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EFFECTIVE DATE NOTES: 2. At 84 FR 51823, Sept. 30, 2019, §482.102 was further amended by revising paragraph (a)(5), effective Nov. 29, 2019. For the convenience of the user, the added and revised text is set forth as follows:

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

* * * * *

(a) * * *

(5) National and transplant program-specific outcomes, from the most recent SRTR program-specific report, including (but not limited to) the transplant program's observed and expected 1-year patient and graft survival, and national 1-year patient and graft survival;

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§ 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.

EFFECTIVE DATE NOTE: At 84 FR 51822, Sept. 30, 2019, §482.104 was amended by removing the words "transplant center" and "transplant centers" in each place they appear and adding in their place the words "transplant program" and "transplant programs", respectively, effective Nov. 29, 2019.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

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AUTHORITY: 42 U.S.C. 1302, 1320a-7, 1395i, 1395hh and 1396r.

EFFECTIVE DATE NOTE: At 84 FR 51824, Sept. 30, 2019, part 483 was amended by revising the authority citation, effective Nov. 29, 2019.

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), (d), and (f) 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.

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(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), (d), and (f) of the Act provide that nursing facilities participating in Medicaid must meet certain specific requirements.

(4) Sections 1128I(b) and (c) require that—

(i) Skilled nursing facilities or nursing facility have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations.

(ii) The Secretary establish and implement a quality assurance and performance improvement program for facilities, including multi-unit chains of facilities.

(5) Section 1150B establishes requirements for reporting to law enforcement crimes occurring in federally funded LTC facilities.

(b) *Scope.* The provisions of this part contain the requirements that an institution must meet in order to qualify to participate as a Skilled Nursing Facility 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; 81 FR 68848, Oct. 4, 2016]

§ 483.5 Definitions.

As used in this subpart, the following definitions apply:

Abuse. Abuse is the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. Abuse also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. Instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through the use of technology. *Willful,*

as used in this definition of abuse, means the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm.

Adverse event. An adverse event is an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof.

Common area. Common areas are areas in the facility where residents may gather together with other residents, visitors, and staff or engage in individual pursuits, apart from their residential rooms. This includes but is not limited to living rooms, dining rooms, activity rooms, outdoor areas, and meeting rooms where residents are located on a regular basis.

Composite distinct part—(1) Definition. A composite distinct part is a distinct part consisting of two or more non-contiguous 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 specified in the definition of “distinct part” 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.

(v) Use of composite distinct parts to segregate residents by payment source or on a basis other than care needs is prohibited.

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 (2) of this definition, 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 comprise 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 with the main buildings but are located within close proximity to 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 specified in the definition of "composite distinct part" 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.

Exploitation. Exploitation means taking advantage of a resident for personal gain through the use of manipulation, intimidation, threats, or coercion.

Facility. 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 individuals with intellectual disabilities 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.

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.

Licensed health professional. A licensed health professional is 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; or registered respiratory therapist or certified respiratory therapy technician.

Major modification means the modification of more than 50 percent, or more than 4,500 square feet, of the smoke compartment.

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.

Mistreatment means inappropriate treatment or exploitation of a resident.

Neglect is the failure of the facility, its employees or service providers to provide goods and services to a resident that are necessary to avoid physical

harm, pain, mental anguish, or emotional distress.

Nurse aide. A nurse aide is any individual providing nursing or nursing-related services to residents in a facility. This term may also include an individual who provides these services through an agency or under a contract with the facility, but 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.

Person-centered care. For purposes of this subpart, person-centered care means to focus on the resident as the locus of control and support the resident in making their own choices and having control over their daily lives.

Resident representative. For purposes of this subpart, the term resident representative means any of the following:

(1) An individual chosen by the resident to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications;

(2) A person authorized by State or Federal law (including but not limited to agents under power of attorney, representative payees, and other fiduciaries) to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications;

(3) Legal representative, as used in section 712 of the Older Americans Act; or

(4) The court-appointed guardian or conservator of a resident.

(5) Nothing in this rule is intended to expand the scope of authority of any resident representative beyond that authority specifically authorized by the resident, State or Federal law, or a court of competent jurisdiction.

Sexual abuse is non-consensual sexual contact of any type with a resident.

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.

[68 FR 46071, Aug. 4, 2003, as amended at 71 FR 39229, July 12, 2006; 71 FR 55340, Sept. 22, 2006; 79 FR 27155, May 12, 2014; 81 FR 68848, Oct. 4, 2016; 82 FR 32259, July 13, 2017]

§ 483.10 Resident rights.

(a) *Residents 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, including those specified in this section.

(1) A facility must treat each resident with respect and dignity and care for each resident in a manner and in an environment that promotes maintenance or enhancement of his or her quality of life, recognizing each resident's individuality. The facility must protect and promote the rights of the resident.

(2) The facility must provide equal access to quality care regardless of diagnosis, severity of condition, or payment source. A facility must establish and maintain identical policies and practices regarding transfer, discharge, and the provision of services under the State plan for all residents regardless of payment source.

(b) *Exercise of rights.* 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.

(1) The facility must ensure that the resident can exercise his or her rights without interference, coercion, discrimination, or reprisal from the facility.

(2) The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights and to be supported by the facility in the exercise of his or her rights as required under this subpart.

(3) In the case of a resident who has not been adjudged incompetent by the state court, the resident has the right to designate a representative, in accordance with State law and any legal surrogate so designated may exercise the resident's rights to the extent provided by state law. The same-sex spouse of a resident must be afforded

treatment equal to that afforded to an opposite-sex spouse if the marriage was valid in the jurisdiction in which it was celebrated.

(i) The resident representative has the right to exercise the resident's rights to the extent those rights are delegated to the resident representative.

(ii) The resident retains the right to exercise those rights not delegated to a resident representative, including the right to revoke a delegation of rights, except as limited by State law.

(4) The facility must treat the decisions of a resident representative as the decisions of the resident to the extent required by the court or delegated by the resident, in accordance with applicable law.

(5) The facility shall not extend the resident representative the right to make decisions on behalf of the resident beyond the extent required by the court or delegated by the resident, in accordance with applicable law.

(6) If the facility has reason to believe that a resident representative is making decisions or taking actions that are not in the best interests of a resident, the facility shall report such concerns in the manner required under State law.

(7) 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 devolve to and are exercised by the resident representative appointed under State law to act on the resident's behalf. The court-appointed resident representative exercises the resident's rights to the extent judged necessary by a court of competent jurisdiction, in accordance with State law.

(i) In the case of a resident representative whose decision-making authority is limited by State law or court appointment, the resident retains the right to make those decision outside the representative's authority.

(ii) The resident's wishes and preferences must be considered in the exercise of rights by the representative.

(iii) To the extent practicable, the resident must be provided with opportunities to participate in the care planning process.

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(c) *Planning and implementing care.* The resident has the right to be informed of, and participate in, his or her treatment, including:

(1) 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.

(2) The right to participate in the development and implementation of his or her person-centered plan of care, including but not limited to:

(i) The right to participate in the planning process, including the right to identify individuals or roles to be included in the planning process, the right to request meetings and the right to request revisions to the person-centered plan of care.

(ii) The right to participate in establishing the expected goals and outcomes of care, the type, amount, frequency, and duration of care, and any other factors related to the effectiveness of the plan of care.

(iii) The right to be informed, in advance, of changes to the plan of care.

(iv) The right to receive the services and/or items included in the plan of care.

(v) The right to see the care plan, including the right to sign after significant changes to the plan of care.

(3) The facility shall inform the resident of the right to participate in his or her treatment and shall support the resident in this right. The planning process must—

(i) Facilitate the inclusion of the resident and/or resident representative.

(ii) Include an assessment of the resident's strengths and needs.

(iii) Incorporate the resident's personal and cultural preferences in developing goals of care.

(4) The right to be informed, in advance, of the care to be furnished and the type of care giver or professional that will furnish care.

(5) The right to be informed in advance, by the physician or other practitioner or professional, of the risks and benefits of proposed care, of treatment and treatment alternatives or treatment options and to choose the alternative or option he or she prefers.

(6) The right to request, refuse, and/or discontinue treatment, to partici-

pate in or refuse to participate in experimental research, and to formulate an advance directive.

(7) The right to self-administer medications if the interdisciplinary team, as defined by § 483.21(b)(2)(ii), has determined that this practice is clinically appropriate.

(8) Nothing in this paragraph should be construed as the right of the resident to receive the provision of medical treatment or medical services deemed medically unnecessary or inappropriate.

(d) *Choice of attending physician.* The resident has the right to choose his or her attending physician.

(1) The physician must be licensed to practice, and

(2) If the physician chosen by the resident refuses to or does not meet requirements specified in this part, the facility may seek alternate physician participation as specified in paragraphs (d)(4) and (5) of this section to assure provision of appropriate and adequate care and treatment.

(3) The facility must ensure that each resident remains informed of the name, specialty, and way of contacting the physician and other primary care professionals responsible for his or her care.

(4) The facility must inform the resident if the facility determines that the physician chosen by the resident is unable or unwilling to meet requirements specified in this part and the facility seeks alternate physician participation to assure provision of appropriate and adequate care and treatment. The facility must discuss the alternative physician participation with the resident and honor the resident's preferences, if any, among options.

(5) If the resident subsequently selects another attending physician who meets the requirements specified in this part, the facility must honor that choice.

(e) *Respect and dignity.* The resident has a right to be treated with respect and dignity, including:

(1) 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, consistent with § 483.12(a)(2).

(2) The right to retain and use personal possessions, including furnishings, and clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.

(3) The right to reside and receive services in the facility with reasonable accommodation of resident needs and preferences except when to do so would endanger the health or safety of the resident or other residents.

(4) 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.

(5) The right to share a room with his or her roommate of choice when practicable, when both residents live in the same facility and both residents consent to the arrangement.

(6) The right to receive written notice, including the reason for the change, before the resident's room or roommate in the facility is changed.

(7) The right to refuse to transfer to another room in the facility, if the purpose of the transfer is:

(i) To relocate 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) to relocate 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.

(iii) solely for the convenience of staff.

(8) A resident's exercise of the right to refuse transfer does not affect the resident's eligibility or entitlement to Medicare or Medicaid benefits.

(f) *Self-determination.* The resident has the right to and the facility must promote and facilitate resident self-determination through support of resident choice, including but not limited to the rights specified in paragraphs (f)(1) through (11) of this section.

(1) The resident has a right to choose activities, schedules (including sleeping and waking times), health care and providers of health care services consistent with his or her interests, assessments, plan of care and other applicable provisions of this part.

(2) The resident has the right to make choices about aspects of his or

her life in the facility that are significant to the resident.

(3) The resident has a right to interact with members of the community and participate in community activities both inside and outside the facility.

(4) The resident has a right to receive visitors of his or her choosing at the time of his or her choosing, subject to the resident's right to deny visitation when applicable, and in a manner that does not impose on the rights of another resident.

(i) The facility must provide immediate access to any resident by—

(A) Any representative of the Secretary,

(B) Any representative of the State,

(C) Any representative of the Office of the State long term care ombudsman, (established under section 712 of the Older Americans Act of 1965, as amended 2016 (42 U.S.C. 3001 *et seq.*),

(D) The resident's individual physician,

(E) Any representative of the protection and advocacy systems, as designated by the state, and as established under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15001 *et seq.*),

(F) Any representative of the agency responsible for the protection and advocacy system for individuals with a mental disorder (established under the Protection and Advocacy for Mentally Ill Individuals Act of 2000 (42 U.S.C. 10801 *et seq.*), and

(G) The resident representative.

(ii) The facility must provide immediate access to a resident by immediate family and other relatives of the resident, subject to the resident's right to deny or withdraw consent at any time;

(iii) The facility must provide immediate access to a resident by others who are visiting with the consent of the resident, subject to reasonable clinical and safety restrictions and the resident's right to deny or withdraw consent at any time;

(iv) The facility must provide reasonable access to a 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; and

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(v) The facility must have written policies and procedures regarding the visitation rights of residents, including those setting forth any clinically necessary or reasonable restriction or limitation or safety restriction or limitation, when such limitations may apply consistent with the requirements of this subpart, that the facility may need to place on such rights and the reasons for the clinical or safety restriction or limitation.

(vi) A facility must meet the following requirements:

(A) Inform each resident (or resident representative, where appropriate) of his or her visitation rights and related facility policy and procedures, including any clinical or safety restriction or limitation on such rights, consistent with the requirements of this subpart, the reasons for the restriction or limitation, and to whom the restrictions apply, when he or she is informed of his or her other rights under this section.

(B) Inform each resident of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse (including a same-sex spouse), a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.

(C) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

(D) Ensure that all visitors enjoy full and equal visitation privileges consistent with resident preferences.

(5) The resident has a right to organize and participate in resident groups in the facility.

(i) The facility must provide a resident or family group, if one exists, with private space; and take reasonable steps, with the approval of the group, to make residents and family members aware of upcoming meetings in a timely manner.

(ii) Staff, visitors, or other guests may attend resident group or family group meetings only at the respective group's invitation.

(iii) The facility must provide a designated staff person who is approved by

the resident or family group and the facility and who is responsible for providing assistance and responding to written requests that result from group meetings.

(iv) The facility must consider the views of a resident or family group and act promptly upon the grievances and recommendations of such groups concerning issues of resident care and life in the facility.

(A) The facility must be able to demonstrate their response and rationale for such response.

(B) This should not be construed to mean that the facility must implement as recommended every request of the resident or family group.

(6) The resident has a right to participate in family groups.

(7) The resident has a right to have family member(s) or other resident representative(s) meet in the facility with the families or resident representative(s) of other residents in the facility.

(8) The resident has a right to participate in other activities, including social, religious, and community activities that do not interfere with the rights of other residents in the facility.

