforcement action.

(c) If a provider is subsequently successful, during the informal dispute resolution process, at demonstrating that deficiencies should not have been cited, the deficiencies are removed from the statement of deficiencies and any enforcement actions imposed solely as a result of those cited deficiencies are rescinded.

(d) *Notification.* Upon request, CMS does and the State must provide the facility with written notification of the informal dispute resolution process.

§ 488.332 Investigation of complaints of violations and monitoring of compliance.

(a) *Investigation of complaints.* (1) The State survey agency must establish procedures and maintain adequate staff to investigate complaints of violations of participation requirements.

(2) The State survey agency takes appropriate precautions to protect a complainant's anonymity and privacy, if possible.

(3) If arrangements have been made with other State components for investigation of complaints, the State must have a means of communicating information among appropriate entities, and the State survey agency retains responsibility for the investigation process.

(4) If, after investigating a complaint, the State has reason to believe that an identifiable individual neglected or abused a resident, or misappropriated a resident's property, the

State survey agency must act on the complaint in accordance with § 488.335.

(b) *On-site monitoring.* The State survey agency conducts on-site monitoring on an as necessary basis when—

(1) A facility is not in substantial compliance with the requirements and is in the process of correcting deficiencies;

(2) A facility has corrected deficiencies and verification of continued substantial compliance is needed; or

(3) The survey agency has reason to question the substantial compliance of the facility with a requirement of participation.

(c) *Composition of the investigative team.* A State may use a specialized team, which may include an attorney, auditor and appropriate health professionals, to identify, survey, gather and preserve evidence, and administer remedies to noncompliant facilities.

§ 488.334 Educational programs.

A State must conduct periodic educational programs for the staff and residents (and their representatives) of SNFs and NFs in order to present current regulations, procedures, and policies on the survey, certification and enforcement process under this subpart and subpart F of this part.

§ 488.335 Action on complaints of resident neglect and abuse, and misappropriation of resident property.

(a) *Investigation.* (1) The State must review all allegations of resident neglect and abuse, and misappropriation of resident property and follow procedures specified in § 488.332.

(2) If there is reason to believe, either through oral or written evidence that an individual used by a facility to provide services to residents could have abused or neglected a resident or misappropriated a resident's property, the State must investigate the allegation.

(3) The State must have written procedures for the timely review and investigation of allegations of resident abuse and neglect, and misappropriation of resident property.

(b) *Source of complaints.* The State must review all allegations regardless of the source.

(c) *Notification*—(1) *Individuals to be notified.* If the State makes a preliminary determination, based on oral or written evidence and its investigation, that the abuse, neglect or misappropriation of property occurred, it must notify in writing—

(i) The individuals implicated in the investigation; and

(ii) The current administrator of the facility in which the incident occurred.

(2) *Timing of the notice.* The State must notify the individuals specified in paragraph (c)(1) of this section in writing within 10 working days of the State's investigation.

(3) *Contents of the notice.* The notice must include the—

(i) Nature of the allegation(s);

(ii) Date and time of the occurrence;

(iii) Right to a hearing;

(iv) Intent to report the substantiated findings in writing, once the individual has had the opportunity for a hearing, to the nurse aide registry or appropriate licensure authority;

(v) Fact that the individual's failure to request a hearing in writing within 30 days from the date of the notice will result in reporting the substantiated findings to the nurse aide registry or appropriate licensure authority.

(vi) Consequences of waiving the right to a hearing;

(vii) Consequences of a finding through the hearing process that the alleged resident abuse or neglect, or misappropriation of resident property did occur; and

(viii) Fact that the individual has the right to be represented by an attorney at the individual's own expense.

(d) *Conduct of hearing.* (1) The State must complete the hearing and the hearing record within 120 days from the day it receives the request for a hearing.

(2) The State must hold the hearing at a reasonable place and time convenient for the individual.

(e) *Factors beyond the individual's control.* A State must not make a finding that an individual has neglected a resident if the individual demonstrates that such neglect was caused by factors beyond the control of the individual.

(f) *Report of findings.* If the finding is that the individual has neglected or abused a resident or misappropriated resident property or if the individual waives the right to a hearing, the State

must report the findings in writing within 10 working days to—

(1) The individual;

(2) The current administrator of the facility in which the incident occurred; and

(3) The administrator of the facility that currently employs the individual, if different than the facility in which the incident occurred;

(4) The licensing authority for individuals used by the facility other than nurse aides, if applicable; and

(5) The nurse aide registry for nurse aides. Only the State survey agency may report the findings to the nurse aide registry, and this must be done within 10 working days of the findings, in accordance with § 483.156(c) of this chapter. The State survey agency may not delegate this responsibility.

(g) *Contents and retention of report of finding to the nurse aide registry*. (1) The report of finding must include information in accordance with § 483.156(c) of this chapter.

(2) The survey agency must retain the information as specified in paragraph (g)(1) of this section, in accordance with the procedures specified in § 483.156(c) of this chapter.

(h) *Survey agency responsibility*. (1) The survey agency must promptly review the results of all complaint investigations and determine whether or not a facility has violated any requirements in part 483, subpart B of this chapter.

(2) If a facility is not in substantial compliance with the requirements in part 483, subpart B of this chapter, the survey agency initiates appropriate actions, as specified in subpart F of this part.

[59 FR 56238, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

Subpart F—Enforcement of Compliance for Long-Term Care Facilities with Deficiencies

SOURCE: 59 FR 56243, Nov. 10, 1994, unless otherwise noted.

§ 488.400 Statutory basis.

Sections 1819(h) and 1919(h) of the Act specify remedies that may be used by the Secretary or the State respectively when a SNF or a NF is not in substantial compliance with the requirements for participation in the Medicare and Medicaid programs. These sections also provide for ensuring prompt compliance and specify that these remedies are in addition to any others available under State or Federal law, and, except for civil money penalties, are imposed prior to the conduct of a hearing.

§ 488.401 Definitions.

As used in this subpart—

New admission means a resident who is admitted to the facility on or after the effective date of a denial of payment remedy and, if previously admitted, has been discharged before that effective date. Residents admitted before the effective date of the denial of payment, and taking temporary leave, are not considered new admissions, nor subject to the denial of payment.

Plan of correction means a plan developed by the facility and approved by CMS or the survey agency that describes the actions the facility will take to correct deficiencies and specifies the date by which those deficiencies will be corrected.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.402 General provisions.

(a) *Purpose of remedies*. The purpose of remedies is to ensure prompt compliance with program requirements.

(b) *Basis for imposition and duration of remedies*. When CMS or the State chooses to apply one or more remedies specified in § 488.406, the remedies are applied on the basis of noncompliance found during surveys conducted by CMS or by the survey agency.

(c) *Number of remedies*. CMS or the State may apply one or more remedies for each deficiency constituting noncompliance or for all deficiencies constituting noncompliance.

(d) *Plan of correction requirement*. (1) Except as specified in paragraph (d)(2) of this section, regardless of which remedy is applied, each facility that has deficiencies with respect to program requirements must submit a plan of correction for approval by CMS or the survey agency.

(2) *Isolated deficiencies.* A facility is not required to submit a plan of correction when it has deficiencies that are isolated and have a potential for minimal harm, but no actual harm has occurred.

(e) *Disagreement regarding remedies.* If the State and CMS disagree on the decision to impose a remedy, the disagreement is resolved in accordance with § 488.452.

(f) *Notification requirements*—(1) Except when the State is taking action against a non-State operated NF, CMS or the State (as authorized by CMS) gives the provider notice of the remedy, including the—

(i) Nature of the noncompliance;

(ii) Which remedy is imposed;

(iii) Effective date of the remedy; and

(iv) Right to appeal the determination leading to the remedy.

(2) When a State is taking action against a non-State operated NF, the State's notice must include the same information required by CMS in paragraph (f)(1) of this section.

(3) *Immediate jeopardy—2 day notice.* Except for civil money penalties and State monitoring imposed when there is immediate jeopardy, for all remedies specified in § 488.406 imposed when there is immediate jeopardy, the notice must be given at least 2 calendar days before the effective date of the enforcement action.

(4) *No immediate jeopardy—15 day notice.* Except for civil money penalties and State monitoring, notice must be given at least 15 calendar days before the effective date of the enforcement action in situations in which there is no immediate jeopardy.

(5) *Date of enforcement action.* The 2- and 15-day notice periods begin when the facility receives the notice.

(6) *Civil money penalties.* For civil money penalties, the notices must be given in accordance with the provisions of §§ 488.434 and 488.440.

(7) *State monitoring.* For State monitoring, no prior notice is required.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995, as amended at 64 FR 13360, Mar. 18, 1999]

§ 488.404 Factors to be considered in selecting remedies.

(a) *Initial assessment.* In order to select the appropriate remedy, if any, to apply to a facility with deficiencies, CMS and the State determine the seriousness of the deficiencies.

(b) *Determining seriousness of deficiencies.* To determine the seriousness of the deficiency, CMS considers and the State must consider at least the following factors:

(1) Whether a facility's deficiencies constitute—

(i) No actual harm with a potential for minimal harm;

(ii) No actual harm with a potential for more than minimal harm, but not immediate jeopardy;

(iii) Actual harm that is not immediate jeopardy; or

(iv) Immediate jeopardy to resident health or safety.

(2) Whether the deficiencies—

(i) Are isolated;

(ii) Constitute a pattern; or

(iii) Are widespread.

(c) *Other factors which may be considered in choosing a remedy within a remedy category.* Following the initial assessment, CMS and the State may consider other factors, which may include, but are not limited to the following:

(1) The relationship of the one deficiency to other deficiencies resulting in noncompliance.

(2) The facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

§ 488.406 Available remedies.

(a) *General.* In addition to the remedy of termination of the provider agreement, the following remedies are available:

(1) Temporary management.

(2) Denial of payment including—

(i) Denial of payment for all individuals, imposed by CMS, to a—

(A) Skilled nursing facility, for Medicare;

(B) State, for Medicaid; or

(ii) Denial of payment for all new admissions.

(3) Civil money penalties.

(4) State monitoring.

(5) Transfer of residents.

(6) Closure of the facility and transfer of residents.

(7) Directed plan of correction.

(8) Directed in-service training.

(9) Alternative or additional State remedies approved by CMS.

(b) *Remedies that must be established.* At a minimum, and in addition to termination of the provider agreement, the State must establish the following remedies or approved alternatives to the following remedies:

(1) Temporary management.

(2) Denial of payment for new admissions.

(3) Civil money penalties.

(4) Transfer of residents.

(5) Closure of the facility and transfer of residents.

(6) State monitoring.

(c) *State plan requirement.* If a State wishes to use remedies for noncompliance that are either additional or alternative to those specified in paragraphs (a) or (b) of this section, it must—

(1) Specify those remedies in the State plan; and

(2) Demonstrate to CMS's satisfaction that those remedies are as effective as the remedies listed in paragraph (a) of this section, for deterring noncompliance and correcting deficiencies.

(d) *State remedies in dually participating facilities.* If the State's remedy is unique to the State plan and has been approved by CMS, then that remedy, as imposed by the State under its Medicaid authority, may be imposed by CMS against the Medicare provider agreement of a dually participating facility.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.408 Selection of remedies.

(a) *Categories of remedies.* In this section, the remedies specified in § 488.406(a) are grouped into categories and applied to deficiencies according to how serious the noncompliance is.

(b) *Application of remedies.* After considering the factors specified in § 488.404, as applicable, if CMS and the State choose to impose remedies, as provided in paragraphs (c)(1), (d)(1) and (e)(1) of this section, for facility noncompliance, instead of, or in addition to, termination of the provider agreement, CMS does and the State must follow the criteria set forth in paragraphs (c)(2), (d)(2), and (e)(2) of this section, as applicable.

(c) *Category 1.* (1) Category 1 remedies include the following:

(i) Directed plan of correction.

(ii) State monitoring.

(iii) Directed in-service training.

(2) CMS does or the State must apply one or more of the remedies in Category 1 when there—

(i) Are isolated deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

(ii) Is a pattern of deficiencies that constitutes no actual harm with a potential for more than minimal harm but not immediate jeopardy.

(3) Except when the facility is in substantial compliance, CMS or the State may apply one or more of the remedies in Category 1 to any deficiency.

(d) *Category 2.* (1) Category 2 remedies include the following:

(i) Denial of payment for new admissions.

(ii) Denial of payment for all individuals imposed only by CMS.

(iii) Civil money penalties of $50–3,000 per day.

(iv) Civil money penalty of $1,000-$10,000 per instance of noncompliance.

(2) CMS applies one or more of the remedies in Category 2, or, except for denial of payment for all individuals, the State must apply one or more of the remedies in Category 2 when there are—

(i) Widespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

(ii) One or more deficiencies that constitute actual harm that is not immediate jeopardy.

(3) CMS or the State may apply one or more of the remedies in Category 2 to any deficiency except when—

(i) The facility is in substantial compliance; or

(ii) CMS or the State imposes a civil money penalty for a deficiency that constitutes immediate jeopardy, the penalty must be in the upper range of penalty amounts, as specified in § 488.438(a).

(e) *Category 3.* (1) Category 3 remedies include the following:

(i) Temporary management.

(ii) Immediate termination.

(iii) Civil money penalties of $3,050–$10,000 per day.

(iv) Civil money penalty of $1,000–$10,000 per instance of noncompliance.

(2) When there are one or more deficiencies that constitute immediate jeopardy to resident health or safety—

(i) CMS does and the State must do one or both of the following:

(A) Impose temporary management; or

(B) Terminate the provider agreement;

(ii) CMS and the State may impose a civil money penalty of $3,050–$10,000 per day or $1,000–$10,000 per instance of noncompliance, in addition to imposing the remedies specified in paragraph (e)(2)(i) of this section.

(3) When there are widespread deficiencies that constitute actual harm that is not immediate jeopardy, CMS and the State may impose temporary management, in addition to Category 2 remedies.

(f) *Plan of correction.* (1) Except as specified in paragraph (f)(2) of this section, each facility that has a deficiency with regard to a requirement for long term care facilities must submit a plan of correction for approval by CMS or the State, regardless of—

(i) Which remedies are imposed; or

(ii) The seriousness of the deficiencies.

(2) When there are only isolated deficiencies that CMS or the State determines constitute no actual harm with a potential for minimal harm, the facility need not submit a plan of correction.

(g) *Appeal of a certification of noncompliance.* (1) A facility may appeal a certification of noncompliance leading to an enforcement remedy.

(2) A facility may not appeal the choice of remedy, including the factors considered by CMS or the State in selecting the remedy, specified in § 488.404.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995, as amended at 64 FR 13360, Mar. 18, 1999]

§ 488.410 Action when there is immediate jeopardy.

(a) If there is immediate jeopardy to resident health or safety, the State must (and CMS does) either terminate the provider agreement within 23 calendar days of the last date of the survey or appoint a temporary manager to remove the immediate jeopardy. The rules for appointment of a temporary manager in an immediate jeopardy situation are as follows:

(1) CMS does and the State must notify the facility that a temporary manager is being appointed.

(2) If the facility fails to relinquish control to the temporary manager, CMS does and the State must terminate the provider agreement within 23 calendar days of the last day of the survey, if the immediate jeopardy is not removed. In these cases, State monitoring may be imposed pending termination.

(3) If the facility relinquishes control to the temporary manager, the State must (and CMS does) notify the facility that, unless it removes the immediate jeopardy, its provider agreement will be terminated within 23 calendar days of the last day of the survey.

(4) CMS does and the State must terminate the provider agreement within 23 calendar days of the last day of survey if the immediate jeopardy has not been removed.

(b) CMS or the State may also impose other remedies, as appropriate.

(c)(1) In a NF or dually participating facility, if either CMS or the State finds that a facility's noncompliance poses immediate jeopardy to resident health or safety, CMS or the State must notify the other of such a finding.

(2) CMS will or the State must do one or both of the following:

(i) Take immediate action to remove the jeopardy and correct the noncompliance through temporary management.

(ii) Terminate the facility's participation under the State plan. If this is done, CMS will also terminate the facility's participation in Medicare if it is a dually participating facility.

(d) The State must provide for the safe and orderly transfer of residents when the facility is terminated.

(e) If the immediate jeopardy is also substandard quality of care, the State survey agency must notify attending

physicians and the State board responsible for licensing the facility administrator of the finding of substandard quality of care, as specified in § 488.325(h).

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.412 Action when there is no immediate jeopardy.

(a) If a facility's deficiencies do not pose immediate jeopardy to residents' health or safety, and the facility is not in substantial compliance, CMS or the State may terminate the facility's provider agreement or may allow the facility to continue to participate for no longer than 6 months from the last day of the survey if—

(1) The State survey agency finds that it is more appropriate to impose alternative remedies than to terminate the facility's provider agreement;

(2) The State has submitted a plan and timetable for corrective action approved by CMS; and

(3) The facility in the case of a Medicare SNF or the State in the case of a Medicaid NF agrees to repay to the Federal government payments received after the last day of the survey that first identified the deficiencies if corrective action is not taken in accordance with the approved plan of correction.

(b) If a facility does not meet the criteria for continuation of payment under paragraph (a) of this section, CMS will and the State must terminate the facility's provider agreement.

(c) CMS does and the State must deny payment for new admissions when a facility is not in substantial compliance 3 months after the last day of the survey.

(d) CMS terminates the provider agreement for SNFs and NFs, and stops FFP to a State for a NF for which participation was continued under paragraph (a) of this section, if the facility is not in substantial compliance within 6 months of the last day of the survey.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.414 Action when there is repeated substandard quality of care.

(a) *General.* If a facility has been found to have provided substandard quality of care on the last three consecutive standard surveys, as defined in § 488.305, regardless of other remedies provided—

(1) CMS imposes denial of payment for all new admissions, as specified in § 488.417, or denial of all payments, as specified in § 488.418;

(2) The State must impose denial of payment for all new admissions, as specified in § 488.417; and

(3) CMS does and the State survey agency must impose State monitoring, as specified in § 488.422, until the facility has demonstrated to the satisfaction of CMS or the State, that it is in substantial compliance with all requirements and will remain in substantial compliance with all requirements.

(b) *Repeated noncompliance.* For purposes of this section, repeated noncompliance is based on the repeated finding of substandard quality of care and not on the basis that the substance of the deficiency or the exact tag number for the deficiency was repeated.

(c) *Standard surveys to which this provision applies.* Standard surveys completed by the State survey agency on or after October 1, 1990, are used to determine whether the threshold of three consecutive standard surveys is met.

(d) *Program participation.* (1) The determination that a certified facility has repeated instances of substandard quality of care is made without regard to any variances in the facility's program participation (that is, any standard survey completed for Medicare, Medicaid or both programs will be considered).

(2) Termination would allow the count of repeated substandard quality of care surveys to start over.

(3) Change of ownership. (i) A facility may not avoid a remedy on the basis that it underwent a change of ownership.

(ii) In a facility that has undergone a change of ownership, CMS does not and the State may not restart the count of repeated substandard quality of care surveys unless the new owner can demonstrate to the satisfaction of CMS or the State that the poor past performance no longer is a factor due to the change in ownership.

(e) *Facility alleges corrections or achieves compliance after repeated substandard quality of care is identified.* (1) If a penalty is imposed for repeated substandard quality of care, it will continue until the facility has demonstrated to the satisfaction of CMS or the State that it is in substantial compliance with the requirements and that it will remain in substantial compliance with the requirements for a period of time specified by CMS or the State.

(2) A facility will not avoid the imposition of remedies or the obligation to demonstrate that it will remain in compliance when it—

(i) Alleges correction of the deficiencies cited in the most recent standard survey; or

(ii) Achieves compliance before the effective date of the remedies.

§ 488.415 Temporary management.

(a) *Definition.* Temporary management means the temporary appointment by CMS or the State of a substitute facility manager or administrator with authority to hire, terminate or reassign staff, obligate facility funds, alter facility procedures, and manage the facility to correct deficiencies identified in the facility's operation.

(b) *Qualifications.* The temporary manager must—

(1) Be qualified to oversee correction of deficiencies on the basis of experience and education, as determined by the State;

(2) Not have been found guilty of misconduct by any licensing board or professional society in any State;

(3) Have, or a member of his or her immediate family have, no financial ownership interest in the facility; and

(4) Not currently serve or, within the past 2 years, have served as a member of the staff of the facility.

(c) *Payment of salary.* The temporary manager's salary—

(1) Is paid directly by the facility while the temporary manager is assigned to that facility; and

(2) Must be at least equivalent to the sum of the following—

(i) The prevailing salary paid by providers for positions of this type in what the State considers to be the facility's geographic area;

(ii) Additional costs that would have reasonably been incurred by the provider if such person had been in an employment relationship; and

(iii) Any other costs incurred by such a person in furnishing services under such an arrangement or as otherwise set by the State.

(3) May exceed the amount specified in paragraph (c)(2) of this section if the State is otherwise unable to attract a qualified temporary manager.

(d) *Failure to relinquish authority to temporary management*—(1) *Termination of provider agreement.* If a facility fails to relinquish authority to the temporary manager as described in this section, CMS will or the State must terminate the provider agreement in accordance with § 488.456.

(2) *Failure to pay salary of temporary manager.* A facility's failure to pay the salary of the temporary manager is considered a failure to relinquish authority to temporary management.

(e) *Duration of temporary management.* Temporary management ends when the facility meets any of the conditions specified in § 488.454(c).

§ 488.417 Denial of payment for all new admissions.

(a) *Optional denial of payment.* Except as specified in paragraph (b) of this section, CMS or the State may deny payment for all new admissions when a facility is not in substantial compliance with the requirements, as defined in § 488.401, as follows:

(1) *Medicare facilities.* In the case of Medicare facilities, CMS may deny payment to the facility.

(2) *Medicaid facilities.* In the case of Medicaid facilities—

(i) The State may deny payment to the facility; and

(ii) CMS may deny payment to the State for all new Medicaid admissions to the facility.

(b) *Required denial of payment.* CMS does or the State must deny payment for all new admissions when—

(1) The facility is not in substantial compliance, as defined in § 488.401, 3 months after the last day of the survey identifying the noncompliance; or

(2) The State survey agency has cited a facility with substandard quality of

care on the last three consecutive standard surveys.

(c) *Resumption of payments: Repeated instances of substandard quality of care.* When a facility has repeated instances of substandard quality of care, payments to the facility or, under Medicaid, CMS payments to the State on behalf of the facility, resume on the date that—

(1) The facility achieves substantial compliance as indicated by a revisit or written credible evidence acceptable to CMS (for all facilities except non-State operated NFs against which CMS is imposing no remedies) or the State (for non-State operated NFs against which CMS is imposing no remedies); and

(2) CMS (for all facilities except non-State operated NFs against which CMS is imposing no remedies) or the State (for non-State operated NFs against which CMS is imposing no remedies) believes that the facility is capable of remaining in substantial compliance.

(d) *Resumption of payments: No repeated instances of substandard quality of care.* When a facility does not have repeated instances of substandard quality of care, payments to the facility or, under Medicaid, CMS payments to the State on behalf of the facility, resume prospectively on the date that the facility achieves substantial compliance, as indicated by a revisit or written credible evidence acceptable to CMS (under Medicare) or the State (under Medicaid).

(e) *Restriction.* No payments to a facility or, under Medicaid, CMS payments to the State on behalf of the facility, are made for the period between the date that the—

(1) Denial of payment remedy is imposed; and

(2) Facility achieves substantial compliance, as determined by CMS or the State.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.418 Secretarial authority to deny all payments.

(a) *CMS option to deny all payment.* If a facility has not met a requirement, in addition to the authority to deny payment for all new admissions as specified in § 488.417, CMS may deny any further payment for all Medicare residents in the facility and to the State for all Medicaid residents in the facility.

(b) *Prospective resumption of payment.* Except as provided in paragraphs (d) and (e) of this section, if the facility achieves substantial compliance, CMS resumes payment prospectively from the date that it verifies as the date that the facility achieved substantial compliance.

(c) *Restriction on payment after denial of payment is imposed.* If payment to the facility or to the State resumes after denial of payment for all residents, no payment is made for the period between the date that—

(1) Denial of payment was imposed; and

(2) CMS verifies as the date that the facility achieved substantial compliance.

(d) *Retroactive resumption of payment.* Except when a facility has repeated instances of substandard quality of care, as specified in paragraph (e) of this section, when CMS or the State finds that the facility was in substantial compliance before the date of the revisit, or before CMS or the survey agency received credible evidence of such compliance, payment is resumed on the date that substantial compliance was achieved, as determined by CMS.

(e) *Resumption of payment—repeated instances of substandard care.* When CMS denies payment for all Medicare residents for repeated instances of substandard quality of care, payment is resumed when—

(1) The facility achieved substantial compliance, as indicated by a revisit or written credible evidence acceptable to CMS; and

(2) CMS believes that the facility will remain in substantial compliance.

§ 488.422 State monitoring.

(a) A State monitor—

(1) Oversees the correction of deficiencies specified by CMS or the State survey agency at the facility site and protects the facility's residents from harm;

(2) Is an employee or a contractor of the survey agency;

(3) Is identified by the State as an appropriate professional to monitor cited deficiencies;

(4) Is not an employee of the facility;

(5) Does not function as a consultant to the facility; and

(6) Does not have an immediate family member who is a resident of the facility to be monitored.

(b) A State monitor must be used when a survey agency has cited a facility with substandard quality of care deficiencies on the last 3 consecutive standard surveys.

(c) State monitoring is discontinued when—

(1) The facility has demonstrated that it is in substantial compliance with the requirements, and, if imposed for repeated instances of substandard quality of care, will remain in compliance for a period of time specified by CMS or the State; or

(2) Termination procedures are completed.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.424 Directed plan of correction.

CMS, the State survey agency, or the temporary manager (with CMS or State approval) may develop a plan of correction and CMS, the State, or the temporary manager require a facility to take action within specified timeframes.

§ 488.425 Directed inservice training.

(a) *Required training*. CMS or the State agency may require the staff of a facility to attend an inservice training program if—

(1) The facility has a pattern of deficiencies that indicate noncompliance; and

(2) Education is likely to correct the deficiencies.

(b) *Action following training*. After the staff has received inservice training, if the facility has not achieved substantial compliance, CMS or the State may impose one or more other remedies specified in § 488.406.

(c) *Payment*. The facility pays for directed inservice training.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.426 Transfer of residents, or closure of the facility and transfer of residents.

(a) *Transfer of residents, or closure of the facility and transfer of residents in an emergency*. In an emergency, the State has the authority to—

(1) Transfer Medicaid and Medicare residents to another facility; or

(2) Close the facility and transfer the Medicaid and Medicare residents to another facility.

(b) *Required transfer when a facility's provider agreement is terminated*. When the State or CMS terminates a facility's provider agreement, the State arranges for the safe and orderly transfer of all Medicare and Medicaid residents to another facility.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.430 Civil money penalties: Basis for imposing penalty.

(a) CMS or the State may impose a civil money penalty for either the number of days a facility is not in substantial compliance with one or more participation requirements or for each instance that a facility is not in substantial compliance, regardless of whether or not the deficiencies constitute immediate jeopardy.

(b) CMS or the State may impose a civil money penalty for the number of days of past noncompliance since the last standard survey, including the number of days of immediate jeopardy.

[59 FR 56243, Nov. 10, 1994, as amended at 64 FR 13360, Mar. 18, 1999]

§ 488.432 Civil money penalties: When a penalty is collected.

(a) *When facility requests a hearing*. (1) A facility must request a hearing on the determination of the noncompliance that is the basis for imposition of the civil money penalty within the time specified in one of the following sections:

(i) Section 498.40 of this chapter for a

(A) SNF;

(B) Dually participating facility;

(C) State-operated NF; or

(D) Non-State operated NF against which CMS is imposing remedies.

(ii) Section 431.153 of this chapter for a non-State operated NF that is not

subject to imposition of remedies by CMS.

(2)(i) If a facility requests a hearing within the time specified in paragraph (a)(1) of this section, for a civil money penalty imposed per day, CMS or the State initiates collection of the penalty when there is a final administrative decision that upholds CMS's or the State's determination of noncompliance after the facility achieves substantial compliance or is terminated.

(ii) If a facility requests a hearing for a civil money penalty imposed per instance of noncompliance within the time specified in paragraph (a)(1) of this section, CMS or the State initiates collection of the penalty when there is a final administrative decision that upholds CMS's or the State's determination of noncompliance.

(b) When a facility does not request a hearing for a civil money penalty imposed per day. (1) If a facility does not request a hearing in accordance with paragraph (a) of this section, CMS or the State initiates collection of the penalty when the facility—

(i) Achieves substantial compliance; or

(ii) Is terminated.

(2) When a facility does not request a hearing for a civil money penalty imposed per instance of noncompliance. If a facility does not request a hearing in accordance with paragraph (a) of this section, CMS or the State initiates collection of the penalty when the time frame for requesting a hearing expires.

(c) When a facility waives a hearing. (1) If a facility waives, in writing, its right to a hearing as specified in § 488.436, for a civil money penalty imposed per day, CMS or the State initiates collection of the penalty when the facility—

(i) Achieves substantial compliance; or (ii) Is terminated.

(2) If a facility waives, in writing, its right to a hearing as specified in § 488.436, for a civil money penalty imposed per instance of noncompliance, CMS or the State initiates collection of the penalty upon receipt of the facility's notification.

(d) Accrual and computation of penalties for a facility that—

(1) Requests a hearing or does not request a hearing are specified in § 488.440;

(2) Waives its right to a hearing in writing, are specified in §§ 488.436(b) and 488.440.

(e) The collection of civil money penalties is made as provided in § 488.442.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995, as amended at 64 FR 13360, Mar. 18, 1999]

§ 488.434 Civil money penalties: Notice of penalty.

(a) *CMS notice of penalty*. (1) CMS sends a written notice of the penalty to the facility for all facilities except non-State operated NFs when the State is imposing the penalty.

(2) *Content of notice*. The notice that CMS sends includes—

(i) The nature of the noncompliance;

(ii) The statutory basis for the penalty;

(iii) The amount of penalty per day of noncompliance or the amount of the penalty per instance of noncompliance;

(iv) Any factors specified in § 488.438(f) that were considered when determining the amount of the penalty;

(v) The date of the instance of noncompliance or the date on which the penalty begins to accrue;

(vi) When the penalty stops accruing, if applicable;

(vii) When the penalty is collected; and

(viii) Instructions for responding to the notice, including a statement of the facility's right to a hearing, and the implication of waiving a hearing, as provided in § 488.436.

(b) *State notice of penalty*. (1) The State must notify the facility in accordance with State procedures for all non-State operated NFs when the State takes the action.

(2) The State's notice must—

(i) Be in writing; and

(ii) Include, at a minimum, the information specified in paragraph (a)(2) of this section.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995, as amended at 64 FR 13360, Mar. 18, 1999]

§ 488.436 Civil money penalties: Waiver of hearing, reduction of penalty amount.

(a) *Waiver of a hearing*. The facility may waive the right to a hearing, in writing, within 60 days from the date of the notice imposing the civil money penalty.

(b) *Reduction of penalty amount*. (1) If the facility waives its right to a hearing in accordance with the procedures specified in paragraph (a) of this section, CMS or the State reduces the civil money penalty amount by 35 percent.

(2) If the facility does not waive its right to a hearing in accordance with the procedures specified in paragraph (a) of this section, the civil money penalty is not reduced by 35 percent.

[59 FR 56243, Nov. 10, 1994; 62 FR 44221, Aug. 20, 1997]

§ 488.438 Civil money penalties: Amount of penalty.

(a) *Amount of penalty*. (1) The penalties are within the following ranges, set at $50 increments:

(i) *Upper range—$3,050–$10,000*. Penalties in the range of $3,050–$10,000 per day are imposed for deficiencies constituting immediate jeopardy, and as specified in paragraph (d)(2) of this section.

(ii) *Lower range—$50–$3,000*. Penalties in the range of $50–$3,000 per day are imposed for deficiencies that do not constitute immediate jeopardy, but either caused actual harm, or caused no actual harm, but have the potential for more than minimal harm.

(2) *Per instance penalty*. When penalties are imposed for an instance of noncompliance, the penalties will be in the range of $1,000-$10,000 per instance.

(b) *Basis for penalty amount*. The amount of penalty is based on CMS's or the State's assessment of factors listed in paragraph (f) of this section.

(c) *Decreased penalty amounts*. Except as specified in paragraph (d)(2) of this section, if immediate jeopardy is removed, but the noncompliance continues, CMS or the State will shift the penalty amount imposed per day to the lower range.

(d) *Increased penalty amounts*. (1) Before a hearing requested in accordance with § 488.432(a), CMS or the State may propose to increase the per day penalty amount for facility noncompliance which, after imposition of a lower level penalty amount, becomes sufficiently serious to pose immediate jeopardy.

(2) CMS does and the State must increase the per day penalty amount for any repeated deficiencies for which a lower level penalty amount was previously imposed, regardless of whether the increased penalty amount would exceed the range otherwise reserved for nonimmediate jeopardy deficiencies.

(3) Repeated deficiencies are deficiencies in the same regulatory grouping of requirements found at the last survey, subsequently corrected, and found again at the next survey.

(e) *Review of the penalty*. When an administrative law judge or State hearing officer (or higher administrative review authority) finds that the basis for imposing a civil money penalty exists, as specified in § 488.430, the administrative law judge or State hearing officer (or higher administrative review authority) may not—

(1) Set a penalty of zero or reduce a penalty to zero;

(2) Review the exercise of discretion by CMS or the State to impose a civil money penalty; and

(3) Consider any factors in reviewing the amount of the penalty other than those specified in paragraph (f) of this section.

(f) *Factors affecting the amount of penalty*. In determining the amount of penalty, CMS does or the State must take into account the following factors:

(1) The facility's history of noncompliance, including repeated deficiencies.

(2) The facility's financial condition.

(3) The factors specified in § 488.404.

(4) *The facility's degree of culpability*. *Culpability* for purposes of this paragraph includes, but is not limited to, neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating circumstance in reducing the amount of the penalty.

[59 FR 56243, Nov. 10, 1994, as amended at 64 FR 13360, Mar. 18, 1999; 68 FR 46072, Aug. 4, 2003]

§ 488.440 Civil money penalties: Effective date and duration of penalty.

(a)(1) The per day civil money penalty may start accruing as early as the date that the facility was first out of compliance, as determined by CMS or the State.

(2) A civil money penalty for each instance of noncompliance is imposed in a specific amount for that particular deficiency .

(b) The per day civil money penalty is computed and collectible, as specified in §§ 488.432 and 488.442, for the number of days of noncompliance until the date the facility achieves substantial compliance, or, if applicable, the date of termination when—

(1) CMS's or the State's decision of noncompliance is upheld after a final administrative decision;

(2) The facility waives its right to a hearing in accordance with § 488.436; or

(3) The time for requesting a hearing has expired and CMS or the State has not received a hearing request from the facility.

(c) The entire penalty, whether imposed on a per day or per instance basis, is due and collectible as specified in the notice sent to the provider under paragraphs (d) and (e) of this section.

(d)(1) When a civil money penalty is imposed on a per day basis and the facility achieves substantial compliance, CMS does or the State must send a separate notice to the facility containing the following information:

(i) The amount of penalty per day.

(ii) The number of days involved.

(iii) The total amount due.

(iv) The due date of the penalty.

(v) The rate of interest assessed on the unpaid balance beginning on the due date, as provided in § 488.442.

(2) When a civil money penalty is imposed for an instance of noncompliance, CMS does or the State must send a separate notice to the facility containing the following information:

(i) The amount of the penalty.

(ii) The total amount due.

(iii) The due date of the penalty.

(iv) The rate of interest assessed on the unpaid balance beginning on the due date, as provided in § 488.442.

(e) In the case of a facility for which the provider agreement has been terminated and on which a civil money penalty was imposed on a per day basis, CMS does or the State must send this penalty information after the—

(1) Final administrative decision is made;

(2) Facility has waived its right to a hearing in accordance with § 488.436; or

(3) Time for requesting a hearing has expired and CMS or the state has not received a hearing request from the facility.

(f) *Accrual of penalties when there is no immediate jeopardy.* (1) In the case of noncompliance that does not pose immediate jeopardy, the daily accrual of per day civil money penalties is imposed for the days of noncompliance prior to the notice specified in § 488.434 and an additional period of no longer than 6 months following the last day of the survey.

(2) After the period specified in paragraph (f)(1) of this section, if the facility has not achieved substantial compliance, CMS terminates the provider agreement and the State may terminate the provider agreement.

(g)(1) In a case when per day civil money penalties are imposed, when a facility has deficiencies that pose immediate jeopardy, CMS does or the State must terminate the provider agreement within 23 calendar days after the last day of the survey if the immediate jeopardy remains.

(2) The accrual of the civil money penalty imposed on a per day basis stops on the day the provider agreement is terminated.

(h)(1) If an on-site revisit is necessary to confirm substantial compliance and the provider can supply documentation acceptable to CMS or the State agency that substantial compliance was achieved on a date preceding the revisit, penalties imposed on a per day basis only accrue until that date of correction for which there is written credible evidence.

(2) If an on-site revisit is not necessary to confirm substantial compliance, penalties imposed on a per day basis only accrue until the date of correction for which CMS or the State receives and accepts written credible evidence.

[59 FR 56243, Nov. 10, 1994, as amended at 64 FR 13361, Mar. 18, 1999]

§ 488.442 Civil money penalties: Due date for payment of penalty.

(a) *When payments are due for a civil money penalty imposed on a per day basis*—(1) *After a final administrative decision*. A civil money penalty payment is due 15 days after a final administrative decision is made when—

(i) The facility achieves substantial compliance before the final administrative decision; or

(ii) The effective date of termination occurs before the final administrative decision.

(2) *When no hearing was requested*. A civil money penalty payment is due 15 days after the time period for requesting a hearing has expired and a hearing request was not received when—

(i) The facility achieved substantial compliance before the hearing request was due; or

(ii) The effective date of termination occurs before the hearing request was due.

(3) *After a request to waive a hearing*. A civil money penalty payment is due 15 days after receipt of the written request to waive a hearing when—

(i) The facility achieved substantial compliance before CMS or the State received the written waiver of hearing; or

(ii) The effective date of termination occurs before CMS or the State received the written waiver of hearing.

(4) *After substantial compliance is achieved*. A civil money penalty payment is due 15 days after substantial compliance is achieved when—

(i) The final administrative decision is made before the facility came into substantial compliance;

(ii) The facility did not file a timely hearing request before it came into substantial compliance; or

(iii) The facility waived its right to a hearing before it came into substantial compliance;

(5) *After the effective date of termination*. A civil money penalty payment is due 15 days after the effective date of termination, if before the effective date of termination—

(i) The final administrative decision was made;

(ii) The time for requesting a hearing has expired and the facility did not request a hearing; or

(iii) The facility waived its right to a hearing.

(6) In the cases specified in paragraph (a)(4) of this section, the period of noncompliance may not extend beyond 6 months from the last day of the survey.

(b) When payments are due for a civil money penalty imposed for an instance of noncompliance. Payment of a civil money penalty is due 15 days after one of the following dates:

(1) The final administrative decision is made;

(2) The time for requesting a hearing has expired and the facility did not request a hearing; or

(3) The facility waived its right to a hearing.

(c) *Deduction of penalty from amount owed*. The amount of the penalty, when determined, may be deducted from any sum then or later owing by CMS or the State to the facility.

(d) *Interest*—(1) *Assessment*. Interest is assessed on the unpaid balance of the penalty, beginning on the due date.

(2) *Medicare interest*. Medicare rate of interest is the higher of—

(i) The rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of the notice of the penalty amount due (published quarterly in the FEDERAL REGISTER by HHS under 45 CFR 30.13(a)); or

(ii) The current value of funds (published annually in the FEDERAL REGISTER by the Secretary of the Treasury, subject to quarterly revisions).

(3) *Medicaid interest*. The interest rate for Medicaid is determined by the State.

(e) *Penalties collected by CMS*. Civil money penalties and corresponding interest collected by CMS from—

(1) Medicare-participating facilities are deposited as miscellaneous receipts of the United States Treasury; and

(2) Medicaid-participating facilities are returned to the State.

(f) *Collection from dually participating facilities*. Civil money penalties collected from dually participating facilities are deposited as miscellaneous receipts of the United States Treasury and returned to the State in proportion commensurate with the relative proportions of Medicare and Medicaid beds

at the facility actually in use by residents covered by the respective programs on the date the civil money penalty begins to accrue.

(g) *Penalties collected by the State.* Civil money penalties collected by the State must be applied to the protection of the health or property of residents of facilities that the State or CMS finds noncompliant, such as—

(1) Payment for the cost of relocating residents to other facilities;

(2) State costs related to the operation of a facility pending correction of deficiencies or closure; and

(3) Reimbursement of residents for personal funds or property lost at a facility as a result of actions by the facility or by individuals used by the facility to provide services to residents.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995, as amended at 64 FR 13361, Mar. 18, 1999]

§ 488.444 Civil money penalties: Settlement of penalties.

(a) CMS has authority to settle cases at any time prior to a final administrative decision for Medicare-only SNFs, State-operated facilities, or other facilities for which CMS's enforcement action prevails, in accordance with § 488.330.

(b) The State has the authority to settle cases at any time prior to the evidentiary hearing decision for all cases in which the State's enforcement action prevails.

§ 488.450 Continuation of payments to a facility with deficiencies.

(a) *Criteria.* (1) CMS may continue payments to a facility not in substantial compliance for the periods specified in paragraph (c) of this section if the following criteria are met:

(i) The State survey agency finds that it is more appropriate to impose alternative remedies than to terminate the facility;

(ii) The State has submitted a plan and timetable for corrective action approved by CMS; and

(iii) The facility, in the case of a Medicare SNF, or the State, in the case of a Medicaid NF, agrees to repay the Federal government payments received under this provision if corrective action is not taken in accordance with the approved plan and timetable for corrective action.

(2) CMS or the State may terminate the SNF or NF agreement before the end of the correction period if the criteria in paragraph (a)(1) of this section are not met.

(b) *Cessation of payments.* If termination is not sought, either by itself or along with another remedy or remedies, or any of the criteria set forth in paragraph (a)(1) of this section are not met or agreed to by either the facility or the State, the facility or State will receive no Medicare or Federal Medicaid payments, as applicable, from the last day of the survey.

(c) *Period of continued payments.* If the conditions in paragraph (a)(1) of this section are met, CMS may continue payments to a Medicare facility or to the State for a Medicaid facility with noncompliance that does not constitute immediate jeopardy for up to 6 months from the last day of the survey.

(d) *Failure to achieve substantial compliance.* If the facility does not achieve substantial compliance by the end of the period specified in paragraph (c) of this section,

(1) CMS will—

(i) Terminate the provider agreement of the Medicare SNF in accordance with § 488.456; or

(ii) Discontinue Federal funding to the SNF for Medicare; and

(iii) Discontinue FFP to the State for the Medicaid NF.

(2) The State may terminate the provider agreement for the NF.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.452 State and Federal disagreements involving findings not in agreement in non-State operated NFs and dually participating facilities when there is no immediate jeopardy.

The following rules apply when CMS and the State disagree over findings of noncompliance or application of remedies in a non-State operated NF or dually participating facility:

(a) *Disagreement over whether facility has met requirements.* (1) The State's finding of noncompliance takes precedence when—

(i) CMS finds that a NF or a dually participating facility is in substantial compliance with the participation requirements; and

(ii) The State finds that a NF or dually participating facility has not achieved substantial compliance.

(2) CMS's findings of noncompliance take precedence when—

(i) CMS finds that a NF or a dually participating facility has not achieved substantial compliance; and

(ii) The State finds that a NF or a dually participating facility is in substantial compliance with the participation requirements.

(3) When CMS's survey findings take precedence, CMS may—

(i) Impose any of the alternative remedies specified in § 488.406;

(ii) Terminate the provider agreement subject to the applicable conditions of § 488.450; and

(iii) Stop FFP to the State for a NF.

(b) *Disagreement over decision to terminate.* (1) CMS's decision to terminate the participation of a facility takes precedence when—

(i) Both CMS and the State find that the facility has not achieved substantial compliance; and

(ii) CMS, but not the State, finds that the facility's participation should be terminated. CMS will permit continuation of payment during the period prior to the effective date of termination not to exceed 6 months, if the applicable conditions of § 488.450 are met.

(2) The State's decision to terminate a facility's participation and the procedures for appealing such termination, as specified in § 431.153(c) of this chapter, takes precedence when—

(i) The State, but not CMS, finds that a NF's participation should be terminated; and

(ii) The State's effective date for the termination of the NF's provider agreement is no later than 6 months after the last day of survey.

(c) *Disagreement over timing of termination of facility.* The State's timing of termination takes precedence if it does not occur later than 6 months after the last day of the survey when both CMS and the State find that—

(1) A facility is not in substantial compliance; and

(2) The facility's participation should be terminated.

(d) *Disagreement over remedies.* (1) When CMS or the State, but not both, establishes one or more remedies, in addition to or as an alternative to termination, the additional or alternative remedies will also apply when—

(i) Both CMS and the State find that a facility has not achieved substantial compliance; and

(ii) Both CMS and the State find that no immediate jeopardy exists.

(2) *Overlap of remedies.* When CMS and the State establish one or more remedies, in addition to or as an alternative to termination, only the CMS remedies apply when both CMS and the State find that a facility has not achieved substantial compliance.

(e) Regardless of whether CMS's or the State's decision controls, only one noncompliance and enforcement decision is applied to the Medicaid agreement, and for a dually participating facility, that same decision will apply to the Medicare agreement.

§ 488.454 Duration of remedies.

(a) Except as specified in paragraphs (b) and (d) of this section, alternative remedies continue until—

(1) The facility has achieved substantial compliance, as determined by CMS or the State based upon a revisit or after an examination of credible written evidence that it can verify without an on-site visit; or

(2) CMS or the State terminates the provider agreement.

(b) In the cases of State monitoring and denial of payment imposed for repeated substandard quality of care, remedies continue until—

(1) CMS or the State determines that the facility has achieved substantial compliance and is capable of remaining in substantial compliance; or

(2) CMS or the State terminates the provider agreement.

(c) In the case of temporary management, the remedy continues until—

(1) CMS or the State determines that the facility has achieved substantial compliance and is capable of remaining in substantial compliance;

(2) CMS or the State terminates the provider agreement; or

(3) The facility which has not achieved substantial compliance reassumes management control. In this case, CMS or the State initiates termination of the provider agreement and may impose additional remedies.

(d) In the case of a civil money penalty imposed for an instance of noncompliance, the remedy is the specific amount of the civil money penalty imposed for the particular deficiency.

(e) If the facility can supply documentation acceptable to CMS or the State survey agency that it was in substantial compliance and was capable of remaining in substantial compliance, if necessary, on a date preceding that of the revisit, the remedies terminate on the date that CMS or the State can verify as the date that substantial compliance was achieved and the facility demonstrated that it could maintain substantial compliance, if necessary.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995, as amended at 64 FR 13361, Mar. 18, 1999]

§ 488.456 Termination of provider agreement.

(a) *Effect of termination.* Termination of the provider agreement ends—

(1) Payment to the facility; and

(2) Any alternative remedy.

(b) *Basis for termination.* (1) CMS and the State may terminate a facility's provider agreement if a facility—

(i) Is not in substantial compliance with the requirements of participation, regardless of whether or not immediate jeopardy is present; or

(ii) Fails to submit an acceptable plan of correction within the timeframe specified by CMS or the State.

(2) CMS and the State terminate a facility's provider agreement if a facility—

(i) Fails to relinquish control to the temporary manager, if that remedy is imposed by CMS or the State; or

(ii) Does not meet the eligibility criteria for continuation of payment as set forth in § 488.412(a)(1).

(c) *Notice of termination.* Before terminating a provider agreement, CMS does and the State must notify the facility and the public—

(1) At least 2 calendar days before the effective date of termination for a facility with immediate jeopardy deficiencies; and

(2) At least 15 calendar days before the effective date of termination for a facility with non-immediate jeopardy deficiencies that constitute noncompliance.

(d) *Procedures for termination.* (1) CMS terminates the provider agreement in accordance with procedures set forth in § 489.53 of this chapter; and

(2) The State must terminate the provider agreement of a NF in accordance with procedures specified in parts 431 and 442 of this chapter.

Subpart G [Reserved]

Subpart H—Termination of Medicare Coverage and Alternative Sanctions for End-Stage Renal Disease (ESRD) Facilities

SOURCE: 73 FR 20475, Apr. 15, 2008, unless otherwise noted.

§ 488.604 Termination of Medicare coverage.

(a) Except as otherwise provided in this subpart, failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in part 494 of this chapter will result in termination of Medicare coverage of the services furnished by the supplier.

(b) If termination of coverage is based solely on a supplier's failure to participate in network activities and pursue network goals, as required at § 494.180(i) of this chapter, coverage may be reinstated when CMS determines that the supplier is making reasonable and appropriate efforts to meet that condition.

(c) If termination of coverage is based on failure to meet any of the other conditions specified in part 494 of this chapter, coverage will not be reinstated until CMS finds that the reason for termination has been removed and there is reasonable assurance that it will not recur.

§ 488.606 Alternative sanctions.

(a) *Basis for application of alternative sanctions.* CMS may, as an alternative to termination of Medicare coverage,

impose one of the sanctions specified in paragraph (b) of this section if CMS finds that—

(1) The supplier fails to participate in the activities and pursue the goals of the ESRD network that is designated to encompass the supplier's geographic area; and

(2) This failure does not jeopardize patient health and safety.

(b) *Alternative sanctions.* The alternative sanctions that CMS may apply in the circumstances specified in paragraph (a) of this section include the following:

(1) Denial of payment for services furnished to patients first accepted for care after the effective date of the sanction as specified in the sanction notice.

(2) Reduction of payments, for all ESRD services furnished by the supplier, by 20 percent for each 30-day period after the effective date of the sanction.

(3) Withholding of all payments, without interest, for all ESRD services furnished by the supplier to Medicare beneficiaries.

(c) *Duration of alternative sanction.* An alternative sanction remains in effect until CMS finds that the supplier is in substantial compliance with the requirement to cooperate in the network plans and goals, or terminates coverage of the supplier's services for lack of compliance.

§ 488.608 Notice of alternative sanction and appeal rights: Termination of coverage.

(a) *Notice of alternative sanction.* CMS gives the supplier and the general public notice of the alternative sanction and of the effective date of the sanction. The effective date of the alternative sanction is at least 30 days after the date of the notice.

(b) *Appeal rights.* Termination of Medicare coverage of a supplier's ESRD services because the supplier no longer meets the conditions for coverage of its services is an initial determination appealable under part 498 of this chapter.

§ 488.610 Notice of appeal rights: Alternative sanctions.

If CMS proposes to apply an alternative sanction specified in § 488.606(b), the following rules apply:

(a) CMS gives the facility notice of the proposed alternative sanction and 15 days in which to request a hearing.

(b) If the facility requests a hearing, CMS provides an informal hearing by a CMS official who was not involved in making the appealed decision.

(c) During the informal hearing, the facility—

(1) May be represented by counsel;

(2) Has access to the information on which the allegation was based; and

(3) May present, orally or in writing, evidence and documentation to refute the finding of failure to participate in network activities and pursue network goals.

(d) If the written decision of the informal hearing supports application of the alternative sanction, CMS provides the facility and the public, at least 30 days before the effective date of the alternative sanction, a written notice that specifies the effective date and the reasons for the alternative sanction.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

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AUTHORITY: Secs. 1102, 1819, 1820(e), 1861, 1864(m), 1866, 1869, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh).

SOURCE: 45 FR 22937, Apr. 4, 1980, unless otherwise noted.

Subpart A—General Provisions

§ 489.1 Statutory basis.

(a) This part implements section 1866 of the Social Security Act (the Act). Section 1866 of the Act specifies the terms of provider agreements, the grounds for terminating a provider agreement, the circumstances under which payment for new admissions may be denied, and the circumstances under which payment may be withheld for failure to make timely utilization review. The sections of the Act specified in paragraphs (a)(1) through (a)(4) of this section are also pertinent.

(1) Section 1861 of the Act defines the services covered under Medicare and the providers that may be reimbursed for furnishing those services.

(2) Section 1864 of the Act provides for the use of State survey agencies to ascertain whether certain entities meet the conditions of participation.

(3) Section 1865(a)(1) of the Act provides that an entity accredited by a national accreditation body found by the Secretary to satisfy the Medicare conditions of participation, conditions for coverage, or conditions of certification or requirements for participation shall be treated as meeting those requirements. Section 1865(a)(2) of the Act requires the Secretary to consider when making such a finding, among other things, the national accreditation body's accreditation requirements and survey procedures.

(4) Section 1871 of the Act authorizes the Secretary to prescribe regulations for the administration of the Medicare program.

(b) Although section 1866 of the Act speaks only to providers and provider agreements, the effective date rules in this part are made applicable also to the approval of suppliers that meet the requirements specified in § 489.13.

(c) Section 1861(o)(7) of the Act requires each HHA to provide CMS with a surety bond.

[75 FR 50418, Aug. 16, 2010]

§ 489.2 Scope of part.

(a) Subpart A of this part sets forth the basic requirements for submittal and acceptance of a provider agreement under Medicare. Subpart B of this part specifies the basic commitments and limitations that the provider must agree to as part of an agreement to provide services. Subpart C specifies the limitations on allowable charges to beneficiaries for deductibles, coinsurance, copayments, blood, and services that must be part of the provider agreement. Subpart D of this part specifies how incorrect collections are to be handled. Subpart F sets forth the circumstances and procedures for denial of payments for new admissions and for withholding of payment as an alternative to termination of a provider agreement.

(b) The following providers are subject to the provisions of this part:

(1) Hospitals.

(2) Skilled nursing facilities (SNFs).

(3) Home health agencies (HHAs).

(4) Clinics, rehabilitation agencies, and public health agencies.

(5) Comprehensive outpatient rehabilitation facilities (CORFs).

(6) Hospices.

(7) Critical access hospital (CAHs).

(8) Community mental health centers (CMHCs).

(9) Religious nonmedical health care institutions (RNHCIs).

(c)(1) Clinics, rehabilitation agencies, and public health agencies may enter into provider agreements only for furnishing outpatient physical therapy, and speech pathology services.

(2) CMHCs may enter into provider agreements only to furnish partial hospitalization services.

[45 FR 22937, Apr. 4, 1980, as amended at 47 FR 56297, Dec. 15, 1982; 48 FR 56036, Dec. 15, 1983; 51 FR 24492, July 3, 1986; 58 FR 30676, May 26, 1993; 59 FR 6578, Feb. 11, 1994; 62 FR 46037, Aug. 29, 1997; 68 FR 66720, Nov. 28, 2003]

§ 489.3 Definitions.

For purposes of this part—

Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.

Physician-owned hospital means any participating hospital (as defined in § 489.24) in which a physician, or an immediate family member of a physician (as defined in § 411.351 of this chapter), has an ownership or investment interest in the hospital. The ownership or investment interest may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in the hospital. This definition does not include a hospital with physician ownership or investment interests that satisfy the requirements at § 411.356(a) or (b) of this chapter.

Provider agreement means an agreement between CMS and one of the providers specified in § 489.2(b) to provide services to Medicare beneficiaries and to comply with the requirements of section 1866 of the Act.

[48 FR 39837, Sept. 1, 1983, as amended at 51 FR 24492, July 3, 1986; 54 FR 5373, Feb. 2, 1989; 59 FR 56250, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995; 72 FR 47412, Aug. 22, 2007; 73 FR 48757, Aug. 19, 2008]

§ 489.10 Basic requirements.

(a) Any of the providers specified in § 489.2 may request participation in Medicare. In order to be accepted, it must meet the conditions of participation or requirements (for SNFs) set forth in this section and elsewhere in this chapter. The RNHCIs must meet the conditions for coverage, conditions for participation and the requirements set forth in this section and elsewhere in this chapter.

(b) In order to participate in the Medicare program, the provider must

meet the applicable civil rights requirements of:

(1) Title VI of the Civil Rights Act of 1964, as implemented by 45 CFR part 80, which provides that no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subject to discrimination under, any program or activity receiving Federal financial assistance (section 601);

(2) Section 504 of the Rehabilitation Act of 1973, as implemented by 45 CFR part 84, which provides that no qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subject to discrimination under any program or activity receiving Federal financial assistance;

(3) The Age Discrimination Act of 1975, as implemented by 45 CFR part 90, which is designed to prohibit discrimination on the basis of age in programs or activities receiving Federal financial assistance. The Age Discrimination Act also permits federally assisted programs and activities, and recipients of Federal funds, to continue to use certain age distinctions, and factors other than age, that meet the requirements of the Age Discrimination Act and 45 CFR part 90; and

(4) Other pertinent requirements of the Office of Civil Rights of HHS.

(c) In order for a hospital, SNF, HHA, hospice, or RNHCI to be accepted, it must also meet the advance directives requirements specified in subpart I of this part.

(d) The State survey agency will ascertain whether the provider meets the conditions of participation or requirements (for SNFs) and make its recommendations to CMS.

(e) In order for a home health agency to be accepted, it must also meet the surety bond requirements specified in subpart F of this part.

(f) In order for a home health agency to be accepted as a new provider, it must also meet the capitalization requirements specified in subpart B of this part.

[58 FR 61843, Nov. 23, 1993, as amended at 59 FR 6578, Feb. 11, 1994; 63 FR 312, Jan. 5, 1998; 68 FR 66720, Nov. 28, 2003]

§ 489.11 Acceptance of a provider as a participant.

(a) *Action by CMS.* If CMS determines that the provider meets the requirements, it will send the provider—

(1) Written notice of that determination; and

(2) Two copies of the provider agreement.

(b) *Action by provider.* If the provider wishes to participate, it must return both copies of the agreement, duly signed by an authorized official, to CMS, together with a written statement indicating whether it has been adjudged insolvent or bankrupt in any State or Federal court, or whether any insolvency or bankruptcy actions are pending.

(c) *Notice of acceptance.* If CMS accepts the agreement, it will return one copy to the provider with a written notice that—

(1) Indicates the dates on which it was signed by the provider's representative and accepted by CMS; and

(2) Specifies the effective date of the agreement.

[45 FR 22937, Apr. 4, 1980, as amended at 59 FR 56251, Nov. 10, 1994; 62 FR 43937, Aug. 18, 1997]

§ 489.12 Decision to deny an agreement.

(a) *Bases for denial.* CMS may refuse to enter into an agreement for any of the following reasons:

(1) Principals of the prospective provider have been convicted of fraud (see § 420.204 of this chapter);

(2) The prospective provider has failed to disclose ownership and control interests in accordance with § 420.206 of this chapter;

(3) The prospective provider is a physician-owned hospital as defined in § 489.3 and does not have procedures in place for making physician ownership disclosures to patients in accordance with § 489.20(u); or

(4) The prospective provider is unable to give satisfactory assurance of compliance with the requirements of title XVIII of the Act.

(b) [Reserved]

(c) *Compliance with civil rights requirements.* CMS will not enter into a provider agreement if the provider fails to comply with civil rights requirements

set forth in 45 CFR parts 80, 84, and 90, subject to the provisions of § 489.10.

[45 FR 22937, Apr. 4, 1980, as amended at 51 FR 34833, Sept. 30, 1986; 54 FR 4027, Jan. 27. 1989; 59 FR 6578, Feb. 11, 1994; 59 FR 56251, Nov. 10, 1994; 72 FR 47413, Aug. 22, 2007]

§ 489.13 Effective date of agreement or approval.

(a) *Applicability*—(1) *General rule*. Except as provided in paragraph (a)(2) of this section, this section applies to Medicare provider agreements with, and supplier approval of, entities that, as a basis for participation in Medicare are subject to a determination by CMS on the basis of—

(i) A survey conducted by the State survey agency or CMS surveyors; or

(ii) In lieu of such State survey agency or CMS conducted survey, accreditation by an accreditation organization whose program has CMS approval in accordance with section 1865 of the Act at the time of the accreditation survey and accreditation decision.

(2) *Exceptions*. (i) For an agreement with a community mental health center (CMHC) or a federally qualified health center (FQHC), the effective date is the date on which CMS accepts a signed agreement which assures that the CMHC or FQHC meets all Federal requirements.

(ii) A Medicare supplier approval of a laboratory is effective only while the laboratory has in effect a valid CLIA certificate issued under part 493 of this chapter, and only for the specialty and subspecialty tests it is authorized to perform.

(b) *All health and safety standards are met on the date of survey*. The agreement or approval is effective on the date the State agency, CMS, or the CMS contractor survey (including the Life Safety Code survey, if applicable) is completed, or on the effective date of the accreditation decision, as applicable, if on that date the provider or supplier meets all applicable Federal requirements as set forth in this chapter. (If the agreement or approval is time-limited, the new agreement or approval is effective on the day following the expiration of the current agreement or approval.) However, the effective date of the agreement or approval may not be earlier than the latest of the dates on which CMS determines that each applicable Federal requirement is met. Federal requirements include, but are not limited to—

(1) Enrollment requirements established in part 424, subpart P, of this chapter. CMS determines, based upon its review and verification of the prospective provider's or supplier's enrollment application, the date on which enrollment requirements have been met;

(2) The requirements identified in §§ 489.10 and 489.12; and

(3) The applicable Medicare health and safety standards, such as the applicable conditions of participation, the requirements for participation, the conditions for coverage, or the conditions for certification.

(c) *All health and safety standards are not met on the date of survey*. If, on the date the survey is completed, the provider or supplier has failed to meet any one of the applicable health and safety standards, the following rules apply for determining the effective date of the provider agreement or supplier approval, assuming that no other Federal requirements remain to be satisfied. However, if other Federal requirements remain to be satisfied, notwithstanding the provisions of paragraphs (c)(1) through (c)(3) of this section, the effective date of the agreement or approval may not be earlier than the latest of the dates on which CMS determines that each applicable Federal requirement is met.

(1) For an agreement with an SNF, the effective date is the date on which—

(i) The SNF is in substantial compliance (as defined in § 488.301 of this chapter) with the requirements for participation; and

(ii) CMS or the State survey agency receives from the SNF, if applicable, an approvable waiver request.

(2) For an agreement with, or an approval of, any other provider or supplier, (except those specified in paragraph (a)(2) of this section), the effective date is the earlier of the following:

(i) The date on which the provider or supplier meets all applicable conditions of participation, conditions for coverage, or conditions for certification; or, if applicable, the date of a

CMS-approved accreditation organization program's positive accreditation decision, issued after the accreditation organization has determined that the provider or supplier meets all applicable conditions.

(ii) The date on which a provider or supplier is found to meet all conditions of participation, conditions for coverage, or conditions for certification, but has lower-level deficiencies, and—

(A) CMS or the State survey agency receives an acceptable plan of correction for the lower-level deficiencies (the date of receipt is the effective date regardless of when the plan of correction is approved); or, if applicable, a CMS-approved accreditation organization program issues a positive accreditation decision after it receives an acceptable plan of correction for the lower-level deficiencies; or

(B) CMS receives an approvable waiver request (the date of receipt is the effective date regardless of when CMS approves the waiver request).

(3) For an agreement with any other provider or an approval of any other supplier (except those specified in paragraph (a)(2) of this section) that is found to meet all conditions of participation, conditions for coverage, or conditions for certification, but has lower-level deficiencies and has submitted both an approvable plan of correction/positive accreditation decision and an approvable waiver request, the effective date is the later of the dates that result when calculated in accordance with paragraph (c)(2)(ii)(A) or (c)(2)(ii)(B) of this section.

[75 FR 50418, Aug. 16, 2010]

§ 489.18 Change of ownership or leasing: Effect on provider agreement.

(a) *What constitutes change of ownership*—(1) *Partnership*. In the case of a partnership, the removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable State law, constitutes change of ownership.

(2) *Unincorporated sole proprietorship*. Transfer of title and property to another party constitutes change of ownership.

(3) *Corporation*. The merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation constitutes change of ownership. Transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute change of ownership.

(4) *Leasing*. The lease of all or part of a provider facility constitutes change of ownership of the leased portion.

(b) *Notice to CMS*. A provider who is contemplating or negotiating a change of ownership must notify CMS.

(c) *Assignment of agreement*. When there is a change of ownership as specified in paragraph (a) of this section, the existing provider agreement will automatically be assigned to the new owner.

(d) *Conditions that apply to assigned agreements*. An assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued including, but not limited to, the following:

(1) Any existing plan of correction.

(2) Compliance with applicable health and safety standards.

(3) Compliance with the ownership and financial interest disclosure requirements of part 420, subpart C, of this chapter.

(4) Compliance with civil rights requirements set forth in 45 CFR Parts 80, 84, and 90.

(e) *Effect of leasing*. The provider agreement will be assigned to the lessee only to the extent of the leased portion of the facility.

[45 FR 22937, Apr. 4, 1980, as amended at 59 FR 56251, Nov. 10, 1994]

Subpart B—Essentials of Provider Agreements

§ 489.20 Basic commitments.

The provider agrees to the following:

(a) To limit its charges to beneficiaries and to other individuals on their behalf, in accordance with provisions of subpart C of this part.

(b) To comply with the requirements of subpart D of this part for the return or other disposition of any amounts incorrectly collected from a beneficiary or any other person in his or her behalf.

(c) To comply with the requirements of § 420.203 of this chapter when it hires certain former employees of intermediaries.

(d) In the case of a hospital or a CAH that furnishes services to Medicare beneficiaries, either to furnish directly or to make arrangements (as defined in § 409.3 of this chapter) for all Medicare-covered services to inpatients and outpatients of a hospital or a CAH except the following:

(1) Physicians' services that meet the criteria of § 415.102(a) of this chapter for payment on a reasonable charge basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act, that are furnished after December 31, 1990.

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Certified nurse-midwife services, as defined in section 1861(ff) of the Act, that are furnished after December 31, 1990.

(5) Qualified psychologist services, as defined in section 1861(ii) of the Act, that are furnished after December 31, 1990.

(6) Services of an anesthetist, as defined in § 410.69 of this chapter.

(e) In the case of a hospital or CAH that furnishes inpatient hospital services or inpatient CAH services for which payment may be made under Medicare, to maintain an agreement with a QIO for that organization to review the admissions, quality, appropriateness, and diagnostic information related to those inpatient services. The requirement of this paragraph (e) applies only if, for the area in which the hospital or CAH is located, there is a QIO that has a contract with CMS under part B of title XI of the Act.

(f) To maintain a system that, during the admission process, identifies any primary payers other than Medicare, so that incorrect billing and Medicare overpayments can be prevented.

(g) To bill other primary payers before Medicare.

(h) If the provider receives payment for the same services from Medicare and another payer that is primary to Medicare, to reimburse Medicare any overpaid amount within 60 days.

(i) If the provider receives, from a payer that is primary to Medicare, a payment that is reduced because the provider failed to file a proper claim—

(1) To bill Medicare for an amount no greater than would have been payable as secondary payment if the primary insurer's payment had been based on a proper claim; and

(2) To charge the beneficiary only: (i) The amount it would have been entitled to charge if it had filed a proper claim and received payment based on such a claim; and

(ii) An amount equal to any primary payment reduction attributable to failure to file a proper claim, but only if the provider can show that—

(A) It failed to file a proper claim solely because the beneficiary, for any reason other than mental or physical incapacity, failed to give the provider the necessary information; or

(B) The beneficiary, who was responsible for filing a proper claim, failed to do so for any reason other than mental or physical incapacity.

(j) In the State of Oregon, because of a court decision, and in the absence of a reversal on appeal or a statutory clarification overturning the decision, hospitals may bill liability insurers first. However, if the liability insurer does not pay ''promptly'', as defined in § 411.50 of this chapter, the hospital must withdraw its claim or lien and bill Medicare for covered services.

(k) In the case of home health agencies that provide home health services to Medicare beneficiaries under subpart E of part 409 and subpart C f part 410 of this chapter, to offer to furnish catheters, catheter supplies, ostomy bags, and supplies related to ostomy care to any individual who requires them as part of their furnishing of home health services.

(l) In the case of a hospital as defined in § 489.24(b) to comply with § 489.24.

(m) In the case of a hospital as defined in § 489.24(b), to report to CMS or the State survey agency any time it has reason to believe it may have received an individual who has been transferred in an unstable emergency medical condition from another hospital in violation of the requirements of § 489.24(e).

(n) In the case of inpatient hospital services, to participate in any health plan contracted for under 10 U.S.C. 1079 or 1086 or 38 U.S.C. 613, in accordance with § 489.25.

(o) In the case of inpatient hospital services, to admit veterans whose admission has been authorized under 38 U.S.C. 603, in accordance with § 489.26.

(p) To comply with § 489.27 of this part concerning notification of Medicare beneficiaries of their rights associated with the termination of Medicare services.

(q) In the case of a hospital as defined in § 489.24(b)—

(1) To post conspicuously in any emergency department or in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments (that is, entrance, admitting area, waiting room, treatment area), a sign (in a form specified by the Secretary) specifying rights of individuals under Section 1867 of the Act with respect to examination and treatment for emergency medical conditions and women in labor; and

(2) To post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital or rural primary care hospital participates in the Medicaid program under a State plan approved under title XIX.

(r) In the case of a hospital as defined in § 489.24(b) (including both the transferring and receiving hospitals), to maintain—

(1) Medical and other records related to individuals transferred to or from the hospital for a period of 5 years from the date of the transfer;

(2) An on-call list of physicians who are on the hospital's medical staff or who have privileges at the hospital, or who are on the staff or have privileges at another hospital participating in a formal community call plan, in accordance with § 489.24(j)(2)(iii), available to provide treatment necessary after the initial examination to stabilize individuals with emergency medical conditions who are receiving services required under § 489.24 in accordance with the resources available to the hospital; and

(3) A central log on each individual who comes to the emergency department, as defined in § 489.24(b), seeking assistance and whether he or she refused treatment, was refused treatment, or whether he or she was transferred, admitted and treated, stabilized and transferred, or discharged.

(s) In the case of an SNF, either to furnish directly or make arrangements (as defined in § 409.3 of this chapter) for all Medicare-covered services furnished to a resident (as defined in § 411.15(p)(3) of this chapter) of the SNF, except the following:

(1) Physicians' services that meet the criteria of § 415.102(a) of this chapter for payment on a fee schedule basis.

(2) Services performed under a physician's supervision by a physician assistant who meets the applicable definition in section 1861(aa)(5) of the Act.

(3) Services performed by a nurse practitioner or clinical nurse specialist who meets the applicable definition in section 1861(aa)(5) of the Act and is working in collaboration (as defined in section 1861(aa)(6) of the Act) with a physician.

(4) Services performed by a certified nurse-midwife, as defined in section 1861(gg) of the Act.

(5) Services performed by a qualified psychologist, as defined in section 1861(ii) of the Act.

(6) Services performed by a certified registered nurse anesthetist, as defined in section 1861(bb) of the Act.

(7) Dialysis services and supplies, as defined in section 1861(s)(2)(F) of the Act, and those ambulance services that are furnished in conjunction with them.

(8) Erythropoietin (EPO) for dialysis patients, as defined in section 1861(s)(2)(O) of the Act.

(9) Hospice care, as defined in section 1861(dd) of the Act.

(10) An ambulance trip that initially conveys an individual to the SNF to be admitted as a resident, or that conveys an individual from the SNF in connection with one of the circumstances specified in § 411.15(p)(3)(i) through (p)(3)(iv) of this chapter as ending the individual's status as an SNF resident.

(11) The transportation costs of electrocardiogram equipment (HCPCS code R0076), but only with respect to those

electrocardiogram test services furnished during 1998.

(12) Services described in paragraphs (s)(1) through (6) of this section when furnished via telehealth under section 1834(m)(4)(C)(ii)(VII) of the Act.

(13) Those chemotherapy items identified, as of July 1, 1999, by HCPCS codes J9000–J9020; J9040–J9151; J9170–J9185; J9200–J9201; J9206–J9208; J9211; J9230–J9245; and J9265–J9600; and, as of January 1, 2004, by HCPCS codes A9522, A9523, A9533, and A9534.

(14) Those chemotherapy administration services identified, as of July 1, 1999, by HCPCS codes 36260–36262; 36489; 36530–36535; 36640; 36823; and 96405–96542.

(15) Those radioisotope services identified, as of July 1, 1999, by HCPCS codes 79030–79440.

(16) Those customized prosthetic devices (including artificial limbs and their components) identified, as of July 1, 1999, by HCPCS codes L5050–L5340; L5500–L5611; L5613–L5986; L5988; L6050–L6370; L6400–6880; L6920–L7274; and L7362–L7366, which are delivered for a resident's use during a stay in the SNF and intended to be used by the resident after discharge from the SNF.

(t) Hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 (or a State occupational safety and health plan that is approved under section 18(b) of the Occupational Safety and Health Act) must comply with the bloodborne pathogens (BBP) standards under 29 CFR 1910.1030. A hospital that fails to comply with the BBP standards may be subject to a civil money penalty in accordance with section 17 of the Occupational Safety and Health Act of 1970, including any adjustments of the civil money penalty amounts under the Federal Civil Penalties Inflation Adjustment Act, for a violation of the BBP standards. A civil money penalty will be imposed and collected in the same manner as civil money penalties under section 1128A(a) of the Social Security Act.

(u) Except as provided in paragraph (v) of this section, in the case of a physician-owned hospital as defined at § 489.3—

(1) To furnish written notice to each patient at the beginning of the patient's hospital stay or outpatient visit that the hospital is a physician-owned hospital, in order to assist the patient in making an informed decision regarding his or her care, in accordance with § 482.13(b)(2) of this subchapter. The notice should disclose, in a manner reasonably designed to be understood by all patients, the fact that the hospital meets the Federal definition of a physician-owned hospital specified in § 489.3 and that the list of the hospital's owners or investors who are physicians or immediate family members (as defined at § 411.351 of this chapter) of physicians is available upon request and must be provided to the patient at the time the request for the list is made by or on behalf of the patient. For purposes of this paragraph (u)(1), the hospital stay or outpatient visit begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or an outpatient service.

(2) To require each physician who is a member of the hospital's medical staff to agree, as a condition of continued medical staff membership or admitting privileges, to disclose, in writing, to all patients the physician refers to the hospital any ownership or investment interest in the hospital that is held by the physician or by an immediate family member (as defined at § 411.351 of this chapter) of the physician. Disclosure must be required at the time the referral is made.

(v) The requirements of paragraph (u) of this section do not apply to any physician-owned hospital that does not have at least one referring physician (as defined at § 411.351 of this chapter) who has an ownership or investment interest in the hospital or who has an immediate family member who has an ownership or investment interest in the hospital, provided that such hospital signs an attestation statement to that effect and maintains such attestation in its records.

(w) In the case of a hospital as defined in § 489.24(b), to furnish written notice to all patients at the beginning of their hospital stay or outpatient visit if a doctor of medicine or a doctor of osteopathy is not present in the hospital 24 hours per day, 7 days per week,

in order to assist the patients in making informed decisions regarding their care, in accordance with § 482.13(b)(2) of this subchapter. The notice must indicate how the hospital will meet the medical needs of any patient who develops an emergency medical condition, as defined in § 489.24(b), at a time when there is no physician present in the hospital. For purposes of this paragraph, the hospital stay or outpatient visit begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or outpatient service.

(x) To comply with § 488.30 of this chapter, to pay revisit user fees when and if assessed.

[45 FR 22937, Apr. 4, 1980, as amended at 48 FR 39837, Sept. 1, 1983; 49 FR 323, Jan. 3, 1984; 54 FR 41747, Oct. 11, 1989; 57 FR 36018, Aug. 12, 1992; 58 FR 30677, May 26, 1993; 59 FR 32120, June 22, 1994; 60 FR 63189, Dec. 8, 1995; 62 FR 46037, Aug. 29, 1997; 63 FR 26312, May 12, 1998; 65 FR 18548, Apr. 7, 2000; 65 FR 46796, July 31, 2000; 66 FR 39601, July 31, 2001; 68 FR 16669, Apr. 4, 2003; 68 FR 43942, July 25, 2003; 68 FR 46072, Aug. 4, 2003; 69 FR 49272, Aug. 11, 2004; 70 FR 45055, Aug. 4, 2005; 71 FR 9471, Feb. 24, 2006; 72 FR 47413, Aug. 22, 2007; 72 FR 53649, Sept. 19, 2007; 73 FR 48757, Aug. 19, 2008; 73 FR 69942, Nov. 19, 2008]

EFFECTIVE DATE NOTE: At 59 FR 32120, June 22, 1994, in § 489.20, paragraphs (l) through (r) were added. Paragraphs (m), (r)(2) and (r)(3) contain information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 489.21 Specific limitations on charges.

Except as specified in subpart C of this part, the provider agrees not to charge a beneficiary for any of the following:

(a) Services for which the beneficiary is entitled to have payment made under Medicare.

(b) Services for which the beneficiary would be entitled to have payment made if the provider—

(1) Had in its files the required certification and recertification by a physician relating to the services furnished to the beneficiary;

(2) Had furnished the information required by the intermediary in order to determine the amount due the provider on behalf of the individual for the period with respect to which payment is to be made or any prior period;

(3) Had complied with the provisions requiring timely utilization review of long stay cases so that a limitation on days of service has not been imposed under section 1866(d) of the Act (see subpart K of part 405 and part 482 of this chapter for utilization review requirements); and

(4) Had obtained, from the beneficiary or a person acting on his or her behalf, a written request for payment to be made to the provider, and had properly filed that request. (If the beneficiary or person on his or her behalf refuses to execute a written request, the provider may charge the beneficiary for all services furnished to him or her.)

(c) Inpatient hospital services furnished to a beneficiary who exhausted his or her Part A benefits, if CMS reimburses the provider for those services.

(d) Custodial care and services not reasonable and necessary for the diagnosis or treatment of illness or injury, if—

(1) The beneficiary was without fault in incurring the expenses; and

(2) The determination that payment was incorrect was not made until after the third year following the year in which the payment notice was sent to the beneficiary.

(e) Inpatient hospital services for which a beneficiary would be entitled to have payment made under Part A of Medicare but for a denial or reduction in payments under regulations at § 412.48 of this chapter or under section 1886(f) of the Act.

(f) Items and services furnished to a hospital inpatient (other than physicians' services as described in § 415.102(a) of this chapter or the services of an anesthetist as described in § 405.553(b)(4) of this chapter) for which Medicare payment would be made if furnished by the hospital or by other providers or suppliers under arrangements made with them by the hospital. For this purpose, a charge by another provider or supplier for such an item or service is treated as a charge by the hospital for the item or service, and is also prohibited.

(g) [Reserved]

(h) Items and services (other than those described in §§ 489.20(s)(1) through (15)) required to be furnished under § 489.20(s) to a resident of an SNF (defined in § 411.15(p) of this chapter), for which Medicare payment would be made if furnished by the SNF or by other providers or suppliers under arrangements made with them by the SNF. For this purpose, a charge by another provider or supplier for such an item or service is treated as a charge by the SNF for the item or service, and is also prohibited.

[49 FR 324, Jan. 3, 1984, as amended at 51 FR 22052, June 17, 1986; 52 FR 27765, July 23, 1987; 60 FR 63189, Dec. 8, 1995; 64 FR 41683, July 30, 1999; 65 FR 46796, July 31, 2000; 65 FR 62646, Oct. 19, 2000; 66 FR 39601, July 31, 2001]

§ 489.22 Special provisions applicable to prepayment requirements.

(a) A provider may not require an individual entitled to hospital insurance benefits to prepay in part or in whole for inpatient services as a condition of admittance as an inpatient, except where it is clear upon admission that payment under Medicare, Part A cannot be made.

(b) A provider may not deny covered inpatient services to an individual entitled to have payment made for those services on the ground of inability or failure to pay a requested amount at or before admission.

(c) A provider may not evict, or threaten to evict, an individual for inability to pay a deductible or a coinsurance amount required under Medicare.

(d) A provider may not charge an individual for (1) its agreement to admit or readmit the individual on some specified future date for covered inpatient services; or (2) for failure to remain an inpatient for any agreed-upon length of time or for failure to give advance notice of departure from the provider's facilities.

[45 FR 22937, Apr. 4, 1980, as amended at 68 FR 46072, Aug. 4, 2003]

§ 489.23 Specific limitation on charges for services provided to certain enrollees of fee-for-service FEHB plans.

A provider that furnishes inpatient hospital services to a retired Federal worker age 65 or older who is enrolled in a fee-for-service FEHB plan and who is not covered under Medicare Part A, must accept, as payment in full, an amount that approximates as closely as possible the Medicare inpatient hospital prospective payment system (PPS) rate established under part 412. The payment to the provider is composed of a payment from the FEHB plan and a payment from the enrollee. This combined payment approximates the Medicare PPS rate. The payment from the FEHB plan approximates, as closely as possible, the Medicare PPS rate minus any applicable enrollee deductible, coinsurance, or copayment amount. The payment from the enrollee is equal to the applicable deductible, coinsurance, or copayment amount.

[62 FR 56111, Oct. 29, 1997]

§ 489.24 Special responsibilities of Medicare hospitals in emergency cases.

(a) *Applicability of provisions of this section.* (1) In the case of a hospital that has an emergency department, if an individual (whether or not eligible for Medicare benefits and regardless of ability to pay) ''comes to the emergency department'', as defined in paragraph (b) of this section, the hospital must—

(i) Provide an appropriate medical screening examination within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition exists. The examination must be conducted by an individual(s) who is determined qualified by hospital bylaws or rules and regulations and who meets the requirements of § 482.55 of this chapter concerning emergency services personnel and direction; and

(ii) If an emergency medical condition is determined to exist, provide any necessary stabilizing treatment, as defined in paragraph (d) of this section, or an appropriate transfer as defined in paragraph (e) of this section. If the hospital admits the individual as an inpatient for further treatment, the hospital's obligation under this section

ends, as specified in paragraph (d)(2) of this section.

(2)(i) When a waiver has been issued in accordance with section 1135 of the Act that includes a waiver under section 1135(b)(3) of the Act, sanctions under this section for an inappropriate transfer or for the direction or relocation of an individual to receive medical screening at an alternate location do not apply to a hospital with a dedicated emergency department if the following conditions are met:

(A) The transfer is necessitated by the circumstances of the declared emergency in the emergency area during the emergency period.

(B) The direction or relocation of an individual to receive medical screening at an alternate location is pursuant to an appropriate State emergency preparedness plan or, in the case of a public health emergency that involves a pandemic infectious disease, pursuant to a State pandemic preparedness plan.

(C) The hospital does not discriminate on the basis of an individual's source of payment or ability to pay.

(D) The hospital is located in an emergency area during an emergency period, as those terms are defined in section 1135(g)(1) of the Act.

(E) There has been a determination that a waiver of sanctions is necessary.

(ii) A waiver of these sanctions is limited to a 72-hour period beginning upon the implementation of a hospital disaster protocol, except that, if a public health emergency involves a pandemic infectious disease (such as pandemic influenza), the waiver will continue in effect until the termination of the applicable declaration of a public health emergency, as provided under section 1135(e)(1)(B) of the Act.

(b) *Definitions.* As used in this subpart—

Capacity means the ability of the hospital to accommodate the individual requesting examination or treatment of the transferred individual. Capacity encompasses such things as numbers and availability of qualified staff, beds and equipment and the hospital's past practices of accommodating additional patients in excess of its occupancy limits.

Comes to the emergency department means, with respect to an individual who is not a patient (as defined in this section), the individual—

(1) Has presented at a hospital's dedicated emergency department, as defined in this section, and requests examination or treatment for a medical condition, or has such a request made on his or her behalf. In the absence of such a request by or on behalf of the individual, a request on behalf of the individual will be considered to exist if a prudent layperson observer would believe, based on the individual's appearance or behavior, that the individual needs examination or treatment for a medical condition;

(2) Has presented on hospital property, as defined in this section, other than the dedicated emergency department, and requests examination or treatment for what may be an emergency medical condition, or has such a request made on his or her behalf. In the absence of such a request by or on behalf of the individual, a request on behalf of the individual will be considered to exist if a prudent layperson observer would believe, based on the individual's appearance or behavior, that the individual needs emergency examination or treatment;

(3) Is in a ground or air ambulance owned and operated by the hospital for purposes of examination and treatment for a medical condition at a hospital's dedicated emergency department, even if the ambulance is not on hospital grounds. However, an individual in an ambulance owned and operated by the hospital is not considered to have ''come to the hospital's emergency department'' if—

(i) The ambulance is operated under communitywide emergency medical service (EMS) protocols that direct it to transport the individual to a hospital other than the hospital that owns the ambulance; for example, to the closest appropriate facility. In this case, the individual is considered to have come to the emergency department of the hospital to which the individual is transported, at the time the individual is brought onto hospital property;

(ii) The ambulance is operated at the direction of a physician who is not employed or otherwise affiliated with the hospital that owns the ambulance; or

(4) Is in a ground or air nonhospital-owned ambulance on hospital property for presentation for examination and treatment for a medical condition at a hospital's dedicated emergency department. However, an individual in a nonhospital-owned ambulance off hospital property is not considered to have come to the hospital's emergency department, even if a member of the ambulance staff contacts the hospital by telephone or telemetry communications and informs the hospital that they want to transport the individual to the hospital for examination and treatment. The hospital may direct the ambulance to another facility if it is in ''diversionary status,'' that is, it does not have the staff or facilities to accept any additional emergency patients. If, however, the ambulance staff disregards the hospital's diversion instructions and transports the individual onto hospital property, the individual is considered to have come to the emergency department.

Dedicated emergency department means any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, that meets at least one of the following requirements:

(1) It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department;

(2) It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or

(3) During the calendar year immediately preceding the calendar year in which a determination under this section is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.

Emergency medical condition means—

(1) A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain, psychiatric disturbances and/or symptoms of substance abuse) such that the absence of immediate medical attention could reasonably be expected to result in—

(i) Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;

(ii) Serious impairment to bodily functions; or

(iii) Serious dysfunction of any bodily organ or part; or

(2) With respect to a pregnant woman who is having contractions—

(i) That there is inadequate time to effect a safe transfer to another hospital before delivery; or

(ii) That transfer may pose a threat to the health or safety of the woman or the unborn child.

Hospital includes a critical access hospital as defined in section 1861(mm)(1) of the Act.

Hospital property means the entire main hospital campus as defined in § 413.65(b) of this chapter, including the parking lot, sidewalk, and driveway, but excluding other areas or structures of the hospital's main building that are not part of the hospital, such as physician offices, rural health centers, skilled nursing facilities, or other entities that participate separately under Medicare, or restaurants, shops, or other nonmedical facilities.

Hospital with an emergency department means a hospital with a dedicated emergency department as defined in this paragraph (b).

Inpatient means an individual who is admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services as described in § 409.10(a) of this chapter with the expectation that he or she will remain at least overnight and occupy a bed even though the situation later develops that the individual can be discharged or transferred to another hospital and does not actually use a hospital bed overnight.

Labor means the process of childbirth beginning with the latent or early phase of labor and continuing through the delivery of the placenta. A woman experiencing contractions is in true labor unless a physician, certified nurse-midwife, or other qualified medical person acting within his or her scope of practice as defined in hospital

medical staff bylaws and State law, certifies that, after a reasonable time of observation, the woman is in false labor.

Participating hospital means (1) a hospital or (2) a critical access hospital as defined in section 1861(mm)(1) of the Act that has entered into a Medicare provider agreement under section 1866 of the Act.

Patient means—

(1) An individual who has begun to receive outpatient services as part of an encounter, as defined in § 410.2 of this chapter, other than an encounter that the hospital is obligated by this section to provide;

(2) An individual who has been admitted as an inpatient, as defined in this section.

Stabilized means, with respect to an ''emergency medical condition'' as defined in this section under paragraph (1) of that definition, that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility or, with respect to an ''emergency medical condition'' as defined in this section under paragraph (2) of that definition, that the woman has delivered the child and the placenta.

To stabilize means, with respect to an ''emergency medical condition'' as defined in this section under paragraph (1) of that definition, to provide such medical treatment of the condition necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility or that, with respect to an ''emergency medical condition'' as defined in this section under paragraph (2) of that definition, the woman has delivered the child and the placenta.

Transfer means the movement (including the discharge) of an individual outside a hospital's facilities at the direction of any person employed by (or affiliated or associated, directly or indirectly, with) the hospital, but does not include such a movement of an individual who (i) has been declared dead, or (ii) leaves the facility without the permission of any such person.

(c) *Use of dedicated emergency department for nonemergency services.* If an individual comes to a hospital's dedicated emergency department and a request is made on his or her behalf for examination or treatment for a medical condition, but the nature of the request makes it clear that the medical condition is not of an emergency nature, the hospital is required only to perform such screening as would be appropriate for any individual presenting in that manner, to determine that the individual does not have an emergency medical condition.

(d) *Necessary stabilizing treatment for emergency medical conditions*—(1) *General.* Subject to the provisions of paragraph (d)(2) of this section, if any individual (whether or not eligible for Medicare benefits) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either—

(i) Within the capabilities of the staff and facilities available at the hospital, for further medical examination and treatment as required to stabilize the medical condition.

(ii) For transfer of the individual to another medical facility in accordance with paragraph (e) of this section.

(2) *Exception: Application to inpatients.* (i) If a hospital has screened an individual under paragraph (a) of this section and found the individual to have an emergency medical condition, and admits that individual as an inpatient in good faith in order to stabilize the emergency medical condition, the hospital has satisfied its special responsibilities under this section with respect to that individual.

(ii) This section is not applicable to an inpatient who was admitted for elective (nonemergency) diagnosis or treatment.

(iii) A hospital is required by the conditions of participation for hospitals under Part 482 of this chapter to provide care to its inpatients in accordance with those conditions of participation.

(3) *Refusal to consent to treatment.* A hospital meets the requirements of paragraph (d)(1)(i) of this section with respect to an individual if the hospital

offers the individual the further medical examination and treatment described in that paragraph and informs the individual (or a person acting on the individual's behalf) of the risks and benefits to the individual of the examination and treatment, but the individual (or a person acting on the individual's behalf) does not consent to the examination or treatment. The medical record must contain a description of the examination, treatment, or both if applicable, that was refused by or on behalf of the individual. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of the person acting on his or her behalf). The written document should indicate that the person has been informed of the risks and benefits of the examination or treatment, or both.

(4) *Delay in examination or treatment.* (i) A participating hospital may not delay providing an appropriate medical screening examination required under paragraph (a) of this section or further medical examination and treatment required under paragraph (d)(1) of this section in order to inquire about the individual's method of payment or insurance status.

(ii) A participating hospital may not seek, or direct an individual to seek, authorization from the individual's insurance company for screening or stabilization services to be furnished by a hospital, physician, or nonphysician practitioner to an individual until after the hospital has provided the appropriate medical screening examination required under paragraph (a) of this section, and initiated any further medical examination and treatment that may be required to stabilize the emergency medical condition under paragraph (d)(1) of this section.

(iii) An emergency physician or nonphysician practitioner is not precluded from contacting the individual's physician at any time to seek advice regarding the individual's medical history and needs that may be relevant to the medical treatment and screening of the patient, as long as this consultation does not inappropriately delay services required under paragraph (a) or paragraphs (d)(1) and (d)(2) of this section.

(iv) Hospitals may follow reasonable registration processes for individuals for whom examination or treatment is required by this section, including asking whether an individual is insured and, if so, what that insurance is, as long as that inquiry does not delay screening or treatment. Reasonable registration processes may not unduly discourage individuals from remaining for further evaluation.

(5) *Refusal to consent to transfer.* A hospital meets the requirements of paragraph (d)(1)(ii) of this section with respect to an individual if the hospital offers to transfer the individual to another medical facility in accordance with paragraph (e) of this section and informs the individual (or a person acting on his or her behalf) of the risks and benefits to the individual of the transfer, but the individual (or a person acting on the individual's behalf) does not consent to the transfer. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of a person acting on his or her behalf). The written document must indicate the person has been informed of the risks and benefits of the transfer and state the reasons for the individual's refusal. The medical record must contain a description of the proposed transfer that was refused by or on behalf of the individual.

(e) *Restricting transfer until the individual is stabilized*—(1) *General.* If an individual at a hospital has an emergency medical condition that has not been stabilized (as defined in paragraph (b) of this section), the hospital may not transfer the individual unless—

(i) The transfer is an appropriate transfer (within the meaning of paragraph (e)(2) of this section); and

(ii)(A) The individual (or a legally responsible person acting on the individual's behalf) requests the transfer, after being informed of the hospital's obligations under this section and of the risk of transfer. The request must be in writing and indicate the reasons for the request as well as indicate that he or she is aware of the risks and benefits of the transfer;

(B) A physician (within the meaning of section 1861(r)(1) of the Act) has signed a certification that, based upon the information available at the time

of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual or, in the case of a woman in labor, to the woman or the unborn child, from being transferred. The certification must contain a summary of the risks and benefits upon which it is based; or

(C) If a physician is not physically present in the emergency department at the time an individual is transferred, a qualified medical person (as determined by the hospital in its bylaws or rules and regulations) has signed a certification described in paragraph (e)(1)(ii)(B) of this section after a physician (as defined in section 1861(r)(1) of the Act) in consultation with the qualified medical person, agrees with the certification and subsequently countersigns the certification. The certification must contain a summary of the risks and benefits upon which it is based.

(2) A transfer to another medical facility will be appropriate only in those cases in which—

(i) The transferring hospital provides medical treatment within its capacity that minimizes the risks to the individual's health and, in the case of a woman in labor, the health of the unborn child;

(ii) The receiving facility—

(A) Has available space and qualified personnel for the treatment of the individual; and

(B) Has agreed to accept transfer of the individual and to provide appropriate medical treatment;

(iii) The transferring hospital sends to the receiving facility all medical records (or copies thereof) related to the emergency condition which the individual has presented that are available at the time of the transfer, including available history, records related to the individual's emergency medical condition, observations of signs or symptoms, preliminary diagnosis, results of diagnostic studies or telephone reports of the studies, treatment provided, results of any tests and the informed written consent or certification (or copy thereof) required under paragraph (e)(1)(ii) of this section, and the name and address of any on-call physician (described in paragraph (g) of this section) who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment. Other records (e.g., test results not yet available or historical records not readily available from the hospital's files) must be sent as soon as practicable after transfer; and

(iv) The transfer is effected through qualified personnel and transportation equipment, as required, including the use of necessary and medically appropriate life support measures during the transfer.

(3) A participating hospital may not penalize or take adverse action against a physician or a qualified medical person described in paragraph (e)(1)(ii)(C) of this section because the physician or qualified medical person refuses to authorize the transfer of an individual with an emergency medical condition that has not been stabilized, or against any hospital employee because the employee reports a violation of a requirement of this section.

(f) *Recipient hospital responsibilities.* A participating hospital that has specialized capabilities or facilities (including, but not limited to, facilities such as burn units, shock-trauma units, neonatal intensive case units, or, with respect to rural areas, regional referral centers (which, for purposes of this subpart, mean hospitals meeting the requirements of referral centers found at § 412.96 of this chapter)) may not refuse to accept from a referring hospital within the boundaries of the United States an appropriate transfer of an individual who requires such specialized capabilities or facilities if the receiving hospital has the capacity to treat the individual.

(1) The provisions of this paragraph (f) apply to any participating hospital with specialized capabilities, regardless of whether the hospital has a dedicated emergency department.

(2) The provisions of this paragraph (f) do not apply to an individual who has been admitted to a referring hospital under the provisions of paragraph (d)(2)(i) of this section.

(g) *Termination of provider agreement.* If a hospital fails to meet the requirements of paragraph (a) through (f) of this section, CMS may terminate the

provider agreement in accordance with § 489.53.

(h) *Consultation with Quality Improvement Organizations (QIOs)*—(1) *General.* Except as provided in paragraph (h)(3) of this section, in cases where a medical opinion is necessary to determine a physician's or hospital's liability under section 1867(d)(1) of the Act, CMS requests the appropriate QIO (with a contract under Part B of title XI of the Act) to review the alleged section 1867(d) violation and provide a report on its findings in accordance with paragraph (h)(2)(iv) and (v) of this section. CMS provides to the QIO all information relevant to the case and within its possession or control. CMS, in consultation with the OIG, also provides to the QIO a list of relevant questions to which the QIO must respond in its report.

(2) *Notice of review and opportunity for discussion and additional information.* The QIO shall provide the physician and hospital reasonable notice of its review, a reasonable opportunity for discussion, and an opportunity for the physician and hospital to submit additional information before issuing its report. When a QIO receives a request for consultation under paragraph (h)(1) of this section, the following provisions apply—

(i) The QIO reviews the case before the 15th calendar day and makes its tentative findings.

(ii) Within 15 calendar days of receiving the case, the QIO gives written notice, sent by certified mail, return receipt requested, to the physician or the hospital (or both if applicable).

(iii)(A) The written notice must contain the following information:

(*1*) The name of each individual who may have been the subject of the alleged violation.

(*2*) The date on which each alleged violation occurred.

(*3*) An invitation to meet, either by telephone or in person, to discuss the case with the QIO, and to submit additional information to the QIO within 30 calendar days of receipt of the notice, and a statement that these rights will be waived if the invitation is not accepted. The QIO must receive the information and hold the meeting within the 30-day period.

(*4*) A copy of the regulations at 42 CFR 489.24.

(B) For purposes of paragraph (h)(2)(iii)(A) of this section, the date of receipt is presumed to be 5 days after the certified mail date on the notice, unless there is a reasonable showing to the contrary.

(iv) The physician or hospital (or both where applicable) may request a meeting with the QIO. This meeting is not designed to be a formal adversarial hearing or a mechanism for discovery by the physician or hospital. The meeting is intended to afford the physician and/or the hospital a full and fair opportunity to present the views of the physician and/or hospital regarding the case. The following provisions apply to that meeting:

(A) The physician and/or hospital has the right to have legal counsel present during that meeting. However, the QIO may control the scope, extent, and manner of any questioning or any other presentation by the attorney. The QIO may also have legal counsel present.

(B) The QIO makes arrangements so that, if requested by CMS or the OIG, a verbatim transcript of the meeting may be generated. If CMS or OIG requests a transcript, the affected physician and/or the affected hospital may request that CMS provide a copy of the transcript.

(C) The QIO affords the physician and/or the hospital an opportunity to present, with the assistance of counsel, expert testimony in either oral or written form on the medical issues presented. However, the QIO may reasonably limit the number of witnesses and length of such testimony if such testimony is irrelevant or repetitive. The physician and/or hospital, directly or through counsel, may disclose patient records to potential expert witnesses without violating any non-disclosure requirements set forth in part 476 of this chapter.

(D) The QIO is not obligated to consider any additional information provided by the physician and/or the hospital after the meeting, unless, before the end of the meeting, the QIO requests that the physician and/or hospital submit additional information to

support the claims. The QIO then allows the physician and/or the hospital an additional period of time, not to exceed 5 calendar days from the meeting, to submit the relevant information to the QIO.

(v) Within 60 calendar days of receiving the case, the QIO must submit to CMS a report on the QIO's findings. CMS provides copies to the OIG and to the affected physician and/or the affected hospital. The report must contain the name of the physician and/or the hospital, the name of the individual, and the dates and times the individual arrived at and was transferred (or discharged) from the hospital. The report provides expert medical opinion regarding whether the individual involved had an emergency medical condition, whether the individual's emergency medical condition was stabilized, whether the individual was transferred appropriately, and whether there were any medical utilization or quality of care issues involved in the case.

(vi) The report required under paragraph (h)(2)(v) of this section should not state an opinion or conclusion as to whether section 1867 of the Act or § 489.24 has been violated.

(3) If a delay would jeopardize the health or safety of individuals or when there was no screening examination, the QIO review described in this section is not required before the OIG may impose civil monetary penalties or an exclusion in accordance with section 1867(d)(1) of the Act and 42 CFR part 1003 of this title.

(4) If the QIO determines after a preliminary review that there was an appropriate medical screening examination and the individual did not have an emergency medical condition, as defined by paragraph (b) of this section, then the QIO may, at its discretion, return the case to CMS and not meet the requirements of paragraph (h) except for those in paragraph (h)(2)(v).

(i) *Release of QIO assessments.* Upon request, CMS may release a QIO assessment to the physician and/or hospital, or the affected individual, or his or her representative. The QIO physician's identity is confidential unless he or she consents to its release. (See §§ 476.132 and 476.133 of this chapter.)

(j) *Availability of on-call physicians.* In accordance with the on-call list requirements specified in § 489.20(r)(2), a hospital must have written policies and procedures in place—

(1) To respond to situations in which a particular specialty is not available or the on-call physician cannot respond because of circumstances beyond the physician's control; and

(2) To provide that emergency services are available to meet the needs of individuals with emergency medical conditions if a hospital elects to—

(i) Permit on-call physicians to schedule elective surgery during the time that they are on call;

(ii) Permit on-call physicians to have simultaneous on-call duties; and

(iii) Participate in a formal community call plan. Notwithstanding participation in a community call plan, hospitals are still required to perform medical screening examinations on individuals who present seeking treatment and to conduct appropriate transfers. The formal community plan must include the following elements:

(A) A clear delineation of on-call coverage responsibilities; that is, when each hospital participating in the plan is responsible for on-call coverage.

(B) A description of the specific geographic area to which the plan applies.

(C) A signature by an appropriate representative of each hospital participating in the plan.

(D) Assurances that any local and regional EMS system protocol formally includes information on community on-call arrangements.

(E) A statement specifying that even if an individual arrives at a hospital that is not designated as the on-call hospital, that hospital still has an obligation under § 489.24 to provide a medical screening examination and stabilizing treatment within its capability, and that hospitals participating in the community call plan must abide by the regulations under § 489.24 governing appropriate transfers.

(F) An annual assessment of the community call plan by the participating hospitals.

[59 FR 32120, June 22, 1994, as amended at 62 FR 46037, Aug. 29, 1997; 65 FR 18548, Apr. 7, 2000; 65 FR 59748, Oct. 6, 2000; 66 FR 1599, Jan. 9, 2001; 66 FR 59923, Nov. 30, 2001; 68 FR 53262, Sept. 9, 2003; 71 FR 48143, Aug. 18, 2006; 72 FR 47413, Aug. 22, 2007; 73 FR 48758, Aug. 19, 2008; 74 FR 44001, Aug. 27, 2009]

EFFECTIVE DATE NOTE: At 59 FR 32120, June 22, 1994, § 489.24 was added. Paragraphs (d) and (g) contain information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 489.25 Special requirements concerning CHAMPUS and CHAMPVA programs.

For inpatient services, a hospital that participates in the Medicare program must participate in any health plan contracted under 10 U.S.C. 1079 or 1086 (Civilian Health and Medical Program of the Uniformed Services) and under 38 U.S.C. 613 (Civilian Health and Medical Program of the Veterans Administration) and accept the CHAMPUS/CHAMPVA-determined allowable amount as payment in full, less applicable deductible, patient cost-share, and noncovered items. Hospitals must meet the requirements of 32 CFR part 199 concerning program benefits under the Department of Defense. This section applies to inpatient services furnished to beneficiaries admitted on or after January 1, 1987.

[59 FR 32123, June 22, 1994]

§ 489.26 Special requirements concerning veterans.

For inpatient services, a hospital that participates in the Medicare program must admit any veteran whose admission is authorized by the Department of Veterans Affairs under 38 U.S.C. 603 and must meet the requirements of 38 CFR part 17 concerning admissions practices and payment methodology and amounts. This section applies to services furnished to veterans admitted on and after July 1, 1987.

[59 FR 32123, June 22, 1994]

§ 489.27 Beneficiary notice of discharge rights.

(a) A hospital that participates in the Medicare program must furnish each Medicare beneficiary or enrollee, (or an individual acting on his or her behalf), timely notice as required by section 1866(A)(1)(M) of the Act and in accordance with § 405.1205 and § 422.620. The hospital must be able to demonstrate compliance with this requirement.

(b) *Notification by hospitals and other providers.* Hospitals and other providers (as identified at 489.2(b)) that participate in the Medicare program must furnish each Medicare beneficiary, or representative, applicable CMS notices in advance of discharge or termination of Medicare services, including the notices required under § 405.1200, § 405.1202, § 405.1206, and § 422.624 of this chapter.

[71 FR 68724, Nov. 27, 2006]

§ 489.28 Special capitalization requirements for HHAs.

(a) *Basic rule.* An HHA entering the Medicare program on or after January 1, 1998, including a new HHA as a result of a change of ownership, if the change of ownership results in a new provider number being issued, must have available sufficient funds, which we term ''initial reserve operating funds,'' to operate the HHA for the three month period after its Medicare provider agreement becomes effective, exclusive of actual or projected accounts receivable from Medicare or other health care insurers.

(b) *Standard.* Initial reserve operating funds are sufficient to meet the requirement of this section if the total amount of such funds is equal to or greater than the product of the actual average cost per visit of three or more similarly situated HHAs in their first year of operation (selected by CMS for comparative purposes) multiplied by the number of visits projected by the HHA for its first three months of operation—or 22.5 percent (one fourth of 90 percent) of the average number of visits reported by the comparison HHAs—whichever is greater.

(c) *Method.* CMS, through the intermediary, will determine the amount of the initial reserve operating funds using reported cost and visit data from

submitted cost reports for the first full year of operation from at least three HHAs that the intermediary serves that are comparable to the HHA that is seeking to enter the Medicare program, considering such factors as geographic location and urban/rural status, number of visits, provider-based versus free-standing, and proprietary versus non-proprietary status. The determination of the adequacy of the required initial reserve operating funds is based on the average cost per visit of the comparable HHAs, by dividing the sum of total reported costs of the HHAs in their first year of operation by the sum of the HHAs' total reported visits. The resulting average cost per visit is then multiplied by the projected visits for the first three months of operation of the HHA seeking to enter the program, but not less than 90 percent of average visits for a three month period for the HHAs used in determining the average cost per visit.

(d) *Required proof of availability of initial reserve operating funds.* The HHA must provide CMS with adequate proof of the availability of initial reserve operating funds. Such proof, at a minimum, will include a copy of the statement(s) of the HHA's savings, checking, or other account(s) that contains the funds, accompanied by an attestation from an officer of the bank or other financial institution that the funds are in the account(s) and that the funds are immediately available to the HHA. In some cases, an HHA may have all or part of the initial reserve operating funds in cash equivalents. For the purpose of this section, cash equivalents are short-term, highly liquid investments that are readily convertible to known amounts of cash and that present insignificant risk of changes in value. A cash equivalent that is not readily convertible to a known amount of cash as needed during the initial three month period for which the initial reserve operating funds are required does not qualify in meeting the initial reserve operating funds requirement. Examples of cash equivalents for the purpose of this section are Treasury bills, commercial paper, and money market funds. As with funds in a checking, savings, or other account, the HHA also must be able to document the availability of any cash equivalents. CMS later may require the HHA to furnish another attestation from the financial institution that the funds remain available, or, if applicable, documentation from the HHA that any cash equivalents remain available, until a date when the HHA will have been surveyed by the State agency or by an approved accrediting organization. The officer of the HHA who will be certifying the accuracy of the information on the HHA's cost report must certify what portion of the required initial reserve operating funds is non-borrowed funds, including funds invested in the business by the owner. That amount must be at least 50 percent of the required initial reserve operating funds. The remainder of the reserve operating funds may be secured through borrowing or line of credit from an unrelated lender.

(e) *Borrowed funds.* If borrowed funds are not in the same account(s) as the HHA's own non-borrowed funds, the HHA also must provide proof that the borrowed funds are available for use in operating the HHA, by providing, at a minimum, a copy of the statement(s) of the HHA's savings, checking, or other account(s) containing the borrowed funds, accompanied by an attestation from an officer of the bank or other financial institution that the funds are in the account(s) and are immediately available to the HHA. As with the HHA's own (that is, non-borrowed) funds, CMS later may require the HHA to establish the current availability of such borrowed funds, including furnishing an attestation from a financial institution or other source, as may be appropriate, and to establish that such funds will remain available until a date when the HHA will have been surveyed by the State agency or by an approved accrediting organization.

(f) *Line of credit.* If the HHA chooses to support the availability of a portion of the initial reserve operating funds with a line of credit, it must provide CMS with a letter of credit from the lender. CMS later may require the HHA to furnish an attestation from the

lender that the HHA, upon its certification into the Medicare program, continues to be approved to borrow the amount specified in the letter of credit.

(g) *Provider agreement.* CMS does not enter into a provider agreement with an HHA unless the HHA meets the initial reserve operating funds requirement of this section.

[63 FR 312, Jan. 5, 1998]

§ 489.29 Special requirements concerning beneficiaries served by the Indian Health Service, Tribal health programs, and urban Indian organization health programs.

(a) Hospitals (as defined in sections 1861(e) and (f) of the Social Security Act) and critical access hospitals (as defined in section 1861(mm)(1) of the Social Security Act) that participate in the Medicare program and furnish inpatient hospital services must accept the payment methodology and no more than the rates of payment established under 42 CFR part 136, subpart D as payment in full for the following programs:

(1) A contract health service (CHS) program under 42 CFR part 136, subpart C, of the Indian Health Service (IHS);

(2) A CHS program under 42 CFR part 136, subpart C, carried out by an Indian Tribe or Tribal organization pursuant to the Indian Self-Determination and Education Assistance Act, as amended, Public Law 93–638, 25 U.S.C. 450 *et seq.*; and

(3) A program funded through a grant or contract by the IHS and operated by an urban Indian organization under which items and services are purchased for an eligible urban Indian (as those terms are defined in 25 U.S.C. 1603 (f) and (h)).

(b) Hospitals and critical access hospitals may not refuse service to an individual on the basis that the payment for such service is authorized under programs described in paragraph (a) of this section.

[72 FR 30711, June 4, 2007]

Subpart C—Allowable Charges

§ 489.30 Allowable charges: Deductibles and coinsurance.

(a) *Part A deductible and coinsurance.* The provider may charge the beneficiary or other person on his or her behalf:

(1) The amount of the inpatient hospital deductible or, if less, the actual charges for the services;

(2) The amount of inpatient hospital coinsurance applicable for each day the individual is furnished inpatient hospital services after the 60th day, during a benefit period; and

(3) The posthospital SNF care coinsurance amount.

(4) In the case of durable medical equipment (DME) furnished as a home health service, 20 percent of the customary charge for the service.

(b) *Part B deductible and coinsurance.* (1) The basic allowable charges are the $75 deductible and 20 percent of the customary (insofar as reasonable) charges in excess of that deductible.

(2) For hospital outpatient services, the allowable deductible charges depend on whether the hospital can determine the beneficiary's deductible status.

