Medicare and Medicaid; Requirements for Long Term Care Facilities
Final Regulations
Department of Health and Human Services, Health Care Financing Administration,
Final Rule, 42 CFR Parts 442, 447, 483, 488, 489, and 498, September 26, 1991

The Health Care Financing Administration (HCFA) has published final regulations regarding "Medicare and Medicaid; Requirements for Long Term Care Facilities (LTCFs)." The final regulations revise the current LTCF requirements to reflect the comments received by HCFA regarding the release of its February 2, 1989 rule. The new regulations also serve to incorporate the statutory provisions that were not in effect when the February 2, 1989 requirements were issued. Additionally, the final rule reflects several changes in the requirements made by the 1990 Omnibus Budget Reconciliation Act (OBRA '90).

This Special Bulletin is an excerpt from the rule which encompasses the entire set of requirements for LTCFs, including a one-page listing of the provisions. Significant requirements for long term care pharmacy include provisions regarding Pharmacy Services (drug regimen review), Quality of Care (drug therapy), Resident Rights (self-administration of drugs), Resident Assessment (preadmission screening for mentally ill individuals and individuals with mental retardation), and Infection Control.

Also excerpted from the rule are the "Conditions for Payment for Nursing Facility and Intermediate Care Facility Services for the Mentally Retarded." These provisions outline the requirements for provider agreements and facility certification regarding the services furnished by nursing facilities and intermediate care facilities for the mentally retarded.

The new LTCF requirements become effective April 1, 1992 and preclude all the provisions of the former rule.

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PART 442—CONDITIONS FOR PAYMENT FOR NURSING FACILITY AND INTERMEDIATE CARE FACILITY SERVICES FOR THE MENTALLY RETARDED

A. Part 442 is amended as follows:

1. The authority citation for part 442 continues to read as follows:
   Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1392), unless otherwise noted.

2. In subpart A, § 442.1, paragraph (a) is revised to read as follows:

\[\text{Subpart A—General Provisions}\]

§ 442.1 Basis and purpose.
(a) This part states requirements for provider agreements and facility certification relating to the provision of services furnished by nursing facilities and intermediate care facilities for the mentally retarded. This part is based on the following sections of the Act:

Section 1902(a)(4), administrative methods for proper and efficient operation of the State plan;
Section 1902(a)(27), provider agreements;
Section 1902(a)(28), skilled nursing facility standards;
Section 1902(a)(33)(B), State survey agency functions;
Section 1902(i), circumstances and procedures for denial of payment and termination of provider agreements in certain situations;
Section 1905(c) and (d), definition of intermediate care facility services;
Section 1905(f) and (i), definition of skilled nursing facility services;
Section 1910, certification and approval of SNFs and of ICFs.
Section 1913, hospital providers of skilled nursing and intermediate care services; and
Section 1922, correction and reduction plans for intermediate care facilities for the mentally retarded.

* * * * *

4. In subpart A, § 442.2 the definition of “Facility,” is revised as follows:
§ 442.2 Terms.

In this part—

Facility refers to a nursing facility, and an intermediate care facility for the mentally retarded or persons with related conditions (ICF/MR).

* * * * *

5. In subpart B, § 442.12(a) is revised to read as follows:
§ 442.12 Provider agreement: General Requirements.
(a) Certification and recertification. Except as provided in paragraph (b) of this section, a Medicaid agency may not execute a provider agreement with a facility for nursing facility services nor make Medicaid payments to a facility for those services unless the Secretary or the State survey agency has certified the facility under this part to provide those services. (See § 442.101 for certification by the Secretary or by the State survey agency).

6. Section 442.13 (b) and (c)(2) are revised to read as follows:
§ 442.13 Effective date of agreement.

(b) All Federal requirements are met on the date of the survey. The agreement must be effective on the date the onsite survey is completed (or on the day following the expiration of a current agreement) if, on the date of the survey the provider meets all Federal requirements and any other requirements imposed by the Medicaid agency.

(c) * * *

(2) The date on which a NF or an ICF/MR is found to meet all conditions of participation, and the facility submits an acceptable correction plan for lower level deficiencies, or an approvable waiver request, or both.

* * * * *

§ 442.20 [Removed]

6a. Section 442.20 is removed.

7. In subpart B, § 442.30(a) introductory text and paragraph (a)(1) are revised to read as follows:
§ 442.30 Agreement as evidence of certification.