(9) The resident has a right to choose to or refuse to perform services for the facility and the facility must not require a resident to perform services for the facility, if he or she chooses, when—

(i) The facility has documented the resident's 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.

(10) The resident has a right to manage his or her financial affairs. This includes the right to know, in advance, what charges a facility may impose against a resident's personal funds.

(i) The facility must not require residents to deposit their personal funds with the facility. If a resident chooses to deposit personal funds with the facility, upon written authorization of a

resident, the facility must act as a fiduciary of the resident's funds and hold, safeguard, manage, and account for the personal funds of the resident deposited with the facility, as specified in this section.

(ii) *Deposit of funds.* (A) In general: Except as set out in paragraph (f)(10)(ii)(B) of this section, the facility must deposit any residents' personal funds in excess of \$100 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.) The facility must maintain a resident's personal funds that do not exceed \$100 in a non-interest bearing account, interest-bearing account, or petty cash fund.

(B) Residents whose care is funded by Medicaid: The facility must deposit the 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.) The facility must maintain personal funds that do not exceed \$50 in a non-interest bearing account, interest-bearing account, or petty cash fund.

(iii) *Accounting and records.* (A) 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.

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

(C) The individual financial record must be available to the resident through quarterly statements and upon request.

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

(A) 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

(B) 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.

(v) Conveyance upon discharge, eviction, or death. Upon the discharge, eviction, or 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 resident, or in the case of death, the individual or probate jurisdiction administering the resident's estate, in accordance with State law.

(vi) 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.

(11) The facility must 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 of this chapter, which limits participation in the Medicaid program to providers who accept, as payment in full, Medicaid payment plus any deductible, coinsurance, or co-payment 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 must not charge a resident for the following categories of items and services:

(A) Nursing services as required at § 483.35.

(B) Food and Nutrition services as required at § 483.60.

(C) An activities program as required at § 483.24(c).

(D) Room/bed maintenance services.

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(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 assistance, and basic personal laundry.

(F) Medically-related social services as required at § 483.40(d).

(G) Hospice services elected by the resident and paid for under the Medicare Hospice Benefit or paid for by Medicaid under a state plan.

(ii) *Items and services that may be charged to residents' funds.* Paragraphs (f)(11)(ii)(A) through (L) of this section 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 they are not required to achieve the goals stated in the resident's care plan, if the facility informs the resident that there will be a charge, and if payment is not made by Medicare or Medicaid:

(A) Telephone, including a cellular phone.

(B) Television/radio, personal computer or other electronic device 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) Cost to participate in social events and entertainment outside the scope of the activities program, provided under § 483.24(c).

(J) Non-covered special care services such as privately hired nurses or aides.

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

(L) Except as provided in (e)(11)(ii)(L)(I) and (2) of this section, specially prepared or alternative food requested instead of the food and meals generally prepared by the facility, as required by § 483.60.

(I) The facility may not charge for special foods and meals, including medically prescribed dietary supplements, ordered by the resident's physician, physician assistant, nurse practitioner, or clinical nurse specialist, as these are included in accordance with § 483.60.

(2) In accordance with § 483.60(c) through (f), when preparing foods and meals, a facility must take into consideration residents' needs and preferences and the overall cultural and religious make-up of the facility's population.

(iii) *Requests for items and services.* (A) The facility can only charge a resident for any non-covered item or service if such item or service is specifically requested by the resident.

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

(C) The facility must inform, orally and in writing, the resident 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.

(g) *Information and communication.* (1) The resident has the right to be informed of his or her rights and of all rules and regulations governing resident conduct and responsibilities during his or her stay in the facility.

(2) The resident has the right to access personal and medical records pertaining to him or herself.

(i) The facility must provide the resident with access to personal and medical records pertaining to him or herself, upon an oral or written request, in the form and format requested by the individual, if it is readily producible in such form and format (including in an electronic form or format when such records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as

agreed to by the facility and the individual, within 24 hours (excluding weekends and holidays); and

(ii) The facility must allow the resident to obtain a copy of the records or any portions thereof (including in an electronic form or format when such records are maintained electronically) upon request and 2 working days advance notice to the facility. The facility may impose a reasonable, cost-based fee on the provision of copies, provided that the fee includes only the cost of:

(A) Labor for copying the records requested by the individual, whether in paper or electronic form;

(B) Supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media; and

(C) Postage, when the individual has requested the copy be mailed.

(3) With the exception of information described in paragraphs (g)(2) and (g)(11) of this section, the facility must ensure that information is provided to each resident in a form and manner the resident can access and understand, including in an alternative format or in a language that the resident can understand. Summaries that translate information described in paragraph (g)(2) of this section may be made available to the patient at their request and expense in accordance with applicable law.

(4) The resident has the right to receive notices orally (meaning spoken) and in writing (including Braille) in a format and a language he or she understands, including:

(i) *Required notices as specified in this section.* The facility must furnish to each resident a written description of legal rights which includes—

(A) A description of the manner of protecting personal funds, under paragraph (f)(10) of this section;

(B) A description of the requirements and procedures for establishing eligibility for Medicaid, including the right to request an assessment of resources under section 1924(c) of the Social Security Act.

(C) A list of names, addresses (mailing and email), and telephone numbers of all pertinent State regulatory and

informational agencies, resident advocacy groups such as the State Survey Agency, the State licensure office, the State Long-Term Care Ombudsman program, the protection and advocacy agency, adult protective services where state law provides for jurisdiction in long-term care facilities, the local contact agency for information about returning to the community and the Medicaid Fraud Control Unit; and

(D) A statement that the resident may file a complaint with the State Survey Agency concerning any suspected violation of state or federal nursing facility regulations, including but not limited to resident abuse, neglect, exploitation, misappropriation of resident property in the facility, non-compliance with the advance directives requirements and requests for information regarding returning to the community.

(ii) Information and contact information for State and local advocacy organizations, including but not limited to the State Survey Agency, the State Long-Term Care Ombudsman program (established under section 712 of the Older Americans Act of 1965, as amended 2016 (42 U.S.C. 3001 *et seq.*) and the protection and advocacy system (as designated by the state, and as established under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15001 *et seq.*);

(iii) Information regarding Medicare and Medicaid eligibility and coverage;

(iv) Contact information for the Aging and Disability Resource Center (established under Section 202(a)(20)(B)(iii) of the Older Americans Act); or other No Wrong Door Program

(v) Contact information for the Medicaid Fraud Control Unit; and

(vi) Information and contact information for filing grievances or complaints concerning any suspected violation of state or federal nursing facility regulations, including but not limited to resident abuse, neglect, exploitation, misappropriation of resident property in the facility, non-compliance with the advance directives requirements and requests for information regarding returning to the community.

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(5) The facility must post, in a form and manner accessible and understandable to residents, and resident representatives:

(i) A list of names, addresses (mailing and email), and telephone numbers of all pertinent State agencies and advocacy groups, such as the State Survey Agency, the State licensure office, adult protective services where state law provides for jurisdiction in long-term care facilities, the Office of the State Long-Term Care Ombudsman program, the protection and advocacy network, home and community based service programs, and the Medicaid Fraud Control Unit; and

(ii) A statement that the resident may file a complaint with the State Survey Agency concerning any suspected violation of state or federal nursing facility regulations, including but not limited to resident abuse, neglect, exploitation, misappropriation of resident property in the facility, non-compliance with the advance directives requirements (42 CFR part 489 subpart I) and requests for information regarding returning to the community.

(6) The resident has the right to have reasonable access to the use of a telephone, including TTY and TDD services, and a place in the facility where calls can be made without being overheard. This includes the right to retain and use a cellular phone at the resident's own expense.

(7) The facility must protect and facilitate that resident's right to communicate with individuals and entities within and external to the facility, including reasonable access to:

(i) A telephone, including TTY and TDD services;

(ii) The internet, to the extent available to the facility; and

(iii) Stationery, postage, writing implements and the ability to send mail.

(8) The resident has the right to send and receive mail, and to receive letters, packages and other materials delivered to the facility for the resident through a means other than a postal service, including the right to:

(i) Privacy of such communications consistent with this section; and

(ii) Access to stationery, postage, and writing implements at the resident's own expense.

(9) The resident has the right to have reasonable access to and privacy in their use of electronic communications such as email and video communications and for Internet research.

(i) If the access is available to the facility

(ii) At the resident's expense, if any additional expense is incurred by the facility to provide such access to the resident.

(iii) Such use must comply with state and federal law.

(10) The resident has the right to—

(i) 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; and

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

(11) The facility must—

(i) Post in a place readily accessible to residents, and family members and legal representatives of residents, the results of the most recent survey of the facility.

(ii) Have reports with respect to any surveys, certifications, and complaint investigations made respecting the facility during the 3 preceding years, and any plan of correction in effect with respect to the facility, available for any individual to review upon request; and

(iii) Post notice of the availability of such reports in areas of the facility that are prominent and accessible to the public.

(iv) The facility shall not make available identifying information about complainants or residents.

(12) The facility must comply with the requirements specified in 42 CFR part 489, subpart I (Advance Directives).

(i) 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 resident's option, formulate an advance directive.

(ii) This includes a written description of the facility's policies to implement advance directives and applicable State law.

(iii) 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.

(iv) If an adult individual is incapacitated at the time of admission and is unable to receive information or articulate whether or not he or she has executed an advance directive, the facility may give advance directive information to the individual's resident representative in accordance with State law.

(v) The facility is not relieved of its obligation to provide this information to the individual once he or she is able to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

(13) The facility must 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.

(14) *Notification of changes.* (i) A facility must immediately inform the resident; consult with the resident's physician; and notify, consistent with his or her authority, the resident representative(s), 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 (that is, a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);

(C) A need to alter treatment significantly (that is, a need to discontinue or change 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 § 483.15(c)(1)(ii).

(ii) When making notification under paragraph (g)(14)(i) of this section, the facility must ensure that all pertinent information specified in § 483.15(c)(2) is

available and provided upon request to the physician.

(iii) The facility must also promptly notify the resident and the resident representative, if any, when there is—

(A) A change in room or roommate assignment as specified in § 483.10(e)(6); or

(B) A change in resident rights under Federal or State law or regulations as specified in paragraph (e)(10) of this section.

(iv) The facility must record and periodically update the address (mailing and email) and phone number of the resident representative(s).

(15) *Admission to a composite distinct part.* A facility that is a composite distinct part (as defined in § 483.5) 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 § 483.15(c)(9).

(16) The facility must provide a notice of rights and services to the resident prior to or upon admission and during the resident's stay.

(i) 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.

(ii) The facility must also provide the resident with the State-developed notice of Medicaid rights and obligations, if any.

(iii) Receipt of such information, and any amendments to it, must be acknowledged in writing;

(17) The facility must—

(i) Inform each Medicaid-eligible resident, in writing, at the time of admission to the nursing facility and 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

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(ii) Inform each Medicaid-eligible resident when changes are made to the items and services specified in § 483.10(g)(17)(i)(A) and (B) of this section.

(18) 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/Medicaid or by the facility's per diem rate.

(i) Where changes in coverage are made to items and services covered by Medicare and/or by the Medicaid State plan, the facility must provide notice to residents of the change as soon as is reasonably possible.

(ii) Where changes are made to charges for other items and services that the facility offers, the facility must inform the resident in writing at least 60 days prior to implementation of the change.

(iii) If a resident dies or is hospitalized or is transferred and does not return to the facility, the facility must refund to the resident, resident representative, or estate, as applicable, any deposit or charges already paid, less the facility's per diem rate, for the days the resident actually resided or reserved or retained a bed in the facility, regardless of any minimum stay or discharge notice requirements.

(iv) The facility must refund to the resident or resident representative any and all refunds due the resident within 30 days from the resident's date of discharge from the facility.

(v) The terms of an admission contract by or on behalf of an individual seeking admission to the facility must not conflict with the requirements of these regulations.

(h) *Privacy and confidentiality.* The resident has a right to personal privacy and confidentiality of his or her personal and medical 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) The facility must respect the residents right to personal privacy, including the right to privacy in his or her oral (that is, spoken), written, and electronic communications, including the right to send and promptly receive unopened mail and other letters, packages and other materials delivered to the facility for the resident, including those delivered through a means other than a postal service.

(3) The resident has a right to secure and confidential personal and medical records.

(i) The resident has the right to refuse the release of personal and medical records except as provided at § 483.70(i)(2) or other applicable federal or state laws.

(ii) The facility must allow representatives of the Office of the State Long-Term Care Ombudsman to examine a resident's medical, social, and administrative records in accordance with State law.

(i) *Safe environment.* The resident has a right to a safe, clean, comfortable and homelike environment, including but not limited to receiving treatment and supports for daily living safely. 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.

(i) This includes ensuring that the resident can receive care and services safely and that the physical layout of the facility maximizes resident independence and does not pose a safety risk.

(ii) The facility shall exercise reasonable care for the protection of the resident's property from loss or theft.

(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 § 483.90(e)(2)(iv);

(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 to 81 °F; and

(7) For the maintenance of comfortable sound levels.

(j) *Grievances.* (1) The resident has the right to voice grievances to the facility or other agency or entity that hears grievances without discrimination or reprisal and without fear of discrimination or reprisal. Such grievances include those with respect to care and treatment which has been furnished as well as that which has not been furnished, the behavior of staff and of other residents; and other concerns regarding their LTC facility stay.

(2) The resident has the right to and the facility must make prompt efforts by the facility to resolve grievances the resident may have, in accordance with this paragraph.

(3) The facility must make information on how to file a grievance or complaint available to the resident.