(i) If the hospital is unable to determine the deductible status, it may charge the beneficiary its full customary charges up to $75.

(ii) If the beneficiary provides official information as to deductible status, the hospital may charge only the unmet portion of the deductible.

(3) In either of the cases discussed in paragraph (b)(2) of this section, the hospital is required to file with the intermediary, on a form prescribed by CMS, information as to the services, charges, and amounts collected.

(4) The intermediary must reimburse the beneficiary if reimbursement is authorized and credit the expenses to the beneficiary's deductible if the deductible has not yet been met.

(5) In the case of DME furnished as a home health service under Medicare Part B, the coinsurance is 20 percent of the customary (insofar as reasonable) charge for the services, with the following exception: If the DME is used DME purchased by or on behalf of the

beneficiary at a price at least 25 percent less than the reasonable charge for comparable new equipment, no coinsurance is required.

[45 FR 22937, Apr. 4, 1980, as amended at 51 FR 41350, Nov. 14, 1986]

§ 489.31 Allowable charges: Blood.

(a) *Limitations on charges.* (1) A provider may charge the beneficiary (or other person on his or her behalf) only for the first three pints of blood or units of packed red cells furnished under Medicare Part A during a calendar year, or furnished under Medicare Part B during a calendar year.

(2) The charges may not exceed the provider's customary charges.

(3) The provider may not charge for any whole blood or packed red cells in any of the circumstances specified in § 409.87(c)(2) of this chapter.

(b) *Offset for excessive charges.* If the charge exceeds the cost to the provider, that excess will be deducted from any Medicare payments due the provider.

[56 FR 23022, May 20, 1991, as amended at 57 FR 36018, Aug. 12, 1992]

§ 489.32 Allowable charges: Noncovered and partially covered services.

(a) *Services requested by beneficiary.* If services furnished at the request of a beneficiary (or his or her representative) are more expensive than, or in excess of, services covered under Medicare—

(1) A provider may charge the beneficiary an amount that does not exceed the difference between—

(i) The provider's customary charges for the services furnished; and

(ii) The provider's customary charges for the kinds and amounts of services that are covered under Medicare.

(2) A provider may not charge for the services unless they have been requested by the beneficiary (or his or her representative) nor require a beneficiary to request services as a condition of admission.

(3) To avoid misunderstanding and disputes, a provider must inform any beneficiary who requests a service for which a charge will be made that there will be a specified charge for that service.

(b) *Services not requested by the beneficiary.* For special provisions that apply when a provider customarily furnishes more expensive services, see § 413.35 of this chapter.

[45 FR 22937, Apr. 4, 1980, as amended at 51 FR 34833, Sept. 30, 1986]

§ 489.34 Allowable charges: Hospitals participating in State reimbursement control systems or demonstration projects.

A hospital receiving payment for a covered hospital stay under either a State reimbursement control system approved under 1886(c) of the Act or a demonstration project authorized under section 402(a) of Pub. L. 90–248 (42 U.S.C. 1395b–1) or section 222(a) of Pub. L. 92–603 (42 U.S.C. 1395b–1 (note)) and that would otherwise be subject to the prospective payment system set forth in part 412 of this chapter may charge a beneficiary for noncovered services as follows:

(a) For the custodial care and medically unnecessary services described in § 412.42(c) of this chapter, after the conditions of § 412.42(c)(1) through (c)(4) are met; and

(b) For all other services in accordance with the applicable rules of this subpart C.

[54 FR 41747, Oct. 11, 1989]

§ 489.35 Notice to intermediary.

The provider must inform its intermediary of any amounts collected from a beneficiary or from other persons on his or her behalf.

Subpart D—Handling of Incorrect Collections

§ 489.40 Definition of incorrect collection.

(a) As used in this subpart, ''incorrect collections'' means any amounts collected from a beneficiary (or someone on his or her behalf) that are not authorized under subpart C of this part.

(b) A payment properly made to a provider by an individual not considered entitled to Medicare benefits will be deemed to be an ''incorrect collection'' when the individual is found to be retroactively entitled to benefits.

§ 489.41 Timing and methods of handling.

(a) *Refund*. Prompt refund to the beneficiary or other person is the preferred method of handling incorrect collections.

(b) *Setting aside*. If the provider cannot refund within 60 days from the date on the notice of incorrect collection, it must set aside an amount, equal to the amount incorrectly collected, in a separate account identified as to the individual to whom the payment is due. This amount incorrectly collected must be carried on the provider's records in this manner until final disposition is made in accordance with the applicable State law.

(c) *Notice to, and action by, intermediary*. (1) The provider must notify the intermediary of the refund or setting aside required under paragraphs (a) and (b) of this section.

(2) If the provider fails to refund or set aside the required amounts, they may be offset against amounts otherwise due the provider.

§ 489.42 Payment of offset amounts to beneficiary or other person.

(a) In order to carry out the commitment to refund amounts incorrectly collected, CMS may determine that amounts offset in accordance with § 489.41 are to be paid directly to the beneficiary or other person from whom the provider received the incorrect collection, if:

(1) CMS finds that the provider has failed, following written request, to refund the amount of the incorrect collection to the beneficiary or other person; and

(2) The provider agreement has been terminated in accordance with the provisions of subpart E of this part.

(b) Before making a determination to make payment under paragraph (a) of this section, CMS will give written notice to the provider (1) explaining that an incorrect collection was made and the amount; (2) requesting the provider to refund the incorrect collection to the beneficiary or other person; and (3) advising of CMS's intention to make a determination under paragraph (a) of this section.

(c) The notice will afford an authorized official of the provider an opportunity to submit, within 20 days from the date on the notice, written statement or evidence with respect to the incorrect collection and/or offset amounts. CMS will consider any written statement or evidence in making a determination.

(d) Payment to a beneficiary or other person under the provisions of paragraph (a) of this section:

(1) Will not exceed the amount of the incorrect collection; and

(2) May be considered as payment made to the provider.

Subpart E—Termination of Agreement and Reinstatement After Termination

§ 489.52 Termination by the provider.

(a) *Notice to CMS*. (1) A provider that wishes to terminate its agreement must send CMS written notice of its intent.

(2) The notice may state the intended date of termination which must be the first day of a month.

(b) *Termination date*. (1) If the notice does not specify a date, or the date is not acceptable to CMS, CMS may set a date that will not be more than 6 months from the date on the provider's notice of intent.

(2) CMS may accept a termination date that is less than 6 months after the date on the provider's notice if it determines that to do so would not unduly disrupt services to the community or otherwise interfere with the effective and efficient administration of the Medicare program.

(3) A cessation of business is deemed to be a termination by the provider, effective with the date on which it stopped providing services to the community.

(c) *Public notice*. (1) The provider must give notice to the public at least 15 days before the effective date of termination.

(2) The notice must be published in one or more local newspapers and must—

(i) Specify the termination date; and

(ii) Explain to what extent services may continue after that date, in accordance with the exceptions set forth in § 489.55.

§ 489.53 Termination by CMS.

(a) *Basis for termination of agreement with any provider.* CMS may terminate the agreement with any provider if CMS finds that any of the following failings is attributable to that provider:

(1) It is not complying with the provisions of title XVIII and the applicable regulations of this chapter or with the provisions of the agreement.

(2) It places restrictions on the persons it will accept for treatment and it fails either to exempt Medicare beneficiaries from those restrictions or to apply them to Medicare beneficiaries the same as to all other persons seeking care.

(3) It no longer meets the appropriate conditions of participation or requirements (for SNFs and NFs) set forth elsewhere in this chapter. In the case of an RNHCI no longer meets the conditions for coverage, conditions of participation and requirements set forth elsewhere in this chapter.

(4) It fails to furnish information that CMS finds necessary for a determination as to whether payments are or were due under Medicare and the amounts due.

(5) It refuses to permit examination of its fiscal or other records by, or on behalf of CMS, as necessary for verification of information furnished as a basis for payment under Medicare.

(6) It failed to furnish information on business transactions as required in § 420.205 of this chapter.

(7) It failed at the time the agreement was entered into or renewed to disclose information on convicted individuals as required in § 420.204 of this chapter.

(8) It failed to furnish ownership information as required in § 420.206 of this chapter.

(9) It failed to comply with civil rights requirements set forth in 45 CFR parts 80, 84, and 90.

(10) In the case of a hospital or a critical access hospital as defined in section 1861(mm)(1) of the Act that has reason to believe it may have received an individual transferred by another hospital in violation of § 489.24(d), the hospital failed to report the incident to CMS or the State survey agency.

(11) In the case of a hospital requested to furnish inpatient services to CHAMPUS or CHAMPVA beneficiaries or to veterans, it failed to comply with § 489.25 or § 489.26, respectively.

(12) It failed to furnish the notice of discharge rights as required by § 489.27.

(13) It refuses to permit photocopying of any records or other information by, or on behalf of CMS, as necessary to determine or verify compliance with participation requirements.

(14) The hospital knowingly and willfully fails to accept, on a repeated basis, an amount that approximates the Medicare rate established under the inpatient hospital prospective payment system, minus any enrollee deductibles or copayments, as payment in full from a fee-for-service FEHB plan for inpatient hospital services provided to a retired Federal enrollee of a fee-for-service FEHB plan, age 65 or older, who does not have Medicare Part A benefits.

(15) It had its enrollment in the Medicare program revoked in accordance to § 424.535 of this chapter.

(b) *Termination of agreements with certain hospitals.* In the case of a hospital or critical access hospital that has an emergency department, as defined in § 489.24(b), CMS may terminate the provider agreement if—

(1) The hospital fails to comply with the requirements of § 489.24 (a) through (e), which require the hospital to examine, treat, or transfer emergency medical condition cases appropriately, and require that hospitals with specialized capabilities or facilities accept an appropriate transfer; or

(2) The hospital fails to comply with § 489.20(m), (q), and (r), which require the hospital to report suspected violations of § 489.24(e), to post conspicuously in emergency departments or in a place or places likely to be noticed by all individuals entering the emergency departments, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments, (that is, entrance, admitting area, waiting room, treatment area), signs specifying

rights of individuals under this subpart, to post conspicuously information indicating whether or not the hospital participates in the Medicaid program, and to maintain medical and other records related to transferred individuals for a period of 5 years, a list of on-call physicians for individuals with emergency medical conditions, and a central log on each individual who comes to the emergency department seeking assistance.

(16) It has failed to pay a revisit user fee when and if assessed.

(c) *Termination of agreements with hospitals that fail to make required disclosures.* In the case of a physician-owned hospital, as defined at § 489.3, CMS may terminate the provider agreement if the hospital failed to comply with the requirements of § 489.20(u) or (w). In the case of other participating hospitals, as defined at § 489.24, CMS may terminate the provider agreement if the participating hospital failed to comply with the requirements of § 489.20(w).

(d) *Notice of termination*—(1) *Timing: Basic rule.* Except as provided in paragraph (d)(2) of this section, CMS gives the provider notice of termination at least 15 days before the effective date of termination of the provider agreement.

(2) *Timing exceptions: Immediate jeopardy situations*—(i) *Hospital with emergency department.* If CMS finds that a hospital with an emergency department is in violation of § 489.24, paragraphs (a) through (e), and CMS determines that the violation poses immediate jeopardy to the health or safety of individuals who present themselves to the hospital for emergency services, CMS—

(A) Gives the hospital a preliminary notice indicating that its provider agreement will be terminated in 23 days if it does not correct the identified deficiencies or refute the finding; and

(B) Gives a final notice of termination, and concurrent notice to the public, at least 2 , but not more than 4, days before the effective date of termination of the provider agreement.

(ii) *Skilled nursing facilities (SNFs).* For an SNF with deficiencies that pose immediate jeopardy to the health or safety of residents, CMS gives notice at least 2 days before the effective date of termination of the provider agreement.

(3) *Content of notice.* The notice states the reasons for, and the effective date of, the termination, and explains the extent to which services may continue after that date, in accordance with § 489.55.

(4) *Notice to public.* CMS concurrently gives notice of the termination to the public.

(e) *Appeal by the provider.* A provider may appeal the termination of its provider agreement by CMS in accordance with part 498 of this chapter.

[51 FR 24492, July 3, 1986, as amended at 52 FR 22454, June 12, 1987; 54 FR 5373, Feb. 2, 1989; 56 FR 48879, Sept. 26, 1991; 59 FR 32123, June 22, 1994; 59 FR 56251, Nov. 10, 1994; 60 FR 45851, Sept. 1, 1995; 60 FR 50119, Sept. 28, 1995; 62 FR 43937, Aug. 18, 1997; 62 FR 46037, Aug. 29, 1997; 62 FR 56111, Oct. 29, 1997; 68 FR 66720, Nov. 28, 2003; 69 FR 49272, Aug. 11, 2004; 71 FR 20781, Apr. 21, 2006; 72 FR 47413, Aug. 22, 2007; 72 FR 53649, Sept. 19, 2007; 73 FR 48758, Aug. 19, 2008]

§ 489.54 Termination by the OIG.

(a) *Basis for termination.* (1) The OIG may terminate the agreement of any provider if the OIG finds that any of the following failings can be attributed to that provider.

(i) It has knowingly and willfully made, or caused to be made, any false statement or representation of a material fact for use in an application or request for payment under Medicare.

(ii) It has submitted, or caused to be submitted, requests for Medicare payment of amounts that substantially exceed the costs it incurred in furnishing the services for which payment is requested.

(iii) It has furnished services that the OIG has determined to be substantially in excess of the needs of individuals or of a quality that fails to meet professionally recognized standards of health care. The OIG will not terminate a provider agreement under paragraph (a) if CMS has waived a disallowance with respect to the services in question on the grounds that the provider and the beneficiary could not reasonably be expected to know that payment would not be made. (The rules for determining such lack of knowledge are set forth in §§ 405.330 through 405.334 of this chapter.)

(b) *Notice of termination.* The OIG will give the provider notice of termination at least 15 days before the effective date of termination of the agreement, and will concurrently give notice of termination to the public.

(c) *Appeal by the provider.* A provider may appeal a termination of its agreement by the OIG in accordance with subpart O of part 405 of this chapter.

(d) *Other applicable rules.* The termination of a provider agreement by the OIG is subject to the additional procedures specified in §§ 1001.105 through 1001.109 of this title for notice and appeals.

[51 FR 24492, July 3, 1986, as amended at 51 FR 34788, Sept. 30, 1986]

§ 489.55 Exceptions to effective date of termination.

Payment is available for up to 30 days after the effective date of termination for—

(a) Inpatient hospital services (including inpatient psychiatric hospital services) and posthospital extended care services furnished to a beneficiary who was admitted before the effective date of termination; and

(b) Home health services and hospice care furnished under a plan established before the effective date of termination.[1]

[50 FR 37376, Sept. 13, 1985]

§ 489.57 Reinstatement after termination.

When a provider agreement has been terminated by CMS under § 489.53, or by the OIG under § 489.54, a new agreement with that provider will not be accepted unless CMS or the OIG, as appropriate, finds—

(a) That the reason for termination of the previous agreement has been removed and there is reasonable assurance that it will not recur; and

(b) That the provider has fulfilled, or has made satisfactory arrangements to fulfill, all of the statutory and regulatory responsibilities of its previous agreement.

[51 FR 24493, July 3, 1986]

[1] For termination before July 18, 1984, payment was available through the calendar year in which the termination was effective.

Subpart F—Surety Bond Requirements for HHAs

SOURCE: 63 FR 313, Jan. 5, 1998, unless otherwise noted.

§ 489.60 Definitions.

As used in this subpart unless the context indicates otherwise—

Assessment means a sum certain that CMS may assess against an HHA in lieu of damages under Titles XI, XVIII, or XXI of the Social Security Act or under regulations in this chapter.

Assets includes but is not limited to any listing that identifies Medicare beneficiaries to whom home health services were furnished by a participating or formerly participating HHA.

Civil money penalty means a sum certain that CMS has the authority to impose on an HHA as a penalty under Titles XI, XVIII, or XXI of the Social Security Act or under regulations in this chapter.

Participating home health agency means a ''home health agency'' (HHA), as that term is defined by section 1861(o) of the Social Security Act, that also meets the definition of a ''provider'' set forth at § 400.202 of this chapter.

Rider means a notice issued by a Surety that a change in the bond has occurred or will occur.

Surety bond means one or more bonds issued by one or more surety companies under 31 U.S.C. 9304 to 9308 and 31 CFR parts 223, 224, and 225, provided the bond otherwise meets the requirements of this section.

Unpaid civil money penalty or assessment means a civil money penalty or assessment imposed by CMS on an HHA under Titles XI, XVIII, or XXI of the Social Security Act, plus accrued interest, that, after the HHA or Surety has exhausted all administrative appeals, remains unpaid (because the civil money penalty or assessment has not been paid to, or offset or compromised by, CMS) and is not the subject of a written arrangement, acceptable to CMS, for payment by the HHA. In the event a written arrangement for payment, acceptable to CMS, is made,

an *unpaid civil money penalty or assessment* also means such civil money penalty or assessment, plus accrued interest, that remains due 60 days after the HHA's default on such arrangement.

Unpaid claim means a Medicare overpayment for which the HHA is responsible, plus accrued interest, that, 90 days after the date of the agency's notice to the HHA of the overpayment, remains due (because the overpayment has not been paid to, or recouped or compromised by, CMS) and is not the subject of a written arrangement, acceptable to CMS, for payment by the HHA. In the event a written arrangement for payment, acceptable to CMS, is made, an *unpaid claim* also means a Medicare overpayment for which the HHA is responsible, plus accrued interest, that remains due 60 days after the HHA's default on such arrangement.

[63 FR 313, Jan. 5, 1998, as amended at 63 FR 29655, June 1, 1998]

§ 489.61 Basic requirement for surety bonds.

Except as provided in § 489.62, each HHA that is a Medicare participating HHA, or that seeks to become a Medicare participating HHA, must obtain a surety bond (and furnish to CMS a copy of such surety bond) that meets the requirements of this subpart F and CMS's instructions.

§ 489.62 Requirement waived for Government-operated HHAs.

An HHA operated by a Federal, State, local, or tribal government agency is deemed to have provided CMS with a comparable surety bond under State law, and CMS therefore waives the requirements of this subpart with respect to such an HHA if, during the preceding 5 years the HHA has—

(a) Not had any unpaid claims or unpaid civil money penalties or assessments; and

(b) Not had any of its claims referred by CMS to the Department of Justice or the General Accounting Office in accordance with part 401 of this chapter.

[63 FR 313, Jan. 5, 1998, as amended at 63 FR 29655, June 1, 1998]

§ 489.63 Parties to the bond.

The surety bond must name the HHA as Principal, CMS as Obligee, and the surety company (and its heirs, executors, administrators, successors and assignees, jointly and severally) as Surety.

§ 489.64 Authorized Surety and exclusion of surety companies.

(a) An HHA may obtain a surety bond required under § 489.61 only from an authorized Surety.

(b) An authorized Surety is a surety company that—

(1) Has been issued a Certificate of Authority by the U.S. Department of the Treasury in accordance with 31 U.S.C. 9304 to 9308 and 31 CFR parts 223, 224, and 225 as an acceptable surety on Federal bonds and the Certificate has neither expired nor been revoked; and

(2) Has not been determined by CMS to be an unauthorized Surety for the purpose of an HHA obtaining a surety bond under this section.

(c) CMS determines that a surety company is an unauthorized Surety under this section—

(1) If, upon request by CMS, the surety company fails to furnish timely confirmation of the issuance of, and the validity and accuracy of information appearing on, a surety bond an HHA presents to CMS that shows the surety company as Surety on the bond;

(2) If, upon presentation by CMS to the surety company of a request for payment on a surety bond and of sufficient evidence to establish the surety company's liability on the bond, the surety company fails to timely pay CMS in full the amount requested, up to the face amount of the bond; or

(3) For other good cause.

(d) Any determination CMS makes under paragraph (c) of this section is effective immediately when notice of the determination is published in the FEDERAL REGISTER and remains in effect until a notice of reinstatement is published in the FEDERAL REGISTER.

(e) Any determination CMS makes under paragraph (c) of this section does not affect the Surety's liability under any surety bond issued by a surety company to an HHA before notice of

such determination is published in accordance with paragraph (d) of this section.

(f) A determination by CMS that a surety company is an unauthorized Surety under this section is not a debarment, suspension, or exclusion for the purposes of Executive Order No. 12549 (3 CFR, 1986 comp., p. 189).

§ 489.65 Amount of the bond.

(a) *Basic rule.* The amount of the surety bond must be $50,000 or 15 percent of the Medicare payments made by CMS to the HHA in the HHA's most recent fiscal year for which a cost report has been accepted by CMS, whichever is greater.

(b) *Computation of the 15 percent: Participating HHA.* The 15 percent is computed as follows:

(1) For the initial bond—on the basis of Medicare payments made by CMS to the HHA in the HHA's most recent fiscal year as shown in the HHA's most recent cost report that has been accepted by CMS. If the initial bond will cover less than a full fiscal year, the computation of the 15 percent will be based on the number of months of the fiscal year that the bond will cover.

(2) For subsequent bonds—on the basis of Medicare payments made by CMS in the most recent fiscal year for which a cost report has been accepted. However, if payments in the first six months of the current fiscal year differ from such an amount by more than 25 percent, then the amount of the bond is 15 percent of such payments projected on an annualized basis.

(c) *Computation of 15 percent: An HHA that seeks to become a participating HHA by obtaining assets or ownership interest.* For an HHA that seeks to become a participating HHA by purchasing the assets or the ownership interest of a participating or formerly participating HHA, the 15 percent is computed on the basis of Medicare payments made by CMS to the participating or formerly participating HHA in the most recent fiscal year that a cost report has been accepted.

(d) *Change of ownership.* For an HHA that undergoes a change of ownership the 15 percent is computed on the basis of Medicare payments made by CMS to the HHA for the most recently accepted cost report.

(e) *An HHA that seeks to become a participating HHA without obtaining assets or ownership interest.* For an HHA that seeks to become a participating HHA without purchasing the assets or the ownership interest of a participating or formerly participating HHA, the 15 percent computation does not apply.

(f) *Exception to the basic rule.* If an HHA's overpayment in the most recently accepted cost report exceeds 15 percent of annual payments, CMS may require the HHA to secure a bond in an amount up to or equal to the amount of overpayment, provided the amount of the bond is not less than $50,000.

(g) *Expiration of the 15 percent provision.* For an annual surety bond, or for a rider on a continuous surety bond, that is required to be submitted on or after June 1, 2005, notwithstanding any reference in this subpart to 15 percent as a basis for determining the amount of the bond, the amount of the bond or rider, as applicable, must be $50,000 or such amount as CMS specifies in accordance with paragraph (f) of this section, whichever amount is greater.

[63 FR 313, Jan. 5, 1998, as amended at 63 FR 29655, June 1, 1998]

§ 489.66 Additional requirements of the surety bond.

The surety bond that an HHA obtains under this subpart must meet the following additional requirements:

(a) The bond must guarantee that within 30 days of receiving written notice from CMS of an unpaid claim or unpaid civil money penalty or assessment, which notice contains sufficient evidence to establish the Surety's liability under the bond, the Surety will pay CMS, up to the stated amount of the bond—

(1) The full amount of any unpaid claim, plus accrued interest, for which the HHA is responsible; and

(2) The full amount of any unpaid civil money penalty or assessment imposed by CMS on the HHA, plus accrued interest.

(b) The bond must provide the following:

(1) The Surety is liable for unpaid claims, unpaid civil money penalties,

and unpaid assessments that are discovered when the surety bond is in effect, regardless of when the payment, overpayment, or other event giving rise to the claim, civil money penalty, or assessment occurred, provided CMS makes a written demand for payment from the Surety during, or within 90 days after, the term of the bond.

(2) If the HHA fails to furnish a bond meeting the requirements of this subpart F for the year following expiration of the term of an annual bond, or if the HHA fails to submit a rider when a rider is required to be submitted under this subpart, or if the HHA's provider agreement is terminated, the last bond or rider, as applicable, submitted by the HHA to CMS, which bond or applicable rider meets the requirements of this subpart, remains effective and the Surety remains liable for unpaid claims, civil money penalties, and assessments that—

(i) CMS determines or imposes on or asserts against the HHA based on overpayments or other events that took place during or prior to the term of the last bond or rider; and

(ii) Were determined or imposed during the 2 years following the date the HHA failed to submit a bond or required rider or the date the HHA's provider agreement is terminated, whichever is later.

(c) The bond must provide that the Surety's liability to CMS under the bond is not extinguished by any action of the HHA, the Surety, or CMS, including but not necessarily limited to any of the following actions:

(1) Action by the HHA or the Surety to terminate or limit the scope or term of the bond. The Surety's liability may be extinguished, however, when—

(i) The Surety furnishes CMS with notice of such action not later than 10 days after receiving notice from the HHA of action by the HHA to terminate or limit the scope of the bond, or not later than 60 days before the effective date of such action by the Surety; or

(ii) The HHA furnishes CMS with a new bond that meets the requirements of this subpart.

(2) The Surety's failure to continue to meet the requirements of § 489.64(a) or CMS's determination that the surety company is an unauthorized Surety under § 489.64(b).

(3) Termination of the HHA's provider agreement.

(4) Any action by CMS to suspend, offset, or otherwise recover payments to the HHA.

(5) Any action by the HHA to—

(i) Cease operation;

(ii) Sell or transfer any asset or ownership interest;

(iii) File for bankruptcy; or

(iv) Fail to pay the Surety.

(6) Any fraud, misrepresentation, or negligence by the HHA in obtaining the surety bond or by the Surety (or by the Surety's agent, if any) in issuing the surety bond, except that any fraud, misrepresentation, or negligence by the HHA in identifying to the Surety (or to the Surety's agent) the amount of Medicare payments upon which the amount of the surety bond is determined will not cause the Surety's liability to CMS to exceed the amount of the bond.

(7) The HHA's failure to exercise available appeal rights under Medicare or to assign such rights to the Surety.

(d) The bond must provide that actions under the bond may be brought by CMS or by CMS's fiscal intermediaries.

(e) The bond must provide the Surety's name, street address or post office box number, city, state, and zipcode to which the CMS notice provided for in paragraph (a) of this section is to be sent.

[63 FR 313, Jan. 5, 1998, as amended at 63 FR 29655, June 1, 1998]

§ 489.67 Term and type of bond.

(a) Each participating HHA that does not meet the criteria for waiver under § 489.62 must submit to CMS in a form as CMS may specify, a surety bond for a term beginning January 1, 1998. If an annual bond is submitted for the initial term, it must be effective through the end of the HHA's current fiscal year.

(b) *Type of bond.* The type of bond required to be submitted by an HHA under this subpart may be either—

(1) An annual bond (that is, a bond that specifies an effective annual period corresponding to the HHA's fiscal year); or

(2) A continuous bond (that is, a bond that remains in full force and effect from term to term unless it is terminated or canceled as provided for in the bond or as otherwise provided by law) that is updated by the Surety, via the issuance of a rider, for a particular fiscal year for which the bond amount has changed or will change.

(c) *HHA that seeks to become a participating HHA.* (1) An HHA that seeks to become a participating HHA must submit a surety bond with its enrollment application (Form CMS–855, OMB number 0938–0685). The term of the initial surety bond must be effective from the effective date of provider agreement as specified in § 489.13 of this part. However, if the effective date of the provider agreement is less than 30 days before the end of the HHA's current fiscal year, the HHA may obtain a bond effective through the end of the next fiscal year, provided the amount of the bond is the greater of $75,000 or 20 percent of the amount determined from the computation specified in § 489.65(c) as applicable.

(2) An HHA that seeks to become a participating HHA through the purchase or transfer of assets or ownership interest of a participating or formerly participating HHA must also ensure that the surety bond is effective from the date of such purchase or transfer.

(d) *Change of ownership.* An HHA that undergoes a change of ownership must submit the surety bond to CMS not later than the effective date of the change of ownership and the bond must be effective from the effective date of the change of ownership through the remainder of the HHA's fiscal year.

(e) *Government-operated HHA that loses its waiver.* A government-operated HHA that, as of January 1, 1998, meets the criteria for waiver under § 489.62 but thereafter is determined by CMS to not meet such criteria, must submit a surety bond to CMS within 60 days after it receives notice from CMS that it no longer meets the criteria for waiver.

(f) *Change of Surety.* An HHA that obtains a replacement surety bond from a different Surety to cover the remaining term of a previously obtained bond must submit the new surety bond to CMS within 30 days of obtaining the bond from the new Surety.

(Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh))

[63 FR 315, Jan. 5, 1998, as amended at 63 FR 10731, Mar. 4, 1998; 63 FR 29656, June 1, 1998; 63 FR 41171, July 31, 1998]

§ 489.68 Effect of failure to obtain, maintain, and timely file a surety bond.

(a) The failure of a participating HHA to obtain, file timely, and maintain a surety bond in accordance with this subpart F and CMS's instructions is sufficient under § 489.53(a)(1) for CMS to terminate the HHA's provider agreement.

(b) The failure of an HHA seeking to become a participating HHA to obtain and file timely a surety bond in accordance with this Subpart F and CMS's instructions is sufficient under § 489.12(a)(3) for CMS to refuse to enter into a provider agreement with the HHA.

§ 489.69 Evidence of compliance.

(a) CMS may at any time require an HHA to make a specific showing of being in compliance with the requirements of this Subpart F and may require the HHA to submit such additional evidence as CMS considers sufficient to demonstrate the HHA's compliance.

(b) If requested by CMS to do so, the failure of an HHA to timely furnish sufficient evidence to CMS to demonstrate compliance with the requirements of this Subpart F is sufficient for CMS to terminate the HHA's provider agreement under § 489.53(a)(1) or to refuse to enter into a provider agreement with the HHA under § 489.12(a)(3), as applicable.

§ 489.70 Effect of payment by the Surety.

A Surety's payment to CMS under a bond for an unpaid claim or an unpaid civil money penalty or assessment, constitutes—

(a) Collection of the unpaid claim or unpaid civil money penalty or assessment (to the extent the Surety's payment on the bond covers such unpaid claim, civil money penalty, or assessment); and

(b) A basis for termination of the HHA's provider agreement under § 489.53(a)(1).

§ 489.71 Surety's standing to appeal Medicare determinations.

A Surety has standing to appeal any matter that the HHA could appeal, provided the Surety satisfies all jurisdictional and procedural requirements that would otherwise have applied to the HHA, and provided the HHA is not, itself, actively pursuing its appeal rights under this chapter, and provided further that, with respect to unpaid claims, the Surety has paid CMS all amounts owed to CMS by the HHA on such unpaid claims, up to the amount of the bond.

[63 FR 29656, June 1, 1998]

§ 489.72 Effect of review reversing determination.

In the event a Surety has paid CMS on the basis of liability incurred under a bond obtained by an HHA under this subpart F, and to the extent the HHA that obtained such bond (or the Surety under § 489.71) is subsequently successful in appealing the determination that was the basis of the unpaid claim or unpaid civil money penalty or assessment that caused the Surety to pay CMS under the bond, CMS will refund to the Surety the amount the Surety paid to CMS to the extent such amount relates to the matter that was successfully appealed by the HHA (or by the Surety), provided all review, including judicial review, has been completed on such matter. Any additional amounts owing as a result of the appeal will be paid to the HHA.

§ 489.73 Effect of conditions of payment.

If a Surety has paid an amount to CMS on the basis of liability incurred under a bond obtained by an HHA under this subpart F, and CMS subsequently collects from the HHA, in whole or in part, on such unpaid claim, civil money penalty, or assessment that was the basis for the Surety's liability, CMS reimburses the Surety such amount as CMS collected from the HHA, up to the amount paid by the Surety to CMS, provided the Surety has no other liability to CMS under the bond.

(Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh))

[63 FR 29656, June 1, 1998]

§ 489.74 Incorporation into existing provider agreements.

The requirements of this subpart F are deemed to be incorporated into existing HHA provider agreements effective January 1, 1998.

[63 FR 315, Jan. 5, 1998. Redesignated at 63 FR 29656, June 1, 1998]

Subparts G–H [Reserved]

Subpart I—Advance Directives

SOURCE: 57 FR 8203, Mar. 6, 1992, unless otherwise noted.

§ 489.100 Definition.

For purposes of this part, *advance directive* means a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of health care when the individual is incapacitated.

§ 489.102 Requirements for providers.

(a) Hospitals, critical access hospitals, skilled nursing facilities, nursing facilities, home health agencies, providers of home health care (and for Medicaid purposes, providers of personal care services), hospices, and religious nonmedical health care institutions must maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care, or patient care in the case of a patient in a religious nonmedical health care institution, by or through the provider and are required to:

(1) Provide written information to such individuals concerning—

(i) An individual's rights under State law (whether statutory or recognized by the courts of the State) to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the

right to formulate, at the individual's option, advance directives. Providers are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. Providers are to update and disseminate amended information as soon as possible, but no later than 90 days from the effective date of the changes to State law; and

(ii) The written policies of the provider or organization respecting the implementation of such rights, including a clear and precise statement of limitation if the provider cannot implement an advance directive on the basis of conscience. At a minimum, a provider's statement of limitation should:

(A) Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians;

(B) Identify the state legal authority permitting such objection; and

(C) Describe the range of medical conditions or procedures affected by the conscience objection.

(2) Document in a prominent part of the individual's current medical record, or patient care record in the case of an individual in a religious nonmedical health care institution, whether or not the individual has executed an advance directive;

(3) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

(4) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives. The provider must inform individuals that complaints concerning the advance directive requirements may be filed with the State survey and certification agency;

(5) Provide for education of staff concerning its policies and procedures on advance directives; and

(6) Provide for community education regarding issues concerning advance directives that may include material required in paragraph (a)(1) of this section, either directly or in concert with other providers and organizations. Separate community education materials may be developed and used, at the discretion of providers. The same written materials do not have to be provided in all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable State law concerning advance directives. A provider must be able to document its community education efforts.

(b) The information specified in paragraph (a) of this section is furnished:

(1) In the case of a hospital, at the time of the individual's admission as an inpatient.

(2) In the case of a skilled nursing facility at the time of the individual's admission as a resident.

(3)(i) In the case of a home health agency, in advance of the individual coming under the care of the agency. The HHA may furnish advance directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.

(ii) In the case of personal care services, in advance of the individual coming under the care of the personal care services provider. The personal care provider may furnish advance directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.

(4) In the case of a hospice program, at the time of initial receipt of hospice care by the individual from the program.

(c) The providers listed in paragraph (a) of this section—

(1) Are not required to provide care that conflicts with an advance directive.

(2) Are not required to implement an advance directive if, as a matter of conscience, the provider cannot implement an advance directive and State law allows any health care provider or any agent of such provider to conscientiously object.

(d) Prepaid or eligible organizations (as specified in sections 1833(a)(1)(A) and 1876(b) of the Act) must meet the

requirements specified in §417.436 of this chapter.

(e) If an adult individual is incapacitated at the time of admission or at the start of care and is unable to receive information (due to the incapacitating conditions or a mental disorder) or articulate whether or not he or she has executed an advance directive, then the provider may give advance directive information to the individual's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. The provider is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

[57 FR 8203, Mar. 6, 1992, as amended at 59 FR 45403, Sept. 1, 1994; 60 FR 33294, June 27, 1995; 62 FR 46037, Aug. 29, 1997; 64 FR 67052, Nov. 30, 1999; 68 FR 66720, Nov. 28, 2003]

§489.104 Effective dates.

These provisions apply to services furnished on or after December 1, 1991 payments made under section 1833(a)(1)(A) of the Act on or after December 1, 1991, and contracts effective on or after December 1, 1991.

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

Subpart A—Rural Health Clinics: Conditions for Certification; and FQHCs Conditions for Coverage

Sec.

491.1 Purpose and scope.
491.2 Definitions.
491.3 Certification procedures.
491.4 Compliance with Federal, State and local laws.
491.5 Location of clinic.
491.6 Physical plant and environment.
491.7 Organizational structure.
491.8 Staffing and staff responsibilities.
491.9 Provision of services.
491.10 Patient health records.
491.11 Program evaluation.

AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

Subpart A—Rural Health Clinics: Conditions for Certification; and FQHCs Conditions for Coverage

§491.1 Purpose and scope.

This subpart sets forth the conditions that rural health clinics or FQHCs must meet in order to qualify for reimbursement under Medicare (title XVIII of the Social Security Act) and that rural health clinics must meet in order to qualify for reimbursement under Medicaid (title XIX of the Act).

[57 FR 24982, June 12, 1992]

§491.2 Definitions.

As used in this subpart, unless the context indicates otherwise:

Direct services means services provided by the clinic's staff.

FQHC means an entity as defined in §405.2401(b).

Nurse practitioner means a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualifications of nurse practitioners, and who meets one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates; or

(2) Has satisfactorily completed a formal 1 academic year educational program that:

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program; or

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an

expanded role in the delivery of primary care) that does not meet the requirements of paragraph (2) of this definition, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding the effective date of this subpart.

Physician means a doctor of medicine or osteopathy legally authorized to practice medicine or surgery in the State.

Physician assistant means a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians; or

(2) Has satisfactorily completed a program for preparing physician's assistants that:

(i) Was at least 1 academic year in length;

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation; or

(3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (2) of this definition and assisted primary care physicians for a total of 12 months during the 18-month period that ended on December 31, 1986.

Rural area means an area that is not delineated as an urbanized area by the Bureau of the Census.

Rural health clinic or clinic means a clinic that is located in a rural area designated as a shortage area, is not a rehabilitation agency or a facility primarily for the care and treatment of mental diseases, and meets all other requirements of this subpart.

Shortage area means a defined geographic area designated by the Department as having either a shortage of personal health services (under section 1302(7) of the Public Health Service Act) or a shortage of primary medical care manpower (under section 332 of that Act).

Secretary means the Secretary of Health and Human Services, or any official to whom he has delegated the pertinent authority.

[71 FR 55345, Sept. 22, 2006]

§ 491.3 Certification procedures.

A rural health clinic will be certified for participation in Medicare in accordance with subpart S of 42 CFR part 405. The Secretary will notify the State Medicaid agency whenever he has certified or denied certification under Medicare for a prospective rural health clinic in that State. A clinic certified under Medicare will be deemed to meet the standards for certification under Medicaid.

[71 FR 55346, Sept. 22, 2006]

§ 491.4 Compliance with Federal, State and local laws.

The rural health clinic or FQHC and its staff are in compliance with applicable Federal, State and local laws and regulations.

(a) *Licensure of clinic or center.* The clinic or center is licensed pursuant to applicable State and local law.

(b) *Licensure, certification or registration of personnel.* Staff of the clinic or center are licensed, certified or registered in accordance with applicable State and local laws.

[57 FR 24982, June 12, 1992]

§ 491.5 Location of clinic.

(a) *Basic requirements.* (1) An RHC is located in a rural area that is designated as a shortage area.

(2) An FQHC is located in a rural or urban area that is designated as either a shortage area or an area that has a medically underserved population.

(3) Both the RHC and the FQHC may be permanent or mobile units.

(i) *Permanent unit.* The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic or center are housed in a permanent structure.

(ii) *Mobile unit.* The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic or center are

housed in a mobile structure, which has fixed, scheduled location(s).

(iii) *Permanent unit in more than one location*. If clinic or center services are furnished at permanent units in more than one location, each unit is independently considered for approval as a rural health clinic or for approval as an FQHC.

(b) *Exceptions*. (1) CMS does not disqualify an RHC approved under this subpart if the area in which it is located subsequently fails to meet the definition of a rural, shortage area.

(2) A private, nonprofit facility that meets all other conditions of this subpart except for location in a shortage area will be certified if, on July 1, 1977, it was operating in a rural area that is determined by the Secretary (on the basis of the ratio of primary care physicians to the general population) to have an insufficient supply of physicians to meet the needs of the area served.

(3) Determinations on these exceptions will be made by the Secretary upon application by the facility.

(c) *Criteria for designation of rural areas*. (1) Rural areas are areas not delineated as urbanized areas in the last census conducted by the Census Bureau.

(2) Excluded from the rural area classification are:

(i) Central cities of 50,000 inhabitants or more;

(ii) Cities with at least 25,000 inhabitants which, together with contiguous areas having stipulated population density, have combined populations of 50,000 and constitute, for general economic and social purposes, single communities;

(iii) Closely settled territories surrounding cities and specifically designated by the Census Bureau as urban.

(3) Included in the rural area classification are those portions of extended cities that the Census Bureau has determined to be rural.

(d) *Criteria for designation of shortage areas*. (1) The criteria for determination of shortage of personal health services (under section 1302(7) of the Public Health Services Act), are:

(i) The ratio of primary care physicians practicing within the area to the resident population;

(ii) The infant mortality rate;

(iii) The percent of the population 65 years of age or older; and

(iv) The percent of the population with a family income below the poverty level.

(2) The criteria for determination of shortage of primary medical care manpower (under section 332(a)(1)(A) of the Public Health Services Act) are:

(i) The area served is a rational area for the delivery of primary medical care services;

(ii) The ratio of primary care physicians practicing within the area to the resident population; and

(iii) The primary medical care manpower in contiguous areas is overutilized, excessively distant, or inaccessible to the population in this area.

(e) *Medically underserved population*. A medically underserved population includes the following:

(1) A population of an urban or rural area that is designated by PHS as having a shortage of personal health services.

(2) A population group that is designated by PHS as having a shortage of personal health services.

(f) *Requirements specific to FQHCs*. An FQHC approved for participation in Medicare must meet one of the following criteria:

(1) Furnish services to a medically underserved population.

(2) Be located in a medically underserved area, as demonstrated by an application approved by PHS.

CROSS REFERENCE: See 42 CFR 110.203(g) (41 FR 45718, Oct. 15, 1976) and 42 CFR Part 5 (42 FR 1586, Jan. 10, 1978).

[43 FR 5375, Feb. 8, 1978. Redesignated at 50 FR 33034, Aug. 16, 1985, and amended at 57 FR 24982, June 12, 1992; 61 FR 14658, Apr. 3, 1996; 68 FR 74816, Dec. 24, 2003; 71 FR 55346, Sept. 22, 2006]

§491.6 Physical plant and environment.

(a) *Construction*. The clinic or center is constructed, arranged, and maintained to insure access to and safety of patients, and provides adequate space for the provision of direct services.

(b) *Maintenance*. The clinic or center has a preventive maintenance program to ensure that:

(1) All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition;

(2) Drugs and biologicals are appropriately stored; and

(3) The premises are clean and orderly.

(c) *Emergency procedures*. The clinic or center assures the safety of patients in case of non-medical emergencies by:

(1) Training staff in handling emergencies;

(2) Placing exit signs in appropriate locations; and

(3) Taking other appropriate measures that are consistent with the particular conditions of the area in which the clinic or center is located.

[57 FR 24983, June 12, 1992]

§ 491.7 Organizational structure.

(a) *Basic requirements*. (1) The clinic or center is under the medical direction of a physician, and has a health care staff that meets the requirements of § 491.8.

(2) The organization's policies and its lines of authority and responsibilities are clearly set forth in writing.

(b) *Disclosure*. The clinic or center discloses the names and addresses of:

(1) Its owners, in accordance with section 1124 of the Social Security Act (42 U.S.C. 132 A–3);

(2) The person principally responsible for directing the operation of the clinic or center; and

(3) The person responsible for medical direction.

[57 FR 24983, June 12, 1992]

§ 491.8 Staffing and staff responsibilities.

(a) *Staffing*. (1) The clinic or center has a health care staff that includes one or more physicians. Rural health clinic staffs must also include one or more physician's assistants or nurse practitioners.

(2) The physician member of the staff may be the owner of the rural health clinic, an employee of the clinic or center, or under agreement with the clinic or center to carry out the responsibilities required under this section.

(3) The physician assistant, nurse practitioner, nurse-midwife, clinical social worker, or clinical psychologist member of the staff may be the owner or an employee of the clinic or center, or may furnish services under contract to the center.

(4) The staff may also include ancillary personnel who are supervised by the professional staff.

(5) The staff is sufficient to provide the services essential to the operation of the clinic or center.

(6) A physician, nurse practitioner, physician assistant, nurse-midwife, clinical social worker, or clinical psychologist is available to furnish patient care services at all times the clinic or center operates. In addition, for rural health clinics, a nurse practitioner or a physician assistant is available to furnish patient care services at least 60 percent of the time the clinic operates.

(b) *Physician responsibilities*. (1) The physician:

(i) Except for services furnished by a clinical psychologist in an FQHC, which State law permits to be provided without physician supervision, provides medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff.

(ii) In conjunction with the physician's assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's or center's written policies and the services provided to Federal program patients; and

(iii) Periodically reviews the clinic's or center's patient records, provides medical orders, and provides medical care services to the patients of the clinic or center.

(2) A physician is present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances), to provide the medical direction, medical care services, consultation and supervision described in paragraph (b)(1) of this section and is available through direct telecommunication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the clinic or center.

(c) *Physician assistant and nurse practitioner responsibilities*. (1) The physician assistant and the nurse practitioner

members of the clinic's or center's staff:

(i) Participate in the development, execution and periodic review of the written policies governing the services the clinic or center furnishes;

(ii) Participate with a physician in a periodic review of the patients' health records.

(2) The physician assistant or nurse practitioner performs the following functions, to the extent they are not being performed by a physician:

(i) Provides services in accordance with the clinic's or center's policies;

(ii) Arranges for, or refers patients to, needed services that cannot be provided at the clinic or center; and

(iii) Assures that adequate patient health records are maintained and transferred as required when patients are referred.

[57 FR 24983, June 12, 1992, as amended at 61 FR 14658, Apr. 3, 1996; 68 FR 74817, Dec. 24, 2003; 71 FR 55346, Sept. 22, 2006]

§491.9 Provision of services.

(a) *Basic requirements.* (1) All services offered by the clinic or center are furnished in accordance with applicable Federal, State, and local laws; and

(2) The clinic or center is primarily engaged in providing outpatient health services and meets all other conditions of this subpart.

(3) The laboratory requirements in paragraph (c)(2) of this section apply to RHCs, but do not apply to FQHCs.

(b) *Patient care policies.* (1) The clinic's or center's health care services are furnished in accordance with appropriate written policies which are consistent with applicable State law.

(2) The policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician assistants or nurse practitioners. At least one member is not a member of the clinic or center staff.

(3) The policies include:

(i) A description of the services the clinic or center furnishes directly and those furnished through agreement or arrangement.

(ii) Guidelines for the medical management of health problems which include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the clinic or center.

(iii) Rules for the storage, handling, and administration of drugs and biologicals.

(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (b)(2) of this section and reviewed as necessary by the clinic or center.

(c) *Direct services*—(1) *General.* The clinic or center staff furnishes those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at the entry point into the health care delivery system. These include medical history, physical examination, assessment of health status, and treatment for a variety of medical conditions.

(2) *Laboratory.* These requirements apply to RHCs but not to FQHCs. The RHC provides laboratory services in accordance with part 493 of this chapter, which implements the provisions of section 353 of the Public Health Service Act. The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including:

(i) Chemical examinations of urine by stick or tablet method or both (including urine ketones);

(ii) Hemoglobin or hematocrit;

(iii) Blood glucose;

(iv) Examination of stool specimens for occult blood;

(v) Pregnancy tests; and

(vi) Primary culturing for transmittal to a certified laboratory.

(3) *Emergency.* The clinic or center provides medical emergency procedures as a first response to common life-threatening injuries and acute illness and has available the drugs and biologicals commonly used in life saving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids.

(d) *Services provided through agreements or arrangements.* (1) The clinic or center has agreements or arrangements with one or more providers or suppliers

participating under Medicare or Medicaid to furnish other services to its patients, including:

(i) Inpatient hospital care;

(ii) Physician(s) services (whether furnished in the hospital, the office, the patient's home, a skilled nursing facility, or elsewhere); and

(iii) Additional and specialized diagnostic and laboratory services that are not available at the clinic or center.

(2) If the agreements are not in writing, there is evidence that patients referred by the clinic or center are being accepted and treated.

[57 FR 24983, June 12, 1992, as amended at 58 FR 63536, Dec. 2, 1993]

§ 491.10 Patient health records.

(a) *Records system.* (1) The clinic or center maintains a clinical record system in accordance with written policies and procedures.

(2) A designated member of the professional staff is responsible for maintaining the records and for insuring that they are completely and accurately documented, readily accessible, and systematically organized.

(3) For each patient receiving health care services, the clinic or center maintains a record that includes, as applicable:

(i) Identification and social data, evidence of consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

(ii) Reports of physical examinations, diagnostic and laboratory test results, and consultative findings;

(iii) All physician's orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient's progress;

(iv) Signatures of the physician or other health care professional.

(b) *Protection of record information.* (1) The clinic or center maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use.

(2) Written policies and procedures govern the use and removal of records from the clinic or center and the conditions for release of information.

(3) The patient's written consent is required for release of information not authorized to be released without such consent.

(c) *Retention of records.* The records are retained for at least 6 years from date of last entry, and longer if required by State statute.

(Secs. 1102, 1833 and 1902(a)(13), Social Security Act; 49 Stat. 647, 91 Stat. 1485 (42 U.S.C. 1302, 13951 and 1396a(a)(13)))

[43 FR 30529, July 14, 1978. Redesignated at 50 FR 33034, Aug. 16, 1985, as amended at 57 FR 24984, June 12, 1992]

§ 491.11 Program evaluation.

(a) The clinic or center carries out, or arranges for, an annual evaluation of its total program.

(b) The evaluation includes review of:

(1) The utilization of clinic or center services, including at least the number of patients served and the volume of services;

(2) A representative sample of both active and closed clinical records; and

(3) The clinic's or center's health care policies.

(c) The purpose of the evaluation is to determine whether:

(1) The utilization of services was appropriate;

(2) The established policies were followed; and

(3) Any changes are needed.

(d) The clinic or center staff considers the findings of the evaluation and takes corrective action if necessary.

[71 FR 55346, Sept. 22, 2006]

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493.2001 Establishment and function of the Clinical Laboratory Improvement Advisory Committee.

AUTHORITY: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following sections 1861(s)(11) through 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16)).

SOURCE: 55 FR 9576, Mar. 14, 1990, unless otherwise noted.

Subpart A—General Provisions

SOURCE: 57 FR 7139, Feb. 28, 1992, unless otherwise noted.

§ 493.1 Basis and scope.

This part sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). It implements sections 1861 (e) and (j), the sentence following section 1861(s)(13), and 1902(a)(9) of the Social Security Act, and section 353 of the Public Health Service Act. This part applies to all laboratories as defined under ''laboratory'' in § 493.2 of this part. This part also applies to laboratories seeking payment under the Medicare and Medicaid programs. The requirements are the same for Medicare approval as for CLIA certification.

§ 493.2 Definitions.

As used in this part, unless the context indicates otherwise—

Accredited institution means a school or program which—

(a) Admits as regular student only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such certificate;

(b) Is legally authorized within the State to provide a program of education beyond secondary education;

(c) Provides an educational program for which it awards a bachelor's degree or provides not less than a 2-year program which is acceptable toward such a degree, or provides an educational program for which it awards a master's or doctoral degree;

(d) Is accredited by a nationally recognized accrediting agency or association.

This definition includes any foreign institution of higher education that HHS or its designee determines meets substantially equivalent requirements.

Accredited laboratory means a laboratory that has voluntarily applied for and been accredited by a private, nonprofit accreditation organization approved by CMS in accordance with this part;

Adverse action means the imposition of a principal or alternative sanction by CMS.

ALJ stands for Administrative Law Judge.

Alternative sanctions means sanctions that may be imposed in lieu of or in addition to principal sanctions. The term is synonymous with ''intermediate sanctions'' as used in section 1846 of the Act.

Analyte means a substance or constituent for which the laboratory conducts testing.

Approved accreditation organization for laboratories means a private, nonprofit accreditation organization that has formally applied for and received CMS's approval based on the organization's compliance with this part.

Approved State laboratory program means a licensure or other regulatory program for laboratories in a State, the requirements of which are imposed under State law, and the State laboratory program has received CMS approval based on the State's compliance with this part.

Authorized person means an individual authorized under State law to order tests or receive test results, or both.

Calibration means a process of testing and adjusting an instrument or test system to establish a correlation between the measurement response and the concentration or amount of the substance that is being measured by the test procedure.

Calibration verification means the assaying of materials of known concentration in the same manner as patient samples to substantiate the instrument or test system's calibration throughout the reportable range for patient test results.

Challenge means, for quantitative tests, an assessment of the amount of substance or analyte present or measured in a sample. For qualitative tests, a challenge means the determination of the presence or the absence of an analyte, organism, or substance in a sample.

CLIA means the Clinical Laboratory Improvement Amendments of 1988.

CLIA certificate means any of the following types of certificates issued by CMS or its agent:

(1) *Certificate of compliance* means a certificate issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable condition level requirements, or reissued before the expiration date, pending an appeal, in accordance with §493.49, when an inspection has found the laboratory to be out of compliance with one or more condition level requirements.

(2) *Certificate for provider-performed microscopy (PPM) procedures* means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with §493.47, to a laboratory in which a physician, midlevel practitioner or dentist performs no tests other than PPM procedures and, if desired, waived tests listed in §493.15(c).

(3) *Certificate of accreditation* means a certificate issued on the basis of the laboratory's accreditation by an accreditation organization approved by CMS (indicating that the laboratory is deemed to meet applicable CLIA requirements) or reissued before the expiration date, pending an appeal, in accordance with §493.61, when a validation or complaint survey has found the laboratory to be noncompliant with one or more CLIA conditions.

(4) *Certificate of registration or registration certificate* means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with §493.45, that enables the entity to conduct moderate or high complexity laboratory testing or both until the entity is determined to be in compliance through a survey by CMS or its agent; or in accordance with §493.57 to an entity that is accredited by an approved accreditation organization.

(5) *Certificate of waiver* means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with §493.37, to a laboratory to perform only the waived tests listed at §493.15(c).

CLIA-exempt laboratory means a laboratory that has been licensed or approved by a State where CMS has determined that the State has enacted laws relating to laboratory requirements that are equal to or more stringent than CLIA requirements and the State licensure program has been approved by CMS in accordance with subpart E of this part.

Condition level deficiency means noncompliance with one or more condition level requirements.

Condition level requirements means any of the requirements identified as ''conditions'' in subparts G through Q of this part.

Credible allegation of compliance means a statement or documentation that—

(1) Is made by a representative of a laboratory that has a history of having maintained a commitment to compliance and of taking corrective action when required;

(2) Is realistic in terms of its being possible to accomplish the required corrective action between the date of the exit conference and the date of the allegation; and

(3) Indicates that the problem has been resolved.

Dentist means a doctor of dental medicine or doctor of dental surgery licensed by the State to practice dentistry within the State in which the laboratory is located.

Equivalency means that an accreditation organization's or a State laboratory program's requirements, taken as a whole, are equal to or more stringent than the CLIA requirements established by CMS, taken as whole. It is acceptable for an accreditation organization's or State laboratory program's requirements to be organized differently or otherwise vary from the CLIA requirements, as long as (1) all of the requirements taken as a whole would provide at least the same protection as the CLIA requirements taken as a whole; and (2) a finding of noncompliance with respect to CLIA requirements taken as a whole would be matched by a finding of noncompliance with the accreditation or State requirements taken as a whole.

CMS agent means an entity with which CMS arranges to inspect laboratories and assess laboratory activities against CLIA requirements and may be a State survey agency, a private, nonprofit organization other than an approved accreditation organization, a component of HHS, or any other governmental component CMS approves for this purpose. In those instances where all of the laboratories in a State are exempt from CLIA requirements, based on the approval of a State's exemption request, the State survey agency is not the CMS agent.

FDA-cleared or approved test system means a test system cleared or approved by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for invitro diagnostic use. Unless otherwise stated, this includes test systems exempt from FDA premarket clearance or approval.

HHS means the Department of Health and Human Services, or its designee.

Immediate jeopardy means a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health.

Intentional violation means knowing and willful noncompliance with any CLIA condition.

Kit means all components of a test that are packaged together.

Laboratory means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

Midlevel practitioner means a nurse midwife, nurse practitioner, or physician assistant, licensed by the State within which the individual practices, if such licensing is required in the State in which the laboratory is located.

Nonwaived test means any test system, assay, or examination that has not been found to meet the statutory

criteria specified at section 353(d)(3) of the Public Health Service Act.

Operator means the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory. The term includes—

(1) A director of the laboratory if he or she meets the stated criteria; and

(2) The members of the board of directors and the officers of a laboratory that is a small corporation under subchapter S of the Internal Revenue Code.

Owner means any person who owns any interest in a laboratory except for an interest in a laboratory whose stock and/or securities are publicly traded. (That is e.g., the purchase of shares of stock or securities on the New York Stock Exchange in a corporation owning a laboratory would not make a person an owner for the purpose of this regulation.)

Party means a laboratory affected by any of the enforcement procedures set forth in this subpart, by CMS or the OIG, as appropriate.

Performance characteristic means a property of a test that is used to describe its quality, e.g., accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference range, etc.

Performance specification means a value or range of values for a performance characteristic, established or verified by the laboratory, that is used to describe the quality of patient test results.

Physician means an individual with a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine degree who is licensed by the State to practice medicine, osteopathy, or podiatry within the State in which the laboratory is located.

Principal sanction means the suspension, limitation, or revocation of any type of CLIA certificate or the cancellation of the laboratory's approval to receive Medicare payment for its services.

Prospective laboratory means a laboratory that is operating under a registration certificate or is seeking any of the three other types of CLIA certificates.

Rate of disparity means the percentage of sample validation inspections for a specific accreditation organization or State where CMS, the State survey agency or other CMS agent finds noncompliance with one or more condition level requirements but no comparable deficiencies were cited by the accreditation organization or the State, and it is reasonable to conclude that the deficiencies were present at the time of the most recent accreditation organization or State licensure inspection.

Example: Assume the State survey agency, CMS or other CMS agent performs 200 sample validation inspections for laboratories accredited by a single accreditation organization or licensed in an exempt State during a validation review period and finds that 60 of the 200 laboratories had one or more condition level requirements out of compliance. CMS reviews the validation and accreditation organization's or State's inspections of the validated laboratories and determines that the State or accreditation organization found comparable deficiencies in 22 of the 60 laboratories and it is reasonable to conclude that deficiencies were present in the remaining 38 laboratories at the time of the accreditation organization's or State's inspection. Thirty-eight divided by 200 equals a 19 percent rate of disparity.

Referee laboratory means a laboratory currently in compliance with applicable CLIA requirements, that has had a record of satisfactory proficiency testing performance for all testing events for at least one year for a specific test, analyte, subspecialty, or specialty and has been designated by an HHS approved proficiency testing program as a referee laboratory for analyzing proficiency testing specimens for the purpose of determining the correct response for the specimens in a testing event for that specific test, analyte, subspecialty, or specialty.

Reference range means the range of test values expected for a designated population of individuals, e.g., 95 percent of individuals that are presumed to be healthy (or normal).

Reportable range means the span of test result values over which the laboratory can establish or verify the accuracy of the instrument or test system measurement response.

Sample in proficiency testing means the material contained in a vial, on a

slide, or other unit that contains material to be tested by proficiency testing program participants. When possible, samples are of human origin.

State includes, for purposes of this part, each of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands and a political subdivision of a State where the State, acting pursuant to State law, has expressly delegated powers to the political subdivision sufficient to authorize the political subdivision to act for the State in enforcing requirements equal to or more stringent than CLIA requirements.

State licensure means the issuance of a license to, or the approval of, a laboratory by a State laboratory program as meeting standards for licensing or approval established under State law.

State licensure program means a State laboratory licensure or approval program.

State survey agency means the State health agency or other appropriate State or local agency that has an agreement under section 1864 of the Social Security Act and is used by CMS to perform surveys and inspections.

Substantial allegation of noncompliance means a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that, if substantiated, would have an impact on the health and safety of the general public or of individuals served by a laboratory and raises doubts as to a laboratory's compliance with any condition level requirement.

Target value for quantitative tests means either the mean of all participant responses after removal of outliers (those responses greater than 3 standard deviations from the original mean) or the mean established by definitive or reference methods acceptable for use in the National Reference System for the Clinical Laboratory (NRSCL) by the National Committee for the Clinical Laboratory Standards (NCCLS). In instances where definitive or reference methods are not available or a specific method's results demonstrate bias that is not observed with actual patient specimens, as determined by a defensible scientific protocol, a comparative method or a method group (''peer'' group) may be used. If the method group is less than 10 participants, ''target value'' means the overall mean after outlier removal (as defined above) unless acceptable scientific reasons are available to indicate that such an evaluation is not appropriate.

Test system means the instructions and all of the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results.

Unsatisfactory proficiency testing performance means failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event.

Unsuccessful participation in proficiency testing means any of the following:

(1) Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events.

(2) Repeated unsatisfactory overall testing event scores for two consecutive or two out of three testing events for the same specialty or subspecialty.

(3) An unsatisfactory testing event score for those subspecialties not graded by analyte (that is, bacteriology, mycobacteriology, virology, parasitology, mycology, blood compatibility, immunohematology, or syphilis serology) for the same subspecialty for two consecutive or two out of three testing events.

(4) Failure of a laboratory performing gynecologic cytology to meet the standard at § 493.855.

Unsuccessful proficiency testing performance means a failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two of three consecutive testing events.

Validation review period means the one year time period during which CMS conducts validation inspections and evaluates the results of the most recent surveys performed by an accreditation organization or State laboratory program.

Waived test means a test system, assay, or examination that HHS has determined meets the CLIA statutory criteria as specified for waiver under

section 353(d)(3) of the Public Health Service Act.

[57 FR 7139, Feb. 28, 1992, as amended at 57 FR 7236, Feb. 28, 1992; 57 FR 34013, July 31, 1992; 57 FR 35761, Aug. 11, 1992; 58 FR 5220, Jan. 19, 1993; 58 FR 48323, Sept. 15, 1993; 60 FR 20043, Apr. 24, 1995; 63 FR 26732, May 14, 1998; 68 FR 3702, Jan. 24, 2003; 68 FR 50723, Aug. 22, 2003]

§ 493.3 Applicability.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, a laboratory will be cited as out of compliance with section 353 of the Public Health Service Act unless it—

(1) Has a current, unrevoked or unsuspended certificate of waiver, registration certificate, certificate of compliance, certificate for PPM procedures, or certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory; or

(2) Is CLIA-exempt.

(b) *Exception.* These rules do not apply to components or functions of—

(1) Any facility or component of a facility that only performs testing for forensic purposes;

(2) Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients; or

(3) Laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed which meets SAMHSA guidelines and regulations. However, all other testing conducted by a SAMHSA-certified laboratory is subject to this rule.

(c) *Federal laboratories.* Laboratories under the jurisdiction of an agency of the Federal Government are subject to the rules of this part, except that the Secretary may modify the application of such requirements as appropriate.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5221, Jan. 19, 1993; 60 FR 20043, Apr. 24, 1995; 68 FR 3702, Jan. 24, 2003]

§ 493.5 Categories of tests by complexity.

(a) Laboratory tests are categorized as one of the following:

(1) Waived tests.

(2) Tests of moderate complexity, including the subcategory of PPM procedures.

(3) Tests of high complexity.

(b) A laboratory may perform only waived tests, only tests of moderate complexity, only PPM procedures, only tests of high complexity or any combination of these tests.

(c) Each laboratory must be either CLIA-exempt or possess one of the following CLIA certificates, as defined in § 493.2:

(1) Certificate of registration or registration certificate.

(2) Certificate of waiver.

(3) Certificate for PPM procedures.

(4) Certificate of compliance.

(5) Certificate of accreditation.

[60 FR 20043, Apr. 24, 1995]

§ 493.15 Laboratories performing waived tests.

(a) *Requirement.* Tests for certificate of waiver must meet the descriptive criteria specified in paragraph (b) of this section.

(b) *Criteria.* Test systems are simple laboratory examinations and procedures which—

(1) Are cleared by FDA for home use;

(2) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or

(3) Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

(c) *Certificate of waiver tests.* A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others:

(1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following:

(i) Bilirubin;

(ii) Glucose;

(iii) Hemoglobin;

(iv) Ketone;

(v) Leukocytes;

(vi) Nitrite;

(vii) pH;

(viii) Protein;

(ix) Specific gravity; and

(x) Urobilinogen.

(2) Fecal occult blood;

(3) Ovulation tests—visual color comparison tests for human luteinizing hormone;

(4) Urine pregnancy tests—visual color comparison tests;

(5) Erythrocyte sedimentation rate—non-automated;

(6) Hemoglobin—copper sulfate—non-automated;

(7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use;

(8) Spun microhematocrit; and

(9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.

(d) *Revisions to criteria for test categorization and the list of waived tests.* HHS will determine whether a laboratory test meets the criteria listed under paragraph (b) of this section for a waived test. Revisions to the list of waived tests approved by HHS will be published in the FEDERAL REGISTER in a notice with opportunity for comment.

(e) Laboratories eligible for a certificate of waiver must—

(1) Follow manufacturers' instructions for performing the test; and

(2) Meet the requirements in subpart B, Certificate of Waiver, of this part.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5221, Jan. 19, 1993]

§ 493.17 Test categorization.

(a) *Categorization by criteria.* Notices will be published in the FEDERAL REGISTER which list each specific test system, assay, and examination categorized by complexity. Using the seven criteria specified in this paragraph for categorizing tests of moderate or high complexity, each specific laboratory test system, assay, and examination will be graded for level of complexity by assigning scores of 1, 2, or 3 within each criteria. The score of ''1'' indicates the lowest level of complexity, and the score of ''3'' indicates the highest level. These scores will be totaled. Test systems, assays or examinations receiving scores of 12 or less will be categorized as moderate complexity, while those receiving scores above 12 will be categorized as high complexity.

NOTE: A score of ''2'' will be assigned to a criteria heading when the characteristics for a particular test are intermediate between the descriptions listed for scores of ''1'' and ''3.''

(1) *Knowledge.* (i) *Score 1.* (A) Minimal scientific and technical knowledge is required to perform the test; and

(B) Knowledge required to perform the test may be obtained through on-the-job instruction.

(ii) *Score 3.* Specialized scientific and technical knowledge is essential to perform preanalytic, analytic or postanalytic phases of the testing.

(2) *Training and experience.* (i) *Score 1.* (A) Minimal training is required for preanalytic, analytic and postanalytic phases of the testing process; and

(B) Limited experience is required to perform the test.

(ii) *Score 3.* (A) Specialized training is essential to perform the preanalytic, analytic or postanalytic testing process; or

(B) Substantial experience may be necessary for analytic test performance.

(3) *Reagents and materials preparation.* (i) *Score 1.* (A) Reagents and materials are generally stable and reliable; and

(B) Reagents and materials are prepackaged, or premeasured, or require no special handling, precautions or storage conditions.

(ii) *Score 3.* (A) Reagents and materials may be labile and may require special handling to assure reliability; or

(B) Reagents and materials preparation may include manual steps such as gravimetric or volumetric measurements.

(4) *Characteristics of operational steps.* (i) *Score 1.* Operational steps are either automatically executed (such as pipetting, temperature monitoring, or timing of steps), or are easily controlled.

(ii) *Score 3.* Operational steps in the testing process require close monitoring or control, and may require special specimen preparation, precise temperature control or timing of procedural steps, accurate pipetting, or extensive calculations.

(5) *Calibration, quality control, and proficiency testing materials.* (i) *Score 1.* (A) Calibration materials are stable and readily available;

(B) Quality control materials are stable and readily available; and

(C) External proficiency testing materials, when available, are stable.

(ii) *Score 3.* (A) Calibration materials, if available, may be labile;

(B) Quality control materials may be labile, or not available; or

(C) External proficiency testing materials, if available, may be labile.

(6) *Test system troubleshooting and equipment maintenance.* (i) *Score 1.* (A) Test system troubleshooting is automatic or self-correcting, or clearly described or requires minimal judgment; and

(B) Equipment maintenance is provided by the manufacturer, is seldom needed, or can easily be performed.

(ii) *Score 3.* (A) Troubleshooting is not automatic and requires decision-making and direct intervention to resolve most problems; or

(B) Maintenance requires special knowledge, skills, and abilities.

(7) *Interpretation and judgment.* (i) *Score 1.* (A) Minimal interpretation and judgment are required to perform preanalytic, analytic and postanalytic processes; and

(B) Resolution of problems requires limited independent interpretation and judgment; and

(ii) *Score 3.* (A) Extensive independent interpretation and judgment are required to perform the preanalytic, analytic or postanalytic processes; and

(B) Resolution of problems requires extensive interpretation and judgment.

(b) *Revisions to the criteria for categorization.* The Clinical Laboratory Improvement Advisory Committee, as defined in subpart T of this part, will conduct reviews upon request of HHS and recommend to HHS revisions to the criteria for categorization of tests.

(c) *Process for device/test categorization utilizing the scoring system under § 493.17(a).* (1)(i) For new commercial test systems, assays, or examinations, the manufacturer, as part of its 510(k) and PMA application to FDA, will submit supporting data for device/test categorization. FDA will determine the complexity category, notify the manufacturers directly, and will simultaneously inform both CMS and CDC of the device/test category. FDA will consult with CDC concerning test categorization in the following three situations:

(A) When categorizing previously uncategorized new technology;

(B) When FDA determines it to be necessary in cases involving a request for a change in categorization; and

(C) If a manufacturer requests review of a categorization decision by FDA in accordance with 21 CFR 10.75.

(ii) Test categorization will be effective as of the notification to the applicant.

(2) For test systems, assays, or examinations not commercially available, a laboratory or professional group may submit a written request for categorization to PHS. These requests will be forwarded to CDC for evaluation; CDC will determine complexity category and notify the applicant, CMS, and FDA of the categorization decision. In the case of request for a change of category or for previously uncategorized new technology, PHS will receive the request application and forward it to CDC for categorization.

(3) A request for recategorization will be accepted for review if it is based on new information not previously submitted in a request for categorization or recategorization by the same applicant and will not be considered more frequently than once per year.

(4) If a laboratory test system, assay or examination does not appear on the lists of tests in the FEDERAL REGISTER notices, it is considered to be a test of high complexity until PHS, upon request, reviews the matter and notifies the applicant of its decision. Test categorization is effective as of the notification to the applicant.

(5) PHS will publish revisions periodically to the list of moderate and high complexity tests in the FEDERAL REGISTER in a notice with opportunity for comment.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993]

§ 493.19 Provider-performed microscopy (PPM) procedures.

(a) *Requirement.* To be categorized as a PPM procedure, the procedure must

meet the criteria specified in paragraph (b) of this section.

(b) *Criteria.* Procedures must meet the following specifications:

(1) The examination must be personally performed by one of the following practitioners:

(i) A physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or an employee.

(ii) A midlevel practitioner, under the supervision of a physician or in independent practice only if authorized by the State, during the patient's visit on a specimen obtained from his or her own patient or from a patient of a clinic, group medical practice, or other health care provider of which the midlevel practitioner is a member or an employee.

(iii) A dentist during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

(2) The procedure must be categorized as moderately complex.

(3) The primary instrument for performing the test is the microscope, limited to bright-field or phase-contrast microscopy.

(4) The specimen is labile or delay in performing the test could compromise the accuracy of the test result.

(5) Control materials are not available to monitor the entire testing process.

(6) Limited specimen handling or processing is required.

(c) *Provider-performed microscopy (PPM) examinations.* A laboratory may qualify to perform tests under this section if it restricts PPM examinations to one or more of the following procedures (or additional procedures added to this list as provided under paragraph (d) of this section), waived tests and no others:

(1) All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements.

(2) All potassium hydroxide (KOH) preparations.

(3) Pinworm examinations.

(4) Fern tests.

(5) Post-coital direct, qualitative examinations of vaginal or cervical mucous.

(6) Urine sediment examinations.

(7) Nasal smears for granulocytes.

(8) Fecal leukocyte examinations.

(9) Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

(d) *Revisions to criteria and the list of PPM procedures.* (1) The CLIAC conducts reviews upon HHS' request and recommends to HHS revisions to the criteria for categorization of procedures.

(2) HHS determines whether a laboratory procedure meets the criteria listed under paragraph (b) of this section for a PPM procedure. Revisions to the list of PPM procedures proposed by HHS are published in the FEDERAL REGISTER as a notice with an opportunity for public comment.

(e) *Laboratory requirements.* Laboratories eligible to perform PPM examinations must—

(1) Meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, and M of this part.

(2) Be subject to inspection as specified under subpart Q of this part.

[60 FR 20044, Apr. 24, 1995; 68 FR 50723, Aug. 22, 2003]

§ 493.20 Laboratories performing tests of moderate complexity.

(a) A laboratory may qualify for a certificate to perform tests of moderate complexity provided that it restricts its test performance to waived tests or examinations and one or more tests or examinations meeting criteria for tests of moderate complexity including the subcategory of PPM procedures.

(b) A laboratory that performs tests or examinations of moderate complexity must meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, M, and Q of this part. Under a registration certificate or certificate of compliance, laboratories also performing PPM procedures must meet the inspection requirements at §§ 493.1773 and 493.1777.

(c) If the laboratory also performs waived tests, compliance with subparts H, J, K, and M of this part is not applicable to the waived tests. However, the

laboratory must comply with the requirements in §§ 493.15(e), 493.1773, and 493.1775.

[60 FR 20044, Apr. 24, 1995, as amended at 68 FR 3702, Jan. 24, 2003; 68 FR 50723, Aug. 22, 2003]

§ 493.25 Laboratories performing tests of high complexity.

(a) A laboratory must obtain a certificate for tests of high complexity if it performs one or more tests that meet the criteria for tests of high complexity as specified in § 493.17(a).

(b) A laboratory performing one or more tests of high complexity must meet the applicable requirements of subpart C or subpart D, and subparts F, H, J, K, M, and Q of this part.

(c) If the laboratory also performs tests of moderate complexity, the applicable requirements of subparts H, J, K, M, and Q of this part must be met. Under a registration certificate or certificate of compliance, PPM procedures must meet the inspection requirements at §§ 493.1773 and 493.1777.

(d) If the laboratory also performs waived tests, the requirements of subparts H, J, K, and M are not applicable to the waived tests. However, the laboratory must comply with the requirements in §§ 493.15(e), 493.1773, and 493.1775.

[57 FR 7139, Feb. 28, 1992, as amended at 60 FR 20044, Apr. 24, 1995; 68 FR 3702, Jan. 24, 2003; 68 FR 50723, Aug. 22, 2003]

Subpart B—Certificate of Waiver

SOURCE: 57 FR 7142, Feb. 28, 1992, unless otherwise noted.

§ 493.35 Application for a certificate of waiver.

(a) *Filing of application.* Except as specified in paragraph (b) of this section, a laboratory performing only one or more waived tests listed in § 493.15 must file a separate application for each laboratory location.

(b) *Exceptions.* (1) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

(c) *Application format and contents.* The application must—

(1) Be made to HHS or its designee on a form or forms prescribed by HHS;

(2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with requirements established by the Secretary under section 353 of the PHS Act; and

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including—

(i) The name and the total number of test procedures and examinations performed annually (excluding tests the laboratory may run for quality control, quality assurance or proficiency testing purposes;

(ii) The methodologies for each laboratory test procedure or examination performed, or both; and

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

(d) *Access requirements.* Laboratories that perform one or more waived tests listed in § 493.15(c) and no other tests must meet the following conditions:

(1) Make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section and § 493.15(e);

(2) Agree to permit announced and unannounced inspections by HHS in accordance with subpart Q of this part under the following circumstances:

(i) When HHS has substantive reason to believe that the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health.

(ii) To evaluate complaints from the public.

(iii) On a random basis to determine whether the laboratory is performing tests not listed in § 493.15.

(iv) To collect information regarding the appropriateness of waiver of tests listed in § 493.15.

(e) *Denial of application.* If HHS determines that the application for a certificate of waiver is to be denied, HHS will—

(1) Provide the laboratory with a written statement of the grounds on which the denial is based and an opportunity for appeal, in accordance with the procedures set forth in subpart R of this part;

(2) Notify a laboratory that has its application for a certificate of waiver denied that it cannot operate as a laboratory under the PHS Act unless the denial is overturned at the conclusion of the administrative appeals process provided by subpart R; and

(3) Notify the laboratory that it is not eligible for payment under the Medicare and Medicaid programs.

[57 FR 7142, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993; 60 FR 20044, Apr. 24, 1995]

§ 493.37 Requirements for a certificate of waiver.

(a) HHS will issue a certificate of waiver to a laboratory only if the laboratory meets the requirements of § 493.35.

(b) Laboratories issued a certificate of waiver—

(1) Are subject to the requirements of this subpart and § 493.15(e) of subpart A of this part; and

(2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q of this part.

(c) Laboratories must remit the certificate of waiver fee specified in subpart F of this part.

(d) In accordance with subpart R of this part, HHS will suspend or revoke or limit a laboratory's certificate of waiver for failure to comply with the requirements of this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare and Medicaid in accordance with subpart R of this part.

(e)(1) A certificate of waiver issued under this subpart is valid for no more than 2 years. In the event of a non-compliance determination resulting in HHS action to revoke, suspend, or limit the laboratory's certificate of waiver, HHS will provide the laboratory with a statement of grounds on which the determination of non-compliance is based and offer an opportunity for appeal as provided in subpart R of this part.

(2) If the laboratory requests a hearing within the time specified by HHS, it retains its certificate of waiver or reissued certificate of waiver until a decision is made by an administrative law judge, as specified in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(3) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of a non-compliance determination even if there has been no appeals decision issued.

(f) A laboratory seeking to renew its certificate of waiver must—

(1) Complete the renewal application prescribed by HHS and return it to HHS not less than 9 months nor more than 1 year before the expiration of the certificate; and

(2) Meet the requirements of §§ 493.35 and 493.37.

(g) A laboratory with a certificate of waiver that wishes to perform examinations or tests not listed in the waiver test category must meet the requirements set forth in subpart C or subpart D of this part, as applicable.

[57 FR 7142, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993; 60 FR 20045, Apr. 24, 1995]

§ 493.39 Notification requirements for laboratories issued a certificate of waiver.

Laboratories performing one or more tests listed in § 493.15 and no others must notify HHS or its designee—

(a) Before performing and reporting results for any test or examination that is not specified under § 493.15 for which the laboratory does not have the appropriate certificate as required in subpart C or subpart D of this part, as applicable; and

(b) Within 30 days of any change(s) in—

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director.

[57 FR 7142, Feb. 28, 1992, as amended at 60 FR 20045, Apr. 24, 1995]

Subpart C—Registration Certificate, Certificate for Provider-performed Microscopy Procedures, and Certificate of Compliance

SOURCE: 57 FR 7143, Feb. 28, 1992, unless otherwise noted.

§ 493.43 Application for registration certificate, certificate for provider-performed microscopy (PPM) procedures, and certificate of compliance.

(a) *Filing of application.* Except as specified in paragraph (b) of this section, all laboratories performing nonwaived testing must file a separate application for each laboratory location.

(b) *Exceptions.* (1) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

(c) *Application format and contents.* The application must—(1) Be made to HHS or its designee on a form or forms prescribed by HHS;

(2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with the requirements established by the Secretary under section 353 of the Public Health Service Act; and

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including—

(i) The name and total number of test procedures and examinations performed annually (excluding waived tests or tests for quality control, quality assurance or proficiency testing purposes);

(ii) The methodologies for each laboratory test procedure or examination performed, or both;

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the examinations and test procedures.

(d) *Access and reporting requirements.* All laboratories must make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section.

[57 FR 7143, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993; 58 FR 39155, July 22, 1993; 60 FR 20045, Apr. 24, 1995; 68 FR 3702, Jan. 24, 2003]

§ 493.45 Requirements for a registration certificate.

Laboratories performing only waived tests, PPM procedures, or any combination of these tests, are not required to obtain a registration certificate.

(a) A registration certificate is required—(1) Initially for all laboratories performing test procedures of moderate complexity (other than the subcategory of PPM procedures) or high complexity, or both; and

(2) For all laboratories that have been issued a certificate of waiver or certificate for PPM procedures that intend to perform tests of moderate or high complexity, or both, in addition to those tests listed in § 493.15(c) or specified as PPM procedures.

(b) HHS will issue a registration certificate if the laboratory—

(1) Complies with the requirements of § 493.43;

(2) Agrees to notify HHS or its designee within 30 days of any changes in ownership, name, location, director or technical supervisor (laboratories performing high complexity testing only);

(3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens; and

(4) Remits the fee for the registration certificate, as specified in subpart F of this part.

(c) Prior to the expiration of the registration certificate, a laboratory must—

(1) Remit the certificate fee specified in subpart F of this part;

(2) Be inspected by HHS as specified in subpart Q of this part; and

(3) Demonstrate compliance with the applicable requirements of this subpart and subparts H, J, K, M, and Q of this part.

(d) In accordance with subpart R of this part, HHS will initiate suspension or revocation of a laboratory's registration certificate and will deny the laboratory's application for a certificate of compliance for failure to comply with the requirements set forth in this subpart. HHS may also impose certain alternative sanctions. In addition, failure to meet the requirements of this subpart will result in suspension of payments under Medicare and Medicaid as specified in subpart R of this part.

(e) A registration certificate is—

(1) Valid for a period of no more than two years or until such time as an inspection to determine program compliance can be conducted, whichever is shorter; and

(2) Not renewable; however, the registration certificate may be reissued if compliance has not been determined by HHS prior to the expiration date of the registration certificate.

(f) In the event of a noncompliance determination resulting in an HHS denial of a laboratory's certificate of compliance application, HHS will provide the laboratory with a statement of grounds on which the noncompliance determination is based and offer an opportunity for appeal as provided in subpart R.

(g) If the laboratory requests a hearing within the time specified by HHS, it retains its registration certificate or reissued registration certificate until a decision is made by an administrative law judge as provided in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(h) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of denial of the certificate application even if there has been no appeals decision issued.

[57 FR 7143, Feb. 28, 1992, as amended at 58 FR 5223, Jan. 19, 1993; 60 FR 20045, Apr. 24, 1995; 68 FR 3702, Jan. 24, 2003]

§ 493.47 Requirements for a certificate for provider-performed microscopy (PPM) procedures.

(a) A certificate for PPM procedures is required—

(1) Initially for all laboratories performing test procedures specified as PPM procedures; and

(2) For all certificate of waiver laboratories that intend to perform only test procedures specified as PPM procedures in addition to those tests listed in § 493.15(c).

(b) HHS will issue a certificate for PPM procedures if the laboratory—

(1) Complies with the requirements of § 493.43; and

(2) Remits the fee for the certificate, as specified in subpart F of this part.

(c) Laboratories issued a certificate for PPM procedures are subject to—

(1) The notification requirements of § 493.53;

(2) The applicable requirements of this subpart and subparts H, J, K, and M of this part; and

(3) Inspection only under the circumstances specified under §§ 493.1773 and 493.1775, but are not routinely inspected to determine compliance with

the requirements specified in paragraphs (c) (1) and (2) of this section.

(d) In accordance with subpart R of this part, HHS will initiate suspension, limitation, or revocation of a laboratory's certificate for PPM procedures for failure to comply with the applicable requirements set forth in this subpart. HHS may also impose certain alternative sanctions. In addition, failure to meet the requirements of this subpart may result in suspension of all or part of payments under Medicare and Medicaid, as specified in subpart R of this part.

(e) A certificate for PPM procedures is valid for a period of no more than 2 years.

[58 FR 5223, Jan. 19, 1993, as amended at 60 FR 20045, Apr. 24, 1995; 68 FR 3702, Jan. 24, 2003; 68 FR 50723, Aug. 22, 2003]

§ 493.49 Requirements for a certificate of compliance.

A certificate of compliance may include any combination of tests categorized as high complexity or moderate complexity or listed in § 493.15(c) as waived tests. Moderate complexity tests may include those specified as PPM procedures.

(a) HHS will issue a certificate of compliance to a laboratory only if the laboratory—

(1) Meets the requirements of §§ 493.43 and 493.45;

(2) Remits the certificate fee specified in subpart F of this part; and

(3) Meets the applicable requirements of this subpart and subparts H, J, K, M, and Q of this part.

(b) Laboratories issued a certificate of compliance—

(1) Are subject to the notification requirements of § 493.51; and

(2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q of this part—

(i) To determine compliance with the applicable requirements of this part;

(ii) To evaluate complaints;

(iii) When HHS has substantive reason to believe that tests are being performed, or the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health; and

(iv) To collect information regarding the appropriateness of tests listed in § 493.15 or tests categorized as moderate complexity (including the subcategory) or high complexity.

(c) Failure to comply with the requirements of this subpart will result in—

(1) Suspension, revocation or limitation of a laboratory's certificate of compliance in accordance with subpart R of this part; and

(2) Suspension or denial of payments under Medicare and Medicaid in accordance with subpart R of this part.

(d) A certificate of compliance issued under this subpart is valid for no more than 2 years.

(e) In the event of a noncompliance determination resulting in an HHS action to revoke, suspend or limit the laboratory's certificate of compliance, HHS will—

(1) Provide the laboratory with a statement of grounds on which the determination of noncompliance is based; and

(2) Offer an opportunity for appeal as provided in subpart R of this part. If the laboratory requests a hearing within 60 days of the notice of sanction, it retains its certificate of compliance or reissued certificate of compliance until a decision is made by an administrative law judge (ALJ) as provided in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health or when the criteria at § 493.1840(a) (4) and (5) are met.

(f) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of a noncompliance determination even if there has been no appeals decision issued.

(g) A laboratory seeking to renew its certificate of compliance must—

(1) Complete and return the renewal application to HHS 9 to 12 months prior to the expiration of the certificate of compliance; and

(2) Meet the requirements of § 493.43 and paragraphs (a)(2) and (b)(2) of this section.

(h) If HHS determines that the application for the renewal of a certificate

of compliance must be denied or limited, HHS will notify the laboratory in writing of the—

(1) Basis for denial of the application; and

(2) Opportunity for appeal as provided in subpart R of this part.

(i) If the laboratory requests a hearing within the time period specified by HHS, the laboratory retains its certificate of compliance or reissued certificate of compliance until a decision is made by an ALJ as provided in subpart R, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(j) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of nonrenewal of the certificate of compliance even if there has been no appeals decision issued.

[60 FR 20045, Apr. 24, 1995, as amended at 68 FR 3702, Jan. 24, 2003]

§ 493.51 Notification requirements for laboratories issued a certificate of compliance.

Laboratories issued a certificate of compliance must meet the following conditions:

(a) Notify HHS or its designee within 30 days of any change in—

(1) Ownership;

(2) Name;

(3) Location;

(4) Director; or

(5) Technical supervisor (laboratories performing high complexity only).

(b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory's certificate of compliance, so that compliance with requirements can be determined.

(c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance.

[57 FR 7143, Feb. 28, 1992, as amended at 60 FR 20046, Apr. 24, 1995]

§ 493.53 Notification requirements for laboratories issued a certificate for provider-performed microscopy (PPM) procedures.

Laboratories issued a certificate for PPM procedures must notify HHS or its designee—

(a) Before performing and reporting results for any test of moderate or high complexity, or both, in addition to tests specified as PPM procedures or any test or examination that is not specified under § 493.15(c), for which it does not have a registration certificate as required in subpart C or subpart D, as applicable, of this part; and

(b) Within 30 days of any change in—

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director.

[58 FR 5224, Jan. 19, 1993, as amended at 60 FR 20046, Apr. 24, 1995]

Subpart D—Certificate of Accreditation

SOURCE: 57 FR 7144, Feb. 28, 1992, unless otherwise noted.

§ 493.55 Application for registration certificate and certificate of accreditation.

(a) *Filing of application.* A laboratory may be issued a certificate of accreditation in lieu of the applicable certificate specified in subpart B or subpart C of this part provided the laboratory—

(1) Meets the standards of a private non-profit accreditation program approved by HHS in accordance with subpart E; and

(2) Files a separate application for each location, except as specified in paragraph (b) of this section.

(b) *Exceptions.* (1) Laboratories that are not at fixed locations, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex

or waived tests per certificate) public health testing may file a single application.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

(c) *Application format and contents.* The application must—(1) Be made to HHS on a form or forms prescribed by HHS;

(2) Be signed by an owner or authorized representative of the laboratory who attests that the laboratory will be operated in accordance with the requirements established by the Secretary under section 353 of the Public Health Service Act; and

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including—

(i) The name and total number of tests and examinations performed annually (excluding waived tests and tests for quality control, quality assurance or proficiency testing purposes);

(ii) The methodologies for each laboratory test procedure or examination performed, or both; and

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

(d) *Access and reporting requirements.* All laboratories must make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section.

[57 FR 7144, Feb. 28, 1992, as amended at 58 FR 5224, Jan. 19, 1993; 58 FR 39155, July 22, 1993; 60 FR 20046, Apr. 24, 1995]

§ 493.57 Requirements for a registration certificate.

A registration certificate is required for all laboratories seeking a certificate of accreditation, unless the laboratory holds a valid certificate of compliance issued by HHS.

(a) HHS will issue a registration certificate if the laboratory—

(1) Complies with the requirements of § 493.55;

(2) Agrees to notify HHS within 30 days of any changes in ownership, name, location, director, or supervisor (laboratories performing high complexity testing only);

(3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens; and

(4) Remits the fee for the registration certificate specified in subpart F of this part.

(b)(1) The laboratory must provide HHS with proof of accreditation by an approved accreditation program—

(i) Within 11 months of issuance of the registration certificate; or

(ii) Prior to the expiration of the certificate of compliance.

(2) If such proof of accreditation is not supplied within this timeframe, the laboratory must meet, or continue to meet, the requirements of § 493.49.

(c) In accordance with subpart R of this part, HHS will initiate suspension, revocation, or limitation of a laboratory's registration certificate and will deny the laboratory's application for a certificate of accreditation for failure to comply with the requirements set forth in this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare and Medicaid as specified in subpart R of this part.

(d) A registration certificate is valid for a period of no more than 2 years. However, it may be reissued if the laboratory is subject to subpart C of this part, as specified in § 493.57(b)(2) and compliance has not been determined by HHS before the expiration date of the registration certificate.

(e) In the event that the laboratory does not meet the requirements of this subpart, HHS will—

(1) Deny a laboratory's request for certificate of accreditation;

(2) Notify the laboratory if it must meet the requirements for a certificate as defined in subpart C of this part;

(3) Provide the laboratory with a statement of grounds on which the application denial is based;

(4) Offer an opportunity for appeal on the application denial as provided in subpart R of this part. If the laboratory requests a hearing within the time specified by HHS, the laboratory will

retain its registration certificate or reissued registration certificate until a decision is made by an administrative law judge as provided in subpart R, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and

(5) For those laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of denial of the request even if there has been no appeals decision issued.

[57 FR 7144, Feb. 28, 1992, as amended at 60 FR 20046, Apr. 24, 1995]

§ 493.61 Requirements for a certificate of accreditation.

(a) HHS will issue a certificate of accreditation to a laboratory if the laboratory—

(1) Meets the requirements of § 493.57 or, if applicable, § 493.49 of subpart C of this part; and

(2) Remits the certificate of accreditation fee specified in subpart F of this part.

(b) Laboratories issued a certificate of accreditation must—

(1) Treat proficiency testing samples in the same manner as patient samples;

(2) Meet the requirements of § 493.63;

(3) Comply with the requirements of the approved accreditation program;

(4) Permit random sample validation and complaint inspections as required in subpart Q of this part;

(5) Permit HHS to monitor the correction of any deficiencies found through the inspections specified in paragraph (b)(4) of this section;

(6) Authorize the accreditation program to release to HHS the laboratory's inspection findings whenever HHS conducts random sample or complaint inspections; and

(7) Authorize its accreditation program to submit to HHS the results of the laboratory's proficiency testing.

(c) A laboratory failing to meet the requirements of this section—

(1) Will no longer meet the requirements of this part by virtue of its accreditation in an approved accreditation program;

(2) Will be subject to full determination of compliance by HHS;

(3) May be subject to suspension, revocation or limitation of the laboratory's certificate of accreditation or certain alternative sanctions; and

(4) May be subject to suspension of payments under Medicare and Medicaid as specified in subpart R.

(d) A certificate of accreditation issued under this subpart is valid for no more than 2 years. In the event of a non-compliance determination as a result of a random sample validation or complaint inspection, a laboratory will be subject to a full review by HHS in accordance with § 488.11 of this chapter.

(e) Failure to meet the applicable requirements of part 493, will result in an action by HHS to suspend, revoke or limit the certificate of accreditation. HHS will—

(1) Provide the laboratory with a statement of grounds on which the determination of noncompliance is based;

(2) Notify the laboratory if it is eligible to apply for a certificate as defined in subpart C of this part; and

(3) Offer an opportunity for appeal as provided in subpart R of this part.

(f) If the laboratory requests a hearing within the time frame specified by HHS—

(1) It retains its certificate of accreditation or reissued certificate of accreditation until a decision is made by an administrative law judge as provided in subpart R of this part, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and

(2) For those laboratories receiving payments from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory even if there has been no appeals decision issued.

(g) In the event the accreditation organization's approval is removed by HHS, the laboratory will be subject to the applicable requirements of subpart C of this part or § 493.57.

(h) A laboratory seeking to renew its certificate of accreditation must—

(1) Complete and return the renewal application to HHS 9 to 12 months prior to the expiration of the certificate of accreditation;

(2) Meet the requirements of this subpart; and

(3) Submit the certificate of accreditation fee specified in subpart F of this part.

(i) If HHS determines that the renewal application for a certificate of accreditation is to be denied or limited, HHS will notify the laboratory in writing of—

(1) The basis for denial of the application;

(2) Whether the laboratory is eligible for a certificate as defined in subpart C of this part;

(3) The opportunity for appeal on HHS's action to deny the renewal application for certificate of accreditation as provided in subpart R of this part. If the laboratory requests a hearing within the time frame specified by HHS, it retains its certificate of accreditation or reissued certificate of accreditation until a decision is made by an administrative law judge as provided in subpart R of this part, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and

(4) Suspension of payments under Medicare or Medicaid for those laboratories receiving payments under the Medicare or Medicaid programs.

[57 FR 7144, Feb. 28, 1992, as amended at 58 FR 5224, Jan. 19, 1993]

§ 493.63 Notification requirements for laboratories issued a certificate of accreditation.

Laboratories issued a certificate of accreditation must:

(a) Notify HHS and the approved accreditation program within 30 days of any changes in—

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director.

(b) Notify the approved accreditation program no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included in the laboratory's accreditation, so that the accreditation organization can determine compliance and a new certificate of accreditation can be issued.

(c) Notify the accreditation program no later than 6 months after of any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of accreditation.

Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

SOURCE: 63 FR 26732, May 14, 1998, unless otherwise noted.

§ 493.551 General requirements for laboratories.

(a) *Applicability*. CMS may deem a laboratory to meet all applicable CLIA program requirements through accreditation by a private nonprofit accreditation program (that is, grant deemed status), or may exempt from CLIA program requirements all State licensed or approved laboratories in a State that has a State licensure program established by law, if the following conditions are met:

(1) The requirements of the accreditation organization or State licensure program are equal to, or more stringent than, the CLIA condition-level requirements specified in this part, and the laboratory would meet the condition-level requirements if it were inspected against these requirements.

(2) The accreditation program or the State licensure program meets the requirements of this subpart and is approved by CMS.

(3) The laboratory authorizes the approved accreditation organization or State licensure program to release to CMS all records and information required and permits inspections as outlined in this part.

(b) *Meeting CLIA requirements by accreditation*. A laboratory seeking to meet CLIA requirements through accreditation by an approved accreditation organization must do the following:

(1) Obtain a certificate of accreditation as required in subpart D of this part.

(2) Pay the applicable fees as required in subpart F of this part.

(3) Meet the proficiency testing (PT) requirements in subpart H of this part.

(4) Authorize its PT organization to furnish to its accreditation organization the results of the laboratory's participation in an approved PT program for the purpose of monitoring the laboratory's PT and for making the annual PT results, along with explanatory information required to interpret the PT results, available on a reasonable basis, upon request of any person. A laboratory that refuses to authorize release of its PT results is no longer deemed to meet the condition-level requirements and is subject to a full review by CMS, in accordance with subpart Q of this part, and may be subject to the suspension or revocation of its certificate of accreditation under § 493.1840.

(5) Authorize its accreditation organization to release to CMS or a CMS agent the laboratory's PT results that constitute unsuccessful participation in an approved PT program, in accordance with the definition of ''unsuccessful participation in an approved PT program,'' as specified in § 493.2 of this part, when the laboratory has failed to achieve successful participation in an approved PT program.

(6) Authorize its accreditation organization to release to CMS a notification of the actions taken by the organization as a result of the unsuccessful participation in a PT program within 30 days of the initiation of the action. Based on this notification, CMS may take an adverse action against a laboratory that fails to participate successfully in an approved PT program.

(c) *Withdrawal of laboratory accreditation.* After an accreditation organization has withdrawn or revoked its accreditation of a laboratory, the laboratory retains its certificate of accreditation for 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation, or the effective date of any action taken by CMS, whichever is earlier.

§ 493.553 Approval process (application and reapplication) for accreditation organizations and State licensure programs.

(a) *Information required.* An accreditation organization that applies or reapplies to CMS for deeming authority, or a State licensure program that applies or reapplies to CMS for exemption from CLIA program requirements of licensed or approved laboratories within the State, must provide the following information:

(1) A detailed comparison of the individual accreditation, or licensure or approval requirements with the comparable condition-level requirements; that is, a crosswalk.

(2) A detailed description of the inspection process, including the following:

(i) Frequency of inspections.

(ii) Copies of inspection forms.

(iii) Instructions and guidelines.

(iv) A description of the review and decision-making process of inspections.

(v) A statement concerning whether inspections are announced or unannounced.

(vi) A description of the steps taken to monitor the correction of deficiencies.

(3) A description of the process for monitoring PT performance, including action to be taken in response to unsuccessful participation in a CMS-approved PT program.

(4) Procedures for responding to and for the investigation of complaints against its laboratories.

(5) A list of all its current laboratories and the expiration date of their accreditation or licensure, as applicable.

(6) Procedures for making PT information available (under State confidentiality and disclosure requirements, if applicable) including explanatory information required to interpret PT results, on a reasonable basis, upon request of any person.

(b) *CMS action on an application or reapplication.* If CMS receives an application or reapplication from an accreditation organization, or State licensure program, CMS takes the following actions:

(1) CMS determines if additional information is necessary to make a determination for approval or denial of the application and notifies the accreditation organization or State to afford it an opportunity to provide the additional information.

(2) CMS may visit the accreditation organization or State licensure program offices to review and verify the

policies and procedures represented in its application and other information, including, but not limited to, review and examination of documents and interviews with staff.

(3) CMS notifies the accreditation organization or State licensure program indicating whether CMS approves or denies the request for deeming authority or exemption, respectively, and the rationale for any denial.

(c) *Duration of approval.* CMS approval may not exceed 6 years.

(d) *Withdrawal of application.* The accreditation organization or State licensure program may withdraw its application at any time before official notification, specified at § 493.553(b)(3).

§ 493.555 Federal review of laboratory requirements.

CMS's review of an accreditation organization or State licensure program includes, but is not limited to, an evaluation of the following:

(a) Whether the organization's or State's requirements for laboratories are equal to, or more stringent than, the condition-level requirements for laboratories.

(b) The organization's or State's inspection process to determine the comparability of the full inspection and complaint inspection procedures and requirements to those of CMS, including, but not limited to, inspection frequency and the ability to investigate and respond to complaints against its laboratories.

(c) The organization's or State's agreement with CMS that requires it to do the following:

(1) Notify CMS within 30 days of the action taken, of any laboratory that has—

(i) Had its accreditation or licensure suspended, withdrawn, revoked, or limited;

(ii) In any way been sanctioned; or

(iii) Had any adverse action taken against it.

(2) Notify CMS within 10 days of any deficiency identified in an accredited or CLIA-exempt laboratory if the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public.

(3) Notify CMS, within 30 days, of all newly—

(i) Accredited laboratories (or laboratories whose areas of specialty/subspecialty testing have changed); or

(ii) Licensed laboratories, including the specialty/subspecialty areas of testing.

(4) Notify each accredited or licensed laboratory within 10 days of CMS's withdrawal of the organization's deeming authority or State's exemption.

(5) Provide CMS with inspection schedules, as requested, for validation purposes.

§ 493.557 Additional submission requirements.

(a) *Specific requirements for accreditation organizations.* In addition to the information specified in §§ 493.553 and 493.555, as part of the approval and review process, an accreditation organization applying or reapplying for deeming authority must also provide the following:

(1) The specialty or subspecialty areas for which the organization is requesting deeming authority and its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements within the scope of the specialty or subspecialty areas.

(2) A description of the organization's data management and analysis system with respect to its inspection and accreditation decisions, including the kinds of routine reports and tables generated by the systems.

(3) Detailed information concerning the inspection process, including, but not limited to the following:

(i) The size and composition of individual accreditation inspection teams.

(ii) Qualifications, education, and experience requirements that inspectors must meet.

(iii) The content and frequency of training provided to inspection personnel, including the ability of the organization to provide continuing education and training to inspectors.

(4) Procedures for removal or withdrawal of accreditation status for laboratories that fail to meet the organization's standards.

(5) A proposed agreement between CMS and the accreditation organization with respect to the notification requirements specified in § 493.555(c).

(6) Procedures for monitoring laboratories found to be out of compliance with its requirements. (These monitoring procedures must be used only when the accreditation organization identifies noncompliance. If noncompliance is identified through validation inspections, CMS or a CMS agent monitors corrections, as authorized at § 493.565(d)).

(7) A demonstration of its ability to provide CMS with electronic data and reports in compatible code, including the crosswalk specified in § 493.553(a)(1), that are necessary for effective validation and assessment of the organization's inspection process.

(8) A demonstration of its ability to provide CMS with electronic data, in compatible code, related to the adverse actions resulting from PT results constituting unsuccessful participation in PT programs as well as data related to the PT failures, within 30 days of the initiation of adverse action.

(9) A demonstration of its ability to provide CMS with electronic data, in compatible code, for all accredited laboratories, including the area of specialty or subspecialty.

(10) Information defining the adequacy of numbers of staff and other resources.

(11) Information defining the organization's ability to provide adequate funding for performing required inspections.

(12) Any facility-specific data, upon request by CMS, which includes, but is not limited to, the following:

(i) PT results that constitute unsuccessful participation in a CMS-approved PT program.

(ii) Notification of the adverse actions or corrective actions imposed by the accreditation organization as a result of unsuccessful PT participation.

(13) An agreement to provide written notification to CMS at least 30 days in advance of the effective date of any proposed change in its requirements.

(14) An agreement to disclose any laboratory's PT results upon reasonable request by any person.

(b) *Specific requirements for a State licensure program.* In addition to requirements in §§ 493.553 and 493.555, as part of the approval and review process, when a State licensure program applies or reapplies for exemption from the CLIA program, the State must do the following:

(1) Demonstrate to CMS that it has enforcement authority and administrative structures and resources adequate to enforce its laboratory requirements.

(2) Permit CMS or a CMS agent to inspect laboratories in the State.

(3) Require laboratories in the State to submit to inspections by CMS or a CMS agent as a condition of licensure or approval.

(4) Agree to pay the cost of the validation program administered in that State as specified in §§ 493.645(a) and 493.646(b).

(5) Take appropriate enforcement action against laboratories found by CMS not to be in compliance with requirements equivalent to CLIA requirements.

(6) Submit for Medicare and Medicaid payment purposes, a list of the specialties and subspecialties of tests performed by each laboratory.

(7) Submit a written presentation that demonstrates the agency's ability to furnish CMS with electronic data in compatible code, including the crosswalk specified in § 493.553(a)(1).

(8) Submit a statement acknowledging that the State will notify CMS through electronic transmission of the following:

(i) Any laboratory that has had its licensure or approval revoked or withdrawn or has been in any way sanctioned by the State within 30 days of taking the action.

(ii) Changes in licensure or inspection requirements.

(iii) Changes in specialties or subspecialties under which any licensed laboratory in the State performs testing.

(9) Provide information for the review of the State's enforcement procedures for laboratories found to be out of compliance with the State's requirements.

(10) Submit information that demonstrates the ability of the State to provide CMS with the following:

(i) Electronic data and reports in compatible code with the adverse or corrective actions resulting from PT results that constitute unsuccessful participation in PT programs.

(ii) Other data that CMS determines are necessary for validation and assessment of the State's inspection process requirements.

(11) Agree to provide CMS with written notification of any changes in its licensure/approval and inspection requirements.

(12) Agree to disclose any laboratory's PT results in accordance with a State's confidentiality requirements.

(13) Agree to take the appropriate enforcement action against laboratories found by CMS not to be in compliance with requirements comparable to condition-level requirements and report these enforcement actions to CMS.

(14) If approved, reapply to CMS every 2 years to renew its exempt status and to renew its agreement to pay the cost of the CMS-administered validation program in that State.

§ 493.559 Publication of approval of deeming authority or CLIA exemption.

(a) *Notice of deeming authority or exemption.* CMS publishes a notice in the FEDERAL REGISTER when it grants deeming authority to an accreditation organization or exemption to a State licensure program.

(b) *Contents of notice.* The notice includes the following:

(1) The name of the accreditation organization or State licensure program.

(2) For an accreditation organization:

(i) The specific specialty or subspecialty areas for which it is granted deeming authority.

(ii) A description of how the accreditation organization provides reasonable assurance to CMS that a laboratory accredited by the organization meets CLIA requirements equivalent to those in this part and would meet CLIA requirements if the laboratory had not been granted deemed status, but had been inspected against condition-level requirements.

(3) For a State licensure program, a description of how the laboratory requirements of the State are equal to, or more stringent than, those specified in this part.

(4) The basis for granting deeming authority or exemption.

(5) The term of approval, not to exceed 6 years.

§ 493.561 Denial of application or reapplication.

(a) *Reconsideration of denial.* (1) If CMS denies a request for approval, an accreditation organization or State licensure program may request, within 60 days of the notification of denial, that CMS reconsider its original application or application for renewal, in accordance with part 488, subpart D.

(2) If the accreditation organization or State licensure program requests a reconsideration of CMS's determination to deny its request for approval or reapproval, it may not submit a new application until CMS issues a final reconsideration determination.

(b) *Resubmittal of a request for approval—accreditation organization.* An accreditation organization may resubmit a request for approval if a final reconsideration determination is not pending and the accreditation program meets the following conditions:

(1) It has revised its accreditation program to address the rationale for denial of its previous request.

(2) It demonstrates that it can provide reasonable assurance that its accredited facilities meet condition-level requirements.

(3) It resubmits the application in its entirety.

(c) *Resubmittal of request for approval—State licensure program.* The State licensure program may resubmit a request for approval if a final reconsideration determination is not pending and it has taken the necessary action to address the rationale for any previous denial.

§ 493.563 Validation inspections—Basis and focus.

(a) *Basis for validation inspection*—(1) *Laboratory with a certificate of accreditation.* (i) CMS or a CMS agent may conduct an inspection of an accredited laboratory that has been issued a certificate of accreditation on a representative sample basis or in response to a substantial allegation of noncompliance.

(ii) CMS uses the results of these inspections to validate the accreditation organization's accreditation process.

(2) *Laboratory in a State with an approved State licensure program.* (i) CMS

or a CMS agent may conduct an inspection of any laboratory in a State with an approved State licensure program on a representative sample basis or in response to a substantial allegation of noncompliance.

(ii) The results of these inspections are used to validate the appropriateness of the exemption of that State's licensed or approved laboratories from CLIA program requirements.

(b) *Validation inspection conducted on a representative sample basis.* (1) If CMS or a CMS agent conducts a validation inspection on a representative sample basis, the inspection is comprehensive, addressing all condition-level requirements, or it may be focused on a specific condition-level requirement.

(2) The number of laboratories sampled is sufficient to allow a reasonable estimate of the performance of the accreditation organization or State.

(c) *Validation inspection conducted in response to a substantial allegation of noncompliance.* (1) If CMS or a CMS agent conducts a validation inspection in response to a substantial allegation of noncompliance, the inspection focuses on any condition-level requirement that CMS determines to be related to the allegation.

(2) If CMS or a CMS agent substantiates a deficiency and determines that the laboratory is out of compliance with any condition-level requirement, CMS or a CMS agent conducts a full CLIA inspection.

(d) *Inspection of operations and offices.* As part of the validation review process, CMS may conduct an onsite inspection of the operations and offices to verify the following:

(1) The accreditation organization's representations and to assess the accreditation organization's compliance with its own policies and procedures.

(2) The State's representations and to assess the State's compliance with its own policies and procedures, including verification of State enforcement actions taken on the basis of validation inspections performed by CMS or a CMS agent.

(e) *Onsite inspection of an accreditation organization.* An onsite inspection of an accreditation organization may include, but is not limited to, the following:

(1) A review of documents.

(2) An audit of meetings concerning the accreditation process.

(3) Evaluation of accreditation inspection results and the accreditation decision-making process.

(4) Interviews with the accreditation organization's staff.

(f) *Onsite inspection of a State licensure program.* An onsite inspection of a State licensure program office may include, but is not limited to, the following:

(1) A review of documents.

(2) An audit of meetings concerning the licensure or approval process.

(3) Evaluation of State inspection results and the licensure or approval decision-making process.

(4) Interviews with State employees.

§ 493.565 Selection for validation inspection—laboratory responsibilities.

A laboratory selected for a validation inspection must do the following:

(a) Authorize its accreditation organization or State licensure program, as applicable, to release to CMS or a CMS agent, on a confidential basis, a copy of the laboratory's most recent full, and any subsequent partial inspection.

(b) Authorize CMS or a CMS agent to conduct a validation inspection.

(c) Provide CMS or a CMS agent with access to all facilities, equipment, materials, records, and information that CMS or a CMS agent determines have a bearing on whether the laboratory is being operated in accordance with the requirements of this part, and permit CMS or a CMS agent to copy material or require the laboratory to submit material.

(d) If the laboratory possesses a valid certificate of accreditation, authorize CMS or a CMS agent to monitor the correction of any deficiencies found through the validation inspection.

§ 493.567 Refusal to cooperate with validation inspection.

(a) *Laboratory with a certificate of accreditation.* (1) A laboratory with a certificate of accreditation that refuses to cooperate with a validation inspection by failing to comply with the requirements in § 493.565—

(i) Is subject to full review by CMS or a CMS agent, in accordance with this part; and

(ii) May be subject to suspension, revocation, or limitation of its certificate of accreditation under this part.