(a) Under §§ 440.40(a) and 440.150 of this chapter, FFP is available in expenditures for NF and ICF/MR services only if the facility has been certified as meeting the requirements for Medicaid participation, as evidenced by a provider agreement executed under this part. An agreement is not valid evidence that a facility has met those requirements if HCFA determines that—
(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 results must be made available for examination by the facility in a place readily accessible to residents; and

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

(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 overhead.

(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 transfer. (1) An individual has the right to refuse a transfer to another room within the facility, if the purpose of the transfer is to relocate—

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

(ii) If a resident of a NF from the distinct part of the facility that is a NF to a distinct part of the facility 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 Medicaid benefits.

§ 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—
(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 individuals 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 NF 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.**

§ 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, assessment, 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 grievances and recommendations of residents and families concerning proposed policy and operational decisions affecting resident care and life in the facility;
7. **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.

(d) **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 is—
     A. Licensed or registered, if applicable, by the State in which practicing; and
   - (ii) **Eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on October 1, 1990; or**
   - (iii) **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**
   - (iv) 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)(20)(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 70–80°F; and**
7. **For the maintenance of comfortable sound levels.**

§ 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. **The facility must make a comprehensive assessment of a resident's needs, which—**
   - (i) Is based on a uniform data set specified by the Secretary and uses an instrument that is specified by the State and approved by the Secretary; and
(ii) Describes the resident’s capability to perform daily life functions and significant impairments in functional capacity.

(2) The comprehensive assessment must include at least the following information:

(i) Medically defined conditions and prior medical history;
(ii) Medical status measurement;
(iii) Physical and mental functional status;
(iv) Sensory and physical impairments;
(v) Nutritional status and requirements;
(vi) Special treatments or procedures;
(vii) Mental and psychosocial status;
(viii) Disability potential;
(ix) Dental condition;
(x) Activities potential;
(xi) Rehabilitation potential;
(xii) Cognitive status; and
(xiii) Drug therapy.

(3) [Reserved]

(4) Frequency. Assessments must be conducted:

(i) No later than 14 days after the date of admission;
(ii) For current NF residents not later than October 1, 1991;
(iii) For current SNF residents not later than January 1, 1991;
(iv) Promptly after a significant change in the resident’s physical or mental condition; and
(v) In no case less often than once every 12 months.

(5) Review of assessments. The nursing facility must examine each resident no less often than once every 3 months, and as appropriate, revise the resident’s assessment to assure the continued accuracy of the assessment.

(6) Use. The results of the assessment are used to develop, review, and revise the resident’s comprehensive plan of care under paragraph (d) of this section.

(7) Coordination. The facility must coordinate assessments with any State-required preadmission screening program to the maximum extent practicable to avoid duplicative testing and effort.

(8) Accuracy of assessments. (1) Coordination. (i) Each assessment must be conducted or coordinated with the appropriate participation of health professionals.

(ii) Each assessment must be conducted or coordinated by a registered nurse who signs and certifies the completion of the assessment.

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

(3) Penalty for Falsification. An individual who willfully and knowingly certifies (or causes another individual to certify) a material and false statement in a resident assessment is subject to civil money penalties. The implementing regulations for this statutory authority are located in Part 1003 of this chapter.

(4) Use of independent assessors. If a State determines, under a survey or otherwise, that there has been a knowing and willful certification of false statements under paragraph (c)(3) of this section, the State may require (for a period specified by the State) that resident assessments under this paragraph be conducted and certified by individuals who are independent of the facility and who are approved by the State.

(d) 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 plan of care must deal with the relationship of items or services ordered to be provided (or withheld) to the facility’s responsibility for fulfilling other requirements in these regulations.

(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.

(c) Discharge summary. When the facility anticipates discharges 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.

(f) 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 specialized services the individual requires active treatment for mental illness; 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 active treatment 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 435.1009.

§ 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 function.

(h) Accidents. The facility must ensure that—

(1) The resident environment remains 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, urostomy, or ileostomy care;
(4) Tracheostomy care;
(5) Tracheal suctioning;
(6) Respiratory care;
(7) Foot care; and
(8) Prostheses.

(l) Unnecessary drug. Each resident’s drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:
(1) In excessive dose (including duplicate drug therapy); or
(2) For excessive duration; or
(3) Without adequate monitoring; or
(4) Without adequate indications for its use; or
(5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
(6) 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.