(4) The facility must establish a grievance policy to ensure the prompt resolution of all grievances regarding the residents' rights contained in this paragraph. Upon request, the provider must give a copy of the grievance policy to the resident. The grievance policy must include:

(i) Notifying resident individually or through postings in prominent locations throughout the facility of the right to file grievances orally (meaning spoken) or in writing; the right to file grievances anonymously; the contact information of the grievance official with whom a grievance can be filed, that is, his or her name, business address (mailing and email) and business phone number; a reasonable expected time frame for completing the review of the grievance; the right to obtain a written decision regarding his or her grievance; and the contact information of independent entities with whom grievances may be filed, that is, the pertinent State agency, Quality Improvement Organization, State Survey Agency and State Long-Term Care Ombudsman program or protection and advocacy system;

(ii) Identifying a Grievance Official who is responsible for overseeing the grievance process, receiving and tracking grievances through to their conclusion; leading any necessary investigations by the facility; maintaining the confidentiality of all information asso-

ciated with grievances, for example, the identity of the resident for those grievances submitted anonymously; issuing written grievance decisions to the resident; and coordinating with state and federal agencies as necessary in light of specific allegations;

(iii) As necessary, taking immediate action to prevent further potential violations of any resident right while the alleged violation is being investigated;

(iv) Consistent with § 483.12(c)(1), immediately reporting all alleged violations involving neglect, abuse, including injuries of unknown source, and/or misappropriation of resident property, by anyone furnishing services on behalf of the provider, to the administrator of the provider; and as required by State law;

(v) Ensuring that all written grievance decisions include the date the grievance was received, a summary statement of the resident's grievance, the steps taken to investigate the grievance, a summary of the pertinent findings or conclusions regarding the resident's concern(s), a statement as to whether the grievance was confirmed or not confirmed, any corrective action taken or to be taken by the facility as a result of the grievance, and the date the written decision was issued;

(vi) Taking appropriate corrective action in accordance with State law if the alleged violation of the residents' rights is confirmed by the facility or if an outside entity having jurisdiction, such as the State Survey Agency, Quality Improvement Organization, or local law enforcement agency confirms a violation of any of these residents' rights within its area of responsibility; and

(vii) Maintaining evidence demonstrating the results of all grievances for a period of no less than 3 years from the issuance of the grievance decision.

(k) *Contact with external entities.* A facility must not prohibit or in any way discourage a resident from communicating with federal, state, or local officials, including, but not limited to, federal and state surveyors, other federal or state health department employees, including representatives of the Office of the State Long-Term Care Ombudsman, and any representative of

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the agency responsible for the protection and advocacy system for individuals with mental disorder (established under the Protection and Advocacy for Mentally Ill Individuals Act of 2000 (42 U.S.C. 10801 *et seq.*), regarding any matter, whether or not subject to arbitration or any other type of judicial or regulatory action.

[81 FR 68849, Oct. 4, 2016, as amended at 82 FR 32259, July 13, 2017]

§ 483.12 Freedom from abuse, neglect, and exploitation.

The resident has the right to be free from abuse, neglect, misappropriation of resident property, and exploitation as defined in this subpart. This includes but is not limited to freedom from corporal punishment, involuntary seclusion and any physical or chemical restraint not required to treat the resident's medical symptoms.

(a) The facility must—

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

(2) Ensure that the resident is free from physical or chemical restraints imposed for purposes of discipline or convenience and that are not required to treat the resident's medical symptoms. When the use of restraints is indicated, the facility must use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints.

(3) Not employ or otherwise engage individuals who—

(i) Have been found guilty of abuse, neglect, exploitation, misappropriation of property, or mistreatment by a court of law;

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

(iii) Have a disciplinary action in effect against his or her professional license by a state licensure body as a result of a finding of abuse, neglect, exploitation, mistreatment of residents or misappropriation of resident property.

(4) Report to the State nurse aide registry or licensing authorities any knowledge it has of actions by a court of law against an employee, which

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would indicate unfitness for service as a nurse aide or other facility staff.

(b) The facility must develop and implement written policies and procedures that:

(1) Prohibit and prevent abuse, neglect, and exploitation of residents and misappropriation of resident property,

(2) Establish policies and procedures to investigate any such allegations, and

(3) Include training as required at paragraph § 483.95.

(4) Establish coordination with the QAPI program required under § 483.75.

(5) Ensure reporting of crimes occurring in federally-funded long-term care facilities in accordance with section 1150B of the Act. The policies and procedures must include but are not limited to the following elements.

(i) Annually notifying covered individuals, as defined at section 1150B(a)(3) of the Act, of that individual's obligation to comply with the following reporting requirements.

(A) Each covered individual shall report to the State Agency and one or more law enforcement entities for the political subdivision in which the facility is located any reasonable suspicion of a crime against any individual who is a resident of, or is receiving care from, the facility.

(B) Each covered individual shall report immediately, but not later than 2 hours after forming the suspicion, if the events that cause the suspicion result in serious bodily injury, or not later than 24 hours if the events that cause the suspicion do not result in serious bodily injury.

(ii) Posting a conspicuous notice of employee rights, as defined at section 1150B(d)(3) of the Act.

(iii) Prohibiting and preventing retaliation, as defined at section 1150B(d)(1) and (2) of the Act.

(c) In response to allegations of abuse, neglect, exploitation, or mistreatment, the facility must:

(1) Ensure that all alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property, are reported immediately, but not later than 2 hours after the allegation is made, if the

events that cause the allegation involve abuse or result in serious bodily injury, or not later than 24 hours if the events that cause the allegation do not involve abuse and do not result in serious bodily injury, to the administrator of the facility and to other officials (including to the State Survey Agency and adult protective services where state law provides for jurisdiction in long-term care facilities) in accordance with State law through established procedures.

(2) Have evidence that all alleged violations are thoroughly investigated.

(3) Prevent further potential abuse, neglect, exploitation, or mistreatment while the investigation is in progress.

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

[81 FR 68855, Oct. 4, 2016]

§ 483.15 Admission, transfer, and discharge rights.

(a) *Admissions policy.* (1) The facility must establish and implement an admissions policy.

(2) The facility must—

(i) Not request or require residents or potential residents to waive their rights as set forth in this subpart and in applicable state, federal or local licensing or certification laws, including but not limited to their rights to Medicare or Medicaid; and

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

(iii) Not request or require residents or potential residents to waive potential facility liability for losses of personal property

(3) The facility must not request or 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 request and require a resident representative 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.

(4) 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.

(5) 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.

(6) A nursing facility must disclose and provide to a resident or potential resident prior to time of admission, notice of special characteristics or service limitations of the facility.

(7) A nursing facility that is a composite distinct part as defined in § 483.5 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 paragraph (c)(9) of this section.

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(b) *Equal access to quality care.* (1) A facility must establish, maintain and implement identical policies and practices regarding transfer and discharge, as defined in § 483.5 and the provision of services for all individuals regardless of source of payment, consistent with § 483.10(a)(2);

(2) The facility may charge any amount for services furnished to non-Medicaid residents unless otherwise limited by state law and consistent with the notice requirement in § 483.10(g)(18)(i) and (g)(4)(i) 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.

(c) *Transfer and discharge—(1) Facility requirements—(i)* The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless—

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

(B) 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;

(C) The safety of individuals in the facility is endangered due to the clinical or behavioral status of the resident;

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

(E) 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. Non-payment applies if the resident does not submit the necessary paperwork for third party payment or after the third party, including Medicare or Medicaid, denies the claim and the resident refuses to pay for his or her stay. 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

(F) The facility ceases to operate.

(ii) The facility may not transfer or discharge the resident while the appeal is pending, pursuant to § 431.230 of this chapter, when a resident exercises his

or her right to appeal a transfer or discharge notice from the facility pursuant to § 431.220(a)(3) of this chapter, unless the failure to discharge or transfer would endanger the health or safety of the resident or other individuals in the facility. The facility must document the danger that failure to transfer or discharge would pose.

(2) *Documentation.* When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (c)(1)(i)(A) through (F) of this section, the facility must ensure that the transfer or discharge is documented in the resident's medical record and appropriate information is communicated to the receiving health care institution or provider.

(i) Documentation in the resident's medical record must include:

(A) The basis for the transfer per paragraph (c)(1)(i) of this section.

(B) In the case of paragraph (c)(1)(i)(A) of this section, the specific resident need(s) that cannot be met, facility attempts to meet the resident needs, and the service available at the receiving facility to meet the need(s).

(ii) The documentation required by paragraph (c)(2)(i) of this section must be made by—

(A) The resident's physician when transfer or discharge is necessary under paragraph (c)(1)(A) or (B) of this section; and

(B) A physician when transfer or discharge is necessary under paragraph (c)(1)(i)(C) or (D) of this section.

(iii) Information provided to the receiving provider must include a minimum of the following:

(A) Contact information of the practitioner responsible for the care of the resident

(B) Resident representative information including contact information.

(C) Advance Directive information.

(D) All special instructions or precautions for ongoing care, as appropriate.

(E) Comprehensive care plan goals,

(F) All other necessary information, including a copy of the resident's discharge summary, consistent with § 483.21(c)(2), as applicable, and any other documentation, as applicable, to ensure a safe and effective transition of care.

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

(i) Notify the resident and the resident's representative(s) of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand. The facility must send a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman.

(ii) Record the reasons for the transfer or discharge in the resident's medical record in accordance with paragraph (c)(2) of this section; and

(iii) Include in the notice the items described in paragraph (c)(5) of this section.

(4) *Timing of the notice.* (i) Except as specified in paragraphs (c)(4)(ii) and (8) of this section, the notice of transfer or discharge required under this section must be made by the facility at least 30 days before the resident is transferred or discharged.

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

(A) The safety of individuals in the facility would be endangered under paragraph (c)(1)(i)(C) of this section;

(B) The health of individuals in the facility would be endangered, under paragraph (c)(1)(i)(D) of this section;

(C) The resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (c)(1)(i)(B) of this section;

(D) An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (c)(1)(i)(A) of this section; or

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

(5) *Contents of the notice.* The written notice specified in paragraph (c)(3) 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 of the resident's appeal rights, including the name, address (mailing and email), and telephone number of the entity which receives such requests; and information

on how to obtain an appeal form and assistance in completing the form and submitting the appeal hearing request;

(v) The name, address (mailing and email) and telephone number of the Office of the State Long-Term Care Ombudsman;

(vi) For nursing facility residents with intellectual and developmental disabilities or related disabilities, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with developmental disabilities established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (Pub. L. 106-402, codified at 42 U.S.C. 15001 *et seq.*); and

(vii) For nursing facility residents with a mental disorder or related disabilities, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with a mental disorder established under the Protection and Advocacy for Mentally Ill Individuals Act.

(6) *Changes to the notice.* If the information in the notice changes prior to effecting the transfer or discharge, the facility must update the recipients of the notice as soon as practicable once the updated information becomes available.

(7) *Orientation for transfer or discharge.* A facility must provide and document sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility. This orientation must be provided in a form and manner that the resident can understand.

(8) *Notice in advance of facility closure.* In the case of facility closure, the individual who is the administrator of the facility must provide written notification prior to the impending closure to the State Survey Agency, the Office of the State Long-Term Care Ombudsman, residents of the facility, and the resident representatives, as well as the plan for the transfer and adequate relocation of the residents, as required at § 483.70(1).

(9) *Room changes in a composite distinct part.* Room changes in a facility

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that is a composite distinct part (as defined in § 483.5) are subject to the requirements of § 483.10(e)(7) and 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.

(d) *Notice of bed-hold policy and return*—(1) *Notice before transfer.* Before a nursing facility transfers a resident to a hospital or the resident goes on therapeutic leave, the nursing facility must provide written information to the resident or resident representative that specifies—

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

(ii) The reserve bed payment policy in the state plan, under § 447.40 of this chapter, if any;

(iii) The nursing facility's policies regarding bed-hold periods, which must be consistent with paragraph (e)(1) of this section, permitting a resident to return; and

(iv) The information specified in paragraph (e)(1) of this section.

(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 the resident representative written notice which specifies the duration of the bed-hold policy described in paragraph (d)(1) of this section.

(e)(1) *Permitting residents to return to facility.* A facility must establish and follow a written policy on permitting residents to return to the facility after they are hospitalized or placed on therapeutic leave. The policy must provide for the following.

(i) A resident, whose hospitalization or therapeutic leave exceeds the bed-hold period under the State plan, returns to the facility to their previous room if available or immediately upon the first availability of a bed in a semi-private room if the resident

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

(B) Is eligible for Medicare skilled nursing facility services or Medicaid nursing facility services.

(ii) If the facility that determines that a resident who was transferred with an expectation of returning to the facility cannot return to the facility, the facility must comply with the requirements of paragraph (c) as they apply to discharges.

(2) *Readmission to a composite distinct part.* When the facility to which a resident returns is a composite distinct part (as defined in § 483.5), 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 return, the resident must be given the option to return to that location upon the first availability of a bed there.

[81 FR 68855, Oct. 4, 2016, as amended at 82 FR 32259, July 13, 2017]

§ 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, strengths, goals, life history and preferences, using the resident assessment instrument (RAI) specified by CMS. 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 planning.

(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 of care.

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

(1) Incorporating the recommendations from the PASARR level II determination and the PASARR evaluation report into a resident's assessment, care planning, and transitions of care.

(2) Referring all level II residents and all residents with newly evident or possible serious mental disorder, intellectual disability, or a related condition for level II resident review upon a significant change in status assessment.

(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.

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(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 as adjusted annually under 45 CFR part 102 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

as adjusted annually under 45 CFR part 102 for each assessment.

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

(k) *Preadmission screening for individuals with a mental disorder and individuals with intellectual disability.* (1) A nursing facility must not admit, on or after January 1, 1989, any new resident with—

(i) Mental disorder as defined in paragraph (k)(3)(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) Intellectual disability, as defined in paragraph (k)(3)(ii) of this section, unless the State intellectual disability 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 intellectual disability.

(2) *Exceptions.* For purposes of this section—

(i) The preadmission screening program under paragraph (k)(1) of this section need not provide for determinations in the case of the readmission to a nursing facility of an individual who, after being admitted to the nursing facility, was transferred for care in a hospital.