(2) A laboratory with a certificate of accreditation is again deemed to meet the condition-level requirements by virtue of its accreditation when the following conditions exist:

(i) The laboratory withdraws any prior refusal to authorize its accreditation organization to release a copy of the laboratory's current accreditation inspection, PT results, or notification of any adverse actions resulting from PT failure.

(ii) The laboratory withdraws any prior refusal to allow a validation inspection.

(iii) CMS finds that the laboratory meets all the condition-level requirements.

(b) *CLIA-exempt laboratory*. If a CLIA-exempt laboratory fails to comply with the requirements specified in § 493.565, CMS notifies the State of the laboratory's failure to meet the requirements.

§ 493.569 Consequences of a finding of noncompliance as a result of a validation inspection.

(a) *Laboratory with a certificate of accreditation*. If a validation inspection results in a finding that the accredited laboratory is out of compliance with one or more condition-level requirements, the laboratory is subject to—

(1) The same requirements and survey and enforcement processes applied to laboratories that are not accredited and that are found out of compliance following an inspection under this part; and

(2) Full review by CMS, in accordance with this part; that is, the laboratory is subject to the principal and alternative sanctions in § 493.1806.

(b) *CLIA-exempt laboratory*. If a validation inspection results in a finding that a CLIA-exempt laboratory is out of compliance with one or more condition-level requirements, CMS directs the State to take appropriate enforcement action.

§ 493.571 Disclosure of accreditation, State and CMS validation inspection results.

(a) *Accreditation organization inspection results*. CMS may disclose accreditation organization inspection results to the public only if the results are related to an enforcement action taken by the Secretary.

(b) *State inspection results*. Disclosure of State inspection results is the responsibility of the approved State licensure program, in accordance with State law.

(c) *CMS validation inspection results*. CMS may disclose the results of all validation inspections conducted by CMS or its agent.

§ 493.573 Continuing Federal oversight of private nonprofit accreditation organizations and approved State licensure programs.

(a) *Comparability review*. In addition to the initial review for determining equivalency of specified organization or State requirements to the comparable condition-level requirements, CMS reviews the equivalency of requirements in the following cases:

(1) When CMS promulgates new condition-level requirements.

(2) When CMS identifies an accreditation organization or a State licensure program whose requirements are no longer equal to, or more stringent than, condition-level requirements.

(3) When an accreditation organization or State licensure program adopts new requirements.

(4) When an accreditation organization or State licensure program adopts changes to its inspection process, as required by § 493.575(b)(1), as applicable.

(5) Every 6 years, or sooner if CMS determines an earlier review is required.

(b) *Validation review*. Following the end of a validation review period, CMS evaluates the validation inspection results for each approved accreditation organization and State licensure program.

(c) *Reapplication procedures*. (1) Every 6 years, or sooner, as determined by CMS, an approved accreditation organization must reapply for continued approval of deeming authority and a State licensure program must reapply

for continued approval of a CLIA exemption. CMS provides notice of the materials that must be submitted as part of the reapplication procedure.

(2) An accreditation organization or State licensure program that does not meet the requirements of this subpart, as determined through a comparability or validation review, must furnish CMS, upon request, with the reapplication materials CMS requests. CMS establishes a deadline by which the materials must be submitted.

(d) *Notice.* (1) CMS provides written notice, as appropriate, to the following:

(i) An accreditation organization indicating that its approval may be in jeopardy if a comparability or validation review reveals that it is not meeting the requirements of this subpart and CMS is initiating a review of the accreditation organization's deeming authority.

(ii) A State licensure program indicating that its CLIA exemption may be in jeopardy if a comparability or validation review reveals that it is not meeting the requirements of this subpart and that a review is being initiated of the CLIA exemption of the State's laboratories.

(2) The notice contains the following information:

(i) A statement of the discrepancies that were found as well as other related documentation.

(ii) An explanation of CMS's review process on which the final determination is based and a description of the possible actions, as specified in § 493.575, that CMS may impose based on the findings from the comparability or validation review.

(iii) A description of the procedures available if the accreditation organization or State licensure program, as applicable, desires an opportunity to explain or justify the findings made during the comparability or validation review.

(iv) The reapplication materials that the accreditation organization or State licensure program must submit and the deadline for that submission.

§ 493.575 Removal of deeming authority or CLIA exemption and final determination review.

(a) *CMS review.* CMS conducts a review of the following:

(1) A deeming authority review of an accreditation organization's program if the comparability or validation review produces findings, as described at § 493.573. CMS reviews, as appropriate, the criteria described in §§ 493.555 and 493.557(a) to reevaluate whether the accreditation organization continues to meet all these criteria.

(2) An exemption review of a State's licensure program if the comparability or validation review produces findings, as described at § 493.573. CMS reviews, as appropriate, the criteria described in §§ 493.555 and 493.557(b) to reevaluate whether the licensure program continues to meet all these criteria.

(3) A review of an accreditation organization or State licensure program, at CMS's discretion, if validation review findings, irrespective of the rate of disparity, indicate widespread or systematic problems in the organization's accreditation or State's licensure process that provide evidence that the requirements, taken as a whole, are no longer equivalent to CLIA requirements, taken as a whole.

(4) A review of the accreditation organization or State licensure program whenever validation inspection results indicate a rate of disparity of 20 percent or more between the findings of the organization or State and those of CMS or a CMS agent for the following periods:

(i) One year for accreditation organizations.

(ii) Two years for State licensure programs.

(b) *CMS action after review.* Following the review, CMS may take the following action:

(1) If CMS determines that the accreditation organization or State has failed to adopt requirements equal to, or more stringent than, CLIA requirements, CMS may give a conditional approval for a probationary period of its deeming authority to an organization 30 days following the date of CMS's determination, or exempt status to a State within 30 days of CMS's determination, both not to exceed 1 year, to

afford the organization or State an opportunity to adopt equal or more stringent requirements.

(2) If CMS determines that there are widespread or systematic problems in the organization's or State's inspection process, CMS may give conditional approval during a probationary period, not to exceed 1 year, effective 30 days following the date of the determination.

(c) *Final determination.* CMS makes a final determination as to whether the organization or State continues to meet the criteria described in this subpart and issues a notice that includes the reasons for the determination to the organization or State within 60 days after the end of any probationary period. This determination is based on an evaluation of any of the following:

(1) The most recent validation inspection and review findings. To continue to be approved, the organization or State must meet the criteria of this subpart.

(2) Facility-specific data, as well as other related information.

(3) The organization's or State's inspection procedures, surveyors' qualifications, ongoing education, training, and composition of inspection teams.

(4) The organization's accreditation requirements, or the State's licensure or approval requirements.

(d) *Date of withdrawal of approval.* CMS may withdraw its approval of the accreditation organization or State licensure program, effective 30 days from the date of written notice to the organization or State of this proposed action, if improvements acceptable to CMS have not been made during the probationary period.

(e) *Continuation of validation inspections.* The existence of any validation review, probationary status, or any other action, such as a deeming authority review, by CMS does not affect or limit the conduct of any validation inspection.

(f) *Federal Register notice.* CMS publishes a notice in the FEDERAL REGISTER containing a justification for removing the deeming authority from an accreditation organization, or the CLIA-exempt status of a State licensure program.

(g) *Withdrawal of approval-effect on laboratory status*—(1) *Accredited laboratory.* After CMS withdraws approval of an accreditation organization's deeming authority, the certificate of accreditation of each affected laboratory continues in effect for 60 days after it receives notification of the withdrawal of approval.

(2) *CLIA-exempt laboratory.* After CMS withdraws approval of a State licensure program, the exempt status of each licensed or approved laboratory in the State continues in effect for 60 days after a laboratory receives notification from the State of the withdrawal of CMS's approval of the program.

(3) *Extension.* After CMS withdraws approval of an accreditation organization or State licensure program, CMS may extend the period for an additional 60 days for a laboratory if it determines that the laboratory submitted an application for accreditation to an approved accreditation organization or an application for the appropriate certificate to CMS or a CMS agent before the initial 60-day period ends.

(h) *Immediate jeopardy to patients.* (1) If at any time CMS determines that the continued approval of deeming authority of any accreditation organization poses immediate jeopardy to the patients of the laboratories accredited by the organization, or continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of deeming authority for that accreditation organization.

(2) If at any time CMS determines that the continued approval of a State licensure program poses immediate jeopardy to the patients of the laboratories in that State, or continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of that State licensure program.

(i) *Failure to pay fees.* CMS withdraws the approval of a State licensure program if the State fails to pay the applicable fees, as specified in §§493.645(a) and 493.646(b).

(j) *State refusal to take enforcement action.* (1) CMS may withdraw approval of a State licensure program if the State

refuses to take enforcement action against a laboratory in that State when CMS determines it to be necessary.

(2) A laboratory that is in a State in which CMS has withdrawn program approval is subject to the same requirements and survey and enforcement processes that are applied to a laboratory that is not exempt from CLIA requirements.

(k) *Request for reconsideration.* Any accreditation organization or State that is dissatisfied with a determination to withdraw approval of its deeming authority or remove approval of its State licensure program, as applicable, may request that CMS reconsider the determination, in accordance with subpart D of part 488.

Subpart F—General Administration

SOURCE: 57 FR 7138, 7213, Feb. 28, 1992, unless otherwise noted.

§ 493.602 Scope of subpart.

This subpart sets forth the methodology for determining the amount of the fees for issuing the appropriate certificate, and for determining compliance with the applicable standards of the Public Health Service Act (the PHS Act) and the Federal validation of accredited laboratories and of CLIA-exempt laboratories.

[60 FR 20047, Apr. 24, 1995]

§ 493.606 Applicability of subpart.

The rules of this subpart are applicable to those laboratories specified in § 493.3.

[58 FR 5212, Jan. 19, 1993]

§ 493.638 Certificate fees.

(a) *Basic rule.* Laboratories must pay a fee for the issuance of a registration certificate, certificate for PPM procedures, certificate of waiver, certificate of accreditation, or a certificate of compliance, as applicable. Laboratories must also pay a fee to reapply for a certificate for PPM procedures, certificate of waiver, certificate of accreditation, or a certificate of compliance. The total of fees collected by HHS under the laboratory program must be sufficient to cover the general costs of administering the laboratory certification program under section 353 of the PHS Act.

(1) For registration certificates and certificates of compliance, the costs include issuing the certificates, collecting the fees, evaluating and monitoring proficiency testing programs, evaluating which procedures, tests or examinations meet the criteria for inclusion in the appropriate complexity category, and implementing section 353 of the PHS Act.

(2) For a certificate of waiver, the costs include issuing the certificate, collecting the fees, determining if a certificate of waiver should be issued, evaluating which tests qualify for inclusion in the waived category, and other direct administrative costs.

(3) For a certificate for PPM procedures, the costs include issuing the certificate, collecting the fees, determining if a certificate for PPM procedures should be issued, evaluating which procedures meet the criteria for inclusion in the subcategory of PPM procedures, and other direct administrative costs.

(4) For a certificate of accreditation, the costs include issuing the certificate, collecting the fees, evaluating the programs of accrediting bodies, and other direct administrative costs.

(b) *Fee amount.* The fee amount is set annually by HHS on a calendar year basis and is based on the category of test complexity, or on the category of test complexity and schedules or ranges of annual laboratory test volume (excluding waived tests and tests performed for quality control, quality assurance, and proficiency testing purposes) and specialties tested, with the amounts of the fees in each schedule being a function of the costs for all aspects of general administration of CLIA as set forth in § 493.649 (b) and (c). This fee is assessed and payable at least biennially. The methodology used to determine the amount of the fee is found in § 493.649. The amount of the fee applicable to the issuance of the registration certificate or the issuance or renewal of the certificate for PPM procedures, certificate of waiver, certificate of accreditation, or certificate of compliance is the amount in effect at the time the application is received.

Upon receipt of an application for a certificate, HHS or its designee notifies the laboratory of the amount of the required fee for the requested certificate.

[60 FR 20047, Apr. 24, 1995]

§ 493.639 Fee for revised certificate.

(a) If, after a laboratory is issued a registration certificate, it changes its name or location, the laboratory must pay a fee to cover the cost of issuing a revised registration certificate. The fee for the revised registration certificate is based on the cost to issue the revised certificate to the laboratory.

(b) A laboratory must pay a fee to cover the cost of issuing a revised certificate in any of the following circumstances:

(1) The fee for issuing an appropriate revised certificate is based on the cost to issue the revised certificate to the laboratory as follows:

(i) If a laboratory with a certificate of waiver wishes to perform tests in addition to those listed in § 493.15(c) as waived tests, it must, as set forth in § 493.638, pay an additional fee for the appropriate certificate to cover the additional testing.

(ii) If a laboratory with a certificate for PPM procedures wishes to perform tests in addition to those specified as PPM procedures or listed in § 493.15(c) as waived tests, it must, as set forth in § 493.638, pay an additional fee for the appropriate certificate to cover the additional testing.

(2) A laboratory must pay a fee to cover the cost of issuing a revised certificate when—

(i) A laboratory changes its name, location, or its director; or

(ii) A laboratory deletes services or wishes to add services and requests that its certificate be changed. (An additional fee is also required under § 493.643(d) if it is necessary to determine compliance with additional requirements.)

[57 FR 7213, Feb. 28, 1992, as amended at 60 FR 20047, Apr, 24, 1995]

§ 493.643 Fee for determination of program compliance.

(a) *Fee requirement*. In addition to the fee required under § 493.638, a laboratory subject to routine inspections must pay a fee to cover the cost of determining program compliance. Laboratories issued a certificate for PPM procedures, certificate of waiver, or a certificate of accreditation are not subject to this fee for routine inspections.

(b) *Costs included in the fee*. Included in the fee for determining program compliance is the cost of evaluating qualifications of personnel; monitoring proficiency testing; conducting onsite inspections; documenting deficiencies; evaluating laboratories' plans to correct deficiencies; and necessary administrative costs. HHS sets the fee amounts annually on a calendar year basis. Laboratories are inspected biennially; therefore, fees are assessed and payable biennially. If additional expenses are incurred to conduct follow up visits to verify correction of deficiencies, to impose sanctions, and/or for surveyor preparation for and attendance at ALJ hearings, HHS assesses an additional fee to include these costs. The additional fee is based on the actual resources and time necessary to perform the activities.

(c) *Classification of laboratories that require inspection for purpose of determining amount of fee*. (1) There are ten classifications (schedules) of laboratories for the purpose of determining the fee amount a laboratory is assessed. Each laboratory is placed into one of the ten following schedules based on the laboratory's scope and volume of testing (excluding tests performed for quality control, quality assurance, and proficiency testing purposes).

(i) (A) *Schedule A Low Volume*. The laboratory performs not more than 2,000 laboratory tests annually.

(B) *Schedule A*. The laboratory performs tests in no more than 3 specialties of service with a total annual volume of more than 2,000 but not more than 10,000 laboratory tests.

(ii) *Schedule B*. The laboratory performs tests in at least 4 specialties of service with a total annual volume of not more than 10,000 laboratory tests.

(iii) *Schedule C*. The laboratory performs tests in no more 3 specialties of service with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.

(iv) *Schedule D*. The laboratory performs tests in at least 4 specialties with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.

(v) *Schedule E*. The laboratory performs more than 25,000 but not more than 50,000 laboratory tests annually.

(vi) *Schedule F*. The laboratory performs more than 50,000 but not more than 75,000 laboratory tests annually.

(vii) *Schedule G*. The laboratory performs more than 75,000 but not more than 100,000 laboratory tests annually.

(viii) *Schedule H*. The laboratory performs more than 100,000 but not more than 500,000 laboratory tests annually.

(ix) *Schedule I*. The laboratory performs more than 500,000 but not more than 1,000,000 laboratory tests annually.

(x) *Schedule J*. The laboratory performs more than 1,000,000 laboratory tests annually.

(2) For purposes of determining a laboratory's classification under this section, a test is a procedure or examination for a single analyte. (Tests performed for quality control, quality assurance, and proficiency testing are excluded from the laboratory's total annual volume). Each profile (that is, group of tests) is counted as the number of separate procedures or examinations; for example, a chemistry profile consisting of 18 tests is counted as 18 separate procedures or tests.

(3) For purposes of determining a laboratory's classification under this section, the specialties and subspecialties of service for inclusion are:

(i) The specialty of Microbiology, which includes one or more of the following subspecialties:

(A) Bacteriology.

(B) Mycobacteriology.

(C) Mycology.

(D) Parasitology.

(E) Virology.

(ii) The specialty of Serology, which includes one or more of the following subspecialties:

(A) Syphilis Serology.

(B) General immunology

(iii) The specialty of Chemistry, which includes one or more of the following subspecialties:

(A) Routine chemistry.

(B) Endocrinology.

(C) Toxicology.

(D) Urinalysis.

(iv) The specialty of Hematology.

(v) The specialty of Immunohematology, which includes one or more of the following subspecialties:

(A) ABO grouping and Rh typing.

(B) Unexpected antibody detection.

(C) Compatibility testing.

(D) Unexpected antibody identification.

(vi) The specialty of Pathology, which includes the following subspecialties:

(A) Cytology.

(B) Histopathology.

(C) Oral pathology.

(vii) The specialty of Radiobioassay.

(viii) The specialty of Histocompatibility.

(ix) The specialty of Clinical Cytogenetics.

(d) *Additional fees*. (1) If after a certificate of compliance is issued, a laboratory adds services and requests that its certificate be upgraded, the laboratory must pay an additional fee if, in order to determine compliance with additional requirements, it is necessary to conduct an inspection, evaluate personnel, or monitor proficiency testing performance. The additional fee is based on the actual resources and time necessary to perform the activities. HHS revokes the laboratory's certificate for failure to pay the compliance determination fee.

(2) If it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses the laboratory holding a certificate of compliance a fee to cover the cost of these activities. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the government's costs of these activities are not imposed upon the laboratory. Costs for these activities are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the laboratory's

certificate of compliance for failure to pay the assessed costs.

[57 FR 7138 and 7213, Feb. 28, 1992, as amended at 60 FR 20047, Apr. 24, 1995; 68 FR 3702, Jan. 24, 2003]

§ 493.645 Additional fee(s) applicable to approved State laboratory programs and laboratories issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures.

(a) *Approved State laboratory programs.* State laboratory programs approved by HHS are assessed a fee for the following:

(1) Costs of Federal inspections of laboratories in that State (that is, CLIA-exempt laboratories) to verify that standards are being enforced in an appropriate manner.

(2) Costs incurred for investigations of complaints against the State's CLIA-exempt laboratories if the complaint is substantiated.

(3) Costs of the State's prorata share of general overhead to develop and implement CLIA.

(b) *Accredited laboratories.* (1) In addition to the certificate fee, a laboratory that is issued a certificate of accreditation is also assessed a fee to cover the cost of evaluating individual laboratories to determine overall whether an accreditation organization's standards and inspection policies are equivalent to the Federal program. All accredited laboratories share in the cost of these inspections. These costs are the same as those that are incurred when inspecting nonaccredited laboratories.

(2) If a laboratory issued a certificate of accreditation has been inspected and followup visits are necessary because of identified deficiencies, HHS assesses the laboratory a fee to cover the cost of these visits. The fee is based on the actual resources and time necessary to perform the followup visits. HHS revokes the laboratory's certificate of accreditation for failure to pay the assessed fee.

(c) If, in the case of a laboratory that has been issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures, it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses that laboratory a fee to cover the cost of these activities. Costs are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the laboratory's certificate for failure to pay the assessed costs. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the costs of these activities are not imposed upon the laboratory.

[60 FR 20047, Apr. 24, 1995]

§ 493.646 Payment of fees.

(a) Except for CLIA-exempt laboratories, all laboratories are notified in writing by HHS or its designee of the appropriate fee(s) and instructions for submitting the fee(s), including the due date for payment and where to make payment. The appropriate certificate is not issued until the applicable fees have been paid.

(b) For State-exempt laboratories, HHS estimates the cost of conducting validation surveys within the State for a 2-year period. HHS or its designee notifies the State by mail of the appropriate fees, including the due date for payment and the address of the United States Department of Treasury designated commercial bank to which payment must be made. In addition, if complaint investigations are conducted in laboratories within these States and are substantiated, HHS bills the State(s) the costs of the complaint investigations.

[57 FR 7138 and 7213, Feb. 28, 1992, as amended at 60 FR 20048, Apr. 24, 1995]

§ 493.649 Methodology for determining fee amount.

(a) *General rule.* The amount of the fee in each schedule for compliance determination inspections is based on the average hourly rate (which includes the costs to perform the required activities and necessary administration costs) multiplied by the average number of hours required or, if activities are performed by more than one of the entities listed in paragraph (b) of this section, the sum of the products of the

applicable hourly rates multiplied by the average number of hours required by the entity to perform the activity. The fee for issuance of the registration certificate or certificate of compliance is based on the laboratory's scope and volume of testing.

(b) *Determining average hourly rates used in fee schedules.* Three different entities perform activities related to the issuance or reissuance of any certificate. HHS determines the average hourly rates for the activities of each of these entities.

(1) *State survey agencies.* The following costs are included in determining an average hourly rate for the activities performed by State survey agencies:

(i) The costs incurred by the State survey agencies in evaluating personnel qualifications and monitoring each laboratory's participation in an approved proficiency testing program. The cost of onsite inspections and monitoring activities is the hourly rate derived as a result of an annual budget negotiation process with each State. The hourly rate encompasses salary costs (as determined by each State's civil service pay scale) and fringe benefit costs to support the required number of State inspectors, management and direct support staff.

(ii) Travel costs necessary to comply with each State's administrative requirements and other direct costs such as equipment, printing, and supplies. These costs are established based on historical State requirements.

(iii) Indirect costs as negotiated by HHS.

(2) *Federal agencies.* The hourly rate for activities performed by Federal agencies is the most recent average hourly cost to HHS to staff and support a full time equivalent employee. Included in this cost are salary and fringe benefit costs, necessary administrative costs, such as printing, training, postage, express mail, supplies, equipment, computer system and building service charges associated with support services provided by organizational components such as a computer center, and any other oversight activities necessary to support the program.

(3) *HHS contractors.* The hourly rate for activities performed by HHS contractors is the average hourly rate established for contractor assistance based on an independent government cost estimate for the required workload. This rate includes the cost of contractor support to provide proficiency testing programs to laboratories that do not participate in an approved proficiency testing program, provide specialized assistance in the evaluation of laboratory performance in an approved proficiency testing program, perform assessments of cytology testing laboratories, conduct special studies, bill and collect fees, issue certificates, establish accounting, monitoring and reporting systems, and assist with necessary surveyor training.

(c) *Determining number of hours.* The average number of hours used to determine the overall fee in each schedule is HHS's estimate, based on historical experience, of the average time needed by each entity to perform the activities for which it is responsible.

[57 FR 7138 and 7213, Feb. 28, 1992, as amended at 60 FR 20048, Apr. 24, 1995]

Subpart G [Reserved]

Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

SOURCE: 57 FR 7146, Feb. 28, 1992, unless otherwise noted.

§ 493.801 Condition: Enrollment and testing of samples.

Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.

(a) *Standard; Enrollment.* The laboratory must—

(1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart.

(2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; and

(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with § 493.1236(c)(1).

(3) For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation; and

(4) Authorize the proficiency testing program to release to HHS all data required to—

(i) Determine the laboratory's compliance with this subpart; and

(ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.

(b) *Standard; Testing of proficiency testing samples.* The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens.

(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

(2) The laboratory must test samples the same number of times that it routinely tests patient samples.

(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

(4) The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year. Any laboratory that receives proficiency testing samples from another laboratory for testing must notify CMS of the receipt of those samples.

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.

(6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

[57 FR 7146, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

§ 493.803 Condition: Successful participation.

(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable,

as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.

(b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part.

(c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists:

(1) There is immediate jeopardy to patient health and safety.

(2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance.

(3) The laboratory has a poor compliance history.

[57 FR 7146, Feb. 28, 1992, as amended at 60 FR 20048, Apr. 24, 1995; 63 FR 26737, May 14, 1998; 68 FR 3702, Jan. 24, 2003]

§ 493.807 Condition: Reinstatement of laboratories performing nonwaived testing.

(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test.

(b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.

[58 FR 5228, Jan. 19, 1993, as amended at 60 FR 20048, Apr. 24, 1995]

PROFICIENCY TESTING BY SPECIALTY AND SUBSPECIALTY FOR LABORATORIES PERFORMING TESTS OF MODERATE COMPLEXITY (INCLUDING THE SUBCATEGORY), HIGH COMPLEXITY, OR ANY COMBINATION OF THESE TESTS

§ 493.821 Condition: Microbiology.

The specialty of microbiology includes, for purposes of proficiency testing, the subspecialties of bacteriology, mycobacteriology, mycology, parasitology and virology.

§ 493.823 Standard; Bacteriology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory

performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.825 Standard; Mycobacteriology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.827 Standard; Mycology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events

or two out of three consecutive testing events is unsuccessful performance.

§ 493.829 Standard; Parasitology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.831 Standard; Virology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing events, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.833 Condition: Diagnostic immunology.

The specialty of diagnostic immunology includes for purposes of proficiency testing the subspecialties of syphilis serology and general immunology.

§ 493.835 Standard; Syphilis serology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance

and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.837 Standard; General immunology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.839 Condition: Chemistry.

The specialty of chemistry includes for the purposes of proficiency testing the subspecialties of routine chemistry, endocrinology, and toxicology.

§ 493.841 Standard; Routine chemistry.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event

is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.843 Standard; Endocrinology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events

or two out of three consecutive testing events is unsuccessful performance.

§ 493.845 Standard; Toxicology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.849 Condition: Hematology.

The specialty of hematology, for the purpose of proficiency testing, is not subdivided into subspecialties of testing.

§ 493.851 Standard; Hematology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and

the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.853 Condition: Pathology.

The specialty of pathology includes, for purposes of proficiency testing, the subspecialty of cytology limited to gynecologic examinations.

§ 493.855 Standard; Cytology: gynecologic examinations.

To participate successfully in a cytology proficiency testing program for gynecologic examinations (Pap smears), the laboratory must meet the requirements of paragraphs (a) through (c) of this section.

(a) The laboratory must ensure that each individual engaged in the examination of gynecologic preparations is enrolled in a proficiency testing program approved by CMS by January 1, 1995, if available in the State in which he or she is employed. The laboratory must ensure that each individual is tested at least once per year and obtains a passing score. To ensure this annual testing of individuals, an announced or unannounced testing event will be conducted on-site in each laboratory at least once each year. Laboratories will be notified of the time of each announced on-site testing event at least 30 days prior to each event. Additional testing events will be conducted as necessary in each State or region for the purpose of testing individuals who miss the on-site testing event and for retesting individuals as described in paragraph (b) of this section.

(b) The laboratory must ensure that each individual participates in an annual testing event that involves the examination of a 10-slide test set as described in § 493.945. Individuals who fail this testing event are retested with another 10-slide test set as described in paragraphs (b)(1) and (b)(2) of this section. Individuals who fail this second test are subsequently retested with a 20-slide test set as described in paragraphs (b)(2) and (b)(3) of this section. Individuals are given not more than 2 hours to complete a 10-slide test and not more than 4 hours to complete a 20-slide test. Unexcused failure to appear by an individual for a retest will result in test failure with resulting remediation and limitations on slide examinations as specified in (b)(1), (b)(2), and (b)(3) of this section.

(1) An individual is determined to have failed the annual testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails an annual proficiency testing event, the laboratory must schedule a retesting event which must take place not more than 45 days after receipt of the notification of failure.

(2) An individual is determined to have failed the second testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails a second testing event, the laboratory must provide him or her with documented, remedial training and education in the area of failure, and must assure that all gynecologic slides evaluated subsequent to the notice of failure are reexamined until the individual is again retested with a 20-slide test set and scores at least 90 percent. Reexamination of slides must be documented.

(3) An individual is determined to have failed the third testing event if he or she scores less than 90 percent on a 20-slide test set. An individual who fails the third testing event must cease examining gynecologic slide preparations immediately upon notification of test failure and may not resume examining gynecologic slides until the laboratory assures that the individual obtains at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations, and until he or she is retested with a 20-slide test set and scores at least 90 percent.

(c) If a laboratory fails to ensure that individuals are tested or those who fail a testing event are retested, or fails to

take required remedial actions as described in paragraphs (b)(1), (b)(2) or (b)(3) of this section, CMS will initiate intermediate sanctions or limit the laboratory's certificate to exclude gynecologic cytology testing under CLIA, and, if applicable, suspend the laboratory's Medicare and Medicaid payments for gynecologic cytology testing in accordance with subpart R of this part.

[57 FR 7146, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993; 59 FR 62609, Dec. 6, 1994]

§ 493.857 Condition: Immunohematology.

The specialty of immunohematology includes four subspecialties for the purposes of proficiency testing: ABO group and D (Rho) typing; unexpected antibody detection; compatibility testing; and antibody identification.

§ 493.859 Standard; ABO group and D (Rho) typing.

(a) Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.861 Standard; Unexpected antibody detection.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.863 Standard; Compatibility testing.

(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.865 Standard; Antibody identification.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to identify the same antibody in two consecutive or two out of three consecutive testing events is unsuccessful performance.

(f) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

Subpart I—Proficiency Testing Programs for Nonwaived Testing

SOURCE: 57 FR 7151, Feb. 28, 1992, unless otherwise noted.

§493.901 Approval of proficiency testing programs.

In order for a proficiency testing program to receive HHS approval, the program must be offered by a private nonprofit organization or a Federal or State agency, or entity acting as a designated agent for the State. An organization, Federal, or State program seeking approval or reapproval for its program for the next calendar year must submit an application providing the required information by July 1 of the current year. The organization, Federal, or State program must provide technical assistance to laboratories seeking to qualify under the program, and must, for each specialty, subspecialty, and analyte or test for which it provides testing—

(a) Assure the quality of test samples, appropriately evaluate and score the testing results, and identify performance problems in a timely manner;

(b) Demonstrate to HHS that it has—

(1) The technical ability required to—

(i) Prepare or purchase samples from manufacturers who prepare the samples in conformance with the appropriate good manufacturing practices required in 21 CFR parts 606, 640, and 820; and

(ii) Distribute the samples, using rigorous quality control to assure that samples mimic actual patient specimens when possible and that samples are homogeneous, except for specific subspecialties such as cytology, and will be stable within the time frame for analysis by proficiency testing participants;

(2) A scientifically defensible process for determining the correct result for each challenge offered by the program;

(3) A program of sufficient annual challenge and with the frequency specified in §§493.909 through 493.959 to establish that a laboratory has met minimum performance requirements;

(4) The resources needed to provide Statewide or nationwide reports to regulatory agencies on individual's performance for gynecologic cytology and on individual laboratory performance on testing events, cumulative reports and scores for each laboratory or individual, and reports of specific laboratory failures using grading criteria acceptable to HHS. These reports must be provided to HHS on a timely basis when requested;

(5) Provisions to include on each proficiency testing program report form used by the laboratory to record testing event results, an attestation statement that proficiency testing samples were tested in the same manner as patient specimens with a signature block to be completed by the individual performing the test as well as by the laboratory director;

(6) A mechanism for notifying participants of the PT shipping schedule and for participants to notify the proficiency testing program within three days of the expected date of receipt of the shipment that samples have not arrived or are unacceptable for testing. The program must have provisions for replacement of samples that are lost in transit or are received in a condition that is unacceptable for testing; and

(7) A process to resolve technical, administrative, and scientific problems about program operations;

(c) Meet the specific criteria for proficiency testing programs listed by specialty, subspecialty, and analyte or test contained in §§493.901 through 493.959 for initial approval and thereafter provide HHS, on an annual basis, with the information necessary to assure that the proficiency testing program meets the criteria required for approval; and

(d) Comply with all applicable packaging, shipment, and notification requirements of 42 CFR part 72.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993]

§ 493.903 Administrative responsibilities.

The proficiency testing program must—

(a)(1) Provide HHS or its designees and participating laboratories with an electronic or a hard copy, or both, of reports of proficiency testing results and all scores for each laboratory's performance in a format as required by and approved by CMS for each CLIA-certified specialty, subspecialty, and analyte or test within 60 days after the date by which the laboratory must report proficiency testing results to the proficiency testing program.

(2) Provide HHS with reports of PT results and scores of individual performance in cytology and provide copies of reports to participating individuals, and to all laboratories that employ the individuals, within *15* working days of the testing event;

(b) Furnish to HHS cumulative reports on an individual laboratory's performance and aggregate data on CLIA-certified laboratories for the purpose of establishing a system to make the proficiency testing program's results available, on a reasonable basis, upon request of any person, and include such explanatory information as may be appropriate to assist in the interpretation of the proficiency testing program's results;

(c) Provide HHS with additional information and data upon request and submit such information necessary for HHS to conduct an annual evaluation to determine whether the proficiency testing program continues to meet the requirements of §§ 493.901 through 493.959;

(d) Maintain records of laboratories' performance for a period of five years or such time as may be necessary for any legal proceedings; and

(e) Provide HHS with an annual report and, if needed, an interim report which identifies any previously unrecognized sources of variability in kits, instruments, methods, or PT samples, which adversely affect the programs' ability to evaluate laboratory performance.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993]

§ 493.905 Nonapproved proficiency testing programs.

If a proficiency testing program is determined by HHS to fail to meet any criteria contained in §§ 493.901 through 493.959 for approval of the proficiency testing program, CMS will notify the program and the program must notify all laboratories enrolled of the nonapproval and the reasons for nonapproval within 30 days of the notification.

PROFICIENCY TESTING PROGRAMS BY SPECIALTY AND SUBSPECIALTY

§ 493.909 Microbiology.

The subspecialties under the specialty of microbiology for which a program may offer proficiency testing are bacteriology, mycobacteriology, mycology, parasitology and virology. Specific criteria for these subspecialties are found at §§ 493.911 through 493.919.

§ 493.911 Bacteriology.

(a) *Types of services offered by laboratories.* In bacteriology, for proficiency testing purposes, there are five types of laboratories:

(1) Those that interpret Gram stains or perform primary inoculation, or both; and refer cultures to another laboratory appropriately certified for the subspecialty of bacteriology for identification;

(2) Those that use direct antigen techniques to detect an organism and may also interpret Gram stains or perform primary inoculation, or perform any combination of these;

(3) Those that, in addition to interpreting Gram stains, performing primary inoculations, and using direct antigen tests, also isolate and identify aerobic bacteria from throat, urine, cervical, or urethral discharge specimens to the genus level and may also perform antimicrobial susceptibility tests on selected isolated microorganisms;

(4) Those that perform the services in paragraph (a)(3) of this section and also isolate and identify aerobic bacteria from any source to the species level and may also perform antimicrobial susceptibility tests; and

(5) Those that perform the services in paragraph (a)(4) of this section and also

isolate and identify anaerobic bacteria from any source.

(b) *Program content and frequency of challenge*. To be approved for proficiency testing for bacteriology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided to the laboratory through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing. For the types of laboratories specified in paragraph (a) of this section, an annual program must include samples that contain organisms that are representative of the six major groups of bacteria: anaerobes, Enterobacteriaceae, gram-positive bacilli, gram-positive cocci, gram-negative cocci, and miscellaneous gram-negative bacteria, as appropriate. The specific organisms included in the samples may vary from year to year. The annual program must include samples for bacterial antigen detection, bacterial isolation and identification, Gram stain, and antimicrobial susceptibility testing.

(1) An approved program must furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. At least 50 percent of the samples must be mixtures of the principal organism and appropriate normal flora. The program must include other important emerging pathogens (as determined by HHS) and either organisms commonly occurring in patient specimens or opportunistic pathogens. The program must include the following two types of samples; each type of sample must meet the 50 percent mixed culture criterion:

(i) Samples that require laboratories to report only organisms that the testing laboratory considers to be a principal pathogen that is clearly responsible for a described illness (excluding immuno-compromised patients). The program determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

(ii) Samples that require laboratories to report all organisms present. Samples must contain multiple organisms frequently found in specimens such as urine, blood, abscesses, and aspirates where multiple isolates are clearly significant or where specimens are derived from immuno-compromised patients. The program determines the reportable isolates.

(2) An approved program may vary over time. For example, the types of organisms that might be included in an approved program over time are—

Anaerobes:
- *Bacteroides fragilis group*
- *Clostridium perfringens*
- *Peptostreptococcus anaerobius*

Enterobacteriaceae
- *Citrobacter freundii*
- *Enterobacter aerogenes*
- *Escherichia coli*
- *Klebsiella pneumoniae*
- *Proteus mirabilis*
- *Salmonella typhimurium*
- *Serratia marcescens*
- *Shigella sonnei*
- *Yersinia enterocolitica*

Gram-positive bacilli:
- *Listeria monocytogenes*
- *Corynebacterium species CDC Group JK*

Gram-positive cocci:
- *Staphylococcus aureus*
- *Streptococcus Group A*
- *Streptococcus Group B*
- *Streptococcus Group D (S. bovis and enterococcus)*
- *Streptococcus pneumoniae*

Gram-negative cocci:
- *Branhamella catarrhalis*
- *Neisseria gonorrhoeae*
- *Neisseria meningitidis*

Miscellaneous Gram-negative bacteria:
- *Campylobacter jejuni*
- *Haemophilis influenza, Type B*
- *Pseudomonas aeruginosa*

(3) For antimicrobial susceptibility testing, the program must provide at least one sample per testing event that includes gram-positive or gram-negative strains that have a predetermined pattern of sensitivity or resistance to the common antimicrobial agents.

(c) *Evaluation of a laboratory's performance*. HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (7) of this section.

(1) The program determines staining characteristics to be interpreted by Gram stain. The program determines the reportable bacteria to be detected by direct antigen techniques or isolation. To determine the accuracy of a laboratory's response for Gram stain

interpretation, direct antigen detection, identification, or antimicrobial susceptibility testing, the program must compare the laboratory's response for each sample with the response which reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the organisms to the same extent it performs these procedures on patient specimens. A laboratory's performance will be evaluated on the basis of its final answer, for example, a laboratory specified in paragraph (a)(3) of this section will be evaluated on the basis of the average of its scores for paragraphs (c)(3) through (c)(6) as determined in paragraph (c)(7) of this section.

(3) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must provide a means of deducting credit for additional erroneous organisms that are reported. Therefore, the total number of correct responses for organism isolation and identification submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not considered reportable, the sample grade would be 1/(1+1)×100=50 percent.

(4) For antimicrobial susceptibility testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient samples. A laboratory's performance will be evaluated for only those antibiotics for which service is offered. A correct response for each antibiotic will be determined as described in §§ 493.911(c) (1) using criteria such as the guidelines established by the National Committee for Clinical Laboratory Standards. Grading is based on the number of correct susceptibility responses reported by the laboratory divided by the actual number of correct susceptibility responses determined by the program, multiplied by 100. For example, if a laboratory offers susceptibility testing for *Enterobacteriaceae* using amikacin, cephalothin, and tobramycin, and the organism in the proficiency testing sample is an *Enterobacteriaceae*, and the laboratory reports correct responses for two of three antimicrobial agents, the laboratory's grade would be 2/3×100=67 percent.

(5) The performance criterion for qualitative antigen tests is the presence or absence of the bacterial antigen. The score for antigen tests is the number of correct responses divided by the number of samples to be tested for the antigen, multiplied by 100.

(6) The performance criteria for Gram stain is staining reaction, i.e., gram positive or gram negative. The score for Gram stain is the number of correct responses divided by the number of challenges to be tested, multiplied by 100.

(7) The score for a testing event in bacteriology is the average of the scores determined under paragraphs (c)(3) through (c)(6) of this section kbased on the type of service offered by the laboratory.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

§ 493.913 Mycobacteriology.

(a) *Types of services offered by laboratories.* In mycobacteriology, there are five types of laboratories for proficiency testing purposes:

(1) Those that interpret acid-fast stains and refer specimen to another laboratory appropriately certified in the subspecialty of mycobacteriology;

(2) Those that interpret acid-fast stains, perform primary inoculation, and refer cultures to another laboratory appropriately certified in the subspecialty of mycobacteriology for identification;

(3) Those that interpret acid-fast stains, isolate and perform identification and/or antimycobacterial susceptibility of *Mycobacterium tuberculosis*, but

refer other mycobacteria species to another laboratory appropriately certified in the subspecialty of mycobacteriology for identification and/or susceptibility tests;

(4) Those that interpret acid-fast stains, isolate and identify all mycobacteria to the extent required for correct clinical diagnosis, but refer antimycobacterial susceptibility tests to another laboratory appropriately certified in the subspecialty of mycobacteriology; and

(5) Those that interpret acid-fast stains, isolate and identify all mycobacteria to the extent required for correct clinical diagnosis, and perform antimycobacterial susceptibility tests on the organisms isolated.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for mycobacteriology, the annual program must provide a minimum of five samples per testing event. There must be at least two testing events per year. The samples may be provided through mailed shipments or, at HHS' option, provided to HHS or its designee for on-site testing events. For types of laboratories specified in paragraphs (a)(1) and (a) (3) through (5) of this section, an annual program must include samples that contain species that are representative of the 5 major groups (complexes) of mycobacteria encountered in human specimens. The specific mycobacteria included in the samples may vary from year to year.

(1) An approved program must furnish HHS and its agents with a description of samples that it plans to include in its annual program no later than six months before each calendar year. At least 50 percent of the samples must be mixtures of the principal mycobacteria and appropriate normal flora. The program must include mycobacteria commonly occurring in patient specimens and other important emerging mycobacteria (as determined by HHS). The program determines the reportable isolates and correct responses for antimycobacterial susceptibility for any designated isolate.

(2) An approved program may vary over time. For example, the types of mycobacteria that might be included in an approved program over time are—

TB
Mycobacterium tuberculosis
Mycobacterium bovis
Group I
Mycobacterium kansasii
Group II
Mycobacterium szulgai
Group III
Mycobacterium avium-intracellulare
Mycobacterium terrae
Group IV
Mycobacterium fortuitum

(3) For antimycobacterial susceptibility testing, the program must provide at least one sample per testing event that includes mycobacterium tuberculosis that has a predetermined pattern of sensitivity or resistance to the common antimycobacterial agents.

(4) For laboratories specified in paragraphs (a)(1) and (a)(2), the program must provide at least five samples per testing event that includes challenges that are acid-fast and challenges which do not contain acid-fast organisms.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (c)(1) through (6) of this section.

(1) The program determines the reportable mycobacteria to be detected by acid-fast stain, for isolation and identification, and for antimycobacterial susceptibility. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must interpret acid-fast stains and isolate and identify the organisms to the same extent it performs these procedures on patient specimens. A laboratory's performance will be evaluated on the basis of the average of its scores as determined in paragraph (c)(6) of this section.

(3) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified

principal organism(s), the grading system must provide a means of deducting credit for additional erroneous organisms reported. Therefore, the total number of correct responses submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not present, the sample grade would be

$1 / (1 + 1) \times 100 = 50$ percent

(4) For antimycobacterial susceptibility testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient samples. A laboratory's performance will be evaluated for only those antibiotics for which susceptibility testing is routinely performed on patient specimens. A correct response for each antibiotic will be determined as described in § 493.913(c)(1). Grading is based on the number of correct susceptibility responses reported by the laboratory divided by the actual number of correct susceptibility responses as determined by the program, multiplied by 100. For example, if a laboratory offers susceptibility testing using three antimycobacterial agents and the laboratory reports correct response for two of the three antimycobacterial agents, the laboratory's grade would be $\frac{2}{3} \times 100 = 67$ percent.

(5) The performance criterion for qualitative tests is the presence or absence of acid-fast organisms. The score for acid-fast organism detection is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(6) The score for a testing event in mycobacteriology is the average of the scores determined under paragraphs (c)(3) through (c)(5) of this section based on the type of service offered by the laboratory.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

§ 493.915 Mycology.

(a) *Types of services offered by laboratories.* In mycology, there are four types of laboratories for proficiency testing purposes that may perform different levels of service for yeasts, dimorphic fungi, dermatophytes, and aerobic actinomycetes:

(1) Those that isolate and identify only yeasts and/or dermatophytes to the genus level;

(2) Those that isolate and identify yeasts and/or dermatophytes to the species level;

(3) Those that isolate and perform identification of all organisms to the genus level; and

(4) Those that isolate and perform identification of all organisms to the species level.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for mycology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that contain organisms that are representative of five major groups of fungi: Yeast or yeast-like fungi; dimorphic fungi; dematiaceous fungi; dermatophytes; and saprophytes, including opportunistic fungi. The specific fungi included in the samples may vary from year to year.

(1) An approved program must, before each calendar year, furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. At least 50 percent of the samples must be mixtures of the principal organism and appropriate normal background flora. Other important emerging pathogens (as determined by HHS) and organisms commonly occurring in patient specimens must be included periodically in the program.

(2) An approved program may vary over time. As an example, the types of organisms that might be included in an approved program over time are—

Candida albicans

Candida (other species)
Cryptococcus neoformans
Sporothrix schenckii
Exophiala jeanselmei
Fonsecaea pedrosoi
Microsporum sp.
Acremonium sp.
Trichophvton sp.
Aspergillus fumigatus
Nocardia sp.
Blastomyces dermatitidis[1]
Zygomycetes sp.

[1] NOTE: Provided as a nonviable sample.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response, in accordance with paragraphs (c)(1) through (5) of this section.

(1) The program determines the reportable organisms. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the organisms to the same extent it performs these procedures on patient specimens.

(3) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must deduct credit for additional erroneous organisms reported. Therefore, the total number of correct responses submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each shipment or testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not present, the sample grade would be 1/(1+1)x100=50 percent.

(4) The score for the antigen tests is the number of correct responses divided by the number of samples to be tested for the antigen, multiplied by 100.

(5) The score for a testing event is the average of the sample scores as determined under paragraph (c)(3) or (c)(4), or both, of this section.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

§493.917 Parasitology.

(a) *Types of services offered by laboratories.* In parasitology there are two types of laboratories for proficiency testing purposes—

(1) Those that determine the presence or absence of parasites by direct observation (wet mount) and/or pinworm preparations and, if necessary, refer specimens to another laboratory appropriately certified in the subspecialty of parasitology for identification;

(2) Those that identify parasites using concentration preparations and/or permanent stains.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing in parasitology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments or, at HHS's option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that contain parasites that are commonly encountered in the United States as well as those recently introduced into the United States. Other important emerging pathogens (as determined by HHS) and parasites commonly occurring in patient specimens must be included periodically in the program.

(1) An approved program must, before each calendar year furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. Samples must include both formalinized specimens and PVA (polyvinyl alcohol) fixed specimens as well as blood smears, as appropriate for a particular parasite and stage of the parasite. The majority of samples must contain protozoa or helminths or a combination of parasites. Some samples must be devoid of parasites.

(2) An approved program may vary over time. As an example, the types of parasites that might be included in an approved program over time are—

Enterobius vermicularis
Entamoeba histolytica
Entamoeba coli
Giardia lamblia
Endolimax nana
Dientamoeba fragilis
Iodamoeba butschli
Chilomastix mesnili
Hookworm
Ascaris lumbricoides
Strongyloides stercoralis
Trichuris trichiura
Diphyllobothrium latum
Cryptosporidium sp.
Plasmodium falciparum

(3) For laboratories specified in paragraph (a)(1) of this section, the program must provide at least five samples per testing event that include challenges which contain parasites and challenges that are devoid of parasites.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (6) of this section.

(1) The program must determine the reportable parasites. It may elect to establish a minimum number of parasites to be identified in samples before they are reported. Parasites found in rare numbers by referee laboratories are not considered in scoring a laboratory's performance; such findings are neutral. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must determine the presence or absence of a parasite(s) or concentrate and identify the parasites to the same extent it performs these procedures on patient specimens.

(3) Since laboratories may incorrectly report the presence of parasites in addition to the correctly identified principal parasite(s), the grading system must deduct credit for these additional erroneous parasites reported and not found in rare numbers by the program's referencing process. Therefore, the total number of correct responses submitted by the laboratory divided by the number of parasites present plus the number of incorrect parasites reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal parasite and the laboratory reported it correctly but reported the presence of an additional parasite, which was not present, the sample grade would be

$1/(1+1)\times 100=50$ percent.

(4) The criterion for acceptable performance for qualitative parasitology examinations is presence or absence of a parasite(s).

(5) The score for parasitology is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(6) The score for a testing event is the average of the sample scores as determined under paragraphs (c)(3) through (c)(5) of this section.

[57 FR 7151, Feb. 28, 1992, as amended at 68 FR 3702, Jan. 24, 2003]

§ 493.919 Virology.

(a) *Types of services offered by laboratories.* In virology, there are two types of laboratories for proficiency testing purposes—

(1) Those that only perform tests that directly detect viral antigens or structures, either in cells derived from infected tissues or free in fluid specimens; and

(2) Those that are able to isolate and identify viruses and use direct antigen techniques.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing in virology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided to the laboratory through mailed shipments or, at HHS's option, may be provided to HHS or its designee for on-site testing. An annual program must include viral species that are the more commonly

identified viruses. The specific organisms found in the samples may vary from year to year. The annual program must include samples for viral antigen detection and viral isolation and identification.

(1) An approved program must furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. The program must include other important emerging viruses (as determined by HHS) and viruses commonly occurring in patient specimens.

(2) An approved program may vary over time. For example, the types of viruses that might be included in an approved program over time are the more commonly identified viruses such as Herpes simplex, respiratory syncytial virus, adenoviruses, enteroviruses, and cytomegaloviruses.

(c) *Evaluation of laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (c)(1) through (5) of this section.

(1) The program determines the reportable viruses to be detected by direct antigen techniques or isolated by laboratories that perform viral isolation procedures. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the viruses to the same extent it performs these procedures on patient specimens.

(3) Since laboratories may incorrectly report the presence of viruses in addition to the correctly identified principal virus, the grading system must provide a means of deducting credit for additional erroneous viruses reported. Therefore, the total number of correct responses determined by virus culture techniques submitted by the laboratory divided by the number of viruses present plus the number of incorrect viruses reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal virus and the laboratory reported it correctly but reported the presence of an additional virus, which was not present, the sample grade would be $1/(1+1)\times100=50$ percent.

(4) The performance criterion for qualitative antigen tests is presence or absence of the viral antigen. The score for the antigen tests is the number of correct responses divided by the number of samples to be tested for the antigen, multiplied by 100.

(5) The score for a testing event is the average of the sample scores as determined under paragraph (c)(3) and (c)(4) of this section.

[57 FR 7151, Feb. 28, 1992, as amended at 68 FR 3702, Jan. 24, 2003]

§ 493.921 Diagnostic immunology.

The subspecialties under the specialty of immunology for which a program may offer proficiency testing are syphilis serology and general immunology. Specific criteria for these subspecialties are found at §§ 493.923 and 493.927.

§ 493.923 Syphilis serology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing in syphilis serology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that cover the full range of reactivity from highly reactive to non-reactive.

(b) *Evaluation of test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (b)(1) through (4) of this section.

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative syphilis tests, the

program must compare the laboratory's response with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The proficiency testing program must indicate the minimum concentration, by method, that will be considered as indicating a positive response. The score for a sample in syphilis serology is the average of scores determined under paragraphs (b)(2) and (b)(3) of this section.

(2) For quantitative syphilis tests, the program must determine the correct response for each method by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using fixed criteria. The criterion for acceptable performance for quantitative syphilis serology tests is the target value ±1 dilution.

(3) The criterion for acceptable performance for qualitative syphilis serology tests is reactive or nonreactive.

(4) To determine the overall testing event score, the number of correct responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

§ 493.927 General immunology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for immunology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of reactivity from highly reactive to nonreactive. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event the program must provide for each analyte or test procedure is five. Analytes or tests for which laboratory performance is to be evaluated include:

Analyte or Test Procedure

Alpha-l antitrypsin
Alpha-fetoprotein (tumor marker)
Antinuclear antibody
Antistreptolysin O
Anti-human immunodeficiency virus (HIV)
Complement C3
Complement C4
Hepatitis markers (HBsAg, anti-HBc, HBeAg)
IgA
IgG
IgE
IgM
Infectious mononucleosis
Rheumatoid factor
Rubella

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response for quantitative and qualitative immunology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The proficiency testing program must indicate the minimum concentration that will be considered as indicating a positive response. The score for a sample in general immunology is either the score determined under paragraph (c)(2) or (3) of this section.

(2) For quantitative immunology analytes or tests, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target

value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Alpha-1 antitrypsin	Target value ±3 SD.
Alpha-fetoprotein (tumor marker).	Target value ±3 SD.
Antinuclear antibody	Target value ±2 dilutions or positive or negative.
Antistreptolysin O	Target value ±2 dilution or positive or negative.
Anti-Human Immunodeficiency virus.	Reactive or nonreactive.
Complement C3	Target value ±3 SD.
Complement C4	Target value ±3 SD.
Hepatitis (HBsAg, anti-HBc, HBeAg).	Reactive (positive) or nonreactive (negative).
IgA	Target value ±3 SD.
IgE	Target value ±3 SD.
IgG	Target value ±25%.
IgM	Target value ±3 SD.
Infectious mononucleosis	Target value ±2 dilutions or positive or negative.
Rheumatoid factor	Target value ±2 dilutions or positive or negative.
Rubella	Target value ±2 dilutions or immune or nonimmune or positive or negative.

(3) The criterion for acceptable performance for qualitative general immunology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

§ 493.929 Chemistry.

The subspecialties under the specialty of chemistry for which a proficiency testing program may offer proficiency testing are routine chemistry, endocrinology, and toxicology. Specific criteria for these subspecialties are listed in §§ 493.931 through 493.939.

§ 493.931 Routine chemistry.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for routine chemistry, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in patient specimens. The specimens may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure listed below is five serum, plasma or blood samples.

Analyte or Test Procedure

Alanine aminotransferase (ALT/SGPT)
Albumin
Alkaline phosphatase

Amylase
Aspartate aminotransferase (AST/SGOT)
Bilirubin, total
Blood gas (pH, pO2, and pCO2)
Calcium, total
Chloride
Cholesterol, total
Cholesterol, high density lipoprotein
Creatine kinase
Creatine kinase, isoenzymes
Creatinine
Glucose (Excluding measurements on devices cleared by FDA for home use)
Iron, total
Lactate dehydrogenase (LDH)
LDH isoenzymes
Magnesium
Potassium
Sodium
Total Protein
Triglycerides
Urea Nitrogen
Uric Acid

(c) *Evaluation of a laboratory's analyte or test performance*. HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative chemistry tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The score for a sample in routine chemistry is either the score determined under paragraph (c)(2) or (3) of this section.

(2) For quantitative chemistry tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Alanine aminotransferase (ALT/SGPT).	Target value ±20%.
Albumin	Target value ±10%.
Alkaline phosphatase	Target value ±30%.
Amylase	Target value ±30%.
Aspartate aminotransferase (AST/SGOT).	Target value ±20%.
Bilirubin, total	Target value ±0.4 mg/dL or ±20% (greater).
Blood gas pO2	Target value ±3 SD.
pCO2	Target value ±5 mm Hg or ±8% (greater).
pH	Target value ±0.04.
Calcium, total	Target value ±1.0 mg/dL.
Chloride	Target value ±5%.
Cholesterol, total	Target value ±10%.
Cholesterol, high density lipoprotein.	Target value ±30%.
Creatine kinase	Target value ±30%.
Creatine kinase isoenzymes	MB elevated (presence or absence) or Target value ±3SD.
Creatinine	Target value ±0.3 mg/dL or ±15% (greater).
Glucose (excluding glucose performed on monitoring devices cleared by FDA for home use.	Target value ±6 mg/dl or ±10% (greater).
Iron, total	Target value ±20%.
Lactate dehydrogenase (LDH).	Target value ±20%.
LDH isoenzymes	LDH1/LDH2 (+ or −) or Target value ±30%.
Magnesium	Target value ±25%.
Potassium	Target value ±0.5 mmol/L.
Sodium	Target value ±4 mmol/L.
Total Protein	Target value ±10%.
Triglycerides	Target value ±25%.
Urea nitrogen	Target value ±2 mg/dL or ±9% (greater).
Uric acid	Target value ±17%.

(3) The criterion for acceptable performance for qualitative routine chemistry tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 68 FR 3702, Jan. 24, 2003]

§ 493.933 Endocrinology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for endocrinology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five serum, plasma, blood, or urine samples.

Analyte or Test

Cortisol
Free Thyroxine
Human Chorionic gonadotropin (excluding urine pregnancy tests done by visual color comparison categorized as waived tests)
T3 Uptake
Triiodothyronine
Thyroid-stimulating hormone
Thyroxine

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative endocrinology tests or analytes, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The score for a sample in endocrinology is either the score determined under paragraph (c)(2) or (c)(3) of this section.

(2) For quantitative endocrinology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Cortisol	Target value ±25%.
Free Thyroxine	Target value ±3 SD.
Human Chorionic Gonadotropin (excluding urine pregnancy tests done by visual color comparison categorized as waived tests).	Target value ±3 SD positive or negative.
T3 Uptake	Target value ±3 SD.
Triiodothyronine	Target value ±3 SD.
Thyroid-stimulating hormone	Target value ±3 SD.
Thyroxine	Target value ±20% or 1.0 mcg/dL (greater).

(3) The criterion for acceptable performance for qualitative endocrinology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

§ 493.937 Toxicology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for toxicology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in specimens of patients on drug therapy and that cover the level of clinical significance for the particular drug. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five serum, plasma, or blood samples.

Analyte or Test Procedure

Alcohol (blood)	Phenytoin
Blood lead	Primidone
Carbamazepine	Procainamide (and metabolite)
Digoxin	Quinidine
Ethosuximide	Theophylline
Gentamicin	Tobramycin
Lithium	Valproic Acid
Phenobarbital	

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (4) of this section.

(1) To determine the accuracy of a laboratory's responses for quantitative toxicology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The score for a sample in toxicology is the score determined under paragraph (c)(2) of this section.

(2) For quantitative toxicology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using fixed criteria based on the percentage difference from the target value

Criteria for Acceptable Performance

The criteria for acceptable performance are:

Analyte or test	Criteria for acceptable performance
Alcohol, blood	Target Value ±25%.
Blood lead	Target Value ±10% or 4 mcg/dL (greater).
Carbamazepine	Target Value ±25%.
Digoxin	Target Value ±20% or ±0.2 ng/mL (greater).
Ethosuximide	Target Value ±20%.
Gentamicin	Target Value ±25%.
Lithium	Target Value ±0.3 mmol/L or ±20% (greater).
Phenobarbital	Target Value ±20%
Phenytoin	Target Value ±25%.
Primidone	Target Value ±25%.
Procainamide (and metabolite).	Target Value ±25%.
Quinidine	Target Value ±25%.
Tobramycin	Target Value ±25%.
Theophylline	Target Value ±25%.

Analyte or test	Criteria for acceptable performance
Valproic Acid	Target Value ±25%.

(3) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(4) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

§493.941 Hematology (including routine hematology and coagulation).

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for hematology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of values that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS and or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five.

Analyte or Test Procedure

Cell identification or white blood cell differential
Erythrocyte count
Hematocrit (excluding spun microhematocrit)
Hemoglobin
Leukocyte count
Platelet count
Fibrinogen
Partial thromboplastin time
Prothrombin time

(1) An approved program for cell identification may vary over time. The types of cells that might be included in an approved program over time are—

Neutrophilic granulocytes
Eosinophilic granulocytes
Basophilic granulocytes
Lymphocytes
Monocytes
Major red and white blood cell abnormalities
Immature red and white blood cells

(2) White blood cell differentials should be limited to the percentage distribution of cellular elements listed above.

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (5) of this section.

(1) To determine the accuracy of a laboratory's responses for qualitative and quantitative hematology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The score for a sample in hematology is either the score determined under paragraph (c) (2) or (3) of this section.

(2) For quantitative hematology tests or analytes, the program must determine the correct response for each

analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response is determined using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are:

Analyte or test	Criteria for acceptable performance
Cell identification	90% or greater consensus on identification.
White blood cell differential	Target ±3SD based on the percentage of different types of white blood cells in the samples.
Erythrocyte count	Target ±6%.
Hematocrit (Excluding spun hematocrits).	Target ±6%.
Hemoglobin	Target ±7%.
Leukocyte count	Target ±15%.
Platelet count	Target ±25%.
Fibrinogen	Target ±20%.
Partial thromboplastin time	Target ±15%.
Prothrombin time	Target ±15%.

(3) The criterion for acceptable performance for the qualitative hematology test is correct cell identification.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

§ 493.945 Cytology; gynecologic examinations.

(a) *Program content and frequency of challenge.* (1) To be approved for proficiency testing for gynecologic examinations (Pap smears) in cytology, a program must provide test sets composed of 10- and 20-glass slides. Proficiency testing programs may obtain slides for test sets from cytology laboratories, provided the slides have been retained by the laboratory for the required period specified in §§ 493.1105(a)(7)(i)(A) and 493.1274(f)(2). If slide preparations are still subject to retention by the laboratory, they may be loaned to a proficiency testing program if the program provides the laboratory with documentation of the loan of the slides and ensures that slides loaned to it are retrievable upon request. Each test set must include at least one slide representing each of the response categories described in paragraph (b)(3)(ii)(A) of this section, and test sets should be comparable so that equitable testing is achieved within and between proficiency testing providers.

(2) To be approved for proficiency testing in gynecologic cytology, a program must provide announced and unannounced on-site testing for each individual at least once per year and must provide an initial retesting event for each individual within 45 days after

notification of test failure and subsequent retesting events within 45 days after completion of remedial action described in §493.855.

(b) *Evaluation of an individual's performance*. HHS approves only those programs that assess the accuracy of each individual's responses on both 10- and 20-slide test sets in which the slides have been referenced as specified in paragraph (b)(1) of this section.

(1) To determine the accuracy of an individual's response on a particular challenge (slide), the program must compare the individual's response for each slide preparation with the response that reflects the predetermined consensus agreement or confirmation on the diagnostic category, as described in the table in paragraph (b)(3)(ii)(A) of this section. For all slide preparations, a 100% consensus agreement among a minimum of three physicians certified in anatomic pathology is required. In addition, for premalignant and malignant slide preparations, confirmation by tissue biopsy is required either by comparison of the reported biopsy results or reevaluation of biopsy slide material by a physician certified in anatomic pathology.

(2) An individual qualified as a technical supervisor under §493.1449 (b) or (k) who routinely interprets gynecologic slide preparations only after they have been examined by a cytotechnologist can either be tested using a test set that has been screened by a cytotechnologist in the same laboratory or using a test set that has not been screened. A technical supervisor who screens and interprets slide preparations that have not been previously examined must be tested using a test set that has not been previously screened.

(3) The criteria for acceptable performance are determined by using the scoring system in paragraphs (b)(3) (i) and (ii) of this section.

(i) Each slide set must contain 10 or 20 slides with point values established for each slide preparation based on the significance of the relationship of the interpretation of the slide to a clinical condition and whether the participant in the testing event is a cytotechnologist qualified under §§493.1469 or 493.1483 or functioning as a technical supervisor in cytology qualified under §493.1449 (b) or (k) of this part.

(ii) The scoring system rewards or penalizes the participants in proportion to the distance of their answers from the correct response or target diagnosis and the penalty or reward is weighted in proportion to the severity of the lesion.

(A) The four response categories for reporting proficiency testing results and their descriptions are as follows:

Category	Description
A	Unsatisfactory for diagnosis due to: (1) Scant cellularity. (2) Air drying. (3) Obscuring material (blood, inflammatory cells, or lubricant).
B	Normal or Benign Changes—includes: (1) Normal, negative or within normal limits. (2) Infection other than Human Papillomavirus (HPV) (e.g., *Trichomonas vaginalis,* changes or morphology consistent with *Candida* spp., *Actinomyces* spp. or *Herpes simplex* virus). (3) Reactive and reparative changes (e.g., inflammation, effects of chemotherapy or radiation).
C	Low Grade Squamous Intraepithelial Lesion—includes: (1) Cellular changes associated with HPV. (2) Mild dysplasia/CIN–1.
D	High Grade Lesion and Carcinoma—includes: (1) High grade squamous intraepithelial lesions which include moderate dysplasia/CIN–2 and severe dysplasia/carcinoma in-situ/CIN–3. (2) Squamous cell carcinoma. (3) Adenocarcinoma and other malignant neoplasms.

(B) In accordance with the criteria for the scoring system, the charts in paragraphs (b)(3)(ii)(C) and (D) of this section, for technical supervisors and cytotechnologists, respectively, provide a maximum of 10 points for a correct response and a maximum of minus five (−5) points for an incorrect response on a 10-slide test set. For example, if the correct response on a slide is ''high grade squamous intraepithelial lesion'' (category ''D'' on the scoring system chart) and an examinee calls it

''normal or negative'' (category ''B'' on the scoring system chart), then the examinee's point value on that slide is calculated as minus five (−5). Each slide is scored individually in the same manner. The individual's score for the testing event is determined by adding the point value achieved for each slide preparation, dividing by the total points for the testing event and multiplying by 100.

(C) Criteria for scoring system for a 10-slide test set. (See table at (b)(3)(ii)(A) of this section for a description of the response categories.) For technical supervisors qualified under § 493.1449(b) or (k):

Examinee's response:	A	B	C	D
Correct response category:				
A	10	0	0	0
B	5	10	0	0
C	5	0	10	5
D	0	−5	5	10

(D) Criteria for scoring system for a 10-slide test set. (See table at paragraph (b)(3)(ii)(A) of this section for a description of the response categories.) For cytotechnologists qualified under §§ 493.1469 or 493.1483:

Examinee's response:	A	B	C	D
Correct response category:				
A	10	0	5	5
B	5	10	5	5
C	5	0	10	10
D	0	−5	10	10

(E) In accordance with the criteria for the scoring system, the charts in paragraphs (b)(3)(ii)(F) and (G) of this section, for technical supervisors and cytotechnologists, respectively, provide maximums of 5 points for a correct response and minus ten (−10) points for an incorrect response on a 20-slide test set.

(F) Criteria for scoring system for a 20-slide test set. (See table at paragraph (b)(3)(ii)(A) of this section for a description of the response categories.) For technical supervisors qualified under § 493.1449(b) or (k):

Examinee's response:	A	B	C	D
Correct response category:				
A	5	0	0	0
B	2.5	5	0	0
C	2.5	0	5	2.5
D	0	−10	2.5	5

(G) Criteria for scoring system for a 20-slide test set. (See table at (b)(3)(ii)(A) of this section for a description of the response categories.) For cytotechnologists qualified under §§ 493.1469 or 493.1483:

Examinee's response:	A	B	C	D
Correct response category:				
A	5	0	2.5	2.5
B	2.5	5	2.5	2.5
C	2.5	0	5	5
D	0	−10	5	5

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

§ 493.959 Immunohematology.

(a) *Types of services offered by laboratories.* In immunohematology, there are four types of laboratories for proficiency testing purposes—

(1) Those that perform ABO group and/or D (Rho) typing;

(2) Those that perform ABO group and/or D (Rho) typing, and unexpected antibody detection;

(3) Those that in addition to paragraph (a)(2) of this section perform compatibility testing; and

(4) Those that perform in addition to paragraph (a)(3) of this section antibody identification.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for immunohematology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of interpretation that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(c) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five.

Analyte or Test Procedure

ABO group (excluding subgroups)
D (Rho) typing
Unexpected antibody detection
Compatibility testing

Antibody identification

(d) *Evaluation of a laboratory's analyte or test performance*. HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (d)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 100 percent of ten or more referee laboratories or 95 percent or more of all participating laboratories except for unexpected antibody detection and antibody identification. To determine the accuracy of a laboratory's response for unexpected antibody detection and antibody identification, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 95 percent of ten or more referee laboratories or 95 percent or more of all participating laboratories. The score for a sample in immunohematology is either the score determined under paragraph (d)(2) or (3) of this section.

(2) *Criteria for acceptable performance*. The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
ABO group	100% accuracy.
D (Rho) typing	100% accuracy.
Unexpected antibody detection	80% accuracy.
Compatibility testing	100% accuracy.
Antibody identification	80% accuracy.

(3) The criterion for acceptable performance for qualitative immunohematology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

Subpart J—Facility Administration for Nonwaived Testing

SOURCE: 68 FR 3703, Jan. 24, 2003, unless otherwise noted.

§493.1100 Condition: Facility administration.

Each laboratory that performs nonwaived testing must meet the applicable requirements under §§493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7).

§493.1101 Standard: Facilities.

(a) The laboratory must be constructed, arranged, and maintained to ensure the following:

(1) The space, ventilation, and utilities necessary for conducting all phases of the testing process.

(2) Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.

(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate

areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.

(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.

(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.

(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.

§ 493.1103 Standard: Requirements for transfusion services.

A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities.

(a) *Arrangement for services.* The facility must have a transfusion service agreement reviewed and approved by the responsible party(ies) that govern the procurement, transfer, and availability of blood and blood products.

(b) *Provision of testing.* The facility must provide prompt ABO grouping, D(Rho) typing, unexpected antibody detection, compatibility testing, and laboratory investigation of transfusion reactions on a continuous basis through a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.

(c) *Blood and blood products storage and distribution.* (1) If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.

(2) The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient.

(d) *Investigation of transfusion reactions.* The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities.

§ 493.1105 Standard: Retention requirements.

(a) The laboratory must retain its records and, as applicable, slides, blocks, and tissues as follows:

(1) *Test requisitions and authorizations.* Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.

(2) *Test procedures.* Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.

(3) *Analytic systems records.* Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in §§ 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:

(i) Records of test system performance specifications that the laboratory establishes or verifies under § 493.1253 for the period of time the laboratory uses the test system but no less than 2 years.

(ii) Immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v) and (d).

(4) *Proficiency testing records.* Retain all proficiency testing records for at least 2 years.

(5) *Quality system assessment records.* Retain all laboratory quality systems assessment records for at least 2 years.

(6) *Test reports.* Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. In addition, retain the following:

(i) Immunohematology reports as specified in 21 CFR 606.160(d).

(ii) Pathology test reports for at least 10 years after the date of reporting.

(7) *Slide, block, and tissue retention*—(i) *Slides*. (A) Retain cytology slide preparations for at least 5 years from the date of examination (see § 493.1274(f) for proficiency testing exception).

(B) Retain histopathology slides for at least 10 years from the date of examination.

(ii) *Blocks*. Retain pathology specimen blocks for at least 2 years from the date of examination.

(iii) *Tissue*. Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.

(b) If the laboratory ceases operation, the laboratory must make provisions to ensure that all records and, as applicable, slides, blocks, and tissue are retained and available for the time frames specified in this section.

[68 FR 3703, Jan. 24, 2003; 68 FR 50723, Aug. 22, 2003]

Subpart K—Quality System for Nonwaived Testing

SOURCE: 68 FR 3703, Jan. 24, 2003, unless otherwise noted.

§ 493.1200 Introduction.

(a) Each laboratory that performs nonwaived testing must establish and maintain written policies and procedures that implement and monitor a quality system for all phases of the total testing process (that is, preanalytic, analytic, and postanalytic) as well as general laboratory systems.

(b) The laboratory's quality systems must include a quality assessment component that ensures continuous improvement of the laboratory's performance and services through ongoing monitoring that identifies, evaluates and resolves problems.

(c) The various components of the laboratory's quality system are used to meet the requirements in this part and must be appropriate for the specialties and subspecialties of testing the laboratory performs, services it offers, and clients it serves.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§ 493.1201 Condition: Bacteriology.

If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1261, and §§ 493.1281 through 493.1299.

§ 493.1202 Condition: Mycobacteriology.

If the laboratory provides services in the subspecialty of Mycobacteriology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1262, and §§ 493.1281 through 493.1299.

§ 493.1203 Condition: Mycology.

If the laboratory provides services in the subspecialty of Mycology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1263, and §§ 493.1281 through 493.1299.

§ 493.1204 Condition: Parasitology.

If the laboratory provides services in the subspecialty of Parasitology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1264, and §§ 493.1281 through 493.1299.

§ 493.1205 Condition: Virology.

If the laboratory provides services in the subspecialty of Virology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1265, and §§ 493.1281 through 493.1299.

§ 493.1207 Condition: Syphilis serology.

If the laboratory provides services in the subspecialty of Syphilis serology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

§ 493.1208 Condition: General immunology.

If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§ 493.1210 Condition: Routine chemistry.

If the laboratory provides services in the subspecialty of Routine chemistry, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1267, and §§ 493.1281 through 493.1299.

§ 493.1211 Condition: Urinalysis.

If the laboratory provides services in the subspecialty of Urinalysis, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

§ 493.1212 Condition: Endocrinology.

If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

§ 493.1213 Condition: Toxicology.

If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

§ 493.1215 Condition: Hematology.

If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1269, and §§ 493.1281 through 493.1299.

§ 493.1217 Condition: Immunohematology.

If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1271, and §§ 493.1281 through 493.1299.

§ 493.1219 Condition: Histopathology.

If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1273, and §§ 493.1281 through 493.1299.

§ 493.1220 Condition: Oral pathology.

If the laboratory provides services in the subspecialty of Oral pathology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

§ 493.1221 Condition: Cytology.

If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1274, and §§ 493.1281 through 493.1299.

§ 493.1225 Condition: Clinical cytogenetics.

If the laboratory provides services in the specialty of Clinical cytogenetics, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1276, and §§ 493.1281 through 493.1299.

§ 493.1226 Condition: Radiobioassay.

If the laboratory provides services in the specialty of Radiobioassay, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

§ 493.1227 Condition: Histocompatibility.

If the laboratory provides services in the specialty of Histocompatibility, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1278, and §§ 493.1281 through 493.1299.

GENERAL LABORATORY SYSTEMS

§ 493.1230 Condition: General laboratory systems.

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in §§ 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems as specified in § 493.1239 for each specialty and subspecialty of testing performed.

§ 493.1231 Standard: Confidentiality of patient information.

The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.

§ 493.1232 Standard: Specimen identification and integrity.

The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

§ 493.1233 Standard: Complaint investigations.

The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.

§ 493.1234 Standard: Communications.

The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§ 493.1235 Standard: Personnel competency assessment policies.

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

§ 493.1236 Standard: Evaluation of proficiency testing performance.

(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

(b) The laboratory must verify the accuracy of the following:

(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

(2) Any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return of results).

(c) At least twice annually, the laboratory must verify the accuracy of the following:

(1) Any test or procedure it performs that is not included in subpart I of this part.

(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.

(d) All proficiency testing evaluation and verification activities must be documented.

§ 493.1239 Standard: General laboratory systems quality assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at §§ 493.1231 through 493.1236.

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff.

(c) The laboratory must document all general laboratory systems quality assessment activities.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

PREANALYTIC SYSTEMS

§ 493.1240 Condition: Preanalytic systems.

Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in §§ 493.1241 and 493.1242, unless HHS

approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in § 493.1249 for each specialty and subspecialty of testing performed.

§ 493.1241 Standard: Test request.

(a) The laboratory must have a written or electronic request for patient testing from an authorized person.

(b) The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization.

(c) The laboratory must ensure the test requisition solicits the following information:

(1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values.

(2) The patient's name or unique patient identifier.

(3) The sex and age or date of birth of the patient.

(4) The test(s) to be performed.

(5) The source of the specimen, when appropriate.

(6) The date and, if appropriate, time of specimen collection.

(7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy.

(8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

(d) The patient's chart or medical record may be used as the test requisition or authorization but must be available to the laboratory at the time of testing and available to CMS or a CMS agent upon request.

(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.

§ 493.1242 Standard: Specimen submission, handling, and referral.

(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable:

(1) Patient preparation.

(2) Specimen collection.

(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source.

(4) Specimen storage and preservation.

(5) Conditions for specimen transportation.

(6) Specimen processing.

(7) Specimen acceptability and rejection.

(8) Specimen referral.

(b) The laboratory must document the date and time it receives a specimen.

(c) The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.

(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

§ 493.1249 Standard: Preanalytic systems quality assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at §§ 493.1241 through 493.1242.

(b) The preanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and

discussion of preanalytic systems quality assessment reviews with appropriate staff.

(c) The laboratory must document all preanalytic systems quality assessment activities.

[68 FR 3703, Jan. 24, 2003; 68 FR 3703, Aug. 22, 2003]

ANALYTIC SYSTEMS

§ 493.1250 Condition: Analytic systems.

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in §§ 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in § 493.1289 for each specialty and subspecialty of testing performed.

§ 493.1251 Standard: Procedure manual.

(a) A written procedure manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

(b) The procedure manual must include the following when applicable to the test procedure:

(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in § 493.1242.

(2) Microscopic examination, including the detection of inadequately prepared slides.

(3) Step-by-step performance of the procedure, including test calculations and interpretation of results.

(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing.

(5) Calibration and calibration verification procedures.

(6) The reportable range for test results for the test system as established or verified in § 493.1253.

(7) Control procedures.

(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.

(9) Limitations in the test methodology, including interfering substances.

(10) Reference intervals (normal values).

(11) Imminently life-threatening test results, or panic or alert values.

(12) Pertinent literature references.

(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life-threatening results, or panic, or alert values.

(14) Description of the course of action to take if a test system becomes inoperable.

(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in § 493.1105(a)(2).

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§ 493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies.

(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under § 493.1253.

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result

reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following:

(1) Water quality.

(2) Temperature.

(3) Humidity.

(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following:

(1) Identity and when significant, titer, strength or concentration.

(2) Storage requirements.

(3) Preparation and expiration dates.

(4) Other pertinent information required for proper use.

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

(e) Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer.

§ 493.1253 Standard: Establishment and verification of performance specifications.

(a) *Applicability*. Laboratories are not required to verify or establish performance specifications for any test system used by the laboratory before April 24, 2003.

(b)(1) *Verification of performance specifications*. Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results:

(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics:

(A) Accuracy.

(B) Precision.

(C) Reportable range of test results for the test system.

(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

(2) *Establishment of performance specifications*. Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable:

(i) Accuracy.

(ii) Precision.

(iii) Analytical sensitivity.

(iv) Analytical specificity to include interfering substances.

(v) Reportable range of test results for the test system.

(vi) Reference intervals (normal values).

(vii) Any other performance characteristic required for test performance.

(3) *Determination of calibration and control procedures*. The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.

(c) *Documentation*. The laboratory must document all activities specified in this section.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§ 493.1254 Standard: Maintenance and function checks.

(a) *Unmodified manufacturer's equipment, instruments, or test systems*. The laboratory must perform and document the following:

(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the

manufacturer's established limits before patient testing is conducted.

(b) *Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer*. The laboratory must do the following:

(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting.

(ii) Perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting.

(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

§ 493.1255 Standard: Calibration and calibration verification procedures.

Calibration and calibration verification procedures are required to substantiate the continued accuracy of the test system throughout the laboratory's reportable range of test results for the test system. Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following:

(a) Perform and document calibration procedures—

(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer;

(2) Using the criteria verified or established by the laboratory as specified in § 493.1253(b)(3)—

(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and

(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and

(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

(b) Perform and document calibration verification procedures—

(1) Following the manufacturer's calibration verification instructions;

(2) Using the criteria verified or established by the laboratory under § 493.1253(b)(3)—

(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and

(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and

(3) At least once every 6 months and whenever any of the following occur:

(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes.

(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance.

(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem.

(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

§ 493.1256 Standard: Control procedures.

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process.

(b) The laboratory must establish the number, type, and frequency of testing

control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in § 493.1253(b)(3).

(c) The control procedures must—

(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance.

(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

(d) Unless CMS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must—

(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at §§ 493.1261 through 493.1278.

(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section.

(3) At least once each day patient specimens are assayed or examined perform the following for—

(i) Each quantitative procedure, include two control materials of different concentrations;

(ii) Each qualitative procedure, include a negative and positive control material;

(iii) Test procedures producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively;

(iv) Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; and

(v) Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition.

(4) For thin layer chromatography—

(i) Spot each plate or card, as applicable, with a calibrator containing all known substances or drug groups, as appropriate, which are identified by thin layer chromatography and reported by the laboratory; and

(ii) Include at least one control material on each plate or card, as applicable, which must be processed through each step of patient testing, including extraction processes.

(5) For each electrophoretic procedure include, concurrent with patient specimens, at least one control material containing the substances being identified or measured.

(6) Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced.

(7) Over time, rotate control material testing among all operators who perform the test.

(8) Test control materials in the same manner as patient specimens.

(9) When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system.

(10) Establish or verify the criteria for acceptability of all control materials.

(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available.

(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory.

(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

(e) For reagent, media, and supply checks, the laboratory must do the following:

(1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in §493.1261(a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable.

(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.

(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use.

(4) Before, or concurrent with the initial use—

(i) Check each batch of media for sterility if sterility is required for testing;

(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and

(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer.

(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results.

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results.

(g) The laboratory must document all control procedures performed.

(h) If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§493.1261 Standard: Bacteriology.

(a) The laboratory must check the following for positive and negative reactivity using control organisms:

(1) Each day of use for beta-lactamase methods other than Cefinase™.

(2) Each week of use for Gram stains.

(3) When each batch (prepared in-house), lot number (commercially prepared), and shipment of antisera is prepared or opened, and once every 6 months thereafter.

(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms.

(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results.

(c) The laboratory must document all control procedures performed, as specified in this section.

§493.1262 Standard: Mycobacteriology.

(a) Each day of use, the laboratory must check all reagents or test procedures used for mycobacteria identification with at least one acid-fast organism that produces a positive reaction and an acid-fast organism that produces a negative reaction.

(b) For antimycobacterial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimycobacterial agent(s) before, or concurrent with, initial use, using an appropriate control organism(s).

(1) The laboratory must establish limits for acceptable control results.

(2) Each week tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

(3) The results for the control organism(s) must be within established limits before reporting patient results.

(c) The laboratory must document all control procedures performed, as specified in this section.

§493.1263 Standard: Mycology.

(a) The laboratory must check each batch (prepared in-house), lot number

(commercially prepared), and shipment of lactophenol cotton blue when prepared or opened for intended reactivity with a control organism(s).

(b) For antifungal susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antifungal agent(s) before, or concurrent with, initial use, using an appropriate control organism(s).

(1) The laboratory must establish limits for acceptable control results.

(2) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

(3) The results for the control organism(s) must be within established limits before reporting patient results.

(c) The laboratory must document all control procedures performed, as specified in this section.

§ 493.1264 Standard: Parasitology.

(a) The laboratory must have available a reference collection of slides or photographs and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens.

(b) The laboratory must calibrate and use the calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter.

(c) Each month of use, the laboratory must check permanent stains using a fecal sample control material that will demonstrate staining characteristics.

(d) The laboratory must document all control procedures performed, as specified in this section.

§ 493.1265 Standard: Virology.

(a) When using cell culture to isolate or identify viruses, the laboratory must simultaneously incubate a cell substrate control or uninoculated cells as a negative control material.

(b) The laboratory must document all control procedures performed, as specified in this section.

§ 493.1267 Standard: Routine chemistry.

For blood gas analyses, the laboratory must perform the following:

(a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer.

(b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing.

(c) Test one sample of control material each time specimens are tested unless automated instrumentation internally verifies calibration at least every 30 minutes.

(d) Document all control procedures performed, as specified in this section.

§ 493.1269 Standard: Hematology.

(a) For manual cell counts performed using a hemocytometer—

(1) One control material must be tested each 8 hours of operation; and

(2) Patient specimens and control materials must be tested in duplicate.

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed.

(c) For manual coagulation tests—

(1) Each individual performing tests must test two levels of control materials before testing patient samples and each time a reagent is changed; and

(2) Patient specimens and control materials must be tested in duplicate.

(d) The laboratory must document all control procedures performed, as specified in this section.

§ 493.1271 Standard: Immunohematology.

(a) *Patient testing.* (1) The laboratory must perform ABO grouping, D(Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e).

(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells.

(3) The laboratory must determine the D(Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent.

(b) *Immunohematological testing and distribution of blood and blood products.* Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b).

(c) *Blood and blood products storage.* Blood and blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected.

(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period.

(2) Inspections of the alarm system must be documented.

(d) *Retention of samples of transfused blood.* According to the laboratory's established procedures, samples of each unit of transfused blood must be retained for further testing in the event of transfusion reactions. The laboratory must promptly dispose of blood not retained for further testing that has passed its expiration date.

(e) *Investigation of transfusion reactions.* (1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures.

(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused.

(f) *Documentation.* The laboratory must document all control procedures performed, as specified in this section.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§ 493.1273 Standard: Histopathology.

(a) As specified in § 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reaction(s) of the control slide with each special stain must be documented.

(b) The laboratory must retain stained slides, specimen blocks, and tissue remnants as specified in § 493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under §§ 493.1449(b), (l), or (m).

(c) An individual who has successfully completed a training program in neuromuscular pathology approved by HHS may examine and provide reports for neuromuscular pathology.

(d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis.

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results.

(f) The laboratory must document all control procedures performed, as specified in this section.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§ 493.1274 Standard: Cytology.

(a) *Cytology slide examination site.* All cytology slide preparations must be evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.

(b) *Staining.* The laboratory must have available and follow written policies and procedures for each of the following, if applicable:

(1) All gynecologic slide preparations must be stained using a Papanicolaou

or modified Papanicolaou staining method.

(2) Effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process must be used.

(3) Nongynecologic specimens that have a high potential for cross-contamination must be stained separately from other nongynecologic specimens, and the stains must be filtered or changed following staining.

(c) *Control procedures.* The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following:

(1) A review of slides from at least 10 percent of the gynecologic cases interpreted by individuals qualified under §§ 493.1469 or 493.1483, to be negative for epithelial cell abnormalities and other malignant neoplasms (as defined in paragraph (e)(1) of this section).

(i) The review must be performed by an individual who meets one of the following qualifications:

(A) A technical supervisor qualified under §§ 493.1449(b) or (k).

(B) A cytology general supervisor qualified under § 493.1469.

(C) A cytotechnologist qualified under § 493.1483 who has the experience specified in § 493.1469(b)(2).

(ii) Cases must be randomly selected from the total caseload and include negatives and those from patients or groups of patients that are identified as having a higher than average probability of developing cervical cancer based on available patient information.

(iii) The review of those cases selected must be completed before reporting patient results.

(2) Laboratory comparison of clinical information, when available, with cytology reports and comparison of all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with the histopathology report, if available in the laboratory (either on-site or in storage), and determination of the causes of any discrepancies.

(3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report.

(4) Records of initial examinations and all rescreening results must be documented.

(5) An annual statistical laboratory evaluation of the number of—

(i) Cytology cases examined;

(ii) Specimens processed by specimen type;

(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation);

(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison;

(v) Gynecologic cases where cytology and histology are discrepant; and

(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.

(6) An evaluation of the case reviews of each individual examining slides against the laboratory's overall statistical values, documentation of any discrepancies, including reasons for the deviation and, if appropriate, corrective actions taken.

(d) *Workload limits.* The laboratory must establish and follow written policies and procedures that ensure the following:

(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

(i) The workload limit is based on the individual's performance using evaluations of the following:

(A) Review of 10 percent of the cases interpreted as negative for the conditions defined in paragraph (e)(1) of this section.

(B) Comparison of the individual's interpretation with the technical supervisor's confirmation of patient smears specified in paragraphs (e)(1) and (e)(3) of this section.

(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition—

(i) The maximum number of 100 slides is examined in no less than an 8-hour workday;

(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula—

$$\frac{\text{Number of hours examining slides} \times 100}{8}$$

is used to determine maximum slide volume to be examined;

(iii) Nongynecologic slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over one-half or less of the total available slide may be counted as one-half slide; and

(iv) Technical supervisors who perform primary screening are not required to include tissue pathology slides and previously examined cytology slides (gynecologic and nongynecologic) in the 100 slide workload limit.

(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory.

(4) Records are available to document the workload limit for each individual.

(e) *Slide examination and reporting.* The laboratory must establish and follow written policies and procedures that ensure the following:

(1) A technical supervisor confirms each gynecologic slide preparation interpreted to exhibit reactive or reparative changes or any of the following epithelial cell abnormalities:

(i) Squamous cell.

(A) Atypical squamous cells of undetermined significance (ASC-US) or cannot exclude HSIL (ASC-H).

(B) LSIL-Human papillomavirus (HPV)/mild dysplasia/cervical intraepithelial neoplasia 1 (CIN 1).

(C) HSIL-moderate and severe dysplasia, carcinoma in situ (CIS)/CIN 2 and CIN 3 or with features suspicious for invasion.

(D) Squamous cell carcinoma.

(ii) Glandular cell.

(A) Atypical cells not otherwise specified (NOS) or specified in comments (endocervical, endometrial, or glandular).

(B) Atypical cells favor neoplastic (endocervical or glandular).

(C) Endocervical adenocarcinoma in situ.

(D) Adenocarcinoma endocervical, adenocarcinoma endometrial, adenocarcinoma extrauterine, and adenocarcinoma NOS.

(iii) Other malignant neoplasms.

(2) The report of gynecologic slide preparations with conditions specified in paragraph (e)(1) of this section must be signed to reflect the technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review.

(3) All nongynecologic preparations are reviewed by a technical supervisor. The report must be signed to reflect technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review.

(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.

(5) The report contains narrative descriptive nomenclature for all results.

(6) Corrected reports issued by the laboratory indicate the basis for correction.

(f) *Record and slide retention.* (1) The laboratory must retain all records and slide preparations as specified in § 493.1105.

(2) Slides may be loaned to proficiency testing programs in lieu of maintaining them for the required time period, provided the laboratory receives written acknowledgment of the receipt of slides by the proficiency testing program and maintains the acknowledgment to document the loan of these slides.

(3) Documentation of slides loaned or referred for purposes other than proficiency testing must be maintained.

(4) All slides must be retrievable upon request.

(g) *Automated and semi-automated screening devices.* When performing evaluations using automated and semi-automated screening devices, the laboratory must follow manufacturer's instructions for preanalytic, analytic, and postanalytic phases of testing, as applicable, and meet the applicable requirements of this subpart K.

(h) *Documentation.* The laboratory must document all control procedures performed, as specified in this section.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§ 493.1276 Standard: Clinical cytogenetics.

(a) The laboratory must have policies and procedures for ensuring accurate and reliable patient specimen identification during the process of accessioning, cell preparation, photographing or other image reproduction technique, photographic printing, and reporting and storage of results, karyotypes, and photographs.

(b) The laboratory must have records that document the following:

(1) The media used, reactions observed, number of cells counted, number of cells karyotyped, number of chromosomes counted for each metaphase spread, and the quality of the banding.

(2) The resolution is appropriate for the type of tissue or specimen and the type of study required based on the clinical information provided to the laboratory.

(3) An adequate number of karyotypes are prepared for each patient.

(c) Determination of sex must be performed by full chromosome analysis.

(d) The laboratory report must include a summary and interpretation of the observations, number of cells counted and analyzed, and use the International System for Human Cytogenetic Nomenclature.

(e) The laboratory must document all control procedures performed, as specified in this section.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§ 493.1278 Standard: Histocompatibility.

(a) *General.* The laboratory must meet the following requirements:

(1) An audible alarm system must be used to monitor the storage temperature of specimens (donor and recipient) and reagents. The laboratory must have an emergency plan for alternate storage.

(2) All patient specimens must be easily retrievable.

(3) Reagent typing sera inventory prepared in-house must indicate source, bleeding date and identification number, reagent specificity, and volume remaining.

(4) If the laboratory uses immunologic reagents (for example, antibodies, antibody-coated particles, or complement) to facilitate or enhance the isolation of lymphocytes, or lymphocyte subsets, the efficacy of the methods must be monitored with appropriate quality control procedures.

(5) Participate in at least one national or regional cell exchange program, if available, or develop an exchange system with another laboratory in order to validate interlaboratory reproducibility.

(b) *HLA typing.* The laboratory must do the following:

(1) Use a technique(s) that is established to optimally define, as applicable, HLA Class I and II specificities.

(2) HLA type all potential transplant recipients at a level appropriate to support clinical transplant protocol and donor selection.

(3) HLA type cells from organ donors referred to the laboratory.

(4) Use HLA antigen terminology that conforms to the latest report of the World Health Organization (W.H.O.) Committee on Nomenclature. Potential new antigens not yet approved by this committee must have a designation that cannot be confused with W.H.O. terminology.

(5) Have available and follow written criteria for the following:

(i) The preparation of cells or cellular extracts (for example, solubilized antigens and nucleic acids), as applicable to the HLA typing technique(s) performed.

(ii) Selecting typing reagents, whether prepared in-house or commercially.

(iii) Ensuring that reagents used for typing are adequate to define all HLA-A, B and DR specificities that are officially recognized by the most recent W.H.O. Committee on Nomenclature and for which reagents are readily available.

(iv) The assignment of HLA antigens.

(v) When antigen redefinition and retyping are required.

(6) Check each HLA typing by testing, at a minimum the following:

(i) A positive control material.

(ii) A negative control material in which, if applicable to the technique performed, cell viability at the end of incubation is sufficient to permit accurate interpretation of results. In assays in which cell viability is not required, the negative control result must be sufficiently different from the positive control result to permit accurate interpretation of results.

(iii) Positive control materials for specific cell types when applicable (that is, T cells, B cells, and monocytes).

(c) *Disease-associated studies*. The laboratory must check each typing for disease-associated HLA antigens using control materials to monitor the test components and each phase of the test system to ensure acceptable performance.

(d) *Antibody Screening*. The laboratory must do the following:

(1) Use a technique(s) that detects HLA-specific antibody with a specificity equivalent or superior to that of the basic complement-dependent microlymphocytotoxicity assay.

(2) Use a method that distinguishes antibodies to HLA Class II antigens from antibodies to Class I antigens to detect antibodies to HLA Class II antigens.

(3) Use a panel that contains all the major HLA specificities and common splits. If the laboratory does not use commercial panels, it must maintain a list of individuals for fresh panel bleeding.

(4) Make a reasonable attempt to have available monthly serum specimens for all potential transplant recipients for periodic antibody screening and crossmatch.

(5) Have available and follow a written policy consistent with clinical transplant protocols for the frequency of screening potential transplant recipient sera for preformed HLA-specific antibodies.

(6) Check each antibody screening by testing, at a minimum the following:

(i) A positive control material containing antibodies of the appropriate isotype for the assay.

(ii) A negative control material.

(7) As applicable, have available and follow written criteria and procedures for antibody identification to the level appropriate to support clinical transplant protocol.

(e) *Crossmatching*. The laboratory must do the following:

(1) Use a technique(s) documented to have increased sensitivity in comparison with the basic complement-dependent microlymphocytotoxicity assay.

(2) Have available and follow written criteria for the following:

(i) Selecting appropriate patient serum samples for crossmatching.

(ii) The preparation of donor cells or cellular extracts (for example, solubilized antigens and nucleic acids), as applicable to the crossmatch technique(s) performed.

(3) Check each crossmatch and compatibility test for HLA Class II antigenic differences using control materials to monitor the test components and each phase of the test system to ensure acceptable performance.

(f) *Transplantation*. Laboratories performing histocompatibility testing for

transfusion and transplantation purposes must do the following:

(1) Have available and follow written policies and protocols specifying the histocompatibility testing (that is, HLA typing, antibody screening, compatibility testing and crossmatching) to be performed for each type of cell, tissue or organ to be transfused or transplanted. The laboratory's policies must include, as applicable—

(i) Testing protocols for cadaver donor, living, living-related, and combined organ and tissue transplants;

(ii) Testing protocols for patients at high risk for allograft rejection; and

(iii) The level of testing required to support clinical transplant protocols (for example, antigen or allele level).

(2) For renal allotransplantation and combined organ and tissue transplants in which a kidney is to be transplanted, have available results of final crossmatches before the kidney is transplanted.

(3) For nonrenal transplantation, if HLA testing and final crossmatches were not performed prospectively because of an emergency situation, the laboratory must document the circumstances, if known, under which the emergency transplant was performed, and records of the transplant must reflect any information provided to the laboratory by the patient's physician.

(g) *Documentation.* The laboratory must document all control procedures performed, as specified in this section.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§ 493.1281 Standard: Comparison of test results.

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

(b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available:

(1) Patient age.

(2) Sex.

(3) Diagnosis or pertinent clinical data.

(4) Distribution of patient test results.

(5) Relationship with other test parameters.

(c) The laboratory must document all test result comparison activities.

§ 493.1282 Standard: Corrective actions.

(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur:

(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in § 493.1253(b), which include but are not limited to—

(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications;

(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and

(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

(3) The criteria for proper storage of reagents and specimens, as specified under § 493.1252(b), are not met.

§493.1283 Standard: Test records.

(a) The laboratory must maintain an information or record system that includes the following:

(1) The positive identification of the specimen.

(2) The date and time of specimen receipt into the laboratory.

(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability.

(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

(b) Records of patient testing including, if applicable, instrument printouts, must be retained.

§493.1289 Standard: Analytic systems quality assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in §§493.1251 through 493.1283.

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff.

(c) The laboratory must document all analytic systems quality assessment activities.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

POSTANALYTIC SYSTEMS

§493.1290 Condition: Postanalytic systems.

Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in §493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in §493.1299 for each specialty and subspecialty of testing performed.

§493.1291 Standard: Test report.

(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following:

(1) Results reported from calculated data.

(2) Results and patient-specific data electronically reported to network or interfaced systems.

(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

(c) The test report must indicate the following:

(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number.

(2) The name and address of the laboratory location where the test was performed.

(3) The test report date.

(4) The test performed.

(5) Specimen source, when appropriate.

(6) The test result and, if applicable, the units of measurement or interpretation, or both.

(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

(d) Pertinent ''reference intervals'' or ''normal'' values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

(e) The laboratory must, upon request, make available to clients a list

of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in § 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

(f) Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test.

(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing.

(i) If a laboratory refers patient specimens for testing—

(1) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory;

(2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report; and

(3) The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed.

(j) All test reports or records of the information on the test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.

(k) When errors in the reported patient test results are detected, the laboratory must do the following:

(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors.

(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results.

(3) Maintain duplicates of the original report, as well as the corrected report.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§ 493.1299 Standard: Postanalytic systems quality assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in § 493.1291.

(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff.

(c) The laboratory must document all postanalytic systems quality assessment activities.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

Subpart L [Reserved]

Subpart M—Personnel for Nonwaived Testing

SOURCE: 57 FR 7172, Feb. 28, 1992, unless otherwise noted.

§ 493.1351 General.

This subpart consists of the personnel requirements that must be met by laboratories performing moderate complexity testing, PPM procedures, high complexity testing, or any combination of these tests.

[60 FR 20049, Apr. 24, 1995]

LABORATORIES PERFORMING PROVIDER-PERFORMED MICROSCOPY (PPM) PROCEDURES

SOURCE: 60 FR 20049, Apr. 24, 1995, unless otherwise noted.

§493.1353 Scope.

In accordance with §493.19(b), the moderate complexity procedures specified as PPM procedures are considered such only when personally performed by a health care provider during a patient visit in the context of a physical examination. PPM procedures are subject to the personnel requirements in §§493.1355 through 493.1365.

§493.1355 Condition: Laboratories performing PPM procedures; laboratory director.

The laboratory must have a director who meets the qualification requirements of §493.1357 and provides overall management and direction in accordance with §493.1359.

§493.1357 Standard; laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of PPM procedures as specified in §493.19(c) and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part.

(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if the licensing is required.

(b) The laboratory director must meet one of the following requirements:

(1) Be a physician, as defined in §493.2.

(2) Be a midlevel practitioner, as defined in §493.2, authorized by a State to practice independently in the State in which the laboratory is located.

(3) Be a dentist, as defined in §493.2.

§493.1359 Standard; PPM laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the prompt, accurate, and proficient reporting of test results. The laboratory director must—

(a) Direct no more than five laboratories; and

(b) Ensure that any procedure listed under §493.19(c)—

(1) Is personally performed by an individual who meets the qualification requirements in §493.1363; and

(2) Is performed in accordance with applicable requirements in subparts H, J, K, and M of this part.

[57 FR 7172, Feb. 28, 1992, as amended at 68 FR 3713, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§493.1361 Condition: Laboratories performing PPM procedures; testing personnel.

The laboratory must have a sufficient number of individuals who meet the qualification requirements of §493.1363 to perform the functions specified in §493.1365 for the volume and complexity of testing performed.

§493.1363 Standard: PPM testing personnel qualifications.

Each individual performing PPM procedures must—

(a) Possess a current license issued by the State in which the laboratory is located if the licensing is required; and

(b) Meet one of the following requirements:

(1) Be a physician, as defined in §493.2.

(2) Be a midlevel practitioner, as defined in §493.2, under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located.

(3) Be a dentist as defined in §493.2 of this part.

§493.1365 Standard; PPM testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance, and for reporting test results. Any PPM procedure must be—

(a) Personally performed by one of the following practitioners:

(1) A physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee.

(2) A midlevel practitioner, under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located, during the patient's visit on a specimen obtained from his or her own patient or from the patient of a clinic, group medical practice, or other health care provider, in which the midlevel practitioner is a member or an employee.

(3) A dentist during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee; and

(b) Performed using a microscope limited to a brightfield or a phase/contrast microscope.

LABORATORIES PERFORMING MODERATE COMPLEXITY TESTING

§ 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.

The laboratory must have a director who meets the qualification requirements of § 493.1405 of this subpart and provides overall management and direction in accordance with § 493.1407 of this subpart.

§ 493.1405 Standard; Laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part.

(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and

(b) The laboratory director must—

(1) (i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have had laboratory training or experience consisting of:

(A) At least one year directing or supervising non-waived laboratory testing; or

(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in § 493.1407; or

(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and

(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or

(ii) Have had at least one year experience directing or supervising non-waived laboratory testing;

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution;

(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and

(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or

(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution;

(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and

(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing;

(6) Be serving as a laboratory director and must have previously qualified

or could have qualified as a laboratory director under §493.1406; or

(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5233, Jan. 19, 1993]

§493.1406 Standard; Laboratory director qualifications on or before February 28, 1992.

The laboratory director must be qualified to manage and direct the laboratory personnel and test performance.

(a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and

(b) The laboratory director must:

(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification;

(2) Be a physician who:

(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or

(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or

(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or

(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties;

(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification;

(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and

(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or

(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties;

(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either:

(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience;

(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience;

(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or

(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or

(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located.

NOTE: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of

the 5 years preceding the date of submission of his qualifications.

[58 FR 5233, Jan. 19, 1993]

§ 493.1407 Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations.

(a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of §§ 493.1409, 493.1415, and 493.1421, respectively.

(b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

(c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

(d) Each individual may direct no more than five laboratories.

(e) The laboratory director must—

(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

(3) Ensure that—

(i) The test methodologies selected have the capability of providing the quality of results required for patient care;

(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that—

(i) The proficiency testing samples are tested as required under subpart H of this part;

(ii) The results are returned within the timeframes established by the proficiency testing program;

(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;

(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that patient test results are reported only when the system is functioning properly;

(8) Ensure that reports of test results include pertinent information required for interpretation;

(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;

(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

[57 FR 7172, Feb. 28, 1992, as amended at 68 FR 3713, Jan. 24, 2003]

§493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.

The laboratory must have a technical consultant who meets the qualification requirements of §493.1411 of this subpart and provides technical oversight in accordance with §493.1413 of this subpart.

§493.1411 Standard; Technical consultant qualifications.

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

(a) The technical consultant must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

(b) The technical consultant must—

(1) (i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or

(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or

(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated

specialty or subspecialty areas of service for which the technical consultant is responsible.

NOTE: The technical consultant requirements for ''laboratory training or experience, or both'' in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993]

§ 493.1413 Standard; Technical consultant responsibilities.

The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.

(a) The technical consultant must be accessible to the laboratory to provide on-site, telephone, or electronic consultation; and

(b) The technical consultant is responsible for—

(1) Selection of test methodology appropriate for the clinical use of the test results;

(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;

(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to—

(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

(ii) Monitoring the recording and reporting of test results;

(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;

(iv) Direct observation of performance of instrument maintenance and function checks;

(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

(vi) Assessment of problem solving skills; and

(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

§493.1415 Condition: Laboratories performing moderate complexity testing; clinical consultant.

The laboratory must have a clinical consultant who meets the qualification requirements of §493.1417 of this part and provides clinical consultation in accordance with §493.1419 of this part.

§493.1417 Standard; Clinical consultant qualifications.

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must—

(a) Be qualified as a laboratory director under §493.1405(b) (1), (2), or (3)(i); or

(b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993]

§493.1419 Standard; Clinical consultant responsibilities.

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results. The clinical consultant must—

(a) Be available to provide clinical consultation to the laboratory's clients;

(b) Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

(d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

§493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.

The laboratory must have a sufficient number of individuals who meet the qualification requirements of §493.1423, to perform the functions specified in §493.1425 for the volume and complexity of tests performed.

§493.1423 Standard; Testing personnel qualifications.

Each individual performing moderate complexity testing must—

(a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) Meet one of the following requirements:

(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or

(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or

(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or

(4)(i) Have earned a high school diploma or equivalent; and

(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has—

(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;

(B) The skills required for implementing all standard laboratory procedures;

(C) The skills required for performing each test method and for proper instrument use;

(D) The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed;

(E) A working knowledge of reagent stability and storage;

(F) The skills required to implement the quality control policies and procedures of the laboratory;

(G) An awareness of the factors that influence test results; and

(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993]

§ 493.1425 Standard; Testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance, and for reporting test results.

(a) Each individual performs only those moderate complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

(b) Each individual performing moderate complexity testing must—

(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples;

(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

(4) Follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;

(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director; and

(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.

LABORATORIES PERFORMING HIGH COMPLEXITY TESTING

§ 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.

The laboratory must have a director who meets the qualification requirements of § 493.1443 of this subpart and provides overall management and direction in accordance with § 493.1445 of this subpart.

§ 493.1443 Standard; Laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R.

(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and

(b) The laboratory director must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and

(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

(ii) Have at least 2 years of experience directing or supervising high complexity testing; or

(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution and—

(i) Be certified and continue to be certified by a board approved by HHS; or

(ii) Before February 24, 2003, must have served or be serving as a director of a laboratory performing high complexity testing and must have at least—

(A) Two years of laboratory training or experience, or both; and

(B) Two years of laboratory experience directing or supervising high complexity testing.

(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or

(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or

(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993; 59 FR 62609, Dec. 6, 1994; 62 FR 25858, May 12, 1997; 63 FR 55034, Oct. 14, 1998; 65 FR 82944, Dec. 29, 2000; 68 FR 3713, Jan. 24, 2003]

§493.1445 Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.

(a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under §§493.1447, 493.1453, 493.1459, and 493.1487, respectively.

(b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

(c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

(d) Each individual may direct no more than five laboratories.

(e) The laboratory director must—

(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

(3) Ensure that—

(i) The test methodologies selected have the capability of providing the quality of results required for patient care;

(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that—

(i) The proficiency testing samples are tested as required under subpart H of this part;

(ii) The results are returned within the timeframes established by the proficiency testing program;

(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory;

(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and that patient test results are reported only when the system is functioning properly;

(8) Ensure that reports of test results include pertinent information required for interpretation;

(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;

(10) Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under § 493.1489(b)(4);

(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

(12) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

[57 FR 7172, Feb. 28, 1992, as amended at 68 FR 3714, Jan. 24, 2003]

§ 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor.

The laboratory must have a technical supervisor who meets the qualification requirements of § 493.1449 of this subpart and provides technical supervision in accordance with § 493.1451 of this subpart.

§ 493.1449 Standard; Technical supervisor qualifications.

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.

(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor—

(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification.

(c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology.

(d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum

of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology.

(e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the speciality of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology.

(f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology;

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology.

(g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology.

(h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high

complexity testing within the specialty of diagnostic immunology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or

(5) (i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology.

(i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry.

(j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological

science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology.

(k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must—

(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Meet one of the following requirements—

(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification;

(2) An individual qualified under §493.1449(b) or paragraph (k)(1) of this section may delegate some of the cytology technical supervisor responsibilities to an individual who is in the final year of full-time training leading to certification specified in paragraphs (b) or (k)(1)(ii)(A) of this section provided the technical supervisor qualified under §493.1449(b) or paragraph (k)(1) of this section remains ultimately responsible for ensuring that all of the responsibilities of the cytology technical supervisor are met.

(l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must—

(1) Meet one of the following requirements:

(i) (A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification;

(ii) An individual qualified under §493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens.

(2) For tests in dermatopathology, meet one of the following requirements:

(i) (A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and—

(B) Meet one of the following requirements:

(*1*) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(*2*) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(*3*) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or

(ii) An individual qualified under §493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens.

(3) For tests in ophthalmic pathology, meet one of the following requirements:

(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and—

(B) Must meet one of the following requirements:

(*1*) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board

of Pathology or possess qualifications that are equivalent to those required for such certification; or

(*2*) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certitication and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or

(ii) An individual qualified under § 493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or

(m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements:

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and—

(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or

(3) An individual qualified under § 493.1449(b) or paragraph (m) (1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m) (1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens.

(n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay.

(o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either—

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have training or experience that meets one of the following requirements:

(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(B)(*1*) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(*2*) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or

(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and

(ii) Have training or experience that meets one of the following requirements:

(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(B)(*1*) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(*2*) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility.

(p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or

(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and

(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics.

(q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology.

NOTE: The technical supervisor requirements for ''laboratory training or experience, or both'' in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993]

§493.1451 Standard: Technical supervisor responsibilities.

The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.

(a) The technical supervisor must be accessible to the laboratory to provide on-site, telephone, or electronic consultation; and

(b) The technical supervisor is responsible for—

(1) Selection of the test methodology that is appropriate for the clinical use of the test results;

(2) Verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;

(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

(4) Establishing a quality control program appropriate for the testing

performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to—

(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

(ii) Monitoring the recording and reporting of test results;

(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;

(iv) Direct observation of performance of instrument maintenance and function checks;

(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

(vi) Assessment of problem solving skills; and

(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

(c) In cytology, the technical supervisor or the individual qualified under § 493.1449(k)(2)—

(1) May perform the duties of the cytology general supervisor and the cytotechnologist, as specified in §§ 493.1471 and 493.1485, respectively;

(2) Must establish the workload limit for each individual examining slides;

(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary;

(4) Must perform the functions specified in § 493.1274(d) and (e);

(5) Must ensure that each individual examining gynecologic preparations participates in an HHS approved cytology proficiency testing program, as specified in § 493.945 and achieves a passing score, as specified in § 493.855; and

(6) If responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5235, Jan. 19, 1993; 68 FR 3714, Jan. 24, 2003]

§ 493.1453 Condition: Laboratories performing high complexity testing; clinical consultant.