§ 483.28 and 483.29 [Removed]

4. Sections 483.28 and 483.29 are removed.

5. In Subpart B, §§ 483.30, 483.35, 483.40, 483.45, 483.46, 483.60, 483.65, 483.70 and 483.75 are revised as follows:

§ 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 American 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.

§ 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 meal times 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) 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.

§§ 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.
(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 (c) 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.
§ 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 health rehabilitative services for mental
   illness and mental retardation, are required in the resident’s compre-
   hensive 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(j) 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 person-
   nel.
§ 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
   (u) 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.
§ 483.60 Pharmacy services.
The facility must provide routine and emergency drugs and
biologics to its residents, or obtain them under an agreement
described in § 483.75(h) of this part. The facility may permit unli-
censed 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 biologics) 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 reconcilia-
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 biologics. Drugs and biologics used
in the facility must be labeled in accordance with currently accepted
professional principles, and including the appropriate accessory and
cautionary instructions, and the expiration date when applicable.
(e) Storage of drugs and biologics.
(1) In accordance with State and Federal laws, the facility must
store all drugs and biologics 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.
§ 483.65 Infusion control.
The facility must establish and maintain an infusion control
program designed to provide a safe, sanitary, and comfortable envi-
ronment and to help prevent the development and transmission of
disease and infection.
(a) Infusion control program. The facility must establish an
infusion control program under which it—
(1) Investigates, controls, and prevents infections in the facility;
(2) Directs 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.
in judging 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 nurse aides—

(1) General rule. Effective October 1, 1990, a facility must not use any individual working in the facility as a nurse aide for more than 4 months, on a full-time temporary, per diem, or other basis, unless—

(i) That individual has completed a training and competency evaluation program, or a competency evaluation program approved by the State, and

(ii) That individual is competent to provide nursing and nursing-related services.

(2) Rule for non-full-time employees. A facility may not use an individual as a nurse aide on a temporary, per diem, leased, or any basis other than a permanent employee after January 1, 1991 unless the individual meets the requirements in paragraph (e)(1)(i) and (ii) of this section.

(3) Competency evaluation programs for current employees. A facility must provide, for individuals used as nurse aides as of January 1, 1990, a competency evaluation program approved by the State, and preparation necessary for the individual to complete the program by October 1, 1990.

(4) Competency. Effective October 1, 1990, a facility may permit an individual to serve as a nurse aide or provide services of a type for which the individual has not demonstrated competence only when—

(i) The individual is in a training or competency evaluation program approved by the State; and

(ii) The facility has asked and not yet evaluated a reply from the State registry for information concerning the individual.

(5) State nurse aide registry checks. A facility must check with all State nurse aide registries if it has reason to believe contain information on an individual before using that individual as a nurse aide.

(6) Required retraining. When an individual has not performed paid nursing or nursing-related services for a continuous period of 24 consecutive months since the most recent completion of a training and competency evaluation program, the facility must require the individual to complete a new training and competency evaluation program.

(7) Regular in-service education. The facility must provide regular performance review and regular in-service education to ensure that individuals used as nurse aides are competent to perform services as nurse aides. In-service education must include training for individuals providing nursing and nursing-related services to residents with cognitive impairments.

(8) Definition of nurse aide. For purposes of this section, the term, nurse aide, means any individual providing nursing or nursing-related services to residents in a facility. This definition does not include an individual who volunteers to provide such services without pay, who is a registered dietitian, or who is a licensed health professional.

(9) Definition of licensed health professional. For purposes of this section, the term "licensed health professional" means a physician; physician assistant; nurse practitioner; physical, speech, or occupational therapy assistant; registered professional nurse; licensed practical nurse; or licensed or certified social worker.

(I) 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 an agreement described in paragraph (b)(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—

(/) Implementation of resident care policies; and

(j) Laboratory services. (1) The facility must provide or obtain clinical 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 conditions for coverage of the services furnished by laboratories specified in part 493 of this chapter;

(ii) If the facility provides blood bank and transfusion services, it must meet the 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 approved or licensed to test specimens in the appropriate specialties and/or subspecialties of service in accordance with 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 only from a laboratory that meets the requirements of part 493 of this chapter or from a physician's office.

(2) The facility must—

(i) Provide or obtain laboratory services only when ordered by the attending physicians;

(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.

(iv) File in the resident's clinical record laboratory reports that are dated and contain the name and address of the issuing 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—