(ii) The State may choose not to apply the preadmission screening program under paragraph (k)(1) of this section to the admission to a nursing facility of an individual—

(A) Who is admitted to the facility directly from a hospital after receiving acute inpatient care at the hospital,

(B) Who requires nursing facility services for the condition for which the

individual 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 of nursing facility services.

(3) *Definition.* For purposes of this section—

(i) An individual is considered to have a mental disorder if the individual has a serious mental disorder as defined in § 483.102(b)(1).

(ii) An individual is considered to have an intellectual disability if the individual has an intellectual disability as defined in § 483.102(b)(3) or is a person with a related condition as described in § 435.1010 of this chapter.

(4) A nursing facility must notify the state mental health authority or state intellectual disability authority, as applicable, promptly after a significant change in the mental or physical condition of a resident who has a mental disorder or intellectual disability for resident review.

[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; 81 FR 61563, Sept. 6, 2016; 81 FR 68857, Oct. 4, 2016]

§ 483.21 Comprehensive person-centered care planning.

(a) *Baseline care plans.* (1) The facility must develop and implement a baseline care plan for each resident that includes the instructions needed to provide effective and person-centered care of the resident that meet professional standards of quality care. The baseline care plan must—

(i) Be developed within 48 hours of a resident's admission.

(ii) Include the minimum healthcare information necessary to properly care for a resident including, but not limited to:

(A) Initial goals based on admission orders.

(B) Physician orders.

(C) Dietary orders.

(D) Therapy services.

(E) Social services.

(F) PASARR recommendation, if applicable.

(2) The facility may develop a comprehensive care plan in place of the baseline care plan if the comprehensive care plan—

(i) Is developed within 48 hours of the resident's admission.

(ii) Meets the requirements set forth in paragraph (b) of this section (excepting paragraph (b)(2)(i) of this section).

(3) The facility must provide the resident and their representative with a summary of the baseline care plan that includes but is not limited to:

(i) The initial goals of the resident.

(ii) A summary of the resident's medications and dietary instructions.

(iii) Any services and treatments to be administered by the facility and personnel acting on behalf of the facility.

(iv) Any updated information based on the details of the comprehensive care plan, as necessary.

(b) *Comprehensive care plans.* (1) The facility must develop and implement a comprehensive person-centered care plan for each resident, consistent with the resident rights set forth at § 483.10(c)(2) and § 483.10(c)(3), that includes measurable objectives and timeframes to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment. The comprehensive 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 § 483.24, § 483.25, or § 483.40; and

(ii) Any services that would otherwise be required under § 483.24, § 483.25, or § 483.40 but are not provided due to the resident's exercise of rights under § 483.10, including the right to refuse treatment under § 483.10(c)(6).

(iii) Any specialized services or specialized rehabilitative services the nursing facility will provide as a result of PASARR recommendations. If a facility disagrees with the findings of the PASARR, it must indicate its rationale in the resident's medical record.

(iv) In consultation with the resident and the resident's representative(s)—

(A) The resident's goals for admission and desired outcomes.

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(B) The resident's preference and potential for future discharge. Facilities must document whether the resident's desire to return to the community was assessed and any referrals to local contact agencies and/or other appropriate entities, for this purpose.

(C) Discharge plans in the comprehensive care plan, as appropriate, in accordance with the requirements set forth in paragraph (c) of this section.

(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 but is not limited to—

(A) The attending physician.

(B) A registered nurse with responsibility for the resident.

(C) A nurse aide with responsibility for the resident.

(D) A member of food and nutrition services staff.

(E) To the extent practicable, the participation of the resident and the resident's representative(s). An explanation must be included in a resident's medical record if the participation of the resident and their resident representative is determined not practicable for the development of the resident's care plan.

(F) Other appropriate staff or professionals in disciplines as determined by the resident's needs or as requested by the resident.

(iii) Reviewed and revised by the interdisciplinary team after each assessment, including both the comprehensive and quarterly review assessments.

(3) The services provided or arranged by the facility, as outlined by the comprehensive care plan, must—

(i) Meet professional standards of quality.

(ii) Be provided by qualified persons in accordance with each resident's written plan of care.

(iii) Be culturally-competent and trauma-informed.

(c) *Discharge planning*—(1) *Discharge planning process*. The facility must develop and implement an effective discharge planning process that focuses on the resident's discharge goals, the

preparation of residents to be active partners and effectively transition them to post-discharge care, and the reduction of factors leading to preventable readmissions. The facility's discharge planning process must be consistent with the discharge rights set forth at § 483.15(b) as applicable and—

(i) Ensure that the discharge needs of each resident are identified and result in the development of a discharge plan for each resident.

(ii) Include regular re-evaluation of residents to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.

(iii) Involve the interdisciplinary team, as defined by § 483.21(b)(2)(ii), in the ongoing process of developing the discharge plan.

(iv) Consider caregiver/support person availability and the resident's or caregiver's/support person(s) capacity and capability to perform required care, as part of the identification of discharge needs.

(v) Involve the resident and resident representative in the development of the discharge plan and inform the resident and resident representative of the final plan.

(vi) Address the resident's goals of care and treatment preferences.

(vii) Document that a resident has been asked about their interest in receiving information regarding returning to the community.

(A) If the resident indicates an interest in returning to the community, the facility must document any referrals to local contact agencies or other appropriate entities made for this purpose.

(B) Facilities must update a resident's comprehensive care plan and discharge plan, as appropriate, in response to information received from referrals to local contact agencies or other appropriate entities.

(C) If discharge to the community is determined to not be feasible, the facility must document who made the determination and why.

(viii) For residents who are transferred to another SNF or who are discharged to a HHA, IRF, or LTCH, assist

residents and their resident representatives in selecting a post-acute care provider by using data that includes, but is not limited to SNF, HHA, IRF, or LTCH standardized patient assessment data, data on quality measures, and data on resource use to the extent the data is available. The facility must ensure that the post-acute care standardized patient assessment data, data on quality measures, and data on resource use is relevant and applicable to the resident's goals of care and treatment preferences.

(ix) Document, complete on a timely basis based on the resident's needs, and include in the clinical record, the evaluation of the resident's discharge needs and discharge plan. The results of the evaluation must be discussed with the resident or resident's representative. All relevant resident information must be incorporated into the discharge plan to facilitate its implementation and to avoid unnecessary delays in the resident's discharge or transfer.

(2) *Discharge summary.* When the facility anticipates discharge a resident must have a discharge summary that includes, but is not limited to, the following:

(i) A recapitulation of the resident's stay that includes, but is not limited to, diagnoses, course of illness/treatment or therapy, and pertinent lab, radiology, and consultation results.

(ii) A final summary of the resident's status to include items in paragraph (b)(1) of §483.20, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or resident's representative.

(iii) Reconciliation of all pre-discharge medications with the resident's post-discharge medications (both prescribed and over-the-counter).

(iv) A post-discharge plan of care that is developed with the participation of the resident and, with the resident's consent, the resident representative(s), which will assist the resident to adjust to his or her new living environment. The post-discharge plan of care must indicate where the individual plans to reside, any arrangements that have been made for the resident's fol-

low up care and any post-discharge medical and non-medical services.

[81 FR 68858, Oct. 4, 2016]

§ 483.24 Quality of life.

Quality of life is a fundamental principle that applies to all care and services provided to facility residents. 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, consistent with the resident's comprehensive assessment and plan of care.

(a) Based on the comprehensive assessment of a resident and consistent with the resident's needs and choices, the facility must provide the necessary care and services to ensure that a resident's abilities in activities of daily living do not diminish unless circumstances of the individual's clinical condition demonstrate that such diminution was unavoidable. This includes the facility ensuring that:

(1) A resident is given the appropriate treatment and services to maintain or improve his or her ability to carry out the activities of daily living, including those specified in paragraph (b) of this section,

(2) 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, and

(3) Personnel provide basic life support, including CPR, to a resident requiring such emergency care prior to the arrival of emergency medical personnel and subject to related physician orders and the resident's advance directives.

(b) *Activities of daily living.* The facility must provide care and services in accordance with paragraph (a) of this section for the following activities of daily living:

(1) Hygiene—bathing, dressing, grooming, and oral care,

(2) Mobility—transfer and ambulation, including walking,

(3) Elimination—toileting,

(4) Dining—eating, including meals and snacks,

(5) Communication, including

(i) Speech,

(ii) Language,

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(iii) Other functional communication systems.

(c) *Activities.* (1) The facility must provide, based on the comprehensive assessment and care plan and the preferences of each resident, an ongoing program to support residents in their choice of activities, both facility-sponsored group and individual activities and independent activities, designed to meet the interests of and support the physical, mental, and psychosocial well-being of each resident, encouraging both independence and interaction in the community.

(2) The activities program must be directed by a qualified professional who is a qualified therapeutic recreation specialist or an activities professional who—

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

(ii) Is:

(A) 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

(B) Has 2 years of experience in a social or recreational program within the last 5 years, one of which was full-time in a therapeutic activities program; or

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

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

[81 FR 68859, Oct. 4, 2016]

§ 483.25 **Quality of care.**

Quality of care is a fundamental principle that applies to all treatment and care provided to facility residents. Based on the comprehensive assessment of a resident, the facility must ensure that residents receive treatment and care in accordance with professional standards of practice, the comprehensive person-centered care plan, and the resident's choices, including but not limited to the following:

(a) *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.

(b) *Skin integrity—(1) Pressure ulcers.* Based on the comprehensive assessment of a resident, the facility must ensure that—

(i) A resident receives care, consistent with professional standards of practice, to prevent pressure ulcers and does not develop pressure ulcers unless the individual's clinical condition demonstrates that they were unavoidable; and

(ii) A resident with pressure ulcers receives necessary treatment and services, consistent with professional standards of practice, to promote healing, prevent infection and prevent new ulcers from developing.

(2) *Foot care.* To ensure that residents receive proper treatment and care to maintain mobility and good foot health, the facility must—

(i) Provide foot care and treatment, in accordance with professional standards of practice, including to prevent complications from the resident's medical condition(s) and

(ii) If necessary, assist the resident in making appointments with a qualified person, and arranging for transportation to and from such appointments.

(c) *Mobility.* (1) The facility must ensure that a resident who enters the facility without 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 limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion.

(3) A resident with limited mobility receives appropriate services, equipment, and assistance to maintain or improve mobility with the maximum practicable independence unless a reduction in mobility is demonstrably unavoidable.

(d) *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.

(e) *Incontinence.* (1) The facility must ensure that a resident who is continent of bladder and bowel on admission receives services and assistance to maintain continence unless his or her clinical condition is or becomes such that continence is not possible to maintain.

(2) For a resident with urinary incontinence, based on the resident's comprehensive assessment, the facility must ensure that—

(i) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary;

(ii) A resident who enters the facility with an indwelling catheter or subsequently receives one is assessed for removal of the catheter as soon as possible unless the resident's clinical condition demonstrates that catheterization is necessary, and

(iii) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore continence to the extent possible.

(3) For a resident with fecal incontinence, based on the resident's comprehensive assessment, the facility must ensure that a resident who is incontinent of bowel receives appropriate treatment and services to restore as much normal bowel function as possible.

(f) *Colostomy, urostomy, or ileostomy care.* The facility must ensure that residents who require colostomy, urostomy, or ileostomy services, receive such care consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

(g) *Assisted nutrition and hydration.* (Includes naso-gastric and gastrostomy tubes, both percutaneous endoscopic gastrostomy and percutaneous endoscopic jejunostomy, and enteral fluids). Based on a resident's comprehensive assessment, the facility must ensure that a resident—

(1) Maintains acceptable parameters of nutritional status, such as usual body weight or desirable body weight range and electrolyte balance, unless the resident's clinical condition demonstrates that this is not possible or resident preferences indicate otherwise;

(2) Is offered sufficient fluid intake to maintain proper hydration and health; and

(3) Is offered a therapeutic diet when there is a nutritional problem and the health care provider orders a therapeutic diet.

(4) A resident who has been able to eat enough alone or with assistance is not fed by enteral methods unless the resident's clinical condition demonstrates that enteral feeding was clinically indicated and consented to by the resident; and

(5) A resident who is fed by enteral means receives the appropriate treatment and services to restore, if possible, oral eating skills and to prevent complications of enteral feeding including but not limited to aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers.

(h) *Parenteral fluids.* Parenteral fluids must be administered consistent with professional standards of practice and in accordance with physician orders, the comprehensive person-centered care plan, and the resident's goals and preferences.

(i) *Respiratory care, including tracheostomy care and tracheal suctioning.* The facility must ensure that a resident who needs respiratory care, including tracheostomy care and tracheal suctioning, is provided such care, consistent with professional standards of practice, the comprehensive person-centered care plan, the residents' goals and preferences, and § 483.65 of this subpart.

(j) *Prostheses.* The facility must ensure that a resident who has a prosthesis is provided care and assistance, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences, to wear and be able to use the prosthetic device.

(k) *Pain management.* The facility must ensure that pain management is

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provided to residents who require such services, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

(l) *Dialysis*. The facility must ensure that residents who require dialysis receive such services, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

(m) *Trauma-informed care*. The facility must ensure that residents who are trauma survivors receive culturally-competent, trauma-informed care in accordance with professional standards of practice and accounting for residents' experiences and preferences in order to eliminate or mitigate triggers that may cause re-traumatization of the resident.

(n) *Bed rails*. The facility must attempt to use appropriate alternatives prior to installing a side or bed rail. If a bed or side rail is used, the facility must ensure correct installation, use, and maintenance of bed rails, including but not limited to the following elements.

(1) Assess the resident for risk of entrapment from bed rails prior to installation.

(2) Review the risks and benefits of bed rails with the resident or resident representative and obtain informed consent prior to installation.

(3) Ensure that the bed's dimensions are appropriate for the resident's size and weight.