The laboratory must have a clinical consultant who meets the requirements of § 493.1455 of this subpart and provides clinical consultation in accordance with § 493.1457 of this subpart.

§ 493.1455 Standard; Clinical consultant qualifications.

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must—

(a) Be qualified as a laboratory director under § 493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, § 493.1443(b)(6); or

(b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5235, Jan. 19, 1993]

§493.1457 Standard; Clinical consultant responsibilities.

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results. The clinical consultant must—

(a) Be available to provide consultation to the laboratory's clients;

(b) Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

(d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

§493.1459 Condition: Laboratories performing high complexity testing; general supervisor.

The laboratory must have one or more general supervisors who are qualified under §493.1461 of this subpart to provide general supervision in accordance with §493.1463 of this subpart.

§493.1461 Standard: General supervisor qualifications.

The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) The general supervisor must be qualified as a—

(1) Laboratory director under §493.1443; or

(2) Technical supervisor under §493.1449.

(c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must—

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or

(2)(i) Qualify as testing personnel under §493.1489(b)(2); and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or

(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under §493.1462 on or before February 28, 1992.

(ii) *Exception*. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of §493.1462 on or before January 1, 1994.''

(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995—

(i) Meet one of the following requirements:

(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS.

(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held

the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).

(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or

(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and—

(i) Be a high school graduate or equivalent; and

(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992.

(d) For blood gas analysis, the individual providing general supervision must—

(1) Be qualified under §§ 493.1461(b) (1) or (2), or 493.1461(c); or

(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and

(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or

(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and

(ii) Have at least two years of training or experience, or both in blood gas analysis.

(e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed:

(1) In histopathology, by an individual who is qualified as a technical supervisor under §§ 493.1449(b) or 493.1449(l)(1);

(2) In dermatopathology, by an individual who is qualified as a technical supervisor under §§ 493.1449(b) or 493.1449(l) or (2);

(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under §§ 493.1449(b) or 493.1449(1)(3); and

(4) In oral pathology, by an individual who is qualified as a technical supervisor under §§ 493.1449(b) or 493.1449(m).

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5235, Jan. 19, 1993; 58 FR 39155, July 22, 1993; 60 FR 20049, Apr. 24, 1995]

§ 493.1462 General supervisor qualifications on or before February 28, 1992.

To qualify as a general supervisor under § 493.1461(c)(3), an individual must have met or could have met the following qualifications as they were in effect on or before February 28, 1992.

(a) Each supervisor possesses a current license as a laboratory supervisor issued by the State, if such licensing exists; and

(b) The laboratory supervisor—

(1) Who qualifies as a laboratory director under § 493.1406(b)(1), (2), (4), or (5) is also qualified as a general supervisor; therefore, depending upon the size and functions of the laboratory, the laboratory director may also serve as the laboratory supervisor; or

(2)(i) Is a physician or has earned a doctoral degree from an accredited institution with a major in one of the chemical, physical, or biological sciences; and

(ii) Subsequent to graduation, has had at least 2 years of experience in one of the laboratory specialties in a laboratory; or

(3)(i) Holds a master's degree from an accredited institution with a major in one of the chemical, physical, or biological sciences; and

(ii) Subsequent to graduation has had at least 4 years of pertinent full-time laboratory experience of which not less than 2 years have been spent working in the designated specialty in a laboratory; or

(4)(i) Is qualified as a laboratory technologist under § 493.1491; and

(ii) After qualifying as a laboratory technologist, has had at least 6 years of pertinent full-time laboratory experience of which not less than 2 years have been spent working in the designated laboratory specialty in a laboratory; or

(5) With respect to individuals first qualifying before July 1, 1971, has had at least 15 years of pertinent full-time laboratory experience before January 1, 1968; this required experience may be met by the substitution of education for experience.

[58 FR 39155, July 22, 1993]

§ 493.1463 Standard: General supervisor responsibilities.

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

(a) The general supervisor—(1) Must be accessible to testing personnel at all times testing is performed to provide on-site, telephone or electronic consultation to resolve technical problems in accordance with policies and procedures established either by the laboratory director or technical supervisor;

(2) Is responsible for providing day-to-day supervision of high complexity test performance by a testing personnel qualified under § 493.1489;

(3) Except as specified in paragraph (c) of this section, must be onsite to provide direct supervision when high complexity testing is performed by any individuals qualified under § 493.1489(b)(5); and

(4) Is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

(b) The director or technical supervisor may delegate to the general supervisor the responsibility for—

(1) Assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

(2) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning;

(3) Providing orientation to all testing personnel; and

(4) Annually evaluating and documenting the performance of all testing personnel.

(c) *Exception*. For individuals qualified under § 493.1489(b)(5), who were performing high complexity testing on or before January 19, 1993, the requirements of paragraph (a)(3) of this section are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under § 493.1461.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5235, Jan. 19, 1993; 60 FR 20050, Apr. 24, 1995]

§ 493.1467 Condition: Laboratories performing high complexity testing; cytology general supervisor.

For the subspecialty of cytology, the laboratory must have a general supervisor who meets the qualification requirements of § 493.1469 of this subpart, and provides supervision in accordance with § 493.1471 of this subpart.

§ 493.1469 Standard: Cytology general supervisor qualifications.

The cytology general supervisor must be qualified to supervise cytology services. The general supervisor in cytology must possess a current license issued by the State in which the laboratory is located, if such licensing is required, and must—

(a) Be qualified as a technical supervisor under § 493.1449 (b) or (k); or

(b)(1) Be qualified as a cytotechnologist under § 493.1483; and

(2) Have at least 3 years of full-time (2,080 hours per year) experience as a cytotechnologist within the preceding 10 years.

§ 493.1471 Standard: Cytology general supervisor responsibilities.

The technical supervisor of cytology may perform the duties of the cytology general supervisor or delegate the responsibilities to an individual qualified under § 493.1469.

(a) The cytology general supervisor is responsible for the day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

(b) The cytology general supervisor must—

(1) Be accessible to provide on-site, telephone, or electronic consultation to resolve technical problems in accordance with policies and procedures established by the technical supervisor of cytology;

(2) Document the slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified under § 493.1274(c));

(3) For each 24-hour period, document the total number of slides he or she examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer; and

(4) Document the number of hours spent examining slides in each 24-hour period.

[57 FR 7172, Feb. 28, 1992, as amended at 68 FR 3714, Jan. 24, 2003]

§ 493.1481 Condition: Laboratories performing high complexity testing; cytotechnologist.

For the subspecialty of cytology, the laboratory must have a sufficient number of cytotechnologists who meet the qualifications specified in § 493.1483 to perform the functions specified in § 493.1485.

§ 493.1483 Standard: Cytotechnologist qualifications.

Each person examining cytology slide preparations must meet the qualifications of § 493.1449 (b) or (k), or—

(a) Possess a current license as a cytotechnologist issued by the State in which the laboratory is located, if such licensing is required; and

(b) Meet one of the following requirements:

(1) Have graduated from a school of cytotechnology accredited by the Committee on Allied Health Education and Accreditation or other organization approved by HHS; or

(2) Be certified in cytotechnology by a certifying agency approved by HHS; or

(3) Before September 1, 1992—

(i) Have successfully completed 2 years in an accredited institution with at least 12 semester hours in science, 8 hours of which are in biology; and

(A) Have had 12 months of training in a school of cytotechnology accredited by an accrediting agency approved by HHS; or

(B) Have received 6 months of formal training in a school of cytotechnology accredited by an accrediting agency approved by HHS and 6 months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed the formal 6 months of training; or

(ii) Have achieved a satisfactory grade to qualify as a cytotechnologist in a proficiency examination approved by HHS and designed to qualify persons as cytotechnologists; or

(4) Before September 1, 1994, have full-time experience of at least 2 years or equivalent within the preceding 5 years examining slide preparations under the supervision of a physician qualified under § 493.1449(b) or (k)(1), and before January 1, 1969, must have—

(i) Graduated from high school;

(ii) Completed 6 months of training in cytotechnology in a laboratory directed by a pathologist or other physician providing cytology services; and

(iii) Completed 2 years of full-time supervised experience in cytotechnology; or

(5)(i) On or before September 1, 1994, have full-time experience of at least 2 years or equivalent examining cytology slide preparations within the preceding 5 years in the United States under the supervision of a physician qualified under § 493.1449(b) or (k)(1); and

(ii) On or before September 1, 1995, have met the requirements in either paragraph (b)(1) or (2) of this section.

[57 FR 7172, Feb. 28, 1992, as amended at 59 FR 685, Jan. 6, 1994]

§ 493.1485 Standard; Cytotechnologist responsibilities.

The cytotechnologist is responsible for documenting—

(a) The slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified in § 493.1274(c));

(b) For each 24-hour period, the total number of slides examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer; and

(c) The number of hours spent examining slides in each 24-hour period.

[57 FR 7172, Feb. 28, 1992, as amended at 68 FR 3714, Jan. 24, 2003]

§ 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.

The laboratory has a sufficient number of individuals who meet the qualification requirements of § 493.1489 of this subpart to perform the functions specified in § 493.1495 of this subpart for the volume and complexity of testing performed.

§493.1489 Standard; Testing personnel qualifications.

Each individual performing high complexity testing must—

(a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) Meet one of the following requirements:

(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution;

(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or—

(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes—

(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either—

(*1*) 24 semester hours of medical laboratory technology courses; or

(*2*) 24 semester hours of science courses that include—

(*i*) Six semester hours of chemistry;

(*ii*) Six semester hours of biology; and

(*iii*) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and

(B) Have laboratory training that includes either of the following:

(*1*) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.)

(*2*) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing.

(3) Have previously qualified or could have qualified as a technologist under §493.1491 on or before February 28, 1992;

(4) On or before April 24, 1995 be a high school graduate or equivalent and have either—

(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or

(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician);

(5)(i) Until September 1, 1997—

(A) Have earned a high school diploma or equivalent; and

(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has—

(*1*) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;

(*2*) The skills required for implementing all standard laboratory procedures;

(*3*) The skills required for performing each test method and for proper instrument use;

(*4*) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;

(*5*) A working knowledge of reagent stability and storage;

(*6*) The skills required to implement the quality control policies and procedures of the laboratory;

(*7*) An awareness of the factors that influence test results; and

(*8*) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and

(ii) As of September 1, 1997, be qualified under §493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995;

(6) For blood gas analysis—

(i) Be qualified under § 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5);

(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or

(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or

(7) For histopathology, meet the qualifications of § 493.1449 (b) or (l) to perform tissue examinations.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5236, Jan. 19, 1993; 58 FR 39155, July 22, 1993; 60 FR 20050, Apr. 24, 1995]

§ 493.1491 Technologist qualifications on or before February 28, 1992.

In order to qualify as high complexity testing personnel under § 493.1489(b)(3), the individual must have met or could have met the following qualifications for technologist as they were in effect on or before February 28, 1992. Each technologist must—

(a) Possess a current license as a laboratory technologist issued by the State, if such licensing exists; and

(b)(1) Have earned a bachelor's degree in medical technology from an accredited university; or

(2) Have successfully completed 3 years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university, which met the specific requirements for entrance into a school of medical technology accredited by an accrediting agency approved by the Secretary, and has successfully completed a course of training of at least 12 months in such a school; or

(3) Have earned a bachelor's degree in one of the chemical, physical, or biological sciences and, in addition, has at least 1 year of pertinent full-time laboratory experience or training, or both, in the specialty or subspecialty in which the individual performs tests; or

(4)(i) Have successfully completed 3 years (90 semester hours or equivalent) in an accredited college or university with the following distribution of courses—

(A) *For those whose training was completed before September 15, 1963.* At least 24 semester hours in chemistry and biology courses of which—

(*1*) At least 6 semester hours were in inorganic chemistry and at least 3 semester hours were in other chemistry courses; and

(*2*) At least 12 semester hours in biology courses pertinent to the medical sciences; or

(B) *For those whose training was completed after September 14, 1963.*

(*1*) 16 semester hours in chemistry courses that included at least 6 semester hours in inorganic chemistry and that are acceptable toward a major in chemistry;

(*2*) 16 semester hours in biology courses that are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and

(*3*) 3 semester hours of mathematics; and

(ii) Has experience, training, or both, covering several fields of medical laboratory work of at least 1 year and of such quality as to provide him or her with education and training in medical technology equivalent to that described in paragraphs (b)(1) and (2) of this section; or

(5) With respect to individuals first qualifying before July 1, 1971, the technologist—

(i) Was performing the duties of a laboratory technologist at any time between July 1, 1961, and January 1, 1968, and

(ii) Has had at least 10 years of pertinent laboratory experience prior to January 1, 1968. (This required experience may be met by the substitution of education for experience); or

(6) Achieves a satisfactory grade in a proficiency examination approved by HHS.

[58 FR 39155, July 22, 1993]

§ 493.1495 Standard; Testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance and for reporting test results.

(a) Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

(b) Each individual performing high complexity testing must—

(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens;

(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

(4) Follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;

(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director;

(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications; and

(7) Except as specified in paragraph (c) of this section, if qualified under §493.1489(b)(5), perform high complexity testing only under the onsite, direct supervision of a general supervisor qualified under §493.1461.

(c) *Exception*. For individuals qualified under §493.1489(b)(5), who were performing high complexity testing on or before January 19, 1993, the requirements of paragraph (b)(7) of this section are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under §493.1461.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5236, Jan. 19, 1993; 60 FR 20050, Apr. 24, 1995]

Subparts N–P [Reserved]

Subpart Q—Inspection

SOURCE: 57 FR 7184, Feb. 28, 1992, unless otherwise noted.

§493.1771 Condition: Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories.

(a) Each laboratory issued a CLIA certificate must meet the requirements in §493.1773 and the specific requirements for its certificate type, as specified in §§493.1775 through 493.1780.

(b) All CLIA-exempt laboratories must comply with the inspection requirements in §§493.1773 and 493.1780, when applicable.

[63 FR 26737, May 14, 1998]

§493.1773 Standard: Basic inspection requirements for all laboratories issued a CLIA certificate and CLIA-exempt laboratories.

(a) A laboratory issued a certificate must permit CMS or a CMS agent to conduct an inspection to assess the laboratory's compliance with the requirements of this part. A CLIA-exempt laboratory and a laboratory that requests, or is issued a certificate of accreditation, must permit CMS or a CMS agent to conduct validation and complaint inspections.

(b) *General requirements*. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following:

(1) Test samples, including proficiency testing samples, or perform procedures.

(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part.

(3) Permit laboratory personnel to be observed performing all phases of the total testing process (preanalytic, analytic, and postanalytic).

(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following:

(i) Specimen procurement and processing areas.

(ii) Storage facilities for specimens, reagents, supplies, records, and reports.

(iii) Testing and reporting areas.

(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires.

(c) *Accessible records and data*. A laboratory must have all records and data

accessible and retrievable within a reasonable time frame during the course of the inspection.

(d) *Requirement to provide information and data.* A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

(e) *Reinspection.* CMS or a CMS agent may reinspect a laboratory at any time to evaluate the ability of the laboratory to provide accurate and reliable test results.

(f) *Complaint inspection.* CMS or a CMS agent may conduct an inspection when there are complaints alleging noncompliance with any of the requirements of this part.

(g) *Failure to permit an inspection or reinspection.* Failure to permit CMS or a CMS agent to conduct an inspection or reinspection results in the suspension or cancellation of the laboratory's participation in Medicare and Medicaid for payment, and suspension or limitation of, or action to revoke the laboratory's CLIA certificate, in accordance with subpart R of this part.

[63 FR 26737, May 14, 1998; 63 FR 32699, June 15, 1998]

§ 493.1775 Standard: Inspection of laboratories issued a certificate of waiver or a certificate for provider-performed microscopy procedures.

(a) A laboratory that has been issued a certificate of waiver or a certificate for provider-performed microscopy procedures is not subject to biennial inspections.

(b) If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at any time during the laboratory's hours of operation to do the following:

(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health.

(2) Evaluate a complaint from the public.

(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory.

(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures.

(c) The laboratory must comply with the basic inspection requirements of § 493.1773.

[63 FR 26737, May 14, 1998]

§ 493.1777 Standard: Inspection of laboratories that have requested or have been issued a certificate of compliance.

(a) *Initial inspection.* (1) A laboratory issued a registration certificate must permit an initial inspection to assess the laboratory's compliance with the requirements of this part before CMS issues a certificate of compliance.

(2) The inspection may occur at any time during the laboratory's hours of operation.

(b) *Subsequent inspections.* (1) CMS or a CMS agent may conduct subsequent inspections on a biennial basis or with such other frequency as CMS determines to be necessary to ensure compliance with the requirements of this part.

(2) CMS bases the nature of subsequent inspections on the laboratory's compliance history.

(c) *Provider-performed microscopy procedures.* The inspection sample for review may include testing in the subcategory of provider-performed microscopy procedures.

(d) *Compliance with basic inspection requirements.* The laboratory must comply with the basic inspection requirements of § 493.1773.

[63 FR 26738, May 14, 1998]

§ 493.1780 Standard: Inspection of CLIA-exempt laboratories or laboratories requesting or issued a certificate of accreditation.

(a) *Validation inspection.* CMS or a CMS agent may conduct a validation inspection of any accredited or CLIA-exempt laboratory at any time during its hours of operation.

(b) *Complaint inspection.* CMS or a CMS agent may conduct a complaint inspection of a CLIA-exempt laboratory or a laboratory requesting or issued a certificate of accreditation at any time during its hours of operation

upon receiving a complaint applicable to the requirements of this part.

(c) *Noncompliance determination.* If a validation or complaint inspection results in a finding that the laboratory is not in compliance with one or more condition-level requirements, the following actions occur:

(1) A laboratory issued a certificate of accreditation is subject to a full review by CMS, in accordance with subpart E of this part and §488.11 of this chapter.

(2) A CLIA-exempt laboratory is subject to appropriate enforcement actions under the approved State licensure program.

(d) *Compliance with basic inspection requirements.* CLIA-exempt laboratories and laboratories requesting or issued a certificate of accreditation must comply with the basic inspection requirements in §493.1773.

[63 FR 26738, May 14, 1998]

Subpart R—Enforcement Procedures

SOURCE: 57 FR 7237, Feb. 28, 1992, unless otherwise noted.

§493.1800 Basis and scope.

(a) *Statutory basis.* (1) Section 1846 of the Act—

(i) Provides for intermediate sanctions that may be imposed on laboratories that perform clinical diagnostic tests on human specimens when those laboratories are found to be out of compliance with one or more of the conditions for Medicare coverage of their services; and

(ii) Requires the Secretary to develop and implement a range of such sanctions, including four that are specified in the statute.

(2) The Clinical Laboratories Improvement Act of 1967 (section 353 of the Public Health Service Act) as amended by CLIA '88—

(i) Establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens;

(ii) Requires a Federal certification scheme to be applied to all such laboratories; and

(iii) Grants the Secretary broad enforcement authority, including—

(A) Use of intermediate sanctions;

(B) Suspension, limitation, or revocation of the certificate of a laboratory that is out of compliance with one or more requirements for a certificate; and

(C) Civil suit to enjoin any laboratory activity that constitutes a significant hazard to the public health.

(3) Section 353 also—

(i) Provides for imprisonment or fine for any person convicted of intentional violation of CLIA requirements;

(ii) Specifies the administrative hearing and judicial review rights of a laboratory that is sanctioned under CLIA; and

(iii) Requires the Secretary to publish annually a list of all laboratories that have been sanctioned during the preceding year.

(b) *Scope and applicability.* This subpart sets forth—

(1) The policies and procedures that CMS follows to enforce the requirements applicable to laboratories under CLIA and under section 1846 of the Act; and

(2) The appeal rights of laboratories on which CMS imposes sanctions.

§493.1804 General considerations.

(a) *Purpose.* The enforcement mechanisms set forth in this subpart have the following purposes:

(1) To protect all individuals served by laboratories against substandard testing of specimens.

(2) To safeguard the general public against health and safety hazards that might result from laboratory activities.

(3) To motivate laboratories to comply with CLIA requirements so that they can provide accurate and reliable test results.

(b) *Basis for decision to impose sanctions.* (1) CMS's decision to impose sanctions is based on one or more of the following:

(i) Deficiencies found by CMS or its agents in the conduct of inspections to certify or validate compliance with Federal requirements, or through review of materials submitted by the laboratory (e.g., personnel qualifications).

(ii) Unsuccessful participation in proficiency testing.

(2) CMS imposes one or more of the alternative or principal sanctions specified in §§ 493.1806 and 493.1807 when CMS or CMS's agent finds that a laboratory has condition-level deficiencies.

(c) *Imposition of alternative sanctions.* (1) CMS may impose alternative sanctions in lieu of, or in addition to principal sanctions, (CMS does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not inspected for compliance with condition-level requirements.)

(2) CMS may impose alternative sanctions other than a civil money penalty after the laboratory has had an opportunity to respond, but before the hearing specified in § 493.1844.

(d) *Choice of sanction: Factors considered.* CMS bases its choice of sanction or sanctions on consideration of one or more factors that include, but are not limited to, the following, as assessed by the State or by CMS, or its agents:

(1) Whether the deficiencies pose immediate jeopardy.

(2) The nature, incidence, severity, and duration of the deficiencies or noncompliance.

(3) Whether the same condition level deficiencies have been identified repeatedly.

(4) The accuracy and extent of laboratory records (e.g., of remedial action) in regard to the noncompliance, and their availability to the State, to other CMS agents, and to CMS.

(5) The relationship of one deficiency or group of deficiencies to other deficiencies.

(6) The overall compliance history of the laboratory including but not limited to any period of noncompliance that occurred between certifications of compliance.

(7) The corrective and long-term compliance outcomes that CMS hopes to achieve through application of the sanction.

(8) Whether the laboratory has made any progress toward improvement following a reasonable opportunity to correct deficiencies.

(9) Any recommendation by the State agency as to which sanction would be appropriate.

(e) *Number of alternative sanctions.* CMS may impose a separate sanction for each condition level deficiency or a single sanction for all condition level deficiencies that are interrelated and subject to correction by a single course of action.

(f) *Appeal rights.* The appeal rights of laboratories dissatisfied with the imposition of a sanction are set forth in § 493.1844.

[57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992, as amended at 60 FR 20051, Apr. 24, 1995]

§ 493.1806 Available sanctions: All laboratories.

(a) *Applicability.* CMS may impose one or more of the sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions.

(b) *Principal sanction.* CMS may impose any of the three principal CLIA sanctions, which are suspension, limitation, or revocation of any type of CLIA certificate.

(c) *Alternative sanctions.* CMS may impose one or more of the following alternative sanctions in lieu of or in addition to imposing a principal sanction, except on a laboratory that has a certificate of waiver.

(1) Directed plan of correction, as set forth at § 493.1832.

(2) State onsite monitoring as set forth at § 493.1836.

(3) Civil money penalty, as set forth at § 493.1834.

(d) *Civil suit.* CMS may bring suit in the appropriate U.S. District Court to enjoin continuation of any activity of any laboratory (including a CLIA-exempt laboratory that has been found with deficiencies during a validation survey), if CMS has reason to believe that continuation of the activity would constitute a significant hazard to the public health.

(e) *Criminal sanctions.* Under section 353(1) of the PHS Act, an individual who is convicted of intentionally violating any CLIA requirement may be imprisoned or fined.

[57 FR 7237, Feb. 28, 1992, as amended at 58 FR 5237, Jan. 19, 1993]

§493.1807 Additional sanctions: Laboratories that participate in Medicare.

The following additional sanctions are available for laboratories that are out of compliance with one or more CLIA conditions and that have approval to receive Medicare payment for their services.

(a) *Principal sanction.* Cancellation of the laboratory's approval to receive Medicare payment for its services.

(b) *Alternative sanctions.* (1) Suspension of payment for tests in one or more specific specialties or subspecialties, performed on or after the effective date of sanction.

(2) Suspension of payment for all tests in all specialties and subspecialties performed on or after the effective date of sanction.

§493.1808 Adverse action on any type of CLIA certificate: Effect on Medicare approval.

(a) *Suspension or revocation of any type of CLIA certificate.* When CMS suspends or revokes any type of CLIA certificate, CMS concurrently cancels the laboratory's approval to receive Medicare payment for its services.

(b) *Limitation of any type of CLIA certificate.* When CMS limits any type of CLIA certificate, CMS concurrently limits Medicare approval to only those specialties or subspecialties that are authorized by the laboratory's limited certificate.

§493.1809 Limitation on Medicaid payment.

As provided in section 1902(a)(9)(C) of the Act, payment for laboratory services may be made under the State plan only if those services are furnished by a laboratory that has a CLIA certificate or is licensed by a State whose licensure program has been approved by the Secretary under this part.

[57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992]

§493.1810 Imposition and lifting of alternative sanctions.

(a) *Notice of noncompliance and of proposed sanction: Content.* If CMS or its agency identifies condition level noncompliance in a laboratory, CMS or its agent gives the laboratory written notice of the following:

(1) The condition level noncompliance that it has identified.

(2) The sanction or sanctions that CMS or its agent proposes to impose against the laboratory.

(3) The rationale for the proposed sanction or sanctions.

(4) The projected effective date and duration of the proposed sanction or sanctions.

(5) The authority for the proposed sanction or sanctions.

(6) The time allowed (at least 10 days) for the laboratory to respond to the notice.

(b) *Opportunity to respond.* During the period specified in paragraph (a)(6) of this section, the laboratory may submit to CMS or its agent written evidence or other information against the imposition of the proposed sanction or sanctions.

(c) *Notice of imposition of sanction*—(1) *Content.* CMS gives the laboratory written notice that acknowledges any evidence or information received from the laboratory and specifies the following:

(i) The sanction or sanctions to be imposed against the laboratory.

(ii) The authority and rationale for the imposing sanction or sanctions.

(iii) The effective date and duration of sanction.

(2) *Timing.* (i) If CMS or its agent determines that the deficiencies pose immediate jeopardy, CMS provides notice at least 5 days before the effective date of sanction.

(ii) If CMS or its agent determines that the deficiencies do not pose immediate jeopardy, CMS provides notice at least 15 days before the effective date of the sanction.

(d) *Duration of alternative sanctions.* An alternative sanction continues until the earlier of the following occurs:

(1) The laboratory corrects all condition level deficiencies.

(2) CMS's suspension, limitation, or revocation of the laboratory's CLIA certificate becomes effective.

(e) *Lifting of alternative sanctions*—(1) *General rule.* Alternative sanctions are

not lifted until a laboratory's compliance with all condition level requirements is verified.

(2) *Credible allegation of compliance.* When a sanctioned laboratory submits a credible allegation of compliance, CMS's agent determines whether—

(i) It can certify compliance on the basis of the evidence presented by the laboratory in its allegation; or

(ii) It must revisit to verify whether the laboratory has, in fact, achieved compliance.

(3) *Compliance achieved before the date of revisit.* If during a revisit, the laboratory presents credible evidence (as determined by CMS or its agent) that it achieved compliance before the date of revisit, sanctions are lifted as of that earlier date.

§ 493.1812 Action when deficiencies pose immediate jeopardy.

If a laboratory's deficiencies pose immediate jeopardy, the following rules apply:

(a) CMS requires the laboratory to take immediate action to remove the jeopardy and may impose one or more alternative sanctions to help bring the laboratory into compliance.

(b) If the findings of a revisit indicate that a laboratory has not eliminated the jeopardy, CMS suspends or limits the laboratory's CLIA certificate no earlier than 5 days after the date of notice of suspension or limitation. CMS may later revoke the certificate.

(c) In addition, if CMS has reason to believe that the continuation of any activity by any laboratory (either the entire laboratory operation or any specialty or subspecialty of testing) would constitute a significant hazard to the public health, CMS may bring suit and seek a temporary injunction or restraining order against continuation of that activity by the laboratory, regardless of the type of CLIA certificate the laboratory has and of whether it is State-exempt.

§ 493.1814 Action when deficiencies are at the condition level but do not pose immediate jeopardy.

If a laboratory has condition level deficiencies that do not pose immediate jeopardy, the following rules apply:

(a) *Initial action.* (1) CMS may cancel the laboratory's approval to receive Medicare payment for its services.

(2) CMS may suspend, limit, or revoke the laboratory's CLIA certificate.

(3) If CMS does not impose a principal sanction under paragraph (a)(1) or (a)(2) of this section, it imposes one or more alternative sanctions. In the case of unsuccessful participation in proficiency testing, CMS may impose the training and technical assistance requirement set forth at § 493.1838 in lieu of, or in addition to, one or more alternative sanctions.

(b) *Failure to correct condition level deficiencies.* If CMS imposes alternative sanctions for condition level deficiencies that do not pose immediate jeopardy, and the laboratory does not correct the condition level deficiencies within 12 months after the last day of inspection, CMS—

(1) Cancels the laboratory's approval to receive Medicare payment for its services, and discontinues the Medicare payment sanctions as of the day cancellation is effective.

(2) Following a revisit which indicates that the laboratory has not corrected its condition level deficiencies, notifies the laboratory that it proposes to suspend, limit, or revoke the certificate, as specified in § 493.1816(b), and the laboratory's right to hearing; and

(3) May impose (or continue, if already imposed) any alternative sanctions that do not pertain to Medicare payments. (Sanctions imposed under the authority of section 353 of the PHS Act may continue for more than 12 months from the last date of inspection, while a hearing on the proposed suspension, limitation, or revocation of the certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures is pending.)

(c) *Action after hearing.* If a hearing decision upholds a proposed suspension, limitation, or revocation of a laboratory's CLIA certificate, CMS discontinues any alternative sanctions as of the day it makes the suspension, limitation, or revocation effective.

[57 FR 7237, Feb. 28, 1992, as amended at 60 FR 20051, Apr. 24, 1995]

§ 493.1816 Action when deficiencies are not at the condition level.

If a laboratory has deficiencies, that are not at the condition level, the following rules apply:

(a) *Initial action*. The laboratory must submit a plan of correction that is acceptable to CMS in content and time frames.

(b) *Failure to correct deficiencies*. If, on revisit, it is found that the laboratory has not corrected the deficiencies within 12 months after the last day of inspection, the following rules apply:

(1) CMS cancels the laboratory's approval to receive Medicare payment for its services.

(2) CMS notifies the laboratory of its intent to suspend, limit, or revoke the laboratory's CLIA certificate and of the laboratory's right to a hearing.

§ 493.1820 Ensuring timely correction of deficiencies.

(a) *Timing of visits*. CMS, the State survey agency or other CMS agent may visit the laboratory at any time to evaluate progress, and at the end of the period to determine whether all corrections have been made.

(b) *Deficiencies corrected before a visit*. If during a visit, a laboratory produces credible evidence that it achieved compliance before the visit, the sanctions are lifted as of that earlier date.

(c) *Failure to correct deficiencies*. If during a visit it is found that the laboratory has not corrected its deficiencies, CMS may propose to suspend, limit, or revoke the laboratory's CLIA certificate.

(d) *Additional time for correcting lower level deficiencies* not at the condition level. If at the end of the plan of correction period all condition level deficiencies have been corrected, and there are deficiencies, that are not at the condition level, CMS may request a revised plan of correction. The revised plan may not extend beyond 12 months from the last day of the inspection that originally identified the cited deficiencies.

(e) *Persistence of deficiencies*. If at the end of the period covered by the plan of correction, the laboratory still has deficiencies, the rules of §§ 493.1814 and 493.1816 apply.

§ 493.1826 Suspension of part of Medicare payments.

(a) *Application*. (1) CMS may impose this sanction if a laboratory—

(i) Is found to have condition level deficiencies with respect to one or more specialties or subspecialties of tests; and

(ii) Agrees (in return for not having its Medicare approval cancelled immediately) not to charge Medicare beneficiaries or their private insurance carriers for the services for which Medicare payment is suspended.

(2) CMS suspends Medicare payment for those specialities or subspecialties of tests for which the laboratory is out of compliance with Federal requirements.

(b) *Procedures*. Before imposing this sanction, CMS provides notice of sanction and opportunity to respond in accordance with § 493.1810.

(c) *Duration and effect of sanction*. This sanction continues until the laboratory corrects the condition level deficiencies or CMS cancels the laboratory's approval to receive Medicare payment for its services, but in no event longer than 12 months.

(1) If the laboratory corrects all condition level deficiencies, CMS resumes Medicare payment effective for all services furnished on or after the date the deficiencies are corrected.

(2) [Reserved]

[57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992]

§ 493.1828 Suspension of all Medicare payments.

(a) *Application*. (1) CMS may suspend payment for all Medicare-approved laboratory services when the laboratory has condition level deficiencies.

(2) CMS suspends payment for all Medicare covered laboratory services when the following conditions are met:

(i) Either—

(A) The laboratory has not corrected its condition level deficiencies included in the plan of correction within 3 months from the last date of inspection; or

(B) The laboratory has been found to have the same condition level deficiencies during three consecutive inspections; and

(ii) The laboratory has chosen (in return for not having its Medicare approval immediately cancelled), to not charge Medicare beneficiaries or their private insurance carriers for services for which Medicare payment is suspended.

(3) CMS suspends payment for services furnished on and after the effective date of sanction.

(b) *Procedures*. Before imposing this sanction, CMS provides notice of sanction and opportunity to respond in accordance with § 493.1810.

(c) *Duration and effect of sanction*. (1) Suspension of payment continues until all condition level deficiencies are corrected, but never beyond twelve months.

(2) If all the deficiencies are not corrected by the end of the 12 month period, CMS cancels the laboratory's approval to receive Medicare payment for its services.

§ 493.1832 Directed plan of correction and directed portion of a plan of correction.

(a) *Application*. CMS may impose a directed plan of correction as an alternative sanction for any laboratory that has condition level deficiencies. If CMS does not impose a directed plan of correction as an alternative sanction for a laboratory that has condition level deficiencies, it at least imposes a directed portion of a plan of correction when it imposes any of the following alternative sanctions:

(1) State onsite monitoring.

(2) Civil money penalty.

(3) Suspension of all or part of Medicare payments.

(b) *Procedures*—(1) *Directed plan of correction*. When imposing this sanction, CMS—

(i) Gives the laboratory prior notice of the sanction and opportunity to respond in accordance with § 493.1810;

(ii) Directs the laboratory to take specific corrective action within specific time frames in order to achieve compliance; and

(iii) May direct the laboratory to submit the names of laboratory clients for notification purposes, as specified in paragraph (b)(3) of this section.

(2) *Directed portion of a plan of correction*. CMS may decide to notify clients of a sanctioned laboratory, because of the seriousness of the noncompliance (e.g., the existence of immediate jeopardy) or for other reasons. When imposing this sanction, CMS takes the following steps—

(i) Directs the laboratory to submit to CMS, the State survey agency, or other CMS agent, within 10 calendar days after the notice of the alternative sanction, a list of names and addresses of all physicians, providers, suppliers, and other clients who have used some or all of the services of the laboratory since the last certification inspection or within any other timeframe specified by CMS.

(ii) Within 30 calendar days of receipt of the information, may send to each laboratory client, via the State survey agency, a notice containing the name and address of the laboratory, the nature of the laboratory's noncompliance, and the kind and effective date of the alternative sanction.

(iii) Sends to each laboratory client, via the State survey agency, notice of the recission of an adverse action within 30 days of the rescission.

(3) *Notice of imposition of a principal sanction following the imposition of an alternative sanction*. If CMS imposes a principal sanction following the imposition of an alternative sanction, and for which CMS has already obtained a list of laboratory clients, CMS may use that list to notify the clients of the imposition of the principal sanction.

(c) *Duration of a directed plan of correction*. If CMS imposes a directed plan of correction, and on revisit it is found that the laboratory has not corrected the deficiencies within 12 months from the last day of inspection, the following rules apply:

(1) CMS cancels the laboratory's approval for Medicare payment of its services, and notifies the laboratory of CMS's intent to suspend, limit, or revoke the laboratory's CLIA certificate.

(2) The directed plan of correction continues in effect until the day suspension, limitation, or revocation of the laboratory's CLIA certificate.

§ 493.1834 Civil money penalty.

(a) *Statutory basis*. Sections 1846 of the Act and 353(h)(2)(B) of the PHS Act authorize the Secretary to impose civil

money penalties on laboratories. Section 1846(b)(3) of the Act specifically provides that incrementally more severe fines may be imposed for repeated or uncorrected deficiencies.

(b) *Scope*. This section sets forth the procedures that CMS follows to impose a civil money penalty in lieu of, or in addition to, suspending, limiting, or revoking the certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures of a laboratory that is found to have condition level deficiencies.

(c) *Basis for imposing a civil money penalty*. CMS may impose a civil money penalty against any laboratory determined to have condition level deficiencies regardless of whether those deficiencies pose immediate jeopardy.

(d) *Amount of penalty*—(1) *Factors considered*. In determining the amount of the penalty, CMS takes into account the following factors:

(i) The nature, scope, severity, and duration of the noncompliance.

(ii) Whether the same condition level deficiencies have been identified during three consecutive inspections.

(iii) The laboratory's overall compliance history including but not limited to any period of noncompliance that occurred between certifications of compliance.

(iv) The laboratory's intent or reason for noncompliance.

(v) The accuracy and extent of laboratory records and their availability to CMS, the State survey agency, or other CMS agent.

(2) *Range of penalty amount*. (i) For a condition level deficiency that poses immediate jeopardy, the range is $3,050–$10,000 per day of noncompliance or per violation.

(ii) For a condition level deficiency that does not pose immediate jeopardy, the range is $50–$3,000 per day of noncompliance or per violation.

(3) *Decreased penalty amounts*. If the immediate jeopardy is removed, but the deficiency continues, CMS shifts the penalty amount to the lower range.

(4) *Increased penalty amounts*. CMS may, before the hearing, propose to increase the penalty amount for a laboratory that has deficiencies which, after imposition of a lower level penalty amount, become sufficiently serious to pose immediate jeopardy.

(e) *Procedures for imposition of civil money penalty*—(1) *Notice of intent*. (i) CMS sends the laboratory written notice, of CMS's intent to impose a civil money penalty.

(ii) The notice includes the following information:

(A) The statutory basis for the penalty.

(B) The proposed daily or per violation amount of the penalty.

(C) The factors (as described in paragraph (d)(1) of this section) that CMS considered.

(D) The opportunity for responding to the notice in accordance with §493.1810(c).

(E) A specific statement regarding the laboratory's appeal rights.

(2) *Appeal rights*. (i) The laboratory has 60 days from the date of receipt of the notice of intent to impose a civil money penalty to request a hearing in accordance with §493.1844(g).

(ii) If the laboratory requests a hearing, all other pertinent provisions of §493.1844 apply.

(iii) If the laboratory does not request a hearing, CMS may reduce the proposed penalty amount by 35 percent.

(f) *Accrual and duration of penalty*—(1) *Accrual of penalty*. The civil money penalty begins accruing as follows:

(i) 5 days after notice of intent if there is immediate jeopardy.

(ii) 15 days after notice of intent if there is not immediate jeopardy.

(2) *Duration of penalty*. The civil money penalty continues to accrue until the earliest of the following occurs:

(i) The laboratory's compliance with condition level requirements is verified on the basis of the evidence presented by the laboratory in its credible allegation of compliance or at the time or revisit.

(ii) Based on credible evidence presented by the laboratory at the time of revisit, CMS determines that compliance was achieved before the revisit. (In this situation, the money penalty stops accruing as of the date of compliance.)

(iii) CMS suspends, limits, or revokes the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures.

(g) *Computation and notice of total penalty amount*—(1) *Computation*. CMS computes the total penalty amount after the laboratory's compliance is verified or CMS suspends, limits, or revokes the laboratory's CLIA certificate but in no event before—

(i) The 60 day period for requesting a hearing has expired without a request or the laboratory has explicitly waived its right to a hearing; or

(ii) Following a hearing requested by the laboratory, the ALJ issues a decision that upholds imposition of the penalty.

(2) *Notice of penalty amount and due date of penalty*. The notice includes the following information:

(i) Daily or per violation penalty amount.

(ii) Number of days or violations for which the penalty is imposed.

(iii) Total penalty amount.

(iv) Due date for payment of the penalty.

(h) *Due date for payment of penalty*. (1) Payment of a civil money penalty is due 15 days from the date of the notice specified in paragraph (g)(2) of this section.

(2) CMS may approve a plan for a laboratory to pay a civil money penalty, plus interest, over a period of up to one year from the original due date.

(i) *Collection and settlement*—(1) *Collection of penalty amounts*. (i) The determined penalty amount may be deducted from any sums then or later owing by the United States to the laboratory subject to the penalty.

(ii) Interest accrues on the unpaid balance of the penalty, beginning on the due date. Interest is computed at the rate specified in § 405.378(d) of this chapter.

(2) *Settlement*. CMS has authority to settle any case at any time before the ALJ issues a hearing decision.

[57 FR 7237, Feb. 28, 1992, as amended at 60 FR 20051, Apr. 24, 1995; 61 FR 63749, Dec. 2, 1996]

§ 493.1836 State onsite monitoring.

(a) *Application*. (1) CMS may require continuous or intermittent monitoring of a plan of correction by the State survey agency to ensure that the laboratory makes the improvements necessary to bring it into compliance with the condition level requirements. (The State monitor does not have management authority, that is, cannot hire or fire staff, obligate funds, or otherwise dictate how the laboratory operates. The monitor's responsibility is to oversee whether corrections are made.)

(2) The laboratory must pay the costs of onsite monitoring by the State survey agency.

(i) The costs are computed by multiplying the number of hours of onsite monitoring in the laboratory by the hourly rate negotiated by CMS and the State.

(ii) The hourly rate includes salary, fringe benefits, travel, and other direct and indirect costs approved by CMS.

(b) *Procedures*. Before imposing this sanction, CMS provides notice of sanction and opportunity to respond in accordance with § 493.1810.

(c) *Duration of sanction*. (1) If CMS imposes onsite monitoring, the sanction continues until CMS determines that the laboratory has the capability to ensure compliance with all condition level requirements.

(2) If the laboratory does not correct all deficiencies within 12 months, and a revisit indicates that deficiencies remain, CMS cancels the laboratory's approval for Medicare payment for its services and notifies the laboratory of its intent to suspend, limit, or revoke the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures.

(3) If the laboratory still does not correct its deficiencies, the Medicare sanction continues until the suspension, limitation, or revocation of the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures is effective.

[57 FR 7237, Feb. 28, 1992, as amended at 60 FR 20051, Apr. 24, 1995]

§493.1838 Training and technical assistance for unsuccessful participation in proficiency testing.

If a laboratory's participation in proficiency testing is unsuccessful, CMS may require the laboratory to undertake training of its personnel, or to obtain necessary technical assistance, or both, in order to meet the requirements of the proficiency testing program. This requirement is separate from the principal and alternative sanctions set forth in §§493.1806 and 493.1807.

§493.1840 Suspension, limitation, or revocation of any type of CLIA certificate.

(a) *Adverse action based on actions of the laboratory's owner, operator or employees.* CMS may initiate adverse action to suspend, limit or revoke any CLIA certificate if CMS finds that a laboratory's owner or operator or one of its employees has—

(1) Been guilty of misrepresentation in obtaining a CLIA certificate;

(2) Performed, or represented the laboratory as entitled to perform, a laboratory examination or other procedure that is not within a category of laboratory examinations or other procedures authorized by its CLIA certificate;

(3) Failed to comply with the certificate requirements and performance standards;

(4) Failed to comply with reasonable requests by CMS for any information or work on materials that CMS concludes is necessary to determine the laboratory's continued eligibility for its CLIA certificate or continued compliance with performance standards set by CMS;

(5) Refused a reasonable request by CMS or its agent for permission to inspect the laboratory and its operation and pertinent records during the hours that the laboratory is in operation;

(6) Violated or aided and abetted in the violation of any provisions of CLIA and its implementing regulations;

(7) Failed to comply with an alternative sanction imposed under this subpart; or

(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked. (This provision applies only to the owner or operator, not to all of the laboratory's employees.)

(b) *Adverse action based on improper referrals in proficiency testing.* If CMS determines that a laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis, CMS revokes the laboratory's CLIA certificate for at least one year, and may also impose a civil money penalty.

(c) *Adverse action based on exclusion from Medicare.* If the OIG excludes a laboratory from participation in Medicare, CMS suspends the laboratory's CLIA certificate for the period during which the laboratory is excluded.

(d) *Procedures for suspension or limitation*—(1) *Basic rule.* Except as provided in paragraph (d)(2) of this section, CMS does not suspend or limit a CLIA certificate until after an ALJ hearing decision (as provided in §493.1844) that upholds suspension or limitation.

(2) *Exceptions.* CMS may suspend or limit a CLIA certificate before the ALJ hearing in any of the following circumstances:

(i) The laboratory's deficiencies pose immediate jeopardy.

(ii) The laboratory has refused a reasonable request for information or work on materials.

(iii) The laboratory has refused permission for CMS or a CMS agent to inspect the laboratory or its operation.

(e) *Procedures for revocation.* (1) CMS does not revoke any type of CLIA certificate until after an ALJ hearing that upholds revocation.

(2) CMS may revoke a CLIA certificate after the hearing decision even if it had not previously suspended or limited that certificate.

(f) *Notice to the OIG.* CMS notifies the OIG of any violations under paragraphs (a)(1), (a)(2), (a)(6), and (b) of this section within 30 days of the determination of the violation.

§493.1842 Cancellation of Medicare approval.

(a) *Basis for cancellation.* (1) CMS always cancels a laboratory's approval to receive Medicare payment for its services if CMS suspends or revokes the laboratory's CLIA certificate.

(2) CMS may cancel the laboratory's approval under any of the following circumstances:

(i) The laboratory is out of compliance with a condition level requirement.

(ii) The laboratory fails to submit a plan of correction satisfactory to CMS.

(iii) The laboratory fails to correct all its deficiencies within the time frames specified in the plan of correction.

(b) *Notice and opportunity to respond.* Before canceling a laboratory's approval to receive Medicare payment for its services, CMS gives the laboratory—

(1) Written notice of the rationale for, effective date, and effect of, cancellation;

(2) Opportunity to submit written evidence or other information against cancellation of the laboratory's approval.

This sanction may be imposed before the hearing that may be requested by a laboratory, in accordance with the appeals procedures set forth in § 493.1844.

(c) *Effect of cancellation.* Cancellation of Medicare approval terminates any Medicare payment sanctions regardless of the time frames originally specified.

§ 493.1844 Appeals procedures.

(a) *General rules.* (1) The provisions of this section apply to all laboratories and prospective laboratories that are dissatisfied with any initial determination under paragraph (b) of this section.

(2) Hearings are conducted in accordance with procedures set forth in subpart D of part 498 of this chapter, except that the authority to conduct hearings and issue decisions may be exercised by ALJs assigned to, or detailed to, the Departmental Appeals Board.

(3) Any party dissatisfied with a hearing decision is entitled to request review of the decision as specified in subpart E of part 498 of this chapter, except that the authority to review the decision may be exercised by the Departmental Appeals Board.

(4) When more than one of the actions specified in paragraph (b) of this section are carried out concurrently, the laboratory has a right to only one hearing on all matters at issue.

(b) *Actions that are initial determinations.* The following actions are initial determinations and therefore are subject to appeal in accordance with this section:

(1) The suspension, limitation, or revocation of the laboratory's CLIA certificate by CMS because of noncompliance with CLIA requirements.

(2) The denial of a CLIA certificate.

(3) The imposition of alternative sanctions under this subpart (but not the determination as to which alternative sanction or sanctions to impose).

(4) The denial or cancellation of the laboratory's approval to receive Medicare payment for its services.

(c) *Actions that are not initial determinations.* Actions that are not listed in paragraph (b) of this section are not initial determinations and therefore are not subject to appeal under this section. They include, but are not necessarily limited to, the following:

(1) The finding that a laboratory accredited by a CMS-approved accreditation organization is no longer deemed to meet the conditions set forth in subparts H, J, K, M, and Q of this part. However, the suspension, limitation or revocation of a certificate of accreditation is an initial determination and is appealable.

(2) The finding that a laboratory determined to be in compliance with condition-level requirements but has deficiencies that are not at the condition level.

(3) The determination not to reinstate a suspended CLIA certificate because the reason for the suspension has not been removed or there is insufficient assurance that the reason will not recur.

(4) The determination as to which alternative sanction or sanctions to impose, including the amount of a civil money penalty to impose per day or per violation.

(5) The denial of approval for Medicare payment for the services of a laboratory that does not have in effect a valid CLIA certificate.

(6) The determination that a laboratory's deficiencies pose immediate jeopardy.

(7) The amount of the civil money penalty assessed per day or for each violation of Federal requirements.

(d) *Effect of pending appeals*—(1) *Alternative sanctions*. The effective date of an alternative sanction (other than a civil money penalty) is not delayed because the laboratory has appealed and the hearing or the hearing decision is pending.

(2) *Suspension, limitation, or revocation of a laboratory's CLIA certificate*—(i) *General rule*. Except as provided in paragraph (d)(2)(ii) of this section, suspension, limitation, or revocation of a CLIA certificate is not effective until after a hearing decision by an ALJ is issued.

(ii) *Exceptions*. (A) If CMS determines that conditions at a laboratory pose immediate jeopardy, the effective date of the suspension or limitation of a CLIA certificate is not delayed because the laboratory has appealed and the hearing or the hearing decision is pending.

(B) CMS may suspend or limit a laboratory's CLIA certificate before an ALJ hearing or hearing decision if the laboratory has refused a reasonable request for information (including but not limited to billing information), or for work on materials, or has refused permission for CMS or a CMS agent to inspect the laboratory or its operation.

(3) *Cancellation of Medicare approval*. The effective date of the cancellation of a laboratory's approval to receive Medicare payment for its services is not delayed because the laboratory has appealed and the hearing or hearing decision is pending.

(4) *Effect of ALJ decision*. (i) An ALJ decision is final unless, as provided in paragraph (a)(3) of this section, one of the parties requests review by the Departmental Appeals Board within 60 days, and the Board reviews the case and issues a revised decision.

(ii) If an ALJ decision upholds a suspension imposed because of immediate jeopardy, that suspension becomes a revocation.

(e) *Appeal rights for prospective laboratories*—(1) *Reconsideration*. Any prospective laboratory dissatisfied with a denial of a CLIA certificate, or of approval for Medicare payment for its services, may initiate the appeals process by requesting reconsideration in accordance with §§498.22 through 498.25 of this chapter.

(2) *Notice of reopening*. If CMS reopens an initial or reconsidered determination, CMS gives the prospective laboratory notice of the revised determination in accordance with §498.32 of this chapter.

(3) *ALJ hearing*. Any prospective laboratory dissatisfied with a reconsidered determination under paragraph (e)(1) of this section or a revised reconsidered determination under §498.30 of this chapter is entitled to a hearing before an ALJ, as specified in paragraph (a)(2) of this section.

(4) *Review of ALJ hearing decisions*. Any prospective laboratory that is dissatisfied with an ALJ's hearing decision or dismissal of a request for hearing may file a written request for review by the Departmental Appeals Board as provided in paragraph (a)(3) of this section.

(f) *Appeal rights of laboratories*—(1) *ALJ hearing*. Any laboratory dissatisfied with the suspension, limitation, or revocation of its CLIA certificate, with the imposition of an alternative sanction under this subpart, or with cancellation of the approval to receive Medicare payment for its services, is entitled to a hearing before an ALJ as specified in paragraph (a)(2) of this section and has 60 days from the notice of sanction to request a hearing.

(2) *Review of ALJ hearing decisions*. Any laboratory that is dissatisfied with an ALJ's hearing decision or dismissal of a request for hearing may file a written request for review by the Departmental Appeals Board, as provided in paragraph (a)(3) of this section.

(3) *Judicial review*. Any laboratory dissatisfied with the decision to impose a civil money penalty or to suspend, limit, or revoke its CLIA certificate may, within 60 days after the decision becomes final, file with the U.S. Court of Appeals of the circuit in which the laboratory has its principal place of business, a petition for judicial review.

(g) *Notice of adverse action*. (1) If CMS suspends, limits, or revokes a laboratory's CLIA certificate or cancels the approval to receive Medicare payment for its services, CMS gives notice to the laboratory, and may give notice to

physicians, providers, suppliers, and other laboratory clients, according to the procedures set forth at § 493.1832. In addition, CMS notifies the general public each time one of these principal sanctions is imposed.

(2) The notice to the laboratory—

(i) Sets forth the reasons for the adverse action, the effective date and effect of that action, and the appeal rights if any; and

(ii) When the certificate is limited, specifies the specialties or subspecialties of tests that the laboratory is no longer authorized to perform, and that are no longer covered under Medicare.

(3) The notice to other entities includes the same information except the information about the laboratory's appeal rights.

(h) *Effective date of adverse action.* (1) When the laboratory's deficiencies pose immediate jeopardy, the effective date of the adverse action is at least 5 days after the date of the notice.

(2) When CMS determines that the laboratory's deficiencies do not pose immediate jeopardy, the effective date of the adverse action is at least 15 days after the date of the notice.

[57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992, as amended at 68 FR 3714, Jan. 24, 2003]

§ 493.1846 Civil action.

If CMS has reason to believe that continuation of the activities of any laboratory, including a State-exempt laboratory, would constitute a significant hazard to the public health, CMS may bring suit in a U.S. District Court to enjoin continuation of the specific activity that is causing the hazard or to enjoin the continued operation of the laboratory if CMS deems it necessary. Upon proper showing, the court shall issue a temporary injunction or restraining order without bond against continuation of the activity.

§ 493.1850 Laboratory registry.

(a) Once a year CMS makes available to physicians and to the general public specific information (including information provided to CMS by the OIG) that is useful in evaluating the performance of laboratories, including the following:

(1) A list of laboratories that have been convicted, under Federal or State laws relating to fraud and abuse, false billing, or kickbacks.

(2) A list of laboratories that have had their CLIA certificates suspended, limited, or revoked, and the reason for the adverse actions.

(3) A list of persons who have been convicted of violating CLIA requirements, as specified in section 353(1) of the PHS Act, together with the circumstances of each case and the penalties imposed.

(4) A list of laboratories on which alternative sanctions have been imposed, showing—

(i) The effective date of the sanctions;

(ii) The reasons for imposing them;

(iii) Any corrective action taken by the laboratory; and

(iv) If the laboratory has achieved compliance, the verified date of compliance.

(5) A list of laboratories whose accreditation has been withdrawn or revoked and the reasons for the withdrawal or revocation.

(6) All appeals and hearing decisions.

(7) A list of laboratories against which CMS has brought suit under § 493.1846 and the reasons for those actions.

(8) A list of laboratories that have been excluded from participation in Medicare or Medicaid and the reasons for the exclusion.

(b) The laboratory registry is compiled for the calendar year preceding the date the information is made available and includes appropriate explanatory information to aid in the interpretation of the data. It also contains corrections of any erroneous statements or information that appeared in the previous registry.

Subpart S [Reserved]

Subpart T—Consultations

SOURCE: 57 FR 7185, Feb. 28, 1992, unless otherwise noted.

§493.2001 Establishment and function of the Clinical Laboratory Improvement Advisory Committee.

(a) HHS will establish a Clinical Laboratory Improvement Advisory Committee to advise and make recommendations on technical and scientific aspects of the provisions of this part 493.

(b) The Clinical Laboratory Improvement Advisory Committee will be comprised of individuals involved in the provision of laboratory services, utilization of laboratory services, development of laboratory testing or methodology, and others as approved by HHS.

(c) HHS will designate specialized subcommittees as necessary.

(d) The Clinical Laboratory Improvement Advisory Committee or any designated subcommittees will meet as needed, but not less than once each year.

(e) The Clinical Laboratory Improvement Advisory Committee or subcommittee, at the request of HHS, will review and make recommendations concerning:

(1) Criteria for categorizing nonwaived testing;

(2) Determination of waived tests;

(3) Personnel standards;

(4) Facility administration and quality systems standards.

(5) Proficiency testing standards;

(6) Applicability to the standards of new technology; and

(7) Other issues relevant to part 493, if requested by HHS.

(f) HHS will be responsible for providing the data and information, as necessary, to the members of the Clinical Laboratory Improvement Advisory Committee.

[57 FR 7185, Feb. 28, 1992, as amended at 58 FR 5237, Jan. 19, 1993; 60 FR 20051, Apr. 24, 1995; 68 FR 3714, Jan. 24, 2003]

PART 494— CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 73 FR 20475, Apr. 15, 2008, unless otherwise noted.

Subpart A—General Provisions

§494.1 Basis and scope.

(a) *Statutory basis.* This part is based on the following provisions:

(1) Section 299I of the Social Security Amendments of 1972 (Pub. L. 92–603), which extended Medicare coverage to insured individuals, their spouses, and their dependent children with ESRD who require dialysis or transplantation.

(2) Section 1861(e)(9) of the Act, which requires hospitals to meet such other requirements as the Secretary finds necessary in the interest of health and safety of individuals who are furnished services in the institution.

(3) Section 1861(s)(2)(F) of the Act, which describes ''medical and other health services'' covered under Medicare to include home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies.

(4) Section 1862(a) of the Act, which specifies exclusions from coverage.

(5) Section 1881 of the Act, which authorizes Medicare coverage and payment for the treatment of ESRD in approved facilities, including institutional dialysis services, transplantation services, self-care home dialysis services, and the administration of erythropoiesis-stimulating agent(s).

(6) Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113), which requires Federal agencies to use technical standards that are developed or adopted by voluntary consensus standards bodies, unless their use would be inconsistent with applicable law or otherwise impractical.

(b) *Scope*. The provisions of this part establish the conditions for coverage of services under Medicare and are the basis for survey activities for the purpose of determining whether an ESRD facility's services may be covered.

§ 494.10 Definitions.

As used in this part—

Dialysis facility means an entity that provides outpatient maintenance dialysis services, or home dialysis training and support services, or both. A dialysis facility may be an independent or hospital-based unit (as described in § 413.174(b) and (c) of this chapter) that includes a self-care dialysis unit that furnishes only self-dialysis services.

Discharge means the termination of patient care services by a dialysis facility or the patient voluntarily terminating dialysis when he or she no longer wants to be dialyzed by that facility.

Furnishes directly means the ESRD facility provides the service through its own staff and employees or through individuals who are under direct contract to furnish these services personally for the facility.

Home dialysis means dialysis performed at home by an ESRD patient or caregiver who has completed an appropriate course of training as described in § 494.100(a) of this part.

Self-dialysis means dialysis performed with little or no professional assistance by an ESRD patient or caregiver who has completed an appropriate course of training as specified in § 494.100(a) of this part.

Transfer means a temporary or permanent move of a patient from one dialysis facility to another that requires a transmission of the patient's medical record to the facility receiving the patient.

§ 494.20 Condition: Compliance with Federal, State, and local laws and regulations.

The facility and its staff must operate and furnish services in compliance with applicable Federal, State, and local laws and regulations pertaining to licensure and any other relevant health and safety requirements.

Subpart B—Patient Safety

§ 494.30 Condition: Infection control.

The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.

(a) *Standard: Procedures for infection control*. The facility must demonstrate that it follows standard infection control precautions by implementing—

(1)(i) The recommendations (with the exception of screening for hepatitis C), found in ''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients,'' developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html*. The recommendation found under section header ''HBV-Infected Patients'', found on pages 27 and 28 of RR05 (''Recommendations for Preventing

Transmission of Infections Among Chronic Hemodialysis Patients''), concerning isolation rooms, must be complied with by February 9, 2009.

(ii) When dialysis isolation rooms as required by (a)(1)(i) are available locally that sufficiently serve the needs of patients in the geographic area, a new dialysis facility may request a waiver of such requirement. Isolation room waivers may be granted at the discretion of, and subject to, additional qualifications as may be deemed necessary by the Secretary.

(2) The ''Guidelines for the Prevention of Intravascular Catheter-Related Infections'' entitled ''Recommendations for Placement of Intravascular Catheters in Adults and Children'' parts I–IV; and ''Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters, in Adult and Pediatric Patients,'' Morbidity and Mortality Weekly Report, volume 51 number RR–10, pages 16 through 18, August 9, 2002. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html*.

(3) Patient isolation procedures to minimize the spread of infectious agents and communicable diseases; and

(4) Maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the—

(i) Handling, storage, and disposal of potentially infectious waste; and

(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.

(b) *Standard: Oversight*. The facility must—

(1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit;

(2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and

(3) Require all clinical staff to report infection control issues to the dialysis facility's medical director (see § 494.150 of this part) and the quality improvement committee.

(c) *Standard: Reporting*. The facility must report incidences of communicable diseases as required by Federal, State, and local regulations.

§ 494.40 Condition: Water and dialysate quality.

The facility must be able to demonstrate the following:

(a) *Standard: Water purity*. Water and equipment used for dialysis meets the water and dialysate quality standards and equipment requirements found in the Association for the Advancement of Medical Instrumentation (AAMI) publication, ''Dialysate for hemodialysis,'' ANSI/AAMI RD52: 2004. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html*. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201–4598.

(b) *Standard: Chlorine/chloramines*. (1) The water treatment system must include a component or carbon tank which removes chlorine/chloramine along with a backup component or second carbon tank in series for chlorine/chloramine removal;

(2)(i) If the test results from the port of the initial component or carbon tank referred to in section 6.2.5 of AAMI RD52:2004 are greater than 0.5 mg/L for free chlorine or 0.1 mg/L for chloramines, or equal to or greater than 0.1 mg/L of total chlorine, then

the second component or carbon tank which removes chlorine/chloramine must be tested;

(ii) If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (b)(2)(i) of this section the facility must—

(A) Immediately take corrective action to bring chlorine or chloramine levels into compliance with paragraph (b)(2)(i) of this section and confirm through testing that the corrective action has been effective, or terminate dialysis treatment to protect patients from exposure to chlorine/chloramine;

(B) Only allow use of purified water in a holding tank, if appropriate, and if testing shows water chlorine or chloramine levels that are in compliance with paragraph (b)(2)(i) of this section; and

(C) Immediately notify the medical director; and

(D) Take corrective action to ensure ongoing compliance with acceptable chlorine and chloramine levels as described in paragraph (b)(2)(i) of this section.

(c) *Standard: Corrective action plan.* Water testing results including, but not limited to, chemical, microbial, and endotoxin levels which meet AAMI action levels or deviate from the AAMI standards must be addressed with a corrective action plan that ensures patient safety.

(d) *Standard: Adverse events.* A dialysis facility must maintain active surveillance of patient reactions during and following dialysis. When clinically indicated (for example, after adverse patient reactions) the facility must—

(1) Obtain blood and dialysate cultures and endotoxin levels;

(2) Evaluate the water purification system; and

(3) Take corrective action.

(e) *Standard: In-center use of preconfigured hemodialysis systems.* When using a preconfigured, FDA-approved hemodialysis system designed, tested and validated to yield AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate, the system's FDA-approved labeling must be adhered to for machine use and monitoring of the water and dialysate quality. The facility must meet all AAMI RD52:2004 requirements for water and dialysate. Moreover, the facility must perform bacteriological and endotoxin testing on a quarterly, or more frequent basis, as needed, to ensure that the water and dialysate are within AAMI limits.

§ 494.50 Condition: Reuse of hemodialyzers and bloodlines.

(a) *Standard: General requirements for the reuse of hemodialyzers and bloodlines.* Certain hemodialyzers and bloodlines—

(1) May be reused for certain patients with the exception of Hepatitis B positive patients;

(2) Must be reused only for the same patient; and

(3) Must be labeled for multiple reuse in accordance with the premarket notification provisions of section 510(k) of the Food, Drug, and Cosmetics Act and 21 CFR 876.5860.

(b) *Standard: Reprocessing requirements for the reuse of hemodialyzers and bloodlines.* A dialysis facility that reuses hemodialyzers and bloodlines must adhere to the following reprocessing guidelines:

(1) Meet the requirements of AAMI published in ''Reuse of Hemodialyzers,'' third edition, ANSI/AAMI RD47:2002 and RD47:2002/A1:2003. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html.* Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201–4598.

(2) Reprocess hemodialyzers and bloodlines—

(i) By following the manufacturer's recommendations; or

(ii) Using an alternate method and maintaining documented evidence that the method is safe and effective.

(3) Not expose hemodialyzers to more than one chemical germicide, other than bleach (used as a cleaner in this application), during the life of the dialyzer. All hemodialyzers must be discarded before a different chemical germicide is used in the facility.

(c) *Standard: Monitoring, evaluation, and reporting requirements for the reuse of hemodialyzers and bloodlines.* In addition to the requirements for hemodialyzer and bloodline reuse specified in paragraphs (a) and (b) of this section, the dialysis facility must adhere to the following:

(1) Monitor patient reactions during and following dialysis.

(2) When clinically indicated (for example, after adverse patient reactions), the facility must—

(i) Obtain blood and dialysate cultures and endotoxin levels; and

(ii) Undertake evaluation of its dialyzer reprocessing and water purification system. When this evaluation suggests a cluster of adverse patient reactions is associated with hemodialyzer reuse, the facility must suspend reuse of hemodialyzers until it is satisfied the problem has been corrected.

(iii) Report the adverse outcomes to the FDA and other Federal, State or local government agencies as required by law.

§ 494.60 Condition: Physical environment.

The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.

(a) *Standard: Building.* The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff, and the public.

(b) *Standard: Equipment maintenance.* The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.

(c) *Standard: Patient care environment.* (1) The space for treating each patient must be sufficient to provide needed care and services, prevent cross-contamination, and to accommodate medical emergency equipment and staff.

(2) The dialysis facility must:

(i) Maintain a comfortable temperature within the facility; and

(ii) Make reasonable accommodations for the patients who are not comfortable at this temperature.

(3) The dialysis facility must make accommodations to provide for patient privacy when patients are examined or treated and body exposure is required.

(4) Patients must be in view of staff during hemodialysis treatment to ensure patient safety (video surveillance will not meet this requirement).

(d) *Standard: Emergency preparedness.* The dialysis facility must implement processes and procedures to manage medical and nonmedical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.

(1) *Emergency preparedness of staff.* The dialysis facility must provide appropriate training and orientation in emergency preparedness to the staff. Staff training must be provided and evaluated at least annually and include the following:

(i) Ensuring that staff can demonstrate a knowledge of emergency procedures, including informing patients of—

(A) What to do;

(B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated;

(C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a

working phone number under such emergency conditions); and

(D) How to disconnect themselves from the dialysis machine if an emergency occurs.

(ii) Ensuring that, at a minimum, patient care staff maintain current CPR certification; and

(iii) Ensuring that nursing staff are properly trained in the use of emergency equipment and emergency drugs.

(2) *Emergency preparedness patient training*. The facility must provide appropriate orientation and training to patients, including the areas specified in paragraph (d)(1)(i) of this section.

(3) *Emergency equipment*. Emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available.

(4) *Emergency plans*. The facility must—

(i) Have a plan to obtain emergency medical system assistance when needed;

(ii) Evaluate at least annually the effectiveness of emergency and disaster plans and update them as necessary; and

(iii) Contact its local disaster management agency at least annually to ensure that such agency is aware of dialysis facility needs in the event of an emergency.

(e) *Standard: Fire safety*. (1) Except as provided in paragraph (e)(2) of this section, by February 9, 2009. The dialysis facility must comply with applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference at § 403.744(a)(1)(i) of this chapter).

(2) Notwithstanding paragraph (e)(1) of this section, dialysis facilities participating in Medicare as of October 14, 2008. Utilizing non-sprinklered buildings on such date may continue to use such facilities if such buildings were constructed before January 1, 2008 and State law so permits.

(3) If CMS finds that a fire and safety code imposed by the facility's State law adequately protects a dialysis facility's patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the Life Safety Code.

(4) After consideration of State survey agency recommendations, CMS may waive, for individual dialysis facilities and for appropriate periods, specific provisions of the Life Safety Code, if the following requirements are met:

(i) The waiver would not adversely affect the health and safety of the dialysis facility's patients; and

(ii) Rigid application of specific provisions of the Life Safety Code would result in an unreasonable hardship for the dialysis facility.

Subpart C—Patient Care

§ 494.70 Condition: Patients' rights.

The dialysis facility must inform patients (or their representatives) of their rights (including their privacy rights) and responsibilities when they begin their treatment and must protect and provide for the exercise of those rights.

(a) *Standard: Patients' rights*. The patient has the right to—

(1) Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with ESRD;

(2) Receive all information in a way that he or she can understand;

(3) Privacy and confidentiality in all aspects of treatment;

(4) Privacy and confidentiality in personal medical records;

(5) Be informed about and participate, if desired, in all aspects of his or her care, and be informed of the right to refuse treatment, to discontinue treatment, and to refuse to participate in experimental research;

(6) Be informed about his or her right to execute advance directives, and the facility's policy regarding advance directives;

(7) Be informed about all treatment modalities and settings, including but not limited to, transplantation, home dialysis modalities (home hemodialysis, intermittent peritoneal dialysis, continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis),and in-facility hemodialysis.

The patient has the right to receive resource information for dialysis modalities not offered by the facility, including information about alternative scheduling options for working patients;

(8) Be informed of facility policies regarding patient care, including, but not limited to, isolation of patients;

(9) Be informed of facility policies regarding the reuse of dialysis supplies, including hemodialyzers;

(10) Be informed by the physician, nurse practitioner, clinical nurse specialist, or physician's assistant treating the patient for ESRD of his or her own medical status as documented in the patient's medical record, unless the medical record contains a documented contraindication;

(11) Be informed of services available in the facility and charges for services not covered under Medicare;

(12) Receive the necessary services outlined in the patient plan of care described in § 494.90;

(13) Be informed of the rules and expectations of the facility regarding patient conduct and responsibilities;

(14) Be informed of the facility's internal grievance process;

(15) Be informed of external grievance mechanisms and processes, including how to contact the ESRD Network and the State survey agency;

(16) Be informed of his or her right to file internal grievances or external grievances or both without reprisal or denial of services; and

(17) Be informed that he or she may file internal or external grievances, personally, anonymously or through a representative of the patient's choosing.

(b) *Standard: Right to be informed regarding the facility's discharge and transfer policies.* The patient has the right to—

(1) Be informed of the facility's policies for transfer, routine or involuntary discharge, and discontinuation of services to patients; and

(2) Receive written notice 30 days in advance of an involuntary discharge, after the facility follows the involuntary discharge procedures described in § 494.180(f)(4). In the case of immediate threats to the health and safety of others, an abbreviated discharge procedure may be allowed.

(c) *Standard: Posting of rights.* The dialysis facility must prominently display a copy of the patient's rights in the facility, including the current State agency and ESRD network mailing addresses and telephone complaint numbers, where it can be easily seen and read by patients.

§ 494.80 Condition: Patient assessment.

The facility's interdisciplinary team consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian. The interdisciplinary team is responsible for providing each patient with an individualized and comprehensive assessment of his or her needs. The comprehensive assessment must be used to develop the patient's treatment plan and expectations for care.

(a) *Standard: Assessment criteria.* The patient's comprehensive assessment must include, but is not limited to, the following:

(1) Evaluation of current health status and medical condition, including co-morbid conditions.

(2) Evaluation of the appropriateness of the dialysis prescription, blood pressure, and fluid management needs.

(3) Laboratory profile, immunization history, and medication history.

(4) Evaluation of factors associated with anemia, such as hematocrit, hemoglobin, iron stores, and potential treatment plans for anemia, including administration of erythropoiesis-stimulating agent(s).

(5) Evaluation of factors associated with renal bone disease.

(6) Evaluation of nutritional status by a dietitian.

(7) Evaluation of psychosocial needs by a social worker.

(8) Evaluation of dialysis access type and maintenance (for example, arteriovenous fistulas, arteriovenous grafts, and peritoneal catheters).

(9) Evaluation of the patient's abilities, interests, preferences, and goals, including the desired level of participation in the dialysis care process; the preferred modality (hemodialysis or peritoneal dialysis), and setting, (for

example, home dialysis), and the patient's expectations for care outcomes.

(10) Evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s). If the patient is not suitable for transplantation referral, the basis for nonreferral must be documented in the patient's medical record.

(11) Evaluation of family and other support systems.

(12) Evaluation of current patient physical activity level.

(13) Evaluation for referral to vocational and physical rehabilitation services.

(b) *Standard: Frequency of assessment for patients admitted to the dialysis facility*. (1) An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.

(2) A follow up comprehensive reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care specified in § 494.90.

(c) *Standard: Assessment of treatment prescription*. The adequacy of the patient's dialysis prescription, as described in § 494.90(a)(1), must be assessed on an ongoing basis as follows:

(1) *Hemodialysis patients*. At least monthly by calculating delivered Kt/V or an equivalent measure.

(2) *Peritoneal dialysis patients*. At least every 4 months by calculating delivered weekly Kt/V or an equivalent measure.

(d) *Standard: Patient reassessment*. In accordance with the standards specified in paragraphs (a)(1) through (a)(13) of this section, a comprehensive reassessment of each patient and a revision of the plan of care must be conducted—

(1) At least annually for stable patients; and

(2) At least monthly for unstable patients including, but not limited to, patients with the following:

(i) Extended or frequent hospitalizations;

(ii) Marked deterioration in health status;

(iii) Significant change in psychosocial needs; or

(iv) Concurrent poor nutritional status, unmanaged anemia, and inadequate dialysis.

§ 494.90 Condition: Patient plan of care.

The interdisciplinary team as defined at § 494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards.

(a) *Standard: Development of patient plan of care*. The interdisciplinary team must develop a plan of care for each patient. The plan of care must address, but not be limited to, the following:

(1) *Dose of dialysis*. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; and achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.

(2) *Nutritional status*. The interdisciplinary team must provide the necessary care and counseling services to achieve and sustain an effective nutritional status. A patient's albumin level and body weight must be measured at least monthly. Additional evidence-based professionally-accepted clinical nutrition indicators may be monitored, as appropriate.

(3) *Mineral metabolism*. Provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease.

(4) *Anemia*. The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level. The patient's hemoglobin/hematocrit must be measured at

least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs. For a home dialysis patient, the facility must evaluate whether the patient can safely, aseptically, and effectively administer erythropoiesis-stimulating agents and store this medication under refrigeration if necessary. The patient's response to erythropoiesis-stimulating agent(s), including blood pressure levels and utilization of iron stores, must be monitored on a routine basis.

(5) *Vascular access.* The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement. The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis.

(6) *Psychosocial status.* The interdisciplinary team must provide the necessary monitoring and social work interventions. These include counseling services and referrals for other social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis.

(7) *Modality*—(i) *Home dialysis.* The interdisciplinary team must identify a plan for the patient's home dialysis or explain why the patient is not a candidate for home dialysis.

(ii) *Transplantation status.* When the patient is a transplant referral candidate, the interdisciplinary team must develop plans for pursuing transplantation. The patient's plan of care must include documentation of the—

(A) Plan for transplantation, if the patient accepts the transplantation referral;

(B) Patient's decision, if the patient is a transplantation referral candidate but declines the transplantation referral; or

(C) Reason(s) for the patient's nonreferral as a transplantation candidate as documented in accordance with § 494.80(a)(10).

(8) *Rehabilitation status.* The interdisciplinary team must assist the patient in achieving and sustaining an appropriate level of productive activity, as desired by the patient, including the educational needs of pediatric patients (patients under the age of 18 years), and make rehabilitation and vocational rehabilitation referrals as appropriate.

(b) *Standard: Implementation of the patient plan of care.* (1) The patient's plan of care must—

(i) Be completed by the interdisciplinary team, including the patient if the patient desires; and

(ii) Be signed by team members, including the patient or the patient's designee; or, if the patient chooses not to sign the plan of care, this choice must be documented on the plan of care, along with the reason the signature was not provided.

(2) Implementation of the initial plan of care must begin within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. Implementation of monthly or annual updates of the plan of care must be performed within 15 days of the completion of the additional patient assessments specified in § 494.80(d).

(3) If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must—

(i) Adjust the plan of care to reflect the patient's current condition;

(ii) Document in the record the reasons why the patient was unable to achieve the goals; and

(iii) Implement plan of care changes to address the issues identified in paragraph (b)(3)(ii) of this section.

(4) The dialysis facility must ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical

record, and periodically while the hemodialysis patient is receiving in-facility dialysis.

(c) *Standard: Transplantation referral tracking*. The interdisciplinary team must—

(1) Track the results of each kidney transplant center referral;

(2) Monitor the status of any facility patients who are on the transplant wait list; and

(3) Communicate with the transplant center regarding patient transplant status at least annually, and when there is a change in transplant candidate status.

(d) *Standard: Patient education and training*. The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, in aspects of the dialysis experience, dialysis management, infection prevention and personal care, home dialysis and self-care, quality of life, rehabilitation, transplantation, and the benefits and risks of various vascular access types.

§ 494.100 Condition: Care at home.

A dialysis facility that is certified to provide services to home patients must ensure through its interdisciplinary team, that home dialysis services are at least equivalent to those provided to in-facility patients and meet all applicable conditions of this part.

(a) *Standard: Training*. The interdisciplinary team must oversee training of the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in § 494.10) and when the home dialysis caregiver or home dialysis modality changes. The training must—

(1) Be provided by a dialysis facility that is approved to provide home dialysis services;

(2) Be conducted by a registered nurse who meets the requirements of § 494.140(b)(2); and

(3) Be conducted for each home dialysis patient and address the specific needs of the patient, in the following areas:

(i) The nature and management of ESRD.

(ii) The full range of techniques associated with the treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective administration of erythropoiesis-stimulating agent(s) (if prescribed) to achieve and maintain a target level hemoglobin or hematocrit as written in patient's plan of care.

(iii) How to detect, report, and manage potential dialysis complications, including water treatment problems.

(iv) Availability of support resources and how to access and use resources.

(v) How to self-monitor health status and record and report health status information.

(vi) How to handle medical and nonmedical emergencies.

(vii) Infection control precautions.

(viii) Proper waste storage and disposal procedures.

(b) *Standard: Home dialysis monitoring*. The dialysis facility must—

(1) Document in the medical record that the patient, the caregiver, or both received and demonstrated adequate comprehension of the training;

(2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and

(3) Maintain this information in the patient's medical record.

(c) *Standard: Support services*. (1) A home dialysis facility must furnish (either directly, under agreement, or by arrangement with another ESRD facility) home dialysis support services regardless of whether dialysis supplies are provided by the dialysis facility or a durable medical equipment company. Services include, but are not limited to, the following:

(i) Periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel in accordance with the patient's plan of care.

(ii) Coordination of the home patient's care by a member of the dialysis facility's interdisciplinary team.

(iii) Development and periodic review of the patient's individualized comprehensive plan of care that specifies the services necessary to address the

patient's needs and meets the measurable and expected outcomes as specified in § 494.90 of this part.

(iv) Patient consultation with members of the interdisciplinary team, as needed.

(v) Monitoring of the quality of water and dialysate used by home hemodialysis patients including conducting an onsite evaluation and testing of the water and dialysate system in accordance with—

(A) The recommendations specified in the manufacturers' instructions; and

(B) The system's FDA-approved labeling for preconfigured systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate. The facility must meet testing and other requirements of AAMI RD52:2004. In addition, bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits.

(C) The dialysis facility must correct any water and dialysate quality problem for the home hemodialysis patient, and if necessary, arrange for backup dialysis until the problem is corrected if—

(*1*) Analysis of the water and dialysate quality indicates contamination; or

(*2*) The home hemodialysis patient demonstrates clinical symptoms associated with water and dialysate contamination.

(vi) Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician.

(vii) Identifying a plan and arranging for emergency back-up dialysis services when needed.

(2) The dialysis facility must maintain a recordkeeping system that ensures continuity of care and patient privacy. This includes items and services furnished by durable medical equipment (DME) suppliers referred to in § 414.330(a)(2) of this chapter.

§ 494.110 Condition: Quality assessment and performance improvement.

The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team. The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.

(a) *Standard: Program scope.* (1) The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.

(2) The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves. The program must include, but not be limited to, the following:

(i) Adequacy of dialysis.

(ii) Nutritional status.

(iii) Mineral metabolism and renal bone disease.

(iv) Anemia management.

(v) Vascular access.

(vi) Medical injuries and medical errors identification.

(vii) Hemodialyzer reuse program, if the facility reuses hemodialyzers.

(viii) Patient satisfaction and grievances.

(ix) Infection control; with respect to this component the facility must—

(A) Analyze and document the incidence of infection to identify trends

and establish baseline information on infection incidence;

(B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and

(C) Take actions to reduce future incidents.

(b) *Standard: Monitoring performance improvement*. The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time.

(c) *Standard: Prioritizing improvement activities*. The dialysis facility must set priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes or patient safety. The facility must immediately correct any identified problems that threaten the health and safety of patients.

§ 494.120 Condition: Special purpose renal dialysis facilities.

A special purpose renal dialysis facility is approved to furnish dialysis on a short-term basis at special locations. Special purpose dialysis facilities are divided into two categories: vacation camps (locations that serve ESRD patients while the patients are in a temporary residence) and facilities established to serve ESRD patients under emergency circumstances.

(a) *Standard: Approval period*. The period of approval for a special purpose renal dialysis facility may not exceed 8 months in any 12-month period.

(b) *Standard: Service limitation*. Special purpose renal dialysis facilities are limited to areas in which there are limited dialysis resources or access-to-care problems due to an emergency circumstance. A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic locality served by the facility.

(c) *Standard: Scope of requirements*—(1) *Scope of requirements for a vacation camp*. A vacation camp that provides dialysis services must be operated under the direction of a certified renal dialysis facility that assumes full responsibility for the care provided to patients. A special purpose renal dialysis facility established as a vacation camp must comply with the following conditions for coverage—

(i) Infection control at § 494.30;

(ii) Water and dialysate quality at § 494.40 (except as provided in paragraph (c)(1)(viii) of this section);

(iii) Reuse of hemodialyzers at § 494.50 (if reuse is performed);

(iv) Patients' rights and posting of patients' rights at § 494.70(a) and § 494.70(c);

(v) Laboratory services at § 494.130;

(vi) Medical director responsibilities for staff education and patient care policies and procedures at § 494.150(c) and § 494.150(d);

(vii) Medical records at § 494.170; and

(viii) When portable home water treatment systems are used in place of a central water treatment system, the facility may adhere to § 494.100(c)(1)(v) (home monitoring of water quality), in place of § 494.40 (water quality).

(2) *Scope of requirements for an emergency circumstance facility*. A special purpose renal dialysis facility set up due to emergency circumstances may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic areas served by the facility. These types of special purpose dialysis facilities must comply with paragraph (c)(1) of this section and addition to complying with the following conditions:

(i) Section 494.20 (compliance with Federal, State, and local laws and regulations).

(ii) Section 494.60 (physical environment).

(iii) Section 494.70(a) through section 494.70(c) (patient rights).

(iv) Section 494.140 (personnel qualifications).

(v) Section 494.150 (medical director).

(vi) Section 494.180 (governance).

(d) *Standard: Physician contact*. The facility must contact the patient's physician, if possible, prior to initiating dialysis in the special purpose renal dialysis facility, to discuss the patient's current condition to assure care provided in the special purpose renal dialysis facility is consistent with the patient plan of care (described in § 494.90).

(e) *Standard: Documentation*. All patient care provided in the special purpose facility is documented and forwarded to the patient's usual dialysis facility, if possible, within 30 days of the last scheduled treatment in the special purpose renal dialysis facility.

§ 494.130 Condition: Laboratory services.

The dialysis facility must provide, or make available, laboratory services (other than tissue pathology and histocompatibility) to meet the needs of the ESRD patient. Any laboratory services, including tissue pathology and histocompatibility must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter.

Subpart D—Administration

§ 494.140 Condition: Personnel qualifications.

All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed. The dialysis facility's staff (employee or contractor) must meet the personnel qualifications and demonstrated competencies necessary to serve collectively the comprehensive needs of the patients. The dialysis facility's staff must have the ability to demonstrate and sustain the skills needed to perform the specific duties of their positions.

(a) *Standard: Medical director*. (1) The medical director must be a board-certified physician in internal medicine or pediatrics by a professional board who has completed a board-approved training program in nephrology and has at least 12-months of experience providing care to patients receiving dialysis.

(2) If a physician, as specified in paragraph (a)(1) of this section, is not available to direct a certified dialysis facility another physician may direct the facility, subject to the approval of the Secretary.

(b) *Standard: Nursing services*. (1) *Nurse manager*. The facility must have a nurse manager responsible for nursing services in the facility who must—

(i) Be a full time employee of the facility;

(ii) Be a registered nurse; and

(iii) Have at least 12 months of experience in clinical nursing, and an additional 6 months of experience in providing nursing care to patients on maintenance dialysis.

(2) *Self-care and home dialysis training nurse*. The nurse responsible for self-care and/or home care training must—

(i) Be a registered nurse; and

(ii) Have at least 12 months experience in providing nursing care and an additional 3 months of experience in the specific modality for which the nurse will provide self-care training.

(3) *Charge nurse*. The charge nurse responsible for each shift must—

(i) Be a registered nurse, a licensed practical nurse, or vocational nurse who meets the practice requirements in the State in which he or she is employed;

(ii) Have at least 12 months experience in providing nursing care, including 3 months of experience in providing nursing care to patients on maintenance dialysis; and

(iii) If such nurse is a licensed practical nurse or licensed vocational nurse, work under the supervision of a registered nurse in accordance with state nursing practice act provisions.

(4) *Staff nurse*. Each nurse who provides care and treatment to patients must be either a registered nurse or a practical nurse who meets the practice requirements in the State in which he or she is employed.

(c) *Standard: Dietitian*. The facility must have a dietitian who must—

(1) Be a registered dietitian with the Commission on Dietetic Registration; and

(2) Have a minimum of 1 year professional work experience in clinical nutrition as a registered dietitian.

(d) *Standard: Social worker*. The facility must have a social worker who—

(1) Holds a master's degree in social work with a specialization in clinical practice from a school of social work accredited by the Council on Social Work Education; or

(2) Has served at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and

has established a consultative relationship with a social worker who qualifies under § 494.140(d)(1).

(e) *Standard: Patient care dialysis technicians.* Patient care dialysis technicians must—

(1) Meet all applicable State requirements for education, training, credentialing, competency, standards of practice, certification, and licensure in the State in which he or she is employed as a dialysis technician; and

(2) Have a high school diploma or equivalency;

(3) Have completed a training program that is approved by the medical director and governing body, under the direction of a registered nurse, focused on the operation of kidney dialysis equipment and machines, providing direct patient care, and communication and interpersonal skills, including patient sensitivity training and care of difficult patients. The training program must include the following subjects:

(i) Principles of dialysis.

(ii) Care of patients with kidney failure, including interpersonal skills.

(iii) Dialysis procedures and documentation, including initiation, proper cannulation techniques, monitoring, and termination of dialysis.

(iv) Possible complications of dialysis.

(v) Water treatment and dialysate preparation.

(vi) Infection control.

(vii) Safety.

(viii) Dialyzer reprocessing, if applicable.

(4) Be certified under a State certification program or a national commercially available certification program, as follows—

(i) For newly employed patient care technicians, within 18 months of being hired as a dialysis patient care technician; or

(ii) For patient care technicians employed on October 14, 2008, within 18 months after such date.

(f) *Standard: Water treatment system technicians.* Technicians who perform monitoring and testing of the water treatment system must complete a training program that has been approved by the medical director and the governing body.

§ 494.150 Condition: Responsibilities of the medical director.

The dialysis facility must have a medical director who meets the qualifications of § 494.140(a) to be responsible for the delivery of patient care and outcomes in the facility. The medical director is accountable to the governing body for the quality of medical care provided to patients. Medical director responsibilities include, but are not limited to, the following:

(a) Quality assessment and performance improvement program.

(b) Staff education, training, and performance.

(c) Policies and procedures. The medical director must—

(1) Participate in the development, periodic review and approval of a ''patient care policies and procedures manual'' for the facility; and

(2) Ensure that—

(i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; and

(ii) The interdisciplinary team adheres to the discharge and transfer policies and procedures specified in § 494.180(f).

§ 494.160 [Reserved]

§ 494.170 Condition: Medical records.

The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.

(a) *Standard: Protection of the patient's record.* The dialysis facility must—

(1) Safeguard patient records against loss, destruction, or unauthorized use; and

(2) Keep confidential all information contained in the patient's record, except when release is authorized pursuant to one of the following:

(i) The transfer of the patient to another facility.

(ii) Certain exceptions provided for in the law.

(iii) Provisions allowed under third party payment contracts.

(iv) Approval by the patient.

(v) Inspection by authorized agents of the Secretary, as required for the administration of the dialysis program.

(3) Obtaining written authorization from the patient or legal representative before releasing information that is not authorized by law.

(b) *Standard: Completion of patient records and centralization of clinical information.* (1) Current medical records and those of discharged patients must be completed promptly.

(2) All clinical information pertaining to a patient must be centralized in the patient's record, including whether the patient has executed an advance directive. These records must be maintained in a manner such that each member of the interdisciplinary team has access to current information regarding the patient's condition and prescribed treatment.

(3) The dialysis facility must complete, maintain, and monitor home care patients' records, including the records of patients who receive supplies and equipment from a durable medical equipment supplier.

(c) *Standard: Record retention and preservation.* In accordance with 45 CFR § 164.530(j)(2), all patient records must be retained for 6 years from the date of the patient's discharge, transfer, or death.

(d) *Standard: Transfer of patient record information.* When a dialysis patient is transferred, the dialysis facility releasing the patient must send all requested medical record information to the receiving facility within 1 working day of the transfer.

§ 494.180 Condition: Governance.

The ESRD facility is under the control of an identifiable governing body, or designated person(s) with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility.

(a) *Standard: Designating a chief executive officer or administrator.* The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, including, but not limited to—

(1) Staff appointments;

(2) Fiscal operations;

(3) The relationship with the ESRD networks; and

(4) Allocation of necessary staff and other resources for the facility's quality assessment and performance improvement program as described in § 494.110.

(b) *Standard: Adequate number of qualified and trained staff.* The governing body or designated person responsible must ensure that—

(1) An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients; and the registered nurse, social worker and dietitian members of the interdisciplinary team are available to meet patient clinical needs;

(2) A registered nurse, who is responsible for the nursing care provided, is present in the facility at all times that in-center dialysis patients are being treated;

(3) All staff, including the medical director, have appropriate orientation to the facility and their work responsibilities; and

(4) All employees have an opportunity for continuing education and related development activities.

(c) *Standard: Medical staff appointments.* The governing body—

(1) Is responsible for all medical staff appointments and credentialing in accordance with State law, including attending physicians, physician assistants, nurse practitioners, and clinical nurse specialists; and

(2) Ensures that all medical staff who provide care in the facility are informed of all facility policies and procedures, including the facility's quality

assessment and performance improvement program specified in § 494.110.

(3) Communicates expectations to the medical staff regarding staff participation in improving the quality of medical care provided to facility patients.

(d) *Standard: Furnishing services.* The governing body is responsible for ensuring that the dialysis facility furnishes services directly on its main premises or on other premises that are contiguous with the main premises and are under the direction of the same professional staff and governing body as the main premises (except for services provided under § 494.100).

(e) *Standard: Internal grievance process.* The facility's internal grievance process must be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services. The grievance process must include:

(1) A clearly explained procedure for the submission of grievances.

(2) Timeframes for reviewing the grievance.

(3) A description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance.

(f) *Standard: Involuntary discharge and transfer policies and procedures.* The governing body must ensure that all staff follow the facility's patient discharge and transfer policies and procedures. The medical director ensures that no patient is discharged or transferred from the facility unless—

(1) The patient or payer no longer reimburses the facility for the ordered services;

(2) The facility ceases to operate;

(3) The transfer is necessary for the patient's welfare because the facility can no longer meet the patient's documented medical needs; or

(4) The facility has reassessed the patient and determined that the patient's behavior is disruptive and abusive to the extent that the delivery of care to the patient or the ability of the facility to operate effectively is seriously impaired, in which case the medical director ensures that the patient's interdisciplinary team—

(i) Documents the reassessments, ongoing problem(s), and efforts made to resolve the problem(s), and enters this documentation into the patient's medical record;

(ii) Provides the patient and the local ESRD Network with a 30-day notice of the planned discharge;

(iii) Obtains a written physician's order that must be signed by both the medical director and the patient's attending physician concurring with the patient's discharge or transfer from the facility;

(iv) Contacts another facility, attempts to place the patient there, and documents that effort; and

(v) Notifies the State survey agency of the involuntary transfer or discharge.

(5) In the case of immediate severe threats to the health and safety of others, the facility may utilize an abbreviated involuntary discharge procedure.

(g) *Standard: Emergency coverage.* (1) The governing body is responsible for ensuring that the dialysis facility provides patients and staff with written instructions for obtaining emergency medical care.

(2) The dialysis facility must have available at the nursing/monitoring station, a roster with the names of physicians to be called for emergencies, when they can be called, and how they can be reached.

(3) The dialysis facility must have an agreement with a hospital that can provide inpatient care, routine and emergency dialysis and other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week. The agreement must:

(i) Ensure that hospital services are available promptly to the dialysis facility's patients when needed.

(ii) Include reasonable assurances that patients from the dialysis facility are accepted and treated in emergencies.

(h) *Standard: Furnishing data and information for ESRD program administration.* Effective February 1, 2009, the dialysis facility must furnish data and information to CMS and at intervals as specified by the Secretary. This information is used in a national ESRD information system and in compilations relevant to program administration, including claims processing and reimbursement, quality improvement, and

performance assessment. The data and information must—

(1) Be submitted at the intervals specified by the Secretary;

(2) Be submitted electronically in the format specified by the Secretary;

(3) Include, but not be limited to—

(i) Cost reports;

(ii) ESRD administrative forms;

(iii) Patient survival information; and

(iv) Existing ESRD clinical performance measures, and any future clinical performance standards developed in accordance with a voluntary consensus standards process identified by the Secretary.

(i) *Standard: Relationship with the ESRD network.* The governing body receives and acts upon recommendations from the ESRD network. The dialysis facility must cooperate with the ESRD network designated for its geographic area, in fulfilling the terms of the Network's current statement of work. Each facility must participate in ESRD network activities and pursue network goals.

(j) *Standard: Disclosure of ownership.* In accordance with §420.200 through §420.206 of this chapter, the governing body must report ownership interests of 5 percent or more to its State survey agency.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

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495.370 Appeals process for a Medicaid provider receiving electronic health record incentive payments.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 75 FR 44565, July 28, 2010, unless otherwise noted.

Subpart A—General Provisions

§ 495.2 Basis and purpose.

This part implements the following:

(a) Section 1848(o) of the Act by establishing payment incentives under Medicare Part B for eligible professionals who adopt and meaningfully use certified electronic health record (EHR) technology.

(b) Section 1853(l) of the Act to provide incentive payments to Medicare Advantage organizations for certain affiliated professionals who meaningfully use certified EHR technology and meet certain other requirements.

(c) Section 1886(n) of the Act by establishing incentives payments for the meaningful use of certified EHR technology by subsection (d) hospitals, as defined under section 1886(d)(1)(B) of the Act, participating in the Medicare FFS program.

(d) Section 1814(l) of the Act to provide an incentive payment to critical access hospitals that meaningfully use certified EHR technology based on the hospitals' reasonable costs.

(e) Section 1853(m) of the Act to provide incentive payments to MA organizations for certain affiliated hospitals that meaningfully use certified EHR technology.

(f) Sections 1903(a)(3)(F) and 1903(t) of the Act to provide 100 percent Federal financial participation (FFP) to States for incentive payments to certain eligible providers participating in the Medicaid program to purchase, implement, and operate (including support services and training for staff) certified EHR technology and 90 percent FFP for State administrative expenses related to such incentive payments.

(g) Sections 1848(a)(7), 1853(l)(4), 1886(b)(3)(B)(ix)(I), and 1853(m)(4) of the Act, providing for payment reductions for inpatient services furnished on or after October 1, 2014 to Medicare beneficiaries by hospitals that are not meaningful users of certified EHR technology, and for covered professional services furnished on or after January 1, 2015 to Medicare beneficiaries by certain professionals who are not meaningful users of certified EHR technology.

§ 495.4 Definitions.

In this part, unless otherwise indicated—

Certified electronic health record technology has the same definition as this term is defined at 45 CFR 170.102.

Critical access hospital (CAH) means a facility that has been certified as a critical access hospital under section 1820(e) of the Act and for which Medicare payment is made under section 1814(l) of the Act for inpatient services and under section 1834(g) of the Act for outpatient services.

EHR reporting period means either of the following:

(1) For an eligible professional (EP)—

(i) For the first payment year, any continuous 90-day period within a calendar year;

(ii)(A) Except as specified in paragraph (1)(ii)(B) of this definition, for the second, third, fourth, fifth, or sixth payment year, the calendar year.

(B) For Medicaid providers who are demonstrating they are meaningful EHR users for the first time in their second payment year, the EHR reporting period during such second payment year is any continuous 90-day period within the calendar year.

(2) For an eligible hospital or a CAH—

(i) For the first payment year, any continuous 90-day period within a federal fiscal year; and

(ii)(A) Except as specified in paragraph (2)(ii)(B) of this definition, for

the second, third, fourth, fifth, or sixth payment year, the Federal fiscal year.

(B) For Medicaid providers who are demonstrating they are meaningful EHR users for the first time in their second payment year, the EHR reporting period during such second payment year is any continuous 90-day period within the Federal fiscal year.

Eligible hospital means an eligible hospital as defined under § 495.100 or Medicaid eligible hospital under subpart D of this part.

Eligible professional (EP) means an eligible professional as defined under § 495.100 or a Medicaid eligible professional under subpart D of this part.

Hospital-based EP is an EP (as defined under this section) who furnishes 90 percent or more of his or her covered professional services in a hospital setting in the year preceding the payment year. For Medicare, this will be calculated based on the Federal FY prior to the payment year. For Medicaid, it is at the State's discretion if the data is gathered on the Federal FY or CY prior to the payment year. A setting is considered a hospital setting if it is a site of service that would be identified by the codes used in the HIPAA standard transactions as an inpatient hospital, or emergency room setting.

Meaningful EHR user means:

(1) Subject to paragraph (3) of this definition, an EP, eligible hospital or CAH that, for an EHR reporting period for a payment year, demonstrates in accordance with § 495.8 meaningful use of certified EHR technology by meeting the applicable objectives and associated measures under § 495.6; and

(2)(i) Except as specified in paragraph (2)(ii) of this definition, a Medicaid EP or Medicaid eligible hospital, that meets the requirements of paragraph (1) of this definition and any additional criteria for meaningful use imposed by the State and approved by CMS under § 495.316 and § 495.332.

(ii) An eligible hospital or CAH is deemed to be a meaningful EHR user for purposes of receiving an incentive payment under subpart D of this Part, if the hospital participates in both the Medicare and Medicaid EHR incentive programs, and the hospital meets the requirements of paragraph (1) of this definition.

(3) To be considered a meaningful EHR user, at least 50 percent of an EP's patient encounters during the EHR reporting period during the payment year must occur at a practice/location or practices/locations equipped with certified EHR technology.

Payment year means:

(1) For an EP, a calendar year beginning with CY 2011; and

(2) For a CAH or an eligible hospital, a Federal fiscal year beginning with FY 2011.

Qualified EHR has the same definition as this term is defined at 45 CFR 170.102.

First, second, third, fourth, fifth, or sixth payment years mean as follows:

(1) The first payment year is: with respect to an EP, the first calendar year for which the EP receives an incentive payment under this part; and with respect to an eligible hospital or CAH, the first FY for which the hospital receives an incentive payment under this part.

(2) The second, third, fourth, fifth, or sixth payment year is:

(i) With respect to a Medicare EP, the second, third, fourth or fifth successive CY immediately following the first payment year; and with respect to a Medicare eligible hospital or CAH, the second, third, or fourth successive Federal FY immediately following the first payment year. (Note: Medicare EPs are not eligible for a sixth payment year and Medicare eligible hospitals are not eligible for a fifth or sixth payment year.)

(ii)(A) With respect to a Medicaid EP, the second, third, fourth, fifth, or sixth CY for which the EP receives an incentive payment under subpart D, regardless of whether the year immediately follows the prior payment year; and

(B) With respect to a Medicaid eligible hospital, for years prior to FY 2017, the second, third, fourth, fifth, or sixth Federal FY for which the hospital receives an incentive payment under subpart D of this part, regardless of whether the year immediately follows the prior payment year. Beginning with FY 2017, payments to Medicaid eligible hospitals must be consecutive, and the hospital is not eligible for an incentive payment under subpart D of

this part unless it received such incentive payment for the prior fiscal year.

§ 495.6 Meaningful use objectives and measures for EPs, eligible hospitals, and CAHs.

(a) *Stage 1 criteria for EPs*—(1) *General rule regarding Stage 1 criteria for meaningful use for EPs.* Except as specified in paragraphs (a)(2) and (a)(3) of this section, EPs must meet all objectives and associated measures of the Stage 1 criteria specified in paragraph (d) of this section and five objectives of the EP's choice from paragraph (e) of this section to meet the definition of a meaningful EHR user.

(2) *Exclusion for non-applicable objectives.* (i) An EP may exclude a particular objective contained in paragraphs (d) or (e) of this section, if the EP meets all of the following requirements:

(A) Must ensure that the objective in paragraph (d) or (e) of this section includes an option for the EP to attest that the objective is not applicable.

(B) Meets the criteria in the applicable objective that would permit the attestation.

(C) Attests.

(ii) An exclusion will reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply. For example, an EP that has an exclusion from one of the objectives in paragraph (e) of this section must meet four (and not five) objectives of the EP's choice from such paragraph to meet the definition of a meaningful EHR user.

(3) *Exception for Medicaid EPs who adopt, implement or upgrade in their first payment year.* For Medicaid EPs who adopt, implement, or upgrade certified EHR technology in their first payment year, the meaningful use objectives and associated measures of the Stage 1 criteria specified in paragraphs (d) and (e) apply beginning with the second payment year, and do not apply to the first payment year.

(b) *Stage 1 criteria for eligible hospitals and CAHs*—(1) *General rule regarding Stage 1 criteria for meaningful use for eligible hospitals or CAHs.* Except as specified in paragraphs (b)(2) and (b)(3) of this section, eligible hospitals and CAHs must meet all objectives and associated measures of the Stage 1 criteria specified in paragraph (f) of this section and five objectives of the eligible hospital's or CAH's choice from paragraph (g) of this section to meet the definition of a meaningful EHR user.

(2) *Exclusions for nonapplicable objectives.* (i) An eligible hospital or CAH may exclude a particular objective that includes an option for exclusion contained in paragraphs (f) or (g) of this section, if the hospital meets all of the following requirements:

(A) The hospital meets the criteria in the applicable objective that would permit an exclusion.

(B) The hospital so attests.

(ii) An exclusion will reduce (by the number of exclusions received) the number of objectives that would otherwise apply. For example, an eligible hospital that is excluded from one of the objectives in paragraph (g) of this section must meet four (and not five) objectives of the hospital's choice from such paragraph to meet the definition of a meaningful EHR user.

(3) *Exception for Medicaid eligible hospitals that adopt, implement or upgrade in their first payment year.* For Medicaid eligible hospitals that adopt, implement, or upgrade certified EHR technology in their first payment year, the meaningful use objectives and associated measures of the Stage 1 criteria specified in paragraphs (f) and (g) of this section apply beginning with the second payment year, and do not apply to the first payment year.

(c) Many of the objective and associated measures in paragraphs (d) through (g) of this section rely on measures that count unique patients or actions.

(1) If a measure (or associated objective) in paragraphs (d) through (g) of this section references paragraph (c) of this section, then the measure may be calculated by reviewing only the actions for patients whose records are maintained using certified EHR technology. A patient's record is maintained using certified EHR technology if sufficient data was entered in the certified EHR technology to allow the record to be saved, and not rejected due to incomplete data.

(2) If the objective and associated measure does not reference this paragraph (c) of this section, then the measure must be calculated by reviewing all patient records, not just those maintained using certified EHR technology.

(d) *Stage 1 core criteria for EPs.* An EP must satisfy the following objectives and associated measures, except those objectives and associated measures for which an EP qualifies for an exclusion under paragraph (a)(2) of this section specified in this paragraph:

(1)(i) *Objective.* Use computerized provider order entry (CPOE) for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 30 percent of all unique patients with at least one medication in their medication list seen by the EP have at least one medication order entered using CPOE.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section* Any EP who writes fewer than 100 prescriptions during the EHR reporting period.

(2)(i) *Objective.* Implement drug-drug and drug-allergy interaction checks.

(ii) *Measure.* The EP has enabled this functionality for the entire EHR reporting period.

(3)(i) *Objective.* Maintain an up-to-date problem list of current and active diagnoses.

(ii) *Measure.* More than 80 percent of all unique patients seen by the EP have at least one entry or an indication that no problems are known for the patient recorded as structured data.

(4)(i) *Objective.* Generate and transmit permissible prescriptions electronically (eRx).

(ii) *Measure.* Subject to paragraph (c) of this section, more than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section* Any EP who writes fewer than 100 prescriptions during the EHR reporting period.

(5)(i) *Objective.* Maintain active medication list.

(ii) *Measure.* More than 80 percent of all unique patients seen by the EP have at least one entry (or an indication that the patient is not currently prescribed any medication) recorded as structured data.

(6)(i) *Objective.* Maintain active medication allergy list.

(ii) *Measure.* More than 80 percent of all unique patients seen by the EP have at least one entry (or an indication that the patient has no known medication allergies) recorded as structured data.

(7)(i) *Objective.* Record all of the following demographics:

(A) Preferred language.

(B) Gender.

(C) Race.

(D) Ethnicity.

(E) Date of birth.

(ii) *Measure.* More than 50 percent of all unique patients seen by the EP have demographics recorded as structured data.

(8)(i) *Objective.* Record and chart changes in the following vital signs:

(A) Height.

(B) Weight.

(C) Blood pressure.

(D) Calculate and display body mass index (BMI).

(E) Plot and display growth charts for children 2–20 years, including BMI.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 50 percent of all unique patients age 2 and over seen by the EP, height, weight and blood pressure are recorded as structured data.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* Any EP who either see no patients 2 years or older, or who believes that all three vital signs of height, weight, and blood pressure of their patients have no relevance to their scope of practice.

(9)(i) *Objective.* Record smoking status for patients 13 years old or older.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 50 percent of all unique patients 13 years old or older seen by the EP have smoking status recorded as structured data.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* Any EP who sees no patients 13 years or older.

(10)(i) *Objective*. Report ambulatory clinical quality measures to CMS or, in the case of Medicaid EPs, the States.

(ii) *Measure*. Subject to paragraph (c) of this section, successfully report to CMS (or, in the case of Medicaid EPs, the States) ambulatory clinical quality measures selected by CMS in the manner specified by CMS (or in the case of Medicaid EPs, the States).

(11)(i) *Objective*. Implement one clinical decision support rules relevant to specialty or high clinical priority along with the ability to track compliance with that rule.

(ii) *Measure*. Implement one clinical decision support rule.

(12)(i) *Objective*. Provide patients with an electronic copy of their health information (including diagnostics test results, problem list, medication lists, medication allergies) upon request.

(ii) *Measure*. Subject to paragraph (c) of this section, more than 50 percent of all patients who request an electronic copy of their health information are provided it within 3 business days.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section*. Any EP that has no requests from patients or their agents for an electronic copy of patient health information during the EHR reporting period.

(13)(i) *Objective*. Provide clinical summaries for patients for each office visit.

(ii) *Measure*. Subject to paragraph (c) of this section, clinical summaries provided to patients for more than 50 percent of all office visits within 3 business days.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section*. Any EP who has no office visits during the EHR reporting period.

(14)(i) *Objective*. Capability to exchange key clinical information (for example, problem list, medication list, allergies, and diagnostic test results), among providers of care and patient authorized entities electronically.

(ii) *Measure*. Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information.

(15)(i) *Objective*. Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.

(ii) *Measure*. Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process.

(e) *Stage 1 menu set criteria for EPs*. An EP must meet five of the following objectives and associated measures, one of which must be either paragraph (e)(9) or (e)(10) of this section, except that the required number of objectives and associated measures is reduced by an EP's paragraph (a)(2) of this section exclusions specified in this paragraph:

(1)(i) *Objective*. Implement drug-formulary checks.

(ii) *Measure*. The EP has enabled this functionality and has access to at least one internal or external formulary for the entire EHR reporting period.

(2)(i) *Objective*. Incorporate clinical lab-test results into EHR as structured data.

(ii) *Measure*. Subject to paragraph (c) of this section, more than 40 percent of all clinical lab tests results ordered by the EP during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in certified EHR technology as structured data.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section*. An EP who orders no lab tests whose results are either in a positive/negative or numeric format during the EHR reporting period.

(3)(i) *Objective*. Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.

(ii) *Measure*. Subject to paragraph (c) of this section, generate at least one report listing patients of the EP with a specific condition.

(4)(i) *Objective*. Send reminders to patients per patient preference for preventive/follow-up care.

(ii) *Measure*. Subject to paragraph (c) of this section, more than 20 percent of all patients 65 years or older or 5 years old or younger were sent an appropriate reminder during the EHR reporting period.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* An EP who has no patients 65 years old or older or 5 years old or younger with records maintained using certified EHR technology.

(5)(i) *Objective.* Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, and allergies) within 4 business days of the information being available to the EP.

(ii) *Measure.* At least 10 percent of all unique patients seen by the EP are provided timely (available to the patient within four business days of being updated in the certified EHR technology) electronic access to their health information subject to the EP's discretion to withhold certain information.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* Any EP that neither orders nor creates any of the information listed at 45 CFR 170.304(g) during the EHR reporting period.

(6)(i) *Objective.* Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate.

(ii) *Measure.* More than 10 percent of all unique patients seen by the EP are provided patient-specific education resources.

(7)(i) *Objective.* The EP who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.

(ii) *Measure.* Subject to paragraph (c) of this section, the EP performs medication reconciliation for more than 50 percent of transitions of care in which the patient is transitioned into the care of the EP.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* An EP who was not the recipient of any transitions of care during the EHR reporting period.

(8)(i) *Objective.* The EP who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.

(ii) *Measure.* Subject to paragraph (c) of this section, the EP who transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* An EP who neither transfers a patient to another setting nor refers a patient to another provider during the EHR reporting period.

(9)(i) *Objective.* Capability to submit electronic data to immunization registries or immunization information systems and actual submission according to applicable law and practice.

(ii) *Measure.* Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries and follow up submission if the test is successful (unless none of the immunization registries to which the EP submits such information has the capacity to receive the information electronically).