(4) Follow the manufacturers' recommendations and specifications for installing and maintaining bed rails.

[81 FR 68860, Oct. 4, 2016]

§ 483.30 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, physician assistant, nurse practitioner, or clinical nurse specialist must provide orders for the resident's immediate care and needs.

(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 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)(4) 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 resident's attending physician may delegate the task of writing dietary orders, consistent with § 483.60, to

a qualified dietitian or other clinically qualified nutrition professional who—

(i) Is acting within the scope of practice as defined by State law; and

(ii) Is under the supervision of the physician.

(3) A resident's attending physician may delegate the task of writing therapy orders, consistent with § 483.65, to a qualified therapist who—

(i) Is acting within the scope of practice as defined by State law; and

(ii) Is under the supervision of the physician.

(4) 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. Redesignated and amended at 81 FR 68861, Oct. 4, 2016]

§ 483.35 Nursing services.

The facility must have sufficient nursing staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and 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 and considering the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at § 483.70(e).

(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 (e) of this section, licensed nurses; and

(ii) Other nursing personnel, including but not limited to nurse aides.

(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.

(3) The facility must ensure that licensed nurses have the specific competencies and skill sets necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.

(4) Providing care includes but is not limited to assessing, evaluating, planning and implementing resident care plans and responding to resident's needs.

(b) *Registered nurse.* (1) Except when waived under paragraph (e) or (f) 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 (e) or (f) 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) *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.

(d) *Requirements for facility hiring and use of nursing aides—*(1) *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 through 483.154; or

(B) That individual has been deemed or determined competent as provided in § 483.150(a) and (b).

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(2) *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 (d)(1) (i) and (ii) of this section.

(3) *Minimum 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).

(4) *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.

(5) *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 that the facility believes will include information on the individual.

(6) *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 com-

petency evaluation program or a new competency evaluation program.

(7) *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. In-service training must comply with the requirements of § 483.95(g).

(e) *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 Office of the State Long-Term Care Ombudsman (established under section 712 of the Older Americans Act of 1965) and the protection and advocacy system in the State for individuals with a mental disorder who are eligible for such services as provided by the protection and advocacy agency; and

(7) The nursing facility that is granted such a waiver by a State notifies residents of the facility and their resident representatives of the waiver.

(f) *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-hour 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 Office of the State Long-Term Care Ombudsman (established under section 712 of the Older Americans Act of 1965) and the protection and advocacy system in the State for individuals with developmental disabilities or mental disorders; and

(v) The facility that is granted such a waiver notifies residents of the facility and their resident representatives 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.

(g) *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. Redesignated and amended at 81 FR 68861, Oct. 4, 2016]

§ 483.40 Behavioral health services.

Each resident must receive and the facility must provide the necessary behavioral health 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. Behavioral health encompasses a resident's whole emotional and mental well-being, which includes, but is not limited to, the prevention and treatment of mental and substance use disorders.

(a) The facility must have sufficient staff who provide direct services to residents with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and 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 and considering the number, acuity and diagnoses of the facility's resident population in accordance with § 483.70(e). These competencies and skills sets include, but are not limited to, knowledge of and appropriate training and supervision for:

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(1) Caring for residents with mental and psychosocial disorders, as well as residents with a history of trauma and/or post-traumatic stress disorder, that have been identified in the facility assessment conducted pursuant to § 483.70(e), and

(2) Implementing non-pharmacological interventions.

(b) Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident who displays or is diagnosed with mental disorder or psychosocial adjustment difficulty, or who has a history of trauma and/or post-traumatic stress disorder, receives appropriate treatment and services to correct the assessed problem or to attain the highest practicable mental and psychosocial well-being;

(2) A resident whose assessment did not reveal or who does not have a diagnosis of a mental or psychosocial adjustment difficulty or a documented history of trauma and/or post-traumatic stress disorder 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 development of such a pattern was unavoidable; and

(3) A resident who displays or is diagnosed with dementia, receives the appropriate treatment and services to attain or maintain his or her highest practicable physical, mental, and psychosocial well-being.

(c) If rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, and rehabilitative services for mental disorders and intellectual disability, are required in the resident's comprehensive plan of care, the facility must—

(1) Provide the required services, including specialized rehabilitation services as required in § 483.65; or

(2) Obtain the required services from an outside resource (in accordance with § 483.70(g) of this part) from a Medicare and/or Medicaid provider of specialized rehabilitative services.

(d) The facility must provide medically-related social services to attain or maintain the highest practicable

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physical, mental and psychosocial well-being of each resident.

[81 FR 68862, Oct. 4, 2016]

§ 483.45 Pharmacy services.

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in § 483.70(g). 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) This review must include a review of the resident's medical chart.

(3) A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories:

- (i) Anti-psychotic;
- (ii) Anti-depressant;
- (iii) Anti-anxiety; and
- (iv) Hypnotic.

(4) The pharmacist must report any irregularities to the attending physician and the facility's medical director and director of nursing, and these reports must be acted upon.

(i) Irregularities include, but are not limited to, any drug that meets the criteria set forth in paragraph (d) of this section for an unnecessary drug.

(ii) Any irregularities noted by the pharmacist during this review must be documented on a separate, written report that is sent to the attending physician and the facility's medical director and director of nursing and lists, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified.

(iii) The attending physician must document in the resident's medical record that the identified irregularity has been reviewed and what, if any, action has been taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident's medical record.

(5) The facility must develop and maintain policies and procedures for the monthly drug regimen review that include, but are not limited to, time frames for the different steps in the process and steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident.

(d) *Unnecessary drugs—General.* 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 stated in paragraphs (d)(1) through (5) of this section.

(e) *Psychotropic drugs.* Based on a comprehensive assessment of a resident, the facility must ensure that—

(1) Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record;

(2) Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;

(3) Residents do not receive psychotropic drugs pursuant to a PRN order

unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and

(4) PRN orders for psychotropic drugs are limited to 14 days. Except as provided in § 483.45(e)(5), if the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident's medical record and indicate the duration for the PRN order.

(5) PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.

(f) *Medication errors.* The facility must ensure that its—

(1) Medication error rates are not 5 percent or greater; and

(2) Residents are free of any significant medication errors.

(g) *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.

(h) *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. Redesignated and amended at 81 FR 68861, 68863, Oct. 4, 2016; 82 FR 32259, July 13, 2017]

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§ 483.50 Laboratory, radiology, and other diagnostic services.

(a) *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 a physician; physician assistant; nurse practitioner or clinical nurse specialist in accordance with State law, including scope of practice laws.

(ii) Promptly notify the ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist of laboratory results that fall outside of clinical reference ranges in accordance with facility policies and procedures for notification of a practitioner or per the ordering physician's orders.

(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 laboratory reports that are dated and contain the name and address of the testing laboratory.

(b) *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

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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 a physician; physician assistant; nurse practitioner or clinical nurse specialist in accordance with State law, including scope of practice laws.

(ii) Promptly notify the ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist of results that fall outside of clinical reference ranges in accordance with facility policies and procedures for notification of a practitioner or per the ordering physician's orders.

(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.

[81 FR 68863, Oct. 4, 2016, as amended at 82 FR 32259, July 13, 2017]

§ 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 § 483.70(g), 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 have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility

policy to be the facility's responsibility;

(4) Must if necessary or if requested, assist the resident—

(i) In making appointments; and

(ii) By arranging for transportation to and from the dental services location; and

(5) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay.

(b) *Nursing facilities.* The facility (1) Must provide or obtain from an outside resource, in accordance with §483.70(g), 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 or if requested, assist the resident—

(i) In making appointments; and

(ii) By arranging for transportation to and from the dental services locations;

(3) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay;

(4) Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility; and

(5) Must assist residents who are eligible and wish to participate to apply for reimbursement of dental services as an incurred medical expense under the State plan.

[56 FR 48875, Sept. 26, 1991, as amended at 81 FR 68864, Oct. 4, 2016]

§ 483.60 Food and nutrition services.

The facility must provide each resident with a nourishing, palatable, well-balanced diet that meets his or her daily nutritional and special dietary needs, taking into consideration the preferences of each resident.

(a) *Staffing.* The facility must employ sufficient staff with the appropriate competencies and skills sets to carry out the functions of the food and nutrition service, taking into consideration resident assessments, individual plans of care and the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at §483.70(e). This includes:

(1) A qualified dietitian or other clinically qualified nutrition professional either full-time, part-time, or on a consultant basis. A qualified dietitian or other clinically qualified nutrition professional is one who—

(i) Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose.

(ii) Has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional.

(iii) Is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed. In a state that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a "registered dietitian" by the Commission on Dietetic Registration or its successor organization, or meets the requirements of paragraphs (a)(1)(i) and (ii) of this section.

(iv) For dietitians hired or contracted with prior to November 28, 2016, meets these requirements no later than 5 years after November 28, 2016 or as required by state law.

(2) If a qualified dietitian or other clinically qualified nutrition professional is not employed full-time, the facility must designate a person to

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serve as the director of food and nutrition services who—

(i) For designations prior to November 28, 2016, meets the following requirements no later than 5 years after November 28, 2016, or no later than 1 year after November 28, 2016 for designations after November 28, 2016, is:

(A) A certified dietary manager; or

(B) A certified food service manager, or

(C) Has similar national certification for food service management and safety from a national certifying body; or

(D) Has an associate's or higher degree in food service management or in hospitality, if the course study includes food service or restaurant management, from an accredited institution of higher learning; and

(ii) In States that have established standards for food service managers or dietary managers, meets State requirements for food service managers or dietary managers, and

(iii) Receives frequently scheduled consultations from a qualified dietitian or other clinically qualified nutrition professional.

(3) *Support staff.* The facility must provide sufficient support personnel to safely and effectively carry out the functions of the food and nutrition service.

(b) A member of the Food and Nutrition Services staff must participate on the interdisciplinary team as required in § 483.21(b)(2)(ii).

(c) *Menus and nutritional adequacy.* Menus must—

(1) Meet the nutritional needs of residents in accordance with established national guidelines.;

(2) Be prepared in advance;

(3) Be followed;

(4) Reflect, based on a facility's reasonable efforts, the religious, cultural, and ethnic needs of the resident population, as well as input received from residents and resident groups;

(5) Be updated periodically;

(6) Be reviewed by the facility's dietitian or other clinically qualified nutrition professional for nutritional adequacy; and

(7) Nothing in this paragraph should be construed to limit the resident's right to make personal dietary choices.

(d) *Food and drink.* Each resident receives and the facility provides—

(1) Food prepared by methods that conserve nutritive value, flavor, and appearance;

(2) Food and drink that is palatable, attractive, and at a safe and appetizing temperature;

(3) Food prepared in a form designed to meet individual needs;

(4) Food that accommodates resident allergies, intolerances, and preferences;

(5) Appealing options of similar nutritive value to residents who choose not to eat food that is initially served or who request a different meal choice; and

(6) Drinks, including water and other liquids consistent with resident needs and preferences and sufficient to maintain resident hydration.

(e) *Therapeutic diets.* (1) Therapeutic diets must be prescribed by the attending physician.

(2) The attending physician may delegate to a registered or licensed dietitian the task of prescribing a resident's diet, including a therapeutic diet, to the extent allowed by State law.

(f) *Frequency of meals.* (1) Each resident must receive and the facility must provide at least three meals daily, at regular times comparable to normal mealtimes in the community or in accordance with resident needs, preferences, requests, and plan of care.

(2) There must be no more than 14 hours between a substantial evening meal and breakfast the following day, except when a nourishing snack is served 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.

(3) Suitable, nourishing alternative meals and snacks must be provided to residents who want to eat at non-traditional times or outside of scheduled meal service times, consistent with the resident plan of care.

(g) *Assistive devices.* The facility must provide special eating equipment and utensils for residents who need them and appropriate assistance to ensure that the resident can use the assistive devices when consuming meals and snacks.

(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.

(3) *Resident selection criteria*. (i) A facility must ensure that a feeding assistant provides dining assistance only for 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 interdisciplinary team's assessment and the resident's latest assessment and plan of care. Appropriateness for this program should be reflected in the comprehensive care plan.

(i) *Food safety requirements*. The facility must—

(1) Procure food from sources approved or considered satisfactory by federal, state, or local authorities;

(i) This may include food items obtained directly from local producers, subject to applicable State and local laws or regulations.

(ii) This provision does not prohibit or prevent facilities from using produce grown in facility gardens, subject to compliance with applicable safe growing and food-handling practices.

(iii) This provision does not preclude residents from consuming foods not procured by the facility.

(2) Store, prepare, distribute, and serve food in accordance with professional standards for food service safety.

(3) Have a policy regarding use and storage of foods brought to residents by family and other visitors to ensure safe and sanitary storage, handling, and consumption, and

(4) Dispose of garbage and refuse properly.

[81 FR 68864, Oct. 4, 2016]

§ 483.65 Specialized rehabilitative services.

(a) *Provision of services*. If specialized rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, respiratory therapy, and rehabilitative services for a mental disorder and intellectual disability or services of a lesser intensity as set forth at § 483.120(c), are required in the resident's comprehensive plan of care, the facility must—

(1) Provide the required services; or

(2) In accordance with § 483.70(g), obtain the required services from an outside resource that is a provider of specialized rehabilitative services and is not excluded from participating in any federal or state health care programs pursuant to section 1128 and 1156 of the Act.

(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. Redesignated and amended at 81 FR 68861, 68865, Oct. 4, 2016]

§ 483.70 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

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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 disability (45 CFR part 84); nondiscrimination on the basis of age (45 CFR part 91); nondiscrimination on the basis of race, color, national origin, sex, age, or disability (45 CFR part 92); protection of human subjects of research (45 CFR part 46); and fraud and abuse (42 CFR part 455) and protection of individually identifiable health information (45 CFR parts 160 and 164). Violations of such other provisions may result in a finding of non-compliance with this paragraph.