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* An EP who administers no immunizations during the EHR reporting period or where no immunization registry has the capacity to receive the information electronically.

(10)(i) *Objective.* Capability to submit electronic syndromic surveillance data to public health agencies and actual submission according to applicable law and practice.

(ii) *Measure.* Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies and follow-up submission if the test is successful (unless none of the public health agencies to which an EP submits such information has the capacity to receive the information electronically).

(iii) Exclusion in accordance with paragraph (a)(2) of this section. An EP who does not collect any reportable syndromic information on their patients during the EHR reporting period or does not submit such information to any public health agency that has the capacity to receive the information electronically.

(f) *Stage 1 core criteria for eligible hospitals or CAHs.* An eligible hospital or CAH must meet the following objectives and associated measures except

those objectives and associated measures for which an eligible hospital or CAH qualifies for a paragraph (b)(2) of this section exclusion specified in this paragraph:

(1)(i) *Objective*. Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per State, local, and professional guidelines.

(ii) *Measure*. Subject to paragraph (c) of this section, more than 30 percent of all unique patients with at least one medication in their medication list admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one medication order entered using CPOE.

(2)(i) *Objective*. Implement drug-drug and drug-allergy interaction checks.

(ii) *Measure*. The eligible hospital or CAH has enabled this functionality for the entire EHR reporting period.

(3)(i) *Objective*. Maintain an up-to-date problem list of current and active diagnoses.

(ii) *Measure*. More than 80 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry or an indication that no problems are known for the patient recorded as structured data.

(4)(i) *Objective*. Maintain active medication list.

(ii) *Measure*. More than 80 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry (or an indication that the patient is not currently prescribed any medication) recorded as structured data.

(5)(i) *Objective*. Maintain active medication allergy list.

(ii) *Measure*. More than 80 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry (or an indication that the patient has no known medication allergies) recorded as structured data.

(6)(i) *Objective*. Record all of the following demographics;

(A) Preferred language.

(B) Gender.

(C) Race.

(D) Ethnicity.

(E) Date of birth.

(F) Date and preliminary cause of death in the event of mortality in the eligible hospital or CAH.

(ii) *Measure*. More than 50 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have demographics recorded as structured data.

(7)(i) *Objective*. Record and chart changes in the following vital signs:

(A) Height.

(B) Weight.

(C) Blood pressure.

(D) Calculate and display body mass index (BMI).

(E) Plot and display growth charts for children 2–20 years, including BMI.

(ii) *Measure*. Subject to paragraph (c) of this section, for more than 50 percent of all unique patients age 2 and over admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23), height, weight, and blood pressure are recorded as structured data.

(8)(i) *Objective*. Record smoking for patients 13 years old or older.

(ii) *Measure*. Subject to paragraph (c) of this section, more than 50 percent of all unique patients 13 years old or older or admitted to the eligible hospital's inpatient or emergency department (POS 21 or 23) have smoking status recorded as structured data.

(iii) *Exclusion in accordance with paragraph (b)(2) of this section*. Any eligible hospital or CAH that admits no patients 13 years or older to their inpatient or emergency department (POS 21 or 23).

(9)(i) *Objective*. Report hospital clinical quality measures to CMS or, in the case of Medicaid eligible hospitals, the States.

(ii) *Measure*. Subject to paragraph (c) of this section, successfully report to CMS (or, in the case of Medicaid eligible hospitals or CAHs, the States) hospital clinical quality measures selected by CMS in the manner specified by CMS (or, in the case of Medicaid eligible hospitals or CAHs, the States).

(10)(i) *Objective*. Implement one clinical decision support rule related to a high priority hospital condition along

with the ability to track compliance with that rule.

(ii) *Measure*. Implement one clinical decision support rule.

(11)(i) *Objective*. Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies, discharge summary, procedures), upon request.

(ii) *Measure*. Subject to paragraph (c) of this section, more than 50 percent of all patients of the inpatient or emergency departments of the eligible hospital or CAH (POS 21 or 23) who request an electronic copy of their health information are provided it within 3 business days.

(iii) *Exclusion in accordance with paragraph (b)(2) of this section*. Any eligible hospital or CAH that has no requests from patients or their agents for an electronic copy of patient health information during the EHR reporting period.

(12)(i) *Objective*. Provide patients with an electronic copy of their discharge instructions at time of discharge, upon request.

(ii) *Measure*. Subject to paragraph (c) of this section, more than 50 percent of all patients who are discharged from an eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) and who request an electronic copy of their discharge instructions are provided it.

(iii) *Exclusion in accordance with paragraph (b)(2) of this section*. Any eligible hospital or CAH that has no requests from patients or their agents for an electronic copy of the discharge instructions during the EHR reporting period.

(13)(i) *Objective*. Capability to exchange key clinical information (for example, problem list, medication list, medication allergies, and diagnostic test results), among providers of care and patient authorized entities electronically.

(ii) *Measure*. Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information.

(14)(i) *Objective*. Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.

(ii) *Measure*. Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process.

(g) *Stage 1 menu set criteria for eligible hospitals or CAHs*. Eligible hospitals or CAHs must meet five of the following objectives and associated measures, one which must be specified in paragraph (g)(8), (g)(9), or (g)(10) of this section, except that the required number of objectives and associated measures is reduced by a hospital's paragraph (b)(2) of this section exclusions specified in this paragraph:

(1)(i) *Objective*. Implement drug-formulary checks.

(ii) *Measure*. The eligible hospital or CAH has enabled this functionality and has access to at least one internal or external formulary for the entire EHR reporting period.

(2)(i) *Objective*. Record advance directives for patient 65 years old or older.

(ii) *Measure*. Subject to paragraph (c) of this section, more than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient (POS 21) have an indication of an advance directive status recorded as structured data.

(iii) *Exclusion in accordance with paragraph (b)(2) of this section*. An eligible hospital or CAH that admits no patients age 65 years old or older during the EHR reporting period.

(3)(i) *Objective*. Incorporate clinical lab-test results into EHR as structured data.

(ii) *Measure*. Subject to paragraph (c) of this section, more than 40 percent of all clinical lab test results ordered by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 and 23) during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in certified EHR technology as structured data.

(4)(i) *Objective*. Generate lists of patients by specific conditions to use for

quality improvement, reduction of disparities, research, or outreach.

(ii) *Measure.* Subject to paragraph (c) of this section, generate at least one report listing patients of the eligible hospital or CAH with a specific condition.

(5)(i) *Objective.* Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate.

(ii) *Measure.* More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient-specific education resources.

(6)(i) *Objective.* The eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.

(ii) *Measure.* Subject to paragraph (c) of this section, the eligible hospital or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the patient is admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).

(7)(i) *Objective.* The eligible hospital or CAH that transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.

(ii) *Measure.* Subject to paragraph (c) of this section, the eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals.

(8)(i) *Objective.* Capability to submit electronic data to immunization registries or immunization information systems and actual submission according to applicable law and practice.

(ii) *Measure.* Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries and follow up submission if the test is successful (unless none of the immunization registries to which the eligible hospital or CAH submits such information has the capacity to receive the information electronically).

(iii) *Exclusion in accordance with paragraph (b)(2) of this section.* An eligible hospital or CAH that administers no immunizations during the EHR reporting period or where no immunization registry has the capacity to receive the information electronically.

(9)(i) *Objective.* Capability to submit electronic data on reportable (as required by State or local law) lab results to public health agencies and actual submission according to applicable law and practice.

(ii) *Measure.* Performed at least one test of certified EHR technology's capacity to provide electronic submission of reportable lab results to public health agencies and follow-up submission if the test is successful (unless none of the public health agencies to which an eligible hospital or CAH submits such information has the capacity to receive the information electronically).

(iii) *Exclusion in accordance with paragraph (b)(2) of this section.* No public health agency to which the eligible hospital or CAH submits such information has the capacity to receive the information electronically.

(10)(i) *Objective.* Capability to submit electronic syndromic surveillance data to public health agencies and actual submission according to applicable law and practice.

(ii) *Measure.* Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies and follow-up submission if the test is successful (unless none of the public health agencies to which an eligible hospital or CAH submits information has the capacity to receive the information electronically).

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* No public health agency to which the eligible hospital or CAH submits information has the capacity to receive the information electronically.

(h) *Stage 2 criteria for EPs.* Beginning when final regulations for Stage 2 are effective, an EP must satisfy the following objectives and associated measures:

(1)(i) *Objective*. Use computerized provider order entry (CPOE) for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines.

(ii) *Measure*. More than 60 percent of all unique patients with at least one medication in their medication list seen by the EP have at least one medication order entered using CPOE.

(iii) *Exclusion*. Any EP who writes fewer than 100 prescriptions during the EHR reporting period.

(2) [Reserved]

(i) *Stage 2 criteria for eligible hospitals or CAHs*. Beginning when final regulations for Stage 2 are effective, an eligible hospital or CAH must satisfy the following objectives and associated measures:

(1)(i) *Objective*. Use computerized provider order entry (CPOE) for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines.

(ii) *Measure*. More than 60 percent of all unique patients with at least one medication in their medication list admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one medication order entered using CPOE.

(2) [Reserved]

§ 495.8 Demonstration of meaningful use criteria.

(a) *Demonstration by EPs*. An EP must demonstrate that he or she satisfies each of the applicable objectives and associated measures under § 495.6 of this subpart as follows:

(1) For CY 2011—(i) *Attestation*. Attest, through a secure mechanism, in a manner specified by CMS (or for a Medicaid EP, in a manner specified by the State), that during the EHR reporting period, the EP—

(A) Used certified EHR technology, and specify the technology used;

(B) Satisfied the required objectives and associated measures under § 495.6(d) and § 495.6(e) of this subpart;

(C) Must specify the EHR reporting period and provide the result of each applicable measure for all patients seen during the EHR reporting period for which a selected measure is applicable;

(ii) *Additional requirements for Medicaid EPs*. For Medicaid EPs, if, in accordance with § 495.316 and § 495.332, CMS has approved a State's revised definition for meaningful use, in addition to meeting paragraphs (a)(1)(i) through (ii) of this section, the EP must also demonstrate meeting the State revised definition using the method approved by CMS; and

(iii) *Exception for Medicaid EPs*. If a Medicaid EP has adopted, implemented or upgraded certified EHR technology in the first payment year, the EP need not demonstrate meaningful use until the second payment year, as described in § 495.6 and § 495.8 of this subpart.

(2) For CY 2012 and subsequent years—

(i) *Attestation*. Attest, through a secure mechanism, in a manner specified by CMS (or for a Medicaid EP, in a manner specified by the State) that during the EHR reporting period, the EP—

(A) Used certified EHR technology and specify the technology used.

(B) Satisfied the required objectives and associated measures under § 495.6(d) and § 495.6(e), except § 495.6(d)(10) ''Report ambulatory clinical quality measures to CMS or, in the case of Medicaid EPs, the States.''

(C) Must specify the EHR reporting period and provide the result of each applicable measure for all patients seen during the EHR reporting period for which a selected measure is applicable.

(ii) *Reporting of clinical quality information*. For § 495.6(d)(10), ''Report ambulatory clinical quality measures to CMS or, in the case of Medicaid EPs, the States,'' report the ambulatory clinical quality measures selected by CMS electronically to CMS (or in the case of Medicaid EPs, the States) in the manner specified by CMS (or in the case of Medicaid EPs, the States).

(iii) *Additional requirements for Medicaid EPs*. For Medicaid EPs, if, in accordance with § 495.316 and § 495.332, CMS has approved a State's additional criteria for meaningful use, in addition to meeting paragraphs (a)(2)(i) through (iii), the EP must also demonstrate

meeting such additional criteria using the method approved by CMS.

(iv) *Exception for Medicaid EPs.* If a Medicaid EP has adopted, implemented, or upgrade certified EHR technology in the first payment year, the EP need not demonstrate that it is a meaningful EHR user until the second payment year, as described in § 495.6 and § 495.8 of this subpart.

(3) For all CYs, an EP who practices in multiple physical locations, not all of which have certified EHR technology available, will demonstrate meaningful use using only the locations where the EP has certified EHR technology available. (See also § 495.4 regarding the definition of meaningful EHR user).

(b) *Demonstration by eligible hospitals and CAHs.* To successfully demonstrate that it is a meaningful EHR user, an eligible hospital or CAH must the following requirements:

(1) For FY 2011—

(i) *Attestation.* Attest, through a secure mechanism, in a manner specified by CMS (or for a Medicaid eligible hospital, in a manner specified by the State), that during the EHR reporting period, the eligible hospital or CAH—

(A) Used certified EHR and specify the technology used.

(B) Satisfied the required objectives and associated measures under § 495.6(f) and § 495.6(g).

(C) Must specify the EHR reporting period and provide the result of each applicable measure for all patients admitted to the inpatient or emergency department (POS 21 or 23) of the hospital during the EHR reporting period for which a selected measure is applicable.

(ii) *Additional requirements for Medicaid eligible hospitals.* For Medicaid eligible hospitals, if, in accordance with § 495.316 and § 495.332, CMS has approved a State's revised definition for meaningful use, in addition to meeting paragraphs (b)(1)(i) through (ii) of this section, the eligible hospital must also demonstrate meeting the State's revised definition using the method approved by CMS.

(iv) *Exception for Medicaid eligible hospitals.* If a Medicaid eligible hospital has adopted, implemented or upgraded certified EHR technology in the first payment year, the eligible hospital need not demonstrate meaningful use until the second payment year, as described in § 495.6 and § 495.8 of this subpart.

(2) For FY 2012 and subsequent years—

(i) *Attestation.* Attest, through a secure mechanism, in a manner specified by CMS (or for a Medicaid eligible hospital, in a manner specified by the State), that during the EHR reporting period, the eligible hospital or CAH—

(A) Used certified EHR and specify the technology used;

(B) Satisfied the required objectives and associated measures under § 495.6(f) and § 495.6(g), except § 495.6(f)(9) ''Report hospital clinical quality measures to CMS or, in the case of Medicaid eligible hospitals, the States;''

(C) Must specify the EHR reporting period and provide the result of each applicable measure for all patients admitted to the inpatient or emergency department (POS 21 or 23) of the hospital during the EHR reporting period for which a selected measure is applicable.

(ii) *Reporting clinical quality information.* For § 495.6(f)(9) ''Report hospital clinical quality measures to CMS or, in the case of Medicaid eligible hospitals, the States,'' report the hospital quality measures selected by CMS electronically to CMS (or in the case of Medicaid eligible hospitals, the States), in the manner specified by CMS (or in the case of Medicaid eligible hospitals, the States).

(iv) *Additional requirements for Medicaid eligible hospitals.* For Medicaid eligible hospitals if, in accordance with § 495.316 and § 495.332, CMS has approved a State's revised definition for meaningful use, in addition to meeting paragraphs (b)(2)(i) through (iii) of this section, the eligible hospital must also demonstrate meeting the State's revised definition using the method approved by CMS.

(v) *Exception for Medicaid eligible hospitals.* If a Medicaid eligible hospital has adopted, implemented, or upgraded certified EHR technology in the first payment year, the eligible hospital need not demonstrate that it is a meaningful EHR user until the second

payment year, as described in §495.6 and §495.8 of this subpart.

(c) *Review of meaningful use.* (1) CMS (and in the case of Medicaid EPs and eligible hospitals, States) may review an EP, eligible hospital or CAH's demonstration of meaningful use.

(2) All EPs, eligible hospitals, and CAHs must keep documentation supporting their demonstration of meaningful use for 6 years.

§495.10 Participation requirements for EPs, eligible hospitals, and CAHs.

(a) An eligible hospital, CAH or EP must submit in a manner specified by CMS the following information in the first payment year:

(1) Name of the EP, eligible hospital or CAH.

(2) National Provider Identifier (NPI).

(3) Business address and phone number.

(4) Such other information as specified by CMS.

(b) In addition to the information submitted under paragraph (a) of this section, an eligible hospital or CAH, must, in the first payment year, submit in a manner specified by CMS its CMS Certification Number (CCN) and its Taxpayer Identification Number (TIN).

(c) Subject to paragraph (f) of this section, in addition to the information submitted under paragraph (a) of this section, an EP must submit in a manner specified by CMS, the Taxpayer Identification Number (TIN) which may be the EP's Social Security Number (SSN) to which the EP's incentive payment should be made.

(d) In the event the information specified in paragraphs (a) through (c) of this section as previously submitted to CMS is no longer accurate, the EP, eligible hospital or CAH must provide updated information to CMS or the State on a timely basis in the manner specified by CMS or the State.

(e) An EP that qualifies as both a Medicaid EP and Medicare EP—

(1) Must notify CMS in the manner specified by CMS as to whether he or she elects to participate in the Medicare or the Medicaid EHR incentive program;

(2) After receiving at least one EHR incentive payment, may switch between the two EHR incentive programs only one time, and only for a payment year before 2015;

(3) Must, for each payment year, meet all of the applicable requirements, including applicable patient volume requirements, for the program in which he or she chooses to participate (Medicare or Medicaid);

(4) Is limited to receiving, in total, the maximum payments the EP would receive under the Medicaid EHR program, as described in subpart D of this part; and

(5) Is placed in the payment year the EP would have been in had the EP begun in and remained in the program to which he or she has switched. For example, an EP that begins receiving Medicaid incentive payments in 2011, and then switches to the Medicare program for 2012, is in his or her second payment year in 2012.

(f) *Limitations on incentive payment reassignments.* (1) EPs are permitted to reassign their incentive payments to their employer or to an entity with which they have a contractual arrangement allowing the employer or entity to bill and receive payment for the EP's covered professional services.

(2)(i) Assignments in Medicare must be consistent with Section 1842(b)(6)(A) of the Act and 42 CFR part 424 subpart F.

(ii) Medicaid EPs may also assign their incentive payments to a TIN for an entity promoting the adoption of EHR technology, consistent with subpart D of this part.

(3) Each EP may reassign the entire amount of the incentive payment to only one employer or entity.

Subpart B—Requirements Specific to the Medicare Program

§495.100 Definitions.

In this subpart unless otherwise indicated—

Covered professional services means (as specified in section 1848(k)(3) of the Act) services furnished by an EP for which payment is made under, or is based on, the Medicare physician fee schedule.

Eligible hospital means a hospital subject to the prospective payment system specified in § 412.1(a)(1) of this chapter, excluding those hospitals specified in § 412.23 of this chapter, and excluding those hospital units specified in § 412.25 of this chapter.

Eligible professional (EP) means a physician as defined in section 1861(r) of the Act, which includes, with certain limitations, all of the following types of professionals:

(1) A doctor of medicine or osteopathy.

(2) A doctor of dental surgery or medicine.

(3) A doctor of podiatric medicine.

(4) A doctor of optometry.

(5) A chiropractor.

Geographic health professional shortage area (HPSA) means a geographic area that is designated by the Secretary under section 332(a)(1)(A) of the PHS Act as of December 31 of the year prior to the payment year as having a shortage of health professionals.

Qualifying CAH means a CAH that is a meaningful EHR user for the EHR reporting period for a cost reporting period beginning during a payment year.

Qualifying eligible professional (qualifying EP) means an EP who is a meaningful EHR user for the EHR reporting period for a payment year and who is not a hospital-based EP, as determined for that payment year.

Qualifying hospital means an eligible hospital that is a meaningful EHR user for the EHR reporting period for a payment year.

§ 495.102 Incentive payments to EPs.

(a) *General rules.* (1) Subject to paragraph (b) of this section, in addition to the amount otherwise paid under section 1848 of the Act, there must be paid to a qualifying EP (or to an employer or entity in the cases described in section 1842(b)(6)(A) of the Act) for a payment year an amount equal to 75 percent of the estimated allowed charges for covered professional services furnished by the EP during the payment year.

(2) For purposes of this paragraph (a) of this section, the estimated allowed charges for the qualifying EP's covered professional services during the payment year are determined based on claims submitted no later than 2 months after the end of the payment year, and, in the case of a qualifying EP who furnishes covered professional services in more than one practice, are determined based on claims submitted for the EP's covered professional services across all such practices.

(b) *Limitations on amounts of incentive payments.*

(1) Except as otherwise provided in paragraphs (b)(2) and (c) of this section, the amount of the incentive payment under paragraph (a) of this section for each payment year is limited to the following amounts:

(i) For the first payment year, $15,000 (or, if the first payment year for such qualifying EP is 2011 or 2012, $18,000).

(ii) For the second payment year, $12,000.

(iii) For the third payment year, $8,000.

(iv) For the fourth payment year, $4,000.

(v) For the fifth payment year, $2,000.

(vi) For any succeeding payment year for such professional, $0.

(2)(i) If the first payment year for a qualifying EP is 2014, then the payment limit for a payment year for the qualifying EP is the same as the amount specified in paragraph (b)(1) of this section for such payment year for a qualifying EP whose first payment year is 2013.

(ii) If the first payment year for a qualifying EP is after 2014, then the payment limit specified in this paragraph for such EP for such year and any subsequent year is $0.

(c) *Increase in incentive payment limit for EPs who predominantly furnish services in a geographic HPSA.* In the case of a qualifying EP who in the year prior to the payment year furnishes more than 50 percent of his or her covered professional services in a geographic HPSA that is designated as of December 31 of such year, the incentive payment limit determined under paragraph (b) of this section is to be increased by 10 percent.

(d) *Payment adjustment effective in CY 2015 and subsequent years for nonqualifying EPs.*

(1) Subject to paragraph (d)(3) of this section, beginning in 2015, for covered professional services furnished by an

EP who is not a qualifying EP or a hospital-based EP for the year, the payment amount for such services is equal the product of the applicable percent specified in paragraph (d)(2) of this section and the Medicare physician fee schedule amount for such services.

(2) *Applicable percent.* Applicable percent is as follows:

(i) For 2015, 99 percent if the EP is not subject to the payment adjustment for an EP who is not a successful electronic prescriber under section 1848(a)(5) of the Act, or 98 percent if the EP is subject to the payment adjustment for an EP who is not a successful electronic prescriber under section 1848(a)(5) of the Act).

(ii) For 2016, 98 percent.

(iii) For 2017 and each subsequent year, 97 percent.

(3) *Significant hardship exception.* (i) The Secretary may, on a case-by-case basis, exempt an EP who is not a qualifying EP from the application of the payment adjustment under paragraph (d)(1) of this section if the Secretary determines that compliance with the requirement for being a meaningful EHR user would result in a significant hardship for the EP.

(ii) The Secretary's determination to grant an EP an exemption under paragraph (d)(3)(i) of this section may be renewed on an annual basis, provided that in no case may an EP be granted an exemption under paragraph (d)(3)(i) of this section for more than 5 years.

§ 495.104 Incentive payments to eligible hospitals.

(a) *General rule.* A qualifying hospital (as defined in this subpart) must receive the special incentive payment as determined under the formulas described in paragraph (c) of this section for the period specified in paragraph (b) of this section.

(b) *Transition periods.* Subject to paragraph (d) of this section and the payment formula specified in paragraph (c) of this section, qualifying hospitals may receive incentive payments during transition periods which comprise the following fiscal years:

(1) Hospitals whose first payment year is FY 2011 may receive such payments for FYs 2011 through 2014.

(2) Hospitals whose first payment year is FY 2012 may receive such payments for FYs 2012 through 2015.

(3) Hospitals whose first payment year is FY 2013 may receive such payments for FYs 2013 through 2016.

(4) Hospitals whose first payment year is FY 2014 may receive such payments for FY 2014 through 2016.

(5) Hospitals whose first payment year is FY 2015 may receive such payments for FY 2015 through 2016.

(c) *Payment methodology.* (1) The incentive payment for each payment year is calculated as the product of the following:

(i) The initial amount determined under paragraph (c)(3) of this section.

(ii) The Medicare share fraction determined under paragraph (c)(4) of this section.

(iii) The transition factor determined under paragraph (c)(5) of this section.

(2) *Interim and final payments.* CMS uses data on hospital acute care inpatient discharges, Medicare Part A acute care inpatient-bed-days, Medicare Part C acute care inpatient-bed-days, and total acute care inpatient-bed-days, from the latest submitted 12-month hospital cost report as the basis for making preliminary incentive payments. Final payments are determined at the time of settling the first 12-month hospital cost report for the hospital fiscal year that begins on or after the first day of the payment year, and settled on the basis of data from that cost reporting period.

(3) *Initial amount.* The initial amount is equal to one of the following:

(i) For each hospital with 1,149 acute care inpatient discharges or fewer, $2,000,000.

(ii) For each hospital with at least 1,150 but no more than 23,000 acute care inpatient discharges, $2,000,000 + [$200 × (n − 1,149)], where n is the number of discharges for the hospital.

(iii) For each hospital with more than 23,000 acute care inpatient discharges, $6,370,200.

(4) *Medicare share fraction*—(i) *General.* (A) CMS determines the Medicare share fraction for an eligible hospital by using the number of Medicare Part A, Medicare Part C, and total acute care inpatient-bed-days using data

from the Medicare cost report as specified by CMS.

(B) CMS computes the denominator of the Medicare share fraction using the charity care charges reported on the hospital's Medicare cost report.

(ii) The Medicare share fraction is the ratio of—

(A) A numerator which is the sum of—

(*1*) The number of inpatient-bed-days which are attributable to individuals with respect to whom payment may be made under Part A, including individuals enrolled in section 1876 Medicare cost plans; and

(*2*) The number of inpatient-bed-days which are attributable to individuals who are enrolled with a Medicare Advantage organization (as defined in § 422.2 of this chapter).

(B) A denominator which is the product of—

(1) The total number of acute care inpatient-bed-days; and

(2) The total amount of the eligible hospital's charges, not including any charges that are attributable to charity care, divided by the estimated total amount of the hospitals charges.

(5) *Transition factor*. For purposes of the payment formula, the transition factor is as follows:

(i) For hospitals whose first payment year is FY 2011—

(A) 1 for FY 2011;

(B) ¾ for FY 2012;

(C) ½ for FY 2013; and

(D) ¼ for FY 2014.

(ii) For hospitals whose first payment year is FY 2012—

(A) 1 for FY 2012;

(B) ¾ for FY 2013;

(C) ½ for FY 2014; and

(D) ¼ for FY 2015;

(iii) For hospitals whose first payment year is FY 2013—

(A) 1 for FY 2013;

(B) ¾ for FY 2014;

(C) ½ for FY 2015; and

(D) ¼ for FY 2016.

(iv) For hospitals whose first payment year is FY 2014—

(A) ¾ for FY 2014;

(B) ½ for FY 2015; and

(C) ¼ for FY 2016.

(v) For hospitals whose first payment year is FY 2015—

(A) ½ for FY 2015; and

(B) ¼ for FY 2016.

(d) No incentive payment for nonqualifying hospitals. After the first payment year, an eligible hospital will not receive an incentive payment for any payment year during which it is not a qualifying hospital.

§ 495.106 Incentive payments to CAHs.

(a) *Definitions*. In this section, unless otherwise indicated—

Payment year means a Federal fiscal year beginning after FY 2010 but before FY 2016.

Qualifying CAH means a CAH that would meet the definition of a meaningful EHR user at § 495.4, if it were an eligible hospital.

Reasonable costs incurred for the purchase of certified EHR technology for a qualifying CAH means the reasonable acquisition costs incurred for the purchase of depreciable assets as described in part 413 subpart G of this chapter, such as computers and associated hardware and software, necessary to administer certified EHR technology as defined in § 495.4, excluding any depreciation and interest expenses associated with the acquisition.

(b) *General rule*. A qualifying CAH receives an incentive payment for its reasonable costs incurred for the purchase of certified EHR technology, as defined in paragraph (a) of this section, in the manner described in paragraph (c) of this section for a cost reporting period beginning during a payment year as defined in paragraph (a) of this section.

(c) *Payment methodology*. (1) *Payment amount*. A qualifying CAH receives an incentive payment amount equal to the product of its reasonable costs incurred for the purchase of certified EHR technology and the Medicare share percentage.

(2) *Calculation of reasonable costs*. CMS or its Medicare contractor computes a qualifying CAH's reasonable costs incurred for the purchase of certified EHR technology, as defined in paragraph (a) of this section, as the sum of—

(i) The reasonable costs incurred for the purchase of certified EHR technology during the cost reporting period that begins in a payment year; and

(ii) Any reasonable costs incurred for the purchase of certified EHR technology in cost reporting periods beginning in years prior to the payment year which have not been fully depreciated as of the cost reporting period beginning in the payment year.

(3) *Medicare share percentage.* Notwithstanding the percentage applicable under §413.70(a)(1) of this chapter, the Medicare share percentage equals the lesser of—

(i) 100 percent; or

(ii) The sum of the Medicare share fraction for the CAH as calculated under §495.104(c)(4) of this subpart and 20 percentage points.

(d) *Incentive payments made to CAHs.* (1) The amount of the incentive payment made to a qualifying CAH under this section represents the expensing and payment of the reasonable costs computed in paragraph (c) of this section in a single payment year and, as specified in §413.70(a)(5) of this chapter, such payment is made in lieu of payment that would have been made under §413.70(a)(1) of this chapter for the reasonable costs of the purchase of certified EHR technology including depreciation and interest expenses associated with the acquisition.

(2) The amount of the incentive payment made to a qualifying CAH under this section is paid through a prompt interim payment for the applicable payment year after—

(i) The CAH submits the necessary documentation, as specified by CMS or its Medicare contractors, to support the computation of the incentive payment amount under this section; and

(ii) CMS or its Medicare contractor reviews such documentation and determines the interim amount of the incentive payment.

(3) The interim incentive payment made under this paragraph is subject to a reconciliation process as specified by CMS and the final incentive payment as determined by CMS or its Medicare contractor is considered payment in full for the reasonable costs incurred for the purchase of certified EHR technology in a single payment year.

(4) In no case may an incentive payment be made with respect to a cost reporting period beginning during a payment year before FY 2011 or after FY 2015 and in no case may a CAH receive an incentive payment under this section with respect to more than 4 consecutive payment years.

(e) *Reductions in payment to CAHs.* For cost reporting periods beginning in FY 2015, if a CAH is not a qualifying CAH for a payment year, then the payment for inpatient services furnished by a CAH under §413.70(a) of this chapter is adjusted by the applicable percentage described in §413.70(a)(6) of this chapter unless otherwise exempt from such adjustment.

(f) *Administrative or judicial review.* There is no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the—

(1) Methodology and standards for determining the amount of payment, the reasonable cost, and adjustments described in this section including selection of periods for determining, and making estimates or using proxies of, inpatient-bed-days, hospital charges, charity charges, and the Medicare share percentage as described in this section;

(2) Methodology and standards for determining if a CAH is a qualifying CAH under this section;

(3) Specification of EHR reporting periods, cost reporting periods, payment years, and fiscal years used to compute the CAH incentive payment as specified in this section; and

(4) Identification of the reasonable costs used to compute the CAH incentive payment under paragraph (c) of this section including any reconciliation of the CAH incentive payment amount made under paragraph (d) of this section.

§495.108 Posting of required information.

(a) CMS posts, on its Internet Web site, the following information regarding EPs, eligible hospitals, and CAHs receiving an incentive payment under subparts B and C of this part:

(1) Name.

(2) Business addressee.

(3) Business phone number.

(4) Such other information as specified by CMS.

(b) CMS posts, on its Internet Web site, the following information for

qualifying MA organizations that receive an incentive payment under subpart C of this part—

(1) The information specified in paragraph (a) of this section for each of the qualifying MA organization's MA plan information; and

(2) The information specified in paragraph (a) of this section for each of the qualifying MA organization's MA EPs and MA-affiliated eligible hospitals.

§ 495.110 Preclusion on administrative and judicial review.

There is no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the following:

(a) For EPs—

(1) The methodology and standards for determining EP incentive payment amounts;

(2) The methodology and standards for determining the payment adjustments that apply to EPs beginning with 2015;

(3) The methodology and standards for determining whether an EP is a meaningful EHR user, including—

(i) The selection of clinical quality measures; and

(ii) The means of demonstrating meaningful EHR use.

(4) The methodology and standards for determining the hardship exception to the payment adjustments;

(5) The methodology and standards for determining whether an EP is hospital-based; and

(6) The specification of the EHR reporting period, as well as whether payment will be made only once, in a single consolidated payment, or in periodic installments.

(b) For eligible hospitals—

(1) The methodology and standards for determining the incentive payment amounts made to eligible hospitals, including—

(i) The estimates or proxies for determining discharges, inpatient-bed-days, hospital charges, charity charges, and Medicare share; and

(ii) The period used to determine such estimate or proxy;

(2) The methodology and standards for determining the payment adjustments that apply to eligible hospitals beginning with FY 2015;

(3) The methodology and standards for determining whether an eligible hospital is a meaningful EHR user, including—

(i) The selection of clinical quality measures; and

(ii) The means of demonstrating meaningful EHR use.

(4) The methodology and standards for determining the hardship exception to the payment adjustments; and

(5) The specification of the EHR reporting period, as well as whether payment will be made only once, in a single consolidated payment, or in periodic installments.

Subpart C—Requirements Specific to Medicare Advantage (MA) Organizations

§ 495.200 Definitions.

As used in this subpart:

First payment year means with respect to—

(1) Covered professional services furnished by a qualifying MA EP, the first calendar year for which an incentive payment is made for such services under this subsection to a qualifying MA organization.

(2) Qualifying MA-affiliated eligible hospitals, the first fiscal year for which an incentive payment is made for qualifying MA-affiliated eligible hospitals under this section to a qualifying MA organization.

Inpatient-bed-days is defined in the same manner and is used in the same manner as that term is defined and used for purposes of implementing section 4201(a) of the American Recovery and Reinvestment Act of 2009 with respect to the Medicare FFS hospital EHR incentive program in § 495.104 of this part.

Patient care services means health care services for which payment would be made under, or for which payment would be based on, the fee schedule established under Medicare Part B if they were furnished by an EP to a Medicare beneficiary.

Payment year means—

(1) For a qualifying MA EP, a calendar year (CY) beginning with CY 2011 and ending with CY 2016; and

(2) For an eligible hospital, a Federal fiscal year (FY) beginning with FY 2011 and ending with FY 2016.

Qualifying MA-affiliated eligible hospital means an eligible hospital under section 1886(n)(6) of the Act that is under common corporate governance with a qualifying MA organization, for which at least two thirds of the Medicare hospital discharges (or bed-days) are of (or for) Medicare individuals enrolled under MA plans, and that is a meaningful user of certified EHR technology as defined by § 495.4 of this part. In the case of a hospital for which at least one-third of whose Medicare bed-days for the year are covered under Part A rather than Part C, payment for that payment year must only be made under section 1886(n) of the Act and not under this section.

Qualifying MA EP means all of the following:

(1) A physician (as described in section 1861(r) of the Act), including a doctor of medicine or osteopathy who is either of the following:

(i) Employed by a qualifying MA organization.

(ii) Employed by, or is a partner of, an entity that through a contract with a qualifying MA organization furnishes at least 80 percent of the entity's Medicare patient care services to enrollees of such organization.

(2) Furnishes at least 80 percent of his or her professional services covered under Title XVIII to enrollees of the qualifying MA organization.

(3) Furnishes, on average, at least 20 hours per week of patient care services to enrollees of the qualifying MA organization during the EHR reporting period.

(4) Is a meaningful user of certified EHR technology in accordance with § 495.4 of this part.

(5) Is not a ''hospital-based EP'' as that term is defined in § 495.4 of this Part.

Qualifying MA organization means a MA organization that is organized as a health maintenance organization (HMO) as defined in section 2791(b)(3) of the Public Health Service (PHS) Act which includes a Federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as an HMO.

Second, third, fourth, and fifth payment year means with respect to incentive payments for qualifying—

(1) MA EPs to a qualifying MA organization, each successive calendar year immediately following the first payment year for the qualifying MA organization. The first payment year and each successive year immediately following the first payment year, for the qualifying MA organizations, through 2016, is the same for all qualifying MA EPs with respect to any specific qualifying MA organization.

(2) MA-affiliated eligible hospitals to a qualifying MA organization, each successive fiscal year immediately following the first payment year for the qualifying MA organization.

Under common corporate governance means that a qualifying MA organization and a qualifying MA-affiliated eligible hospital have a common parent corporation, that one is a subsidiary of the other, or that the organization and the hospital have a common board of directors.

§ 495.202 Identification of qualifying MA organizations, MA–EPs and MA-affiliated eligible hospitals.

(a) *Identification of qualifying MA organizations.* (1) Beginning with bids due in June 2011 (for plan year 2012), MA organizations seeking reimbursement for qualifying MA EPs and qualifying MA-affiliated eligible hospitals under the MA EHR incentive program are required to identify themselves to CMS in a form and manner specified by CMS, as part of submissions of initial bids under section 1854(a)(1)(A) of the Act.

(2) Qualifying MA organizations offering MA HMO plans, absent evidence to the contrary, are deemed to meet the definition of HMO in 42 U.S.C. 300gg–91(b)(3)—section 2791(b)(3) of the PHS Act.

(3) Qualifying MA organizations offering MA plan types other than HMOs, must attest to the fact that they meet the definition of HMO in 42 U.S.C. 300gg–91(b)(3)—section 2791(b)(3) of the PHS Act.

(4) Beginning with bids due in June 2014 (for plan year 2015), all MA organizations with potentially qualifying MA EPs or potentially qualifying MA-affiliated eligible hospitals under the MA EHR incentive program must identify themselves to CMS in a form and manner specified by CMS, as part of submissions of initial bids under section 1854(a)(1)(A) of the Act. ''Potentially qualifying MA EPs'' and ''potentially qualifying MA-affiliated eligible hospitals'' are those EPs and hospitals that meet the respective definitions of ''qualifying MA EP'' and ''qualifying MA-affiliated eligible hospital'' in § 495.200 but who (or which) are not meaningful users of certified EHR technology.

(b) *Identification of qualifying MA EPs and qualifying MA-affiliated eligible hospitals.*

(1) A qualifying MA organization, as part of its initial bid starting with plan year 2012, must make a preliminary identification of potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals for which the organization is seeking incentive payments for the current plan year.

(2) A qualifying MA organization must provide CMS with the following for each MA EP or eligible hospital when reporting under either paragraph (b)(1) or (b)(3) of this section:

(i) The MA EP's or MA-affiliated eligible hospital's name.

(ii) The address of the MA EP's practice or MA-affiliated eligible hospital's location.

(iii) NPI.

(iv) An attestation by MA organization specifying that the MA EP or MA-affiliated eligible hospital meets the eligibility criteria.

(3) Final identification of potentially qualifying MA EP or MA-affiliated eligible hospital must be made within 60 days of the close of the payment year as defined in § 495.200 for which MA EHR incentive payments are being sought.

(4) Beginning plan year 2015 and for subsequent plan years, all qualifying MA organizations, as part of their initial bids in June for the following plan year must—

(i) Identify potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals;

(ii) Include information specified in paragraph (b)(2)(i)(A) through (C) of this section for each professional and hospital.

(iii) Include an attestation that each professional and hospital either meets or does not meet the EHR incentive payment eligibility criteria.

§ 495.204 Incentive payments to qualifying MA organizations for MA–EPs and MA-affiliated eligible hospitals.

(a) *General rule.* A qualifying MA organization receives an incentive payment for its qualifying MA–EPs and its qualifying MA-eligible hospitals. The incentive payment amount paid to a qualifying MA organization for a—

(1) Qualifying MA–EP is the amount determined under paragraph (b) of this section; and

(2) Qualifying MA-eligible hospital is the amount determined under paragraph (c) of this section.

(b) *Amount payable to qualifying MA organization for qualifying MA EPs.*

(1) CMS substitutes an amount determined to be equivalent to the amount computed under § 495.102 of this part.

(2) The qualifying MA organization must report to CMS within 60 days of the close of the calendar year, the aggregate annual amount of revenue attributable to providing services that would otherwise be covered as professional services under Part B received by each qualifying MA EP for enrollees in MA plans of the MA organization in the payment year.

(3) CMS calculates the incentive amount for the MA organization for each qualifying MA EP as an amount equal to 75 percent of the reported annual revenue specified in paragraph (b)(2) of this section, up to the maximum amounts specified under section 1848(o)(1)(B) of the Act.

(4) For qualifying MA EPs who are compensated on a salaried basis, CMS requires the qualifying MA organization to develop a methodology for estimating the portion of each qualifying MA EP's salary attributable to providing services that would otherwise be covered as professional services under Part B to MA plan enrollees of the MA

organization in the payment year. The methodology—

(i) Must be approved by CMS; and

(ii) May include an additional amount related to overhead, where appropriate, estimated to account for the MA-enrollee related Part B practice costs of the salaried qualifying MA EP.

(iii) Methodological proposals must be submitted to CMS by June of the payment year and must be auditable by an independent third-party. CMS will review and approve or disapprove such proposals in a timely manner.

(5) For qualifying MA EPs who are not salaried, qualifying MA organizations may obtain attestations from such qualifying MA EPs (or from entities that the MA EPs are employed by or with which they have a partnership interest) as to the amount of compensation received by such EPs for MA plan enrollees of the MA organization. The organizations may submit to CMS compensation information for each such MA EP based on such attestations.

(6) For qualifying MA EPs who are not salaried, qualified MA organizations may have qualifying MA EPs (or from entities that the MA EPs are employed by or with which they have a partnership interest) send MA organization compensation information directly to CMS. CMS will use the information provided in this subparagraph or paragraph (b)(5) of this section for no other purpose than to compute the amount of EHR incentive payment due the MA organization.

(c) *Amount payable to qualifying MA organization for qualifying MA-affiliated eligible hospitals.* (1)(i) CMS substitutes an amount determined to be equivalent to the amount computed under § 495.104, to the extent data are not available to compute payments for qualifying MA-affiliated eligible hospitals under the Medicare FFS EHR hospital incentive program.

(ii) CMS uses the same methodology and defines ''inpatient-bed-days''and other terms as used under the Medicare FFS EHR hospital incentive program in § 495.104 of this part in computing amounts due qualifying MA organizations for MA-affiliated eligible hospitals.

(2) To the extent data are available, qualifying MA organizations must receive hospital incentive payments through their affiliated hospitals under the Medicare FFS EHR hospital incentive program, rather than through the MA EHR hospital incentive program.

(d) *Payment to qualifying MA organizations.* CMS makes payment to qualifying MA organizations for qualifying MA EPs only under the MA EHR incentive program and not under the Medicare FFS EHR incentive program to the extent an EP has earned less than the maximum incentive payment for the same period under the Medicare FFS EHR incentive program.

(e) *Payment review under MA.* To ensure the accuracy of the incentive payments, CMS conducts selected compliance reviews of qualifying MA organizations to ensure that EPs and eligible hospitals for which such qualifying organizations received incentive payments were meaningful EHR users in accordance with § 422.504 of this chapter.

(1) The reviews include validation of the status of the organization as a qualifying MA organization, verification of meaningful use and review of data used to calculate incentive payments.

(2) MA organizations are required to maintain evidence of their qualification to receive incentive payments and the data necessary to accurately calculate incentive payments.

(3) Documents and records must be maintained for 6 years from the date such payments are made with respect to a given payment year.

(4) Payments that result from incorrect or fraudulent attestations, cost data, or any other submission required to establish eligibility or to qualify for such payment, will be recouped by CMS from the MA organization.

§ 495.206 Timeframe for payment to qualifying MA organizations.

(a) CMS makes payment to qualifying MA organizations for qualifying MA EPs under the MA EHR incentive program after computing incentive payments due under the Medicare FFS EHR incentive program according to § 495.102.

(b) Payments to qualifying MA organizations for qualifying MA-affiliated eligible hospitals under common corporate governance are made under the Medicare FFS EHR incentive program, following the timeline in specified in § 495.104 of this part. To the extent sufficient data do not exist to pay qualifying MA-affiliated eligible hospitals under common corporate governance under the Medicare FFS EHR incentive program, payment is made under the MA EHR incentive program, following the same timeline in § 495.104 of this part.

§ 495.208 Avoiding duplicate payment.

(a) Unless a qualifying MA EP is entitled to a maximum payment for a year under the Medicare FFS EHR incentive program, payment for such an individual is only made under the MA EHR incentive program to a qualifying MA organization.

(b) Payment to qualifying MA organizations for a qualifying MA-affiliated eligible hospital under common governance only occurs under the MA EHR incentive program to the extent that sufficient data does not exist to pay such hospital under the Medicare FFS hospital incentive program under § 495.104 of this part. In no event are EHR incentive payments made for a hospital for a payment year under this section to the extent they have been made for the same hospital for the same payment year under § 495.104 of this part.

(c) Each qualifying MA organization must ensure that all potentially qualifying MA EPs are enumerated through the NPI system and that other identifying information required under § 495.202(b) is provided to CMS.

§ 495.210 Meaningful EHR user attestation.

(a) Qualifying MA organizations are required to attest, in a form and manner specified by CMS, that each qualifying MA EP and qualifying MA-affiliated eligible hospitals is a meaningful EHR user.

(b) Qualifying MA organizations are required to attest within 60 days after the close of a calendar year whether each qualifying MA EP is a meaningful EHR user.

(c) Qualifying MA organizations are required to attest within 60 days after close of the FY whether each qualifying MA-affiliated eligible hospital is a meaningful EHR user.

§ 495.212 Limitation on review.

(a) There is no administrative or judicial review under section 1869 or 1878 of the Act, or otherwise of the methodology and standards for determining payment amounts and payment adjustments under the MA EHR EP incentive program. This includes provisions related to duplication of payment avoidance and rules developed related to the fixed schedule for application of limitation on incentive payments for all qualifying MA EPs related to a specific qualifying MA organization. It also includes the methodology and standards developed for determining qualifying MA EPs and the methodology and standards for determining a meaningful EHR user, including the means of demonstrating meaningful use and the selection of measures.

(b) There is no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the methodology and standards for determining payment amounts and payment adjustments under the MA EHR hospital incentive program. This includes provisions related to duplication of payment avoidance. It also includes the methodology and standards developed for determining qualifying MA-affiliated eligible hospitals and the methodology and standards for determining a meaningful EHR user, including the means of demonstrating meaningful use and the selection of measures.

Subpart D—Requirements Specific to the Medicaid Program

§ 495.300 Basis and purpose.

This subpart implements section 4201 of the American Reinvestment and Recovery Act of 2009 and sections 1903(a)(3)(F) and 1903(t) of the Act, which authorize States, at their option, to provide for incentive payments to Medicaid providers for adopting, implementing, or upgrading certified EHR technology or for meaningful use of

such technology. This subpart also provides enhanced Federal financial participation (FFP) to States to administer these incentive payments.

§ 495.302 Definitions.

As used in this subpart—

Acceptance documents mean written evidence of satisfactory completion of an approved phase of work or contract and acceptance thereof by the State agency.

Acquisition means to acquire health information technology (HIT) equipment or services for the purpose of implementation and administration under this part from commercial sources or from State or local government resources.

Acute care hospital means a health care facility—

(1) Where the average length of patient stay is 25 days or fewer; and

(2) With a CMS certification number (previously known as the Medicare provider number) that has the last four digits in the series 0001–0879 or 1300–1399

Adopt, implement or upgrade means—

(1) Acquire, purchase, or secure access to certified EHR technology;

(2) Install or commence utilization of certified EHR technology capable of meeting meaningful use requirements; or

(3) Expand the available functionality of certified EHR technology capable of meeting meaningful use requirements at the practice site, including staffing, maintenance, and training, or upgrade from existing EHR technology to certified EHR technology per the ONC EHR certification criteria.

Children's hospital means a separately certified children's hospital, either freestanding or hospital-within-hospital that—

(1) Has a CMS certification number, (previously known as the Medicare provider number), that has the last 4 digits in the series 3300–3399; and

(2) Predominantly treats individuals under 21 years of age.

Entities promoting the adoption of certified electronic health record technology means the State-designated entities that are promoting the adoption of certified EHR technology by enabling oversight of the business, operational and legal issues involved in the adoption and implementation of certified EHR technology or by enabling the exchange and use of electronic clinical and administrative data between participating providers, in a secure manner, including maintaining the physical and organizational relationship integral to the adoption of certified EHR technology by eligible providers.

Health information technology planning advance planning document (HIT PAPD) means a plan of action that requests FFP and approval to accomplish the planning necessary for a State agency to determine the need for and plan the acquisition of HIT equipment or services or both and to acquire information necessary to prepare a HIT implementation advanced planning document or request for proposal to implement the State Medicaid HIT plan.

HIT implementation advance planning document (HIT IAPD) means a plan of action that requests FFP and approval to acquire and implement the proposed State Medicaid HIT plan services or equipment or both.

Medicaid information technology architecture (MITA) is both an initiative and a framework. It is a national framework to support improved systems development and health care management for the Medicaid enterprise. It is an initiative to establish national guidelines for technologies and processes that enable improved program administration for the Medicaid enterprise. The MITA initiative includes an architecture framework, models, processes, and planning guidelines for enabling State Medicaid enterprises to meet common objectives with the framework while supporting unique local needs.

Medicaid management information system (MMIS) means a mechanized claims processing and information retrieval system—referred to as Medicaid Management Information Systems (MMIS)—that meets specified requirements and that the Department has found (among other things) is compatible with the claims processing and information retrieval systems used in the administration of the Medicare program. The objectives of the MMIS are to include claims processing and retrieval of utilization and management

information necessary for program administration and audit and must coordinate with other mechanized systems and subsystems that perform other functions, such as eligibility determination.

Needy individuals mean individuals that meet one of following:

(1) Received medical assistance from Medicaid or the Children's Health Insurance Program. (or a Medicaid or CHIP demonstration project approved under section 1115 of the Act).

(2) Were furnished uncompensated care by the provider.

(3) Were furnished services at either no cost or reduced cost based on a sliding scale determined by the individuals' ability to pay.

Patient volume means the minimum participation threshold (as described at § 495.304(c) through (e)) that is estimated through a numerator and denominator, consistent with the SMHP, and that meets the requirements of § 495.306.

Practices predominantly means an EP for whom the clinical location for over 50 percent of his or her total patient encounters over a period of 6 months in the most recent calendar year occurs at a federally qualified health center or rural health clinic.

Service oriented architecture or service component based architecture means organizing and developing information technology capabilities as collaborating services that interact with each other based on open standards.

State Medicaid health information technology plan (SMHP) means a document that describes the State's current and future HIT activities.

State self-assessment means a process that a State uses to review its strategic goals and objectives, measure its current business processes and capabilities against the (MITA) business capabilities and ultimately develops target capabilities to transform its Medicaid enterprise to be consistent with the MITA principles.

§ 495.304 Medicaid provider scope and eligibility.

(a) *General rule*. The following Medicaid providers are eligible to participate in the HIT incentives program:

(1) Medicaid EPs.

(2) Acute care hospitals.

(3) Children's hospitals.

(b) *Medicaid EP*. The Medicaid professional eligible for an EHR incentive payment is limited to the following when consistent with the scope of practice regulations, as applicable for each professional (§ 440.50, § 440.60, § 440.100; § 440.165, and § 440.166):

(1) A physician.

(2) A dentist.

(3) A certified nurse-midwife.

(4) A nurse practitioner.

(5) A physician assistant practicing in a Federally qualified health center (FQHC) led by a physician assistant or a rural health clinic (RHC), that is so led by a physician assistant.

(c) *Additional requirements for the Medicaid EP*. To qualify for an EHR incentive payment, a Medicaid EP must, for each year for which the EP seeks an EHR incentive payment, not be hospital-based as defined at § 495.4 of this subpart, and meet one of the following criteria:

(1) Have a minimum 30 percent patient volume attributable to individuals receiving Medicaid.

(2) Have a minimum 20 percent patient volume attributable to individuals receiving Medicaid, and be a pediatrician.

(3) Practice predominantly in a FQHC or RHC and have a minimum 30 percent patient volume attributable to needy individuals, as defined at § 495.302.

(d) *Exception*. The hospital-based exclusion in paragraph (c) of this section does not apply to the Medicaid-EP qualifying based on practicing predominantly at a FQHC or RHC.

(e) *Additional requirement for the eligible hospital*. To be eligible for an EHR incentive payment for each year for which the eligible hospital seeks an EHR incentive payment, the eligible hospital must meet the following criteria:

(1) An acute care hospital must have at least a 10 percent Medicaid patient volume for each year for which the hospital seeks an EHR incentive payment.

(2) A children's hospital is exempt from meeting a patient volume threshold.

§ 495.306 Establishing patient volume.

(a) *General rule.* A Medicaid provider must annually meet patient volume requirements of § 495.304, as these requirements are established through the State's SMHP in accordance with the remainder of this section.

(b) *State option(s) through SMHP.* A State must submit through the SMHP the option or options it has selected for measuring patient volume. A State must select the methodology described in either paragraph (c) or paragraph (d) of section (or both methodologies). In addition, or as an alternative, a State may select the methodology described in paragraph (g) of this section.

(c) *Methodology, patient encounter.*

(1) *EPs.* To calculate Medicaid patient volume, an EP must divide:

(*i*) The total Medicaid patient encounters in any representative, continuous 90-day period in the preceding calendar year; by

(*ii*) The total patient encounters in the same 90-day period.

(2) *Eligible hospitals.* To calculate Medicaid patient volume, an eligible hospital must divide—

(i) The total Medicaid encounters in any representative, continuous 90-day period in the preceding fiscal year; by

(ii) The total encounters in the same 90-day period.

(3) *Needy individual patient volume.* To calculate needy individual patient volume, an EP must divide—

(*i*) The total needy individual patient encounters in any representative, continuous 90-day period in the preceding calendar year; by

(ii) The total patient encounters in the same 90-day period.

(d) *Methodology, patient panel.*

(1) *EPs.* To calculate Medicaid patient volume, an EP must divide:

(i) (A) The total Medicaid patients assigned to the EP's panel in any representative, continuous 90-day period in the preceding calendar year when at least one Medicaid encounter took place with the Medicaid patient in the year prior to the 90-day period; plus

(B) Unduplicated Medicaid encounters in the same 90-day period; by

(ii)(A) The total patients assigned to the provider in that same 90-day period with at least one encounter taking place with the patient during the year prior to the 90-day period; plus

(B) All unduplicated patient encounters in the same 90-day period.

(2) *Needy individual patient volume.* To calculate needy individual patient volume an EP must divide—

(i)(A) The total Needy Individual patients assigned to the EP's panel in any representative, continuous 90-day period in the preceding calendar year when at least one Needy Individual encounter took place with the Medicaid patient in the year prior to the 90-day period; plus

(B) Unduplicated Needy Individual encounters in the same 90-day period, by

(ii)(A) The total patients assigned to the provider in that same 90-day period with at least one encounter taking place with the patient during the year prior to the 90-day period, plus

(B) All unduplicated patient encounters in the same 90-day period.

(e) For purposes of this section, the following rules apply:

(1) For purposes of calculating EP patient volume, a Medicaid encounter means services rendered to an individual on any one day where—

(i) Medicaid (or a Medicaid demonstration project approved under section 1115 of the Act) paid for part or all of the service; or

(ii) Medicaid (or a Medicaid demonstration project approved under section 1115 of the Act) paid all or part of the individual's premiums, co-payments, and cost-sharing.

(2) For purposes of calculating hospital patient volume, both of the following definitions in paragraphs (e)(2)(i) and (e)(2)(ii) of this section may apply:

(i) A Medicaid encounter means services rendered to an individual per inpatient discharge where—

(A) Medicaid (or a Medicaid demonstration project approved under section 1115 of the Act) paid for part or all of the service; or

(B) Medicaid (or a Medicaid demonstration project approved under section 1115 of the Act) paid all or part of the individual's premiums, co-payments, and/or cost-sharing.

(ii) A Medicaid encounter means services rendered in an emergency department on any one day where—

(A) Medicaid (or a Medicaid demonstration project approved under section 1115 of the Act) paid for part or all of the service; or

(B) Medicaid (or a Medicaid demonstration project approved under section 1115 of the Act) paid all or part of the individual's premiums, co-payments, and cost-sharing.

(3) For purposes of calculating needy individual patient volume, a needy patient encounter means services rendered to an individual on any one day where—

(i) Medicaid or CHIP (or a Medicaid or CHIP demonstration project approved under section 1115 of the Act) paid for part or all of the service;

(ii) Medicaid or CHIP (or a Medicaid or CHIP demonstration project approved under section 1115 of the Act) paid all or part of the individual's premiums, co-payments, or cost-sharing;

(iii) The services were furnished at no cost; and calculated consistent with § 495.310(h); or

(iv) The services were paid for at a reduced cost based on a sliding scale determined by the individual's ability to pay.

(f) *Exception*. A children's hospital is not required to meet Medicaid patient volume requirements.

(g) *Establishing an alternative methodology*. A State may submit to CMS for review and approval through the SMHP an alternative from the options included in paragraphs (c) and (d) of this section, so long as it meets the following requirements:

(1) It is submitted consistent with all rules governing the SMHP at § 495.332.

(2) Has an auditable data source.

(3) Has received input from the relevant stakeholder group.

(4) It does not result, in the aggregate, in fewer providers becoming eligible than the methodologies in either paragraphs (c) and (d) of this section.

(h) *Group practices*. Clinics or group practices will be permitted to calculate patient volume at the group practice/clinic level, but only in accordance with all of the following limitations:

(1) The clinic or group practice's patient volume is appropriate as a patient volume methodology calculation for the EP.

(2) There is an auditable data source to support the clinic's or group practice's patient volume determination.

(3) All EPs in the group practice or clinic must use the same methodology for the payment year.

(4) The clinic or group practice uses the entire practice or clinic's patient volume and does not limit patient volume in any way.

(5) If an EP works inside and outside of the clinic or practice, then the patient volume calculation includes only those encounters associated with the clinic or group practice, and not the EP's outside encounters.

§ 495.308 Net average allowable costs as the basis for determining the incentive payment.

(a) *The first year of payment*. (1) The incentive is intended to offset the costs associated with the initial adoption, implementation or upgrade of certified electronic health records technology.

(2) The maximum net average allowable costs for the first year are $25,000.

(b) *Subsequent payment years*. (1) The incentive is intended to offset maintenance and operation of certified EHR technology.

(2) The maximum net average allowable costs for each subsequent year are $10,000.

§ 495.310 Medicaid provider incentive payments.

(a) *Rules for Medicaid EPs*. The Medicaid EP's incentive payments are subject to all of the following limitations:

(1) *First payment year*. (i) For the first payment year, payment under this subpart may not exceed 85 percent of the maximum threshold of $25,000, which equals $21,250.

(ii) Medicaid EPs are responsible for payment for the remaining 15 percent of the net average allowable cost of certified EHR technology, or $3,750 for the first payment year.

(iii) An EP may not begin receiving payments any later than CY 2016.

(2) *Subsequent annual payment years*.

(i) For subsequent payment years, payment may not exceed 85 percent of the maximum threshold of $10,000, which equals $8,500.

(ii) Medicaid EPs are responsible for payment for the remaining 15 percent of the net average allowable cost of certified EHR technology, or $1,500 per payment year.

(iii) Payments after the first payment year may continue for a maximum of 5 years.

(iv) Medicaid EPs may receive payments on a non-consecutive, annual basis.

(v) No payments may be made after CY 2021.

(3) *Maximum incentives*. In no case may a Medicaid EP participate for more than a total of 6 years, and in no case will the maximum incentive over a 6-year period exceed $63,750.

(4) *Limitation*. For a Medicaid EP who is a pediatrician described in paragraph (b) of this section payment is limited as follows:

(i) The maximum payment in the first payment year is further reduced by two-thirds, which equals $14,167.

(ii) The maximum payment in subsequent payment years is further reduced by two-thirds, which equals $5,667.

(iii) In no case will the maximum incentive payment to a pediatrician under this limitation exceed $42,500 over a 6-year period.

(b) *Optional exception for pediatricians*. A pediatrician described in this paragraph is a Medicaid EP who does not meet the 30 percent patient volume requirements described in §495.304 and §495.306, but who meets the 20 percent patient volume requirements described in such sections.

(c) *Limitation to only one EHR incentive program*. An EP may only receive an incentive payment from either Medicare or Medicaid in a payment year, but not both.

(d) *Exception for EPs to switch programs*. An EP may change his or her EHR incentive payment program election once, consistent with §495.10 of this part.

(e) *Limitation to one State only*. A Medicaid EP or eligible hospital may receive an incentive payment from only one State in a payment year.

(f) *Incentive payments to hospitals*. Incentive payments to an eligible hospital under this subpart are subject to all of the following conditions:

(1) The payment is provided over a minimum of a 3-year period and maximum of a 6-year period.

(2) The total incentive payment received over all payment years of the program is not greater than the aggregate EHR incentive amount, as calculated under paragraph (g) of this section.

(3) No single incentive payment for a payment year may exceed 50 percent of the aggregate EHR hospital incentive amount calculated under paragraph (g) of this section for an individual hospital.

(4) No incentive payments over a 2-year period may exceed 90 percent of the aggregate EHR hospital incentive amount calculated under paragraph (g) of this section for an individual hospital.

(5) No hospital may begin receiving incentive payments for any year after FY 2016, and after FY 2016, a hospital may not receive an incentive payment unless it received an incentive payment in the prior fiscal year.

(6) Prior to FY 2016, payments can be made to an eligible hospital on a non-consecutive, annual basis for the fiscal year.

(7) A multi-site hospital with one CMS Certification Number is considered one hospital for purposes of calculating payment.

(g) *Calculation of the aggregate EHR hospital incentive amount*. The aggregate EHR hospital incentive amount is calculated as the product of the (overall EHR amount) times (the Medicaid Share).

(1) *Overall EHR amount*. The overall EHR amount for an eligible hospital is based upon a theoretical 4 years of payment the hospital would receive based, for each of such 4 years, upon the product of the following:

(i) *Initial amount*. The initial amount is equal to the sum of—

(A) The base amount which is set at $2,000,000 for each of the theoretical 4 years; plus

(B) The discharge-related amount for a 12-month period selected by the State, but ending in the Federal fiscal year before the hospital's fiscal year that serves as the first payment year. The discharge-related amount is the sum of the following, with discharges

over the 12-month period and based upon the total discharges for the eligible hospital (regardless of any source of payment):

(*1*) For the first through 1,149th discharge, $0.

(*2*) For the 1,150th through the 23,000th discharge, $200.

(*3*) For any discharge greater than the 23,000th, $0.

(C) For purposes of calculating the discharge-related amount under paragraph (g)(1)(i)(B) of this section, for the last 3 of the theoretical 4 years of payment, discharges are assumed to increase by the provider's average annual rate of growth for the most recent 3 years for which data are available per year. Negative rates of growth must be applied as such.

(ii) *Medicare share*. The Medicare share, which equals 1.

(iii) *Transition factor*. The transition factor which equals as follows:

(A) For the first of the theoretical 4 years, 1.

(B) For the second of the theoretical 4 years, ¾.

(C) For the third of the theoretical 4 years, ½.

(D) For the fourth of the theoretical 4 years, ¼.

(2) *Medicaid share*. The Medicaid share specified under this paragraph for an eligible hospital is equal to a fraction—

(i) The numerator of which is the sum (for the 12-month period selected by the State and with respect to the eligible hospital) of—

(A) The estimated number of inpatient-bed-days which are attributable to Medicaid individuals; and

(B) The estimated number of inpatient-bed-days which are attributable to individuals who are enrolled in a managed care organization, a pre-paid inpatient health plan, or a pre-paid ambulatory health plan under part 438 of this chapter; and

(ii) The denominator of which is the product of—

(A) The estimated total number of inpatient-bed-days with respect to the eligible hospital during such period; and

(B) The estimated total amount of the eligible hospital's charges during such period, not including any charges that are attributable to charity care, divided by the estimated total amount of the hospital's charges during such period.

(iii) In computing inpatient-bed-days under paragraph (g)(2)(i) of this section, a State may not include estimated inpatient-bed-days attributable to individuals with respect to whom payment may be made under Medicare Part A, or inpatient-bed-days attributable to individuals who are enrolled with a Medicare Advantage organization under Medicare Part C.

(h) *Approximate proxy for charity care*. If the State determines that an eligible provider's data are not available on charity care necessary to calculate the portion of the formula specified in paragraph (g)(2)(ii)(B) of this section, the State may use that provider's data on uncompensated care to determine an appropriate proxy for charity care, but must include a downward adjustment to eliminate bad debt from uncompensated care data. The State must use auditable data sources.

(i) *Deeming*. In the absence of the data necessary, with respect to an eligible hospital the amount described in paragraph (g)(2)(ii)(B) of this section must be deemed to be 1. In the absence of data, with respect to an eligible hospital, necessary to compute the amount described in paragraph (g)(2)(i)(B) of this section, the amount under such clause must be deemed to be 0.

(j) *Dual eligibility for incentives payments*. A hospital may receive incentive payments from both Medicare and Medicaid if it meets all eligibility criteria in the payment year.

(k) *Payments to State-designated entities*. Payments to entities promoting the adoption of certified EHR technology as designated by the State must meet the following requirements:

(1) A Medicaid EP may reassign his or her incentive payment to an entity promoting the adoption of certified EHR technology, as defined in § 495.302, and as designated by the State, only under the following conditions:

(i) The State has established a method to designate entities promoting the adoption of EHR technology that comports with the Federal definition in § 495.302.

(ii) The State publishes and makes available to all EPs a voluntary mechanism for reassigning annual payments and includes information about the verification mechanism the State will use to ensure that the reassignment is voluntary and that no more than 5 percent of the annual payment is retained by the entity for costs not related to certified EHR technology.

(2) [Reserved]

§ 495.312 Process for payments.

(a) *General rule*. States must have a process for making payments consistent with the requirements in subparts A and D of this part.

(b) *Reporting data consistent with this subpart*. In order to receive a payment under this part, a provider must report the required data under subpart A and this subpart within the EHR reporting period described in § 495.4.

(c) *State role*. The State determines the provider's eligibility for the EHR incentive payment under subpart A and this subpart and approves, processes, and makes timely payments using a process approved by CMS.

(d) *State disbursement*. The State disburses an incentive payment to the provider based on the criteria described in subpart A and this subpart.

(e) *Timeframes*. Payments are disbursed consistent with the following timeframes for each type of Medicaid eligible provider:

(1) *Medicaid EPs*. States disburse payments consistent with the calendar year on a rolling basis following verification of eligibility for the payment year.

(2) *Medicaid eligible hospitals*. States disburse payments consistent with the Federal fiscal year on a rolling basis following verification of eligibility for the payment year.

§ 495.314 Activities required to receive an incentive payment.

(a) *First payment year*. (1) In the first payment year, to receive an incentive payment, the Medicaid EP or eligible hospital must meet one of the following:

(i) Demonstrate that during the payment year, it has adopted, implemented, or upgraded certified EHR technology, as defined in § 495.302.

(ii) Demonstrate that during the EHR reporting period for a payment year, it is a meaningful EHR user as defined in § 495.4.

(2) A provider may notify the State of its non-binding intention to participate in the incentives program prior to having fulfilled all of the eligibility criteria.

(b) *Subsequent payment years*. (1) In the second, third, fourth, fifth, and sixth payment years, to receive an incentive payment, the Medicaid EP or eligible hospital must demonstrate that during the EHR reporting period for the applicable payment year, it is a meaningful EHR user, as defined in § 495.4.

(2) The automated reporting of the clinical quality measures will be accomplished using certified EHR technology interoperable with the system designated by the State to receive the data.

§ 495.316 State monitoring and reporting regarding activities required to receive an incentive payment.

(a) Subject to § 495.332 the State is responsible for tracking and verifying the activities necessary for a Medicaid EP or eligible hospital to receive an incentive payment for each payment year, as described in § 495.314.

(b) Subject to § 495.332, the State must submit a State Medicaid HIT Plan to CMS that includes—

(1) A detailed plan for monitoring, verifying and periodic auditing of the requirements for receiving incentive payments, as described in § 495.314; and

(2) A description of the how the State will collect and report on provider meaningful use of certified EHR technology.

(c) Subject to § 495.332 and § 495.352 the State is required to submit to CMS annual reports on the following:

(1) Provider adoption, implementation, or upgrade of certified EHR technology activities and payments; and

(2) Aggregated, de-identified meaningful use data.

(d)(1) The annual report described in paragraph (c) of this section must include, but is not limited to the following:

(i) The number, type, and practice location(s) of providers who qualified for

an incentive payment on the basis of having adopted, implemented, or upgraded certified EHR technology.

(ii) Aggregated data tables representing the provider adoption, implementation, or upgrade of certified EHR technology.

(iii) The number, type, and practice location(s) of providers who qualified for an incentive payment on the basis of demonstrating that they are meaningful users of certified EHR technology;

(iv) Aggregated data tables representing the provider's clinical quality measures data; and

(v) A description and quantitative data on how its incentive payment program addressed individuals with unique needs such as children.

(2) Subject to § 495.332, the State may propose a revised definition of meaningful use of certified EHR technology, subject to CMS prior approval, but only with respect to the following objectives:

(i) Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research or outreach.

(ii) Capability to submit electronic data to immunization registries or immunization information systems and actual submission in accordance with applicable law and practice.

(iii) Capability to provide electronic submission of reportable (as required by State or local law) lab results to public health agencies and actual submission in accordance with applicable law and practice; and

(iv) Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission in accordance with applicable law and practice.

(e) State failure to submit the required reports to CMS may result in discontinued or disallowed funding.

§ 495.318 State responsibilities for receiving FFP.

In order to be provided FFP under section 1903(a)(3)(F) of the Act, a State must demonstrate to the satisfaction of HHS, that the State is—

(a) Using the funds provided for the purposes of administering incentive payments to providers under this program, including tracking of meaningful use by Medicaid providers of EHR technology;

(b) Conducting adequate oversight of the program, including routine tracking of meaningful use attestations and reporting mechanisms; and

(c) Is pursuing initiatives to encourage the adoption of certified EHR technology to promote health care quality and the exchange of health care information, subject to applicable laws and regulations governing such exchange.

§ 495.320 FFP for payments to Medicaid providers.

Subject to the requirements outlined in this subpart, FFP is available at 100 percent of State expenditures for payments to Medicaid eligible providers to encourage the adoption and meaningful use of certified EHR technology.

§ 495.322 FFP for reasonable administrative expenses.

Subject to prior approval conditions at § 495.324 of this subpart, FFP is available at 90 percent in State expenditures for administrative activities in support of implementing incentive payments to Medicaid eligible providers.

§ 495.324 Prior approval conditions.

(a) A State must obtain prior written approval as specified in paragraph (b) of this section, when the State plans to initiate planning and implementation activities in support of Medicaid provider incentive payments encouraging the adoption and meaningful use of certified EHR technology with proposed Federal financial participation.

(b) To receive 90 percent match, each State must receive prior approval for all of the following:

(1) The HIT advance planning document and the implementation advance planning document.

(2) A request for proposal and any contract that a State may utilize to complete activities under this subpart, unless specifically exempted by the Department of Health and Human Services, prior to release of the request for proposal or prior to execution of a contract.

(3) For contract amendments, unless specifically exempted by HHS, before execution of the contract amendment,

involving contract cost increases exceeding $100,000 or contract time extensions of more than 60 days.

(4) The State Medicaid HIT plan.

(c) Failure to submit any of the information specified in paragraph (b) of this section to the satisfaction of HHS may result in disapproval or suspension of project funding.

(d) A State must obtain prior written approval from HHS of its justification for a sole source acquisition, when it plans to acquire non-competitively from a nongovernmental source HIT equipment or services, with proposed FFP under this subpart if the total State and Federal acquisition cost is more than $100,000.

§ 495.326 Disallowance of FFP.

If the HHS finds that any acquisition approved or modified under the provisions of this subpart fails to comply with the criteria, requirements, and other undertakings described in the approved HIT planning advance planning document and HIT implementation advance planning document to the detriment of the proper and efficient operation of the Medicaid program, payment of FFP may be disallowed. In the case of a suspension of approval of a HIT planning advance planning document and HIT implementation advance planning document, suspension would occur in the same manner as 45 CFR 205.37(c) and 307.40(a).

§ 495.328 Request for reconsideration of adverse determination.

If CMS disapproves a State request for any elements of a State's advance planning document or State Medicaid HIT Plan under this subpart, or determines that requirements are met for approval on a date later than the date requested, the decision notice includes the following:

(a) The finding of fact upon which the determination was made.

(b) The procedures for appeal of the determination in the form of a request for reconsideration.

§ 495.330 Termination of FFP for failure to provide access to information.

(a) HHS terminates FFP at any time if the Medicaid agency fails to provide State and Federal representatives with full access to records relating to HIT planning and implementation efforts, and the systems used to interoperate with electronic HIT, including on-site inspection.

(b) The Department may request such access at any time to determine whether the conditions in this subpart are being met.

§ 495.332 State Medicaid health information technology (HIT) plan requirements.

Each State Medicaid HIT plan must include all of the following elements:

(a) *State systems*. For State systems, interoperability, and the current and future visions:

(1) A baseline assessment of the current HIT landscape environment in the State including the inventory of existing HIT in the State. The assessment must include a comprehensive—

(i) Description of the HIT ''as-is'' landscape;

(ii) Description of the HIT ''to-be'' landscape; and

(iii) HIT roadmap and strategic plan for the next 5 years.

(2) A description of how the State Medicaid HIT plan will be planned, designed, developed and implemented, including how it will be implemented in accordance with the Medicaid Information Technology Architecture (MITA) principles as described in the Medicaid Information Technology Framework 2.0. The MITA initiative—

(i) Establishes national guidelines for technologies and processes that enable improved program administration for the Medicaid enterprise;

(ii) Includes business, information and technology architectures that provide an overall framework for interoperability, as well as processes and planning guidelines for enabling State Medicaid enterprises to meet common objectives within the framework while supporting unique local needs; and

(iii) Is important to the design and development of State EHR incentive payment systems.

(3) A description of how intrastate systems, including the Medicaid Management Information System (MMIS) and other automated mechanized

claims processing and information retrieval systems—

(i) Have been considered in developing a HIT solution; and

(ii) A plan that incorporates the design, development, and implementation phases for interoperability of such State systems with a description of how any planned systems enhancements support overall State and Medicaid goals.

(4) A description of data-sharing components of HIT solutions.

(5) A description of how each State will promote secure data exchange, where permissible under the Health Insurance Portability and Accountability Act (HIPAA) and other requirements included in ARRA.

(6) A description of how each State will promote the use of data and technical standards to enhance data consistency and data sharing through common data-access mechanisms.

(7) A description of how each State will support integration of clinical and administrative data.

(8) A description of the process in place for ensuring improvements in health outcomes, clinical quality, or efficiency resulting from the adoption of certified EHR technology by recipients of Medicaid incentive payments and a methodology for verifying such information.

(9) A description of the process in place for ensuring that any certified EHR technology used as the basis for a payment incentive to Medicaid providers is compatible with State or Federal administrative management systems, including the MMIS or other automated claims processing system or information retrieval system and a methodology for verifying such information.

(10) A description of how each State will adopt national data standards for health and data exchange and open standards for technical solutions as they become available.

(11) A description of how the State intends to address the needs of underserved and vulnerable populations such as children, individuals with chronic conditions, Title IV–E foster care children, individuals in long-term care settings and the aged, blind, and disabled. This description must address the following:

(i) Person centered goals and objectives and shared decision-making;

(ii) Coordination of care across multiple service providers, funding sources, settings, and patient conditions—

(iii) Universal design to ensure access by people with disabilities and older Americans; and

(iv) Institutional discharge planning and diversion activities that are tied to community based service availability.

(b) *Eligibility*. For eligibility, a description of the process in place for all of the following:

(1) For ensuring that each EP and eligible hospital meets all provider enrollment eligibility criteria upon enrollment and re-enrollment to the Medicaid EHR payment incentive program.

(2) For ensuring patient volume consistent with the criteria in § 495.304 and § 495.306 for each EP who practices predominantly in a FQHC or RHC and for each Medicaid EP who is a physician, pediatrician, nurse practitioner, certified nurse midwife or dentist and a methodology in place used to verify such information.

(3) For ensuring that the EP or eligible hospital is a provider who meets patient volume consistent with the criteria in § 495.304 and § 495.306 and a methodology in place used to verify such information.

(4) For ensuring that each Medicaid EP is not hospital-based and a methodology in place used to verify such information.

(5) To ensure that a hospital eligible for incentive payments has demonstrated an average length of stay of 25 days or less and a methodology for verifying such information.

(c) *Monitoring and validation*. For monitoring and validation of information, States must include the following:

(1) A description of the process in place for ensuring that, because of CMS' and the States' oversight responsibilities, all provider information for attestations including meaningful use, efforts to adopt, implement, or upgrade and any information added to the CMS Single Provider Repository including

all information related to patient volume, NPI, Tax identification number (TIN), are all true and accurate and that any concealment or falsification of a material fact related to the attestation may result in prosecution under Federal and State laws and a methodology in place used to verify such information.

(2) A description of the process in place for ensuring that the EP or eligible hospital is eligible to receive an incentive payment consistent with the criteria outlined in §495.314 and a methodology in place used to verify such information.

(3) A description of the process in place for capturing attestations from each EP or eligible hospital that they have meaningfully used certified EHR technology during the EHR reporting period, and that they have adopted, implemented, or upgraded certified EHR technology and a description of the methodology in place used to verify such information.

(4) A description of the process in place for capturing clinical quality data from each EP or eligible hospital and a description of the methodology in place used to verify such information.

(5) A description of the process in place for monitoring the compliance of providers coming onto the program with different requirements depending upon their participation year and a methodology for verifying such information.

(6) A list of the specific actions planned to implement the EHR incentive program, including a description and organizational charts for workgroups within State government including external partners.

(7) A description of the process in place to ensure that no amounts higher than 100 percent of FFP will be claimed by the State for reimbursement of expenditures for State payments to Medicaid eligible providers for the certified EHR technology incentive payment program and a methodology for verifying such information.

(8) A description of the process in place to ensure that no amounts higher than 90 percent of FFP will be claimed by the State for administrative expenses in administering the certified EHR technology incentive payment program and a methodology for verifying such information.

(9) A description of the process and methodology for ensuring and verifying the following:

(i) Amounts received under section 1903(a)(3)(F) of the Act with respect to payments to a Medicaid EP or eligible hospital are paid directly to such provider (or to an employer or facility to which such provider has assigned payments) without any deduction or rebate.

(ii) All incentive payment reassignments to an entity promoting the adoption of certified EHR technology, as designated by the State, are voluntary for the Medicaid EP involved.

(iii) Entities promoting the adoption of certified EHR technology do not retain more than 5 percent of such payments for costs not related to certified EHR technology (and support services including maintenance and training) that is for, or is necessary for the operation of, such technology.

(10) A description of the process in place for ensuring that each Medicaid EP or eligible hospital that collects an EHR payment incentive has collected a payment incentive from only one State even if the provider is licensed to practice in multiple States and a methodology for verifying such information.

(11)(i) A description of the process in place for ensuring that each EP or eligible hospital that wishes to participate in the EHR incentive payment program will receive a NPI; and

(ii) A description of how the NPI will be used to coordinate with the CMS so that the EP will choose only one program from which to receive the incentive payment and the hospital payments are tracked accordingly.

(12) A description of the process in place for ensuring that each EP or eligible hospital who wishes to participate in the EHR incentive payment program will provide a TIN to the State for purposes of the incentive payment.

(d) *Payments*. For payments, States must provide descriptions of the following processes that are in place:

(1) The process in place for ensuring that there is no duplication of Medicare and Medicaid incentive payments

to EPs and a methodology for verifying such information.

(2) The process in place to ensure that any existing fiscal relationships with providers to disburse the incentive payments through Medicaid managed care plans does not result in payments that exceed 105 percent of the capitation rate, in order to comply with the Medicaid managed care incentive payment rules at § 438.6(v)(5)(iii) of this chapter and a methodology for verifying such information.

(3) The process in place to ensure that only appropriate funding sources are used to make Medicaid EHR incentive payments and the methodology for verifying such information.

(4) The process in place and the methodology for verifying that information is available in order to ensure that Medicaid EHR incentive payments are made for no more than a total of 6 years; that no EP or eligible hospital begins receiving payments after 2016; that incentive payments cease after 2021; and that an eligible hospital does not receive incentive payments after FY 2016 unless the hospital received an incentive payment in the prior fiscal year.

(5) The process in place to ensure that Medicaid EHR incentive payments are not paid at amounts higher than 85 percent of the net average allowable cost of certified EHR technology and the yearly maximum allowable payment thresholds and a methodology for verifying such information.

(6) The process in place to ensure that all hospital calculations and hospital payment incentives are made consistent with the requirements of this part and a methodology for verifying such information.

(7) The process in place to provide for the timely and accurate payment of incentive payments to EPs and eligible hospitals, including the timeframe specified by the State to meet the timely payment requirement.

(8) The process in place and a methodology for verifying such information to provide that any monies that have been paid inappropriately as an improper payment or otherwise not in compliance with this subpart will be recouped and FFP will be repaid.

(9) The process in place and the methodology for verifying that EPs meet their responsibility for 15 percent of the net average allowable cost for certified EHR technology.

(e) *For combating fraud and abuse and for provider appeals.* (1) A description of the process in place for a provider to appeal consistent with the criteria described in § 495.370 and a methodology for verifying the following related to the EHR incentives payment program:

(i) Incentive payments.

(ii) Provider eligibility determinations.

(iii) Demonstration of efforts to adopt, implement or upgrade and meaningful use eligibility for incentive payments under this part.

(2) A description of the process in place, and a methodology for verifying such information, to address Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (32 U.S.C. 3729 *et seq.*), and the anti-kickback statute (section 1128B(b) of the Act).

(f) *Optional—proposed alternatives.* A State may choose to propose any of the following, but they must be included as an element in the State Medicaid HIT Plan for review and approval:

(1) An alternative methodology for measuring patient volume, consistent with § 495.306(g).

(2)(i) A revised definition of meaningful use of certified EHR technology consistent with § 495.4 and § 495.316(d)(2) of this part.

(ii) Any revised definition of meaningful use may not require additional functionality beyond that of certified EHR technology and conform with CMS guidance on Stage 1. See also § 495.316(d)(2).

§ 495.334 [Reserved]

§ 495.336 Health information technology planning advance planning document requirements (HIT PAPD).

Each State's HIT PAPD must contain the following:

(a) A statement of need and objective which clearly state the purpose and objectives of the project to be accomplished and the necessity for the project.

(b) A project management plan which addresses the following:

(1) The planning project organization.

(2) Planning activities and deliverables.

(3) State and contractor resource needs.

(4) Planning project procurement activities and schedule.

(c) A specific budget for the planning of the project.

(d) An estimated total project cost and a prospective State and Federal cost distribution, including planning and implementation.

(e) A commitment to submit a HIT implementation advance planning document.

(f) A commitment to conduct and complete activities which will result in the production of the State Medicaid HIT plan that includes conduct of the following activities:

(1) A statewide HIT environmental baseline self-assessment.

(2) An assessment of desired HIT future environment.

(3) Development of benchmarks and transition strategies to move from the current environment to the desired future environment.

(g) A commitment to submit the plan to CMS for approval.

§ 495.338 Health information technology implementation advance planning document requirements (HIT IAPD).

Each State's HIT IAPD must contain the following:

(a) The results of the activities conducted as a result of the HIT planning advance planning document, including the approved state Medicaid HIT plan.

(b) A statement of needs and objectives.

(c) A statement of alternative considerations.

(d) A personnel resource statement indicating availability of qualified and adequate staff, including a project director to accomplish the project objectives.

(e) A detailed description of the nature and scope of the activities to be undertaken and the methods to be used to accomplish the project.

(f) The proposed activity schedule for the project.

(g) A proposed budget including a consideration of all HIT implementation advance planning document activity costs, including but not limited to the following:

(1) The cost to implement and administer incentive payments.

(2) Procurement or acquisition.

(3) State personnel.

(4) Contractor services.

(5) Hardware, software, and licensing.

(6) Equipment and supplies.

(7) Training and outreach.

(8) Travel.

(9) Administrative operations.

(10) Miscellaneous expenses for the project.

(h) An estimate of prospective cost distribution to the various State and Federal funding sources and the proposed procedures for distributing costs including:

(1) Planned annual payment amounts;

(2) Total of planned payment amounts; and

(3) Calendar year of each planned annual payment amount.

(4) A statement setting forth the security and interface requirements to be employed for all State HIT systems, and related systems, and the system failure and disaster recovery procedures available.

§ 495.340 As-needed HIT PAPD update and as-needed HIT IAPD update requirements.

Each State must submit a HIT PAPD update or a HIT IAPD no later than 60 days after the occurrence of project changes including but not limited to any of the following:

(a) A projected cost increase of $100,000 or more.

(b) A schedule extension of more than 60 days for major milestones.

(c) A significant change in planning approach or implementation approach, or scope of activities beyond that approved in the HIT planning advance planning document or the HIT implementation advance planning document.

(d) A change in implementation concept or a change to the scope of the project.

(e) A change to the approved cost allocation methodology.

§ 495.342 Annual HIT IAPD requirements.

Each State's annual HIT IAPD is due 60 days from the HIT IAPD approved anniversary date and must contain the following:

(a) A reference to the approved HIT PAPD/IAPD and all approved changes.

(b) A project activity status which reports the status of the past year's major project tasks and milestones, addressing the degree of completion and tasks/milestones remaining to be completed and discusses past and anticipated problems or delays in meeting target dates in the approved HIT technology PAPD/IAPD and approved changes to it.

(c) A report of all project deliverables completed in the past year and degree of completion for unfinished products.

(d) A project activity schedule for the remainder of the project.

(e) A project expenditure status which consists of a detailed accounting of all expenditures for project development over the past year and an explanation of the differences between projected expenses in the approved HIT PAPD/IAPD and actual expenditures for the past year.

(f) A report of any approved or anticipated changes to the allocation basis in the advance planning document's approved cost methodology.

§ 495.344 Approval of the State Medicaid HIT plan, the HIT PAPD and update, the HIT IAPD and update, and the annual HIT IAPD.

HHS will not approve the State Medicaid HIT plan, HIT PAPD and update, HIT–IAPD and update, or annual IAPD if any of these documents do not include all of the information required under this subpart.

§ 495.346 Access to systems and records.

The State agency must allow HHS access to all records and systems operated by the State in support of this program, including cost records associated with approved administrative funding and incentive payments to Medicaid providers. State records related to contractors employed for the purpose of assisting with implementation or oversight activities or providing assistance, at such intervals as are deemed necessary by the Department to determine whether the conditions for approval are being met and to determine the efficiency, economy, and effectiveness of the program.

§ 495.348 Procurement standards.

(a) *General rule.* Procurements of HIT equipment and services are subject to the following procurement standards in paragraphs (b) through (f) of this section regardless of any conditions for prior approval. These standards—

(1) Include a requirement for maximum practical open and free competition regardless of whether the procurement is formally advertised or negotiated.

(2) Are established to ensure that such materials and services are obtained in a cost effective manner and in compliance with the provisions of applicable Federal statutes and executive orders.

(3) Apply when the cost of the procurement is treated as a direct cost of an award.

(b) *Grantee responsibilities.* The standards contained in this section do not relieve the Grantee of the contractual responsibilities arising under its contract(s).

(1) The grantee is the responsible authority, without recourse to the Departmental awarding agency, regarding the settlement and satisfaction of all contractual and administrative issues arising out of procurements entered into in support of an award or other agreement. This includes disputes, claims, and protests of award, source evaluation or other matters of a contractual nature.

(2) Matters concerning violation of statute are to be referred to such Federal, State or local authority as may have proper jurisdiction.

(c) *Codes of conduct.* The grantee must maintain written standards of conduct governing the performance of its employees engaged in the award and administration of contracts.

(1) No employee, officer, or agent must participate in the selection, award, or administration of a contract supported by Federal funds if a real or apparent conflict of interest would be involved.

(2) Such a conflict would arise when the employee, officer, or agent, or any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of the parties indicated herein, has a financial or other interest in the firm selected for an award.

(3) The officers, employees, and agents of the grantee must neither solicit nor accept gratuities, favors, or anything of monetary value from contractors, or parties to sub agreements.

(4) Grantees may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value.

(5) The standards of conduct provide for disciplinary actions to be applied for violations of such standards by officers, employers, or agents of the grantees.

(d) *Competition*. All procurement transactions must be conducted in a manner to provide, to the maximum extent practical, open and free competition.

(1) The grantee must be alert to organizational conflicts of interest as well as noncompetitive practices among contractors that may restrict or eliminate competition or otherwise restrain trade.

(2) In order to ensure objective contractor performance and eliminate unfair competitive advantage, contractors that develop or draft grant applications, or contract specifications, requirements, statements of work, invitations for bids and requests for proposals must be excluded from competing for such procurements.

(3) Awards must be made to the bidder or offer or whose bid or offer is responsive to the solicitation and is most advantageous to the grantee, price, quality, and other factors considered.

(4) Solicitations must clearly set forth all requirements that the bidder or offer or must fulfill in order for the bid or offer to be evaluated by the grantee.

(5) Any and all bids or offers may be rejected when it is in the grantee's interest to do so.

(e) *Procurement procedures*. All grantees must establish written procurement procedures. These procedures must provide, at a minimum, the following:

(1) Grantees avoid purchasing unnecessary items.

(2) When appropriate, an analysis is made of lease and purchase alternatives to determine which would be the most economical and practical procurement for the grantee and the Federal government.

(3) Solicitations for goods and services provide for all of the following:

(i) A clear and accurate description of the technical requirements for the material, product or service to be procured. In competitive procurements, such a description must not contain features which unduly restrict competition.

(ii) Requirements which the bidder or offer must fulfill and all other factors to be used in evaluating bids or proposals.

(iii) A description, whenever practicable, of technical requirements in terms of functions to be performed or performance required, including the range of acceptable characteristics or minimum acceptable standards.

(iv) The specific features of brand name or equal descriptions that bidders are required to meet when such items are included in the solicitation.

(v) The acceptance, to the extent practicable and economically feasible, of products and services dimensioned in the metric system of measurement.

(vi) Preference, to the extent practicable and economically feasible, for products and services that conserve natural resources and protect the environment and are energy efficient.

(4) Positive efforts must be made by grantees to utilize small businesses, minority-owned firms, and women's business enterprises, whenever possible. Grantees of Departmental awards must take all of the following steps to further this goal:

(i) Ensure that small businesses, minority-owned firms, and women's business enterprises are used to the fullest extent practicable.

(ii) Make information on forthcoming opportunities available and arrange time frames for purchases and contracts to encourage and facilitate participation by small businesses, minority-owned firms, and women's business enterprises.

(iii) Consider in the contract process whether firms competing for larger contracts intend to subcontract with small businesses, minority-owned firms, and women's business enterprises.

(iv) Encourage contracting with consortia of small businesses, minority-owned firms and women's business enterprises when a contract is too large for one of these firms to handle individually.

(v) Use the services and assistance, as appropriate, of such organizations as the Small Business Administration and the Department of Commerce's Minority Business Development Agency in the solicitation and utilization of small businesses, minority-owned firms and women's business enterprises.

(5) The type of procuring instruments used (for example, fixed price contracts, cost reimbursable contracts, purchase orders, and incentive contracts) must be determined by the grantee but must be appropriate for the particular procurement and for promoting the best interest of the program or project involved.

(6) The ''cost-plus-a-percentage-of-cost'' or ''percentage of construction cost'' methods of contracting must not be used.

(7) Contracts must be made only with responsible contractors who possess the potential ability to perform successfully under the terms and conditions of the proposed procurement.

(8) Consideration must be given to such matters as contractor integrity, record of past performance, financial and technical resources or accessibility to other necessary resources.

(9) In certain circumstances, contracts with certain parties are restricted by agencies' implementation of Executive Orders 12549 and 12689, ''Debarment and Suspension'' as described in 2 CFR part 376.

(10) Some form of cost or price analysis must be made and documented in the procurement files in connection with every procurement action.

(11) Price analysis may be accomplished in various ways, including the comparison of price quotations submitted, market prices, and similar indicia, together with discounts.

(12) Cost analysis is the review and evaluation of each element of cost to determine reasonableness, allocability, and allowability.

(13) Procurement records and files for purchases in excess of the simplified acquisition threshold must include the following at a minimum:

(i) Basis for contractor selection.

(ii) Justification for lack of competition when competitive bids or offers are not obtained.

(iii) Basis for award cost or price.

(f) *Contract administration.* A system for contract administration must be maintained to ensure contractor conformance with the terms, conditions and specifications of the contract and to ensure adequate and timely follow up of all purchases. Grantees must evaluate contractor performance and document, as appropriate, whether contractors have met the terms, conditions, and specifications of the contract.

(g) *Additional contract requirements.* The grantee must include, in addition to provisions to define a sound and complete agreement, the following provisions in all contracts, which must also be applied to subcontracts:

(1) Contracts in excess of the simplified acquisition threshold must contain contractual provisions or conditions that allow for administrative, contractual, or legal remedies in instances in which a contractor violates or breaches the contract terms, and provide for such remedial actions as may be appropriate.

(2) All contracts in excess of the simplified acquisition threshold (currently $100,000) must contain suitable provisions for termination by the grantee, including the manner by which termination must be effected and the basis for settlement.

(h) *Conditions for default or termination.* Such contracts must describe conditions under which the contract may be terminated for default as well as conditions where the contract may

be terminated because of circumstances beyond the control of the contractor.

(i) *Access to contract materials and staff.* All negotiated contracts (except those for less than the simplified acquisition threshold) awarded by grantees must include a provision to the effect that the grantee, the Departmental awarding agency, the U.S. Comptroller General, or any of their duly authorized representatives, must have access to any books, documents, papers and records and staff of the contractor which are directly pertinent to a specific program for the purpose of making audits, examinations, excerpts and transcriptions.

§ 495.350 State Medicaid agency attestations.

(a) The State must provide assurances to HHS that amounts received with respect to sums expended that are attributable to payments to a Medicaid provider for the adoption of EHR are paid directly to such provider, or to an employer or facility to which such provider has assigned payments, without any deduction or rebate.

§ 495.352 Reporting requirements.

Each State must submit to HHS on a quarterly basis a progress report documenting specific implementation and oversight activities performed during the quarter, including progress in implementing the State's approved Medicaid HIT plan.

§ 495.354 Rules for charging equipment.

Equipment acquired under this subpart is subject to the public assistance program requirements concerning the computation of claims for Federal financial participation in accordance with the provisions of 45 CFR part 95, subpart G.

§ 495.356 Nondiscrimination requirements.

State agencies and any other recipients or subrecipients of Federal financial assistance provided under this subpart are subject to the nondiscrimination requirements in 45 CFR parts 80, 84, and 91.

(a) These regulations in 45 CFR parts 80, 84, and 91 prohibit individuals from being excluded from participation in, being denied the benefits of, or being otherwise subjected to discrimination under any program or activity which received Federal financial assistance.

(b) Specifically, 45 CFR part 80 prohibits discrimination on the basis of race, color, or national origin; 45 CFR part 84 prohibits discrimination on the basis of disability; and 45 CFR part 91 prohibits discrimination on the basis of age.

§ 495.358 Cost allocation plans.

State agencies that acquire HIT equipment and services under this subpart are subject to cost allocation plan requirements in 45 CFR part 95.

§ 495.360 Software and ownership rights.

(a) *General rule.* The State or local government must include a clause in all procurement instruments that provides that the State or local government will have all ownership rights in software or modifications thereof and associated documentation designed, developed or installed with FFP under this Subpart.

(b) *Federal license.* HHS reserves a royalty-free, non-exclusive, and irrevocable license to reproduce, publish or otherwise use and to authorize others to use for Federal government purposes, the software, modifications, and documentation designed, developed or installed with FFP under this Subpart.

(c) *Proprietary software.* Proprietary operating/vendor software packages such as software that is owned and licensed for use by third parties, which are provided at established catalog or market prices and sold or leased to the general public must not be subject to the ownership provisions in paragraphs (a) and (b) of this section.

(d) *Limitation.* Federal financial participation is not available for proprietary applications software developed specifically for the public assistance programs covered under this subpart.

§ 495.362 Retroactive approval of FFP with an effective date of February 18, 2009.

For administrative activities performed by a State, without obtaining prior approval, which are in support of planning for incentive payments to providers, a State may request consideration of FFP by recorded request in a HIT advance planning document or implementation advance planning document update. In such a consideration, the agency takes into consideration overall Federal interests which may include any of the following:

(a) The acquisition must not be before February 18, 2009.

(b) The acquisition must be reasonable, useful, and necessary.

(c) The acquisition must be attributable to payments for reasonable administrative expenses under section 1903(a)(3)(F)(ii) of the Act.

§ 495.364 Review and assessment of administrative activities and expenses of Medicaid provider health information technology adoption and operation.

(a) CMS conducts periodic reviews on an as needed basis to assess the State's progress described in its approved HIT planning advance planning document and health information technology implementation advance planning document.

(b) During planning, development, and implementation, these reviews will generally be limited to the overall progress, work performance, expenditure reports, project deliverables, and supporting documentation.

(c) CMS assesses the State's overall compliance with the approved advance planning document and provide technical assistance and information sharing from other State projects.

(d) CMS will, on a continuing basis, review, assess and inspect the planning, design, development, implementation, and operation of activities and payments for reasonable administrative expenses related to the administration of payment for Medicaid provider HIT adoption and operation payments to determine the extent to which such activities meet the following:

(1) All requirements of this subpart.

(2) The goals and objectives stated in the approved HIT implementation advance planning document and State Medicaid HIT plan.

(3) The schedule, budget, and other conditions of the approved HIT implementation advance planning document and State Medicaid HIT plan.

§ 495.366 Financial oversight and monitoring of expenditures.

(a) *General rule.* (1) The State must have a process in place to estimate expenditures for the Medicaid EHR payment incentive program using the Medicaid Budget Expenditure System.

(2) The State must have a process in place to report actual expenditures for the Medicaid EHR payment incentive program using the Medicaid Budget Expenditure System.

(3) The State must have an automated payment and information retrieval mechanized system, (Medicaid Management Information System) to make EHR payment incentives, to ensure Medicaid provider eligibility, to ensure the accuracy of payment incentives, and to identify potential improper payments.

(b) *Provider eligibility as basis for making payment.* Subject to § 495.332, the State must do all of the following:

(1) Collect and verify basic information on Medicaid providers to assure provider enrollment eligibility upon enrollment or re-enrollment to the Medicaid EHR payment incentive program.

(2) Collect and verify basic information on Medicaid providers to assure patient volume.

(3) Collect and verify basic information on Medicaid providers to assure that EPs are not hospital-based including the determination that substantially all health care services are not furnished in a hospital setting, either inpatient or outpatient.

(4) Collect and verify basic information on Medicaid providers to assure that EPs are practicing predominantly in a Federally-qualified health center or rural health clinic.

(5) Have a process in place to assure that Medicaid providers who wish to participate in the EHR incentive payment program has or will have a NPI and will choose only one program from

which to receive the incentive payment using the NPI, a TIN, and CMS' national provider election database.

(c) *Meaningful use and efforts to adopt, implement, or upgrade to certified electronic health record technology to make payment.* Subject to § 495.312, 495.314, and § 495.332, the State must annually collect and verify information regarding the efforts to adopt, implement, or upgrade certified EHR technology and the meaningful use of said technology before making any payments to providers.

(d) *Claiming Federal reimbursement for State expenditures.* Subject to § 495.332, the State must do the following:

(1) Assure that State expenditures are claimed in accordance with, including but not limited to, applicable Federal laws, regulations, and policy guidance.

(2) Have a process in place to assure that expenditures for administering the Medicaid EHR incentive payment program will not be claimed at amounts higher than 90 percent of the cost of such administration.

(3) Have a process in place to assure that expenditures for payment of Medicaid EHR incentive payments will not be claimed at amounts higher than 100 percent of the cost of such payments to Medicaid providers.

(e) *Improper Medicaid electronic health record payment incentives.*

(1) Subject to § 495.332, the State must have a process in place to assure that no duplicate Medicaid EHR payment incentives are paid between the Medicare and Medicaid programs, or paid by more than one State even if the provider is licensed to practice in multiple States, or paid within more than one area of a State.

(2) Subject to § 495.332, the State must have a process in place to assure that Medicaid EHR incentive payments are made without reduction or rebate, have been paid directly to an eligible provider or to an employer, a facility, or an eligible third-party entity to which the Medicaid eligible provider has assigned payments.

(3) Subject to § 495.332, the State must have a process in place to assure that that Medicaid EHR incentive payments are made for no more than 6 years; that no EP or eligible hospital begins receiving payments after 2016; that incentive payments cease after 2021; and that an eligible hospital does not receive incentive payments after FY 2016 unless the hospital received an incentive payment in the prior fiscal year.

(4) Subject to § 495.332, the State must have a process in place to assure that only appropriate funding sources are used to make Medicaid EHR incentive payments.

(5) Subject to § 495.332, the State must have a process in place to assure that Medicaid EHR incentive payments are not paid at amounts higher than 85 percent of the net average allowable cost of certified EHR technology and the yearly maximum allowable payment thresholds.

(6) Subject to § 495.332, the State must have a process in place to assure that for those entities promoting the adoption of EHR technology, the Medicaid EHR incentive payments are paid on a voluntary basis and that these entities do not retain more than 5 percent of such payments for costs not related to certified EHR technology.

(7) Subject to § 495.332, the State must have a process in place to assure that any existing fiscal relationships with providers to disburse the incentive through Medicaid managed care plans does not exceed 105 percent of the capitation rate, in order to comply with the Medicaid managed care incentive payment rules at § 438.6(c)(5)(iii) of this chapter and a methodology for verifying such information.

(8) The State must not request reimbursement for Federal financial participation unless all requirements of this subpart have been satisfied.

§ 495.368 Combating fraud and abuse.

(a) *General rule.* (1) The State must comply with Federal requirements to—

(i) Ensure the qualifications of the providers who request Medicaid EHR incentive payments;

(ii) Detect improper payments; and

(iii) In accordance with § 455.15 and § 455.21 of this chapter, refer suspected cases of fraud and abuse to the Medicaid Fraud Control Unit.

(2) The State must take corrective action in the case of improper EHR

payment incentives to Medicaid providers.

(b) *Providers' statements regarding submission of documentation containing falsification or concealment of a material fact on EHR incentive payment documentation.* For any forms on which a provider submits information necessary to the determination of eligibility to receive EHR payments, the State must obtain a statement that meets the following requirements:

(1) Is signed by the provider and contains the following statement: ''This is to certify that the foregoing information is true, accurate, and complete. I understand that Medicaid EHR incentive payments submitted under this provider number will be from Federal funds, and that any falsification, or concealment of a material fact may be prosecuted under Federal and State laws.''

(2) Appears directly above the claimant's signature, or if it is printed on the reverse of the form, a reference to the statements must appear immediately preceding the provider's signature.

(3) Is resubmitted upon a change in provider representative.

(4) Is updated as needed.

(c) *Overpayments.* States must repay to CMS all Federal financial participation received by providers identified as an overpayment regardless of recoupment from such providers, within 60 days of discovery of the overpayment, in accordance with sections 1903(a)(1), (d)(2), and (d)(3) of the Act and part 433 subpart F of the regulations.

(d) *Complying with Federal laws and regulations.* States must comply with all Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (32 U.S.C. 3729 et seq.), and the anti-kickback statute (section 1128B(b) of the Act).

§ 495.370 Appeals process for a Medicaid provider receiving electronic health record incentive payments.

(a) The State must have a process in place consistent with the requirements established in § 447.253(e) of this chapter for a provider or entity to appeal the following issues related to the HIT incentives payment program:

(1) Incentive payments.

(2) Incentive payment amounts.

(3) Provider eligibility determinations.

(4) Demonstration of adopting, implementing, and upgrading, and meaningful use eligibility for incentives under this subpart.

(b) Subject to paragraph (a) of this section, the State's process must ensure the following:

(1) That the provider (whether an individual or an entity) has an opportunity to challenge the State's determination under this Part by submitting documents or data or both to support the provider's claim.

(2) That such process employs methods for conducting an appeal that are consistent with the State's Administrative Procedure law(s).

(c) The State must provide that the provider (whether individual or entity) is also given any additional appeals rights that would otherwise be available under procedures established by the State.

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/MR AND CERTAIN NFs IN THE MEDICAID PROGRAM

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 52 FR 22446, June 12, 1987, unless otherwise noted.

Subpart A—General Provisions

§ 498.1 Statutory basis.

(a) Section 1866(h) of the Act provides for a hearing and for judicial review of the hearing for any institution or agency dissatisfied with a determination that it is not a provider, or with any determination described in section 1866(b)(2) of the Act.

(b) Section 1866(b)(2) of the Act lists determinations that serve as a basis for termination of a provider agreement.

(c) Sections 1128 (a) and (b) of the Act provide for exclusion of certain individuals or entities because of conviction of crimes related to their participation in Medicare and section 1128(f) provides for hearing and judicial review for exclusions.

(d) Section 1156 of the Act establishes certain obligations for practitioners and providers of health care services, and provides sanctions and penalties for those that fail to meet those obligations.

(e)–(f) [Reserved]

(g) Section 1866(j) of the Act provides for a hearing and judicial review for any provider or supplier whose application for enrollment or reenrollment in Medicare is denied or whose billing privileges are revoked.

(h) Section 1128A(c)(2) of the Act provides that the Secretary may not collect a civil money penalty until the affected entity has had notice and opportunity for a hearing.

(i) Section 1819(h) of the Act—

(1) Provides that, for SNFs found to be out of compliance with the requirements for participation, specified remedies may be imposed instead of, or in addition to, termination of the facility's Medicare provider agreement; and

(2) Makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on SNFs.

(j) Section 1891(e) of the Act provides that, for home health agencies (HHAs) found to be out of compliance with the conditions of participation, specified remedies may be imposed instead of, or in addition to, termination of the HHA's Medicare provider agreement.

(k) Section 1891(f) of the Act—

(1) Requires the Secretary to develop a range of such remedies; and

(2) Makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on HHAs.

[52 FR 22446, June 12, 1987, as amended at 59 FR 56251, Nov. 10, 1994; 61 FR 32349, June 24, 1996; 73 FR 36462, June 27, 2008]

§ 498.2 Definitions.

As used in this part—

Affected party means a provider, prospective provider, supplier, prospective supplier, or practitioner that is affected by an initial determination or by any subsequent determination or decision issued under this part, and ''party'' means the affected party or CMS, as appropriate. For provider or supplier enrollment appeals, an affected party includes CMS or a CMS contractor.

ALJ stands for Administrative Law Judge.

Departmental Appeals Board or *Board* means a Board established in the Office of the Secretary to provide impartial review of disputed decisions made by the operating components of the Department.

OIG stands for the Department's Office of the Inspector General.

Prospective provider means any of the entities specified in the definition of provider under this section that seeks to be approved for coverage of its services by Medicare or to have any facility or organization determined to be a department of the provider or provider-based entity under § 413.65 of this chapter.

Prospective supplier means any of the listed entities specified in the definition of supplier in this section that seek to be approved for coverage of its services by Medicare.

Provider means either of the following:

(1) Any of the following entities that have in effect an agreement to participate in Medicare:

(i) Hospital.

(ii) Transplant center.

(iii) Critical access hospital (CAH).

(iv) Skilled nursing facility (SNF).

(v) Comprehensive outpatient rehabilitation facility (CORF).

(vi) Home health agency (HHA).

(vii) Hospice.

(viii) Religious nonmedical health care institution (RNHCI).

(2) Any of the following entities that have in effect an agreement to participate in Medicare but only to furnish outpatient physical therapy or outpatient speech pathology services.

(i) Clinic.

(ii) Rehabilitation agency.

(iii) Public health agency.

Supplier means any of the following entities that have in effect an agreement to participate in Medicare:

(1) An independent laboratory.

(2) Supplier of durable medical equipment prosthetics, orthotics, or supplies (DMEPOS).

(3) Ambulance service provider.

(4) Independent diagnostic testing facility.

(5) Physician or other practitioner such as physician assistant.

(6) Physical therapist in independent practice.

(7) Supplier of portable X-ray services.

(8) Rural health clinic (RHC).

(9) Federally qualified health center (FQHC).

(10) Ambulatory surgical center (ASC).

(11) An entity approved by CMS to furnish outpatient diabetes self-management training.

(12) End-stage renal disease (ESRD) treatment facility that is approved by CMS as meeting the conditions for coverage of its services.

(13) A site approved by CMS to furnish intensive cardiac rehabilitation services.

[52 FR 22446, June 12, 1987, as amended at 53 FR 6551, March 1, 1988; 57 FR 24984, June 12, 1992; 58 FR 30677, May 26, 1993; 59 FR 6579, Feb. 11, 1994; 59 FR 56251, Nov. 10, 1994; 61 FR 32350, June 24, 1996; 62 FR 46037, Aug. 29, 1997; 65 FR 18549, Apr. 7, 2000; 65 FR 83154, Dec. 29, 2000; 68 FR 66721, Nov. 28, 2003; 71 FR 31054, May 31, 2006; 72 FR 15280, Mar. 30, 2007; 73 FR 36462, June 27, 2008; 74 FR 62014, Nov. 25, 2009]

§498.3 Scope and applicability.

(a) *Scope.* (1) This part sets forth procedures for reviewing initial determinations that CMS makes with respect to the matters specified in paragraph (b) of this section, and that the OIG makes with respect to the matters specified in paragraph (c) of this section. It also specifies, in paragraph (d) of this section, administrative actions that are not subject to appeal under this part.

(2) The determinations listed in this section affect participation in the Medicare program. Many of the procedures of this part also apply to other determinations that do not affect participation in Medicare. Some examples follow:

(i) CMS's determination to terminate an NF's Medicaid provider agreement.

(ii) CMS's determination to cancel the approval of an ICF/MR under section 1910(b) of the Act.

(iii) CMS's determination, under the Clinical Laboratory Improvement Act (CLIA), to impose alternative sanctions or to suspend, limit, or revoke the certificate of a laboratory even though it does not participate in Medicare.

(3) The following parts of this chapter specify the applicability of the provisions of this part 498 to sanctions or remedies imposed on the indicated entities:

(i) Part 431, subpart D—for nursing facilities (NFs).

(ii) Part 488, subpart E (§488.330(e))—for SNFs and NFs.

(iii) Part 493, subpart R (§493.1844)—for laboratories.

(b) *Initial determinations by CMS.* CMS makes initial determinations with respect to the following matters:

(1) Whether a prospective provider qualifies as a provider.

(2) Whether a prospective department of a provider, remote location of a hospital, satellite facility, or provider-based entity qualifies for provider-based status under §413.65 of this chapter, or whether such a facility or entity currently treated as a department of a provider, remote location of a hospital, satellite facility, or a provider-based entity no longer qualifies for that status under §413.65 of this chapter.