(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;

(ii) Responsible for management of the facility; and

(iii) Reports to and is accountable to the governing body.

(3) The governing body is responsible and accountable for the QAPI program, in accordance with § 483.75(f).

(e) *Facility assessment.* The facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must review and update that assessment, as necessary, and at least annually. The facility must also review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment. The facility assessment must address or include:

(1) The facility's resident population, including, but not limited to,

(i) Both the number of residents and the facility's resident capacity;

(ii) The care required by the resident population considering the types of diseases, conditions, physical and cog-

nitive disabilities, overall acuity, and other pertinent facts that are present within that population;

(iii) The staff competencies that are necessary to provide the level and types of care needed for the resident population;

(iv) The physical environment, equipment, services, and other physical plant considerations that are necessary to care for this population; and

(v) Any ethnic, cultural, or religious factors that may potentially affect the care provided by the facility, including, but not limited to, activities and food and nutrition services.

(2) The facility's resources, including but not limited to,

(i) All buildings and/or other physical structures and vehicles;

(ii) Equipment (medical and non-medical);

(iii) Services provided, such as physical therapy, pharmacy, and specific rehabilitation therapies;

(iv) All personnel, including managers, staff (both employees and those who provide services under contract), and volunteers, as well as their education and/or training and any competencies related to resident care;

(v) Contracts, memorandums of understanding, or other agreements with third parties to provide services or equipment to the facility during both normal operations and emergencies; and

(vi) Health information technology resources, such as systems for electronically managing patient records and electronically sharing information with other organizations.

(3) A facility-based and community-based risk assessment, utilizing an all-hazards approach.

(f) *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.

(g) *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 (g)(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.

(h) *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.

(i) *Medical records.* (1) In accordance with accepted professional standards and practices, the facility must maintain medical records on each resident that are—

(i) Complete;

(ii) Accurately documented;

(iii) Readily accessible; and

(iv) Systematically organized.

(2) 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—

(i) To the individual, or their resident representative where permitted by applicable law;

(ii) Required by law;

(iii) For treatment, payment, or health care operations, as permitted by and in compliance with 45 CFR 164.506;

(iv) For public health activities, reporting of abuse, neglect, or domestic violence, health oversight activities, judicial and administrative proceedings, law enforcement purposes, organ donation purposes, research purposes, or to coroners, medical examiners, funeral directors, and to avert a serious threat to health or safety as

permitted by and in compliance with 45 CFR 164.512.

(3) The facility must safeguard medical record information against loss, destruction, or unauthorized use;

(4) Medical 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, 3 years after a resident reaches legal age under State law.

(5) The medical record must contain—

(i) Sufficient information to identify the resident;

(ii) A record of the resident's assessments;

(iii) The comprehensive plan of care and services provided;

(iv) The results of any preadmission screening and resident review evaluations and determinations conducted by the State;

(v) Physician's, nurse's, and other licensed professional's progress notes; and

(vi) Laboratory, radiology and other diagnostic services reports as required under § 483.50.

(j) *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 or, in an emergency situation, by another practitioner in accordance with facility policy and consistent with state law; 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 receive appropriate services or receive services in a less restrictive setting than either the facility or the hospital,

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or reintegrated into the community, will be exchanged between the providers, including but not limited to the information required under § 483.15(c)(2)(iii).

(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.

(k) *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 (k)(2) of this section must include the identity of each new individual or company.

(l) *Facility closure-Administrator.* Any individual who is the administrator of the facility must:

(1) Submit to the State Survey Agency, the State LTC ombudsman, residents of the facility, and the legal representatives of such residents or other responsible parties, written notification of an impending closure:

(i) At least 60 days prior to the date of closure; or

(ii) In the case of a facility where the Secretary or a State terminates the facility's participation in the Medicare and/or Medicaid programs, not later than the date that the Secretary determines appropriate;

(2) Ensure that the facility does not admit any new residents on or after the date on which such written notification is submitted; and

(3) Include in the notice the plan, that has been approved by the State, for the transfer and adequate relocation of the residents of the facility by a date that would be specified by the

State prior to closure, including assurances that the residents would be transferred to the most appropriate facility or other setting in terms of quality, services, and location, taking into consideration the needs, choice, and best interests of each resident.

(m) *Facility closure.* The facility must have in place policies and procedures to ensure that the administrator's duties and responsibilities involve providing the appropriate notices in the event of a facility closure, as required at paragraph (1) of this section.

(n) *Binding arbitration agreements.* If a facility chooses to ask a resident or his or her representative to enter into an agreement for binding arbitration, the facility must comply with all of the requirements in this section.

(1) The facility must not require any resident or his or her representative to sign an agreement for binding arbitration as a condition of admission to, or as a requirement to continue to receive care at, the facility and must explicitly inform the resident or his or her representative of his or her right not to sign the agreement as a condition of admission to, or as a requirement to continue to receive care at, the facility.

(2) The facility must ensure that:

(i) The agreement is explained to the resident and his or her representative in a form and manner that he or she understands, including in a language the resident and his or her representative understands;

(ii) The resident or his or her representative acknowledges that he or she understands the agreement;

(iii) The agreement provides for the selection of a neutral arbitrator agreed upon by both parties; and

(iv) The agreement provides for the selection of a venue that is convenient to both parties.

(3) The agreement must explicitly grant the resident or his or her representative the right to rescind the agreement within 30 calendar days of signing it.

(4) The agreement must explicitly state that neither the resident nor his or her representative is required to sign an agreement for binding arbitration as a condition of admission to, or

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as a requirement to continue to receive care at, the facility.

(5) The agreement may not contain any language that prohibits or discourages the resident or anyone else from communicating with federal, state, or local officials, including but not limited to, federal and state surveyors, other federal or state health department employees, and representatives of the Office of the State Long-Term Care Ombudsman, in accordance with § 483.10(k).

(6) When the facility and a resident resolve a dispute through arbitration, a copy of the signed agreement for binding arbitration and the arbitrator's final decision must be retained by the facility for 5 years after the resolution of that dispute on and be available for inspection upon request by CMS or its designee.

(o) *Hospice services.* (1) A long-term care (LTC) facility may do either of the following:

(i) Arrange for the provision of hospice services through an agreement with one or more Medicare-certified hospices.

(ii) Not arrange for the provision of hospice services at the facility through an agreement with a Medicare-certified hospice and assist the resident in transferring to a facility that will arrange for the provision of hospice services when a resident requests a transfer.

(2) If hospice care is furnished in an LTC facility through an agreement as specified in paragraph (o)(1)(i) of this section with a hospice, the LTC facility must meet the following requirements:

(i) Ensure that the hospice services meet professional standards and principles that apply to individuals providing services in the facility, and to the timeliness of the services.

(ii) Have a written agreement with the hospice that is signed by an authorized representative of the hospice and an authorized representative of the LTC facility before hospice care is furnished to any resident. The written agreement must set out at least the following:

(A) The services the hospice will provide.

(B) The hospice's responsibilities for determining the appropriate hospice

plan of care as specified in § 418.112 (d) of this chapter.

(C) The services the LTC facility will continue to provide, based on each resident's plan of care.

(D) A communication process, including how the communication will be documented between the LTC facility and the hospice provider, to ensure that the needs of the resident are addressed and met 24 hours per day.

(E) A provision that the LTC facility immediately notifies the hospice about the following:

(1) A significant change in the resident's physical, mental, social, or emotional status.

(2) Clinical complications that suggest a need to alter the plan of care.

(3) A need to transfer the resident from the facility for any condition.

(4) The resident's death.

(F) A provision stating that the hospice assumes responsibility for determining the appropriate course of hospice care, including the determination to change the level of services provided.

(G) An agreement that it is the LTC facility's responsibility to furnish 24-hour room and board care, meet the resident's personal care and nursing needs in coordination with the hospice representative, and ensure that the level of care provided is appropriately based on the individual resident's needs.

(H) A delineation of the hospice's responsibilities, including but not limited to, providing medical direction and management of the patient; nursing; counseling (including spiritual, dietary, and bereavement); social work; providing medical supplies, durable medical equipment, and drugs necessary for the palliation of pain and symptoms associated with the terminal illness and related conditions; and all other hospice services that are necessary for the care of the resident's terminal illness and related conditions.

(I) A provision that when the LTC facility personnel are responsible for the administration of prescribed therapies, including those therapies determined appropriate by the hospice and delineated in the hospice plan of care, the LTC facility personnel may administer the therapies where permitted by State

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law and as specified by the LTC facility.

(J) A provision stating that the LTC facility must report all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by hospice personnel, to the hospice administrator immediately when the LTC facility becomes aware of the alleged violation.

(K) A delineation of the responsibilities of the hospice and the LTC facility to provide bereavement services to LTC facility staff.

(3) Each LTC facility arranging for the provision of hospice care under a written agreement must designate a member of the facility's interdisciplinary team who is responsible for working with hospice representatives to coordinate care to the resident provided by the LTC facility staff and hospice staff. The interdisciplinary team member must have a clinical background, function within their State scope of practice act, and have the ability to assess the resident or have access to someone that has the skills and capabilities to assess the resident. The designated interdisciplinary team member is responsible for the following:

(i) Collaborating with hospice representatives and coordinating LTC facility staff participation in the hospice care planning process for those residents receiving these services.

(ii) Communicating with hospice representatives and other healthcare providers participating in the provision of care for the terminal illness, related conditions, and other conditions, to ensure quality of care for the patient and family.

(iii) Ensuring that the LTC facility communicates with the hospice medical director, the patient's attending physician, and other practitioners participating in the provision of care to the patient as needed to coordinate the hospice care with the medical care provided by other physicians.

(iv) Obtaining the following information from the hospice:

(A) The most recent hospice plan of care specific to each patient.

(B) Hospice election form.

(C) Physician certification and recertification of the terminal illness specific to each patient.

(D) Names and contact information for hospice personnel involved in hospice care of each patient.

(E) Instructions on how to access the hospice's 24-hour on-call system.

(F) Hospice medication information specific to each patient.

(G) Hospice physician and attending physician (if any) orders specific to each patient.

(v) Ensuring that the LTC facility staff provides orientation in the policies and procedures of the facility, including patient rights, appropriate forms, and record keeping requirements, to hospice staff furnishing care to LTC residents.

(4) Each LTC facility providing hospice care under a written agreement must ensure that each resident's written plan of care includes both the most recent hospice plan of care and a description of the services furnished by the LTC facility to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being, as required at § 483.25.

(p) *Social worker.* Any facility with more than 120 beds must employ a qualified social worker on a full-time basis. A qualified social worker is:

(1) An individual with a minimum of a bachelor's degree in social work or a bachelor's degree in a human services field including, but not limited to, sociology, gerontology, special education, rehabilitation counseling, and psychology; and

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

(q) *Mandatory submission of staffing information based on payroll data in a uniform format.* Long-term care facilities must electronically submit to CMS complete and accurate direct care staffing information, including information for agency and contract staff, based on payroll and other verifiable and auditable data in a uniform format according to specifications established by CMS.

(1) *Direct Care Staff.* Direct Care Staff are those individuals who, through interpersonal contact with residents or resident care management, provide

care and services to allow residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being. Direct care staff does not include individuals whose primary duty is maintaining the physical environment of the long term care facility (for example, housekeeping).

(2) *Submission requirements.* The facility must electronically submit to CMS complete and accurate direct care staffing information, including the following:

(i) The category of work for each person on direct care staff (including, but not limited to, whether the individual is a registered nurse, licensed practical nurse, licensed vocational nurse, certified nursing assistant, therapist, or other type of medical personnel as specified by CMS);

(ii) Resident census data; and

(iii) Information on direct care staff turnover and tenure, and on the hours of care provided by each category of staff per resident per day (including, but not limited to, start date, end date (as applicable), and hours worked for each individual).

(3) *Distinguishing employee from agency and contract staff.* When reporting information about direct care staff, the facility must specify whether the individual is an employee of the facility, or is engaged by the facility under contract or through an agency.

(4) *Data format.* The facility must submit direct care staffing information in the uniform format specified by CMS.

(5) *Submission schedule.* The facility must submit direct care staffing information on the schedule specified by CMS, but no less frequently than quarterly.

[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; 76 FR 9511, Feb. 18, 2011; 78 FR 16805, Mar. 19, 2013; 78 FR 38605, June 27, 2013; 80 FR 46477, Aug. 4, 2015; 81 FR 64032, Sept. 16, 2016. Redesignated and amended at 81 FR 68861, 68865, Oct. 4, 2016; 82 FR 32259, July 13, 2017; 84 FR 34735, July 18, 2019]

§ 483.73 Emergency preparedness.

The LTC facility must comply with all applicable Federal, State and local

emergency preparedness requirements. The LTC facility must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The LTC facility must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach, including missing residents.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address resident population, including, but not limited to, persons at-risk; the type of services the LTC facility has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, or Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the LTC facility's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The LTC facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and residents, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, medical, and pharmaceutical supplies.

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(ii) Alternate sources of energy to maintain—

(A) Temperatures to protect resident health and safety and for the safe and sanitary storage of provisions;

(B) Emergency lighting;

(C) Fire detection, extinguishing, and alarm systems; and

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered residents in the LTC facility's care during and after an emergency. If on-duty staff and sheltered residents are relocated during the emergency, the LTC facility must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the LTC facility, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for residents, staff, and volunteers who remain in the LTC facility.

(5) A system of medical documentation that preserves resident information, protects confidentiality of resident information, and secures and maintains the availability of records.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other LTC facilities and other providers to receive residents in the event of limitations or cessation of operations to maintain the continuity of services to LTC residents.

(8) The role of the LTC facility under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The LTC facility must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be re-

viewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Residents' physicians.

(iv) Other LTC facilities.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, or local emergency preparedness staff.

(ii) The State Licensing and Certification Agency.

(iii) The Office of the State Long-Term Care Ombudsman.

(iv) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) LTC facility's staff.

(ii) Federal, State, tribal, regional, or local emergency management agencies.

(4) A method for sharing information and medical documentation for residents under the LTC facility's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release resident information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of residents under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the LTC facility's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(8) A method for sharing information from the emergency plan that the facility has determined is appropriate with residents and their families or representatives.

(d) *Training and testing.* The LTC facility must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies

and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training program.* The LTC facility must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Demonstrate staff knowledge of emergency procedures.

(2) *Testing.* The LTC facility must conduct exercises to test the emergency plan at least annually, including unannounced staff drills using the emergency procedures. The LTC facility must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the LTC facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the LTC facility is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the LTC facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the LTC facility's emergency plan, as needed.

(e) *Emergency and standby power systems.* The LTC facility must implement emergency and standby power systems

based on the emergency plan set forth in paragraph (a) of this section.

(1) *Emergency generator location.* The generator must be located in accordance with the location requirements found in the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6), Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4), and NFPA 110, when a new structure is built or when an existing structure or building is renovated.

(2) *Emergency generator inspection and testing.* The LTC facility must implement the emergency power system inspection, testing, and maintenance requirements found in the Health Care Facilities Code, NFPA 110, and Life Safety Code.

(3) *Emergency generator fuel.* LTC facilities that maintain an onsite fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.

(f) *Integrated healthcare systems.* If a LTC facility is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the LTC facility may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4)

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of this section. The unified and integrated emergency plan must also be based on and include—

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

(g) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain the material from the sources listed below. You may inspect a copy 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. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the FEDERAL REGISTER to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

(i) NFPA 99, Health Care Facilities Code 2012 edition, issued August 11, 2011.

(ii) Technical interim amendment (TIA) 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

(xii) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009.

(2) [Reserved]

[81 FR 64030, Sept. 16, 2016; 81 FR 80594, Nov. 16, 2016]

EFFECTIVE DATE NOTE: At 84 FR 51824, Sept. 30, 2019, § 483.73 was amended by revising paragraphs (a)(4) and (d)(2), effective Nov. 29, 2019. For the convenience of the user, the revised text is set forth as follows:

§ 483.73 Emergency preparedness.

* * * * *

(a) * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, or Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

* * * * *

(d) * * *

(2) *Testing.* The LTC facility must conduct exercises to test the emergency plan at least twice per year, including unannounced staff drills using the emergency procedures. The LTC facility must do the following:

(i) Participate in an annual full-scale exercise that is community-based; or

(A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise.

(B) If the LTC facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the LTC facility is exempt from engaging its next required a full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional annual exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the LTC facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the LTC facility's emergency plan, as needed.

* * * * *

§ 483.75 Quality assurance and performance improvement.

(a) *Quality assurance and performance improvement (QAPI) program.* Each LTC facility, including a facility that is part of a multiunit chain, must develop, implement, and maintain an effective, comprehensive, data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life. The facility must—

(1) Maintain documentation and demonstrate evidence of its ongoing QAPI program that meets the requirements of this section. This may include but is not limited to systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events; and documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities;

(2) Present its QAPI plan to the State Survey Agency no later than 1 year after the promulgation of this regulation;

(3) Present its QAPI plan to a State Survey Agency or Federal surveyor at each annual recertification survey and upon request during any other survey and to CMS upon request; and

(4) Present documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with requirements to a State Survey Agency, Federal surveyor or CMS upon request.

(b) *Program design and scope.* A facility must design its QAPI program to be ongoing, comprehensive, and to address the full range of care and services provided by the facility. It must:

(1) Address all systems of care and management practices;

(2) Include clinical care, quality of life, and resident choice;

(3) Utilize the best available evidence to define and measure indicators of quality and facility goals that reflect processes of care and facility operations that have been shown to be predictive of desired outcomes for residents of a SNF or NF.

(4) Reflect the complexities, unique care, and services that the facility provides.

(c) *Program feedback, data systems and monitoring.* A facility must establish and implement written policies and procedures for feedback, data collections systems, and monitoring, including adverse event monitoring. The policies and procedures must include, at a minimum, the following:

(1) Facility maintenance of effective systems to obtain and use of feedback and input from direct care staff, other staff, residents, and resident representatives, including how such information will be used to identify problems that are high risk, high volume, or problem-prone, and opportunities for improvement.

(2) Facility maintenance of effective systems to identify, collect, and use data and information from all departments, including but not limited to the facility assessment required at § 483.70(e) and including how such information will be used to develop and monitor performance indicators.

(3) Facility development, monitoring, and evaluation of performance indicators, including the methodology and frequency for such development, monitoring, and evaluation.

(4) Facility adverse event monitoring, including the methods by which the facility will systematically identify, report, track, investigate, analyze and use data and information relating to adverse events in the facility, including how the facility will use the data to develop activities to prevent adverse events.

(d) *Program systematic analysis and systemic action.* (1) The facility must take actions aimed at performance improvement and, after implementing those actions, measure its success, and track performance to ensure that improvements are realized and sustained.

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(2) The facility will develop and implement policies addressing:

(i) How they will use a systematic approach to determine underlying causes of problems impacting larger systems;

(ii) How they will develop corrective actions that will be designed to effect change at the systems level to prevent quality of care, quality of life, or safety problems ; and

(iii) How the facility will monitor the effectiveness of its performance improvement activities to ensure that improvements are sustained.

(e) *Program activities.* (1) The facility must set priorities for its performance improvement activities that focus on high-risk, high-volume, or problem-prone areas; consider the incidence, prevalence, and severity of problems in those areas; and affect health outcomes, resident safety, resident autonomy, resident choice, and quality of care.

(2) Performance improvement activities must track medical errors and adverse resident events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the facility.

(3) As a part of their performance improvement activities, the facility must conduct distinct performance improvement projects. The number and frequency of improvement projects conducted by the facility must reflect the scope and complexity of the facility's services and available resources, as reflected in the facility assessment required at §483.70(e). Improvement projects must include at least annually a project that focuses on high risk or problem-prone areas identified through the data collection and analysis described in paragraphs (c) and (d) of this section.

(f) *Governance and leadership.* The governing body and/or executive leadership (or organized group or individual who assumes full legal authority and responsibility for operation of the facility) is responsible and accountable for ensuring that—

(1) An ongoing QAPI program is defined, implemented, and maintained and addresses identified priorities.

(2) The QAPI program is sustained during transitions in leadership and staffing;

(3) The QAPI program is adequately resourced, including ensuring staff time, equipment, and technical training as needed;

(4) The QAPI program identifies and prioritizes problems and opportunities that reflect organizational process, functions, and services provided to resident based on performance indicator data, and resident and staff input, and other information.

(5) Corrective actions address gaps in systems, and are evaluated for effectiveness; and

(6) Clear expectations are set around safety, quality, rights, choice, and respect.

(g) *Quality assessment and assurance.*

(1) A facility must maintain a quality assessment and assurance committee consisting at a minimum of:

(i) The director of nursing services;

(ii) The Medical Director or his or her designee;

(iii) At least three other members of the facility's staff, at least one of who must be the administrator, owner, a board member or other individual in a leadership role; and

(iv) The infection preventionist.

(2) The quality assessment and assurance committee reports to the facility's governing body, or designated person(s) functioning as a governing body regarding its activities, including implementation of the QAPI program required under paragraphs (a) through (e) of this section. The committee must:

(i) Meet at least quarterly and as needed to coordinate and evaluate activities under the QAPI program, such as identifying issues with respect to which quality assessment and assurance improvement projects required under the QAPI program, are necessary; and

(ii) Develop and implement appropriate plans of action to correct identified quality deficiencies; and

(iii) Regularly review and analyze data, including data collected under the QAPI program and data resulting from drug regimen reviews, and act on available data to make improvements.

(h) *Disclosure of information.* 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.

(i) *Sanctions.* Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.

[81 FR 68867, Oct. 4, 2016, as amended at 82 FR 32259, July 13, 2017]

§ 483.80 Infection control.

The facility must establish and maintain an infection prevention and control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections.

(a) *Infection prevention and control program.* The facility must establish an infection prevention and control program (IPCP) that must include, at a minimum, the following elements:

(1) A system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement based upon the facility assessment conducted according to § 483.70(e) and following accepted national standards;

(2) Written standards, policies, and procedures for the program, which must include, but are not limited to:

(i) A system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility;

(ii) When and to whom possible incidents of communicable disease or infections should be reported;

(iii) Standard and transmission-based precautions to be followed to prevent spread of infections;

(iv) When and how isolation should be used for a resident; including but not limited to:

(A) The type and duration of the isolation, depending upon the infectious agent or organism involved, and

(B) A requirement that the isolation should be the least restrictive possible

for the resident under the circumstances.

(v) The circumstances under which 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; and

(vi) The hand hygiene procedures to be followed by staff involved in direct resident contact.

(3) An antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.

(4) A system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility.

(b) *Infection preventionist.* The facility must designate one or more individual(s) as the infection preventionist(s) (IPs) who are responsible for the facility's IPCP. The IP must:

(1) Have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field;

(2) Be qualified by education, training, experience or certification;

(3) Work at least part-time at the facility; and

(4) Have completed specialized training in infection prevention and control.

(c) *IP participation on quality assessment and assurance committee.* The individual designated as the IP, or at least one of the individuals if there is more than one IP, must be a member of the facility's quality assessment and assurance committee and report to the committee on the IPCP on a regular basis.

(d) *Influenza and pneumococcal immunizations—*(1) *Influenza.* The facility must develop policies and procedures to ensure that—

(i) Before offering the influenza immunization, each resident or the resident's 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;

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(iii) The resident or the resident's 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 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 to ensure that—

(i) Before offering the pneumococcal immunization, each resident or the resident's 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 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 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.

(e) *Linens.* Personnel must handle, store, process, and transport linens so as to prevent the spread of infection.

(f) *Annual review.* The facility will conduct an annual review of its IPCP and update their program, as necessary.

[81 FR 68868, Oct. 4, 2016]

§ 483.85 Compliance and ethics program.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Compliance and ethics program means, with respect to a facility, a program of the operating organization that—

(1) Has been reasonably designed, implemented, and enforced so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care; and

(2) Includes, at a minimum, the required components specified in paragraph (c) of this section.

High-level personnel means individual(s) who have substantial control over the operating organization or who have a substantial role in the making of policy within the operating organization.

Operating organization means the individual(s) or entity that operates a facility.

(b) *General rule.* Beginning November 28, 2019, the operating organization for each facility must have in operation a compliance and ethics program (as defined in paragraph (a) of this section) that meets the requirements of this section.

(c) *Required components for all facilities.* The operating organization for each facility must develop, implement, and maintain an effective compliance and ethics program that contains, at a minimum, the following components:

(1) Established written compliance and ethics standards, policies, and procedures to follow that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under the Act and promote quality of care, which include, but are not limited to, the designation of an appropriate compliance and ethics program contact to which individuals may report suspected violations, as well as an alternate method of reporting suspected violations anonymously without fear of retribution; and disciplinary standards that set out the consequences for committing violations for the operating organization's entire staff; individuals providing services under a contractual arrangement; and

volunteers, consistent with the volunteers' expected roles.

(2) Assignment of specific individuals within the high-level personnel of the operating organization with the overall responsibility to oversee compliance with the operating organization's compliance and ethics program's standards, policies, and procedures, such as, but not limited to, the chief executive officer (CEO), members of the board of directors, or directors of major divisions in the operating organization.

(3) Sufficient resources and authority to the specific individuals designated in paragraph (c)(2) of this section to reasonably assure compliance with such standards, policies, and procedures.

(4) Due care not to delegate substantial discretionary authority to individuals who the operating organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under the Social Security Act.

(5) The facility takes steps to effectively communicate the standards, policies, and procedures in the operating organization's compliance and ethics program to the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles. Requirements include, but are not limited to, mandatory participation in training as set forth at § 483.95(f) or orientation programs, or disseminating information that explains in a practical manner what is required under the program.

(6) The facility takes reasonable steps to achieve compliance with the program's standards, policies, and procedures. Such steps include, but are not limited to, utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under the Act by any of the operating organization's staff, individuals providing services under a contractual arrangement, or volunteers, having in place and publicizing a reporting system whereby any of these individuals could report violations by others anonymously within the operating organization without

fear of retribution, and having a process for ensuring the integrity of any reported data.

(7) Consistent enforcement of the operating organization's standards, policies, and procedures through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect and report a violation to the compliance and ethics program contact identified in the operating organization's compliance and ethics program.

(8) After a violation is detected, the operating organization must ensure that all reasonable steps identified in its program are taken to respond appropriately to the violation and to prevent further similar violations, including any necessary modification to the operating organization's program to prevent and detect criminal, civil, and administrative violations under the Act.

(d) *Additional required components for operating organizations with five or more facilities.* In addition to all of the other requirements in paragraphs (a), (b), (c), and (e) of this section, operating organizations that operate five or more facilities must also include, at a minimum, the following components in their compliance and ethics program:

(1) A mandatory annual training program on the operating organization's compliance and ethics program that meets the requirements set forth in § 483.95(f).

(2) A designated compliance officer for whom the operating organization's compliance and ethics program is a major responsibility. This individual must report directly to the operating organization's governing body and not be subordinate to the general counsel, chief financial officer or chief operating officer.

(3) Designated compliance liaisons located at each of the operating organization's facilities.

(e) *Annual review.* The operating organization for each facility must review its compliance and ethics program annually and revise its program as needed to reflect changes in all applicable laws or regulations and within the operating organization and its facilities to improve its performance in

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detering, reducing, and detecting violations under the Act and in promoting quality of care.

[81 FR 68869, Oct. 4, 2016, as amended at 82 FR 32259, July 13, 2017]

§ 483.90 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 LTC facility must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.)