(3) Whether an institution is a hospital qualified to elect to claim payment for all emergency hospital services furnished in a calendar year.

(4) Whether an institution continues to remain in compliance with the qualifications for claiming reimbursement for all emergency services furnished in a calendar year.

(5) Whether a prospective supplier meets the conditions for coverage of its services as those conditions are set forth elsewhere in this chapter.

(6) Whether the services of a supplier continue to meet the conditions for coverage.

(7) Whether a physical therapist in independent practice or a chiropractor meets the requirements for coverage of his or her services as set forth in subpart D of part 486 of this chapter and §410.22 of this chapter, respectively.

(8) The termination of a provider agreement in accordance with §489.53 of this chapter, or the termination of a rural health clinic agreement in accordance with §405.2404 of this chapter, or the termination of a Federally qualified health center agreement in accordance with §405.2436 of this chapter.

(9) CMS's cancellation, under section 1910(b) of the Act, of an ICF/MR's approval to participate in Medicaid.

(10) Whether, for purposes of rate setting and reimbursement, an ESRD treatment facility is considered to be hospital-based or independent.

(11) [Reserved]

(12) Whether a hospital, skilled nursing facility, home health agency, or hospice program meets or contimues to meet the advance directives requirements specified in subpart I of part 489 of this chapter.

(13) With respect to an SNF or NF, a finding of noncompliance that results in the imposition of a remedy specified

in § 488.406 of this chapter, except the State monitoring remedy.

(14) The level of noncompliance found by CMS in a SNF or NF but only if a successful challenge on this issue would affect—

(i) The range of civil money penalty amounts that CMS could collect (The scope of review during a hearing on imposition of a civil money penalty is set forth in § 488.438(e) of this chapter); or

(ii) A finding of substandard quality of care that results in the loss of approval for a SNF or NF of its nurse aide training program.

(15) The effective date of a Medicare provider agreement or supplier approval.

(16) The finding of substandard quality of care that leads to the loss by a SNF or NF of the approval of its nurse aide training program.

(17) Whether to deny or revoke a provider or supplier's Medicare enrollment in accordance with § 424.530 or § 424.535 of this chapter.

(c) *Initial determinations by the OIG.* The OIG makes initial determinations with respect to the following matters:

(1) The termination of a provider agreement in accordance with part 1001, subpart C of this title.

(2) The suspension, or exclusion from coverage and the denial of reimbursement for services furnished by a provider, practitioner, or supplier, because of fraud or abuse, or conviction of crimes related to participation in the program, in accordance with part 1001, subpart B of this title.

(3) The imposition of sanctions in accordance with part 1004 of this title.

(d) *Administrative actions that are not initial determinations.* Administrative actions that are not initial determination (and therefore not subject to appeal under this part) include but are not limited to the following:

(1) The finding that a provider or supplier determined to be in compliance with the conditions or requirements for participation or for coverage has deficiencies.

(2) The finding that a prospective provider does not meet the conditions of participation set forth elsewhere in this chapter, if the prospective provider is, nevertheless, approved for participation in Medicare on the basis of special access certification, as provided in subpart B of part 488 of this chapter.

(3) The refusal to enter into a provider agreement because the prospective provider is unable to give satisfactory assurance of compliance with the requirements of title XVIII of the Act.

(4) The finding that an entity that had its provider agreement terminated may not file another agreement because the reasons for terminating the previous agreement have not been removed or there is insufficient assurance that the reasons for the exclusion will not recur.

(5) The determination not to reinstate a suspended or excluded practitioner, provider, or supplier because the reason for the suspension or exclusion has not been removed, or there is insufficient assurance that the reason will not recur.

(6) The finding that the services of a laboratory are covered as hospital services or as physician's services, rather than as services of an independent laboratory, because the laboratory is not independent of the hospital or of the physician's office.

(7) The refusal to accept for filing an election to claim payment for all emergency hospital services furnished in a calendar year because the institution—

(i) Had previously charged an individual or other person for services furnished during that calendar year;

(ii) Submitted the election after the close of that calendar year; or

(iii) Had previously been notified of its failure to continue to comply.

(8) The finding that the reason for the revocation of a supplier's right to accept assignment has not been removed or there is insufficient assurance that the reason will not recur.

(9) The finding that a hospital accredited by the Joint Commission on Accreditation of Hospitals or the American Osteopathic Association is not in compliance with a condition of participation, and a finding that that hospital is no longer deemed to meet the conditions of participation.

(10) With respect to an SNF or NF–(i) The finding that the SNF's or NF's deficiencies pose immediate jeopardy to the health or safety of its residents;

(ii) Except as provided in paragraph (b)(13) of this section, a determination

by CMS as to the facility's level of noncompliance; and

(iii) The imposition of State monitoring.

(11) The choice of alternative sanction or remedy to be imposed on a provider or supplier.

(12) The determination that the accreditation requirements of a national accreditation organization do not provide (or do not continue to provide) reasonable assurance that the entities accredited by the accreditation organization meet the applicable long-term care requirements, conditions for coverage, conditions of certification, conditions of participation, or CLIA condition level requirements.

(13) The determination that requirements imposed on a State's laboratories under the laws of that State do not provide (or do not continue to provide) reasonable assurance that laboratories licensed or approved by the State meet applicable CLIA requirements.

(14) The choice of alternative sanction or remedy to be imposed on a provider or supplier.

(15) A decision by the State survey agency as to when to conduct an initial survey of a prospective provider or supplier.

(e) *Exclusion of civil rights issues.* The procedures in this subpart do not apply to the adjudication of issues relating to a provider's compliance with civil rights requirements that are set forth in part 489 of this chapter. Those issues are handled through the Department's Office of Civil Rights.

[52 FR 22446, June 12, 1987, as amended at 52 FR 27765, July 23, 1987; 53 FR 6551, March 1, 1988; 53 FR 6649, March 2, 1988; 54 FR 5373, Feb. 2, 1989; 56 FR 8854, Mar. 1, 1991; 56 FR 48879, Sept. 26, 1991; 57 FR 8204, Mar. 6, 1992; 57 FR 34021, July 31, 1992; 57 FR 43925, Sept. 23, 1992; 59 FR 56251, Nov. 10, 1994; 60 FR 2330, Jan. 9, 1995; 60 FR 50120, Sept. 28, 1995; 61 FR 32350, June 24, 1996; 62 FR 43937, Aug. 18, 1997; 64 FR 24957, May 10, 1999; 64 FR 39937, July 23, 1999; 64 FR 43295, Aug. 10, 1999; 65 FR 18549, Apr. 7, 2000; 65 FR 62646, Oct. 19, 2000; 71 FR 20781, Apr. 21, 2006; 71 FR 37505, June 30, 2006]

§ 498.4 NFs subject to appeals process in part 498.

A NF is considered a provider for purposes of this part when it has in effect an agreement to participate in Medicaid, including an agreement to participate in both Medicaid and Medicare and it is a—

(a) State-operated NF; or

(b) Non State-operated NF that is subject to compliance action as a result of—

(1) A validation survey by CMS; or

(2) CMS's review of the State's survey findings.

[59 FR 56252, Nov. 10, 1994]

§ 498.5 Appeal rights.

(a) *Appeal rights of prospective providers.* (1) Any prospective provider dissatisfied with an initial determination or revised initial determination that it does not qualify as a provider may request reconsideration in accordance with § 498.22(a).

(2) Any prospective provider dissatisfied with a reconsidered determination under paragraph (a)(1) of this section, or a revised reconsidered determination under § 498.30, is entitled to a hearing before an ALJ.

(b) *Appeal rights of providers.* Any provider dissatisfied with an initial determination to terminate its provider agreement is entitled to a hearing before an ALJ.

(c) *Appeal rights of providers and prospective providers.* Any provider or prospective provider dissatisfied with a hearing decision may request Departmental Appeals Board review, and has a right to seek judicial review of the Board's decision.

(d) *Appeal rights of prospective suppliers.* (1) Any prospective supplier dissatisfied with an initial determination or a revised initial determination that its services do not meet the conditions for coverage may request reconsideration in accordance with § 498.22(a).

(2) Any prospective supplier dissatisfied with a reconsidered determination under paragraph (d)(1) of this section, or a revised reconsidered determination under § 498.30, is entitled to a hearing before an ALJ.

(e) *Appeal rights of suppliers.* Any supplier dissatisfied with an initial determination that the services subject to the determination no longer meet the conditions for coverage, is entitled to a hearing before an ALJ.

(f) *Appeal rights of suppliers and prospective suppliers.* (1) Any supplier or

prospective supplier dissatisfied with the hearing decision may request Departmental Appeals Board review of the ALJ's decision.

(2) A supplier or prospective supplier dissatisfied with an ALJ decision may request Board review, and has a right to seek judicial review of the Board's decision.

(g) *Appeal rights for certain practitioners.* A physical therapist in independent practice or a chiropractor dissatisfied with a determination that he or she does not meet the requirements for coverage of his or her services has the same appeal rights as suppliers have under paragraphs (d), (e) and (f) of this section.

(h) *Appeal rights for nonparticipating hospitals that furnish emergency services.* A nonparticipating hospital dissatisfied with a determination or decision that it does not qualify to elect to claim payment for all emergency services furnished during a calendar year has the same appeal rights that providers have under paragraph (a), (b), and (c) of this section.

(i) *Appeal rights for suspended or excluded practitioners, providers, or suppliers.* (1) Any practitioner, provider, or supplier who has been suspended, or whose services have been excluded from coverage in accordance with § 498.3(c)(2), or has been sanctioned in accordance with § 498.3(c)(3), is entitled to a hearing before an ALJ.

(2) Any suspended or excluded practitioner, provider, or supplier dissatisfied with a hearing decision may request Departmental Appeals Board review and has a right to seek judicial review of the Board's decision by filing an action in Federal district court.

(j) *Appeal rights for Medicaid ICFs/MR terminated by CMS.* (1) Any Medicaid ICF/MR that has had its approval cancelled by CMS in accordance with § 498.3(b)(8) has a right to a hearing before an ALJ, to request Departmental Appeals Board review of the hearing decision, and to seek judicial review of the Board's decision.

(2) The Medicaid agreement remains in effect until the period for requesting a hearing has expired or, if the facility requests a hearing, until a hearing decision is issued, unless CMS—

(i) Makes a written determination that continuation of provider status for the SNF or ICF constitutes an immediate and serious threat to the health and safety of patients and specifies the reasons for that determination; and

(ii) Certifies that the facility has been notified of its deficiencies and has failed to correct them.

(k) *Appeal rights of NFs.* Under the circumstances specified in § 431.153 (g) and (h) of this chapter, an NF has a right to a hearing before an ALJ, to request Board review of the hearing decision, and to seek judicial review of the Board's decision.

(l) *Appeal rights related to provider enrollment.* 1) Any prospective provider, an existing provider, prospective supplier or existing supplier dissatisfied with an initial determination or revised initial determination related to the denial or revocation of Medicare billing privileges may request reconsideration in accordance with § 498.22(a).

(2) CMS, a CMS contractor, any prospective provider, an existing provider, prospective supplier, or existing supplier dissatisfied with a reconsidered determination under paragraph (l)(1) of this section, or a revised reconsidered determination under § 498.30, is entitled to a hearing before an ALJ.

(3) CMS, a CMS contractor, any prospective provider, an existing provider, prospective supplier, or existing supplier dissatisfied with a hearing decision may request Board review, and any prospective provider, an existing provider, prospective supplier, or existing supplier has a right to seek judicial review of the Board's decision.

[52 FR 22446, June 12, 1987, as amended at 57 FR 43925, Sept. 23, 1992; 59 FR 56252, Nov. 10, 1994; 61 FR 32350, June 24, 1996; 73 FR 36462, June 27, 2008]

§ 498.10 Appointment of representatives.

(a) An affected party may appoint as its representative anyone not disqualified or suspended from acting as a representative in proceedings before the Secretary or otherwise prohibited by law.

(b) If the representative appointed is not an attorney, the party must file written notice of the appointment with

CMS, the ALJ, or the Departmental Appeals Board.

(c) If the representative appointed is an attorney, the attorney's statement that he or she has the authority to represent the party is sufficient.

§ 498.11 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 498.10 may, on behalf of the represented party—

(1) Give and accept any notice or request pertinent to the proceedings set forth in this part;

(2) Present evidence and allegations as to facts and law in any proceedings affecting that party to the same extent as the party; and

(3) Obtain information to the same extent as the party.

(b) A notice or request may be sent to the affected party, to the party's representative, or to both. A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§ 498.13 Fees for services of representatives.

Fees for any services performed on behalf of an affected party by an attorney appointed and qualified in accordance with § 498.10 are not subject to the provisions of section 206 of Title II of the Act, which authorizes the Secretary to specify or limit those fees.

§ 498.15 Charge for transcripts.

A party that requests a transcript of prehearing or hearing proceedings or Board review must pay the actual or estimated cost of preparing the transcript unless, for good cause shown by that party, the payment is waived by the ALJ or the Departmental Appeals Board, as appropriate.

[52 FR 22446, June 12, 1987, as amended at 61 FR 51021, Sept. 30, 1996]

§ 498.17 Filing of briefs with the ALJ or Departmental Appeals Board, and opportunity for rebuttal.

(a) *Filing of briefs and related documents.* If a party files a brief or related document such as a written argument, contention, suggested finding of fact, conclusion of law, or any other written statement, it must submit an original and one copy to the ALJ or the Departmental Appeals Board, as appropriate. The material may be filed by mail or in person and must include a statement certifying that a copy has been furnished to the other party.

(b) *Opportunity for rebuttal.* (1) The other party will have 20 days from the date of mailing or personal service to submit any rebuttal statement or additional evidence. If a party submits a rebuttal statement or additional evidence, it must file an original and one copy with the ALJ or the Board and furnish a copy to the other party.

(2) The ALJ or the Board will grant an opportunity to reply to the rebuttal statement only if the party shows good cause.

Subpart B—Initial, Reconsidered, and Revised Determinations

§ 498.20 Notice and effect of initial determinations.

(a) *Notice of initial determination*—(1) *General rule.* CMS or the OIG, as appropriate, mails notice of an initial determination to the affected party, setting forth the basis or reasons for the determination, the effect of the determination, and the party's right to reconsideration, if applicable, or to a hearing.

(2) *Special rules: Independent laboratories and suppliers of portable x-ray services.* If CMS determines that an independent laboratory or a supplier of portable x-ray services no longer meets the conditions for coverage of some or all of its services, the notice—

(i) Specifies an effective date of termination of coverage that is at least 15 days after the date of the notice;

(ii) Is also sent to physicians, hospitals, and other parties that might use the services of the laboratory or supplier; and

(iii) In the case of laboratories, specifies the categories of laboratory tests that are no longer covered.

(3) *Special rules: Nonparticipating hospitals that elect to claim payment for emergency services.* If CMS determines that a nonparticipating hospital no longer qualifies to elect to claim payment for all emergency services furnished in a calendar year, the notice—

(i) States the calendar year to which the determination applies;

(ii) Specifies an effective date that is at least 5 days after the date of the notice; and

(iii) Specifies that the determination applies to services furnished, in the specified calendar year, to patients accepted (as inpatients or outpatients) on or after the effective date of the determination.

(4) *Other special rules.* Additional rules pertaining, for example, to content and timing of notice, notice to the public and to other entities, and time allowed for submittal of additional information, are set forth elsewhere in this chapter, as follows:

Part 405 Subpart X—for rural health clinics.
Part 416—for ambulatory surgical centers.
Part 489—for providers, when their provider agreements have been terminated.
Part 1001, Subpart B—for excluded or suspended providers, suppliers, physicians, or practitioners.
Part 1001, Subpart C—for providers, when their provider agreements are terminated by the OIG.
Part 1004—for sanctioned providers and practitioners.

(b) *Effect of initial determination.* An initial determination is binding unless it is—

(1) Reconsidered in accordance with § 498.24;

(2) Reversed or modified by a hearing decision in accordance with § 498.78; or

(3) Revised in accordance with § 498.32 or § 498.100.

§ 498.22 Reconsideration.

(a) *Right to reconsideration.* CMS or one of its contractors reconsiders an initial determination that affects a prospective provider or supplier, or a hospital seeking to qualify to claim payment for all emergency hospital services furnished in a calendar year, if the affected party files a written request in accordance with paragraphs (b) and (c) of this section. For denial or revocation of enrollment, prospective providers and suppliers and providers and suppliers have a right to reconsideration.

(b) *Request for reconsideration: Manner and timing.* The affected party specified in paragraph (a) of this section, if dissatisfied with the initial determination may request reconsideration by filing the request—

(1) With CMS or with the State survey agency, or in the case of prospective supplier the entity specified in the notice of initial determination;

(2) Directly or through its legal representative or other authorized official; and

(3) Within 60 days from receipt of the notice of initial determination, unless the time is extended in accordance with paragraph (d) of this section. The date of receipt will be presumed to be 5 days after the date on the notice unless there is a showing that it was, in fact, received earlier or later.

(c) *Content of request.* The request for reconsideration must state the issues, or the findings of fact with which the affected party disagrees, and the reasons for disagreement.

(d) *Extension of time to file a request for reconsideration.* (1) If the affected party is unable to file the request within the 60 days specified in paragraph (b) of this section, it may file a written request with CMS, stating the reasons why the request was not filed timely.

(2) CMS will extend the time for filing a request for reconsideration if the affected party shows good cause for missing the deadline.

[52 FR 22446, June 12, 1987, as amended at 73 FR 36462, June 27, 2008]

§ 498.23 Withdrawal of request for reconsideration.

A request for reconsideration is considered withdrawn if the requestor files a written withdrawal request before CMS mails the notice of reconsidered determination, and CMS approves the withdrawal request.

§ 498.24 Reconsidered determination.

When a request for reconsideration has been properly filed in accordance with § 498.22, CMS—

(a) Receives written evidence and statements that are relevant and material to the matters at issue and are submitted within a reasonable time after the request for reconsideration;

(b) Considers the initial determination, the findings on which the initial determination was based, the evidence considered in making the initial determination, and any other written evidence submitted under paragraph (a) of this section, taking into account facts

relating to the status of the prospective provider or supplier subsequent to the initial determination; and

(c) Makes a reconsidered determination, affirming or modifying the initial determination and the findings on which it was based.

§ 498.25 Notice and effect of reconsidered determination.

(a) *Notice*. (1) CMS mails notice of a reconsidered determination to the affected party.

(2) The notice gives the reasons for the determination.

(3) If the determination is adverse, the notice specifies the conditions or requirements of law or regulations that the affected party fails to meet, and informs the party of its right to a hearing.

(b) *Effect*. A reconsidered determination is binding unless—

(1) CMS or the OIG, as appropriate, further revises the revised determination; or

(2) The revised determination is reversed or modified by a hearing decision.

Subpart C—Reopening of Initial or Reconsidered Determinations

§ 498.30 Limitation on reopening.

An initial or reconsidered determination that a prospective provider is a provider or that a hospital qualifies to elect to claim payment for all emergency services furnished in a calendar year may not be reopened. CMS or the OIG, as appropriate, may on its own initiative, reopen any other initial or reconsidered determination, within 12 months after the date of notice of the initial determination.

§ 498.32 Notice and effect of reopening and revision.

(a) *Notice*. (1) CMS or the OIG, as appropriate, gives the affected party notice of reopening and of any revision of the reopened determination.

(2) The notice of revised determination states the basis or reason for the revised determination.

(3) If the determination is that a supplier or prospective supplier does not meet the conditions for coverage of its services, the notice specifies the conditions with respect to which the affected party fails to meet the requirements of law and regulations, and informs the party of its right to a hearing.

(b) *Effect*. A revised determination is binding unless

(1) The affected party requests a hearing before an ALJ; or

(2) CMS or the OIG further revises the revised determination.

Subpart D—Hearings

§ 498.40 Request for hearing.

(a) *Manner and timing of request*. (1) An affected party entitled to a hearing under § 498.5 may file a request for a hearing with the ALJ office identified in the determination letter.

(2) The affected party or its legal representative or other authorized official must file the request in writing within 60 days from receipt of the notice of initial, reconsidered, or revised determination unless that period is extended in accordance with paragraph (c) of this section. (Presumed date of receipt is determined in accordance with § 498.22(b)(3)).

(b) *Content of request for hearing*. The request for hearing must—

(1) Identify the specific issues, and the findings of fact and conclusions of law with which the affected party disagrees; and

(2) Specify the basis for contending that the findings and conclusions are incorrect.

(c) *Extension of time for filing a request for hearing*. If the request was not filed within 60 days—

(1) The affected party or its legal representative or other authorized official may file with the ALJ a written request for extension of time stating the reasons why the request was not filed timely.

(2) For good cause shown, the ALJ may extend the time for filing the request for hearing.

[52 FR 22446, June 12, 1987, as amended at 73 FR 36462, June 27, 2008]

§ 498.42 Parties to the hearing.

The parties to the hearing are the affected party and CMS or the OIG, as appropriate.

§ 498.44 Designation of hearing official.

(a) The Secretary or his or her delegate designates an ALJ or a member or members of the Board to conduct hearings.

(b) If appropriate, the Secretary or the delegate may designate another ALJ or another member or other members of the Board to conduct the hearing.

(c) As used in this part, ''ALJ'' includes any ALJ of the Department of Health and Human Services or members of the Board who are designated to conduct a hearing.

[73 FR 36462, June 27, 2008]

§ 498.45 Disqualification of Administrative Law Judge.

(a) An ALJ may not conduct a hearing in a case in which he or she is prejudiced or partial to the affected party or has any interest in the matter pending for decision.

(b) A party that objects to the ALJ designated to conduct the hearing must give notice of its objections at the earliest opportunity.

(c) The ALJ will consider the objections and decide whether to withdraw or proceed with the hearing.

(1) If the ALJ withdraws, another will be designated to conduct the hearing.

(2) If the ALJ does not withdraw, the objecting party may, after the hearing, present its objections to the Departmental Appeals Board as reasons for changing, modifying, or reversing the ALJ's decision or providing a new hearing before another ALJ.

§ 498.47 Prehearing conference.

(a) At any time before the hearing, the ALJ may call a prehearing conference for the purpose of delineating the issues in controversy, identifying the evidence and witnesses to be presented at the hearing, and obtaining stipulations accordingly.

(b) On the request of either party or on his or her own motion, the ALJ may adjourn the prehearing conference and reconvene at a later date.

§ 498.48 Notice of prehearing conference.

(a) *Timing of notice.* The ALJ will fix a time and place for the prehearing conference and mail written notice to the parties at least 10 days before the scheduled date.

(b) *Content of notice.* The notice will inform the parties of the purpose of the conference and specify what issues are sought to be resolved, agreed to, or excluded.

(c) *Additional issues.* Issues other than those set forth in the notice of determination or the request for hearing may be considered at the prehearing conference if—

(1) Either party gives timely notice to that effect to the ALJ and the other party; or

(2) The ALJ raises the issues in the notice of prehearing conference or at the conference.

§ 498.49 Conduct of prehearing conference.

(a) The prehearing conference is open to the affected party or its representative, to the CMS or OIG representatives and their technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) The ALJ may accept the agreement of the parties as to the following:

(1) Facts that are not in controversy.

(2) Questions that have been resolved favorably to the affected party after the determination in dispute.

(3) Remaining issues to be resolved.

(c) The ALJ may request the parties to indicate the following:

(1) The witnesses that will be present to testify at the hearing.

(2) The qualifications of those witnesses.

(3) The nature of other evidence to be submitted.

§ 498.50 Record, order, and effect of prehearing conference.

(a) *Record of prehearing conference.* (1) A record is made of all agreements and stipulations entered into at the prehearing conference.

(2) The record may be transcribed at the request of either party or the ALJ.

(b) *Order and opportunity to object.* (1) The ALJ issues an order setting forth

the results of the prehearing conference, including the agreements made by the parties as to facts not in controversy, the matters to be considered at the hearing, and the issues to be resolved.

(2) Copies of the order are sent to all parties and the parties have 10 days to file objections to the order.

(3) After the 10 days have elapsed, the ALJ settles the order.

(c) *Effect of prehearing conference.* The agreements and stipulations entered into at the prehearing conference are binding on all parties, unless a party presents facts that, in the opinion of the ALJ, would make an agreement unreasonable or inequitable.

§ 498.52 Time and place of hearing.

(a) The ALJ fixes a time and place for the hearing and gives the parties written notice at least 10 days before the scheduled date.

(b) The notice informs the parties of the general and specific issues to be resolved at the hearing.

§ 498.53 Change in time and place of hearing.

(a) The ALJ may change the time and place for the hearing either on his or her own initiative or at the request of a party for good cause shown, or may adjourn or postpone the hearing.

(b) The ALJ may reopen the hearing for receipt of new evidence at any time before mailing the notice of hearing decision.

(c) The ALJ gives the parties reasonable notice of any change in time or place or any adjournment or reopening of the hearing.

§ 498.54 Joint hearings.

When two or more affected parties have requested hearings and the same or substantially similar matters are at issue, the ALJ may, if all parties agree, fix a single time and place for the prehearing conference or hearing and conduct all proceedings jointly. If joint hearings are held, a single record of the preceedings is made and a separate decision issued with respect to each affected party.

§ 498.56 Hearing on new issues.

(a) *Basic rules.* (1) Within the time limits specified in paragraph (b) of this section, the ALJ may, at the request of either party, or on his or her own motion, provide a hearing on new issues that impinge on the rights of the affected party.

(2) Except for provider or supplier enrollment appeals which are addressed in § 498.56(e), the ALJ may consider new issues even if CMS or the OIG has not made initial or reconsidered determinations on them, and even if they arose after the request for hearing was filed or after the prehearing conference.

(3) The ALJ may give notice of hearing on new issues at any time after the hearing request is filed and before the hearing record is closed.

(b) *Time limits.* The ALJ will not consider any issue that arose on or after any of the following dates:

(1) The effective date of the termination of a provider agreement.

(2) The date on which it is determined that a supplier no longer meets the conditions for coverage of its services.

(3) The effective date of the notice to a hospital of its failure to remain in compliance with the qualifications for claiming reimbursement for all emergency services furnished to Medicare beneficiaries during the calendar year.

(4) The effective date of the suspension, or of the exclusion from coverage of services furnished by a suspended or excluded practitioner, provider, or supplier.

(5) With respect to Medicaid SNFs or ICFs surveyed under section 1910(c) of the Act—

(i) The completion date of the survey or resurvey that is the basis for a proposed cancellation of approval; or

(ii) If approval was cancelled before the hearings, because of immediate and serious threat to patient health and safety, the effective date of cancellation.

(c) *Notice and conduct of hearing on new issues.* (1) Unless the affected party waives its right to appear and present evidence, notice of the time and place of hearing on any new issue will be given to the parties in accordance with § 498.52.

(2) After giving notice, the ALJ will, except as provided in paragraph (d) of this section, proceed to hearing on new issues in the same manner as on an issue raised in the request for hearing.

(d) *Remand to CMS or the OIG.* At the request of either party, or on his or her own motion, in lieu of a hearing under paragraph (c) of this section, the ALJ may remand the case to CMS or the OIG for consideration of the new issue and, if appropriate, a determination. If necessary, the ALJ may direct CMS or the OIG to return the case to the ALJ for further proceedings.

(e) *Provider and supplier enrollment appeals: Good cause requirement*—(1) *Examination of any new documentary evidence.* After a hearing is requested but before it is held, the ALJ will examine any new documentary evidence submitted to the ALJ by a provider or supplier to determine whether the provider or supplier has good cause for submitting the evidence for the first time at the ALJ level.

(2) *Determining if good cause exists.*—(i) *If good cause exists.* If the ALJ finds that there is good cause for submitting new documentary evidence for the first time at the ALJ level, the ALJ must include evidence and may consider it in reaching a decision.

(ii) *If good cause does not exist.* If the ALJ determines that there was not good cause for submitting the evidence for the first time at the ALJ level, the ALJ must exclude the evidence from the proceeding and may not consider it in reaching a decision.

(2) *Notification to all parties.* As soon as possible, but no later than the start of the hearing, the ALJ must notify all parties of any evidence that is excluded from the hearing.

[52 FR 22446, June 12, 1987, as amended at 53 FR 31335, Aug. 18, 1988; 73 FR 36463, June 27, 2008]

§ 498.58 Subpoenas.

(a) *Basis for issuance.* The ALJ, upon his or her own motion or at the request of a party, may issue subpoenas if they are reasonably necessary for the full presentation of a case.

(b) *Timing of request by a party.* The party must file a written request for a subpoena with the ALJ at least 5 days before the date set for the hearing.

(c) *Content of request.* The request must:

(1) Identify the witnesses or documents to be produced;

(2) Describe their addresses or location with sufficient particularity to permit them to be found; and

(3) Specify the pertinent facts the party expects to establish by the witnesses or documents, and indicate why those facts could not be established without use of a subpoena.

(d) *Method of issuance.* Subpoenas are issued in the name of the Secretary, who pays the cost of issuance and the fees and mileage of any subpoenaed witnesses.

§ 498.60 Conduct of hearing.

(a) *Participants in the hearing.* The hearing is open to the parties and their representatives and technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) *Hearing procedures.* (1) The ALJ inquires fully into all of the matters at issue, and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(2) If the ALJ believes that there is relevant and material evidence available which has not been presented at the hearing, he may, at any time before mailing of notice of the decision, reopen the hearing to receive that evidence.

(3) The ALJ decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

(c) *Scope of review: Civil money penalty.* In civil money penalty cases—

(1) The scope of review is as specified in § 488.438(e) of this chapter; and

(2) CMS's determination as to the level of noncompliance of an SNF or NF must be upheld unless it is clearly erroneous.

[52 FR 22446, June 12, 1987, as amended at 61 FR 32350, June 24, 1996]

§ 498.61 Evidence.

Evidence may be received at the hearing even though inadmissible under the rules of evidence applicable

to court procedure. The ALJ rules on the admissibility of evidence.

[59 FR 56252, Nov. 10, 1994, as amended at 61 FR 32350, June 24, 1996]

§ 498.62 Witnesses.

Witnesses at the hearing testify under oath or affirmation. The representative of each party is permitted to examine his or her own witnesses subject to interrogation by the representative of the other party. The ALJ may ask any questions that he or she deems necessary. The ALJ rules upon any objection made by either party as to the propriety of any question.

§ 498.63 Oral and written summation.

The parties to a hearing are allowed a reasonable time to present oral summation and to file briefs or other written statements of proposed findings of fact and conclusions of law. Copies of any briefs or other written statements must be sent in accordance with § 498.17.

§ 498.64 Record of hearing.

A complete record of the proceedings at the hearing is made and transcribed in all cases.

§ 498.66 Waiver of right to appear and present evidence.

(a) *Waiver procedures*. (1) If an affected party wishes to waive its right to appear and present evidence at the hearing, it must file a written waiver with the ALJ.

(2) If the affected party wishes to withdraw a waiver, it may do so, for good cause, at any time before the ALJ mails notice of the hearing decision.

(b) *Effect of waiver*. If the affected party waives the right to appear and present evidence, the ALJ need not conduct an oral hearing except in one of the following circumstances:

(1) The ALJ believes that the testimony of the affected party or its representatives or other witnesses is necessary to clarify the facts at issue.

(2) CMS or the OIG shows good cause for requiring the presentation of oral evidence.

(c) *Dismissal for failure to appear*. If, despite the waiver, the ALJ sends notice of hearing and the affected party fails to appear, or to show good cause for the failure, the ALJ will dismiss the appeal in accordance with § 498.69.

(d) *Hearing without oral testimony*. When there is no oral testimony, the ALJ will—

(1) Make a record of the relevant written evidence that was considered in making the determination being appealed, and of any additional evidence submitted by the parties;

(2) Furnish to each party copies of the additional evidence submitted by the other party; and

(3) Give both parties a reasonable opportunity for rebuttal.

(e) *Handling of briefs and related statements*. If the parties submit briefs or other written statements of evidence or proposed findings of facts or conclusions of law, those documents will be handled in accordance with § 498.17.

§ 498.68 Dismissal of request for hearing.

(a) The ALJ may, at any time before mailing the notice of the decision, dismiss a hearing request if a party withdraws its request for a hearing or the affected party asks that its request be dismissed.

(b) An affected party may request a dismissal by filing a written notice with the ALJ.

§ 498.69 Dismissal for abandonment.

(a) The ALJ may dismiss a request for hearing if it is abandoned by the party that requested it.

(b) The ALJ may consider a request for hearing to be abandoned if the party or its representative—

(1) Fails to appear at the prehearing conference or hearing without having previously shown good cause for not appearing; and

(2) Fails to respond, within 10 days after the ALJ sends a ''show cause'' notice, with a showing of good cause.

§ 498.70 Dismissal for cause.

On his or her own motion, or on the motion of a party to the hearing, the ALJ may dismiss a hearing request either entirely or as to any stated issue, under any of the following circumstances:

(a) *Res judicata*. There has been a previous determination or decision with

respect to the rights of the same affected party on the same facts and law pertinent to the same issue or issues which has become final either by judicial affirmance or, without judicial consideration, because the affected party did not timely request reconsideration, hearing, or review, or commence a civil action with respect to that determination or decision.

(b) *No right to hearing*. The party requesting a hearing is not a proper party or does not otherwise have a right to a hearing.

(c) *Hearing request not timely filed*. The affected party did not file a hearing request timely and the time for filing has not been extended.

§ 498.71 Notice and effect of dismissal and right to request review.

(a) Notice of the ALJ's dismissal action is mailed to the parties. The notice advises the affected party of its right to request that the dismissal be vacated as provided in § 498.72.

(b) The dismissal of a request for hearing is binding unless it is vacated by the ALJ or the Departmental Appeals Board.

§ 498.72 Vacating a dismissal of request for hearing.

An ALJ may vacate any dismissal of a request for hearing if a party files a request to that effect within 60 days from receipt of the notice of dismissal and shows good cause for vacating the dismissal. (Date of receipt is determined in accordance with § 498.22(b)(3).)

§ 498.74 Administrative Law Judge's decision.

(a) *Timing, basis and content*. As soon as practical after the close of the hearing, the ALJ issues a written decision in the case. The decision is based on the evidence of record and contains separate numbered findings of fact and conclusions of law.

(b) *Notice and effect*. A copy of the decision is mailed to the parties and is binding on them unless—

(1) A party requests review by the Departmental Appeals Board within the time period specified in § 498.82, and the Board reviews the case;

(2) The Departmental Appeals Board denies the request for review and the party seeks judicial review by filing an action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals;

(3) The decision is revised by an ALJ or the Departmental Appeals Board; or

(4) The decision is a recommended decision directed to the Board.

[52 FR 22446, June 12, 1987, as amended at 61 FR 32351, June 24, 1996]

§ 498.76 Removal of hearing to Departmental Appeals Board.

(a) At any time before the ALJ receives oral testimony, the Board may remove to itself any pending request for a hearing.

(b) Notice of removal is mailed to each party.

(c) The Board conducts the hearing in accordance with the rules that apply to ALJ hearings under this subpart.

§ 498.78 Remand by the Administrative Law Judge.

(a) If CMS requests a remand, the ALJ may remand any case properly before him or her to CMS.

(b) The ALJ may remand at any time before notice of hearing decision is mailed.

[52 FR 22446, June 12, 1987, as amended at 73 FR 36463, June 27, 2008]

§ 498.79 Timeframes for deciding an enrollment appeal before an ALJ.

When a request for an ALJ hearing is filed after CMS or a FFS contractor has denied an enrollment application, the ALJ must issue a decision, dismissal order or remand to CMS, as appropriate, no later than the end of the 180-day period beginning from the date the appeal was filed with an ALJ.

[73 FR 36463, June 27, 2008]

Subpart E—Departmental Appeals Board Review

§ 498.80 Right to request Departmental Appeals Board review of Administrative Law Judge's decision or dismissal.

Either of the parties has a right to request Departmental Appeals Board

review of the ALJ's decision or dismissal order, and the parties are so informed in the notice of the ALJ's action.

§ 498.82 Request for Departmental Appeals Board review.

(a) *Manner and time of filing.* (1) Any party that is dissatisfied with an ALJ's decision or dismissal of a hearing request, may file a written request for review by the Departmental Appeals Board.

(2) The requesting party or its representative or other authorized official must file the request with the OHA within 60 days from receipt of the notice of decision or dismissal, unless the Board, for good cause shown by the requesting party, extends the time for filing. The rules set forth in § 498.40(c) apply to extension of time for requesting Departmental Appeals Board review. (The date of receipt of notice is determined in accordance with § 498.22(c)(3).)

(b) *Content of request for review.* A request for review of an ALJ decision or dismissal must specify the issues, the findings of fact or conclusions of law with which the party disagrees, and the basis for contending that the findings and conclusions are incorrect.

§ 498.83 Departmental Appeals Board action on request for review.

(a) *Request by CMS or the OIG.* The Departmental Appeals Board may dismiss, deny, or grant a request made by CMS or the OIG for review of an ALJ decision or dismissal.

(b) *Request by the affected party.* The Board will grant the affected party's request for review unless it dismisses the request for one of the following reasons:

(1) The affected party requests dismissal of its request for review.

(2) The affected party did not file timely or show good cause for late filing.

(3) The affected party does not have a right to review.

(4) A previous determination or decision, based on the same facts and law, and regarding the same issue, has become final through judicial affirmance or because the affected party failed to timely request reconsideration, hearing, Board review, or judicial review, as appropriate.

(c) *Effect of dismissal.* The dismissal of a request for Departmental Appeals Board review is binding and not subject to further review.

(d) *Review panel.* If the Board grants a request for review of the ALJ's decision, the review will be conducted by a panel of at least two members of the Board, designated by the Chairperson or Deputy Chairperson, and one individual designated by the Secretary from the U.S Public Health Service.

§ 498.85 Procedures before the Departmental Appeals Board on review.

The parties are given, upon request, a reasonable opportunity to file briefs or other written statements as to fact and law, and to appear before the Departmental Appeals Board to present evidence or oral arguments. Copies of any brief or other written statement must be sent in accordance with § 498.17.

§ 498.86 Evidence admissible on review.

(a) Except for provider or supplier enrollment appeals, the Board may admit evidence into the record in addition to the evidence introduced at the ALJ hearing (or the documents considered by the ALJ if the hearing was waived) if the Board considers that the additional evidence is relevant and material to an issue before it.

(b) If it appears to the Board that additional relevant evidence is available, the Board will require that it be produced.

(c) Before additional evidence is admitted into the record—

(1) Notice is mailed to the parties (unless they have waived notice) stating that evidence will be received regarding specified issues; and

(2) The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues.

(d) If additional evidence is presented orally to the Board, a transcript is prepared and made available to any party upon request.

[52 FR 22446, June 12, 1987, as amended at 73 FR 36463, June 27, 2008]

§ 498.88 Decision or remand by the Departmental Appeals Board.

(a) When the Departmental Appeals Board reviews an ALJ's decision or order of dismissal, or receives a case remanded by a court, the Board may either issue a decision or remand the case to an ALJ for a hearing and decision or a recommended decision for final decision by the Board.

(b) In a remanded case, the ALJ initiates additional proceedings and takes other actions as directed by the Board in its order of remand, and may take other action not inconsistent with that order.

(c) Upon completion of all action called for by the remand order and any other consistent action, the ALJ promptly makes a decision or, as specified by the Board, certifies the case to the Board with a recommended decision.

(d) The parties have 20 days from the date of a notice of a recommended decision to submit to the Board any exception, objection, or comment on the findings of fact, conclusions of law, and recommended decision.

(e) After the 20-day period, the Board issues its decision adopting, modifying or rejecting the ALJ's recommended decision.

(f) If the Board does not remand the case to an ALJ, the following rules apply:

(1) The Board's decision—

(i) Is based upon the evidence in the hearing record and any further evidence that the Board receives during its review;

(ii) Is in writing and contains separate numbered findings of fact and conclusions of law; and

(iii) May modify, affirm, or reverse the ALJ's decision.

(2) A copy of the Board's decision is mailed to each party.

(g) When a request for Board review of a denial of an enrollment application is filed after an ALJ has issued a decision or dismissal order, the Board must issue a decision, dismissal order or remand to the ALJ, as appropriate, no later than 180 days after the appeal was received by the Board.

[52 FR 22446, June 12, 1987, as amended at 73 FR 36463, June 27, 2008]

§ 498.90 Effect of Departmental Appeals Board decision.

(a) *General rule.* The Board's decision is binding unless—

(1) The affected party has a right to judicial review and timely files a civil action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals; or

(2) The Board reopens and revises its decision in accordance with § 498.102.

(b) *Right to judicial review.* Section 498.5 specifies the circumstances under which an affected party has a right to seek judicial review.

(c) *Special rules: Civil money penalty*—(1) *Finality of Board's decision.* When CMS imposes a civil money penalty, notice of the Board's decision (or denial of review) is the final administrative action that initiates the 60-day period for seeking judicial review.

(2) *Timing for collection of civil money penalty.* For SNFs and NFs, the rules that apply are those set forth in subpart F of part 488 of this chapter.

[61 FR 32351, June 24, 1996]

§ 498.95 Extension of time for seeking judicial review.

(a) Any affected party that is dissatisfied with an Departmental Appeals Board decision and is entitled to judicial review must commence civil action within 60 days from receipt of the notice of the Board's decision (as determined under § 498.22(c)(3)), unless the Board extends the time in accordance with paragraph (c) of this section.

(b) The request for extension must be filed in writing with the Board before the 60-day period ends.

(c) For good cause shown, the Board may extend the time for commencing civil action.

Subpart F—Reopening of Decisions Made by Administrative Law Judges or the Departmental Appeals Board

§ 498.100 Basis, timing, and authority for reopening an ALJ or Board decision.

(a) *Basis and timing for reopening.* An ALJ of Departmental Appeals Board decision may be reopened, within 60

days from the date of the notice of decision, upon the motion of the ALJ or the Board or upon the petition of either party to the hearing.

(b) *Authority to reopen.* (1) A decision of the Departmental Appeals Board may be reopened only by the Departmental Appeals Board.

(2) A decision of an ALJ may be reopened by that ALJ, by another ALJ if that one is not available, or by the Departmental Appeals Board. For purposes of this paragraph, an ALJ is considered to be unavailable if the ALJ has died, terminated employment, or been transferred to another duty station, is on leave of absence, or is unable to conduct a hearing because of illness.

§ 498.102 Revision of reopened decision.

(a) *Revision based on new evidence.* If a reopened decision is to be revised on the basis of new evidence that was not included in the record of that decision, the ALJ or the Departmental Appeals Board—

(1) Notifies the parties of the proposed revision; and

(2) Unless the parties waive their right to hearing or appearance—

(i) Grants a hearing in the case of an ALJ revision; and

(ii) Grants opportunity to appear in the case of a Board revision.

(b) *Basis for revised decision and right to review.* (1) If a revised decision is necessary, the ALJ or the Departmental Appeals Board, as appropriate, renders it on the basis of the entire record.

(2) If the decision is revised by an ALJ, the Departmental Appeals Board may review that revised decision at the request of either party or on its own motion.

§ 498.103 Notice and effect of revised decision.

(a) *Notice.* The notice mailed to the parties states the basis or reason for the revised decision and informs them of their right to Departmental Appeals Board review of an ALJ revised decision, or to judicial review of a Board reviewed decision.

(b) *Effect*—(1) *ALJ revised decision.* An ALJ revised decision is binding unless it is reviewed by the Departmental Appeals Board.

(2) *Departmental Appeals Board revised decision.* A Board revised decision is binding unless a party files a civil action in a district court of the United States within the time frames specified in § 498.95.

SUBCHAPTER H—HEALTH CARE INFRASTRUCTURE IMPROVEMENT PROGRAM

PART 505—ESTABLISHMENT OF THE HEALTH CARE INFRASTRUCTURE IMPROVEMENT PROGRAM

Subpart A—Loan Criteria

Sec.
505.1 Basis and scope.
505.3 Definitions.
505.5 Loan criteria.
505.7 Terms of the loan.
505.9 State and local permits.
505.11 Loan application requirements and procedures.

Subpart B—Forgiveness of Indebtedness

505.13 Conditions for loan forgiveness.
505.15 Plan criteria for meeting the conditions for loan forgiveness.
505.17 Reporting requirements for meeting the conditions for loan forgiveness.
505.19 Approval or denial of loan forgiveness.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C 1302 and 1395hh).

SOURCE: 70 FR 57374, Sept. 30, 2005, unless otherwise noted.

Subpart A—Loan Criteria

§ 505.1 Basis and scope.

This part implements section 1016 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) which amends section 1897 of the Act. Section 1897 of the Act as amended by section 6045 of the Tsunami Relief Act of 2005 authorizes the Secretary to establish a loan program by which qualifying hospitals may apply for a loan for the capital costs of the health care infrastructure improvement projects. Section 1897 of the Act appropriates $142,000,000 for the loan program including program administration. The funds are available beginning July 1, 2004 through September 30, 2008. This part sets forth the criteria that CMS uses to select among qualifying hospitals.

§ 505.3 Definitions.

For purposes of this subpart, the following definitions apply:

Eligible project means the project of a qualifying hospital that is designed to improve the health care infrastructure of the hospital, including construction, renovation, or other capital improvements.

Entity is an entity described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of the code. An entity must also have at least one existing memorandum of understanding or affiliation agreement with a hospital located in the State in which the entity is located and retains clinical outpatient treatment for cancer on site as well as laboratory research, education, and outreach for cancer in the same facility.

*Outreach program*s mean formal cancer programs for teaching, diagnostic screening, therapy or treatment, prevention, or interventions to enhance the health and knowledge of their designated population(s).

Qualifying hospital means a hospital as defined at section 1861(e) of the Act (42 U.S,C. 1395x(e)) or an entity (as defined in this section) that is engaged in research in the causes, prevention, and treatment of cancer; and is either designated as a cancer center for the National Cancer Institute; or designated by the State legislature as the official cancer institute of the State before December 8, 2003.

Unique research resources means resources that are used for the purpose of discovering or testing options related to the causes, prevention, and treatment of cancer.

[70 FR 57374, Sept. 30, 2005, as amended at 71 FR 48143, Aug. 18, 2006]

§ 505.5 Loan criteria.

(a) *Qualifying criteria*. To qualify for the loan program, the applicant must meet the following conditions:

(1) Meet the definition of a ''qualifying hospital'' as set forth in § 505.3 of this part.

(2) Request a loan for the capital costs of an ''eligible project'' as defined in § 505.3 of this part. The capital costs

for which a qualifying hospital may obtain a loan are limited to the reasonable costs incurred by the hospital, and capitalized on the Medicare cost report, for any facility or item of equipment that it has acquired the possession or use of at the time the loan funding is awarded.

(b) *Selection criteria.* In selecting loan recipients, CMS prioritizes qualifying hospitals that meet the following criteria:

(1) The hospital is located in a State that, based on population density, is defined as a rural State. A rural State is one of ten States with the lowest population density. An applicant entity is required to be located in one of these ten States. The ten States are prioritized beginning with the State with the lowest population density. Population density is determined based on the most recent available U.S. Census Bureau data.

(2) The hospital is located in a State with multiple Indian tribes in the State. After prioritizing based on paragraph (b)(1) of this section, States are further prioritized based on the States with the most Indian tribes. The number of Indian tribes in a State is based on the most recent data available published in ''Indian Entities Recognized and Eligible to Receive Services from the United State Bureau of Indian Affairs.'' (68 FR 68180) published on December 5, 2003.

(c) CMS will send written notice to qualifying hospitals that have been selected to participate in the loan program under this part.

§ 505.7 Terms of the loan.

All loan recipients must agree to the following loan terms:

(a) *Loan obligation.* An authorized official of a qualifying hospital must execute a promissory note, loan agreement, or a form approved by CMS and accompanied by any other documents CMS may designate. The loan recipient must provide required documentation in a timely manner.

(b) *Schedule of loan.* A loan recipient receives a lump sum distribution for which payment of principal and interest is deferred for 60 months beginning with the day of award notification from CMS. The loan repayment period is 20 years.

(c) *Bankruptcy protection.* In the event a loan recipient files for bankruptcy protection in a court of competent jurisdiction or otherwise proves to be insolvent, CMS may terminate the deferment period described in paragraph (b) of this section and require immediate payment of the loan. If a loan recipient should file for bankruptcy protection in a court of competent jurisdiction or should otherwise evidence insolvency after the deferment period we will require immediate repayment of the outstanding principal and interest due. Those payments may be deducted from any Medicare payments otherwise due that hospital.

(d) *Loan forgiveness.* CMS does not require a loan recipient to begin making payments of principal or interest at the end of the 60-month deferment period if it determines that the loan recipient meets the criteria for loan forgiveness under section 1897 of the Act, as determined by the Secretary.

(e) *Default.* If a loan recipient fails to make any payment in repayment of a loan under this subpart within 10 days of its due date, the loan recipient may be considered to have defaulted on the loan. Upon default, all principal and accrued interest become due immediately, and CMS may require immediate payment of any outstanding principal and interest due. Those payments may be deducted from any Medicare payments otherwise due that hospital.

(f) *Loan repayment.* The loan recipient must meet the following conditions:

(1) Make payments every month for 20 years until the loan, including interest payments, are paid in full.

(2) Pay interest on the unpaid principal until the full amount of principal has been paid.

(3) Pay interest at a yearly rate based upon the rate as fixed by the Secretary of the Treasury and set forth at 45 CFR 30.13(a).

(4) If a loan recipient fails to make any payment in repayment of a loan under this subpart within 10 days of its due date, that payment may be deducted from any Medicare payments otherwise due to the recipient.

(g) *Interest rate and monthly payment charges.* CMS calculates interest charges and payments consistent with § 405.378 of this chapter.

(h) *Loan recipient's right to prepay.* A loan recipient has the right to make payments of principal at any time before they are due. A loan recipient may make full prepayment or partial prepayment without paying any prepayment charge. If a prepayment is made, the loan recipient must provide written notice to CMS at CMS, Division of Accounting Operations, P.O. Box 75120, Baltimore, MD 21207–0520.

§ 505.9 State and local permits.

With respect to an eligible project, the provision of a loan under this part shall not—

(a) Relieve the recipient of the loan or any obligation to obtain any required State or local permit or approval with respect to the project.

(b) Limit the right of any unit of State or local government to approve or regulate any rate of return on private equity invested in the project.

(c) Supersede any State or local law (including any regulation) applicable to the construction or operation of the project.

§ 505.11 Loan application requirements and procedures.

(a) The loan application must be received by CMS no later than 5 p.m. e.d.t. on December 29, 2005.

(b) The requested information must be typed or clearly printed in ink and the loan recipient must mail or deliver an original copy of the loan to CMS. The loan application must contain the following information:

(1) Qualifying hospital's name and street address.

(2) Qualifying hospital's Medicare provider number.

(3) Name, title, and telephone number of a contact person submitting the application.

(4) Provide all appropriate supporting documentation for each answer made on the loan application.

Subpart B—Forgiveness of Indebtedness

SOURCE: 71 FR 48144, Aug. 18, 2006, unless otherwise noted.

§ 505.13 Conditions for loan forgiveness.

The Secretary may forgive a loan provided under this part if the qualifying hospital—

(a) Has been selected to participate in the loan program specified in § 505.5(c).

(b) Has established the following in accordance with a plan that meets the criteria specified in § 505.15:

(1) An outreach program for cancer prevention, early diagnosis, and treatment that provides services to a substantial majority of the residents of a State or region, including residents of rural areas;

(2) An outreach program for cancer prevention, early diagnosis, and treatment that provides services to multiple Indian tribes; and

(3) Unique research resources (such as population databases) or an affiliation with an entity that has unique research resources.

(c) Submits to CMS, within the timeframe specified by the Secretary, a—

(1) Written request for loan forgiveness; and

(2) Loan forgiveness plan that meets the criteria specified in § 505.15 of this subpart.

§ 505.15 Plan criteria for meeting the conditions for loan forgiveness.

The qualifying hospital requesting loan forgiveness must submit to CMS a plan specifying how it will develop, implement, or maintain an existing outreach program for cancer prevention, early diagnosis, and treatment for a substantial majority of the residents of a State or region, including residents of rural areas and for multiple Indian tribes and specifying how the qualifying hospital will establish or maintain existing unique research resources or an affiliation with an entity that has unique research resources.

(a) *Outreach programs.* The initial plan must specify how the hospital will establish or develop, implement, or

maintain existing outreach programs. The plan must—

(1) Address cancer prevention for cancers that are prevalent in the designated populations or cancers that are targeted by the qualifying hospital, interventions, and goals for decreasing the targeted cancer rates during the loan deferment program; and

(2) Address early diagnosis of cancers that are prevalent in the designated populations or cancers that are targeted by the qualifying hospital, interventions, and goals for improving early diagnosis rates for the targeted cancer(s) during the loan deferment period;

(3) Address cancer treatment for cancers that are prevalent in the designated populations or cancers that are targeted by the qualifying hospital, interventions, and goals for improving cancer treatment rates for the targeted cancer(s) during the loan deferment; and

(4) Identify the measures that will be used to determine the qualifying hospital's annual progress in meeting the initial goals specified in paragraphs (a)(1) through (a)(3) of this section.

(b) *Unique research resources.* The plan must specify how the qualifying hospital will establish or maintain existing unique research resources or an affiliation with an entity that has unique research resources.

§ 505.17 Reporting requirements for meeting the conditions for loan forgiveness.

(a) *Annual reporting requirements.* On an annual basis, beginning one year from the date that CMS notified the qualifying hospital of the loan award, the qualifying hospital must submit a report to CMS that updates the plan specified in § 505.15 by—

(1) Describing the qualifying hospital's progress in meeting its initial plan goals;

(2) Describing any changes to the qualifying hospital's initial plan goals; and

(3) Including at least one measure used to track the qualifying hospital's progress in meeting its plan goals.

(b) *Review of annual reports.* CMS will review each qualifying hospital's annual report to provide the hospital with feedback regarding its loan forgiveness status. If CMS determines that the annual report shows that the qualifying hospital has fulfilled the conditions, plan criteria, and reporting requirements for loan forgiveness specified in §§ 505.13, 505.15, and § 505.17, CMS will notify the qualifying hospital in writing that the loan is forgiven.

(c) *Final annual reporting requirements.* A qualifying hospital must submit its final report to CMS at least 6 months before the end of the loan deferment period specified in § 505.7(b).

§ 505.19 Approval or denial of loan forgiveness.

(a) *Approval of loan forgiveness.* If CMS determines that a qualifying hospital has met the conditions, plan criteria, and reporting requirements for loan forgiveness specified in § 505.13, § 505.15, and § 505.17, CMS will send a written notification of approval for loan forgiveness to the qualifying hospital by the earlier of—

(1) 30 days from the date of receipt of the annual report that shows the qualifying hospital has satisfied the requirements for loan forgiveness; or

(2) 90 days before the end of the loan deferment period defined in § 505.7(b).

(b) *Denial of loan forgiveness.* If CMS determines that a qualifying hospital has not met the conditions, plan criteria, or reporting requirements for loan forgiveness specified in § 505.13, § 505.15, or § 505.17 of this part, CMS will send a written notification of denial of loan forgiveness to the qualifying hospital at least 30 days before the end of the loan deferment period defined in § 505.7(b).

CHAPTER V—OFFICE OF INSPECTOR GENERAL-HEALTH CARE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

EDITORIAL NOTE: Nomenclature changes to chapter V appear at 66 FR 39452, July 31, 2001, and 67 FR 36540, May 24, 2002.

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SUBCHAPTER A—GENERAL PROVISIONS

PART 1000—INTRODUCTION; GENERAL DEFINITIONS

Subpart A [Reserved]

Subpart B—Definitions

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1000.10 General definitions.
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1000.30 Definitions specific to Medicaid.

AUTHORITY: 42 U.S.C. 1320 and 1395hh.

SOURCE: 51 FR 34766, Sept. 30, 1986, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Definitions

§ 1000.10 General definitions.

In this chapter, unless the context indicates otherwise—

Act means the Social Security Act, and titles referred to are titles of that Act.

Administrator means the Administrator, Centers for Medicare & Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA).

Beneficiary means any individual eligible to have benefits paid to him or her, or on his or her behalf, under Medicare or any State health care program.

CFR stands for Code of Federal Regulations.

CMS stands for Centers for Medicare & Medicaid Services, formerly the Health Care Financing Administration (HCFA).

Department means the Department of Health and Human Services (HHS), formerly the Department of Health, Education, and Welfare.

Directly, as used in the definition of ''furnished'' in this section, means the provision of items and services by individuals or entities (including items and services provided by them, but manufactured, ordered or prescribed by another individual or entity) who submit claims to Medicare, Medicaid or other Federal health care programs.

ESRD stands for end-stage renal disease.

FR stands for FEDERAL REGISTER.

Furnished refers to items or services provided or supplied, directly or indirectly, by any individual or entity. This includes items and services manufactured, distributed or otherwise provided by individuals or entities that do not directly submit claims to Medicare, Medicaid or other Federal health care programs, but that supply items or services to providers, practitioners or suppliers who submit claims to these programs for such items or services.

HHS stands for the Department of Health and Human Services.

HHA stands for home health agency.

HMO stands for health maintenance organization.

ICF stands for intermediate care facility.

Indirectly, as used in the definition of ''furnished'' in this section, means the provision of items and services manufactured, distributed or otherwise supplied by individuals or entities who do not directly submit claims to Medicare, Medicaid or other Federal health care programs, but that provide items and services to providers, practitioners or suppliers who submit claims to these programs for such items and services. This term does not include individuals and entities that submit claims directly to these programs for items and services ordered or prescribed by another individual or entity.

Inspector General means the Inspector General for Health and Human Services.

Medicaid means medical assistance provided under a State plan approved under Title XIX of the Act.

Medicare means the health insurance program for the aged and disabled under Title XVIII of the Act.

OIG means the Office of Inspector General within HHS.

QIO stands for Utilization and Quality Control Quality Improvement Organization.

Secretary means the Secretary of Health and Human Services.

SNF stands for skilled nursing facility.

Social security benefits means monthly cash benefits payable under section 202 or 223 of the Act.

SSA stands for Social Security Administration.

United States means the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

U.S.C. stands for United States Code.

[51 FR 34766, Sept. 30, 1986 as amended at 57 FR 3329, Jan. 29, 1992; 63 FR 46685, Sept. 2, 1998; 66 FR 39452, July 31, 2001]

§ 1000.20 Definitions specific to Medicare.

As used in connection with the Medicare program, unless the context indicates otherwise—

Carrier means an entity that has a contract with CMS to determine and make Medicare payments for Part B benefits payable on a charge basis and to perform other related functions.

Entitled means that an individual meets all the requirements for Medicare benefits.

Hospital insurance benefits means payments on behalf of, and in rare circumstances directly to, an entitled individual for services that are covered under Part A of Title XVIII of the Act.

Intermediary means an entity that has a contract with CMS to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis and to perform other related functions.

Medicare Part A means the hospital insurance program authorized under Part A of Title XVIII of the Act.

Medicare Part B means the supplementary medical insurance program authorized under Part B of Title XVIII of the Act.

Provider means a hospital, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or effective November 1, 1983 through September 30, 1986, a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has a similar agreement but only to furnish outpatient physical therapy or speech pathology services.

Railroad retirement benefits means monthly benefits payable to individuals under the Railroad Retirement Act of 1974 (45 U.S.C. beginning at section 231).

Services means medical care or services and items, such as medical diagnosis and treatment, drugs and biologicals, supplies, appliances, and equipment, medical social services, and use of hospital or SNF facilities.

Supplementary medical insurance benefits means payment to or on behalf of an entitled individual for services covered under Part B of Title XVIII of the Act.

Supplier means a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare.

[51 FR 34766, Sept. 30, 1986, as amended at 57 FR 3329, Jan. 29, 1992]

§ 1000.30 Definitions specific to Medicaid.

As used in connection with the Medicaid program, unless the context indicates otherwise—

Applicant means an individual whose written application for Medicaid has been submitted to the agency determining Medicaid eligibility, but has not received final action. This includes an individual (who need not be alive at the time of application) whose application is submitted through a representative or a person acting responsibly for the individual.

Federal financial participation (FFP) means the Federal Government's share of a State's expenditures under the Medicaid program.

FMAP stands for the Federal medical assistance percentage, which is used to calculate the amount of Federal share of State expenditures for services.

Medicaid agency or *agency* means the single State agency administering or supervising the administration of a State Medicaid plan.

Provider means any individual or entity furnishing Medicaid services under a provider agreement with the Medicaid agency.

Recipient means an individual who has been determined eligible for Medicaid.

Services means the types of medical assistance specified in sections 1905(a)(1) through (18) of the Act.

State means the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa and the Northern Mariana Islands.

State plan or *the plan* means a comprehensive written commitment by a Medicaid agency, submitted under section 1902(a) of the Act, to administer or supervise the administration of a Medicaid program in accordance with Federal requirements.

SUBCHAPTER B—OIG AUTHORITIES

PART 1001—PROGRAM INTEGRITY—MEDICARE AND STATE HEALTH CARE PROGRAMS

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AUTHORITY: 42 U.S.C. 1302, 1320a–7, 1320a–7b, 1395u(j), 1395u(k), 1395w–104(e)(6), 1395y(d), 1395y(e), 1395cc(b)(2)(D), (E) and (F), and 1395hh; and sec. 2455, Pub. L. 103–355, 108 Stat. 3327 (31 U.S.C. 6101 note).

SOURCE: 57 FR 3330, Jan. 29, 1992, unless otherwise noted.

Subpart A—General Provisions

§ 1001.1 Scope and purpose.

(a) The regulations in this part specify certain bases upon which individuals and entities may, or in some cases must, be excluded from participation in Medicare, Medicaid and all other Federal health care programs. They also state the effect of exclusion, the factors that will be considered in determining the length of any exclusion, the provisions governing notices of exclusions, and the process by which an excluded individual or entity may seek reinstatement into the programs.

(b) The regulations in this part are applicable to and binding on the Office of Inspector General (OIG) in imposing and proposing exclusions, as well as to Administrative Law Judges (ALJs), the Departmental Appeals Board (DAB), and federal courts in reviewing the imposition of exclusions by the OIG (and,

where applicable, in imposing exclusions proposed by the OIG).

[57 FR 3330, Jan. 29, 1992, as amended at 58 FR 5618, Jan. 22, 1993; 64 FR 39426, July 22, 1999]

§ 1001.2 Definitions.

Controlled substance means a drug or other substance, or immediate precursor:

(a) Included in schedules I, II, III, IV or V of part B of subchapter I in 21 U.S.C. chapter 13, or

(b) That is deemed a controlled substance by the law of any State.

Convicted means that—

(a) A judgment of conviction has been entered against an individual or entity by a Federal, State or local court, regardless of whether:

(1) There is a post-trial motion or an appeal pending, or

(2) The judgment of conviction or other record relating to the criminal conduct has been expunged or otherwise removed;

(b) A Federal, State or local court has made a finding of guilt against an individual or entity;

(c) A Federal, State or local court has accepted a plea of guilty or *nolo contendere* by an individual or entity; or

(d) An individual or entity has entered into participation in a first offender, deferred adjudication or other program or arrangement where judgment of conviction has been withheld.

Exclusion means that items and services furnished, ordered or prescribed by a specified individual or entity will not be reimbursed under Medicare, Medicaid and all other Federal health care programs until the individual or entity is reinstated by the OIG.

Federal health care program means any plan or program providing health care benefits, whether directly through insurance or otherwise, that is funded directly, in whole or part, by the United States Government (other than the Federal Employees Health Benefits Program), or any State health care program as defined in this section.

HHS means Department of Health and Human Services.

Incarceration means imprisonment or any type of confinement with or without supervised release, including, but not limited to, community confinement, house arrest and home detention.

OIG means Office of Inspector General of the Department of Health and Human Services.

Patient means any individual who is receiving health care items or services, including any item or service provided to meet his or her physical, mental or emotional needs or well-being (including a resident receiving care in a facility as described in part 483 of this chapter), whether or not reimbursed under Medicare, Medicaid and any other Federal health care program and regardless of the location in which such item or service is provided.

QIO means Utilization and Quality Control Quality Improvement Organization as created by the Tax Equity and Fiscal Responsibility Act of 1982 (42 U.S.C. 1320c–3).

Professionally recognized standards of health care are Statewide or national standards of care, whether in writing or not, that professional peers of the individual or entity whose provision of care is an issue, recognize as applying to those peers practicing or providing care within a State. When the Department has declared a treatment modality not to be safe and effective, practitioners who employ such a treatment modality will be deemed not to meet professionally recognized standards of health care. This definition will not be construed to mean that all other treatments meet professionally recognized standards.

Sole community physician means a physician who is the only physician who provides primary care services to Federal or State health care program beneficiaries within a defined service area.

Sole source of essential specialized services in the community means that an individual or entity—

(1) Is the only practitioner, supplier or provider furnishing specialized services in an area designated by the Health Resources Services Administration as a health professional shortage area for that medical specialty, as listed in 42 part 5, appendices B–F;

(2) Is a sole community hospital, as defined in § 412.92 of this title; or

(3) Is the only source of specialized services in a reasonably defined service area where services by a non-specialist could not be substituted for the source without jeopardizing the health or safety of beneficiaries.

State health care program means:

(a) A State plan approved under title XIX of the Act (Medicaid),

(b) Any program receiving funds under title V of the Act or from an allotment to a State under such title (Maternal and Child Health Services Block Grant program), or

(c) Any program receiving funds under title XX of the Act or from any allotment to a State under such title (Block Grants to States for Social Services).

State Medicaid Fraud Control Unit means a unit certified by the Secretary as meeting the criteria of 42 U.S.C. 1396b(q) and § 1002.305 of this chapter.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46686, Sept. 2, 1998; 64 FR 39426, July 22, 1999]

Subpart B—Mandatory Exclusions

§ 1001.101 Basis for liability.

The OIG will exclude any individual or entity that—

(a) Has been convicted of a criminal offense related to the delivery of an item or service under Medicare or a State health care program, including the performance of management or administrative services relating to the delivery of items or services under any such program;

(b) Has been convicted, under Federal or State law, of a criminal offense related to the neglect or abuse of a patient, in connection with the delivery of a health care item or service, including any offense that the OIG concludes entailed, or resulted in, neglect or abuse of patients (the delivery of a health care item or service includes the provision of any item or service to an individual to meet his or her physical, mental or emotional needs or well-being, whether or not reimbursed under Medicare, Medicaid or any Federal health care program);

(c) Has been convicted, under Federal or State law, of a felony that occurred after August 21, 1996, relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—

(1) In connection with the delivery of a health care item or service, including the performance of management or administrative services relating to the delivery of such items or services, or

(2) With respect to any act or omission in a health care program (other than Medicare and a State health care program) operated by, or financed in whole or in part, by any Federal, State or local government agency; or

(d) Has been convicted, under Federal or State law, of a felony that occurred after August 21, 1996 relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, as defined under Federal or State law. This applies to any individual or entity that—

(1) Is, or has ever been, a health care practitioner, provider or supplier;

(2) Holds, or has held, a direct or indirect ownership or control interest (as defined in section 1124(a)(3) of the Act) in an entity that is a health care provider or supplier, or is, or has ever been, an officer, director, agent or managing employee (as defined in section 1126(b) of the Act) of such an entity; or

(3) Is, or has ever been, employed in any capacity in the health care industry.

[63 FR 46686, Sept. 2, 1998, as amended at 67 FR 11932, Mar. 18, 2002]

§ 1001.102 Length of exclusion.

(a) No exclusion imposed in accordance with § 1001.101 will be for less than 5 years.

(b) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(1) The acts resulting in the conviction, or similar acts, that caused, or were intended to cause, a financial loss to a Government program or to one or more entities of $5,000 or more. (The entire amount of financial loss to such programs or entities, including any amounts resulting from similar acts not adjudicated, will be considered regardless of whether full or partial restitution has been made);

(2) The acts that resulted in the conviction, or similar acts, were committed over a period of one year or more;

(3) The acts that resulted in the conviction, or similar acts, had a significant adverse physical, mental or financial impact on one or more program beneficiaries or other individuals;

(4) In convictions involving patient abuse or neglect, the action that resulted in the conviction was premeditated, was part of a continuing pattern of behavior, or consisted of non-consensual sexual acts;

(5) The sentence imposed by the court included incarceration;

(6) The convicted individual or entity has a prior criminal, civil or administrative sanction record;

(7) The individual or entity has at any time been overpaid a total of $1,500 or more by Medicare, Medicaid or any other Federal health care programs as a result of *intentional* improper billings;

(8) The individual or entity has previously been convicted of a criminal offense involving the same or similar circumstances; or

(9) Whether the individual or entity was convicted of other offenses besides those which formed the basis for the exclusion, or has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for imposition of the exclusion.

(c) Only if any of the aggravating factors set forth in paragraph (b) of this section justifies an exclusion longer than 5 years, may mitigating factors be considered as a basis for reducing the period of exclusion to no less than 5 years. Only the following factors may be considered mitigating—

(1) The individual or entity was convicted of 3 or fewer misdemeanor offenses, and the entire amount of financial loss (both actual loss and intended loss) to Medicare or any other Federal, State or local governmental health care program due to the acts that resulted in the conviction, and similar acts, is less than $1,500;

(2) The record in the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional or physical condition before or during the commission of the offense that reduced the individual's culpability; or

(3) The individual's or entity's cooperation with Federal or State officials resulted in—

(i) Others being convicted or excluded from Medicare, Medicaid and all other Federal health care programs,

(ii) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or

(iii) The imposition against anyone of a civil money penalty or assessment under part 1003 of this chapter.

(d) In the case of an exclusion under this subpart, based on a conviction occurring on or after August 5, 1997, an exclusion will be—

(1) For not less than 10 years if the individual has been convicted on one other occasion of one or more offenses for which an exclusion may be effected under section 1128(a) of the Act (The aggravating and mitigating factors in paragraphs (b) and (c) of this section can be used to impose a period of time in excess of the 10-year mandatory exclusion); or

(2) Permanent if the individual has been convicted on two or more other occasions of one or more offenses for which an exclusion may be effected under section 1128(a) of the Act.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46686, Sept. 2, 1998; 63 FR 57918, Oct. 29, 1998; 64 FR 39426, July 22, 1999; 67 FR 11932, Mar. 18, 2002]

Subpart C—Permissive Exclusions

§ 1001.201 Conviction relating to program or health care fraud.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity convicted under Federal or State law of—

(1) A misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—

(i) In connection with the delivery of any health care item or service, including the performance of management or

administrative services relating to the delivery of such items or services, or

(ii) With respect to any act or omission in a health care program, other than Medicare and a State health care program, operated by, or financed in whole or in part by, any Federal, State or local government agency; or

(2) Fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct with respect to any act or omission in a program, other than a health care program, operated by or financed in whole or in part by any Federal, State or local government agency.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and (b)(3) of this section form a basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(i) The acts resulting in the conviction, or similar acts that caused, or reasonably could have been expected to cause, a financial loss of $5,000 or more to a Government program or to one or more other entities, or had a significant financial impact on program beneficiaries or other individuals. (The total amount of financial loss will be considered, including any amounts resulting from similar acts not adjudicated, regardless of whether full or partial restitution has been made);

(ii) The acts that resulted in the conviction, or similar acts, were committed over a period of one year or more;

(iii) The acts that resulted in the conviction, or similar acts, had a significant adverse physical or mental impact on one or more program beneficiaries or other individuals;

(iv) The sentence imposed by the court included incarceration;

(v) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

(vi) Whether the individual or entity was convicted of other offenses besides those which formed the basis for the exclusion, or has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) The individual or entity was convicted of 3 or fewer offenses, and the entire amount of financial loss (both actual loss and reasonably expected loss) to a Government program or to other individuals or entities due to the acts that resulted in the conviction and similar acts is less than $1,500;

(ii) The record in the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional or physical condition, before or during the commission of the offense, that reduced the individual's culpability;

(iii) The individual's or entity's cooperation with Federal or State officials resulted in—

(A) Others being convicted or excluded from Medicare, Medicaid or any of the other Federal health care programs, or

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or

(C) The imposition of a civil money penalty against others; or

(iv) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46687, Sept. 2, 1998; 64 FR 39426, July 22, 1999; 67 FR 11932, Mar. 18, 2002; 67 FR 21579, May 1, 2002]

§ 1001.301 Conviction relating to obstruction of an investigation.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity that has been convicted, under Federal or State law, in connection with the interference with or obstruction of any investigation into any criminal offense described in §§ 1001.101 or 1001.201.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years,

unless aggravating or mitigating factors listed in paragraphs (b)(2) and (b)(3) of this section form the basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(i) The interference with, or obstruction of, the investigation caused the expenditure of significant additional time or resources;

(ii) The interference or obstruction had a significant adverse mental, physical or financial impact on program beneficiaries or other individuals or on the Medicare, Medicaid or other Federal health care programs;

(iii) The interference or obstruction also affected a civil or administrative investigation;

(iv) The sentence imposed by the court included incarceration;

(v) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

(vi) Whether the individual or entity was convicted of other offenses besides those which formed the basis for the exclusion, or has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) The record of the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional or physical condition, before or during the commission of the offense, that reduced the individual's culpability;

(ii) The individual's or entity's cooperation with Federal or State officials resulted in—

(A) Others being convicted or excluded from Medicare, Medicaid and all other Federal health care programs,

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or

(C) The imposition of a civil money penalty against others; or

(iii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

[57 FR 3329, Jan. 29, 1992; 57 FR 9669, Mar. 20, 1992; 63 FR 46687, Sept. 2, 1998; 64 FR 39426, July 22, 1999]

§ 1001.401 Conviction relating to controlled substances.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity convicted under Federal or State law of a misdemeanor relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, as defined under Federal or State law. This section applies to any individual or entity that—

(1) Is, or has ever been, a health care practitioner, provider or supplier;

(2) Holds or has held a direct or indirect ownership or control interest, as defined in section 1124(a)(3) of the Act, in an entity that is a health care provider or supplier, or is or has been an officer, director, agent or managing employee, as defined in section 1126(b) of the Act, of such an entity; or

(3) Is, or has ever been, employed in any capacity in the health care industry.

(b) For purposes of this section, the definition of *controlled substance* will be the definition that applies to the law forming the basis for the conviction.

(c) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and (b)(3) of this section form a basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(i) The acts that resulted in the conviction or similar acts were committed over a period of one year or more;

(ii) The acts that resulted in the conviction or similar acts had a significant adverse mental, physical or financial impact on program beneficiaries or other individuals or the Medicare, Medicaid or other Federal health care programs;

(iii) The sentence imposed by the court included incarceration;

(iv) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

(v) Whether the individual or entity was convicted of other offenses besides those which formed the basis for the exclusion, or has been the subject of any other adverse action by any other Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(3) Only the following factors may be considered as mitigating and a basis for shortening the period of exclusion—

(i) The individual's or entity's cooperation with Federal or State officials resulted in—

(A) Others being convicted or excluded from Medicare, Medicaid and all other Federal health care programs,

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or

(C) The imposition of a civil money penalty against others; or

(ii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46687, Sept. 2, 1998; 64 FR 39426, July 22, 1999]

§ 1001.501 License revocation or suspension.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity that has—

(1) Had a license to provide health care revoked or suspended by any State licensing authority, or has otherwise lost such a license (including the right to apply for or renew such a license), for reasons bearing on the individual's or entity's professional competence, professional performance or financial integrity; or

(2) Has surrendered such a license while a formal disciplinary proceeding concerning the individual's or entity's professional competence, professional performance or financial integrity was pending before a State licensing authority.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will not be for a period of time less than the period during which an individual's or entity's license is revoked, suspended or otherwise not in effect as a result of, or in connection with, a State licensing agency action.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The acts that resulted in the revocation, suspension or loss of the individual's or entity's license to provide health care had or could have had a significant adverse physical, emotional or financial impact on one or more program beneficiaries or other individuals;

(ii) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing;

(iii) The acts, or similar acts, had or could have had a significant adverse impact on the financial integrity of the programs; or

(iv) The individual or entity has been the subject of any other adverse action by any other Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(3) Only if any of the aggravating factors listed in paragraph (b)(2) of this section justifies a longer exclusion may mitigating factors be considered as a basis for reducing the period of exclusion to a period not less than that set forth in paragraph (b)(1) of this section. Only the following factors may be considered mitigating—

(i) The individual's or entity's cooperation with a State licensing authority resulted in—

(A) The sanctioning of other individuals or entities, or

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses; or

(ii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

(4) When an individual or entity has been excluded under this section, the OIG will consider a request for reinstatement in accordance with § 1001.3001 if the individual or entity obtains a valid license in the State where the license was originally revoked, suspended, surrendered or otherwise lost.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46688, Sept. 2, 1998]

§ 1001.601 Exclusion or suspension under a Federal or State health care program.

(a) *Circumstance for exclusion.* (1) The OIG may exclude an individual or entity suspended or excluded from participation, or otherwise sanctioned, under—

(i) Any Federal program involving the provision of health care, or

(ii) A State health care program, for reasons bearing on the individual's or entity's professional competence, professional performance or financial integrity.

(2) The term ''or otherwise sanctioned'' in paragraph (a)(1) of this section is intended to cover all actions that limit the ability of a person to participate in the program at issue regardless of what such an action is called, and includes situations where an individual or entity voluntarily withdraws from a program to avoid a formal sanction.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will not be for a period of time less than the period during which the individual or entity is excluded or suspended from a Federal or State health care program.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The acts that resulted in the exclusion, suspension or other sanction under Medicare, Medicaid and all other Federal health care programs had, or could have had, a significant adverse impact on Federal or State health care programs or the beneficiaries of those programs or other individuals;

(ii) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

(iii) The individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(3) Only if any of the aggravating factors set forth in paragraph (b)(2) of this section justifies a longer exclusion may mitigating factors be considered as a basis for reducing the period of exclusion to a period not less than that set forth in paragraph (b)(1) of this section. Only the following factors may be considered mitigating—

(i) The individual's or entity's cooperation with Federal or State officials resulted in—

(A) The sanctioning of other individuals or entities, or

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses; or

(ii) Alternative sources of the types of health care items or services furnished by the individual or entity are not available.

(4) If the individual or entity is eligible to apply for reinstatement in accordance with § 1001.3001 of this part, and the sole reason for the State denying reinstatement is the existing Medicare exclusion imposed by the OIG as a result of the original State action, the OIG will consider a request for reinstatement.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46688, Sept. 2, 1998]

§ 1001.701 Excessive claims or furnishing of unnecessary or substandard items and services.

(a) Circumstance for exclusion. The OIG may exclude an individual or entity that has—

(1) Submitted, or caused to be submitted, bills or requests for payments under Medicare or any of the State health care programs containing charges or costs for items or services furnished that are substantially in excess of such individual's or entity's usual charges or costs for such items or services; or

(2) Furnished, or caused to be furnished, to patients (whether or not covered by Medicare or any of the State health care programs) any items or services substantially in excess of the patient's needs, or of a quality that fails to meet professionally recognized standards of health care.

(b) The OIG's determination under paragraph (a)(2) of this section—that the items or services furnished were excessive or of unacceptable quality—will be made on the basis of information, including sanction reports, from the following sources:

(1) The QIO for the area served by the individual or entity;

(2) State or local licensing or certification authorities;

(3) Fiscal agents or contractors, or private insurance companies;

(4) State or local professional societies; or

(5) Any other sources deemed appropriate by the OIG.

(c) Exceptions. An individual or entity will not be excluded for—

(1) Submitting, or causing to be submitted, bills or requests for payment that contain charges or costs substantially in excess of usual charges or costs when such charges or costs are due to unusual circumstances or medical complications requiring additional time, effort, expense or other good cause; or

(2) Furnishing, or causing to be furnished, items or services in excess of the needs of patients, when the items or services were ordered by a physician or other authorized individual, and the individual or entity furnishing the items or services was not in a position to determine medical necessity or to refuse to comply with the order of the physician or other authorized individual.

(d) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors set forth in paragraphs (d)(2) and (d)(3) of this section form a basis for lengthening or shortening the period. In no case may the period be shorter than 1 year for any exclusion taken in accordance with paragraph (a)(2) of this section.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The violations were serious in nature, and occurred over a period of one year or more;

(ii) The violations had a significant adverse physical, mental or financial impact on program beneficiaries or other individuals;

(iii) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing;

(iv) The violation resulted in financial loss to Medicare, Medicaid and all other Federal health care programs of $1,500 or more; or

(v) The individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(3) Only the following factors may be considered mitigating and a basis for reducing the period of exclusion—

(i) There were few violations and they occurred over a short period of time; or

(ii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46688, Sept. 2, 1998]

§ 1001.801 Failure of HMOs and CMPs to furnish medically necessary items and services.

(a) Circumstances for exclusion. The OIG may exclude an entity—

(1) That is a—

(i) Health maintenance organization (HMO), as defined in section 1903(m) of the Act, providing items or services under a State Medicaid Plan;

(ii) Primary care case management system providing services, in accordance with a waiver approved under section 1915(b)(1) of the Act; or

(iii) HMO or competitive medical plan providing items or services in accordance with a risk-sharing contract under section 1876 of the Act;

(2) That has failed substantially to provide medically necessary items and services that are required under a plan,

waiver or contract described in paragraph (a)(1) of this section to be provided to individuals covered by such plan, waiver or contract; and

(3) Where such failure has adversely affected or has a substantial likelihood of adversely affecting covered individuals.

(b) The OIG's determination under paragraph (a)(2) of this section—that the medically necessary items and services required under law or contract were not provided—will be made on the basis of information, including sanction reports, from the following sources:

(1) The QIO or other quality assurance organization under contract with a State Medicaid plan for the area served by the HMO or competitive medical plan;

(2) State or local licensing or certification authorities;

(3) Fiscal agents or contractors, or private insurance companies;

(4) State or local professional societies;

(5) CMS's HMO compliance office; or

(6) Any other sources deemed appropriate by the OIG.

(c) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors set forth in paragraphs (c)(2) and (c)(3) of this section form a basis for lengthening or shortening the period.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The entity failed to provide a large number or a variety of items or services;

(ii) The failures occurred over a lengthy period of time;

(iii) The entity's failure to provide a necessary item or service that had or could have had a serious adverse effect;

(iv) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

(v) The individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) There were few violations and they occurred over a short period of time; or

(ii) Alternative sources of the type of health care items or services furnished by the entity are not available.

(iii) The entity took corrective action upon learning of impermissible activities by an employee or contractor.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46688, Sept. 2, 1998]

§ 1001.901 False or improper claims.

(a) *Circumstance for exclusion.* The OIG may exclude any individual or entity that it determines has committed an act described in section 1128A of the Act. The imposition of a civil money penalty or assessment is not a prerequisite for an exclusion under this section.

(b) *Length of exclusion.* In determining the length of an exclusion imposed in accordance with this section, the OIG will consider the following factors—

(1) The nature and circumstances surrounding the actions that are the basis for liability, including the period of time over which the acts occurred, the number of acts, whether there is evidence of a pattern and the amount claimed;

(2) The degree of culpability;

(3) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral);

(4) The individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion; or

(5) Other matters as justice may require.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46689, Sept. 2, 1998]

§ 1001.951 Fraud and kickbacks and other prohibited activities.

(a) *Circumstance for exclusion.* (1) Except as provided for in paragraph (a)(2)(ii) of this section, the OIG may

exclude any individual or entity that it determines has committed an act described in section 1128B(b) of the Act.

(2) With respect to acts described in section 1128B of the Act, the OIG—

(i) May exclude any individual or entity that it determines has knowingly and willfully solicited, received, offered or paid any remuneration in the manner and for the purposes described therein, irrespective of whether the individual or entity may be able to prove that the remuneration was also intended for some other purpose; and

(ii) Will not exclude any individual or entity if that individual or entity can prove that the remuneration that is the subject of the exclusion is exempted from serving as the basis for an exclusion.

(b) *Length of exclusion*. (1) The following factors will be considered in determining the length of exclusion in accordance with this section—

(i) The nature and circumstances of the acts and other similar acts;

(ii) The nature and extent of any adverse physical, mental, financial or other impact the conduct had on program beneficiaries or other individuals or the Medicare, Medicaid and all other Federal health care programs;

(iii) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral);

(iv) The individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion; or

(v) Any other facts bearing on the nature and seriousness of the individual's or entity's misconduct.

(2) It will be considered a mitigating factor if—

(i) The individual had a documented mental, emotional, or physical condition before or during the commission of the prohibited act(s) that reduced the individual's culpability for the acts in question;

(ii) The individual's or entity's cooperation with Federal or State officials resulted in the—

(A) Sanctioning of other individuals or entities, or

(B) Imposition of a civil money penalty against others; or

(iii) Alternative sources of the type of health care items or services provided by the individual or entity are not available.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46689, Sept. 2, 1998; 67 FR 11933, Mar. 18, 2002]

§ 1001.952 Exceptions.

The following payment practices shall not be treated as a criminal offense under section 1128B of the Act and shall not serve as the basis for an exclusion:

(a) *Investment interests*. As used in section 1128B of the Act, ''remuneration'' does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor as long as all of the applicable standards are met within one of the following three categories of entities:

(1) If, within the previous fiscal year or previous 12 month period, the entity possesses more than $50,000,000 in undepreciated net tangible assets (based on the net acquisition cost of purchasing such assets from an unrelated entity) related to the furnishing of health care items and services, all of the following five standards must be met—

(i) With respect to an investment interest that is an equity security, the equity security must be registered with the Securities and Exchange Commission under 15 U.S.C. 781 (b) or (g).

(ii) The investment interest of an investor in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be obtained on terms (including any direct or indirect transferability restrictions) and at a price equally available to the public when trading on a registered securities exchange, such as the New York Stock Exchange or the American Stock Exchange, or in accordance with the National Association of Securities Dealers Automated Quotation System.

(iii) The entity or any investor must not market or furnish the entity's items or services (or those of another

entity as part of a cross referral agreement) to passive investors differently than to non-investors.

(iv) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

(v) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment of that investor.

(2) If the entity possesses investment interests that are held by either active or passive investors, all of the following eight applicable standards must be met—

(i) No more than 40 percent of the value of the investment interests of each class of investment interests may be held in the previous fiscal year or previous 12 month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity. (For purposes of paragraph (a)(2)(i) of this section, equivalent classes of equity investments may be combined, and equivalent classes of debt instruments may be combined.)

(ii) The terms on which an investment interest is offered to a passive investor, if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered to other passive investors.

(iii) The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity.

(iv) There is no requirement that a passive investor, if any, make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor.

(v) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross referral agreement) to passive investors differently than to non-investors.

(vi) No more than 40 percent of the entity's gross revenue related to the furnishing of health care items and services in the previous fiscal year or previous 12-month period may come from referrals or business otherwise generated from investors.

(vii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

(viii) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(3)(i) If the entity possesses investment interests that are held by either active or passive investors and is located in an underserved area, all of the following eight standards must be met—

(A) No more than 50 percent of the value of the investment interests of each class of investments may be held in the previous fiscal year or previous 12-month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for, the entity. (For purposes of paragraph (a)(3)(i)(A) of this section, equivalent classes of equity investments may be combined, and equivalent classes of debt instruments may be combined.)

(B) The terms on which an investment interest is offered to a passive investor, if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered to other passive investors.

(C) The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity.

(D) There is no requirement that a passive investor, if any, make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor.

(E) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross-referral agreement) to passive investors differently than to non-investors.

(F) At least 75 percent of the dollar volume of the entity's business in the previous fiscal year or previous 12-month period must be derived from the service of persons who reside in an underserved area or are members of medically underserved populations.

(G) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

(H) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(ii) If an entity that otherwise meets all of the above standards is located in an area that was an underserved area at the time of the initial investment, but subsequently ceases to be an underserved area, the entity will be deemed to comply with paragraph (a)(3)(i) of this section for a period equal to the lesser of:

(A) The current term of the investment remaining after the date upon which the area ceased to be an underserved area or

(B) Three years from the date the area ceased to be an underserved area.

(4) For purposes of paragraph (a) of this section, the following terms apply. *Active investor* means an investor either who is responsible for the day-to-day management of the entity and is a bona fide general partner in a partnership under the Uniform Partnership Act or who agrees in writing to undertake liability for the actions of the entity's agents acting within the scope of their agency. *Investment interest* means a security issued by an entity, and may include the following classes of investments: shares in a corporation, interests or units in a partnership or limited liability company, bonds, debentures, notes, or other debt instruments. *Investor* means an individual or entity either who directly holds an investment interest in an entity, or who holds such investment interest indirectly by, including but not limited to, such means as having a family member hold such investment interest or holding a legal or beneficial interest in another entity (such as a trust or holding company) that holds such investment interest. *Passive investor* means an investor who is not an active investor, such as a limited partner in a partnership under the Uniform Partnership Act, a shareholder in a corporation, or a holder of a debt security. *Underserved area* means any defined geographic area that is designated as a Medically Underserved Area (MUA) in accordance with regulations issued by the Department. *Medically underserved population* means a Medically Underserved Population (MUP) in accordance with regulations issued by the Department.

(b) *Space rental.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made by a lessee to a lessor for the use of premises, as long as all of the following six standards are met—

(1) The lease agreement is set out in writing and signed by the parties.

(2) The lease covers all of the premises leased between the parties for the term of the lease and specifies the premises covered by the lease.

(3) If the lease is intended to provide the lessee with access to the premises

for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such intervals.

(4) The term of the lease is for not less than one year.

(5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

(6) The aggregate space rented does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental. Note that for purposes of paragraph (b) of this section, the term *fair market value* means the value of the rental property for general commercial purposes, but shall not be adjusted to reflect the additional value that one party (either the prospective lessee or lessor) would attribute to the property as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare, Medicaid and all other Federal health care programs.

(c) *Equipment rental.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made by a lessee of equipment to the lessor of the equipment for the use of the equipment, as long as all of the following six standards are met—

(1) The lease agreement is set out in writing and signed by the parties.

(2) The lease covers all of the equipment leased between the parties for the term of the lease and specifies the equipment covered by the lease.

(3) If the lease is intended to provide the lessee with use of the equipment for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such interval.

(4) The term of the lease is for not less than one year.

(5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or all other Federal health care programs.

(6) The aggregate equipment rental does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental. Note that for purposes of paragraph (c) of this section, the term *fair market value* means that the value of the equipment when obtained from a manufacturer or professional distributor, but shall not be adjusted to reflect the additional value one party (either the prospective lessee or lessor) would attribute to the equipment as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

(d) *Personal services and management contracts.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following seven standards are met—

(1) The agency agreement is set out in writing and signed by the parties.

(2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.

(3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.

(4) The term of the agreement is for not less than one year.

(5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-

length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

(6) The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law.

(7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

For purposes of paragraph (d) of this section, an agent of a principal is any person, other than a bona fide employee of the principal, who has an agreement to perform services for, or on behalf of, the principal.

(e) *Sale of practice.* (1) As used in section 1128B of the Act, ''remuneration'' does not include any payment made to a practitioner by another practitioner where the former practitioner is selling his or her practice to the latter practitioner, as long as both of the following two standards are met—

(i) The period from the date of the first agreement pertaining to the sale to the completion of the sale is not more than one year.

(ii) The practitioner who is selling his or her practice will not be in a professional position to make referrals to, or otherwise generate business for, the purchasing practitioner for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs after 1 year from the date of the first agreement pertaining to the sale.

(2) As used in section 1128B of the Act, ''remuneration'' does not include any payment made to a practitioner by a hospital or other entity where the practitioner is selling his or her practice to the hospital or other entity, so long as the following four standards are met:

(i) The period from the date of the first agreement pertaining to the sale to the completion date of the sale is not more than three years.

(ii) The practitioner who is selling his or her practice will not be in a professional position after completion of the sale to make or influence referrals to, or otherwise generate business for, the purchasing hospital or entity for which payment may be made under Medicare, Medicaid or other Federal health care programs.

(iii) The practice being acquired must be located in a Health Professional Shortage Area (HPSA), as defined in Departmental regulations, for the practitioner's specialty area.

(iv) Commencing at the time of the first agreement pertaining to the sale, the purchasing hospital or entity must diligently and in good faith engage in commercially reasonable recruitment activities that:

(A) May reasonably be expected to result in the recruitment of a new practitioner to take over the acquired practice within a one year period and

(B) Will satisfy the conditions of the practitioner recruitment safe harbor in accordance with paragraph (n) of this section.

(f) *Referral services.* As used in section 1128B of the Act, ''remuneration'' does not include any payment or exchange of anything of value between an individual or entity (''participant'') and another entity serving as a referral service (''referral service''), as long as all of the following four standards are met—

(1) The referral service does not exclude as a participant in the referral service any individual or entity who meets the qualifications for participation.

(2) Any payment the participant makes to the referral service is assessed equally against and collected equally from all participants, and is only based on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated by either party for the referral service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

(3) The referral service imposes no requirements on the manner in which the participant provides services to a referred person, except that the referral

service may require that the participant charge the person referred at the same rate as it charges other persons not referred by the referral service, or that these services be furnished free of charge or at reduced charge.

(4) The referral service makes the following five disclosures to each person seeking a referral, with each such disclosure maintained by the referral service in a written record certifying such disclosure and signed by either such person seeking a referral or by the individual making the disclosure on behalf of the referral service—

(i) The manner in which it selects the group of participants in the referral service to which it could make a referral;

(ii) Whether the participant has paid a fee to the referral service;

(iii) The manner in which it selects a particular participant from this group for that person;

(iv) The nature of the relationship between the referral service and the group of participants to whom it could make the referral; and

(v) The nature of any restrictions that would exclude such an individual or entity from continuing as a participant.

(g) *Warranties.* As used in section 1128B of the Act, ''remuneration'' does not include any payment or exchange of anything of value under a warranty provided by a manufacturer or supplier of an item to the buyer (such as a health care provider or beneficiary) of the item, as long as the buyer complies with all of the following standards in paragraphs (g)(1) and (g)(2) of this section and the manufacturer or supplier complies with all of the following standards in paragraphs (g)(3) and (g)(4) of this section—

(1) The buyer must fully and accurately report any price reduction of the item (including a free item), which was obtained as part of the warranty, in the applicable cost reporting mechanism or claim for payment filed with the Department or a State agency.

(2) The buyer must provide, upon request by the Secretary or a State agency, information provided by the manufacturer or supplier as specified in paragraph (g)(3) of this section.

(3) The manufacturer or supplier must comply with either of the following two standards—

(i) The manufacturer or supplier must fully and accurately report the price reduction of the item (including a free item), which was obtained as part of the warranty, on the invoice or statement submitted to the buyer, and inform the buyer of its obligations under paragraphs (a)(1) and (a)(2) of this section.

(ii) Where the amount of the price reduction is not known at the time of sale, the manufacturer or supplier must fully and accurately report the existence of a warranty on the invoice or statement, inform the buyer of its obligations under paragraphs (g)(1) and (g)(2) of this section, and, when the price reduction becomes known, provide the buyer with documentation of the calculation of the price reduction resulting from the warranty.

(4) The manufacturer or supplier must not pay any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the item itself.

For purposes of paragraph (g) of this section, the term *warranty* means either an agreement made in accordance with the provisions of 15 U.S.C. 2301(6), or a manufacturer's or supplier's agreement to replace another manufacturer's or supplier's defective item (which is covered by an agreement made in accordance with this statutory provision), on terms equal to the agreement that it replaces.

(h) *Discounts.* As used in section 1128B of the Act, ''remuneration'' does not include a discount, as defined in paragraph (h)(5) of this section, on an item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs for a buyer as long as the buyer complies with the applicable standards of paragraph (h)(1) of this section; a seller as long as the seller complies with the applicable standards of paragraph (h)(2) of this section; and an offeror of a discount who is not a seller under paragraph (h)(2) of this section so long as such offeror complies

with the applicable standards of paragraph (h)(3) of this section.

(1) With respect to the following three categories of buyers, the buyer must comply with all of the applicable standards within one of the three following categories—

(i) If the buyer is an entity which is a health maintenance organization (HMO) or a competitive medical plan (CMP) acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, it need not report the discount except as otherwise may be required under the risk contract.

(ii) If the buyer is an entity which reports its costs on a cost report required by the Department or a State health care program, it must comply with all of the following four standards—

(A) The discount must be earned based on purchases of that same good or service bought within a single fiscal year of the buyer;

(B) The buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year;

(C) The buyer must fully and accurately report the discount in the applicable cost report; and

(D) the buyer must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(ii) of this section, or information provided by the offeror as specified in paragraph (h)(3)(ii) of this section.

(iii) If the buyer is an individual or entity in whose name a claim or request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs (not including individuals or entities defined as buyers in paragraph (h)(1)(i) or (h)(1)(ii) of this section), the buyer must comply with both of the following standards—

(A) The discount must be made at the time of the sale of the good or service or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service; and

(B) the buyer (if submitting the claim) must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(iii)(B) of this section, or information provided by the offeror as specified in paragraph (h)(3)(iii)(A) of this section.

(2) The seller is an individual or entity that supplies an item or service for which payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs to the buyer and who permits a discount to be taken off the buyer's purchase price. The seller must comply with all of the applicable standards within one of the following three categories—

(i) If the buyer is an entity which is an HMO a CMP acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, the seller need not report the discount to the buyer for purposes of this provision.

(ii) If the buyer is an entity that reports its costs on a cost report required by the Department or a State agency, the seller must comply with either of the following two standards—

(A) Where a discount is required to be reported to Medicare or a State health care program under paragraph (h)(1) of this section, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner that is reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph; or

(B) Where the value of the discount is not known at the time of sale, the seller must fully and accurately report the existence of a discount program on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; when the value of the discount becomes

known, provide the buyer with documentation of the calculation of the discount identifying the specific goods or services purchased to which the discount will be applied; and refrain from doing anything which would impede the buyer from meeting its obligations under this paragraph.

(iii) If the buyer is an individual or entity not included in paragraph (h)(2)(i) or (h)(2)(ii) of this section, the seller must comply with either of the following two standards—

(A) Where the seller submits a claim or request for payment on behalf of the buyer and the item or service is separately claimed, the seller must provide, upon request by the Secretary or a State agency, information provided by the offeror as specified in paragraph (h)(3)(iii)(A) of this section; or

(B) Where the buyer submits a claim, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph.

(3) The offeror of a discount is an individual or entity who is not a seller under paragraph (h)(2) of this section, but promotes the purchase of an item or service by a buyer under paragraph (h)(1) of this section at a reduced price for which payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs. The offeror must comply with all of the applicable standards within the following three categories—

(i) If the buyer is an entity which is an HMO or a CMP acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, the offeror need not report the discount to the buyer for purposes of this provision.

(ii) If the buyer is an entity that reports its costs on a cost report required by the Department or a State agency, the offeror must comply with the following two standards—

(A) The offeror must inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such a discount and to provide information upon request under paragraph (h)(1) of this section; and

(B) The offeror of the discount must refrain from doing anything that would impede the buyer's ability to meet its obligations under this paragraph.

(iii) If the buyer is an individual or entity in whose name a request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs (not including individuals or entities defined as buyers in paragraph (h)(1)(i) or (h)(1)(ii) of this section), the offeror must comply with the following two standards—

(A) The offeror must inform the individual or entity submitting the claim or request for payment in a manner reasonably calculated to give notice to the individual or entity of its obligations to report such a discount and to provide information upon request under paragraphs (h)(1) and (h)(2) of this section; and

(B) The offeror of the discount must refrain from doing anything that would impede the buyer's or seller's ability to meet its obligations under this paragraph.

(4) For purposes of this paragraph, a *rebate* is any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale.

(5) For purposes of this paragraph, the term *discount* means a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction. The term *discount* does not include—

(i) Cash payment or cash equivalents (except that rebates as defined in paragraph (h)(4) of this section may be in the form of a check);

(ii) Supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and

services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology;

(iii) A reduction in price applicable to one payer but not to Medicare, Medicaid or other Federal health care programs;

(iv) A routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary;

(v) Warranties;

(vi) Services provided in accordance with a personal or management services contract; or

(vii) Other remuneration, in cash or in kind, not explicitly described in paragraph (h)(5) of this section.

(i) *Employees.* As used in section 1128B of the Act, ''remuneration'' does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs. For purposes of paragraph (i) of this section, the term *employee* has the same meaning as it does for purposes of 26 U.S.C. 3121(d)(2).

(j) *Group purchasing organizations.* As used in section 1128B of the Act, ''remuneration'' does not include any payment by a vendor of goods or services to a group purchasing organization (GPO), as part of an agreement to furnish such goods or services to an individual or entity as long as both of the following two standards are met—

(1) The GPO must have a written agreement with each individual or entity, for which items or services are furnished, that provides for either of the following—

(i) The agreement states that participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of 3 percent or less of the purchase price of the goods or services provided by that vendor.

(ii) In the event the fee paid to the GPO is not fixed at 3 percent or less of the purchase price of the goods or services, the agreement specifies the amount (or if not known, the maximum amount) the GPO will be paid by each vendor (where such amount may be a fixed sum or a fixed percentage of the value of purchases made from the vendor by the members of the group under the contract between the vendor and the GPO).

(2) Where the entity which receives the goods or service from the vendor is a health care provider of services, the GPO must disclose in writing to the entity at least annually, and to the Secretary upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity. Note that for purposes of paragraph (j) of this section, the term *group purchasing organization* (GPO) means an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs, and who are neither wholly-owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity).

(k) *Waiver of beneficiary coinsurance and deductible amounts.* As used in section 1128B of the Act, ''remuneration'' does not include any reduction or waiver of a Medicare or a State health care program beneficiary's obligation to pay coinsurance or deductible amounts as long as all of the standards are met within either of the following two categories of health care providers:

(1) If the coinsurance or deductible amounts are owed to a hospital for inpatient hospital services for which Medicare pays under the prospective payment system, the hospital must comply with all of the following three standards—

(i) The hospital must not later claim the amount reduced or waived as a bad debt for payment purposes under Medicare or otherwise shift the burden of the reduction or waiver onto Medicare, a State health care program, other payers, or individuals.

(ii) The hospital must offer to reduce or waive the coinsurance or deductible

amounts without regard to the reason for admission, the length of stay of the beneficiary, or the diagnostic related group for which the claim for Medicare reimbursement is filed.

(iii) The hospital's offer to reduce or waive the coinsurance or deductible amounts must not be made as part of a price reduction agreement between a hospital and a third-party payer (including a health plan as defined in paragraph (l)(2) of this section), unless the agreement is part of a contract for the furnishing of items or services to a beneficiary of a Medicare supplemental policy issued under the terms of section 1882(t)(1) of the Act.

(2) If the coinsurance or deductible amounts are owed by an individual who qualifies for subsidized services under a provision of the Public Health Services Act or under titles V or XIX of the Act to a federally qualified health care center or other health care facility under any Public Health Services Act grant program or under title V of the Act, the health care center or facility may reduce or waive the coinsurance or deductible amounts for items or services for which payment may be made in whole or in part under part B of Medicare or a State health care program.

(l) *Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans.* (1) As used in section 1128B of the Act, ''remuneration'' does not include the additional coverage of any item or service offered by a health plan to an enrollee or the reduction of some or all of the enrollee's obligation to pay the health plan or a contract health care provider for cost-sharing amounts (such as coinsurance, deductible, or copayment amounts) or for premium amounts attributable to items or services covered by the health plan, the Medicare program, or a State health care program, as long as the health plan complies with all of the standards within one of the following two categories of health plans:

(i) If the health plan is a risk-based health maintenance organization, competitive medical plan, prepaid health plan, or other health plan under contract with CMS or a State health care program and operating in accordance with section 1876(g) or 1903(m) of the Act, under a Federal statutory demonstration authority, or under other Federal statutory or regulatory authority, it must offer the same increased coverage or reduced cost-sharing or premium amounts to all Medicare or State health care program enrollees covered by the contract unless otherwise approved by CMS or by a State health care program.

(ii) If the health plan is a health maintenance organization, competitive medical plan, health care prepayment plan, prepaid health plan or other health plan that has executed a contract or agreement with CMS or with a State health care program to receive payment for enrollees on a reasonable cost or similar basis, it must comply with both of the following two standards—

(A) The health plan must offer the same increased coverage or reduced cost-sharing or premium amounts to all Medicare or State health care program enrollees covered by the contract or agreement unless otherwise approved by CMS or by a State health care program; and

(B) The health plan must not claim the costs of the increased coverage or the reduced cost-sharing or premium amounts as a bad debt for payment purposes under Medicare or a State health care program or otherwise shift the burden of the increased coverage or reduced cost-sharing or premium amounts to the extent that increased payments are claimed from Medicare or a State health care program.

(2) For purposes of paragraph (l) of this section, the terms—

Contract health care provider means an individual or entity under contract with a health plan to furnish items or services to enrollees who are covered by the health plan, Medicare, or a State health care program.

Enrollee means an individual who has entered into a contractual relationship with a health plan (or on whose behalf an employer, or other private or governmental entity has entered into such a relationship) under which the individual is entitled to receive specified health care items and services, or insurance coverage for such items and services, in return for payment of a premium or a fee.

Health plan means an entity that furnishes or arranges under agreement with contract health care providers for the furnishing of items or services to enrollees, or furnishes insurance coverage for the provision of such items and services, in exchange for a premium or a fee, where such entity:

(i) Operates in accordance with a contract, agreement or statutory demonstration authority approved by CMS or a State health care program;

(ii) Charges a premium and its premium structure is regulated under a State insurance statute or a State enabling statute governing health maintenance organizations or preferred provider organizations;

(iii) Is an employer, if the enrollees of the plan are current or retired employees, or is a union welfare fund, if the enrollees of the plan are union members; or

(iv) Is licensed in the State, is under contract with an employer, union welfare fund, or a company furnishing health insurance coverage as described in conditions (ii) and (iii) of this definition, and is paid a fee for the administration of the plan which reflects the fair market value of those services.

(m) *Price reductions offered to health plans.* (1) As used in section 1128B of the Act, ''remuneration'' does not include a reduction in price a contract health care provider offers to a health plan in accordance with the terms of a written agreement between the contract health care provider and the health plan for the sole purpose of furnishing to enrollees items or services that are covered by the health plan, Medicare, or a State health care program, as long as both the health plan and contract health care provider comply with all of the applicable standards within one of the following four categories of health plans:

(i) If the health plan is a risk-based health maintenance organization, competitive medical plan, or prepaid health plan under contract with CMS or a State agency and operating in accordance with section 1876(g) or 1903(m) of the Act, under a Federal statutory demonstration authority, or under other Federal statutory or regulatory authority, the contract health care provider must not claim payment in any form from the Department or the State agency for items or services furnished in accordance with the agreement except as approved by CMS or the State health care program, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a State health care program.

(ii) If the health plan is a health maintenance organization, competitive medical plan, health care prepayment plan, prepaid health plan, or other health plan that has executed a contract or agreement with CMS or a State health care program to receive payment for enrollees on a reasonable cost or similar basis, the health plan and contract health care provider must comply with all of the following four standards—

(A) The term of the agreement between the health plan and the contract health care provider must be for not less than one year;

(B) The agreement between the health plan and the contract health care provider must specify in advance the covered items and services to be furnished to enrollees, and the methodology for computing the payment to the contract health care provider;

(C) The health plan must fully and accurately report, on the applicable cost report or other claim form filed with the Department or the State health care program, the amount it has paid the contract health care provider under the agreement for the covered items and services furnished to enrollees; and

(D) The contract health care provider must not claim payment in any form from the Department or the State health care program for items or services furnished in accordance with the agreement except as approved by CMS or the State health care program, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a State health care program.

(iii) If the health plan is not described in paragraphs (m)(1)(i) or (m)(1)(ii) of this section and the contract health care provider is not paid on an at-risk, capitated basis, both the health plan and contract health care

provider must comply with all of the following six standards—

(A) The term of the agreement between the health plan and the contract health care provider must be for not less than one year;

(B) The agreement between the health plan and the contract health care provider must specify in advance the covered items and services to be furnished to enrollees, which party is to file claims or requests for payment with Medicare or the State health care program for such items and services, and the schedule of fees the contract health care provider will charge for furnishing such items and services to enrollees;

(C) The fee schedule contained in the agreement between the health plan and the contract health care provider must remain in effect throughout the term of the agreement, unless a fee increase results directly from a payment update authorized by Medicare or the State health care program;

(D) The party submitting claims or requests for payment from Medicare or the State health care program for items and services furnished in accordance with the agreement must not claim or request payment for amounts in excess of the fee schedule;

(E) The contract health care provider and the health plan must fully and accurately report on any cost report filed with Medicare or a State health care program the fee schedule amounts charged in accordance with the agreement and, upon request, will report to the Medicare or a State health care program the terms of the agreement and the amounts paid in accordance with the agreement; and

(F) The party to the agreement, which does not have the responsibility under the agreement for filing claims or requests for payment, must not claim or request payment in any form from the Department or the State health care program for items or services furnished in accordance with the agreement, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a State health care program.

(iv) If the health plan is not described in paragraphs (m)(1)(i) or (m)(1)(ii) of this section, and the contract health care provider is paid on an at-risk, capitated basis, both the health plan and contract health care provider must comply with all of the following five standards—

(A) The term of the agreement between the health plan and the contract health provider must be for not less than one year;

(B) The agreement between the health plan and the contract health provider must specify in advance the covered items and services to be furnished to enrollees and the total amount per enrollee (which may be expressed in a per month or other time period basis) the contract health care provider will be paid by the health plan for furnishing such items and services to enrollees and must set forth any copayments, if any, to be paid by enrollees to the contract health care provider for covered services;

(C) The payment amount contained in the agreement between the health care plan and the contract health care provider must remain in effect throughout the term of the agreement;

(D) The contract health care provider and the health plan must fully and accurately report to the Medicare and State health care program upon request, the terms of the agreement and the amounts paid in accordance with the agreement; and

(E) The contract health care provider must not claim or request payment in any form from the Department, a State health care program or an enrollee (other than copayment amounts described in paragraph (m)(2)(iv)(B) of this section) and the health plan must not pay the contract care provider in excess of the amounts described in paragraph (m)(2)(iv)(B) of this section for items and services covered by the agreement.

(2) For purposes of this paragraph, the terms *contract health care provider*, *enrollee*, and *health plan* have the same meaning as in paragraph (l)(2) of this section.

(n) *Practitioner recruitment*. As used in section 1128B of the Act, ''remuneration'' does not include any payment or exchange of anything of value by an entity in order to induce a practitioner who has been practicing within his or

her current specialty for less than one year to locate, or to induce any other practitioner to relocate, his or her primary place of practice into a HPSA for his or her specialty area, as defined in Departmental regulations, that is served by the entity, as long as all of the following nine standards are met—

(1) The arrangement is set forth in a written agreement signed by the parties that specifies the benefits provided by the entity, the terms under which the benefits are to be provided, and the obligations of each party.

(2) If a practitioner is leaving an established practice, at least 75 percent of the revenues of the new practice must be generated from new patients not previously seen by the practitioner at his or her former practice.

(3) The benefits are provided by the entity for a period not in excess of 3 years, and the terms of the agreement are not renegotiated during this 3-year period in any substantial aspect; provided, however, that if the HPSA to which the practitioner was recruited ceases to be a HPSA during the term of the written agreement, the payments made under the written agreement will continue to satisfy this paragraph for the duration of the written agreement (not to exceed 3 years).

(4) There is no requirement that the practitioner make referrals to, be in a position to make or influence referrals to, or otherwise generate business for the entity as a condition for receiving the benefits; provided, however, that for purposes of this paragraph, the entity may require as a condition for receiving benefits that the practitioner maintain staff privileges at the entity.

(5) The practitioner is not restricted from establishing staff privileges at, referring any service to, or otherwise generating any business for any other entity of his or her choosing.

(6) The amount or value of the benefits provided by the entity may not vary (or be adjusted or renegotiated) in any manner based on the volume or value of any expected referrals to or business otherwise generated for the entity by the practitioner for which payment may be made in whole or in part under Medicare, Medicaid or any other Federal health care programs.

(7) The practitioner agrees to treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(8) At least 75 percent of the revenues of the new practice must be generated from patients residing in a HPSA or a Medically Underserved Area (MUA) or who are part of a Medically Underserved Population (MUP), all as defined in paragraph (a) of this section.

(9) The payment or exchange of anything of value may not directly or indirectly benefit any person (other than the practitioner being recruited) or entity in a position to make or influence referrals to the entity providing the recruitment payments or benefits of items or services payable by a Federal health care program.

(o) *Obstetrical malpractice insurance subsidies.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made by a hospital or other entity to another entity that is providing malpractice insurance (including a self-funded entity), where such payment is used to pay for some or all of the costs of malpractice insurance premiums for a practitioner (including a certified nurse-midwife as defined in section 1861(gg) of the Act) who engages in obstetrical practice as a routine part of his or her medical practice in a primary care HPSA, as long as all of the following seven standards are met—

(1) The payment is made in accordance with a written agreement between the entity paying the premiums and the practitioner, which sets out the payments to be made by the entity, and the terms under which the payments are to be provided.

(2)(i) The practitioner must certify that for the initial coverage period (not to exceed one year) the practitioner has a reasonable basis for believing that at least 75 percent of the practitioner's obstetrical patients treated under the coverage of the malpractice insurance will either—

(A) Reside in a HPSA or MUA, as defined in paragraph (a) of this section; or

(B) Be part of a MUP, as defined in paragraph (a) of this section.

(ii) Thereafter, for each additional coverage period (not to exceed one year), at least 75 percent of the practitioner's obstetrical patients treated under the prior coverage period (not to exceed one year) must have—

(A) Resided in a HPSA or MUA, as defined in paragraph (a) of this section; or

(B) Been part of a MUP, as defined in paragraph (a) of this section.

(3) There is no requirement that the practitioner make referrals to, or otherwise generate business for, the entity as a condition for receiving the benefits.

(4) The practitioner is not restricted from establishing staff privileges at, referring any service to, or otherwise generating any business for any other entity of his or her choosing.

(5) The amount of payment may not vary based on the volume or value of any previous or expected referrals to or business otherwise generated for the entity by the practitioner for which payment may be made in whole or in part under Medicare, Medicaid or any other Federal health care programs.

(6) The practitioner must treat obstetrical patients who receive medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(7) The insurance is a bona fide malpractice insurance policy or program, and the premium, if any, is calculated based on a bona fide assessment of the liability risk covered under the insurance. For purposes of paragraph (o) of this section, *costs of malpractice insurance premiums* means:

(i) For practitioners who engage in obstetrical practice full-time, any costs attributable to malpractice insurance; or

(ii) For practitioners who engage in obstetrical practice on a part-time or sporadic basis, the costs:

(A) Attributable exclusively to the obstetrical portion of the practitioner's malpractice insurance and

(B) Related exclusively to obstetrical services provided in a primary care HPSA.

(p) *Investments in group practices.* As used in section 1128B of the Act, ''remuneration'' does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to a solo or group practitioner investing in his or her own practice or group practice if the following four standards are met—

(1) The equity interests in the practice or group must be held by licensed health care professionals who practice in the practice or group.

(2) The equity interests must be in the practice or group itself, and not some subdivision of the practice or group.

(3) In the case of group practices, the practice must:

(i) Meet the definition of ''group practice'' in section 1877(h)(4) of the Social Security Act and implementing regulations; and

(ii) Be a unified business with centralized decision-making, pooling of expenses and revenues, and a compensation/profit distribution system that is not based on satellite offices operating substantially as if they were separate enterprises or profit centers.

(4) Revenues from ancillary services, if any, must be derived from ''in-office ancillary services'' that meet the definition of such term in section 1877(b)(2) of the Act and implementing regulations.

(q) *Cooperative hospital service organizations.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made between a cooperative hospital service organization (CHSO) and its patron-hospital, both of which are described in section 501(e) of the Internal Revenue Code of 1986 and are tax-exempt under section 501(c)(3) of the Internal Revenue Code, where the CHSO is wholly owned by two or more patron-hospitals, as long as the following standards are met—

(1) If the patron-hospital makes a payment to the CHSO, the payment must be for the purpose of paying for the bona fide operating expenses of the CHSO, or

(2) If the CHSO makes a payment to the patron-hospital, the payment must be for the purpose of paying a distribution of net earnings required to be made under section 501(e)(2) of the Internal Revenue Code of 1986.

(r) *Ambulatory surgical centers.* As used in section 1128B of the Act, ''remuneration'' does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor, as long as the investment entity is a certified ambulatory surgical center (ASC) under part 416 of this title, whose operating and recovery room space is dedicated exclusively to the ASC, patients referred to the investment entity by an investor are fully informed of the investor's investment interest, and all of the applicable standards are met within one of the following four categories—

(1) *Surgeon-owned ASCs*—If all of the investors are general surgeons or surgeons engaged in the same surgical specialty, who are in a position to refer patients directly to the entity and perform surgery on such referred patients; surgical group practices (as defined in this paragraph) composed exclusively of such surgeons; or investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to make or influence referrals directly or indirectly to the entity or any of its investors, all of the following six standards must be met—

(i) The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.

(ii) At least one-third of each surgeon investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the surgeon's performance of procedures (as defined in this paragraph).

(iii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.

(iv) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(v) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.

(vi) The entity and any surgeon investors must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(2) *Single-Specialty ASCs*—If all of the investors are physicians engaged in the same medical practice specialty who are in a position to refer patients directly to the entity and perform procedures on such referred patients; group practices (as defined in this paragraph) composed exclusively of such physicians; or investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to make or influence referrals directly or indirectly to the entity or any of its investors, all of the following six standards must be met—

(i) The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.

(ii) At least one-third of each physician investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the surgeon's performance of procedures (as defined in this paragraph).

(iii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.

(iv) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any

pre-operational services rendered) of that investor.

(v) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.

(vi) The entity and any physician investors must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(3) *Multi-Specialty ASCs*—If all of the investors are physicians who are in a position to refer patients directly to the entity and perform procedures on such referred patients; group practices, as defined in this paragraph, composed exclusively of such physicians; or investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to make or influence referrals directly or indirectly to the entity or any of its investors, all of the following seven standards must be met—

(i) The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.

(ii) At least one-third of each physician investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the physician's performance of procedures (as defined in this paragraph).

(iii) At least one-third of the procedures (as defined in this paragraph) performed by each physician investor for the previous fiscal year or previous 12-month period must be performed at the investment entity.

(iv) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.

(v) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(vi) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.

(vii) The entity and any physician investors must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(4) *Hospital/Physician ASCs*—If at least one investor is a hospital, and all of the remaining investors are physicians who meet the requirements of paragraphs (r)(1), (r)(2) or (r)(3) of this section; group practices (as defined in this paragraph) composed of such physicians; surgical group practices (as defined in this paragraph); or investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to refer patients directly or indirectly to the entity or any of its investors, all of the following eight standards must be met—

(i) The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.

(ii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.

(iii) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(iv) The entity and any hospital or physician investor must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(v) The entity may not use space, including, but not limited to, operating and recovery room space, located in or owned by any hospital investor, unless such space is leased from the hospital in accordance with a lease that complies with all the standards of the space rental safe harbor set forth in paragraph (b) of this section; nor may it use equipment owned by or services provided by the hospital unless such equipment is leased in accordance with a lease that complies with the equipment rental safe harbor set forth in paragraph (c) of this section, and such services are provided in accordance with a contract that complies with the personal services and management contracts safe harbor set forth in paragraph (d) of this section.

(vi) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.

(vii) The hospital may not include on its cost report or any claim for payment from a Federal health care program any costs associated with the ASC (unless such costs are required to be included by a Federal health care program).

(viii) The hospital may not be in a position to make or influence referrals directly or indirectly to any investor or the entity.

(5) For purposes of paragraph (r) of this section, *procedures* means any procedure or procedures on the list of Medicare-covered procedures for ambulatory surgical centers in accordance with regulations issued by the Department and *group practice* means a group practice that meets all of the standards of paragraph (p) of this section. *Surgical group practice* means a group practice that meets all of the standards of paragraph (p) of this section and is composed exclusively of surgeons who meet the requirements of paragraph (r)(1) of this section.

(s) *Referral arrangements for specialty services*. As used in section 1128B of the Act, ''remuneration'' does not include any exchange of value among individuals and entities where one party agrees to refer a patient to the other party for the provision of a specialty service payable in whole or in part under Medicare, Medicaid or any other Federal health care programs in return for an agreement on the part of the other party to refer that patient back at a mutually agreed upon time or circumstance as long as the following four standards are met—

(1) The mutually agreed upon time or circumstance for referring the patient back to the originating individual or entity is clinically appropriate.

(2) The service for which the referral is made is not within the medical expertise of the referring individual or entity, but is within the special expertise of the other party receiving the referral.

(3) The parties receive no payment from each other for the referral and do not share or split a global fee from any Federal health care program in connection with the referred patient.

(4) Unless both parties belong to the same group practice as defined in paragraph (p) of this section, the only exchange of value between the parties is the remuneration the parties receive directly from third-party payors or the patient compensating the parties for the services they each have furnished to the patient.

(t) *Price reductions offered to eligible managed care organizations*. (1) As used in section 1128(B) of the Act, ''remuneration'' does not include any payment between:

(i) An eligible managed care organization and any first tier contractor for providing or arranging for items or services, as long as the following three standards are met—

(A) The eligible managed care organization and the first tier contractor have an agreement that:

(*1*) Is set out in writing and signed by both parties;

(*2*) Specifies the items and services covered by the agreement;

(*3*) Is for a period of at least one year; and

(*4*) Specifies that the first tier contractor cannot claim payment in any form directly or indirectly from a Federal health care program for items or services covered under the agreement, except for:

(*i*) HMOs and competitive medical plans with cost-based contracts under section 1876 of the Act where the agreement with the eligible managed care organization sets out the arrangements in accordance with which the first tier contractor is billing the Federal health care program;

(*ii*) Federally qualified HMOs without a contract under sections 1854 or 1876 of the Act, where the agreement with the eligible managed care organization sets out the arrangements in accordance with which the first tier contractor is billing the Federal health care program; or

(*iii*) First tier contractors that are Federally qualified health centers that claim supplemental payments from a Federal health care program.

(B) In establishing the terms of the agreement, neither party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the agreement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis.

(C) Neither party to the agreement shifts the financial burden of the agreement to the extent that increased payments are claimed from a Federal health care program.

(ii) A first tier contractor and a downstream contractor or between two downstream contractors to provide or arrange for items or services, as long as the following four standards are met—

(A) The parties have an agreement that:

(*1*) Is set out in writing and signed by both parties;

(*2*) Specifies the items and services covered by the agreement;

(*3*) Is for a period of at least one year; and

(*4*) Specifies that the party providing the items or services cannot claim payment in any form from a Federal health care program for items or services covered under the agreement.

(B) In establishing the terms of the agreement, neither party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the agreement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis.

(C) Neither party shifts the financial burden of the agreement to the extent that increased payments are claimed from a Federal health care program.

(D) The agreement between the eligible managed care organization and first tier contractor covering the items or services that are covered by the agreement between the parties does not involve:

(*1*) A Federally qualified health center receiving supplemental payments;

(*2*) A HMO or CMP with a cost-based contract under section 1876 of the Act; or

(*3*) A Federally qualified HMO, unless the items or services are covered by a risk based contract under sections 1854 or 1876 of the Act.

(2) For purposes of this paragraph, the following terms are defined as follows:

(i) *Downstream contractor* means an individual or entity that has a subcontract directly or indirectly with a first tier contractor for the provision or arrangement of items or services that are covered by an agreement between an eligible managed care organization and the first tier contractor.

(ii) *Eligible managed care organization*[1] means—

(A) A HMO or CMP with a risk or cost based contract in accordance with section 1876 of the Act;

(B) Any Medicare Part C health plan that receives a capitated payment from Medicare and which must have its total Medicare beneficiary cost sharing approved by CMS under section 1854 of the Act;

(C) Medicaid managed care organizations as defined in section 1903(m)(1)(A)

[1] The eligible managed care organizations in paragraphs (u)(2)(ii)(A)–(F) of this section are only eligible with respect to items or services covered by the contracts specified in those paragraphs.

that provide or arrange for items or services for Medicaid enrollees under a contract in accordance with section 1903(m) of the Act (except for fee-for-service plans or medical savings accounts);

(D) Any other health plans that provide or arrange for items and services for Medicaid enrollees in accordance with a risk-based contract with a State agency subject to the upper payment limits in §447.361 of this title or an equivalent payment cap approved by the Secretary;

(E) Programs For All Inclusive Care For The Elderly (PACE) under sections 1894 and 1934 of the Act, except for for-profit demonstrations under sections 4801(h) and 4802(h) of Pub. L. 105–33; or

(F) A Federally qualified HMO.

(iii) *First tier contractor* means an individual or entity that has a contract directly with an eligible managed care organization to provide or arrange for items or services.

(iv) *Items and services* means health care items, devices, supplies or services or those services reasonably related to the provision of health care items, devices, supplies or services including, but not limited to, non-emergency transportation, patient education, attendant services, social services (*e.g.*, case management), utilization review and quality assurance. Marketing and other pre-enrollment activities are not ''items or services'' for purposes of this section.

(u) *Price reductions offered by contractors with substantial financial risk to managed care organizations.* (1) As used in section 1128(B) of the Act, ''remuneration'' does not include any payment between:

(i) A qualified managed care plan and a first tier contractor for providing or arranging for items or services, where the following five standards are met—

(A) The agreement between the qualified managed care plan and first tier contractor must:

(*1*) Be in writing and signed by the parties;

(*2*) Specify the items and services covered by the agreement;

(*3*) Be for a period of a least one year;

(*4*) Require participation in a quality assurance program that promotes the coordination of care, protects against underutilization and specifies patient goals, including measurable outcomes where appropriate; and

(*5*) Specify a methodology for determining payment that is commercially reasonable and consistent with fair market value established in an arms-length transaction and includes the intervals at which payments will be made and the formula for calculating incentives and penalties, if any.

(B) If a first tier contractor has an investment interest in a qualified managed care plan, the investment interest must meet the criteria of paragraph (a)(1) of this section.

(C) The first tier contractor must have substantial financial risk for the cost or utilization of services it is obligated to provide through one of the following four payment methodologies:

(*1*) A periodic fixed payment per patient that does not take into account the dates services are provided, the frequency of services, or the extent or kind of services provided;

(*2*) Percentage of premium;

(*3*) Inpatient Federal health care program diagnosis-related groups (DRGs) (other than those for psychiatric services);

(*4*) Bonus and withhold arrangements, provided—

(*i*) The target payment for first tier contractors that are individuals or non-institutional providers is at least 20 percent greater than the minimum payment, and for first tier contractors that are institutional providers, i.e., hospitals and nursing homes, is at least 10 percent greater than the minimum payment;

(*ii*) The amount at risk, *i.e.*, the bonus or withhold, is earned by a first tier contractor in direct proportion to the ratio of the contractor's actual utilization to its target utilization;

(*iii*) In calculating the percentage in accordance with paragraph (u)(1)(i)(C)(*4*)(*i*) of this section, both the target payment amount and the minimum payment amount include any performance bonus, *e.g.*, payments for timely submission of paperwork, continuing medical education, meeting attendance, etc., at a level achieved by 75 percent of the first tier contractors who are eligible for such payments;

(*iv*) Payment amounts, including any bonus or withhold amounts, are reasonable given the historical utilization patterns and costs for the same or comparable populations in similar managed care arrangements; and

(*v*) Alternatively, for a first tier contractor that is a physician, the qualified managed care plan has placed the physician at risk for referral services in an amount that exceeds the substantial financial risk threshold set forth in 42 CFR 417.479(f) and the arrangement is in compliance with the stop-loss and beneficiary survey requirements of 42 CFR 417.479(g).

(D) Payments for items and services reimbursable by Federal health care program must comply with the following two standards—

(*1*) The qualified managed care plan (or in the case of a self-funded employer plan that contracts with a qualified managed care plan to provide administrative services, the self-funded employer plan) must submit the claims directly to the Federal health care program, in accordance with a valid reassignment agreement, for items or services reimbursed by the Federal health care program. (Notwithstanding the foregoing, inpatient hospital services, other than psychiatric services, will be deemed to comply if the hospital is reimbursed by a Federal health care program under a DRG methodology.)

(*2*) Payments to first tier contractors and any downstream contractors for providing or arranging for items or services reimbursed by a Federal health care program must be identical to payment arrangements to or between such parties for the same items or services provided to other beneficiaries with similar health status, provided that such payments may be adjusted where the adjustments are related to utilization patterns or costs of providing items or services to the relevant population.

(E) In establishing the terms of an arrangement—

(*1*) Neither party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the arrangement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis; and

(*2*) Neither party to the arrangement shifts the financial burden of such arrangement to the extent that increased payments are claimed from a Federal health care program.

(ii) A first tier contractor and a downstream contractor, or between downstream contractors, to provide or arrange for items or services, as long as the following three standards are met—

(A) Both parties are being paid for the provision or arrangement of items or services in accordance with one of the payment methodologies set out in paragraph (u)(1)(i)(C) of this section;

(B) Payment arrangements for items and services reimbursable by a Federal health care program comply with paragraph (u)(1)(i)(D) of this section; and

(C) In establishing the terms of an arrangement—

(*1*) Neither party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the arrangement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis; and

(*2*) Neither party to the arrangement shifts the financial burden of the arrangement to the extent that increased payments are claimed from a Federal health care program.

(2) For purposes of this paragraph, the following terms are defined as follows:

(i) *Downstream contractor* means an individual or entity that has a subcontract directly or indirectly with a first tier contractor for the provision or arrangement of items or services that are covered by an agreement between a qualified managed care plan and the first tier contractor.

(ii) *First tier contractor* means an individual or entity that has a contract directly with a qualified managed care plan to provide or arrange for items or services.

(iii) *Is obligated to provide* for a contractor refers to items or services:

(A) Provided directly by an individual or entity and its employees;

(B) For which an individual or entity is financially responsible, but which

are provided by downstream contractors;

(C) For which an individual or entity makes referrals or arrangements; or

(D) For which an individual or entity receives financial incentives based on its own, its provider group's, or its qualified managed care plan's performance (or combination thereof).

(iv) *Items and services* means health care items, devices, supplies or services or those services reasonably related to the provision of health care items, devices, supplies or services including, but not limited to, non-emergency transportation, patient education, attendant services, social services (e.g., case management), utilization review and quality assurance. Marketing or other pre-enrollment activities are not ''items or services'' for purposes of this definition in this paragraph.

(v) *Minimum payment* is the guaranteed amount that a provider is entitled to receive under an agreement with a first tier or downstream contractor or a qualified managed care plan.

(vi) *Qualified managed care plan* means a health plan as defined in paragraph (l)(2) of this section that:

(A) Provides a comprehensive range of health services;

(B) Provides or arranges for—

(*1*) Reasonable utilization goals to avoid inappropriate utilization;

(*2*) An operational utilization review program;

(*3*) A quality assurance program that promotes the coordination of care, protects against underutilization, and specifies patient goals, including measurable outcomes where appropriate;

(*4*) Grievance and hearing procedures;

(*5*) Protection of enrollees from incurring financial liability other than copayments and deductibles; and

(*6*) Treatment for Federal health care program beneficiaries that is not different than treatment for other enrollees because of their status as Federal health care program beneficiaries; and

(C) Covers a beneficiary population of which either—

(*1*) No more than 10 percent are Medicare beneficiaries, not including persons for whom a Federal health care program is the secondary payer; or

(*2*) No more than 50 percent are Medicare beneficiaries (not including persons for whom a Federal health care program is the secondary payer), provided that payment of premiums is on a periodic basis that does not take into account the dates services are rendered, the frequency of services, or the extent or kind of services rendered, and provided further that such periodic payments for the non-Federal health care program beneficiaries do not take into account the number of Federal health care program fee-for-service beneficiaries covered by the agreement or the amount of services generated by such beneficiaries.

(vii) *Target payment* means the fair market value payment established through arms length negotiations that will be earned by an individual or entity that:

(A) Is dependent on the individual or entity's meeting a utilization target or range of utilization targets that are set consistent with historical utilization rates for the same or comparable populations in similar managed care arrangements, whether based on its own, its provider group's or the qualified managed care plan's utilization (or a combination thereof); and

(B) Does not include any bonus or fees that the individual or entity may earn from exceeding the utilization target.

(v) *Ambulance replenishing*. (1) As used in section 1128B of the Act, ''remuneration'' does not include any gift or transfer of drugs or medical supplies (including linens) by a hospital or other receiving facility to an ambulance provider for the purpose of replenishing comparable drugs or medical supplies (including linens) used by the ambulance provider (or a first responder) in connection with the transport of a patient by ambulance to the hospital or other receiving facility if all of the standards in paragraph (v)(2) of this section are satisfied *and* all of the applicable standards in *either* paragraph (v)(3)(i), (v)(3)(ii) or (v)(3)(iii) of this section are satisfied. However, to qualify under paragraph (v), the ambulance that is replenished must be used to provide emergency ambulance services an average of three times per week, as measured over a reasonable period of time. Drugs and medical supplies (including linens) initially used

by a first responder and replenished at the scene of the illness or injury by the ambulance provider that transports the patient to the hospital or other receiving facility will be deemed to have been used by the ambulance provider.

(2) To qualify under paragraph (v) of this section, the ambulance replenishing arrangement must satisfy *all* of the following four conditions—

(i)(A) Under no circumstances may the ambulance provider (or first responder) and the receiving facility both bill for the same replenished drug or supply. Replenished drugs or supplies may only be billed (including claiming bad debt) to a Federal health care program by either the ambulance provider (or first responder) or the receiving facility.

(B) All billing or claims submission by the receiving facility, ambulance provider or first responder for replenished drugs and medical supplies used in connection with the transport of a Federal health care program beneficiary must comply with all applicable Federal health care program payment and coverage rules and regulations.

(C) Compliance with paragraph (v)(2)(i)(B) of this section will be determined separately for the receiving facility and the ambulance provider (and first responder, if any), so long as the receiving facility, ambulance provider (or first responder) refrains from doing anything that would impede the other party or parties from meeting their obligations under paragraph (v)(2)(i)(B).

(ii)(A) The receiving facility or ambulance provider, or both, must

(*1*) Maintain records of the replenished drugs and medical supplies and the patient transport to which the replenished drugs and medical supplies related;

(*2*) Provide a copy of such records to the other party within a reasonable time (unless the other party is separately maintaining records of the replenished drugs and medical supplies); and

(*3*) Make those records available to the Secretary promptly upon request.

(B) A pre-hospital care report (including, but not limited to, a trip sheet, patient care report or patient encounter report) prepared by the ambulance provider and filed with the receiving facility will meet the requirements of paragraph (v)(2)(ii)(A) of this section, provided that it documents the specific type and amount of medical supplies and drugs used on the patient and subsequently replenished.

(C) For purposes of paragraph (v)(2)(ii) of this section, documentation may be maintained and, if required, filed with the other party in hard copy or electronically. If a replenishing arrangement includes linens, documentation need not be maintained for their exchange. If documentation is not maintained for the exchange of linens, the receiving facility will be presumed to have provided an exchange of comparable clean linens for soiled linens for each ambulance transport of a patient to the receiving facility. Records required under paragraph (v)(2)(ii)(A) of this section must be maintained for 5 years.

(iii) The replenishing arrangement must not take into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under any Federal health care program (other than the referral of the particular patient to whom the replenished drugs and medical supplies were furnished).

(iv) The receiving facility and the ambulance provider otherwise comply with all Federal, State, and local laws regulating ambulance services, including, but not limited to, emergency services, and the provision of drugs and medical supplies, including, but not limited to, laws relating to the handling of controlled substances.

(3) To qualify under paragraph (v) of this section, the arrangement must satisfy *all* of the standards in *one* of the following three categories:

(i) *General replenishing*. (A) The receiving facility must replenish medical supplies or drugs on an equal basis for all ambulance providers that bring patients to the receiving facility in any one of the categories described in paragraph (v)(3)(i)(A)(*1*), (*2*), or (*3*) of this section. A receiving facility may offer replenishing to one or more of the categories and may offer different replenishing arrangements to different categories, so long as the replenishing is

conducted uniformly within each category. For example, a receiving facility may offer to replenish a broader array of drugs or supplies for ambulance providers that do no not charge for their services than for ambulance providers that charge for their services. Within each category, the receiving facility may limit its replenishing arrangements to the replenishing of emergency ambulance transports only. A receiving facility may offer replenishing to one or more of the categories—

(*1*) All ambulance providers that do not bill any patient or insurer (including Federal health care programs) for ambulance services, regardless of the payor or the patient's ability to pay (i.e., ambulance providers, such as volunteer companies, that provide ambulance services without charge to any person or entity);

(*2*) All not-for-profit and State or local government ambulance service providers (including, but not limited to, municipal and volunteer ambulance services providers); or

(*3*) All ambulance service providers.

(B)(*1*) The replenishing arrangement must be conducted in an open and public manner. A replenishing arrangement will be considered to be conducted in an open and public manner if one of the following two conditions are satisfied:

(*i*) A written disclosure of the replenishing program is posted conspicuously in the receiving facility's emergency room or other location where the ambulance providers deliver patients and copies are made available upon request to ambulance providers, Government representatives, and members of the public (subject to reasonable photocopying charges). The written disclosure can take any reasonable form and should include the category of ambulance service providers that qualifies for replenishment; the drugs or medical supplies included in the replenishment program; and the procedures for documenting the replenishment. A sample disclosure form is included in Appendix A to subpart C of this part for illustrative purposes only. No written contracts between the parties are required for purposes of paragraph (v)(3)(i)(B)(*1*)(*i*) of this section; or

(*ii*) The replenishment arrangement operates in accordance with a plan or protocol of general application promulgated by an Emergency Medical Services (EMS) Council or comparable entity, agency or organization, provided a copy of the plan or protocol is available upon request to ambulance providers, Government representatives and members of the public (subject to reasonable photocopying charges). While parties are encouraged to participate in collaborative, comprehensive, community-wide EMS systems to improve the delivery of EMS in their local communities, nothing in this paragraph shall be construed as requiring the involvement of such organizations or the development or implementation of ambulance replenishment plans or protocols by such organizations.

(*2*) Nothing in this paragraph (v)(3)(i) shall be construed as requiring disclosure of confidential proprietary or financial information related to the replenishing arrangement (including, but not limited to, information about cost, pricing or the volume of replenished drugs or supplies) to ambulance providers or members of the general public.

(ii) *Fair market value replenishing*. (A) Except as otherwise provided in paragraph (v)(3)(ii)(B) of this section, the ambulance provider must pay the receiving facility fair market value, based on an arms-length transaction, for replenished medical supplies; and

(B) If payment is not made at the same time as the replenishing of the medical supplies, the receiving facility and the ambulance provider must make commercially reasonable payment arrangements in advance.

(iii) *Government mandated replenishing*. The replenishing arrangement is undertaken in accordance with a State or local statute, ordinance, regulation or binding protocol that requires hospitals or receiving facilities in the area subject to such requirement to replenish ambulances that deliver patients to the hospital with drugs or medical supplies (including linens) that are used during the transport of that patient.

(4) For purposes of paragraph (v) of this section—

(i) A *receiving facility* is a hospital or other facility that provides emergency medical services.

(ii) An *ambulance provider* is a provider or supplier of ambulance transport services that provides emergency ambulance services. The term does not include a provider of ambulance transport services that provides only non-emergency transport services.

(iii) A *first responder* includes, but is not limited to, a fire department, paramedic service or search and rescue squad that responds to an emergency call (through 9–1–1 or other emergency access number) and treats the patient, but does not transport the patient to the hospital or other receiving facility.

(iv) An *emergency ambulance service* is a transport by ambulance initiated as a result of a call through 9–1–1 or other emergency access number or a call from another acute care facility unable to provide the higher level care required by the patient and available at the receiving facility.

(v) *Medical supplies* includes linens, unless otherwise provided.

(w) *Health centers.* As used in section 1128B of the Act, ''remuneration'' does not include the transfer of any goods, items, services, donations or loans (whether the donation or loan is in cash or in-kind), or combination thereof from an individual or entity to a health center (as defined in this paragraph), as long as the following nine standards are met—

(1)(i) The transfer is made pursuant to a contract, lease, grant, loan, or other agreement that—

(A) Is set out in writing;

(B) Is signed by the parties; and

(C) Covers, and specifies the amount of, all goods, items, services, donations, or loans to be provided by the individual or entity to the health center.

(ii) The amount of goods, items, services, donations, or loans specified in the agreement in accordance with paragraph (w)(1)(i)(C) of this section may be a fixed sum, fixed percentage, or set forth by a fixed methodology. The amount may not be conditioned on the volume or value of Federal health care program business generated between the parties. The written agreement will be deemed to cover all goods, items, services, donations, or loans provided by the individual or entity to the health center as required by paragraph (w)(1)(i)(C) of this section if all separate agreements between the individual or entity and the health center incorporate each other by reference or if they cross-reference a master list of agreements that is maintained centrally, is kept up to date, and is available for review by the Secretary upon request. The master list should be maintained in a manner that preserves the historical record of arrangements.

(2) The goods, items, services, donations, or loans are medical or clinical in nature or relate directly to services provided by the health center as part of the scope of the health center's section 330 grant (including, by way of example, billing services, administrative support services, technology support, and enabling services, such as case management, transportation, and translation services, that are within the scope of the grant).

(3) The health center reasonably expects the arrangement to contribute meaningfully to the health center's ability to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center, and the health center documents the basis for the reasonable expectation prior to entering the arrangement. The documentation must be made available to the Secretary upon request.

(4) At reasonable intervals, but at least annually, the health center must re-evaluate the arrangement to ensure that the arrangement is expected to continue to satisfy the standard set forth in paragraph (w)(3) of this section, and must document the re-evaluation contemporaneously. The documentation must be made available to the Secretary upon request. Arrangements must not be renewed or renegotiated unless the health center reasonably expects the standard set forth in paragraph (w)(3) of this section to be satisfied in the next agreement term. Renewed or renegotiated agreements must comply with the requirements of paragraph (w)(3) of this section.

(5) The individual or entity does not (i) Require the health center (or its affiliated health care professionals) to

refer patients to a particular individual or entity, or

(ii) restrict the health center (or its affiliated health care professionals) from referring patients to any individual or entity.

(6) Individuals and entities that offer to furnish goods, items, or services without charge or at a reduced charge to the health center must furnish such goods, items, or services to all patients from the health center who clinically qualify for the goods, items, or services, regardless of the patient's payor status or ability to pay. The individual or entity may impose reasonable limits on the aggregate volume or value of the goods, items, or services furnished under the arrangement with the health center, provided such limits do not take into account a patient's payor status or ability to pay.

(7) The agreement must not restrict the health center's ability, if it chooses, to enter into agreements with other providers or suppliers of comparable goods, items, or services, or with other lenders or donors. Where a health center has multiple individuals or entities willing to offer comparable remuneration, the health center must employ a reasonable methodology to determine which individuals or entities to select and must document its determination. In making these determinations, health centers should look to the procurement standards for recipients of Federal grants set forth in 45 CFR 74.40 through 74.48.

(8) The health center must provide effective notification to patients of their freedom to choose any willing provider or supplier. In addition, the health center must disclose the existence and nature of an agreement under paragraph (w)(1) of this section to any patient who inquires. The health center must provide such notification or disclosure in a timely fashion and in a manner reasonably calculated to be effective and understood by the patient.

(9) The health center may, at its option, elect to require that an individual or entity charge a referred health center patient the same rate it charges other similarly situated patients not referred by the health center or that the individual or entity charge a referred health center patient a reduced rate (where the discount applies to the total charge and not just to the cost-sharing portion owed by an insured patient).

For purposes of this paragraph, the term ''health center'' means a Federally Qualified Health Center under section 1905(l)(2)(B)(i) or 1905(l)(2)(B)(ii) of the Act, and ''medically underserved population'' means a medically underserved population as defined in regulations at 42 CFR 51c.102(e).

(x) *Electronic prescribing items and services.* As used in section 1128B of the Act, ''remuneration'' does not include nonmonetary remuneration (consisting of items and services in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information, if all of the following conditions are met:

(1) The items and services are provided by a—

(i) Hospital to a physician who is a member of its medical staff;

(ii) Group practice to a prescribing health care professional who is a member of the group practice; and

(iii) A PDP sponsor or MA organization to pharmacists and pharmacies participating in the network of such sponsor or organization and to prescribing health care professionals.

(2) The items and services are provided as part of, or are used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are provided.

(3) The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems.

(4) For items or services that are of the type that can be used for any patient without regard to payor status, the donor does not restrict, or take any action to limit, the recipient's right or ability to use the items or services for any patient.

(5) Neither the recipient nor the recipient's practice (or any affiliated individual or entity) makes the receipt of

items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(6) Neither the eligibility of a recipient for the items or services, nor the amount or nature of the items or services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.

(7) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items and services being provided and the donor's cost of the items and services; and

(iii) Covers all of the electronic prescribing items and services to be provided by the donor (or affiliated parties). This requirement will be met if all separate agreements between the donor (and affiliated parties) and the recipient incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list should be maintained in a manner that preserves the historical record of agreements.

(8) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the recipient possesses or has obtained items or services equivalent to those provided by the donor.

NOTE TO PARAGRAPH (x): For purposes of paragraph (x) of this section, *group practice* shall have the meaning set forth at 42 CFR 411.352; *member of the group practice* shall mean all persons covered by the definition of ''member of the group or member of a group practice'' at 42 CFR 411.351, as well as other prescribing health care professionals who are owners or employees of the group practice; *prescribing health care professional* shall mean a physician or other health care professional licensed to prescribe drugs in the State in which the drugs are dispensed; *PDP sponsor* or *MA organization* shall have the meanings set forth at 42 CFR 423.4 and 422.2, respectively; *prescription information* shall mean information about prescriptions for drugs or for any other item or service normally accomplished through a written prescription; and *electronic health record* shall mean a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions.

(y) *Electronic health records items and services*. As used in section 1128B of the Act, ''remuneration'' does not include nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive electronic health records, if all of the following conditions are met:

(1) The items and services are provided to an individual or entity engaged in the delivery of health care by—

(i) An individual or entity that provides services covered by a Federal health care program and submits claims or requests for payment, either directly or through reassignment, to the Federal health care program; or

(ii) A health plan.

(2) The software is interoperable at the time it is provided to the recipient. For purposes of this subparagraph, software is deemed to be interoperable if a certifying body recognized by the Secretary has certified the software within no more than 12 months prior to the date it is provided to the recipient.

(3) The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems.

(4) Neither the recipient nor the recipient's practice (or any affiliated individual or entity) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(5) Neither the eligibility of a recipient for the items or services, nor the amount or nature of the items or services, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. For the purposes of this paragraph (y)(5), the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met:

(i) The determination is based on the total number of prescriptions written by the recipient (but not the volume or

value of prescriptions dispensed or paid by the donor or billed to a Federal health care program);

(ii) The determination is based on the size of the recipient's medical practice (for example, total patients, total patient encounters, or total relative value units);

(iii) The determination is based on the total number of hours that the recipient practices medicine;

(iv) The determination is based on the recipient's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor);

(v) The determination is based on whether the recipient is a member of the donor's medical staff, if the donor has a formal medical staff;

(vi) The determination is based on the level of uncompensated care provided by the recipient; or

(vii) The determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.

(6) The arrangement is set forth in a written agreement that —

(i) Is signed by the parties;

(ii) Specifies the items and services being provided, the donor's cost of those items and services, and the amount of the recipient's contribution; and

(iii) Covers all of the electronic health records items and services to be provided by the donor (or any affiliate). This requirement will be met if all separate agreements between the donor (and affiliated parties) and the recipient incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list should be maintained in a manner that preserves the historical record of agreements.

(7) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the recipient possesses or has obtained items or services equivalent to those provided by the donor.

(8) For items or services that are of the type that can be used for any patient without regard to payor status, the donor does not restrict, or take any action to limit, the recipient's right or ability to use the items or services for any patient.

(9) The items and services do not include staffing of the recipient's office and are not used primarily to conduct personal business or business unrelated to the recipient's clinical practice or clinical operations.

(10) The electronic health records software contains electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the recipient's existing electronic prescribing system, that meets the applicable standards under Medicare Part D at the time the items and services are provided.

(11) Before receipt of the items and services, the recipient pays 15 percent of the donor's cost for the items and services. The donor (or any affiliated individual or entity) does not finance the recipient's payment or loan funds to be used by the recipient to pay for the items and services.

(12) The donor does not shift the costs of the items or services to any Federal health care program.

(13) The transfer of the items and services occurs, and all conditions in this paragraph (y) have been satisfied, on or before December 31, 2013.

NOTE TO PARAGRAPH (y): For purposes of paragraph (y) of this section, *health plan* shall have the meaning set forth at § 1001.952(l)(2); *interoperable* shall mean able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings, and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered; and *electronic health record* shall mean a repository of consumer health status information in computer processable form used for clinical diagnosis

and treatment for a broad array of clinical conditions.

[57 FR 3330, Jan. 29, 1992, as amended at 57 FR 52729, Nov. 5, 1992; 61 FR 2135, Jan. 25, 1996; 64 FR 63513, Nov. 19, 1999; 64 FR 63551, Nov. 19, 1999; 64 FR 71317, Dec. 21, 1999; 66 FR 62989, Dec. 4, 2001; 66 FR 63749, Dec. 10, 2001; 67 FR 11933, Mar. 18, 2002; 71 FR 45136, Aug. 8, 2006; 72 FR 56644, Oct. 4, 2007]

§ 1001.1001 Exclusion of entities owned or controlled by a sanctioned person.

(a) *Circumstance for exclusion.* (1) The OIG may exclude an entity if:

(i) A person with a relationship with such entity—

(A) Has been convicted of a criminal offense as described in sections 1128(a) and 1128(b) (1), (2) or (3) of the Act;

(B) Has had civil money penalties or assessments imposed under section 1128A of the Act; or

(C) Has been excluded from participation in Medicare or any of the State health care programs, and

(ii) Such a person—

(A)(*1*) Has a direct or indirect ownership interest (or any combination thereof) of 5 percent or more in the entity;

(*2*) Is the owner of a whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the entity or any of the property assets thereof, in which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the entity;

(*3*) Is an officer or director of the entity, if the entity is organized as a corporation;

(*4*) Is partner in the entity, if the entity is organized as a partnership;

(*5*) Is an agent of the entity; or

(*6*) Is a managing employee, that is, an individual (including a general manager, business manager, administrator or director) who exercises operational or managerial control over the entity or part thereof, or directly or indirectly conducts the day-to-day operations of the entity or part thereof, or

(B) Was formerly described in paragraph (a)(1)(ii)(A) of this section, but is no longer so described because of a transfer of ownership or control interest to an immediate family member or a member of the person's household as defined in paragraph (a)(2) of this section, in anticipation of or following a conviction, assessment of a CMP, or imposition of an exclusion.

(2) For purposes of this section, the term:

Agent means any person who has express or implied authority to obligate or act on behalf of an entity.

Immediate family member means, a person's husband or wife; natural or adoptive parent; child or sibling; stepparent, stepchild, stepbrother or stepsister; father-, mother-, daughter-, son-, brother- or sister-in-law; grandparent or grandchild; or spouse of a grandparent or grandchild.

Indirect ownership interest includes an ownership interest through any other entities that ultimately have an ownership interest in the entity in issue. (For example, an individual has a 10 percent ownership interest in the entity at issue if he or she has a 20 percent ownership interest in a corporation that wholly owns a subsidiary that is a 50 percent owner of the entity in issue.)

Member of household means, with respect to a person, any individual with whom they are sharing a common abode as part of a single family unit, including domestic employees and others who live together as a family unit. A roomer or boarder is not considered a member of household.

Ownership interest means an interest in:

(i) The capital, the stock or the profits of the entity, or

(ii) Any mortgage, deed, trust or note, or other obligation secured in whole or in part by the property or assets of the entity.

(b) *Length of exclusion.* (1) Except as provided in § 1001.3002(c), exclusions under this section will be for the same period as that of the individual whose relationship with the entity is the basis for this exclusion, if the individual has been or is being excluded.

(2) If the individual was not excluded, the length of the entity's exclusion will be determined by considering the factors that would have been considered if the individual had been excluded.

(3) An entity excluded under this section may apply for reinstatement at

any time in accordance with the procedures set forth in § 1001.3001(a)(2).

[57 FR 3330, Jan. 29, 1992, as amended at 64 FR 39427, July 22, 1999]

§ 1001.1051 Exclusion of individuals with ownership or control interest in sanctioned entities.

(a) *Circumstance for exclusion.* The OIG may exclude any individual who—

(1) Has a direct or indirect ownership or control interest in a sanctioned entity, and who knows or should know (as defined in section 1128A(i)(6) of the Act) of the action constituting the basis for the conviction or exclusion set forth in paragraph (b) of this section; or

(2) Is an officer or managing employee (as defined in section 1126(b) of the Act) of such an entity.

(b) For purposes of paragraph (a) of this section, the term ''sanctioned entity'' means an entity that—

(1) Has been convicted of any offense described in §§ 1001.101 through 1001.401 of this part; or

(2) Has been terminated or excluded from participation in Medicare, Medicaid and all other Federal health care programs.

(c) *Length of exclusion.* (1) If the entity has been excluded, the length of the individual's exclusion will be for the same period as that of the sanctioned entity with which the individual has the prohibited relationship.

(2) If the entity was not excluded, the length of the individual's exclusion will be determined by considering the factors that would have been considered if the entity had been excluded.

(3) An individual excluded under this section may apply for reinstatement in accordance with the procedures set forth in § 1001.3001.

[63 FR 46689, Sept. 2, 1998]

§ 1001.1101 Failure to disclose certain information.

(a) *Circumstance for exclusion.* The OIG may exclude any entity that did not fully and accurately, or completely, make disclosures as required by section 1124, 1124A or 1126 of the Act, and by part 455, subpart B and part 420, subpart C of this title.

(b) *Length of exclusion.* The following factors will be considered in determining the length of an exclusion under this section—

(1) The number of instances where full and accurate, or complete, disclosure was not made;

(2) The significance of the undisclosed information;

(3) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral);

(4) Any other facts that bear on the nature or seriousness of the conduct;

(5) The availability of alternative sources of the type of health care services provided by the entity; and

(6) The extent to which the entity knew that the disclosures made were not full or accurate.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46689, Sept. 2, 1998]

§ 1001.1201 Failure to provide payment information.

(a) *Circumstance for exclusion.* The OIG may exclude any individual or entity that furnishes items or services for which payment may be made under Medicare or any of the State health care programs and that:

(1) Fails to provide such information as is necessary to determine whether such payments are or were due and the amounts thereof, or

(2) Has refused to permit such examination and duplication of its records as may be necessary to verify such information.

(b) *Length of exclusion.* The following factors will be considered in determining the length of an exclusion under this section—

(1) The number of instances where information was not provided;

(2) The circumstances under which such information was not provided;

(3) The amount of the payments at issue;

(4) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral); and

(5) The availability of alternative sources of the type of health care items

or services provided by the individual or entity.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46689, Sept. 2, 1998]

§ 1001.1301 Failure to grant immediate access.

(a) *Circumstance for exclusion.* (1) The OIG may exclude any individual or entity that fails to grant immediate access upon reasonable request to—

(i) The Secretary, a State survey agency or other authorized entity for the purpose of determining, in accordance with section 1864(a) of the Act, whether—

(A) An institution is a hospital or skilled nursing facility;

(B) An agency is a home health agency;

(C) An agency is a hospice program;

(D) A facility is a rural health clinic as defined in section 1861(aa)(2) of the Act, or a comprehensive outpatient rehabilitation facility as defined in section 1861(cc)(2) of the Act;

(E) A laboratory is meeting the requirements of section 1861(s) (15) and (16) of the Act, and section 353(f) of the Public Health Service Act;

(F) A clinic, rehabilitation agency or public health agency is meeting the requirements of section 1861(p)(4) (A) or (B) of the Act;

(G) An ambulatory surgical center is meeting the standards specified under section 1832(a)(2)(F)(i) of the Act;

(H) A portable x-ray unit is meeting the requirements of section 1861(s)(3) of the Act;

(I) A screening mammography service is meeting the requirements of section 1834(c)(3) of the Act;

(J) An end-stage renal disease facility is meeting the requirements of section 1881(b) of the Act;

(K) A physical therapist in independent practice is meeting the requirements of section 1861(p) of the Act;

(L) An occupational therapist in independent practice is meeting the requirements of section 1861(g) of the Act;

(M) An organ procurement organization meets the requirements of section 1138(b) of the Act; or.

(N) A rural primary care hospital meets the requirements of section 1820(i)(2) of the Act;

(ii) The Secretary, a State survey agency or other authorized entity to perform the reviews and surveys required under State plans in accordance with sections 1902(a)(26) (relating to inpatient mental hospital services), 1902(a)(31) (relating to intermediate care facilities for the mentally retarded), 1919(g) (relating to nursing facilities), 1929(i) (relating to providers of home and community care and community care settings), 1902(a)(33) and 1903(g) of the Act;

(iii) The OIG for the purposes of reviewing records, documents and other data necessary to the performance of the Inspector General's statutory functions; or

(iv) A State Medicaid fraud control unit for the purpose of conducting its activities.

(2) For purposes of paragraphs (a)(1)(i) and (a)(1)(ii) of this section, the term—

Failure to grant immediate access means the failure to grant access at the time of a reasonable request or to provide a compelling reason why access may not be granted.

Reasonable request means a written request made by a properly identified agent of the Secretary, of a State survey agency or of another authorized entity, during hours that the facility, agency or institution is open for business.

The request will include a statement of the authority for the request, the rights of the entity in responding to the request, the definition of *reasonable request* and *immediate access*, and the penalties for failure to comply, including when the exclusion will take effect.

(3) For purposes of paragraphs (a)(1)(iii) and (a)(1)(iv) of this section, the term—

Failure to grant immediate access means:

(i) Except where the OIG or State Medicaid fraud control unit reasonably believes that requested documents are about to be altered or destroyed, the failure to produce or make available for inspection and copying requested records upon reasonable request, or to provide a compelling reason why they

cannot be produced, within 24 hours of such request;

(ii) Where the OIG or State Medicaid fraud control unit has reason to believe that requested documents are about to be altered or destroyed, the failure to provide access to requested records at the time the request is made.

Reasonable request means a written request for documents, signed by a designated representative of the OIG or the State Medicaid fraud control unit, and made by a properly identified agent of the OIG or a State Medicaid fraud control unit during reasonable business hours, where there is information to suggest that the individual or entity has violated statutory or regulatory requirements under titles V, XI, XVIII, XIX or XX of the Act. The request will include a statement of the authority for the request, the rights of the individual or entity in responding to the request, the definition of *reasonable request* and *immediate access*, and the effective date, length, and scope and effect of the exclusion that would be imposed for failure to comply with the request, and the earliest date that a request for reinstatement would be considered.

(4) Nothing in this section shall in any way limit access otherwise authorized under State or Federal law.

(b) *Length of exclusion*. (1) An exclusion of an individual under this section may be for a period equal to the sum of:

(i) The length of the period during which the immediate access was not granted, and

(ii) An additional period of up to 90 days.

(2) The exclusion of an entity may be for a longer period than the period in which immediate access was not granted based on consideration of the following factors—

(i) The impact of the failure to grant the requested immediate access on Medicare or any of the State health care programs, beneficiaries or the public;

(ii) The circumstances under which such access was refused;

(iii) The impact of the exclusion on Medicare, Medicaid or any of the other Federal health care programs, beneficiaries or the public; and

(iv) Whether the entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral).

(3) For purposes of paragraphs (b)(1) and (b)(2) of this section, the length of the period in which immediate access was not granted will be measured from the time the request is made, or from the time by which access was required to be granted, whichever is later.

(c) The exclusion will be effective as of the date immediate access was not granted.

[57 FR 3330, Jan. 29, 1992, as amended at 58 FR 40753, July 30, 1993; 63 FR 46689, Sept. 2, 1998; 64 FR 39427, July 22, 1999]

§ 1001.1401 Violations of PPS corrective action.

(a) *Circumstance for exclusion*. The OIG may exclude any hospital that CMS determines has failed substantially to comply with a corrective action plan required by CMS under section 1886(f)(2)(B) of the Act.

(b) *Length of exclusion*. The following factors will be considered in determining the length of exclusion under this section—

(1) The impact of the hospital's failure to comply on Medicare, Medicaid or any of the other Federal health care programs, program beneficiaries or other individuals;

(2) The circumstances under which the failure occurred;

(3) The nature of the failure to comply;

(4) The impact of the exclusion on Medicare, Medicaid or any of the other Federal health care programs, beneficiaries or the public; and

(5) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral).

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46689, Sept. 2, 1998; 64 FR 39427, July 22, 1999]

§ 1001.1501 Default of health education loan or scholarship obligations.

(a) *Circumstance for exclusion*. (1) Except as provided in paragraph (a)(4) of this section, the OIG may exclude any

individual that the Public Health Service (PHS) determines is in default on repayments of scholarship obligations or loans in connection with health professions education made or secured in whole or in part by the Secretary.

(2) Before imposing an exclusion in accordance with paragraph (a)(1) of this section, the OIG must determine that PHS has taken all reasonable administrative steps to secure repayment of the loans or obligations. If PHS has offered a Medicare offset arrangement as required by section 1892 of the Act, the OIG will find that all reasonable steps have been taken.

(3) The OIG will take into account access of beneficiaries to physicians' services for which payment may be made under Medicare, Medicaid or other Federal health care programs in determining whether to impose an exclusion.

(4) The OIG will not exclude a physician who is the sole community physician or the sole source of essential specialized services in a community if a State requests that the physician not be excluded.

(b) *Length of exclusion.* The individual will be excluded until such time as PHS notifies the OIG that the default has been cured or that there is no longer an outstanding debt. Upon such notice, the OIG will inform the individual of his or her right to apply for reinstatement.

[57 FR 3330, Jan. 29, 1992, as amended at 64 FR 39427, July 22, 1999; 67 FR 11935, Mar. 18, 2002]

§ 1001.1601 Violations of the limitations on physician charges.

(a) *Circumstance for exclusion.* (1) The OIG may exclude a physician whom it determines—

(i) Is a non-participating physician under section 1842(j) of the Act;

(ii) Furnished services to a beneficiary;

(iii) Knowingly and willfully billed—

(A) On a repeated basis for such services actual charges in excess of the maximum allowable actual charge determined in accordance with section 1842(j)(1)(C) of the Act for the period January 1, 1987 through December 31, 1990, or

(B) Individuals enrolled under part B of title XVIII of the Act during the statutory freeze for actual charges in excess of such physician's actual charges determined in accordance with section 1842(j)(1)(A) of the Act for the period July 1, 1984 to December 31, 1986; and''

(iv) Is not the sole community physician or sole source of essential specialized services in the community.

(2) The OIG will take into account access of beneficiaries to physicians' services for which Medicare payment may be made in determining whether to impose an exclusion.

(b) *Length of exclusion.* (1) In determining the length of an exclusion in accordance with this section, the OIG will consider the following factors—

(i) The number of services for which the physician billed in excess of the maximum allowable charges;

(ii) The number of beneficiaries for whom services were billed in excess of the maximum allowable charges;

(iii) The amount of the charges that were in excess of the maximum allowable charges;

(iv) Whether the physician has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral); and

(v) The availability of alternative sources of the type of health care items or services furnished by the physician.

(2) The period of exclusion may not exceed 5 years.

[57 FR 3329, Jan. 29, 1992; 57 FR 9669, Mar. 20, 1992, as amended at 63 FR 46689, Sept. 2, 1998]

§ 1001.1701 Billing for services of assistant at surgery during cataract operations.

(a) Circumstance for exclusion. The OIG may exclude a physician whom it determines—

(1) Has knowingly and willfully presented or caused to be presented a claim, or billed an individual enrolled under Part B of the Medicare program (or his or her representative) for:

(i) Services of an assistant at surgery during a cataract operation, or

(ii) Charges that include a charge for an assistant at surgery during a cataract operation;

(2) Has not obtained prior approval for the use of such assistant from the appropriate Utilization and Quality Control Quality Improvement Organization (QIO) or Medicare carrier; and

(3) Is not the sole community physician or sole source of essential specialized services in the community.

(b) The OIG will take into account access of beneficiaries to physicians' services for which Medicare payment may be made in determining whether to impose an exclusion.

(c) Length of exclusion. (1) In determining the length of an exclusion in accordance with this section, the OIG will consider the following factors—

(i) The number of instances for which claims were submitted or beneficiaries were billed for unapproved use of assistants during cataract operations;

(ii) The amount of the claims or bills presented;

(iii) The circumstances under which the claims or bills were made, including whether the services were medically necessary;

(iv) Whether approval for the use of an assistant was requested from the QIO or carrier;

(v) Whether the physician has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral); and

(vi) The availability of alternative sources of the type of health care items or services furnished by the physician.

(2) The period of exclusion may not exceed 5 years.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46690, Sept. 2, 1998]

APPENDIX A TO SUBPART C OF PART 1001

The following is a sample written disclosure for purposes of satisfying the requirements of §1001.952(v)(3)(i)(B)(*I*)(*i*) of this part. This form is for illustrative purposes only; parties may, but are not required to, adapt this sample written disclosure form.

NOTICE OF AMBULANCE RESTOCKING PROGRAM

Hospital X offers the following ambulance restocking program:

1. We will restock all ambulance providers (other than ambulance providers that do not provide emergency services) that bring patients to Hospital X [or to a subpart of Hospital X, such as the emergency room] in the following category or categories: [insert description of category of ambulances to be restocked, i.e., all ambulance providers, all ambulance providers that do not charge patients or insurers for their services, or all nonprofit and Government ambulance providers]. [Optional: We only offer restocking of emergency transports.]

2. The restocking will include the following drugs and medical supplies, and linens, used for patient prior to delivery of the patient to Hospital X: [insert description of drugs and medical supplies, and linens to be restocked].

3. The ambulance providers [will/will not] be required to pay for the restocked drugs and medical supplies, and linens.

4. The restocked drugs and medical supplies, and linens, must be documented as follows: [insert description consistent with the documentation requirements described in §1001.952(v). By way of example only, documentation may be by a patient care report filed with the receiving facility within 24 hours of delivery of the patient that records the name of the patient, the date of the transport, and the relevant drugs and medical supplies.]

5. This restocking program does not apply to the restocking of ambulances that only provide non-emergency services or to the general stocking of an ambulance provider's inventory.

6. To ensure that Hospital X does not bill any Federal health care program for restocked drugs or supplies for which a participating ambulance provider bills or is eligible to bill, all participating ambulance providers must notify Hospital X if they intend to submit claims for restocked drugs or supplies to any Federal health care program. Participating ambulance providers must agree to work with Hospital X to ensure that only one party bills for a particular restocked drug or supply.

7. All participants in this ambulance restocking arrangement that bill Federal health care programs for restocked drugs or supplies must comply with all applicable Federal program billing and claims filing rules and regulations.

8. For further information about our restocking program or to obtain a copy of this notice, please contact [name] at [telephone number].

Dated:_____

/s/_____

Appropriate officer or official

[66 FR 62991, Dec. 4, 2001]

Subpart D—Waivers and Effect of Exclusion

§1001.1801 Waivers of exclusions.

(a) The OIG has the authority to grant or deny a request from a State

health care program that an exclusion from that program be waived with respect to an individual or entity, except that no waiver may be granted with respect to an exclusion under § 1001.101(b). The request must be in writing and from an individual directly responsible for administering the State health care program.

(b) With respect to exclusions under § 1001.101(a), a request from a State health care program for a waiver of the exclusion will only be considered if the individual or entity is the sole community physician or the sole source of essential specialized services in a community.

(c) With respect to exclusions imposed under subpart C of this part, a request for waiver will only be granted if the OIG determines that imposition of the exclusion would not be in the public interest.

(d) If the basis for the waiver ceases to exist, the waiver will be rescinded, and the individual or entity will be excluded for the period remaining on the exclusion, measured from the time the exclusion would have been imposed if the waiver had not been granted.

(e) In the event a waiver is granted, it is applicable only to the program(s) for which waiver is requested.

(f) The decision to grant, deny or rescind a request for a waiver is not subject to administrative or judicial review.

(g) The Inspector General may waive the exclusion of an individual or entity from participation in the Medicare program in conjunction with granting a waiver requested by a State health care program. If a State program waiver is rescinded, the derivative waiver of the exclusion from Medicare is automatically rescinded.

§ 1001.1901 Scope and effect of exclusion.

(a) *Scope of exclusion.* Exclusions of individuals and entities under this title will be from Medicare, Medicaid and any of the other Federal health care programs, as defined in § 1001.2.

(b) *Effect of exclusion on excluded individuals and entities.* (1) Unless and until an individual or entity is reinstated into the Medicare, Medicaid and other Federal health care programs in accordance with subpart F of this part, no payment will be made by Medicare, Medicaid or any of the other Federal health care programs for any item or service furnished, on or after the effective date specified in the notice period, by an excluded individual or entity, or at the medical direction or on the prescription of a physician or other authorized individual who is excluded when the person furnishing such item or service knew or had reason to know of the exclusion. This section applies regardless of whether an individual or entity has obtained a program provider number or equivalent, either as an individual or as a member of a group, prior to being reinstated.

(2) An excluded individual or entity may not take assignment of an enrollee's claim on or after the effective date of exclusion.

(3) An excluded individual or entity that submits, or causes to be submitted, claims for items or services furnished during the exclusion period is subject to civil money penalty liability under section 1128A(a)(1)(D) of the Act, and criminal liability under section 1128B(a)(3) of the Act and other provisions. In addition, submitting claims, or causing claims to be submitted or payments to be made for items or services furnished, ordered or prescribed, including administrative and management services or salary, may serve as the basis for denying reinstatement to the programs.

(c) *Exceptions to paragraph (b)(1) of this section.* (1) If an enrollee of Part B of Medicare submits an otherwise payable claim for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician or other authorized individual after the effective date of exclusion, CMS will pay the first claim submitted by the enrollee and immediately notify the enrollee of the exclusion.

(2) CMS will not pay an enrollee for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician or other authorized individual more than 15 days after the date on the notice to the enrollee, or after the effective date of the exclusion, whichever is later.

(3) Unless the Secretary determines that the health and safety of beneficiaries receiving services under Medicare, Medicaid or any of the other Federal health care programs warrants the exclusion taking effect earlier, payment may be made under such program for up to 30 days after the effective date of the exclusion for—

(i) Inpatient institutional services furnished to an individual who was admitted to an excluded institution before the date of the exclusion,

(ii) Home health services and hospice care furnished to an individual under a plan of care established before the effective date of the exclusion, and

(iii) Any health care items that are ordered by a practitioner, provider or supplier from an excluded manufacturer before the effective date of the exclusion and delivered within 30 days of the effective date of such exclusion. (For the period October 2, 1998, to October 4, 1999, payment may be made under Medicare or a State health care program for up to 60 days after the effective date of the exclusion for any health care items that are ordered by a practitioner, provider or supplier from an excluded manufacturer before the effective date of such exclusion and delivered within 60 days of the effect of the exclusion.)

(4) CMS will not pay any claims submitted by, or for items or services ordered or prescribed by, an excluded provider for dates of service 15 days or more after the notice of the provider's exclusion was mailed to the supplier.

(5)(i) Notwithstanding the other provisions of this section, payment may be made under Medicare, Medicaid or other Federal health care programs for certain emergency items or services furnished by an excluded individual or entity, or at the medical direction or on the prescription of an excluded physician or other authorized individual during the period of exclusion. To be payable, a claim for such emergency items or services must be accompanied by a sworn statement of the person furnishing the items or services specifying the nature of the emergency and why the items or services could not have been furnished by an individual or entity eligible to furnish or order such items or services.

(ii) Notwithstanding paragraph (c)(5)(i) of this section, no claim for emergency items or services will be payable if such items or services were provided by an excluded individual who, through an employment, contractual or any other arrangement, routinely provides emergency health care items or services.

[57 FR 3330, Jan. 29, 1992, as amended at 60 FR 32917, June 26, 1995; 63 FR 46690, Sept. 2, 1998; 64 FR 39427, July 22, 1999]

Subpart E—Notice and Appeals

§ 1001.2001 Notice of intent to exclude.

(a) Except as provided in paragraph (c) of this section, if the OIG proposes to exclude an individual or entity in accordance with subpart C of this part, or in accordance with subpart B of this part where the exclusion is for a period exceeding 5 years, it will send written notice of its intent, the basis for the proposed exclusion and the potential effect of an exclusion. Within 30 days of receipt of notice, which will be deemed to be 5 days after the date on the notice, the individual or entity may submit documentary evidence and written argument concerning whether the exclusion is warranted and any related issues.

(b) If the OIG proposes to exclude an individual or entity under the provisions of § 1001.701 or § 1001.801 of this part, in conjunction with the submission of documentary evidence and written argument, an individual or entity may request an opportunity to present oral argument to an OIG official.

(c) *Exception.* If the OIG proposes to exclude an individual or entity under the provisions of §§ 1001.1301, 1001.1401 or 1001.1501 of this part, paragraph (a) of this section will not apply.

(d) If an entity has a provider agreement under section 1866 of the Act, and the OIG proposes to terminate that agreement in accordance with section 1866(b)(2)(C) of the Act, the notice provided for in paragraph (a) of this section will so state.

[63 FR 46690, Sept. 2, 1998, as amended at 63 FR 57918, Oct. 29, 1998]

§ 1001.2002 Notice of exclusion.

(a) Except as provided in § 1001.2003, if the OIG determines that exclusion is warranted, it will send a written notice of this decision to the affected individual or entity.

(b) The exclusion will be effective 20 days from the date of the notice.

(c) The written notice will state—

(1) The basis for the exclusion;

(2) The length of the exclusion and, where applicable, the factors considered in setting the length;

(3) The effect of the exclusion;

(4) The earliest date on which the OIG will consider a request for reinstatement;

(5) The requirements and procedures for reinstatement; and

(6) The appeal rights available to the excluded individual or entity.

(d) Paragraph (b) of this section does not apply to exclusions imposed in accordance with § 1001.1301.

(e) No later than 15 days prior to the final exhibit exchanges required under § 1005.8 of this chapter, the OIG may amend its notice letter if information comes to light that justifies the imposition of a different period of exclusion other than the one proposed in the original notice letter.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46690, Sept. 2, 1998]

§ 1001.2003 Notice of proposal to exclude.

(a) Except as provided in paragraph (c) of this section, if the OIG proposes to exclude an individual or entity in accordance with §§ 1001.901, 1001.951, 1001.1601 or 1001.1701, it will send written notice of this decision to the affected individual or entity. The written notice will provide the same information set forth in § 1001.2002(c). If an entity has a provider agreement under section 1866 of the Act, and the OIG also proposes to terminate that agreement in accordance with section 1866(b)(2)(C) of the Act, the notice will so indicate. The exclusion will be effective 60 days after the receipt of the notice (as defined in § 1005.2 of this chapter) unless, within that period, the individual or entity files a written request for a hearing in accordance with part 1005 of this chapter. Such request must set forth—

(1) The specific issues or statements in the notice with which the individual or entity disagrees;

(2) The basis for that disagreement;

(3) The defenses on which reliance is intended;

(4) Any reasons why the proposed length of exclusion should be modified; and

(5) Reasons why the health or safety of individuals receiving services under Medicare or any of the State health care programs does not warrant the exclusion going into effect prior to the completion of an administrative law judge (ALJ) proceeding in accordance with part 1005 of this chapter.

(b)(1) If the individual or entity does not make a written request for a hearing as provided for in paragraph (a) of this section, the OIG will send a notice of exclusion as described in § 1001.2002.

(2) If the individual or entity makes a timely written request for a hearing and the OIG determines that the health or safety of individuals receiving services under Medicare or any of the State health care programs does not warrant immediate exclusion, an exclusion will only go into effect, with the date of the ALJ's decision, if the ALJ upholds the decision to exclude.

(c) If, prior to issuing a notice of proposal to exclude under paragraph (a) of this section, the OIG determines that the health or safety of individuals receiving services under Medicare or any of the State health care programs warrants the exclusion taking place prior to the completion of an ALJ proceeding in accordance with part 1005 of this chapter, the OIG will proceed under §§ 1001.2001 and 1001.2002.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46690, Sept. 2, 1998; 65 FR 24414, Apr. 26, 2000]

§ 1001.2004 Notice to State agencies.

HHS will promptly notify each appropriate State agency administering or supervising the administration of each State health care program of:

(a) The facts and circumstances of each exclusion, and

(b) The period for which the State agency is being directed to exclude the individual or entity.

§ 1001.2005 Notice to State licensing agencies.

(a) HHS will promptly notify the appropriate State(s) or local agencies or authorities having responsibility for the licensing or certification of an individual or entity excluded (or directed to be excluded) from participation of the facts and circumstances of the exclusion.

(b) HHS will request that appropriate investigations be made and sanctions invoked in accordance with applicable State law and policy, and will request that the State or local agency or authority keep the Secretary and the OIG fully and currently informed with respect to any actions taken in response to the request.

§ 1001.2006 Notice to others regarding exclusion.

(a) HHS will give notice of the exclusion and the effective date to the public, to beneficiaries (in accordance with § 1001.1901(c)), and, as appropriate, to—

(1) Any entity in which the excluded individual is known to be serving as an employee, administrator, operator, or in which the individual is serving in any other capacity and is receiving payment for providing services (The lack of this notice will not affect CMS's ability to deny payment for services);

(2) State Medicaid Fraud Control Units;

(3) Utilization and Quality Control Quality Improvement Organizations;

(4) Hospitals, skilled nursing facilities, home health agencies and health maintenance organizations;

(5) Medical societies and other professional organizations;

(6) Contractors, health care prepayment plans, private insurance companies and other affected agencies and organizations;

(7) The State and Area Agencies on Aging established under title III of the Older Americans Act;

(8) The National Practitioner Data Bank.

(9) Other Departmental operating divisions, Federal agencies, and other agencies or organizations, as appropriate.

(b) In the case of an exclusion under § 1001.101 of this chapter, if section 304(a)(5) of the Controlled Substances Act (21 U.S.C. 824(a)(5)) applies, HHS will give notice to the Attorney General of the United States of the facts and circumstances of the exclusion and the length of the exclusion.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46690, Sept. 2, 1998]

§ 1001.2007 Appeal of exclusions.

(a)(1) Except as provided in § 1001.2003, an individual or entity excluded under this Part may file a request for a hearing before an ALJ only on the issues of whether:

(i) The basis for the imposition of the sanction exists, and

(ii) The length of exclusion is unreasonable.

(2) When the OIG imposes an exclusion under subpart B of this part for a period of 5 years, paragraph (a)(1)(ii) of this section will not apply.

(3) The request for a hearing should contain the information set forth in § 1005.2(d) of this chapter.

(b) The excluded individual or entity has 60 days from the receipt of notice of exclusion provided for in § 1001.2002 to file a request for such a hearing.

(c) The standard of proof at a hearing is preponderance of the evidence.

(d) When the exclusion is based on the existence of a criminal conviction or a civil judgment imposing liability by Federal, State or local court, a determination by another Government agency, or any other prior determination where the facts were adjudicated and a final decision was made, the basis for the underlying conviction, civil judgment or determination is not reviewable and the individual or entity may not collaterally attack it either on substantive or procedural grounds in this appeal.

(e) The procedures in part 1005 of this chapter will apply to the appeal.

[57 FR 3330, Jan. 29, 1992, as amended at 67 FR 11935, Mar. 18, 2002]

Subpart F—Reinstatement into the Programs

§ 1001.3001 Timing and method of request for reinstatement.

(a)(1) Except as provided in paragraphs (a)(2) and (a)(3) of this section

or in § 1001.501(b)(4) of this part, an excluded individual or entity (other than those excluded in accordance with §§ 1001.1001 and 1001.1501) may submit a written request for reinstatement to the OIG only after the date specified in the notice of exclusion. Obtaining a program provider number or equivalent does not reinstate eligibility.

(2) An entity under § 1001.1001 may apply for reinstatement prior to the date specified in the notice of exclusion by submitting a written request for reinstatement that includes documentation demonstrating that the standards set forth in § 1001.3002(c) have been met.

(3) Upon receipt of a written request, the OIG will require the requestor to furnish specific information and authorization to obtain information from private health insurers, peer review bodies, probation officers, professional associates, investigative agencies and such others as may be necessary to determine whether reinstatement should be granted.

(4) Failure to furnish the required information or authorization will result in the continuation of the exclusion.

(b) If a period of exclusion is reduced on appeal (regardless of whether further appeal is pending), the individual or entity may request reinstatement once the reduced exclusion period expires.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46691, Sept. 2, 1998]

§ 1001.3002 Basis for reinstatement.

(a)(1) The OIG will authorize reinstatement if it determines that—

(i) The period of exclusion has expired;

(ii) There are reasonable assurances that the types of actions that formed the basis for the original exclusion have not recurred and will not recur; and

(iii) There is no additional basis under sections 1128(a) or (b) or 1128A of the Act for continuation of the exclusion.

(2) Submitting claims or causing claims to be submitted or payments to be made by the programs for items or services furnished, ordered or prescribed, including administrative and management services or salary, may serve as the basis for denying reinstatement. This section applies regardless of whether an individual or entity has obtained a program provider number or equivalent, either as an individual or as a member of a group, prior to being reinstated.

(b) In making the reinstatement determination, the OIG will consider—

(1) Conduct of the individual or entity occurring prior to the date of the notice of exclusion, if not known to the OIG at the time of the exclusion;

(2) Conduct of the individual or entity after the date of the notice of exclusion;

(3) Whether all fines, and all debts due and owing (including overpayments) to any Federal, State or local government that relate to Medicare, Medicaid and all other Federal health care programs, have been paid or satisfactory arrangements have been made to fulfill obligations;

(4) Whether CMS has determined that the individual or entity complies with, or has made satisfactory arrangements to fulfill, all of the applicable conditions of participation or supplier conditions for coverage under the statutes and regulations; and

(5) [Reserved]

(6) Whether the individual or entity has, during the period of exclusion, submitted claims, or caused claims to be submitted or payment to be made by any Federal health care program, for items or services the excluded party furnished, ordered or prescribed, including health care administrative services.

(c) If the OIG determines that the criteria in paragraphs (a)(1)(ii) and (iii) of this section have been met, an entity excluded in accordance with § 1001.1001 will be reinstated upon a determination by the OIG that the individual whose conviction, exclusion or civil money penalty was the basis for the entity's exclusion—

(1) Has properly reduced his or her ownership or control interest in the entity below 5 percent;

(2) Is no longer an officer, director, agent or managing employee of the entity; or

(3) Has been reinstated in accordance with paragraph (a) of this section or § 1001.3005.

(d) Reinstatement will not be effective until the OIG grants the request and provides notice under § 1001.3003(a) of this part. Reinstatement will be effective as provided in the notice.

(e) A determination with respect to reinstatement is not appealable or reviewable except as provided in § 1001.3004.

(f) An ALJ may not require reinstatement of an individual or entity in accordance with this chapter.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46691, Sept. 2, 1998; 64 FR 39427, July 22, 1999]

§ 1001.3003 Approval of request for reinstatement.

(a) If the OIG grants a request for reinstatement, the OIG will—

(1) Give written notice to the excluded individual or entity specifying the date of reinstatement;

(2) Notify CMS of the date of the individual's or entity's reinstatement;

(3) Notify appropriate Federal and State agencies that administer health care programs that the individual or entity has been reinstated into all Federal health care programs; and

(4) To the extent applicable, give notice to others that were originally notified of the exclusion.

(b) A determination by the OIG to reinstate an individual or entity has no effect if a Federal health care program has imposed a longer period of exclusion under its own authorities.

[64 FR 39428, July 22, 1999]

§ 1001.3004 Denial of request for reinstatement.

(a) If a request for reinstatement is denied, OIG will give written notice to the requesting individual or entity. Within 30 days of the date on the notice, the excluded individual or entity may submit:

(1) Documentary evidence and written argument against the continued exclusion,

(2) A written request to present written evidence and oral argument to an OIG official, or

(3) Both documentary evidence and a written request.

(b) After evaluating any additional evidence submitted by the excluded individual or entity (or at the end of the 30-day period, if none is submitted), the OIG will send written notice either confirming the denial, and indicating that a subsequent request for reinstatement will not be considered until at least one year after the date of denial, or approving the request consistent with the procedures set forth in § 1001.3003(a).

(c) The decision to deny reinstatement will not be subject to administrative or judicial review.

§ 1001.3005 Reversed or vacated decisions.

(a) An individual or entity will be reinstated into Medicare, Medicaid and other Federal health care programs retroactive to the effective date of the exclusion when such exclusion is based on—

(1) A conviction that is reversed or vacated on appeal;

(2) An action by another agency, such as a State agency or licensing board, that is reversed or vacated on appeal; or

(3) An OIG exclusion action that is reversed or vacated at any stage of an individual's or entity's administrative appeal process.

(b) If an individual or entity is reinstated in accordance with paragraph (a) of this section, CMS and other Federal health care programs will make payment for services covered under such program that were furnished or performed during the period of exclusion.

(c) The OIG will give notice of a reinstatement under this section in accordance with § 1001.3003(a).

(d) An action taken by the OIG under this section will not require any other Federal health care program to reinstate the individual or entity if such program has imposed an exclusion under its own authority.

(e) If an action which results in the retroactive reinstatement of an individual or entity is subsequently overturned, the OIG may reimpose the exclusion for the initial period of time, less the period of time that was served prior to the reinstatement of the individual or entity.

[57 FR 3330, Jan. 29, 1992, as amended at 64 FR 39428, July 22, 1999; 67 FR 11935, Mar. 18, 2002]

PART 1002—PROGRAM INTEGRITY—STATE-INITIATED EXCLUSIONS FROM MEDICAID

Subpart A—General Provisions

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Subpart C—Permissive Exclusions

1002.210 Permissive exclusions; general authority.
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Subpart D—Notification to OIG of State or Local Convictions of Crimes Against Medicaid

1002.230 Notification of State or local convictions of crimes against Medicaid.

AUTHORITY: 42 U.S.C. 1302, 1320a–3, 1320a–5, 1320a–7, 1396(a)(4)(A), 1396(p)(1), 1396a(30), 1396a(39), 1396b(a)(6), 1396b(b)(3), 1396b(i)(2) and 1396b(q).

SOURCE: 57 FR 3343, Jan. 29, 1992, unless otherwise noted.

Subpart A—General Provisions

§ 1002.1 Scope and purpose.

The regulations in this part specify certain bases upon which individuals and entities may, or in some cases must, be excluded from participation in the Medicaid program. These regulations specifically address the authority of State agencies to exclude on their own initiative, regardless of whether the OIG has excluded an individual or entity under part 1001 of this chapter. These regulations also delineate the States' obligation to inform the OIG of certain Medicaid-related convictions.

§ 1002.2 General authority.

(a) In addition to any other authority it may have, a State may exclude an individual or entity from participation in the Medicaid program for any reason for which the Secretary could exclude that individual or entity from participation in the Medicare, Medicaid and other Federal health care programs under sections 1128, 1128A or 1866(b)(2) of the Social Security Act.

(b) Nothing contained in this part should be construed to limit a State's own authority to exclude an individual or entity from Medicaid for any reason or period authorized by State law.

[57 FR 3343, Jan. 29, 1992, as amended at 64 FR 39428, July 22, 1999]

§ 1002.3 Disclosure by providers and State Medicaid agencies.

(a) *Information that must be disclosed.* Before the Medicaid agency enters into or renews a provider agreement, or at any time upon written request by the Medicaid agency, the provider must disclose to the Medicaid agency the identity of any person described in § 1001.1001(a)(1) of this chapter.

(b) *Notification to Inspector General.* (1) The Medicaid agency must notify the Inspector General of any disclosures made under paragraph (a) of this section within 20 working days from the date it receives the information.

(2) The agency must promptly notify the Inspector General of any action it takes on the provider's application for participation in the program.

(3) The agency must also promptly notify the Inspector General of any action it takes to limit the ability of an individual or entity to participate in its program, regardless of what such an action is called. This includes, but is not limited to, suspension actions, settlement agreements and situations where an individual or entity voluntarily withdraws from the program to avoid a formal sanction.

(c) *Denial or termination of provider participation.* (1) The Medicaid agency may refuse to enter into or renew an agreement with a provider if any person who has ownership or control interest in the provider, or who is an agent or managing employee of the provider, has been convicted of a criminal offense related to that person's involvement in any program established under Medicare, Medicaid or the title XX Services program.

(2) The Medicaid agency may refuse to enter into, or terminate, a provider agreement if it determines that the provider did not fully and accurately make any disclosure required under paragraph (a) of this section.

[57 FR 3343, Jan. 29, 1992, as amended at 63 FR 46691, Sept. 2, 1998]

§ 1002.100 State plan requirement.

The plan must provide that the requirements of this subpart are met. However, the provisions of these regulations are minimum requirements. The agency may impose broader sanctions if it has the authority to do so under State law.

Subpart B—Mandatory Exclusion

§ 1002.203 Mandatory exclusion.

(a) The State agency, in order to receive Federal financial participation (FFP), must provide that it will exclude from participation any HMO, or entity furnishing services under a waiver approved under section 1915(b)(1) of the Act, if such organization or entity—

(1) Could be excluded under § 1001.1001 or § 1001.1051 of this chapter, or

(2) Has, directly or indirectly, a substantial contractual relationship with an individual or entity that could be excluded under § 1001.1001 or § 1001.1051 of this chapter.

(b) As used in this section, the term—

Exclude includes the refusal to enter into or renew a participation agreement or the termination of such an agreement.

Substantial contractual relationship is one in which the sanctioned individual described in § 1001.1001 of this chapter has direct or indirect business transactions with the organization or entity that, in any fiscal year, amount to more than $25,000 or 5 percent of the organization's or entity's total operating expenses, whichever is less. Business transactions include, but are not limited to, contracts, agreements, purchase orders, or leases to obtain services, supplies, equipment, space or salaried employment.

[57 FR 3343, Jan. 29, 1992, as amended at 63 FR 46691, Sept. 2, 1998]

Subpart C—Permissive Exclusions

§ 1002.210 Permissive exclusions; general authority.

The State agency must have administrative procedures in place that enable it to exclude an individual or entity for any reason for which the Secretary could exclude such individual or entity under parts 1001 or 1003 of this chapter. The period of such exclusion is at the discretion of the State agency.

§ 1002.211 Effect of exclusion.

(a) *Denial of payment*. Except as provided for in § 1001.1901(c)(3), (c)(4) and (c)(5)(i) of this chapter, no payment may be made by the State agency for any item or service furnished on or after the effective date specified in the notice by an excluded individual or entity, or at the medical direction or on the prescription of a physician who is excluded when a person furnishing such item or service knew, or had reason to know, of the exclusion.

(b) *Denial of FFP*. FFP is not available where the State agency is required to deny payment under paragraph (a) of this section. FFP will be reinstated at such time as the excluded individual or entity is reinstated in the Medicaid program.

[57 FR 3343, Jan. 29, 1992, as amended at 63 FR 46691, Sept. 2, 1998]

§ 1002.212 State agency notifications.

When the State agency initiates an exclusion under § 1002.210, it must provide to the individual or entity subject to the exclusion notification consistent with that required in subpart E of part 1001 of this chapter, and must notify other State agencies, the State medical licensing board (where applicable), the public, beneficiaries, and others as provided in §§ 1001.2005 and 1001.2006 of this chapter.

§ 1002.213 Appeals of exclusions.

Before imposing an exclusion under § 1002.210, the State agency must give the individual or entity the opportunity to submit documents and written argument against the exclusion. The individual or entity must also be given any additional appeals rights that would otherwise be available

under procedures established by the State.

§ 1002.214 Basis for reinstatement after State agency-initiated exclusion.

(a) The provisions of this section and § 1002.215 apply to the reinstatement in the Medicaid program of all individuals or entities excluded in accordance with § 1002.210, if a State affords reinstatement opportunity to those excluded parties.

(b) An individual or entity who has been excluded from Medicaid may be reinstated only by the Medicaid agency that imposed the exclusion.

(c) An individual or entity may submit to the State agency a request for reinstatement at any time after the date specified in the notice of exclusion.

§ 1002.215 Action on request for reinstatement.

(a) The State agency may grant reinstatement only if it is reasonably certain that the types of actions that formed the basis for the original exclusion have not recurred and will not recur. In making this determination, the agency will consider, in addition to any factors set forth in State law—

(1) The conduct of the individual or entity occurring prior to the date of the notice of exclusion, if not known to the agency at the time of the exclusion;

(2) The conduct of the individual or entity after the date of the notice of exclusion; and

(3) Whether all fines, and all debts due and owing (including overpayments) to any Federal, State or local government that relate to Medicare or any of the State health care programs, have been paid, or satisfactory arrangements have been made, that fulfill these obligations.

(b) Notice of action on request for reinstatement. (1) If the State agency approves the request for reinstatement, it must give written notice to the excluded party, and to all others who were informed of the exclusion in accordance with § 1002.212, specifying the date on which Medicaid program participation may resume.

(2) If the State agency does not approve the request for reinstatement, it will notify the excluded party of its decision. Any appeal of a denial of reinstatement will be in accordance with State procedures and need not be subject to administrative or judicial review, unless required by State law.

Subpart D—Notification to OIG of State or Local Convictions of Crimes Against Medicaid

§ 1002.230 Notification of State or local convictions of crimes against Medicaid.

(a) The State agency must notify the OIG whenever a State or local court has convicted an individual who is receiving reimbursement under Medicaid of a criminal offense related to participation in the delivery of health care items or services under the Medicaid program, except where the State Medicaid Fraud Control Unit (MFCU) has so notified the OIG.

(b) If the State agency was involved in the investigation or prosecution of the case, it must send notice within 15 days after the conviction.

(c) If the State agency was not so involved, it must give notice within 15 days after it learns of the conviction.

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

Sec.

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AUTHORITY: 42 U.S.C. 262a, 1302, 1320–7, 1320a–7a, 1320b–10, 1395u(j), 1395u(k), 1395cc(j), 1395w–141(i)(3), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c), and 11137(b)(2).

SOURCE: 51 FR 34777, Sept. 30, 1986, unless otherwise noted.

§ 1003.100 Basis and purpose.

(a)*Basis*. This part implements sections 1128(c), 1128A, 1140, 1860D–31(i)(3), 1876(i)(6), 1877(g), 1882(d) and 1903(m)(5) of the Social Security Act; sections 421(c) and 427(b)(2) of Pub. L. 99–660; and section 201(i) of Pub. L. 107–188 (42 U.S.C. 1320–7(c), 1320a–7a, 1320b–10, 1395w–141(i)(3), 1395dd(d)(1), 1395mm, 1395ss(d), 1396b(m), 11131(c), 11137(b)(2) and 262).

(b) *Purpose*. This part—

(1) Provides for the imposition of civil money penalties and, as applicable, assessments against persons who—

(i) Have knowingly submitted certain prohibited claims under Federal health care programs;

(ii) Seek payment in violation of the terms of an agreement or a limitation on charges or payments under the Medicare program, or a requirement not to charge in excess of the amount permitted under the Medicaid program;

(iii) Give false or misleading information that might affect the decision to discharge a Medicare patient from the hospital;

(iv)(A) Fail to report information concerning medical malpractice payments or who improperly disclose, use or permit access to information reported under part B of title IV of Public Law 99–660, and regulations specified in 45 CFR part 60, or

(B) Are health plans and fail to report information concerning sanctions or other adverse actions imposed on providers as required to be reported to the Healthcare Integrity and Protection Data Bank (HIPDB) in accordance with section 1128E of the Act;

(v) Misuse certain Departmental and Medicare and Medicaid program words, letters symbols or emblems;

(vi) Violate a requirement of section 1867 of the Act or § 489.24 of this title;

(vii) Substantially fail to provide an enrollee with required medically necessary items and services; engage in certain marketing, enrollment, reporting, claims payment, employment or contracting abuses; or do not meet the requirements for physician incentive plans for Medicare specified in §§ 417.479(d) through (f) of this title;

(viii) Present or cause to be presented a bill or claim for designated health services (as defined in § 411.351 of this title) that they know, or should know, were furnished in accordance with a referral prohibited under § 411.353 of this title;

(ix) Have collected amounts that they know or should know were billed in violation of § 411.353 of this title and have not refunded the amounts collected on a timely basis;

(x) Are physicians or entities that enter into an arrangement or scheme that they know or should know has as a principal purpose the assuring of referrals by the physician to a particular entity which, if made directly, would violate the provisions of § 411.353 of this title;

(xi) Are excluded, and who retain an ownership or control interest of five percent or more in an entity participating in Medicare or a State health care program, or who are officers or managing employees of such an entity (as defined in section 1126(b) of the Act);

(xii) Offer inducements that they know or should know are likely to influence Medicare or State health care program beneficiaries to order or receive particular items or services;

(xiii) Are physicians who knowingly misrepresent that a Medicare beneficiary requires home health services;

(xiv) Have submitted, or caused to be submitted, certain prohibited claims, including claims for services rendered by excluded individuals employed by or otherwise under contract with such person, under one or more Federal health care programs;

(xv) Violate the Federal health care programs' anti-kickback statute as set forth in section 1128B of the Act;

(xvi) Violate the provisions of part 73 of this title, implementing section 351A(b) and (c) of the Public Health

Service Act, with respect to the possession and use within the United States, receipt from outside the United States, and transfer within the United States, of select agents and toxins in use, or transfer of listed biological agents and toxins; or

(xvii) Violate the provisions of part 403, subpart H of this title, implementing the Medicare prescription drug discount card and transitional assistance program, by misleading or defrauding program beneficiaries, by overcharging a discount program enrollee, or by misusing transitional assistance funds.

(2) Provides for the exclusion of persons from the Medicare or State health care programs against whom a civil money penalty or assessment has been imposed, and the basis for reinstatement of persons who have been excluded; and

(3) Sets forth the appeal rights of persons subject to a penalty, assessment and exclusion.

[65 FR 24414, Apr. 26, 2000, as amended at 67 FR 11935, Mar. 18, 2002; 67 FR 76905, Dec. 13, 2002; 69 FR 28845, May 19, 2004]

§ 1003.101 Definitions.

For purposes of this part:

Act means the Social Security Act.

Adverse effect means medical care has not been provided and the failure to provide such necessary medical care has presented an imminent danger to the health, safety, or well-being of the patient or has placed the patient unnecessarily in a high-risk situation.

ALJ means an Administrative Law Judge.

Assessment means the amount described in § 1003.104, and includes the plural of that term.

Claim means an application for payment for an item or service to a Federal health care program (as defined in section 1128B(f) of the Act).

CMS stands for Centers for Medicare & Medicaid Services, formerly the Health Care Financing Administration (HCFA).

Contracting organization means a public or private entity, including of a health maintenance organization (HMO), competitive medical plan, or health insuring organization (HIO) which meets the requirements of section 1876(b) of the Act or is subject to the requirements in section 1903(m)(2)(A) of the Act and which has contracted with the Department or a State to furnish services to Medicare beneficiaries or Medicaid recipients.

Department means the Department of Health and Human Services.

Enrollee means an individual who is eligible for Medicare or Medicaid and who enters into an agreement to receive services from a contracting organization that contracts with the Department under title XVIII or title XIX of the Act.

Exclusion means the temporary or permanent barring of a person from participation in a Federal health care program (as defined in section 1128B(f) of the Act).

Inspector General means the Inspector General of the Department or his or her designees.

Item or service includes—

(a) Any item, device, medical supply or service provided to a patient (i) which is listed in an itemized claim for program payment or a request for payment, or (ii) for which payment is included in other Federal or State health care reimbursement methods, such as a prospective payment system; and

(b) In the case of a claim based on costs, any entry or omission in a cost report, books of account or other documents supporting the claim.

Maternal and Child Health Services Block Grant program means the program authorized under Title V of the Act.

Medicaid means the program of grants to the States for medical assistance authorized under title XIX of the Act.

Medical malpractice claim or action means a written complaint or claim demanding payment based on a physician's, dentist's or other health care practitioner's provision of, or failure to provide health care services, and includes the filing of a cause of action based on the law of tort brought in any State or Federal court or other adjudicative body.

Medicare means the program of health insurance for the aged and disabled authorized under Title XVIII of the Act.

Participating hospital means (1) a hospital or (2) a rural primary care hospital as defined in section 1861(mm)(1) of the Act that has entered into a Medicare provider agreement under section 1866 of the Act.

Penalty means the amount described in §1003.103 and includes the plural of that term.

Person means an individual, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Physician incentive plan means any compensation arrangement between a contracting organization and a physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to enrollees in the organization.

Preventive care, for purposes of the definition of the term Remuneration as set forth in this section and the preventive care exception to section 231(h) of HIPAA, means any service that—

(1) Is a prenatal service or a postnatal well-baby visit or is a specific clinical service described in the current U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services*, and

(2) Is reimbursable in whole or in part by Medicare or an applicable State health care program.

Remuneration, as set forth in §1003.102(b)(13) of this part, is consistent with the definition contained in section 1128A(i)(6) of the Act, and includes the waiver of coinsurance and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. The term ''remuneration'' does not include—

(1) The waiver of coinsurance and deductible amounts by a person, if the waiver is not offered as part of any advertisement or solicitation; the person does not routinely waive coinsurance or deductible amounts; and the person waives coinsurance and deductible amounts after determining in good faith that the individual is in financial need or failure by the person to collect coinsurance or deductible amounts after making reasonable collection efforts;

(2) Any permissible practice as specified in section 1128B(b)(3) of the Act or in regulations issued by the Secretary;

(3) Differentials in coinsurance and deductible amounts as part of a benefit plan design (as long as the differentials have been disclosed in writing to all beneficiaries, third party payers and providers), to whom claims are presented; or

(4) Incentives given to individuals to promote the delivery of preventive care services where the delivery of such services is not tied (directly or indirectly) to the provision of other services reimbursed in whole or in part by Medicare or an applicable State health care program. Such incentives may include the provision of preventive care, but may not include—

(i) Cash or instruments convertible to cash; or

(ii) An incentive the value of which is disproportionally large in relationship to the value of the preventive care service (*i.e.*, either the value of the service itself or the future health care costs reasonably expected to be avoided as a result of the preventive care).

Request for payment means an application submitted by a person to any person for payment for an item or service.

Respondent means the person upon whom the Department has imposed, or proposes to impose, a penalty, assessment or exclusion.

Responsible physician means a physician who is responsible for the examination, treatment, or transfer of an individual who comes to a participating hospital's emergency department seeking assistance and includes a physician on call for the care of such individual.

Secretary means the Secretary of the Department or his or her designees.

Select agents and toxins means agents and toxins that are listed by the HHS Secretary as having the potential to pose a severe threat to public health and safety, in accordance with section 351A(a)(1) of the Public Health Service Act.

Should know or *should have known* means that a person, with respect to information—

(1) Acts in deliberate ignorance of the truth or falsity of the information; or

(2) Acts in reckless disregard of the truth or falsity of the information. For purposes of this definition, no proof of specific intent to defraud is required.

Social Services Block Grant program means the program authorized under title XX of the Social Security Act.

State includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

State health care program means a State plan approved under title XIX of the Act, any program receiving funds under title V of the Act or from an allotment to a State under such title, or any program receiving funds under title XX of the Act or from an allotment to a State under such title.

Timely basis means, in accordance with §1003.102(b)(9) of this part, the 60-day period from the time the prohibited amounts are collected by the individual or the entity.

Transitional assistance means the subsidy funds that Medicare beneficiaries enrolled in the prescription drug discount card and transitional assistance program may apply toward the cost of covered discount card drugs in the manner described in §403.808(d) of this title.

[51 FR 34777, Sept. 30, 1986, as amended at 56 FR 28492, June 21, 1991; 57 FR 3345, Jan. 29, 1992; 59 FR 32124, June 22, 1994; 59 FR 36086, July 15, 1994; 60 FR 16584, Mar. 31, 1995; 61 FR 13449, Mar. 27, 1996; 65 FR 24415, Apr. 26, 2000; 65 FR 35584, June 5, 2000; 66 FR 39452, July 31, 2001; 67 FR 11935, Mar. 18, 2002; 67 FR 76905, Dec. 13, 2002; 69 FR 28845, May 19, 2004]

§1003.102 Basis for civil money penalties and assessments.

(a) The OIG may impose a penalty and assessment against any person whom it determines in accordance with this part has knowingly presented, or caused to be presented, a claim which is for—

(1) An item or service that the person knew, or should have known, was not provided as claimed, including a claim that is part of a pattern or practice of claims based on codes that the person knows or should know will result in greater payment to the person than the code applicable to the item or service actually provided;

(2) An item or service for which the person knew, or should have known, that the claim was false or fraudulent, including a claim for any item or service furnished by an excluded individual employed by or otherwise under contract with that person;

(3) An item or service furnished during a period in which the person was excluded from participation in the Federal health care program to which the claim was made;

(4) A physician's services (or an item or service) for which the person knew, or should have known, that the individual who furnished (or supervised the furnishing of) the service—

(i) Was not licensed as a physician;

(ii) Was licensed as a physician, but such license had been obtained through a misrepresentation of material fact (including cheating on an examination required for licensing); or

(iii) Represented to the patient at the time the service was furnished that the physician was certified in a medical specialty board when he or she was not so certified;

(5) A payment that such person knows, or should know, may not be made under §411.353 of this title; or

(6) An item or service that a person knows or should know is medically unnecessary, and which is part of a pattern of such claims.

(b) The OIG may impose a penalty, and where authorized, an assessment against any person (including an insurance company in the case of paragraphs (b)(5) and (b)(6) of this section) whom it determines in accordance with this part—

(1) Has knowingly presented or caused to be presented a request for payment in violation of the terms of—

(i) An agreement to accept payments on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act;

(ii) An agreement with a State agency or other requirement of a State Medicaid plan not to charge a person for an item or service in excess of the amount permitted to be charged;

(iii) An agreement to be a participating physician or supplier under section 1842(h)(1); or

(iv) An agreement in accordance with section 1866(a)(1)(G) of the Act not to

charge any person for inpatient hospital services for which payment had been denied or reduced under section 1886(f)(2) of the Act.

(2)–(3) [Reserved]

(4) Has knowingly given or caused to be given to any person, in the case of inpatient hospital services subject to the provisions of section 1886 of the Act, information that he or she knew, or should have known, was false or misleading and that could reasonably have been expected to influence the decision when to discharge such person or another person from the hospital.

(5) Fails to report information concerning—

(i) A payment made under an insurance policy, self-insurance or otherwise, for the benefit of a physician, dentist or other health care practitioner in settlement of, or in satisfaction in whole or in part of, a medical malpractice claim or action or a judgment against such a physician, dentist or other practitioner in accordance with section 421 of Public Law 99–660 (42 U.S.C. 11131) and as required by regulations at 45 CFR part 60; or

(ii) An adverse action required to be reported to the Healthcare Integrity and Protection Data Bank as established by section 221 of Public Law 104–191 and set forth in section 1128E of the Act.

(6) Improperly discloses, uses or permits access to information reported in accordance with part B of title IV of Pub. L. 99–660, in violation of section 427 of Pub. L. 99–660 (42 U.S.C. 11137) or regulations at 45 CFR part 60. (The disclosure of information reported in accordance with part B of title IV in response to a subpoena or a discovery request is considered to be an improper disclosure in violation of section 427 of Pub. L. 99–660. However, disclosure or release by an entity of original documents or underlying records from which the reported information is obtained or derived is not considered to be an improper disclosure in violation of section 427 of Pub. L. 99–660.)

(7) Has made use of the words, letters, symbols or emblems as defined in paragraph (b)(7)(i) of this section in such a manner that such person knew or should have known would convey, or in a manner which reasonably could be interpreted or construed as conveying, the false impression that an advertisement, solicitation or other item was authorized, approved or endorsed by the Department or CMS, or that such person or organization has some connection with or authorization from the Department or CMS. Civil money penalties—

(i) May be imposed, regardless of the use of a disclaimer of affiliation with the United States Government, the Department or its programs, for misuse of—

(A) The words ''Department of Health and Human Services,'' ''Health and Human Services,'' ''Centers for Medicare & Medicaid Services,'' ''Medicare,'' or ''Medicaid,'' or any other combination or variation of such words;

(B) The letters ''DHHS,'' ''HHS,'' or ''CMS,'' or any other combination or variation of such letters; or

(C) A symbol or emblem of the Department or CMS (including the design of, or a reasonable facsimile of the design of, the Medicare card, the check used for payment of benefits under title II, or envelopes or other stationery used by the Department or CMS) or any other combination or variation of such symbols or emblems; and

(ii) Will not be imposed against any agency or instrumentality of a State, or political subdivision of the State, that makes use of any symbol or emblem, or any words or letters which specifically identifies that agency or instrumentality of the State or political subdivision.

(8) Is a contracting organization that CMS determines has committed an act or failed to comply with the requirements set forth in §417.500(a) or §434.67(a) of this title or failed to comply with the requirement set forth in §434.80(c) of this title.

(9) Has not refunded on a timely basis, as defined in §1003.101 of this part, amounts collected as the result of billing an individual, third party payer or other entity for a designated health service that was provided in accordance with a prohibited referral as described in §411.353 of this title.

(10) Is a physician or entity that enters into—

(i) A cross referral arrangement, for example, whereby the physician owners of entity ''X'' refer to entity ''Y,'' and the physician owners of entity ''Y'' refer to entity ''X'' in violation of § 411.353 of this title, or

(ii) Any other arrangement or scheme that the physician or entity knows, or should know, has a principal purpose of circumventing the prohibitions of § 411.353 of this title.

(11) Has violated section 1128B of the Act by unlawfully offering, paying, soliciting or receiving remuneration in return for the referral of business paid for by Medicare, Medicaid or other Federal health care programs.

(12) Who is not an organization, agency or other entity, and who is excluded from participating in Medicare or a State health care program in accordance with sections 1128 or 1128A of the Act, and who—

(i) Knows or should know of the action constituting the basis for the exclusion, and retains a direct or indirect ownership or control interest of five percent or more in an entity that participates in Medicare or a State health care program; or

(ii) Is an officer or managing employee (as defined in section 1126(b) of the Act) of such entity.

(13) Offers or transfers remuneration (as defined in § 1003.101 of this part) to any individual eligible for benefits under Medicare or a State health care program, that such person knows or should know is likely to influence such individual to order or to receive from a particular provider, practitioner or supplier any item or service for which payment may be made, in whole or in part, under Medicare or a State health care program.

(14) Is a physician and who executes a document falsely by certifying that a Medicare beneficiary requires home health services when the physician knows that the beneficiary does not meet the eligibility requirements set forth in sections 1814(a)(2)(C) or 1835(a)(2)(A) of the Act.

(15) Has knowingly and willfully presented, or caused to be presented, a bill or request for payment for items and services furnished to a hospital patient for which payment may be made under the Medicare or another Federal health care program, if that bill or request is inconsistent with an arrangement under section 1866(a)(1)(H) of the Act, or violates the requirements for such an arrangement.

(16) Is involved in the possession or use in the United States, receipt from outside the United States, or transfer within the United States, of select agents and toxins in violation of part 73 of this chapter as determined by the HHS Secretary, in accordance with sections 351A(b) and (c) of the Public Health Service Act.

(17) Is an endorsed sponsor under the Medicare prescription drug discount card program who knowingly misrepresented or falsified information in outreach material or comparable material provided to a program enrollee or other person.

(18) Is an endorsed sponsor under the Medicare prescription drug discount card program who knowingly charged a program enrollee in violation of the terms of the endorsement contract.

(19) Is an endorsed sponsor under the Medicare prescription drug discount card program who knowingly used transitional assistance funds of any program enrollee in any manner that is inconsistent with the purpose of the transitional assistance program.

(c)(1) The Office of the Inspector General (OIG) may impose a penalty for violations of section 1867 of the Act or § 489.24 of this title against—

(i) Any participating hospital with an emergency department that—

(A) Knowingly violates the statute on or after August 1, 1986 or;

(B) Negligently violates the statute on or after May 1, 1991; and

(ii) Any responsible physician who—

(A) Knowingly violates the statute on or after August 1, 1986;

(B) Negligently violates the statute on or after May 1, 1991;

(C) Signs a certification under section 1867(c)(1)(A) of the Act if the physician knew or should have known that the benefits of transfer to another facility did not outweigh the risks of such a transfer; or

(D) Misrepresents an individual's condition or other information, including a hospital's obligations under this section.

(2) For purposes of this section, a responsible physician or hospital ''knowingly'' violates section 1867 of the Act if the responsible physician or hospital recklessly disregards, or deliberately ignores a material fact.

(d)(1) In any case in which it is determined that more than one person was responsible for presenting or causing to be presented a claim as described in paragraph (a) of this section, each such person may be held liable for the penalty prescribed by this part, and an assessment may be imposed against any one such person or jointly and severally against two or more such persons, but the aggregate amount of the assessments collected may not exceed the amount that could be assessed if only one person was responsible.

(2) In any case in which it is determined that more than one person was responsible for presenting or causing to be presented a request for payment or for giving false or misleading information as described in paragraph (b) of this section, each such person may be held liable for the penalty prescribed by this part.

(3) In any case in which it is determined that more than one person was responsible for failing to report information that is required to be reported on a medical malpractice payment, or for improperly disclosing, using, or permitting access to information, as described in paragraphs (b)(5) and (b)(6) of this section, each such person may be held liable for the penalty prescribed by this part.

(4) In any case in which it is determined that more than one responsible physician violated the provisions of section 1867 of the Act or of § 489.24 of this title, a penalty may be imposed against each responsible physician.

(5) Under this section, a principal is liable for penalties and assessments for the actions of his or her agent acting within the scope of the agency.

(e) For purposes of this section, the term ''knowingly'' is defined consistent with the definition set forth in the Civil False Claims Act (31 U.S.C. 3729(b)), that is, a person, with respect to information, has actual knowledge of information, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information, and that no proof of specific intent to defraud is required.

[57 FR 3345, Jan. 29, 1992; 57 FR 9670, Mar. 20, 1992, as amended at 59 FR 32124, June 22, 1994; 59 FR 36086, July 15, 1994; 60 FR 16584, Mar. 31, 1995; 60 FR 58241, Nov. 27, 1995; 64 FR 39428, July 22, 1999; 65 FR 18550, Apr. 7, 2000; 65 FR 24415, Apr. 26, 2000; 65 FR 35584, June 5, 2000; 67 FR 76905, Dec. 13, 2002; 69 FR 28845, May 19, 2004]

§ 1003.103 Amount of penalty.

(a) Except as provided in paragraphs (b) through (k) of this section, the OIG may impose a penalty of not more than—

(1) $2,000 for each wrongful act occurring before January 1, 1997 that is subject to a determination under § 1003.102; and

(2) $10,000 for each wrongful act occurring on or after January 1, 1997 that is subject to a determination under § 1003.102.

(b) The OIG may impose a penalty of not more than $15,000 for each person with respect to whom a determination was made that false or misleading information was given under § 1003.102(b)(4), or for each item and service that is subject to a determination under § 1003.102(a)(5) or § 1003.102(b)(9) of this part. The OIG may impose a penalty of not more than $100,000 for each arrangement or scheme that is subject to a determination under § 1003.102(b)(10) of this part.

(c) The OIG may impose a penalty of not more than $11,000[1] for each payment for which there was a failure to report required information in accordance with § 1003.102(b)(5), or for each improper disclosure, use or access to information that is subject to a determination under § 1003.102(b)(6).

(d)(1) The OIG may impose a penalty of not more than $5,000 for each violation resulting from the misuse of Departmental, CMS, Medicare or Medicaid program words, letters, symbols or emblems as described in § 1003.102(b)(7) relating to printed media, and a penalty of not more than

[1] As adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104–134).

$25,000 in the case of such misuse related to a broadcast or telecast, that is related to a determination under § 1003.102(b)(7).

(2) For purposes of this paragraph, a violation is defined as—

(i) In the case of a direct mailing solicitation or advertisement, each separate piece of mail which contains one or more words, letters, symbols or emblems related to a determination under § 1003.102(b)(7);

(ii) In the case of a printed solicitation or advertisement, each reproduction, reprinting or distribution of such item related to a determination under § 1003.102(b)(7); and

(iii) In the case of a broadcast or telecast, each airing of a single commercial or solicitation related to a determination under § 1003.102(b)(7).

(e) For violations of section 1867 of the Act or § 489.24 of this title, the OIG may impose—

(1) Against each participating hospital with an emergency department, a penalty of not more than $50,000 for each negligent violation occurring on or after May 1, 1991, except that if the participating hospital has fewer than 100 State-licensed, Medicare-certified beds on the date the penalty is imposed, the penalty will not exceed $25,000; and

(2) Against each responsible physician, a penalty of not more than $50,000 for each negligent violation occurring on or after May 1, 1991.

(f)(1) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $25,000 for each determination by CMS that a contracting organization has—

(i) Failed substantially to provide an enrollee with required medically necessary items and services and the failure adversely affects (or has the likelihood of adversely affecting) the enrollee;

(ii) Imposed premiums on enrollees in excess of amounts permitted under section 1876 or title XIX of the Act;

(iii) Acted to expel or to refuse to reenroll a Medicare beneficiary in violation of the provisions of section 1876 of the Act and for reasons other than the beneficiary's health status or requirements for health care services;

(iv) Misrepresented or falsified information furnished to an individual or any other entity under section 1876 or section 1903(m) of the Act;

(v) Failed to comply with the requirements of section 1876(g)(6)(A) of the Act, regarding prompt payment of claims; or

(vi) Failed to comply with the requirements of §§ 417.479 (d) through (i) of this title for Medicare, and §§ 417.479 (d) through (g) and (i) of this title for Medicaid, regarding certain prohibited incentive payments to physicians.

(2) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $25,000 for each determination by CMS that a contracting organization with a contract under section 1876 of the Act—

(i) Employs or contracts with individuals or entities excluded, under section 1128 or section 1128A of the Act, from participation in Medicare for the provision of health care, utilization review, medical social work, or administrative services; or

(ii) Employs or contracts with any entity for the provision of services (directly or indirectly) through an excluded individual or entity.

(3) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $100,000 for each determination that a contracting organization has—

(i) Misrepresented or falsified information to the Secretary under section 1876 of the Act or to the State under section 1903(m) of the Act; or

(ii) Acted to expel or to refuse to reenroll a Medicaid recipient because of the individual's health status or requirements for health care services, or engaged in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by section 1876 or section 1903(m) of the Act) with the contracting organization by Medicare beneficiaries and Medicaid recipients whose medical condition or history indicates a need for substantial future medical services.

(4) If enrolles are charged more than the allowable premium, the OIG will impose an additional penalty equal to double the amount of excess premium

charged by the contracting organization. The excess premium amount will be deducted from the penalty and returned to the enrollee.

(5) The OIG will impose an additional $15,000 penalty for each individual not enrolled when CMS determines that a contracting organization has committed a violation described in paragraph (f)(3)(ii) of this section.

(6) For purposes of paragraph (f) of this section, a violation is each incident where a person has committed an act listed in § 417.500(a) or § 434.67(a) of this title, or failed to comply with a requirement set forth in § 434.80(c) of this title.

(g) The OIG may impose a penalty of not more than $25,000 against a health plan for failing to report information on an adverse action required to be reported to the Healthcare Integrity and Protection Data Bank in accordance with section 1128E of the Act and § 1003.102(b)(5)(ii).

(h) For each violation of § 1003.102(b)(11), the OIG may impose—

(1) A penalty of not more than $50,000, and

(2) An assessment of up to three times the total amount of remuneration offered, paid, solicited or received, as specified in § 1003.104(b).

(i) For violations of § 1003.102(b)(14) of this part, the OIG may impose a penalty of not more than the greater of—

(1) $5,000, or

(2) Three times the amount of Medicare payments for home health services that are made with regard to the false certification of eligibility by a physician in accordance with sections 1814(a)(2)(C) or 1835(a)(2)(A) of the Act.

(j) The OIG may impose a penalty of not more than $10,000 per day for each day that the prohibited relationship described in § 1001.102(b)(12) of this part occurs.

(k) For violations of section 1862(a)(14) of the Act and § 1003.102(b)(15), the OIG may impose a penalty of not more than $2,000 for each bill or request for payment for items and services furnished to a hospital patient.

(l) For violations of section 351A(b) or (c) of the Public Health Service Act and 42 CFR part 73, the OIG may impose a penalty of not more than $250,000 in the case of an individual, and not more than $500,000 in the case of any other person.

(m) For violations of section 1860D–31 of the Act and 42 CFR part 403, subpart H, regarding the misleading or defrauding of program beneficiaries, or the misuse of transitional assistance funds, the OIG may impose a penalty of not more than $10,000 for each individual violation.

[57 FR 3346, Jan. 29, 1992, as amended at 59 FR 32125, June 22, 1994; 59 FR 48566, Sept. 22, 1994; 60 FR 16584, Mar. 31, 1995; 60 FR 58241, Nov. 27, 1995; 61 FR 13449, Mar. 27, 1996; 61 FR 52301, Oct. 7, 1996; 64 FR 39429, July 22, 1999; 65 FR 18550, Apr. 7, 2000; 65 FR 24416, Apr. 26, 2000; 65 FR 35584, June 5, 2000; 67 FR 76905, Dec. 13, 2002; 69 FR 28845, May 19, 2004]

§ 1003.104 Amount of assessment.

(a) The OIG may impose an assessment, where authorized, in accordance with § 1003.102, of not more than—

(1) Two times the amount for each item or service wrongfully claimed prior to January 1, 1997; and

(2) Three times the amount for each item or service wrongfully claimed on or after January 1, 1997.

(b) The assessment is in lieu of damages sustained by the Department or a State agency because of that claim.

[65 FR 24416, Apr. 26, 2000]

§ 1003.105 Exclusion from participation in Medicare, Medicaid and all Federal health care programs.

(a)(1) Except as set forth in paragraph (b) of this section, the following persons may be subject, in lieu of or in addition to any penalty or assessment, to an exclusion from participation in Medicare for a period of time determined under § 1003.107. There will be exclusions from Federal health care programs for the same period as the Medicare exclusion for any person who—

(i) Is subject to a penalty or assessment under § 1003.102(a), (b)(1), (b)(4), (b)(12), (b)(13) or (b)(15); or

(ii) Commits a gross and flagrant, or repeated, violation of section 1867 of the Act or § 489.24 of this title on or after May 1, 1991. For purposes of this section, a gross and flagrant violation is one that presents an imminent danger to the health, safety or well-being of the individual who seeks emergency

examination and treatment or places that individual unnecessarily in a high-risk situation.

(b)(1)(i) With respect to any exclusion based on liability for a penalty or assessment under § 1003.102 (a), (b)(1), or (b)(4), the OIG will consider an application from a State agency for a waiver if the person is the sole community physician or the sole source of essential specialized services in a community. With respect to any exclusion imposed under § 1003.105(a)(1)(ii), the OIG will consider an application from a State agency for a waiver if the physician's exclusion from the State health care program would deny beneficiaries access to medical care or would otherwise cause hardship to beneficiaries.

(ii) If a waiver is granted, it is applicable only to the State health care program for which the State requested the waiver.

(iii) If the OIG subsequently obtains information that the basis for a waiver no longer exists, or the State agency submits evidence that the basis for the waiver no longer exists, the waiver will cease and the person will be excluded from the State health care program for the remainder of the period that the person is excluded from Medicare.

(iv) The OIG notifies the State agency whether its request for a waiver has been granted or denied.

(v) The decision to deny a waiver is not subject to administrative or judicial review.

(2) For purposes of this section, the definitions contained in § 1001.2 of this chapter for ''sole community physician'' and ''sole source of essential specialized services in a community'' apply.

(c) When the Inspector General proposes to exclude a nursing facility from the Medicare and Medicaid programs, he or she will, at the same time he or she notifies the respondent, notify the appropriate State licensing authority, the State Office of Aging, the long-term care ombudsman, and the State Medicaid agency of the Inspector General's intention to exclude the facility.

[59 FR 32125, June 22, 1994, as amended at 64 FR 39429, July 22, 1999; 65 FR 24416, Apr. 26, 2000; 65 FR 35584, June 5, 2000]

§ 1003.106 Determinations regarding the amount of the penalty and assessment.

(a) *Amount of penalty.* (1) In determining the amount of any penalty or assessment in accordance with § 1003.102(a), (b)(1), (b)(4), and (b)(9) through (b)(16) of this part, the Department will take into account—

(i) The nature of the claim, referral arrangement or other wrongdoing;

(ii) The degree of culpability of the person against whom a civil money penalty is proposed;

(iii) The history of prior offenses of the person against whom a civil money penalty is proposed;

(iv) The financial condition of the person against whom a civil money penalty is proposed;

(v) The completeness and timeliness of the refund with respect to § 1003.102(b)(9);

(vi) The amount of financial interest involved with respect to § 1003.102(b)(12);

(vii) The amount of remuneration offered or transferred with respect to § 1003.102(b)(13); and

(viii) Such other matters as justice may require.

(2) In determining the amount of any penalty in accordance with §§ 1003.102 (b)(5) and (b)(6), the Department will take into account—

(i) The nature and circumstances of the failure to properly report information, or the improper disclosure of information, as required;

(ii) The degree of culpability of the person in failing to provide timely and complete data or in improperly disclosing, using or permitting access to information, as appropriate;

(iii) The materiality, or significance of omission, of the information to be reported, or the materiality of the improper disclosure of, or use of, or access to information, as appropriate;

(iv) Any prior history of the person with respect to violations of these provisions; and

(v) Such other matters as justice may require.

(3)(i) In determining the amount of any penalty in accordance with § 1003.102(b)(7), the OIG will take into account—

(A) The nature and objective of the advertisement, solicitation or other communication, and the degree to which it has the capacity to deceive members of the public;

(B) The degree of culpability of the individual, organization or entity in the use of the prohibited words, letters, symbols or emblems;

(C) The frequency and scope of the violation, and whether a specific segment of the population was targeted;

(D) The prior history of the individual, organization or entity in its willingness or refusal to comply with informal requests to correct violations;

(E) The history of prior offenses of the individual, organization or entity in its misuse of Departmental and program words, letters, symbols and emblems;

(F) The financial condition of the individual, organization or entity involved with the violation; and

(G) Such other matters as justice may require.

(ii) The use of a disclaimer of affiliation with the United States Government, the Department or its programs will not be considered as a mitigating factor in determining the amount of penalty in accordance with § 1003.102(b)(7).

(4) In determining the amount of any penalty in accordance with § 1003.102(c), the OIG takes into account—

(i) The degree of culpability of the respondent;

(ii) The seriousness of the condition of the individual seeking emergency medical treatment;

(iii) Any other instances where the respondent failed to provide appropriate emergency medical screening, stabilization and treatment of individuals coming to a hospital's emergency department or to effect an appropriate transfer;

(iv) The respondent's financial condition;

(v) The nature and circumstances of the violation; and

(vi) Such other matters as justice may require.

(5) In determining the appropriate amount of any penalty in accordance with § 1003.103(f), the OIG will consider as appropriate—

(i) The nature and scope of the required medically necessary item or service not provided and the circumstances under which it was not provided;

(ii) The degree of culpability of the contracting organization;

(iii) The seriousness of the adverse effect that resulted or could have resulted from the failure to provide required medically necessary care;

(iv) The harm which resulted or could have resulted from the provision of care by a person that the contracting organization is expressly prohibited, under section 1876(i)(6) or section 1903(p)(2) of the Act, from contracting with or employing;

(v) The harm which resulted or could have resulted from the contracting organization's expulsion or refusal to reenroll a Medicare beneficiary or Medicaid recipient;

(vi) The nature of the misrepresentation or fallacious information furnished by the contracting organization to the Secretary, State, enrollee or other entity under section 1876 or section 1903(m) of the Act;

(vii) The extent to which the failure to provide medically necessary services could be attributed to a prohibited inducement to reduce or limit services under a physician incentive plan and the harm to the enrollee which resulted or could have resulted from such failure. It would be considered an aggravating factor if the contracting organization knowingly or routinely engaged in any prohibited practice which acted as an inducement to reduce or limit medically necessary services provided with respect to a specific enrollee in the organization;

(viii) The history of prior offenses by the contracting organization or principals of the contracting organization, including whether, at any time prior to determination of the current violation or violations, the contracting organization or any of its principals were convicted of a criminal charge or were held liable for civil or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for medical services; and

(ix) Such other matters as justice may require.

(b) *Determining the amount of the penalty or assessment.* As guidelines for taking into account the factors listed in paragraph (a)(1) of this section, the following circumstances are to be considered—

(1) *Nature and circumstances of the incident.* It should be considered a mitigating circumstance if all the items or services or incidents subject to a determination under §1003.102 included in the action brought under this part were of the same type and occurred within a short period of time, there were few such items or services or incidents, and the total amount claimed or requested for such items or services was less than $1,000. It should be considered an aggravating circumstance if—

(i) Such items or services or incidents were of several types, occurred over a lengthy period of time;

(ii) There were many such items or services or incidents (or the nature and circumstances indicate a pattern of claims or requests for payment for such items or services or a pattern of incidents);

(iii) The amount claimed or requested for such items or services was substantial; or

(iv) The false or misleading information given resulted in harm to the patient, a premature discharge or a need for additional services or subsequent hospital admission.

(2) Degree of culpability. It should be considered a mitigating circumstance if corrective steps were taken promptly after the error was discovered. It should be considered an aggravating circumstance if—

(i) The respondent knew the item or service was not provided as claimed or if the respondent knew that the claim was false or fraudulent;

(ii) The respondent knew that the items or services were furnished during a period that he or she had been excluded from participation and that no payment could be made as specified in §§1003.102(a)(3) and 1003.102(b)(12), or because payment would violate the terms of an assignment or an agreement with a State agency or other agreement or limitation on payment under §1003.102(b);

(iii) The respondent knew that the information could reasonably be expected to influence the decision of when to discharge a patient from a hospital; or

(iv) The respondent knew that the offer or transfer of remuneration described in §1003.102(b)(13) of this part would influence a beneficiary to order or receive from a particular provider, practitioner or supplier items or services reimbursable under Medicare or a State health care program.

(3) *Prior offenses.* It should be considered an aggravating circumstance if at any time prior to the incident or presentation of any claim or request for payment which included an item or service subject to a determination under §1003.102, the respondent was held liable for criminal, civil or administrative sanctions in connection with a program covered by this part or any other public or private program of reimbursement for medical services.

(4) *Other wrongful conduct.* It should be considered an aggravating circumstance if there is proof that a respondent engaged in wrongful conduct, other than the specific conduct upon which liability is based, relating to government programs or in connection with the delivery of a health care item or service. The statute of limitations governing civil money penalty proceedings will not apply to proof of other wrongful conduct as an aggravating circumstance.

(5) *Financial condition.* In all cases, the resources available to the respondent will be considered when determining the amount of the penalty and assessment.

(6) *Other matters as justice may require.* Other circumstances of an aggravating or mitigating nature should be taken into account if, in the interests of justice, they require either a reduction of the penalty or assessment or an increase in order to assure the achievement of the purposes of this part.

(c) In determining the amount of the penalty and assessment to be imposed for every item or service or incident subject to a determination under §§1003.102(a), (b)(1) and (b)(4)—

(1) If there are substantial or several mitigating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently below the maximium permitted by §§1003.103(a) and 1003.104, to reflect that fact.

(2) If there are substantial or several aggravating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently close or at the maximum permitted by §§1003.103(a) and 1003.104, to reflect that fact.

(3) Unless there are extraordinary mitigating circumstances, the aggregate amount of the penalty and assessment should never be less than double the approximate amount of damages and costs (as defined in paragraph (f) of this section) sustained by the United States, or any State, as a result of claims or incidents subject to a determination under §§1003.102(a), (b)(1) and (b)(4).

(d) In considering the factors listed in paragraph (a)(4) of this section for violations subject to a determination under §1003.103(e), the following circumstances are to be considered, as appropriate, in determining the amount of any penalty—

(1) *Degree of culpability*. It would be a mitigating circumstance if the respondent hospital had appropriate policies and procedures in place, and had effectively trained all of its personnel in the requirements of section 1867 of the Act and §489.24 of this title, but an employee or responsible physician acted contrary to the respondent hospital's policies and procedures.

(2) *Seriousness of individual's condition*. It would be an aggravating circumstance if the respondent's violation(s) occurred with regard to an individual who presented to the hospital a request for treatment of a medical condition that was clearly an emergency, as defined by §489.24(b) of this title.

(3) *Prior offenses*. It would be an aggravating circumstance if there is evidence that at any time prior to the current violation(s) the respondent was found to have violated any provision of section 1867 of the Act or §489.24 of this title.

(4) *Financial condition*. In all cases, the resources available to the respondent would be considered when determining the amount of the penalty. A respondent's audited financial statements, tax returns or financial disclosure statements, as appropriate, will be reviewed by OIG in making a determination with respect to the respondent's financial condition.

(5) *Nature and circumstances of the incident*. It would be considered a mitigating circumstance if an individual presented a request for treatment, but subsequently exhibited conduct that demonstrated a clear intent to leave the respondent hospital voluntarily. In reviewing such circumstances, the OIG would evaluate the respondent's efforts to—

(i) Provide the services required by section 1867 of the Act and §489.24 of this title, despite the individual's withdrawal of the request for examination or treatment; and

(ii) Document any attempts to inform the individual (or his or her representative) of the risks of leaving the respondent hospital without receiving an appropriate medical screening examination or treatment, and obtain written acknowledgment from the individual (or his or her representative) prior to the individual's departure from the respondent hospital that he or she is leaving contrary to medical advice.

(6) *Other matters as justice may require*. (i) It would be considered a mitigating circumstance if the respondent hospital—

(A) Developed and implemented a corrective action plan;

(B) Took immediate appropriate action against any hospital personnel or responsible physician who violated section 1867 of the Act or §489.24 of this title prior to any investigation of the respondent hospital by CMS; or

(C) Is a rural or publicly-owned facility that is faced with severe physician staffing and financial deficiencies.

(ii) It would be considered an aggravating circumstance if an individual was severely harmed or died as a result, directly or indirectly, of the respondent's violation of section 1867 of the Act or §489.24 of this title.

(iii) Other circumstances of an aggravating or mitigating nature will be taken into account if, in the interests

of justice, they require either a reduction of the penalty or an increase in order to assure the achievement of the purposes of this part.

(e) In considering the factors listed in paragraph (a)(5) of this section for violations subject to a determination under § 1003.103(f), the following circumstances are to be considered, as appropriate, in determining the amount of any penalty—

(f)(1) The standards set forth in this section are binding, except to the extent that their application would result in imposition of an amount that would exceed limits imposed by the United States Constitution.

(2) The amount imposed will not be less than the approximate amount required to fully compensate the United States, or any State, for its damages and costs, tangible and intangible, including but not limited to the costs attributable to the investigation, prosecution and administrative review of the case.

(3) Nothing in this section will limit the authority of the Department to settle any issue or case as provided by § 1003.126, or to compromise any penalty and assessment as provided by § 1003.128.

[57 FR 3347, Jan. 29, 1992, as amended at 59 FR 32125, June 22, 1994; 59 FR 36086, July 15, 1994; 59 FR 48567, Sept. 22, 1994; 60 FR 16584, Mar. 31, 1995; 60 FR 58241, Nov. 27, 1995; 61 FR 13449, Mar. 27, 1996; 64 FR 39429, July 22, 1999; 65 FR 24416, Apr. 26, 2000; 67 FR 11935, Mar. 18, 2002; 70 FR 13325, Mar. 18, 2005]

§ 1003.107 Determinations regarding exclusion.

(a) In determining whether to exclude a person under this part and the duration of any exclusion, the Department considers the circumstances described in § 1003.106(a).

(b) With respect to determinations to exclude a person under §§ 1003.102(a), (b)(1), (b)(4), (b)(12) or (b)(13) of this part, the Department considers those circumstances described in § 1003.106(b). Where there are aggravating circumstances with respect to such determinations, the person should be excluded.

(c) The guidelines set forth in this section are not binding. Nothing in this section limits the authority of the Department to settle any issue or case as provided by § 1003.126 of this part.

[59 FR 32126, June 22, 1994, as amended at 65 FR 24418, Apr. 26, 2000]

§ 1003.108 Penalty, assessment, and exclusion not exclusive.

Penalties, assessments, and exclusions imposed under this part are in addition to any other penalties prescribed by law.

[59 FR 32126, June 22, 1994]

§ 1003.109 Notice of proposed determination.

(a) If the Inspector General proposes a penalty and, when applicable, assessment, or proposes to exclude a respondent from participation in a Federal health care program, as applicable, in accordance with this part, he or she must deliver or send by certified mail, return receipt requested, to the respondent written notice of his or her intent to impose a penalty, assessment and exclusion, as applicable. The notice includes—

(1) Reference to the statutory basis for the penalty, assessment and exclusion;

(2) A description of the claims, requests for payment, or incidents with respect to which the penalty, assessment and exclusion are proposed (except in cases where the Inspector General is relying upon statistical sampling in accordance with § 1003.133 in which case the notice shall describe those claims and requests for payment comprising the sample upon which the Inspector General is relying and will also briefly describe the statistical sampling technique utilized by the Inspector General);

(3) The reason why such claims, requests for payments or incidents subject the respondent to a penalty, assessment and exclusion;

(4) The amount of the proposed penalty, assessment and the period of proposed exclusion (where applicable);

(5) Any circumstances described in § 1003.106 that were considered when determining the amount of the proposed penalty and assessment and the period of exclusion;

(6) Instructions for responding to the notice, including—

(i) A specific statement of respondent's right to a hearing, and

(ii) A statement that failure to request a hearing within 60 days permits the imposition of the proposed penalty, assessment and exclusion without right of appeal; and

(7) In the case of a notice sent to a respondent who has an agreement under section 1866 of the Act, the notice also indicates that the imposition of an exclusion may result in the termination of the provider's agreement in accordance with section 1866(b)(2)(C) of the Act.

(b) Any person upon whom the Inspector General has proposed the imposition of a penalty, assessment or exclusion may appeal such proposed penalty, assessment or exclusion to the DAB in accordance with § 1005.2 of this chapter. The provisions of part 1005 of this chapter govern such appeals.

(c) If the respondent fails, within the time permitted, to exercise his or her right to a hearing under this section, any exclusion, penalty, or assessment becomes final.

[57 FR 3348, Jan. 29, 1992, as amended at 59 FR 32126, June 22, 1994; 64 FR 39429, July 22, 1999; 65 FR 24418, Apr. 26, 2000]

§ 1003.110 Failure to request a hearing.

If the respondent does not request a hearing within the time prescribed by § 1003.109(a), the Inspector General may impose the proposed penalty, assessment, and exclusion, or any less severe penalty, assessment, and suspension. The Inspector General shall notify the respondent by certified mail, return receipt requested, of any penalty, assessment, and exclusion that has been imposed and of the means by which the respondent may satisfy the judgment. The respondent has no right to appeal a penalty, assessment, and exclusion, with respect to which he or she has not requested a hearing.

[51 FR 34777, Sept. 30, 1986, as amended at 57 FR 3348, Jan. 29, 1992]

§ 1003.114 Collateral estoppel.

(a) Where a final determination pertaining to the respondent's liability under § 1003.102 has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent shall be bound by such determination in any proceeding under this part.

(b) In a proceeding under this part that—

(1) Is against a person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements, and

(2) Involves the same transactions as in the criminal action, the person is estopped from denying the essential elements of the criminal offense.

[57 FR 3348, Jan. 29, 1992, as amended at 64 FR 39429, July 22, 1999]

§ 1003.126 Settlement.

The Inspector General has exclusive authority to settle any issues or case, without consent of the ALJ.

[65 FR 24418, Apr. 26, 2000]

§ 1003.127 Judicial review.

Section 1128A(e) of the Act authorizes judicial review of a penalty, assessment or exclusion that has become final. Judicial review may be sought by a respondent only with respect to a penalty, assessment or exclusion with respect to which the respondent filed an exception under § 1005.21(c) of this chapter unless the failure or neglect to urge such exception will be excused by the court in accordance with section 1128A(e) of the Act because of extraordinary circumstances.

[57 FR 3348, Jan. 29, 1992]

§ 1003.128 Collection of penalty and assessment.

(a) Once a determination by the Secretary has become final, collection of any penalty and assessment will be the responsibility of CMS, except in the case of the Maternal and Child Health Services Block Grant program, where the collection will be the responsibility of the PHS, and in the case of the Social Services Block Grant program, where the collection will be the responsibility of the Office of Human Development Services.

(b) A penalty or assessment imposed under this part may be compromised by the Inspector General, and may be recovered in a civil action brought in the United States district court for the

district where the claim was presented, or where the respondent resides.

(c) The amount of a penalty and assessment when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States, or by a State agency, to the respondent.

(d) Matters that were raised or that could have been raised in a hearing before an ALJ or in an appeal under section 1128A(e) of the Act may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

[51 FR 34777, Sept. 30, 1986, as amended at 57 FR 3349, Jan. 29, 1992; 65 FR 24418, Apr. 26, 2000]

§ 1003.129 Notice to other agencies.

Whenever a penalty, assessment or exclusion become final, the following organizations and entities will be notified about such action and the reasons for it—the appropriate State or local medical or professional association; the appropriate Quality Improvement Organization; as appropriate, the State agency responsible or the administration of each State health care program; the appropriate Medicare carrier or intermediary; the appropriate State or local licensing agency or organization (including the Medicare and Medicaid State survey agencies); and the long-term care ombudsman. In cases involving exclusions, notice will also be given to the public of the exclusion and its effective date.

[57 FR 3349, Jan. 29, 1992]

§ 1003.132 Limitations.

No action under this part will be entertained unless commenced, in accordance with § 1003.109(a) of this part, within 6 years from the date on which the claim was presented, the request for payment was made, or the incident occurred.

[57 FR 3349, Jan. 29, 1992]

§ 1003.133 Statistical sampling.

(a) In meeting the burden of proof set forth in § 1005.15, the Inspector General may introduce the results of a statistical sampling study as evidence of the number and amount of claims and/or requests for payment as described in § 1003.102 that were presented or caused to be presented by respondent. Such a statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, shall constitute prima facie evidence of the number and amount of claims or requests for payment as described in § 1003.102.

(b) Once the Inspector General has made a prima facie case as described in paragraph (a) of this section, the burden of production shall shift to respondent to produce evidence reasonably calculated to rebut the findings of the statistical sampling study. The Inspector General will then be given the opportunity to rebut this evidence.

[51 FR 34777, Sept. 30, 1986, as amended at 57 FR 3349, Jan. 29, 1992]

§ 1003.134 Effect of exclusion.

The effect of an exclusion will be as set forth in § 1001.1901 of this chapter.

[57 FR 3349, Jan. 29, 1992]

§ 1003.135 Reinstatement.

A person who has been excluded in accordance with this part may apply for reinstatement at the end of the period of exclusion. The OIG will consider any request for reinstatement in accordance with the provisions of §§ 1001.3001 through 1001.3004 of this chapter.

[57 FR 3349, Jan. 29, 1992]

PART 1004—IMPOSITION OF SANCTIONS ON HEALTH CARE PRACTITIONERS AND PROVIDERS OF HEALTH CARE SERVICES BY A QUALITY IMPROVEMENT ORGANIZATION

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1004.140 Appeal rights.

AUTHORITY: 42 U.S.C. 1302 and 1320c–5.

SOURCE: 60 FR 63640, Dec. 12, 1995, unless otherwise noted.

Subpart A—General Provisions

§ 1004.1 Scope and definitions.

(a) *Scope*. This part implements section 1156 of the Act by—

(1) Setting forth certain obligations imposed on practitioners and providers of services under Medicare;

(2) Establishing criteria and procedures for the reports required from quality improvement organizations (QIOs) when there is failure to meet those obligations;

(3) Specifying the policies and procedures for making determinations on violations and imposing sanctions; and

(4) Defining the procedures for appeals by the affected party and the procedures for reinstatements.

(b) *Definitions*. As used in this part, unless the context indicates otherwise—

Dentist is limited to licensed doctors of dental surgery or dental medicine.

Economically means the services are provided at the least expensive, medically appropriate type of setting or level of care available.

Exclusion means that items and services furnished or ordered (or at the medical direction or on the prescription of a physician) by a specified health care practitioner, provider or other person during a specified period are not reimbursed under titles V, XVIII, XIX, or XX of the Social Security Act and all other Federal non-procurement programs.

Gross and flagrant violation means a violation of an obligation has occurred in one or more instances which presents an imminent danger to the health, safety, or well-being of a program patient or places the program patient unnecessarily in high-risk situations.

Health care service or services means services or items for which payment may be made (in whole or in part) under the Medicare or State health care programs.

Health professional shortage area (HPSA) means an area designated by the Secretary and defined in 42 CFR 5.2.

Metropolitan Statistical Area means an area as defined by the Executive Office of Management and Budget.

Obligation means any of the obligations specified at section 1156(a) of the Act.

Other person means a hospital or other health care facility, an organization or an agency that provides health care services or which payment may be made (in whole or in part) under the Medicare or State health care programs.

Pattern or care means that the care under question has been demonstrated in more than three instances, each of which involved different admissions.

Pharmacy professional is a term limited to individuals who are licensed or registered to provide pharmaceutical services.

Podiatric professional is a term limited to licensed doctors of podiatric medicine.

Practice area means the location where over 50 percent of the practitioner's or other person's patients are seen.

Practitioner means a physician or other health care professional licensed under State law to practice his or her profession.

Primary medical care professional is a term limited to:

(i) Licensed doctors of medicine and doctors of osteopathy providing direct patient care who practice in the fields of general or family practice, general internal medicine, pediatrics, obstetrics and gynecology, surgery, and any other specialty that is not accommodated by the remaining specialty HPSA designator, or

(ii) Those facilities where care and treatment is provided to patients with health problems other than mental disorders.

Pro area means the geographic area subject to review by a particular QIO.

Provider means a hospital or other health care facility, agency, or organization.

Psychiatric professional is a term limited to licensed doctors of medicine who limit their practice to psychiatry or to those facilities where care and treatment is limited to patients with mental disorders.

Rural means any area outside an urban area.

Rural health professional shortage area means any health professional shortage area located outside a Metropolitan Statistical Area.

Sanction means an exclusion or monetary penalty that the Secretary may impose on a practitioner or other person as a result of a recommendation from a QIO.

Serious risk includes situations that may involve the risk of unnecessary treatment, prolonged treatment, lack of treatment, incorrect treatment, medical complication, premature discharge, physiological or anatomical impairment, disability, or death.

State health care program means a State plan approved under title XIX, any program receiving funds under title V or from an allotment to a State under such title, or any program receiving funds under title XX or from an allotment to a State under such title.

Substantial violation in a substantial number of cases means a pattern of providing care, as defined in this section, that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the QIO.

Urban means a Metropolitan Statistical Area as defined by the Executive Office of Management and Budget.

Vision care professional is a term limited to licensed doctors of medicine who limit their practice to ophthalmology and to doctors of optometry.

Subpart B—Sanctions Under the QIO Program; General Provisions

§ 1004.10 Statutory obligations of practitioners and other persons.

It is the obligation of any health care practitioner or other person who furnishes or orders health care services that may be reimbursed under the Medicare or State health care programs to ensure, to the extent of his or her or its authority, that those services are—

(a) Provided economically and only when, and to the extent, medically necessary;

(b) Of a quality that meets professionally recognized standards of health care; and

(c) Supported by evidence of medical necessity and quality in the form and fashion and at such time that the reviewing QIO may reasonably require (including copies of the necessary documentation and evidence of compliance with pre-admission or pre-procedure review requirements) to ensure that the practitioner or other person is meeting the obligations imposed by section 1156(a) of the Act.

§ 1004.20 Sanctions.

In addition to any other sanction provided under the law, a practitioner or other person may be—

(a) Excluded from participating in programs under titles V, XVIII, XIX, and XX of the Social Security Act for a period of no less than 1 year; or

(b) In lieu of exclusion and as a condition for continued participation in titles V, XVIII, XIX, and XX of the Act, if the violation involved the provision or ordering of health care services (or services furnished at the medical direction or on the prescription of a physician) that were medically improper or unnecessary, required to pay an amount of up to $10,000 for each instance in which improper or unnecessary services were furnished or ordered

(or prescribed, if appropriate). The practitioner or other person will be required either to pay the monetary assessment within 6 months of the date of notice or have it deducted from any sums the Federal Government owes the practitioner or other person.

[62 FR 23143, Apr. 29, 1997]

Subpart C—QIO Responsibilities

§ 1004.30 Basic responsibilities.

(a) The QIO must use its authority or influence to enlist the support of other professional or government agencies to ensure that each practitioner or other person complies with the obligations specified in § 1004.10.

(b) When the QIO identifies situations where an obligation specified in § 1004.10 is violated, it will afford the practitioner or other person reasonable notice and opportunity for discussion and, if appropriate, a suggested method for correcting the situation and a time period for a corrective action in accordance with §§ 1004.40 and 1004.60.

(c) The QIO must submit a report to the OIG after the notice and opportunity provided under paragraph (b) of this section and, if appropriate, the opportunity to enter into and complete a corrective action plan (CAP) if the QIO finds that the practitioner or other person has—

(1) Failed substantially to comply with any obligation in a substantial number of admissions; or

(2) Grossly and flagrantly violated any obligation in one or more instances.

(d) The QIO report to the OIG must comply with the provisions of § 1004.80.

(e) If a practitioner or other person relocates to another QIO area prior to a finding of a violation or sanction recommendation, and the originating QIO—

(1) Is able to make a finding, the originating QIO must, as appropriate, close the case or forward a sanction recommendation to the OIG; or

(2) Cannot make a finding, the originating QIO must forward all documentation regarding the case to the QIO with jurisdiction, and notify the practitioner or other person of this action.

(f) The QIO must deny payment for services or items furnished or ordered (or at the medical direction or on the prescription of an excluded physician) by an excluded practitioner or other person when the QIO identifies the services or items. It must report the findings to the Centers for Medicare & Medicaid Services.

§ 1004.40 Action on identification of a violation.

When a QIO identifies a violation, it must—

(a) Indicate whether the violation is a gross and flagrant violation or is a substantial violation in a substantial number of cases; and

(b) Send the practitioner or other person written notice of the identification of a violation containing the following information—

(1) The obligation(s) involved;

(2) The situation, circumstances or activity that resulted in a violation;

(3) The authority and responsibility of the QIO to report violations of any obligation under section 1156(a) of the Act;

(4) A suggested method for correcting the situation and a time period for corrective action, if appropriate;

(5) The sanction that the QIO could recomment to the OIG;

(6) The right of the practitioner or other person to submit to the QIO within 30 days of receipt of the notice additional information or a written request for a meeting with the QIO to review and discuss the finding, or both. The date of receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary. The notice will also state that if a meeting is requested—

(i) It will be held within 30 days of receipt by the QIO of the request, but may be extended for good cause;

(ii) The practitioner or other person may have an attorney present; and

(iii) The attorney, if present, will be permitted to make opening and closing remarks, ask clarifying questions at the meeting and assist the practitioner or other person in presenting the testimony of expert witnesses who may appear on the practitioner's or other person's behalf; and

(7) A copy of the material used by the QIO in arriving at its finding except for QIO deliberations, as set forth in § 476.139 of this part.

§ 1004.50 Meeting with a practitioner or other person.

If the practitioner or other person requests a meeting with the QIO—

(a) The QIO panel that meets with the practitioner or other person must consist of a minimum of 3 physicians;

(b) No physician member of the QIO panel may be in direct economic competition with the practitioner or other person being considered for sanction;

(c) The QIO must ensure that no physician member of the QIO panel has a substantial bias for or against the practitioner or other person being considered for sanction;

(d) At least one member of the QIO panel meeting with the practitioner or other person should practice in a similar area, e.g., urban or rural, and at least one member of the panel must be in the same specialty (both requirements could be met by a single individual);

(e) If the practitioner or other person has an attorney present, that attorney will be permitted to make opening and closing remarks, ask clarifying questions and assist the practitioner or other person in presenting the testimony of expert witnesses who may appear on the practitioner's or other person behalf;

(f) The physician who recommends to the QIO that a practitioner or other person be sanctioned may not vote on that recommendation at the meeting;

(g) The QIO may allow the practitioner or other person 5 working days after the meeting to provide the QIO additional relevant information that may affect its finding; and

(h) A verbatim record must be made of the meeting and must be made available to the practitioner or other person promptly.

§ 1004.60 QIO finding of a violation.

(a) On the basis of any additional information received, the QIO will affirm or modify its finding. If the QIO affirms its finding, it may suggest in writing a method for correcting the situation and a time period for corrective action. This CAP could correspond with, or be a continuation of, a prior CAP or be a new proposal based on additional information received by the QIO. If the finding has been resolved to the QIO's satisfaction, the QIO may modify its initial finding or recommendation or close the case.

(b) The QIO must give written notice to the practitioner or other person of any action it takes as a result of the additional information received, as specified in § 1004.70.

(c) At least one member of the QIO participating in the process which resulted in a recommendation to the OIG that a practitioner or other person be sanctioned should practice in a similar geographic area, e.g. urban or rural, and at least one member of the panel must be in the same medical specialty. Both requirements can be met by a single individual. In addition, no one at the QIO who is a participant in such a finding may be in direct economic competition with, or have a substantial bias for or against, that practitioner or other person being recommended for sanction.

§ 1004.70 QIO action on final finding of a violation.

If the finding is not resolved to the QIO's satisfaction as specified in § 1004.60(a), the QIO must—

(a) Submit its report and recommendation to the OIG;

(b) Send the affected practitioner or other person a concurrent final notice, with a copy of all the material that is being forwarded to the OIG, advising that—

(1) The QIO recommendation has been submitted to the OIG;

(2) The practitioner or other person has 30 days from receipt of this final notice to submit any additional written material or documentary evidence to the OIG at its headquarters location. The date of receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary; and

(3) Due to the 120-day statutory requirement specified in § 1004.100(e), the period for submitting additional information will not be extended and any material received by the OIG after the

30-day period will not be considered; and

(c) Provide notice to the State medical board or to other appropriate licensing boards for other practitioner types when it submits a report and recommendations to the OIG with respect to a physician or other person whom the board is responsible for licensing.

§ 1004.80 QIO report to the OIG.

(a) *Manner of reporting.* If the violation(s) identified by the QIO have not been resolved, it must submit a report and recommendation to the OIG at the field office with jurisdiction.

(b) *Content of report.* The QIO report must include the following information—

(1) Identification of the practitioner or other person and, when applicable, the name of the director, administrator or owner of the entity involved;

(2) The type of health care services involved;

(3) A description of each failure to comply with an obligation, including specific dates, places, circumstances and other relevant facts;

(4) Pertinent documentary evidence;

(5) Copies of written correspondence, including reports of conversations with the practitioner or other person regarding the violation and, if applicable, a copy of the verbatim transcript of the meeting with the practitioner or other person;

(6) The QIO's finding that an obligation under section 1156(a) of the Act has been violated and that the violation is substantial and has occurred in a substantial number of cases or is gross and flagrant;

(7) A case-by-case analysis and evaluation of any additional information provided by the practitioner or other person in response to the QIO's initial finding;

(8) A copy of the CAP that was developed and documentation of the results of such plan;

(9) The number of admissions by the practitioner or other person reviewed by the QIO during the period in which the violation(s) were identified;

(10) The professional qualifications of the QIO's reviewers; and

(11) The QIO's sanction recommendation.

(c) *QIO recommendation.* The QIO must specify in its report—

(1) The sanction recommended;

(2) The amount of the monetary penalty recommended, if applicable;

(3) The period of exclusion recommended, if applicable;

(4) The availability of alternative sources of services in the community, with supporting information; and

(5) The county or counties in which the practitioner or other person furnishes services.

[60 FR 63640, Dec. 12, 1995, as amended at 62 FR 23143, Apr. 29, 1997]

§ 1004.90 Basis for recommended sanction.

The QIO's specific recommendation must be based on documentation provided to the OIG showing its consideration of—

(a) The type of offense involved;

(b) The severity of the offense;

(c) The deterrent value;

(d) The practitioner's or other person's previous sanction record;

(e) The availability of alternative sources of services in the community; and

(f) Any other factors that the QIO considers relevant, such as the duration of the problem.

Subpart D—OIG Responsibilities

§ 1004.100 Acknowledgement and review of report.

(a) *Acknowledgement.* The OIG will inform the QIO of the date it received the QIO's report and recommendation.

(b) *Review.* The OIG will review the QIO report and recommendation to determine whether—

(1) The QIO has followed the regulatory requirements of this part; and

(2) A violation has occurred.

(c) *Rejection of the QIO recommendation.* If the OIG decides that a sanction is not warranted, it will notify the QIO that recommended the sanction, the affected practitioner or other person, and the licensing board informed by the QIO of the sanction recommendation that the recommendation is rejected.

(d) *Decision to sanction.* If the OIG decides that a violation of obligations has occurred, it will determine the appropriate sanction by considering—

(1) The recommendation of the QIO;
(2) The type of offense;
(3) The severity of the offense;
(4) The previous sanction record of the practitioner or other person;
(5) The availability of alternative sources of services in the community;
(6) Any prior problems the Medicare or State health care programs have had with the practitioner or other person; and
(7) Any other matters relevant to the particular case.

(e) *Exclusion sanction.* If the QIO submits a recommendation for exclusion to the OIG, and a determination is not made by the 120th day after actual receipt by the OIG, the exclusion sanction recommended will become effective and the OIG will provide notice in accordance with § 1004.110(f).

(f) *Monetary penalty.* If the QIO recommendation is to assess a monetary penalty, the 120-day provision does not apply and the OIG will provide notice in accordance with § 1004.110 (a)–(e).

[60 FR 63640, Dec. 12, 1995, as amended at 62 FR 23143, Apr. 29, 1997]

§ 1004.110 Notice of sanction.

(a) The OIG must notify the practitioner or other person of the adverse determination and of the sanction to be imposed.

(b) The sanction is effective 20 days from the date of the notice. Receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary.

(c) The notice must specify—
(1) The legal and factual basis for the determination;
(2) The sanction to be imposed;
(3) The effective date and, if appropriate, the duration of the exclusion;
(4) The appeal rights of the practitioner or other person;
(5) The opportunity and the process necessary to provide alternative notification as set forth in paragraphs (d) and (e) of this section; and
(6) In the case of exclusion, the earliest date on which the OIG will accept a request for reinstatement.

(d) *Patient notification.* (1)(i) The OIG will provide a sanctioned practitioner or other person an opportunity to elect to inform each of their patients of the sanction action. In order to elect this option, the sanctioned practitioner or other person must, within 30 calendar days from receipt of the OIG notice, inform both new and existing patients through written notice—based on a suggested (non-mandatory) model provided to the sanctioned individual by the OIG—of the sanction and, in the case of an exclusion, its effective date. Receipt of the OIG notice is presumed to be 5 days after the date of the notice, unless there is a reasonable showing to the contrary. Within this same period, the practitioner or other person must also sign and return the certification that the OIG will provide with the notice. For purposes of this section, the term ''all existing patients'' includes all patients currently under active treatment with the practitioner or other person, as well as all patients who have been treated by the practitioner or other person within the last 3 years. In addition, the practitioner or other person must notify all prospective patients orally at the time such persons request an appointment. If the sanctioned party is a hospital, it must notify all physicians who have privileges at the hospital, and must post a notice in its emergency room, business office and in all affiliated entities regarding the exclusion. In addition, for purposes of this section, the term ''in all affiliated entities'' encompasses all entities and properties in which the hospital has a direct or indirect ownership interest of 5 percent or more and any management, partnership or control of the entity.

(ii) The certification will provide that the practitioner or other person—

(A) Has informed each of his, her or its patients in writing that the practitioner or other person has been sanctioned, or if a hospital, has informed all physicians having privileges at the hospital that it has been sanctioned;

(B) If excluded from Medicare and the State health care programs, has informed his, her or its existing patients in writing that the programs will not pay for items and services furnished or ordered (or at the medical direction or on the prescription of an excluded physician) by the practitioner or other person until they are reinstated, or if a hospital, has provided this information

to all physicians having privileges at that hospital;

(C) If excluded from Medicare and State health care programs, will provide prospective patients—or if a hospital, physicians requesting privileges at that hospital prior to furnishing or ordering (or in the case of an excluded physician, medically directing or prescribing) services—oral information of both the sanction and that the programs will not pay for services provided and written notification of the same at the time of the provision of services;

(D) If excluded from Medicare and State health care programs and is an entity such as a hospital, has posted a notice in its emergency room, business office and in all affiliated entities that the programs will not pay for services provided; and

(E) Certifies to the truthfulness and accuracy of the notification and the statements in the certification.

(2) If the sanctioned practitioner or other person does not inform his, her or its patients *and* does not return the required certification within the 30-day period, or if the sanctioned practitioner or other person returns the certification within the 30-day period but the OIG obtains reliable evidence that such person nevertheless has not adequately informed new and existing patients of the sanction, the OIG—

(i) Will see that the public is notified directly of the identity of the sanctioned practitioner or other person, the finding that the obligation has been violated, and the effective date of any exclusion; and

(ii) May consider this failure to adhere to the certification obligation as an adverse factor at the time the sanctioned practitioner or other person requests reinstatement.

(3) If the sanctioned practitioner or other person is entitled to a preliminary hearing in accordance with §1004.140(a) and requests such a preliminary hearing, and if the administrative law judge (ALJ) decides that he, she or it poses a risk to program beneficiaries, the sanctioned practitioner or other person would have 30 days from the date of receipt of the ALJ's decision to provide certification to the OIG in accordance with §1004.110(d)(1). The date of receipt is presumed to be 5 days after the date of the ALJ's decision, unless there is a reasonable showing to the contrary.

(e) Notice of the sanction is also provided to the following entities as appropriate—

(1) The QIO that originated the sanction report;

(2) QIOs in adjacent areas;

(3) State Medicaid fraud control units and State licensing and accreditation bodies;

(4) Appropriate program contractors and State agencies;

(5) Hospitals, including the hospital where the sanctioned individual's case originated and where the individual currently has privileges, if known; skilled nursing facilities, home health agencies, and health maintenance organizations and Federally-funded community health centers where the practitioner or other person works;

(6) Medical societies and other professional organizations; and

(7) Medicare carriers and fiscal intermediaries, health care prepayment plans and other affected agencies and organizations.

(f) If an exclusion sanction is effectuated because a decision was not made within 120 days after receipt of the QIO recommendation, notification is as follows—

(1) As soon as possible after the 120th day, the OIG will issue a notice to the practitioner or other person, in compliance with the requirements of paragraph (c) of this section, affirming the QIO recommendation based on the OIG's review of the case, and that the exclusion is effective 20 days from the date of the notice; and

(2) Notice of sanction is also provided as specified in paragraph (e) of this section.

[60 FR 63640, Dec. 12, 1995; 61 FR 1841, Jan. 24, 1996, as amended at 62 FR 23143, Apr. 29, 1997]

Subpart E—Effect and Duration of Exclusion

§1004.120 Effect of an exclusion on program payments and services.

The effect of an exclusion is set forth in §1001.1901 of this chapter.

§ 1004.130 Reinstatement after exclusion.

(a) A practitioner or other person who has been excluded in accordance with this part may apply for reinstatement at the end of the period of exclusion. The OIG will consider any request for reinstatement in accordance with provisions of §§ 1001.3001 through 1001.3005 of this chapter.

(b) The OIG may also consider a practitioner's or other person's compliance with the certification obligation in § 1004.110(d) at the time of reinstatement.

Subpart F—Appeals

§ 1004.140 Appeal rights.

(a) *Right to preliminary hearing.* (1)(i) A practitioner or other person excluded from participation in Medicare and any State health care programs under section 1156 of the Act may request a preliminary hearing if the location where services are rendered to over 50 percent of the practitioner's or other person's patients at the time of the exclusion notice is in a rural HPSA or in a county with a population of less than 70,000.

(ii) Unless the practitioner's or other person's practice meets the definition for psychiatric professional, vision care professional, dental professional, podiatric professional or pharmacy professional, the HPSA used by the OIG for determination of entitlement to a preliminary hearing will be the HPSA list for primary medical care professional.

(iii) Information on the population size of a county in order to determine entitlement to a preliminary hearing will be obtained by the OIG from the responsible officials of that county.

(2)(i) A request for a preliminary hearing must be made in writing and received by the Departmental Appeals Board (DAB) no later than the 15th day after the notice of exclusion is received by a practitioner or other person. The date of receipt of the notice of exclusion by the practitioner or other person is presumed to be 5 days after the date appearing on the notice, unless there is a reasonable showing to the contrary.

(ii) A request for a preliminary hearing will stay the effective date of the exclusion pending a decision of the ALJ at the preliminary hearing, and all the parties informed by the OIG of the exclusion will be notified of the stay.

(iii) A request for a preliminary hearing received after the 15-day period has expired will be treated as a request for a hearing before an ALJ in accordance with paragraph (b) of this section.

(iv) If the practitioner or other person exercises his, her or its right to a preliminary hearing, such a hearing must be held by the ALJ in accordance with paragraph (a)(3)(i) of this section unless the OIG waives it in accordance with paragraph (a)(6)(i) of this section.

(v) The ALJ cannot consolidate the preliminary hearing with a full hearing without the approval of all parties to the hearing.

(3)(i) The preliminary hearing will be conducted by an ALJ of the DAB in a city that the ALJ deems equitable to all parties. The ALJ will conduct the preliminary hearing and render a decision no later than 45 days after receipt of the request for such a hearing by the DAB. Unless there is a reasonable showing to the contrary, date of receipt by the DAB is presumed to be 5 days after the date on the request for a preliminary hearing or, if undated, the date of receipt will be the date the DAB actually received the request. A reasonable extension to the 45-day period of up to 15 days may be requested by any party to the preliminary hearing and such a request may be granted upon concurrence by all parties to the preliminary hearing. Such request must be received no later than 15 days prior to the scheduled date of the preliminary hearing.

(ii) The only issue to be heard and decided on by the ALJ at the preliminary hearing, based on the preponderance of the evidence, is whether the practitioner's or other person's continued participation in the Medicare and State health care programs during the appeal of the exclusion before an ALJ would place program beneficiaries at serious risk. The ALJ's decision is to be based on the preponderance of the evidence.

(iii) In the interest of time, the ALJ may issue an oral decision to be followed by a written decision.

(iv) In those cases where the ALJ has stayed an exclusion after a preliminary hearing, a full hearing must be held and a decision rendered by the ALJ within 6 months. If, for any reason, the request for a full hearing before the ALJ is withdrawn or dismissed, the practitioner or other person will be excluded effective 5 days after the notice of the withdrawal or dismissal is received in the OIG headquarters.

(4) The preliminary hearing decision is not appealable or subject to further administrative or judicial review.

(5) A practitioner or other person found at the preliminary hearing not to place program beneficiaries at serious risk, but later determined to have been properly excluded from program participation after a full hearing before an ALJ, is not entitled to have the exclusion stayed further during an appeal to the DAB. Exclusions in such instances will be effective 5 days after receipt of the ALJ decision in the OIG headquarters.

(6)(i) After notice of a timely request for a preliminary hearing, the OIG may determine that the practitioner's or other person's continued program participation during the appeal before the ALJ will not place program beneficiaries at serious risk and waive the preliminary hearing. Under these circumstances, the exclusion will be stayed pending the decision of the ALJ after a full hearing. the hearing must be held, and a decision reached, within 6 months.

(ii) If the OIG decides to waive the preliminary hearing, the request for the preliminary hearing will be considered a request for a hearing before the ALJ in accordance with paragraph (b) of this section.

(b) *Right to administrative review.* (1) A practitioner or other person dissatisfied with an OIG determination, or an exclusion that results from a determination not being made within 120 days, is entitled to appeal such sanction in accordance with part 1005 of this chapter.

(2) Due to the 120-day statutory requirement specified in §1004.100(e), the following limitations apply—

(i) The period of time for submitting additional information will not be extended.

(ii) Any material received by the OIG after the 30-day period allowed will not be considered by the ALJ or the DAB.

(3) The OIG's determination continues in effect unless reversed by a hearing.

(c) *Rights to judicial review.* Any practitioner or other person dissatisfied with a final decision of the Secretary may file a civil action in accordance with the provisions of section 205(g) of the Act.

PART 1005—APPEALS OF EXCLUSIONS, CIVIL MONEY PENALTIES AND ASSESSMENTS

Sec.

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AUTHORITY: 42 U.S.C. 405(a), 405(b), 1302, 1320a–7, 1320a–7a and 1320c–5.

SOURCE: 57 FR 3350, Jan. 29, 1992, unless otherwise noted.

§1005.1 Definitions.

Civil money penalty cases refer to all proceedings arising under any of the statutory bases for which the OIG has been delegated authority to impose civil money penalties under Medicare or the State health care programs.

DAB refers to the Departmental Appeals Board or its delegatee.

Exclusion cases refer to all proceedings arising under any of the statutory bases for which the OIG has been

delegated authority to impose exclusions under Medicare or the State health care programs.

Inspector General (IG) means the Inspector General of the Department of Health and Human Services or his or her designees.

[57 FR 3350, Jan. 29, 1992, as amended at 65 FR 24418, Apr. 26, 2000]

§ 1005.2 Hearing before an administrative law judge.

(a) A party sanctioned under any criteria specified in parts 1001, 1003 and 1004 of this chapter may request a hearing before an ALJ.

(b) In exclusion cases, the parties to the proceeding will consist of the petitioner and the IG. In civil money penalty cases, the parties to the proceeding will consist of the respondent and the IG.

(c) The request for a hearing will be made in writing to the DAB; signed by the petitioner or respondent, or by his or her attorney; and sent by certified mail. The request must be filed within 60 days after the notice, provided in accordance with §§ 1001.2002, 1001.203 or 1003.109, is received by the petitioner or respondent. For purposes of this section, the date of receipt of the notice letter will be presumed to be 5 days after the date of such notice unless there is a reasonable showing to the contrary.

(d) The request for a hearing will contain a statement as to the specific issues or findings of fact and conclusions of law in the notice letter with which the petitioner or respondent disagrees, and the basis for his or her contention that the specific issues or findings and conclusions were incorrect.

(e) The ALJ will dismiss a hearing request where—

(1) The petitioner's or the respondent's hearing request is not filed in a timely manner;

(2) The petitioner or respondent withdraws his or her request for a hearing;

(3) The petitioner or respondent abandons his or her request for a hearing; or

(4) The petitioner's or respondent's hearing request fails to raise any issue which may properly be addressed in a hearing.

[57 FR 3350, Jan. 29, 1992, as amended at 65 FR 24418, Apr. 26, 2000]

§ 1005.3 Rights of parties.

(a) Except as otherwise limited by this part, all parties may—

(1) Be accompanied, represented and advised by an attorney;

(2) Participate in any conference held by the ALJ;

(3) Conduct discovery of documents as permitted by this part;

(4) Agree to stipulations of fact or law which will be made part of the record;

(5) Present evidence relevant to the issues at the hearing;

(6) Present and cross-examine witnesses;

(7) Present oral arguments at the hearing as permitted by the ALJ; and

(8) Submit written briefs and proposed findings of fact and conclusions of law after the hearing.

(b) Fees for any services performed on behalf of a party by an attorney are not subject to the provisions of section 206 of title II of the Act, which authorizes the Secretary to specify or limit these fees.

§ 1005.4 Authority of the ALJ.

(a) The ALJ will conduct a fair and impartial hearing, avoid delay, maintain order and assure that a record of the proceeding is made.

(b) The ALJ has the authority to—

(1) Set and change the date, time and place of the hearing upon reasonable notice to the parties;

(2) Continue or recess the hearing in whole or in part for a reasonable period of time;

(3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;

(4) Administer oaths and affirmations;

(5) Issue subpoenas requiring the attendance of witnesses at hearings and the production of documents at or in relation to hearings;

(6) Rule on motions and other procedural matters;

(7) Regulate the scope and timing of documentary discovery as permitted by this part;

(8) Regulate the course of the hearing and the conduct of representatives, parties, and witnesses;

(9) Examine witnesses;

(10) Receive, rule on, exclude or limit evidence;

(11) Upon motion of a party, take official notice of facts;

(12) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact; and

(13) Conduct any conference, argument or hearing in person or, upon agreement of the parties, by telephone.

(c) The ALJ does not have the authority to—

(1) Find invalid or refuse to follow Federal statutes or regulations or secretarial delegations of authority;

(2) Enter an order in the nature of a directed verdict;

(3) Compel settlement negotiations;

(4) Enjoin any act of the Secretary;

(5) Review the exercise of discretion by the OIG to exclude an individual or entity under section 1128(b) of the Act, or determine the scope or effect of the exclusion,

(6) Set a period of exclusion at zero, or reduce a period of exclusion to zero, in any case where the ALJ finds that an individual or entity committed an act described in section 1128(b) of the Act, or

(7) Review the exercise of discretion by the OIG to impose a CMP, assessment or exclusion under part 1003 of this chapter.

[57 FR 3350, Jan. 29, 1992, as amended at 58 FR 5618, Jan. 22, 1993]

§ 1005.5 Ex parte contacts.

No party or person (except employees of the ALJ's office) will communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 1005.6 Prehearing conferences.

(a) The ALJ will schedule at least one prehearing conference, and may schedule additional prehearing conferences as appropriate, upon reasonable notice to the parties.

(b) The ALJ may use prehearing conferences to discuss the following—

(1) Simplification of the issues;

(2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;

(3) Stipulations and admissions of fact or as to the contents and authenticity of documents;

(4) Whether the parties can agree to submission of the case on a stipulated record;

(5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of other parties) and written argument;

(6) Limitation of the number of witnesses;

(7) Scheduling dates for the exchange of witness lists and of proposed exhibits;

(8) Discovery of documents as permitted by this part;

(9) The time and place for the hearing;

(10) Such other matters as may tend to encourage the fair, just and expeditious disposition of the proceedings; and

(11) Potential settlement of the case.

(c) The ALJ will issue an order containing the matters agreed upon by the parties or ordered by the ALJ at a prehearing conference.

§ 1005.7 Discovery.

(a) A party may make a request to another party for production of documents for inspection and copying which are relevant and material to the issues before the ALJ.

(b) For the purpose of this section, the term documents includes information, reports, answers, records, accounts, papers and other data and documentary evidence. Nothing contained in this section will be interpreted to require the creation of a document, except that requested data stored in an electronic data storage system will be

produced in a form accessible to the requesting party.

(c) Requests for documents, requests for admissions, written interrogatories, depositions and any forms of discovery, other than those permitted under paragraph (a) of this section, are not authorized.

(d) This section will not be construed to require the disclosure of interview reports or statements obtained by any party, or on behalf of any party, of persons who will not be called as witnesses by that party, or analyses and summaries prepared in conjunction with the investigation or litigation of the case, or any otherwise privileged documents.

(e)(1) When a request for production of documents has been received, within 30 days the party receiving that request will either fully respond to the request, or state that the request is being objected to and the reasons for that objection. If objection is made to part of an item or category, the part will be specified. Upon receiving any objections, the party seeking production may then, within 30 days or any other time frame set by the ALJ, file a motion for an order compelling discovery. (The party receiving a request for production may also file a motion for protective order any time prior to the date the production is due.)

(2) The ALJ may grant a motion for protective order or deny a motion for an order compelling discovery if the ALJ finds that the discovery sought—

(i) Is irrelevant,

(ii) Is unduly costly or burdensome,

(iii) Will unduly delay the proceeding, or

(iv) Seeks privileged information.

(3) The ALJ may extend any of the time frames set forth in paragraph (e)(1) of this section.

(4) The burden of showing that discovery should be allowed is on the party seeking discovery.

[57 FR 3350, Jan. 29, 1992, as amended at 58 FR 5618, Jan. 22, 1993; 65 FR 24418, Apr. 26, 2000; 65 FR 35584, June 5, 2000; 67 FR 11936, Mar. 18, 2002]

§ 1005.8 Exchange of witness lists, witness statements and exhibits.

(a) At least 15 days before the hearing, the ALJ will order the parties to exchange witness lists, copies of prior written statements of proposed witnesses and copies of proposed hearing exhibits, including copies of any written statements that the party intends to offer in lieu of live testimony in accordance with § 1005.16.

(b) (1) If at any time a party objects to the proposed admission of evidence not exchanged in accordance with paragraph (a) of this section, the ALJ will determine whether the failure to comply with paragraph (a) of this section should result in the exclusion of such evidence.

(2) Unless the ALJ finds that extraordinary circumstances justified the failure to timely exchange the information listed under paragraph (a) of this section, the ALJ must exclude from the party's case-in-chief:

(i) The testimony of any witness whose name does not appear on the witness list, and

(ii) Any exhibit not provided to the opposing party as specified in paragraph (a) of this section.

(3) If the ALJ finds that extraordinary circumstances existed, the ALJ must then determine whether the admission of such evidence would cause substantial prejudice to the objecting party. If the ALJ finds that there is no substantial prejudice, the evidence may be admitted. If the ALJ finds that there is substantial prejudice, the ALJ may exclude the evidence, or at his or her discretion, may postpone the hearing for such time as is necessary for the objecting party to prepare and respond to the evidence.

(c) Unless another party objects within a reasonable period of time prior to the hearing, documents exchanged in accordance with paragraph (a) of this section will be deemed to be authentic for the purpose of admissibility at the hearing.

§ 1005.9 Subpoenas for attendance at hearing.

(a) A party wishing to procure the appearance and testimony of any individual at the hearing may make a motion requesting the ALJ to issue a subpoena if the appearance and testimony are reasonably necessary for the presentation of a party's case.

(b) A subpoena requiring the attendance of an individual in accordance with paragraph (a) of this section may also require the individual (whether or not the individual is a party) to produce evidence authorized under § 1005.7 of this part at or prior to the hearing.

(c) When a subpoena is served by a respondent or petitioner on a particular individual or particular office of the OIG, the OIG may comply by designating any of its representatives to appear and testify.

(d) A party seeking a subpoena will file a written motion not less than 30 days before the date fixed for the hearing, unless otherwise allowed by the ALJ for good cause shown. Such request will:

(1) Specify any evidence to be produced,

(2) Designate the witnesses, and

(3) Describe the address and location with sufficient particularity to permit such witnesses to be found.

(e) The subpoena will specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) Within 15 days after the written motion requesting issuance of a subpoena is served, any party may file an opposition or other response.

(g) If the motion requesting issuance of a subpoena is granted, the party seeking the subpoena will serve it by delivery to the individual named, or by certified mail addressed to such individual at his or her last dwelling place or principal place of business.

(h) The individual to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within 10 days after service.

(i) The exclusive remedy for contumacy by, or refusal to obey a subpoena duly served upon, any person is specified in section 205(e) of the Social Security Act (42 U.S.C. 405(e)).

[57 FR 3350, Jan. 29, 1992, as amended at 65 FR 24418, Apr. 26, 2000]

§ 1005.10 Fees.

The party requesting a subpoena will pay the cost of the fees and mileage of any witness subpoenaed in the amounts that would be payable to a witness in a proceeding in United States District Court. A check for witness fees and mileage will accompany the subpoena when served, except that when a subpoena is issued on behalf of the IG, a check for witness fees and mileage need not accompany the subpoena.

§ 1005.11 Form, filing and service of papers.

(a) *Forms.* (1) Unless the ALJ directs the parties to do otherwise, documents filed with the ALJ will include an original and two copies.

(2) Every pleading and paper filed in the proceeding will contain a caption setting forth the title of the action, the case number, and a designation of the paper, such as motion to quash subpoena.

(3) Every pleading and paper will be signed by, and will contain the address and telephone number of the party or the person on whose behalf the paper was filed, or his or her representative.

(4) Papers are considered filed when they are mailed.

(b) *Service.* A party filing a document with the ALJ or the Secretary will, at the time of filing, serve a copy of such document on every other party. Service upon any party of any document will be made by delivering a copy, or placing a copy of the document in the United States mail, postage prepaid and addressed, or with a private delivery service, to the party's last known address. When a party is represented by an attorney, service will be made upon such attorney in lieu of the party.

(c) *Proof of service.* A certificate of the individual serving the document by personal delivery or by mail, setting forth the manner of service, will be proof of service.

§ 1005.12 Computation of time.

(a) In computing any period of time under this part or in an order issued thereunder, the time begins with the day following the act, event or default, and includes the last day of the period unless it is a Saturday, Sunday or legal holiday observed by the Federal Government, in which event it includes the next business day.

(b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays and legal holidays observed by the Federal Government will be excluded from the computation.

(c) Where a document has been served or issued by placing it in the mail, an additional 5 days will be added to the time permitted for any response. This paragraph does not apply to requests for hearing under § 1005.2.

§ 1005.13 Motions.

(a) An application to the ALJ for an order or ruling will be by motion. Motions will state the relief sought, the authority relied upon and the facts alleged, and will be filed with the ALJ and served on all other parties.

(b) Except for motions made during a prehearing conference or at the hearing, all motions will be in writing. The ALJ may require that oral motions be reduced to writing.

(c) Within 10 days after a written motion is served, or such other time as may be fixed by the ALJ, any party may file a response to such motion.

(d) The ALJ may not grant a written motion before the time for filing responses has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny such motion without awaiting a response.

(e) The ALJ will make a reasonable effort to dispose of all outstanding motions prior to the beginning of the hearing.

§ 1005.14 Sanctions.

(a) The ALJ may sanction a person, including any party or attorney, for failing to comply with an order or procedure, for failing to defend an action or for other misconduct that interferes with the speedy, orderly or fair conduct of the hearing. Such sanctions will reasonably relate to the severity and nature of the failure or misconduct. Such sanction may include—

(1) In the case of refusal to provide or permit discovery under the terms of this part, drawing negative factual inferences or treating such refusal as an admission by deeming the matter, or certain facts, to be established;

(2) Prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense;

(3) Striking pleadings, in whole or in part;

(4) Staying the proceedings;

(5) Dismissal of the action;

(6) Entering a decision by default; and

(7) Refusing to consider any motion or other action that is not filed in a timely manner.

(b) In civil money penalty cases commenced under section 1128A of the Act or under any provision which incorporates section 1128A(c)(4) of the Act, the ALJ may also order the party or attorney who has engaged in any of the acts described in paragraph (a) of this section to pay attorney's fees and other costs caused by the failure or misconduct.

§ 1005.15 The hearing and burden of proof.

(a) The ALJ will conduct a hearing on the record in order to determine whether the petitioner or respondent should be found liable under this part.

(b) With regard to the burden of proof in civil money penalty cases under part 1003, in Quality Improvement Organization exclusion cases under part 1004, and in exclusion cases under §§ 1001.701, 1001.901 and 1001.951 of this chapter—

(1) The respondent or petitioner, as applicable, bears the burden of going forward and the burden of persuasion with respect to affirmative defenses and any mitigating circumstances; and

(2) The IG bears the burden of going forward and the burden of persuasion with respect to all other issues.

(c) Burden of proof in all other exclusion cases. In all exclusion cases except those governed by paragraph (b) of this section, the ALJ will allocate the burden of proof as the ALJ deems appropriate.

(d) The burden of persuasion will be judged by a preponderance of the evidence.

(e) The hearing will be open to the public unless otherwise ordered by the ALJ for good cause shown.

(f)(1) A hearing under this part is not limited to specific items and information set forth in the notice letter to the petitioner or respondent. Subject to the 15-day requirement under

§ 1005.8, additional items and information, including aggravating or mitigating circumstances that arose or became known subsequent to the issuance of the notice letter, may be introduced by either party during its case-in-chief unless such information or items are—

(i) Privileged;

(ii) Disqualified from consideration due to untimeliness in accordance with § 1004.130(a)(2)(ii); or

(iii) Deemed otherwise inadmissible under § 1005.17.

(2) After both parties have presented their cases, evidence may be admitted on rebuttal even if not previously exchanged in accordance with § 1005.8.

[57 FR 3350, Jan. 29, 1992, as amended at 63 FR 46691, Sept. 2, 1998; 65 FR 24418, Apr. 26, 2000]

§ 1005.16 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing will be given orally by witnesses under oath or affirmation.

(b) At the discretion of the ALJ, testimony (other than expert testimony) may be admitted in the form of a written statement. The ALJ may, at his or her discretion, admit prior sworn testimony of experts which has been subject to adverse examination, such as a deposition or trial testimony. Any such written statement must be provided to all other parties along with the last known address of such witnesses, in a manner that allows sufficient time for other parties to subpoena such witness for cross-examination at the hearing. Prior written statements of witnesses proposed to testify at the hearing will be exchanged as provided in § 1005.8.

(c) The ALJ will exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to:

(1) Make the interrogation and presentation effective for the ascertainment of the truth,

(2) Avoid repetition or needless consumption of time, and

(3) Protect witnesses from harassment or undue embarrassment.

(d) The ALJ will permit the parties to conduct such cross-examination of witnesses as may be required for a full and true disclosure of the facts.

(e) The ALJ may order witnesses excluded so that they cannot hear the testimony of other witnesses. This does not authorize exclusion of—

(1) A party who is an individual;

(2) In the case of a party that is not an individual, an officer or employee of the party appearing for the entity pro se or designated as the party's representative; or

(3) An individual whose presence is shown by a party to be essential to the presentation of its case, including an individual engaged in assisting the attorney for the IG.

[57 FR 3350, Jan. 29, 1992, as amended at 67 FR 11936, Mar. 18, 2002]

§ 1005.17 Evidence.

(a) The ALJ will determine the admissibility of evidence.

(b) Except as provided in this part, the ALJ will not be bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate, for example, to exclude unreliable evidence.

(c) The ALJ must exclude irrelevant or immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence must be excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement made in this action will be inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.

(g) Evidence of crimes, wrongs or acts other than those at issue in the instant case is admissible in order to show motive, opportunity, intent, knowledge, preparation, identity, lack of mistake, or existence of a scheme. Such evidence is admissible regardless of whether the crimes, wrongs or acts occurred during the statute of limitations period applicable to the acts which constitute the basis for liability in the case, and regardless of whether they were referenced in the IG's notice sent in accordance with §§ 1001.2002, 1001.2003 or 1003.109.

(h) The ALJ will permit the parties to introduce rebuttal witnesses and evidence.

(i) All documents and other evidence offered or taken for the record will be open to examination by all parties, unless otherwise ordered by the ALJ for good cause shown.

(j) The ALJ may not consider evidence regarding the issue of willingness and ability to enter into and successfully complete a corrective action plan when such evidence pertains to matters occurring after the submittal of the case to the Secretary. The determination regarding the appropriateness of any corrective action plan is not reviewable.

§ 1005.18 The record.

(a) The hearing will be recorded and transcribed. Transcripts may be obtained following the hearing from the ALJ.

(b) The transcript of testimony, exhibits and other evidence admitted at the hearing, and all papers and requests filed in the proceeding constitute the record for the decision by the ALJ and the Secretary.

(c) The record may be inspected and copied (upon payment of a reasonable fee) by any person, unless otherwise ordered by the ALJ for good cause shown.

(d) For good cause, the ALJ may order appropriate redactions made to the record.

§ 1005.19 Post-hearing briefs.

The ALJ may require the parties to file post-hearing briefs. In any event, any party may file a post-hearing brief. The ALJ will fix the time for filing such briefs which are not to exceed 60 days from the date the parties receive the transcript of the hearing or, if applicable, the stipulated record. Such briefs may be accompanied by proposed findings of fact and conclusions of law. The ALJ may permit the parties to file reply briefs.

§ 1005.20 Initial decision.

(a) The ALJ will issue an initial decision, based only on the record, which will contain findings of fact and conclusions of law.

(b) The ALJ may affirm, increase or reduce the penalties, assessment or exclusion proposed or imposed by the IG, or reverse the imposition of the exclusion. In exclusion cases where the period of exclusion commenced prior to the hearing, any period of exclusion imposed by the ALJ will be deemed to commence on the date such exclusion originally went into effect.

(c) The ALJ will issue the initial decision to all parties within 60 days after the time for submission of post-hearing briefs and reply briefs, if permitted, has expired. The decision will be accompanied by a statement describing the right of any party to file a notice of appeal with the DAB and instructions for how to file such appeal. If the ALJ fails to meet the deadline contained in this paragraph, he or she will notify the parties of the reason for the delay and will set a new deadline.

(d) Except for exclusion actions taken in accordance with § 1001.2003 of this chapter and as provided in paragraph (e) of this section, unless the initial decision is appealed to the DAB, it will be final and binding on the parties 30 days after the ALJ serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(e) If an extension of time within which to appeal the initial decision is granted under § 1005.21(a), except as provided in § 1005.22(a), the initial decision will become final and binding on the day following the end of the extension period.

[57 FR 3350, Jan. 29, 1992, as amended at 65 FR 24418, Apr. 26, 2000]

§ 1005.21 Appeal to DAB.

(a) Any party may appeal the initial decision of the ALJ to the DAB by filing a notice of appeal with the DAB within 30 days of the date of service of the initial decision. The DAB may extend the initial 30 day period for a period of time not to exceed 30 days if a party files with the DAB a request for an extension within the initial 30 day period and shows good cause.

(b) If a party files a timely notice of appeal with the DAB, the ALJ will forward the record of the proceeding to the DAB.

(c) A notice of appeal will be accompanied by a written brief specifying exceptions to the initial decision and reasons supporting the exceptions. Any party may file a brief in opposition to exceptions, which may raise any relevant issue not addressed in the exceptions, within 30 days of receiving the notice of appeal and accompanying brief. The DAB may permit the parties to file reply briefs.

(d) There is no right to appear personally before the DAB or to appeal to the DAB any interlocutory ruling by the ALJ, except on the timeliness of a filing of the hearing request.

(e) The DAB will not consider any issue not raised in the parties' briefs, nor any issue in the briefs that could have been raised before the ALJ but was not.

(f) If any party demonstrates to the satisfaction of the DAB that additional evidence not presented at such hearing is relevant and material and that there were reasonable grounds for the failure to adduce such evidence at such hearing, the DAB may remand the matter to the ALJ for consideration of such additional evidence.

(g) The DAB may decline to review the case, or may affirm, increase, reduce, reverse or remand any penalty, assessment or exclusion determined by the ALJ.

(h) The standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the initial decision is erroneous.

(i) Within 60 days after the time for submission of briefs and reply briefs, if permitted, has expired, the DAB will issue to each party to the appeal a copy of the DAB's decision and a statement describing the right of any petitioner or respondent who is found liable to seek judicial review.

(j) Except with respect to any penalty, assessment or exclusion remanded by the ALJ, the DAB's decision, including a decision to decline review of the initial decision, becomes final and binding 60 days after the date on which the DAB serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(k) (1) Any petition for judicial review must be filed within 60 days after the DAB serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(2) In compliance with 28 U.S.C. 2112(a), a copy of any petition for judicial review filed in any U.S. Court of Appeals challenging a final action of the DAB will be sent by certified mail, return receipt requested, to the Chief Counsel to the IG. The petition copy will be time-stamped by the clerk of the court when the original is filed with the court.

(3) If the Chief Counsel to the IG receives two or more petitions within 10 days after the DAB issues its decision, the Chief Counsel to the IG will notify the U.S. Judicial Panel on Multidistrict Litigation of any petitions that were received within the 10-day period.

[57 FR 3350, Jan. 29, 1992, as amended at 63 FR 46691, Sept. 2, 1998; 65 FR 24419, Apr. 26, 2000]

§ 1005.22 Stay of initial decision.

(a) In a CMP case under section 1128A of the Act, the filing of a respondent's request for review by the DAB will automatically stay the effective date of the ALJ's decision.

(b) (1) After the DAB renders a decision in a CMP case, pending judicial review, the respondent may file a request for stay of the effective date of any penalty or assessment with the ALJ. The request must be accompanied by a copy of the notice of appeal filed with the Federal court. The filing of such a request will automatically act to stay the effective date of the penalty or assessment until such time as the ALJ rules upon the request.

(2) The ALJ may not grant a respondent's request for stay of any penalty or assessment unless the respondent posts a bond or provides other adequate security.

(3) The ALJ will rule upon a respondent's request for stay within 10 days of receipt.

§ 1005.23 Harmless error.

No error in either the admission or the exclusion of evidence, and no error

or defect in any ruling or order or in any act done or omitted by the ALJ or by any of the parties, including Federal representatives such as Medicare carriers and intermediaries and Quality Improvement Organizations, is ground for vacating, modifying or otherwise disturbing an otherwise appropriate ruling or order or act, unless refusal to take such action appears to the ALJ or the DAB inconsistent with substantial justice. The ALJ and the DAB at every stage of the proceeding will disregard any error or defect in the proceeding that does not affect the substantial rights of the parties.

PART 1006—INVESTIGATIONAL INQUIRIES

Sec.
1006.1 Scope.
1006.2 Contents of subpoena.
1006.3 Service and fees.
1006.4 Procedures for investigational inquiries.
1006.5 Enforcement of a subpoena.

AUTHORITY: 42 U.S.C. 405(d), 405(e), 1302 and 1320a–7a.

SOURCE: 57 FR 3354, Jan. 29, 1992, unless otherwise noted.

§ 1006.1 Scope.

(a) The provisions in this part govern subpoenas issued by the Inspector General, or his or her delegates, in accordance with sections 205(d) and 1128A(j) of the Act, and require the attendance and testimony of witnesses and the production of any other evidence at an investigational inquiry.

(b) Such subpoenas may be issued in investigations under section 1128A of the Act or under any other section of the Act that incorporates the provisions of section 1128A(j).

(c) Nothing in this part is intended to apply to or limit the authority of the Inspector General, or his or her delegates, to issue subpoenas for the production of documents in accordance with 5 U.S.C. 6(a)(4), App. 3.

§ 1006.2 Contents of subpoena.

A subpoena issued under this part will—

(a) State the name of the individual or entity to whom the subpoena is addressed;

(b) State the statutory authority for the subpoena;

(c) Indicate the date, time and place that the investigational inquiry at which the witness is to testify will take place;

(d) Include a reasonably specific description of any documents or items required to be produced; and

(e) If the subpoena is addressed to an entity, describe with reasonable particularity the subject matter on which testimony is required. In such event, the named entity will designate one or more individuals who will testify on its behalf, and will state as to each individual so designated that individual's name and address and the matters on which he or she will testify. The individual so designated will testify as to matters known or reasonably available to the entity.

§ 1006.3 Service and fees.

(a) A subpoena under this part will be served by—

(1) Delivering a copy to the individual named in the subpoena;

(2) Delivering a copy to the entity named in the subpoena at its last principal place of business; or

(3) Registered or certified mail addressed to such individual or entity at its last known dwelling place or principal place of business.

(b) A verified return by the individual serving the subpoena setting forth the manner of service or, in the case of service by registered or certified mail, the signed return post office receipt, will be proof of service.

(c) Witnesses will be entitled to the same fees and mileage as witnesses in the district courts of the United States (28 U.S.C. 1821 and 1825). Such fees need not be paid at the time the subpoena is served.

§ 1006.4 Procedures for investigational inquiries.

(a) Testimony at investigational inquiries will be taken under oath or affirmation.

(b) Investigational inquiries are nonpublic investigatory proceedings. Attendance of non-witnesses is within the discretion of the OIG, except that—

(1) A witness is entitled to be accompanied, represented and advised by an attorney; and

(2) Representatives of the OIG are entitled to attend and ask questions.

(c) A witness will have an opportunity to clarify his or her answers on the record following the questions by the OIG.

(d) Any claim of privilege must be asserted by the witness on the record.

(e) Objections must be asserted on the record. Errors of any kind that might be corrected if promptly presented will be deemed to be waived unless reasonable objection is made at the investigational inquiry. Except where the objection is on the grounds of privilege, the question will be answered on the record, subject to the objection.

(f) If a witness refuses to answer any question not privileged or to produce requested documents or items, or engages in conduct likely to delay or obstruct the investigational inquiry, the OIG may seek enforcement of the subpoena under § 1006.5.

(g)(1) The proceedings will be recorded and transcribed.

(2) The witness is entitled to a copy of the transcript, upon payment of prescribed costs, except that, for good cause, the witness may be limited to inspection of the official transcript of his or her testimony.

(3)(i) The transcript will be submitted to the witness for signature.

(ii) Where the witness will be provided a copy of the transcript, the transcript will be submitted to the witness for signature. The witness may submit to the OIG written proposed corrections to the transcript, with such corrections attached to the transcript. If the witness does not return a signed copy of the transcript or proposed corrections within 30 days of its being submitted to him or her for signature, the witness will be deemed to have agreed that the transcript is true and accurate.

(iii) Where, as provided in paragraph (g)(2) of this section, the witness is limited to inspecting the transcript, the witness will have the opportunity at the time of inspection to propose corrections to the transcript, with corrections attached to the transcript. The witness will also have the opportunity to sign the transcript. If the witness does not sign the transcript or offer corrections within 30 days of receipt of notice of the opportunity to inspect the transcript, the witness will be deemed to have agreed that the transcript is true and accurate.

(iv) The OIG's proposed corrections the record of transcript will be attached to the transcript.

(h) Testimony and other evidence obtained in an investigational inquiry may be used by the OIG or DHHS in any of its activities, and may be used or offered into evidence in any administrative or judicial proceeding.

[57 FR 3354, Jan. 29, 1992, as amended at 65 FR 24419, Apr. 26, 2000]

§ 1006.5 Enforcement of a subpoena.

A subpoena to appear at an investigational inquiry is enforceable through the District Court of the United States and the district where the subpoenaed person is found, resides or transacts business.

PART 1007—STATE MEDICAID FRAUD CONTROL UNITS

Sec.

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1007.7 Organization and location requirements.
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1007.11 Duties and responsibilities of the unit.
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1007.19 Federal financial participation (FFP).
1007.21 Other applicable HHS regulations.

AUTHORITY: 42 U.S.C. 1396b(a)(6), 1396b(b)(3) and 1396b(q).

SOURCE: 57 FR 3355, Jan. 29, 1992, unless otherwise noted.

§ 1007.1 Definitions.

As used in this part, unless otherwise indicated by the context:

Employ or *employee*, as the context requires, means full-time duty intended to last at least a year. It includes an arrangement whereby an individual is

on full-time detail or assignment to the unit from another government agency, if the detail or assignment is for a period of at least 1 year and involves supervision by the unit.

Provider means an individual or entity that furnishes items or services for which payment is claimed under Medicaid.

Unit means the State Medicaid fraud control unit.

§ 1007.3 Scope and purpose.

This part implements sections 1903(a)(6), 1903(b)(3), and 1903(q) of the Social Security Act, as amended by the Medicare-Medicaid Anti-Fraud and Abuse Amendments (Pub. L. 95–142). The statute authorizes the Secretary to pay a State 90 percent of the costs of establishing and operating a State Medicaid fraud control unit, as defined by the statute, for the purpose of eliminating fraud in the State Medicaid program.

§ 1007.5 Basic requirement.

A State Medicaid fraud control unit must be a single identifiable entity of the State government certified by the Secretary as meeting the requirements of §§ 1007.7 through 1007.13 of this part.

§ 1007.7 Organization and location requirements.

Any of the following three alternatives is acceptable:

(a) The unit is located in the office of the State Attorney General or another department of State government which has Statewide authority to prosecute individuals for violations of criminal laws with respect to fraud in the provision or administration of medical assistance under a State plan implementing title XIX of the Act;

(b) If there is no State agency with Statewide authority and capability for criminal fraud prosecutions, the unit has established formal procedures that assure that the unit refers suspected cases of criminal fraud in the State Medicaid program to the appropriate State prosecuting authority or authorities, and provides assistance and coordination to such authority or authorities in the prosecution of such cases; or

(c) The unit has a formal working relationship with the office of the State Attorney General and has formal procedures for referring to the Attorney General suspected criminal violations occurring in the State Medicaid program and for effective coordination of the activities of both entities relating to the detection, investigation and prosecution of those violations. Under this requirement, the office of the State Attorney General must agree to assume responsibility for prosecuting alleged criminal violations referred to it by the unit. However, if the Attorney General finds that another prosecuting authority has the demonstrated capacity, experience and willingness to prosecute an alleged violation, he or she may refer a case to that prosecuting authority, as long as the Attorney General's Office maintains oversight responsibility for the prosecution and for coordination between the unit and the prosecuting authority.

§ 1007.9 Relationship to, and agreement with, the Medicaid agency.

(a) The unit must be separate and distinct from the Medicaid agency.

(b) No official of the Medicaid agency will have authority to review the activities of the unit or to review or overrule the referral of a suspected criminal violation to an appropriate prosecuting authority.

(c) The unit will not receive funds paid under this part either from or through the Medicaid agency.

(d) The unit will enter into an agreement with the Medicaid agency under which the Medicaid agency will agree to comply with all requirements of § 455.21(a)(2) of this title.

§ 1007.11 Duties and responsibilities of the unit.

(a) The unit will conduct a Statewide program for investigating and prosecuting (or referring for prosecution) violations of all applicable State laws pertaining to fraud in the administration of the Medicaid program, the provision of medical assistance, or the activities of providers of medical assistance under the State Medicaid plan.

(b) (1) The unit will also review complaints alleging abuse or neglect of patients in health care facilities receiving payments under the State Medicaid plan and may review complaints of the misappropriation of patient's private funds in such facilities.

(2) If the initial review indicates substantial potential for criminal prosecution, the unit will investigate the complaint or refer it to an appropriate criminal investigative or prosecutive authority.

(3) If the initial review does not indicate a substantial potential for criminal prosecution, the unit will refer the complaint to an appropriate State agency.

(c) If the unit, in carrying out its duties and responsibilities under paragraphs (a) and (b) of this section, discovers that overpayments have been made to a health care facility or other provider of medical assistance under the State Medicaid plan, the unit will either attempt to collect such overpayment or refer the matter to an appropriate State agency for collection.

(d) Where a prosecuting authority other than the unit is to assume responsibility for the prosecution of a case investigated by the unit, the unit will insure that those responsible for the prosecutive decision and the preparation of the case for trial have the fullest possible opportunity to participate in the investigation from its inception and will provide all necessary assistance to the prosecuting authority throughout all resulting prosecutions.

(e) The unit will make available to Federal investigators or prosecutors all information in its possession concerning fraud in the provision or administration of medical assistance under the State plan and will cooperate with such officials in coordinating any Federal and State investigations or prosecutions involving the same suspects or allegations.

(f) The unit will safeguard the privacy rights of all individuals and will provide safeguards to prevent the misuse of information under the unit's control.

§ 1007.13 Staffing requirements.

(a) The unit will employ sufficient professional, administrative, and support staff to carry out its duties and responsibilities in an effective and efficient manner. The staff must include:

(1) One or more attorneys experienced in the investigation or prosecution of civil fraud or criminal cases, who are capable of giving informed advice on applicable law and procedures and providing effective prosecution or liaison with other prosecutors;

(2) One or more experienced auditors capable of supervising the review of financial records and advising or assisting in the investigation of alleged fraud; and

(3) A senior investigator with substantial experience in commercial or financial investigations who is capable of supervising and directing the investigative activities of the unit.

(b) The unit will employ, or have available to it, professional staff who are knowledgeable about the provision of medical assistance under title XIX and about the operation of health care providers.

§ 1007.15 Applications, certification and recertification.

(a) *Initial application*. In order to receive FFP under this part, the unit must submit to the Secretary, an application approved by the Governor, containing the following information and documentation—

(1) A description of the applicant's organization, structure, and location within State government, and an indication of whether it seeks certification under § 1007.7 (a), (b), or (c);

(2) A statement from the State Attorney General that the applicant has authority to carry out the functions and responsibilities set forth in this part. If the applicant seeks certification under § 1007.7(b), the statement must also specify either that—

(i) There is no State agency with the authority to exercise Statewide prosecuting authority for the violations with which the unit is concerned, or

(ii) Although the State Attorney General may have common law authority for Statewide criminal prosecutions, he or she has not exercised that authority;

(3) A copy of whatever memorandum of agreement, regulation, or other document sets forth the formal procedures

required under § 1007.7(b), or the formal working relationship and procedures required under § 1007.7(c);

(4) A copy of the agreement with the Medicaid agency required under § 1007.9;

(5) A statement of the procedures to be followed in carrying out the functions and responsibilities of this part;

(6) A projection of the caseload and a proposed budget for the 12-month period for which certification is sought; and

(7) Current and projected staffing, including the names, education, and experience of all senior professional staff already employed and job descriptions, with minimum qualifications, for all professional positions.

(b) *Conditions for, and notification of certification.* (1) The Secretary will approve an application only if he or she has specifically approved the applicant's formal procedures under § 1007.7 (b) or (c), if either of those provisions is applicable, and has specifically certified that the applicant meets the requirements of § 1007.7;

(2) The Secretary will promptly notify the applicant whether the application meets the requirements of this part and is approved. If the application is not approved, the applicant may submit an amended application at any time. Approval and certification will be for a period of 1 year.

(c) *Conditions for recertification.* In order to continue receiving payments under this part, a unit must submit a reapplication to the Secretary at least 60 days prior to the expiration of the 12-month certification period. A reapplication must—

(1) Advise the Secretary of any changes in the information or documentation required under paragraphs (a) (1) through (5) of this section;

(2) Provide projected caseload and proposed budget for the recertification period; and

(3) Include or reference the annual report required under § 1007.17.

(d) *Basis for recertification.* (1) The Secretary will consider the unit's reapplication, the reports required under § 1007.17, and any other reviews or information he or she deems necessary or warranted, and will promptly notify the unit whether he or she has approved the reapplication and recertified the unit.

(2) In reviewing the reapplication, the Secretary will give special attention to whether the unit has used its resources effectively in investigating cases of possible fraud, in preparing cases for prosecution, and in prosecuting cases or cooperating with the prosecuting authorities.

(Approved by the Office of Management and Budget under control number 0990–0162)

§ 1007.17 Annual report.

At least 60 days prior to the expiration of the certification period, the unit will submit to the Secretary a report covering the last 12 months (the first 9 months of the certification period for the first annual report), and containing the following information—

(a) The number of investigations initiated and the number completed or closed, categorized by type of provider;

(b) The number of cases prosecuted or referred for prosecution; the number of cases finally resolved and their outcomes; and the number of cases investigated but not prosecuted or referred for prosecution because of insufficient evidence;

(c) The number of complaints received regarding abuse and neglect of patients in health care facilities; the number of such complaints investigated by the unit; and the number referred to other identified State agencies;

(d) The number of recovery actions initiated by the unit; the number of recovery actions referred to another agency; the total amount of overpayments identified by the unit; and the total amount of overpayments actually collected by the unit;

(e) The number of recovery actions initiated by the Medicaid agency under its agreement with the unit, and the total amount of overpayments actually collected by the Medicaid agency under this agreement;

(f) Projections for the succeeding 12 months for items listed in paragraphs (a) through (e) of this section;

(g) The costs incurred by the unit; and

(h) A narrative that evaluates the unit's performance; describes any specific problems it has had in connection

with the procedures and agreements required under this part; and discusses any other matters that have impaired its effectiveness.

(Approved by the Office of Management and Budget under control number 0990–0162)

§ 1007.19 Federal financial participation (FFP).

(a) *Rate of FFP*. Subject to the limitation of this section, the Secretary will reimburse each State by an amount equal to 90 percent of the costs incurred by a certified unit which are attributable to carrying out its functions and responsibilities under this part.

(b) *Retroactive certification*. The Secretary may grant certification retroactive to the date on which the unit first met all the requirements of the statute and of this part. For any quarter with respect to which the unit is certified, the Secretary will provide reimbursement for the entire quarter.

(c) *Amount of FFP*. FFP for any quarter will not exceed the higher of $125,000 or one-quarter of 1 percent of the sums expended by the Federal, State, and local governments during the previous quarter in carrying out the State Medicaid program.

(d) *Costs subject to FFP*. (1) FFP is available under this part for the expenditures attributable to the establishment and operation of the unit, including the cost of training personnel employed by the unit. Reimbursement will be limited to costs attributable to the specific responsibilities and functions set forth in this part in connection with the investigation and prosecution of suspected fraudulent activities and the review of complaints of alleged abuse or neglect of patients in health care facilities.

(2) (i) Establishment costs are limited to clearly identifiable costs of personnel that—

(A) Devote full time to the establishment of the unit which does achieve certification; and

(B) Continue as full-time employees after the unit is certified.

(ii) All establishment costs will be deemed made in the first quarter of certification.

(e) *Costs not subject to FFP*. FFP is not available under this part for expenditures attributable to—

(1) The investigation of cases involving program abuse or other failures to comply with applicable laws and regulations, if these cases do not involve substantial allegations or other indications of fraud;

(2) Efforts to identify situations in which a question of fraud may exist, including the screening of claims, analysis of patterns of practice, or routine verification with recipients of whether services billed by providers were actually received;

(3) The routine notification of providers that fraudulent claims may be punished under Federal or State law;

(4) The performance by a person other than a full-time employee of the unit of any management function for the unit, any audit or investigation, any professional legal function, or any criminal, civil or administrative prosecution of suspected providers;

(5) The investigation or prosecution of cases of suspected recipient fraud not involving suspected conspiracy with a provider; or

(6) Any payment, direct or indirect, from the unit to the Medicaid agency, other than payments for the salaries of employees on detail to the unit.

§ 1007.21 Other applicable HHS regulations.

Except as otherwise provided in this part, the following regulations from 45 CFR subtitle A apply to grants under this part:

Part 16, subpart C—Department Grant Appeals Process—Special Provisions Applicable to Reconsideration of Disallowances [Note that this applies only to disallowance determinations and not to any other determinations, e.g., over certification or recertification];

Part 74—Administration of Grants;

Part 75—Informal Grant Appeals Procedures;

Part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services, Effectuation of title VI of the Civil Rights Act of 1964;

Part 81—Practice and Procedure for Hearings Under 45 CFR part 80;

Part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting From Federal Financial Assistance;

Part 91—Nondiscrimination on the Basis of Age in HHS Programs or Activities Receiving Federal Financial Assistance.

PART 1008—ADVISORY OPINIONS BY THE OIG

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AUTHORITY: 42 U.S.C. 1320a-7d(b).

SOURCE: 62 FR 7357, Feb. 19, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 1008.1 Basis and purpose.

(a) This part contains the specific procedures for the submission of requests by an individual or entity for advisory opinions to, and the issuance of advisory opinions by, the OIG, in consultation with the Department of Justice (DoJ), in accordance with section 1128D(b) of the Social Security Act (Act), 42 U.S.C. 1320a–7d(b). The OIG will issue such advisory opinions based on actual or proposed factual circumstances submitted by the requesting individual or entity, or by counsel on behalf of the requesting individual or entity, provided all other requirements of this part are satisfied (including the requirement that the requesting individual or entity provide the certifications required in accordance with § 1008.38 of this part).

(b) An individual or entity may request an advisory opinion from the OIG regarding any of five specific subject matters described in § 1008.5 of this part.

(c) The requesting party must provide a complete description of the facts as set forth in subpart B of this part, and pay the costs to the OIG of processing the request for an advisory opinion as set forth in subpart C of this part.

(d) Nothing in this part limits the investigatory or prosecutorial authority of the OIG, DoJ or any other agency of the Government.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38324, July 16, 1998]

§ 1008.3 Effective period.

The provisions in this part are applicable to requests for advisory opinions submitted on or after February 21, 1997, and before August 21, 2000, and to any requests submitted during any other time period for which the OIG is required by law to issue advisory opinions.

§ 1008.5 Matters subject to advisory opinions.

(a) An individual or entity may request an advisory opinion from the OIG regarding—

(1) What constitutes prohibited remuneration within the meaning of section 1128B(b) of the Act;

(2) Whether an arrangement, or proposed arrangement, satisfies the criteria set forth in section 1128B(b)(3) of the Act for activities that do not result in prohibited remuneration;

(3) Whether an arrangement, or proposed arrangement, satisfies the criteria set forth in § 1001.952 of this chapter for activities that do not result in prohibited remuneration;

(4) What constitutes an inducement to reduce or limit services under section 1128A(b) of the Act to Medicare or Medicaid program beneficiaries; and

(5) Whether any activity, or proposed activity, constitutes grounds for the imposition of a sanction under sections 1128, 1128A or 1128B of the Act.

(b) *Exceptions.* The OIG will not address through the advisory opinion process—

(1) What the fair market value will be, or whether fair market value was paid or received, for any goods, services or property; or

(2) Whether an individual is a bona fide employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38324, July 16, 1998]

Subpart B—Preliminary Obligations and Responsibilities of the Requesting Party

§ 1008.11 Who may submit a request.

Any individual or entity may submit a request to the OIG for an advisory opinion regarding an existing arrangement or one which the requestor in good faith specifically plans to undertake. The requestor must be a party to the arrangement, or proposed arrangement, that is the subject of the request.

§ 1008.15 Facts subject to advisory opinions.

(a) The OIG will consider requests from a requesting party for advisory opinions regarding the application of specific facts to the subject matters set forth in § 1008.5(a) of this part. The facts must relate to an existing arrangement, or one which the requestor in good faith plans to undertake. The plans may be contingent upon receiving a favorable advisory opinion. The advisory opinion request should contain a complete description of the arrangement that the requestor is undertaking, or plans to undertake.

(b) Requests presenting a general question of interpretation, posing a hypothetical situation, or regarding the activities of third parties do not qualify as advisory opinion requests.

(c) Advisory opinion request will not be accepted, and/or opinions will not be issued when—

(1) The request is not related to a named individual or entity;

(2) The same, or substantially the same, course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency; or

(3) An informed opinion cannot be made, or could be made only after extensive investigation, clinical study, testing, or collateral inquiry.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38324, July 16, 1998]

§ 1008.18 Preliminary questions suggested for the requesting party.

(a) The OIG may establish and maintain a set of questions corresponding to the categories of opinion subject matter as set forth in § 1008.5(a) of this part as appropriate. The questions will be designed to elicit specific information relevant to the advisory opinion being sought; however, answering the questions is voluntary.

(b) Questions the OIG suggests that the requestor address may be obtained from the OIG. Requests should be made in writing, specify the subject matter, and be sent to the headquarter offices of the OIG.

(c) When submitting a request for an advisory opinion, a requestor may answer the questions corresponding to

the subject matter for which the opinion is requested. The extent to which any of the questions is not fully answered may effect the content of the advisory opinion.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38324, July 16, 1998]

Subpart C—Advisory Opinion Fees

§ 1008.31 OIG fees for the cost of advisory opinions.

(a) *Responsibility for fees.* The requestor is responsible for paying a fee equal to the costs incurred by the Department in responding to the request for an advisory opinion.

(b) *Payment Method.* Payment for a request for an advisory opinion must be made to the Treasury of the United States, as directed by OIG.

(c) *Calculation of costs:* Prior to the issuance of the advisory opinion, the OIG will calculate the costs incurred by the Department in responding to the request. The calculation will include the costs of salaries and benefits payable to attorneys and others who have worked on the request in question, as well as administrative and supervisory support for such person. The OIG has the exclusive authority to determine the cost of responding to a request for an advisory opinion and such determination is not reviewable or waiveable.

(d) *Agreement to pay all costs.* (1) By submitting the request for an advisory opinion, the requestor agrees, except as indicated in paragraph (d)(4) of this section, to pay all costs incurred by the OIG in responding to the request for an advisory opinion.

(2) In its request for an advisory opinion, the requestor may request a written estimate of the cost involved in processing the advisory opinion. Within 10 business days of receipt of the request, the OIG will notify in writing of such estimate. Such estimate will not be binding on the Department, and the actual cost to be paid may be higher or lower than estimated. The time period for issuing the advisory opinion will be tolled from the time the OIG notifies the requestor of the estimate until the OIG receives written confirmation from the requestor that the requestor wants the OIG to continue processing the request. Such notice may include a new or revised triggering dollar amount, as set forth in paragraph (d)(3) of this section.

(3) In its request for an advisory opinion, the requestor may designate a triggering dollar amount. If the OIG estimates that the costs of processing the advisory opinion request have reached, or are likely to exceed, the designated triggering dollar amount, the OIG will notify the requestor. The requestor may revise its designated triggering dollar amount in writing in its response to notification of a cost estimate in accordance with paragraph (d)(2) of this section.

(4) If the OIG notifies the requestor that the estimated cost of processing the request has reached or is likely to exceed the triggering dollar amount, the OIG will stop processing the request until such time as the requestor makes a written request for the OIG to continue processing the request. Any delay in the processing of the request for an advisory opinion attributable to these procedures will toll the time for issuance of an advisory opinion until the requestor asks the OIG to continue working on the request.

(5) If the requestor chooses not to pay for completion of an advisory opinion, or withdraws the request, the requestor is still obligated to pay for all costs incurred and identified by the OIG attributable to processing the request for an advisory opinion up to that point.

(6) If the costs incurred by the OIG in responding to the request are greater than the amount paid by the requestor, the OIG will, prior to the issuance of the advisory opinion, notify the requestor of any additional amount due. The OIG will not issue an advisory opinion until the full amount owed by the requestor has been paid. Once the requestor has paid the OIG the total amount due for the costs of processing the request, the OIG will issue the advisory opinion. The time period for issuing advisory opinions will be tolled from the time the OIG notifies the requestor of the amount owed until the time full payment is received.

(e) *Fees for outside experts.* (1) In addition to the fees identified in this section, the requestor also must pay any

required fees for expert opinions, if any, from outside sources, as described in § 1008.33.

(2) If the OIG determines that it is necessary to obtain expert advice to issue a requested advisory opinion, the OIG will notify the requestor of that fact and provide the identity of the appropriate expert and an estimate of the costs of the expert advice.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38324, July 16, 1998; 73 FR 15939, Mar. 26, 2008]

§ 1008.33 Expert opinions from outside sources.

(a) The OIG may request expert advice from qualified sources on nonlegal issues if necessary to respond to the advisory opinion request. For example, the OIG may require the use of appropriate medical reviewers, such as quality improvement organizations, to obtain medical opinions on specific issues.

(b) The time period for issuing an advisory opinion will be tolled from the time that the OIG notifies the requestor of the need for an outside expert opinion until the time the OIG receives the necessary expert opinion.

(c) Once payment is made for the cost of the expert opinion, as set forth in § 1008.31(e) of this part, either directly to the expert or otherwise, the OIG will arrange for a prompt expert review of the issue or issues in question. Regardless of the manner of payment, the expert's work and opinion will be subject to the sole direction of the OIG.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38325, July 16, 1998]

Subpart D—Submission of a Formal Request for an Advisory Opinion

§ 1008.36 Submission of a request.

(a) A request for a formal advisory opinion must be submitted in writing. An original and 2 copies of the request should be addressed to the headquarter offices of the OIG.

(b) Each request for an advisory opinion must include—

(1) To the extent known to the requestor, the identities, including the names and addresses, of the requestor and of all other actual and potential parties to the arrangement, that are the subject of the request for an advisory opinion;

(2) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request for an advisory opinion with the OIG on behalf of the requestor;

(3) A declaration of the subject category or categories as described in § 1008.5 of this part for which the advisory opinion is requested. To the extent an individual or entity requests an advisory opinion in accordance with §§ 1008.5(a)(3) or (a)(5) of this part, the requesting individual or entity should identify the specific subsections of sections 1128, 1128A or 1128B of the Act or the specific provision of § 1001.952 of this chapter about which an advisory opinion is sought:

(4) A complete and specific description of all relevant information bearing on the arrangement for which an advisory opinion is requested and on the circumstances of the conduct,[1] including—

(i) Background information,

(ii) For existing arrangements, complete copies of all operative documents,

(iii) For proposed arrangements, complete copies of all operative documents, if possible, and otherwise descriptions of proposed terms, drafts, or models of documents sufficient to permit the OIG to render an informed opinion,

(iv) Detailed statements of all collateral or oral understandings, if any, and

(v) If applicable, a designation of trade secrets or confidential commercial or financial information in the manner described in 45 CFR 5.65;

(5) Signed certifications by the requestor(s), as described in § 1008.37 of this part;

(6) A declaration regarding whether an advisory opinion in accordance with part 411 of this title has been or will be requested from CMS about the arrangement that is the subject of the advisory opinion request; and

[1] The requestor is under an affirmative obligation to make full and true disclosure with respect to the facts regarding the advisory opinion being requested.

(7) Each requesting party's Taxpayer Identification Number.

(Approved by the Office of Management and Budget under control number 0990–0213)

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38325, July 16, 1998; 73 FR 15939, Mar. 26, 2008]

§ 1008.37 Disclosure of ownership and related information.

Each individual or entity requesting an advisory opinion must supply full and complete information as to the identity of each entity owned or controlled by the individual or entity, and of each person with an ownership or control interest in the entity, as defined in section 1124(a)(1) of the Social Security Act (42 U.S.C. 1320a–3(a)(1)) and part 420 of this chapter.

(Approved by the Office of Management and Budget under control number 0990–0213)

[67 FR 11936, Mar. 18, 2002]

§ 1008.38 Signed certifications by the requestor.

(a) Every request must include the following signed certification from all requestors: ''With knowledge of the penalties for false statements provided by 18 U.S.C. 1001 and with knowledge that this request for an advisory opinion is being submitted to the Department of Health and Human Services, I certify that all of the information provided is true and correct, and constitutes a complete description of the facts regarding which an advisory opinion is sought, to the best of my knowledge and belief.''

(b) If the advisory opinion relates to a proposed arrangement, the request must also include the following signed certification from all requestors: ''The arrangement described in this request for an advisory opinion is one that [the requestor(s)] in good faith plan(s) to undertake.'' This statement may be made contingent on a favorable OIG advisory opinion, in which case, the phrase ''if the OIG issues a favorable advisory opinion'' should be added to the certification.

(c) The certification(s) must be signed by—

(1) The requestor, if the requestor is an individual;

(2) The chief executive officer, or comparable officer, of the requestor, if the requestor is a corporation;

(3) The managing partner of the requestor, if the requestor is a partnership; or

(4) The managing member, or comparable person, if the requestor is a limited liability company.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38325, July 16, 1998]

§ 1008.39 Additional information.

(a) If the request for an advisory opinion does not contain all of the information required by § 1008.36 of this part, or the OIG believes it needs more information prior to rendering an advisory opinion, the OIG may, at any time, request whatever additional information or documents it deems necessary. The time period for the issuance of an advisory opinion will be tolled from the time the OIG requests the additional information from the requestor until such time as the OIG determines that it has received the requested information.

(b) The OIG may request additional information before or after the request for an advisory opinion has been accepted.

(c) Additional information should be provided in writing and certified to be a true, correct and complete disclosure of the requested information in a manner equivalent to that described in § 1008.38 of this part.

(d) In connection with any request for an advisory opinion, the OIG or DoJ may conduct whatever independent investigation they believe appropriate.

(e) Requesting parties are required to notify the OIG if they request an advisory opinion in accordance with part 411 of this title from CMS about the arrangement that is the subject of their advisory opinion request.

(f) Where appropriate, after receipt of an advisory opinion request, the OIG may consult with the requesting parties to the extent the OIG deems necessary.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38325, July 16, 1998]

§ 1008.40 Withdrawal.

The requestor of an advisory opinion may withdraw the request prior to the issuance of a formal advisory opinion by the OIG. The withdrawal must be written and must be submitted to the same address as the submitted request, as indicated in §§ 1008.18(b) and 1008.36(a) of this part. Regardless of whether the request is withdrawn, the requestor must pay the costs expended by the OIG in processing the opinion, as discussed in § 1008.31(d) of this part. The OIG reserves the right to retain any request for an advisory opinion, documents and information submitted to it under these procedures, and to use them for any governmental purposes.

Subpart E—Obligations and Responsibilities of the OIG

§ 1008.41 OIG acceptance of the request.

(a) Upon receipt of a request for an advisory opinion, the OIG will promptly make an initial determination whether the submission includes all of the information the OIG will require to process the request.

(b) Within 10 working days of receipt of the request, the OIG will—

(1) Formally accept the request for an advisory opinion,

(2) Notify the requestor of what additional information is needed, or

(3) Formally decline to accept the request.

(c) If the requestor provides the additional information requested, or otherwise resubmits the request, the OIG will process the resubmission in accordance with paragraphs (a) and (b) of this section as if it was an initial request for an advisory opinion.

(d) Upon acceptance of the request, the OIG will notify the requestor by regular U.S. mail of the date that the request for the advisory opinion was formally accepted.

(e) The 60-day period for issuance of an advisory opinion set forth in § 1008.43(c) of this part will not commence until the OIG has formally accepted the request for an advisory opinion.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38326, July 16, 1998]

§ 1008.43 Issuance of a formal advisory opinion.

(a) An advisory opinion will be considered issued once payment is received and it is dated, numbered, and signed by an authorized official of the OIG.

(b) An advisory opinion will contain a description of the material facts provided to the OIG with regard to the arrangement for which an advisory opinion has been requested. The advisory opinion will state the OIG's opinion regarding the subject matter of the request based on the facts provided to the OIG. If necessary, to fully describe the arrangement, the OIG is authorized to include in the advisory opinion the material facts of the arrangement, notwithstanding that some of these facts could be considered confidential information or trade secrets within the meaning of 18 U.S.C. 1905.

(c)(1) The OIG will issue an advisory opinion, in accordance with the provisions of this part, within 60 days after the request for an advisory opinion has been formally accepted;

(2) If the 60th day falls on a Saturday, Sunday, or Federal holiday, the time period will end at the close of the next business day following the weekend or holiday;

(3) The 60 day period will be tolled from the time the OIG—

(i) Notifies the requestor that the costs have reached, or are likely to exceed, the triggering amount until the time when the OIG receives written notice from the requestor to continue processing the request;

(ii) Requests additional information from the requestor until the time the OIG receives the requested information;

(iii) Notifies the requestor of the full amount due until the time the OIG receives payment of the full amount owed; and

(iv) Notifies the requestor of the need for expert advice until the time the OIG receives the expert advice.

(d) After OIG has notified the requestor of the full amount owed and OIG has determined that the full payment of that amount has been properly paid by the requestor, OIG will issue the advisory opinion and promptly

mail it to the requestor by regular first class U.S. mail.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38326, July 16, 1998; 73 FR 15939, Mar. 26, 2008]

§ 1008.45 Rescission, termination or modification.

(a) Any advisory opinion given by the OIG is without prejudice to the right of the OIG to reconsider the questions involved and, where the public interest requires, to rescind, terminate or modify the advisory opinion. Requestors will be given a preliminary notice of the OIG's intent to rescind, terminate or modify the opinion, and will be provided a reasonable opportunity to respond. A final notice of rescission, termination or modification will be given to the requestor so that the individual or entity may discontinue or modify, as the case may be, the course of action taken in accordance with the OIG advisory opinion.

(b) For purposes of this part—

(1) To *rescind* an advisory opinion means that the advisory opinion is revoked retroactively to the original date of issuance with the result that the advisory opinion will be deemed to have been without force and effect from the original date of issuance. Recission may occur only where relevant and material facts were not fully, completely and accurately disclosed to the OIG.

(2) To *terminate* an advisory opinion means that the advisory opinion is revoked as of the termination date and is no longer in force and effect after the termination date. The OIG will not proceed against the requestor under this part if such action was promptly, diligently, and in good faith discontinued in accordance with reasonable time frames established by the OIG after consultation with the requestor.

(3) To *modify* an advisory opinion means that the advisory opinion is amended, altered, or limited, and that the advisory opinion continues in full force and effect in modified form thereafter. The OIG will not proceed against the requestor under this part if such action was promptly, diligently, and in good faith modified in accordance with reasonable time frames established by the OIG after consultation with the requestor.

[63 FR 38326, July 16, 1998]

§ 1008.47 Disclosure.

(a) Advisory opinions issued and released in accordance with the provisions set forth in this part will be available to the public.

(b) Promptly after the issuance and release of an advisory opinion to the requestor, a copy of the advisory opinion will be available for public inspection between the hours of 10:00 a.m. and 3:00 p.m. on normal business days at the headquarter offices of the OIG and on the DHHS/OIG web site.

(c) Any pre-decisional document, or part of such pre-decisional document, that is prepared by the OIG, DoJ, or any other Department or agency of the United States in connection with an advisory opinion request under the procedures set forth in this part generally will be exempt from disclosure under 5 U.S.C. 552, and will not be made publicly available.

(d) Documents submitted by the requestor to the OIG in connection with a request for an advisory opinion may be available to the public in accordance with 5 U.S.C. 552 through procedures set forth in 45 CFR part 5.

(e) Nothing in this section will limit the OIG's right, in its discretion, to issue a press release or otherwise publicly disclose the identity of the requesting party or parties, and the nature of the action taken by the OIG upon the request.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38326, July 16, 1998]

Subpart F—Scope and Effect of OIG Advisory Opinions

§ 1008.51 Exclusivity of OIG advisory opinions.

The only method for obtaining a binding advisory opinion regarding any of the subject matters set forth in § 1008.5(a) is through the procedures described in this part. No binding advisory opinion, oral or written, has or may be issued by the OIG regarding the specific matters set forth in § 1008.5(a) except through written opinions issued in accordance with this part.

§ 1008.53 Affected parties.

An advisory opinion issued by the OIG will have no application to any individual or entity that does not join in the request for the opinion. No individual or entity other than the requestor(s) may rely on an advisory opinion.

§ 1008.55 Admissibility of evidence.

(a) The failure of a party to seek an advisory opinion may not be introduced into evidence to prove that the party intended to violate the provisions of sections 1128, 1128A or 1128B of the Act.

(b) An advisory opinion may not be introduced into evidence by a person or entity that was not the requestor of the advisory opinion to prove that the person or entity did not violate the provisions of sections 1128, 1128A or 1128B of the Act or any other law.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38326, July 16, 1998]

§ 1008.59 Range of the advisory opinion.

(a) An advisory opinion will state only the OIG's opinion regarding the subject matter of the request. If the arrangement for which an advisory opinion is requested is subject to approval or regulation by any other Federal, State or local government agency, such advisory opinion may not be taken to indicate the OIG's views on the legal or factual issues that may be raised before that agency. The OIG will not provide any legal opinion on questions or issues regarding an authority which is vested in other Federal, State or local government agencies.

(b) An advisory opinion issued under this part will not bind or obligate any agency other than the Department. It will not affect the requestor's, or anyone else's, obligations to any other agency, or under any statutory or regulatory provision other than that which is the specific subject matter of the advisory opinion.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38326, July 16, 1998]

FINDING AIDS

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Table of OMB Control Numbers

The OMB control numbers for chapter IV of title 42 appear in § 400.310. Sections 400.300 and 400.310 are reprinted below for the convenience of the user.

Subpart C—OMB Control Numbers for Approved Collections of Information

SOURCE: 49 FR 4477, Feb. 7, 1984, unless therwise noted.

§ 400.300 Scope.

This subpart collects and displays control numbers assigned by the Office of Management and Budget (OMB) to collections of information contained in CMS regulations, in accordance with OMB's regulations for controlling paperwork burdens on the public, 5 CFR part 1320. CMS intends that the subpart comply with the requirements of section 3507(f) of the Paperwork Reduction Act of 1980, 44 U.S.C. chapter 35 which requires that agencies shall not engage in a ''collection of information'' without obtaining a control number from OMB.

§ 400.310 Display of currently valid OMB control numbers.

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