(ii) Notwithstanding paragraph (a)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors.

(2) In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a long-term care facility, but only if the waiver will 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) A long-term care facility may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

(5) 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 re-

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placement 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*.

(6) 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/](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html)

[code_of_federal_regulations/ibr_locations.html](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.

(iii) Subject to approval by CMS, a long term care facility may be granted an extension of the sprinkler installation deadline for a time period not to exceed 2 years from August 13, 2013, if the facility meets all of the following conditions:

(A) It is in the process of replacing its current building, or undergoing major modifications to improve the living conditions for residents in all unsprinklered living areas that requires the movement of corridor, room, partition, or structural walls or supports, in addition to the installation of a sprinkler system; or, has had its planned sprinkler installation so impaired by a disaster or emergency, as indicated by a declaration under section 319 of the Public Health Service Act, that CMS finds it would be impractical to meet the sprinkler installation due date.

(B) It demonstrates that it has made the necessary financial commitments to complete the building replacement or modification; or pursuant to a declared disaster or emergency, CMS finds it impractical to make reasonable and necessary financial commitments.

(C) Before applying for the deadline extension, it has submitted plans to State and local authorities that are necessary for approval of the replacement building or major modification that includes the required sprinkler installation, and has received approval of the plans from State and local authorities.

(D) It agrees to complete interim steps to improve fire safety, as determined by CMS.

(iv) An extension granted under paragraph (a)(8)(iii) of this section may be renewed once, for an additional period not to exceed 1 year, if the following conditions are met:

(A) CMS finds that extenuating circumstances beyond the control of the facility will prevent full compliance with the provisions in paragraph (a)(8)(i) of this section by the end of the first waiver period.

(B) All other conditions of paragraph (a)(8)(iii) of this section are met.

(7) Buildings must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement.

(8) When a sprinkler system is shut down for more than 10 hours, the LTC facility must:

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

(ii) Establish a fire watch until the system is back in service.

(b) *Standard: Building safety.* Except as otherwise provided in this section, the LTC facility must meet the applicable provisions and must proceed in accordance with the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a LTC facility.

(2) If application of the Health Care Facilities Code required under paragraph (b) of this section would result in unreasonable hardship for the LTC facility, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of residents.

(c) *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.

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(d) *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.

(e) *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. For facilities that receive approval of construction or reconstruction plans by State and local authorities or are newly certified after November 28, 2016, bedrooms must accommodate no more than two 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 safety and 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.

(f) *Bathroom facilities.* Each resident room must be equipped with or located near toilet and bathing facilities. For facilities that receive approval of construction from State and local authorities or are newly certified after November 28, 2016, each resident room must have its own bathroom equipped with at least a commode and sink.

(g) *Resident call system.* The facility must be adequately equipped to allow residents to call for staff assistance through a communication system which relays the call directly to a staff member or to a centralized staff work area from—

(1) Each resident's bedside; and

(2) Toilet and bathing facilities.

(h) *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;

(3) Be adequately furnished; and

(4) Have sufficient space to accommodate all activities.

(i) *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.

(5) Establish policies, in accordance with applicable Federal, State, and local laws and regulations, regarding smoking, smoking areas, and smoking safety that also take into account non-smoking residents.

(j) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy 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. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the FEDERAL REGISTER to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.

(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

(2) [Reserved]

[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; 79 FR 27155, May 12, 2014; 81 FR 26899, May 4, 2016; 81 FR 42548, June 30, 2016. Redesignated and amended at 81 FR 68861, 68870, Oct. 4, 2016; 82 FR 32259, July 13, 2017]

§ 483.95 Training requirements.

A facility must develop, implement, and maintain an effective training program for all new and existing staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles. A facility must determine the amount and types of training necessary based on a facility assessment as specified at § 483.70(e). Training topics must include but are not limited to—

(a) *Communication*. A facility must include effective communications as mandatory training for direct care staff.

(b) *Resident's rights and facility responsibilities*. A facility must ensure that staff members are educated on the rights of the resident and the responsibilities of a facility to properly care for its residents as set forth at § 483.10, respectively.

(c) *Abuse, neglect, and exploitation*. In addition to the freedom from abuse, neglect, and exploitation requirements in § 483.12, facilities must also provide training to their staff that at a minimum educates staff on—

(1) Activities that constitute abuse, neglect, exploitation, and misappropriation of resident property as set forth at § 483.12.

(2) Procedures for reporting incidents of abuse, neglect, exploitation, or the misappropriation of resident property.

(3) Dementia management and resident abuse prevention.

(d) *Quality assurance and performance improvement*. A facility must include as part of its QAPI program mandatory training that outlines and informs staff of the elements and goals of the facility's QAPI program as set forth at § 483.75.

(e) *Infection control*. A facility must include as part of its infection prevention and control program mandatory training that includes the written standards, policies, and procedures for the program as described at § 483.80(a)(2).

(f) *Compliance and ethics*. The operating organization for each facility must include as part of its compliance and ethics program, as set forth at § 483.85—

(1) An effective way to communicate that program's standards, policies, and

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procedures through a training program or in another practical manner which explains the requirements under the program.

(2) Annual training if the operating organization operates five or more facilities.

(g) *Required in-service training for nurse aides.* In-service training must—

(1) Be sufficient to ensure the continuing competence of nurse aides, but must be no less than 12 hours per year.

(2) Include dementia management training and resident abuse prevention training.

(3) Address areas of weakness as determined in nurse aides' performance reviews and facility assessment at § 483.70(e) and may address the special needs of residents as determined by the facility staff.

(4) For nurse aides providing services to individuals with cognitive impairments, also address the care of the cognitively impaired.

(h) *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.

(i) *Behavioral health.* A facility must provide behavioral health training consistent with the requirements at § 483.40 and as determined by the facility assessment at § 483.70(e).

[81 FR 68870, Oct. 4, 2016]

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 intellectual disability are based on section 1919(e)(7) of the Act.

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§ 483.102 Applicability and definitions.

(a) This subpart applies to the screening or reviewing of all individuals with mental illness or intellectual disability 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

¹The 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.

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 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 de-

scribed 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 intellectual disability (IID) if he or she has—

(i) A level of retardation (mild, moderate, severe or profound) described in the American Association on Intellectual Disability's Manual on Classification in Intellectual Disability (1983). Incorporation by reference of the 1983 edition of the American Association on Intellectual Disability's Manual on Classification in Intellectual Disability 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 483.138.

§ 483.106 Basic rule.

(a) *Requirement.* The State PASARR program must require—(1) Preadmission screening of all individuals with mental illness or intellectual disability who apply as new admissions

²The American Association on Intellectual Disability's Manual on Classification in Intellectual Disability 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 Intellectual Disability, 1719 Kalorama Rd., NW., Washington, DC 20009.

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to Medicaid NFs on or after January 1, 1989;

(2) Initial review, by April 1, 1990, of all current residents with intellectual disability 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 intellectual disability, 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) *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 intellectual disability 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 IID 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 intellectual disability, 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 intellectual disability, must be made by the State intellectual disability or developmental disabilities authority.

(e) *Delegation of responsibility*—(1) The State mental health and intellectual disability 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 intellectual disability 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 intellectual disability authority has responsibility for both the evaluation and determination functions for individuals with IID 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 intellectual disability 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 intellectual disability authorities.

(b) In making their determinations, however, the State mental health and intellectual disability 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 fa-

cilities 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 IID, the State mental health or intellectual disability 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 intellectual disability is determined to require a NF level of care, the State mental health or intellectual disability authority (as appropriate) must also determine, in accordance with § 483.130, whether the individual requires specialized services for the mental illness or intellectual disability, 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 IID by whatever agent performs the Level I identification, under § 483.128(a) of this part, to the State mental health or intellectual disability 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 individuals with intellectual disabilities/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.

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§ 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 intellectual disability.* For each resident of a NF who has intellectual disability, the State intellectual disability 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 individuals with intellectual disabilities; and

(2) Specialized services for intellectual disability 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 intellectual disability 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 intellectual disability 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 intellectual disability authority determines that a resident or applicant for admission requires both a NF level of services and specialized services for the mental illness or intellectual disability—

(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 intellectual disability 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 IID.* If the State mental health or intellectual disability authority determines that a resident requires neither the level of services provided by a NF nor specialized services for MI or IID, 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 § 483.15(b); and

(2) Prepare and orient the resident for discharge.

(c) *Residents who do not require NF services but require specialized services for MI or IID*—(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 re-admission 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 intellectual disability.

(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 § 483.15(b);

(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 intellectual disability.

(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 residencies in more than one NF.

[57 FR 56506, Nov. 30, 1992, as amended at 81 FR 68871, Oct. 4, 2016]

§ 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 intellectual disability, 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 IID whose needs are such that continuous supervision, treatment and training by qualified mental health or intellectual disability 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 intellectual disability 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—

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(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 IID 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 IID.* The State's PASARR program must identify all individuals who are suspected of having MI or IID 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 IID and is being referred to the State mental health or intellectual disability authority for Level II screening.

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(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 IID, §§ 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 IID 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 intellectual disability 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 intellectual disability 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 de-

terminations 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.

(1) *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 IID; 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 IID 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 intellectual disability authority as to whether NF level of services and specialized services are needed must be based on an evaluation of data

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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 IID and MI, §§ 483.134 and 483.136).

(c) *Group determinations by category.* Advance group determinations by category developed by the State mental health or intellectual disability 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 intellectual disability or developmental disability providers.

(d) *Examples of categories.* Examples of categories for which the State mental health or intellectual disability 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, func-

tioning 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 IID 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 intellectual disability 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 intellectual disability 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 IID.* The State intellectual disability authority may make categorical determinations that individuals with dementia, which exists in combination with intellectual disability or a related condition, do not need specialized services.

(i) If a State mental health or intellectual disability 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 intellectual disability 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 intellectual disability 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 intellectual disability 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 IID 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 IID 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 IID 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 IID 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 IID 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 § 483.15(b) 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 IID 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 § 483.15(b). 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 IID 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, as amended at 81 FR 68871, Oct. 4, 2016]

§ 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 resi-

dent who has MI or IID, 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/IID (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 intellectual disability 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 nu-

tritional 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 intellectual disability requires specialized services (PASARR/IID).

(a) *Purpose.* The purpose of this section is to identify the minimum data needs and process requirements for the State intellectual disability authority to determine whether or not the applicant or resident with intellectual disability, 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 IID or a related condition.

(2) Based on the data compiled in paragraph (b) of this section, the State intellectual disability authority, using appropriate personnel, as designated by the State, must validate that the individual has IID or is a person with a related condition and must determine whether specialized services for intellectual disability are needed. In making this determination, the State intellectual disability 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 IID

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 § 483.15(b) 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 beneficiaries during—

(1) The 30 day notice period specified in § 483.15(b) of this chapter; or

(2) During the period an appeal is in progress.

[57 FR 56506, Nov. 30, 1992, as amended at 81 FR 68871, Oct. 4, 2016]

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.

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(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 §§ 483.35(c) and (d) and 483.95(g) 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 as adjusted annually under 45 CFR part 102; 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 as adjusted annually under 45 CFR part 102 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 as adjusted annually under 45 CFR part 102 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 from 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; 81 FR 61563, Sept. 6, 2016; 81 FR 68871, Oct. 4, 2016]

§ 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;

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(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—

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(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.

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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, § 483.15(h), and part 431 subpart E of this chapter.

[57 FR 56506, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993, as amended at 81 FR 68871, Oct. 4, 2016]

§ 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).

(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.

[57 FR 56514, Nov. 30, 1992, as amended at 81 FR 68871, Oct. 4, 2016]

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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 pur-

poses 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 beneficiary 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.

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§ 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 beneficiaries 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.

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(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 resi-

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dent'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 discussion 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.

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§ 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 Individuals with Intellectual Disabilities**

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 individuals with intellectual disabilities 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

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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/IID, the ICF/IID remains directly responsible for the standards relating to physical environment that are specified in § 483.470 (a) through (g), (j) and (k).

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(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 intellectual disability professional.* Each client's active treatment program must be integrated, coordinated and monitored by a qualified intellectual disability professional who—

(1) Has at least one year of experience working directly with persons with intellectual disability or other developmental disabilities; and

(2) Is one of the following:

(i) A doctor of medicine or osteopathy.

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(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, non-professional 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 non-professional 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 Ther-

apy 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 intellectual disability 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 func-

tional 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 intellectual disability 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;

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(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),

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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 Committee 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—

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(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.

(1) *Standard: Drug storage and record-keeping.* (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.

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(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 subspecialties 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 intellectual disability 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, non-abrasive, 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

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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) [Reserved]

(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 and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.)

(ii) Notwithstanding paragraph (j)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors.

(iii) Chapters 32.3.2.11.2 and 33.3.2.11.2 of the adopted 2012 Life Safety Code do not apply to a facility.

(iv) Beginning July 5, 2019, an ICF-IID must be in compliance with Chapter 33.2.3.5.7.1, Sprinklers in attics, or Chapter 33.2.3.5.7.2, Heat detection systems in attics of the Life Safety Code.

(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) *Facilities that meet the Life Safety Code definition of a health care occupancy.* (i) In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a residential board and care facility, but only if the waiver will not adversely affect the health and safety of the patients.

(ii) A facility may install alcohol-based hand rub dispensers if the dispensers are installed in a manner that adequately protects against inappropriate access.

(iii) When a sprinkler system is shut down for more than 10 hours, the ICF-IID must:

(A) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

(B) Establish a fire watch until the system is back in service.

(iv) Beginning July 5, 2019, an ICF-IID must be in compliance with Chapter 33.2.3.5.7.1, sprinklers in attics, or Chapter 33.2.3.5.7.2, heat detection systems in attics of the Life Safety Code.

(v) Except as otherwise provided in this section, ICF-IIDs must meet the applicable provisions and must proceed in accordance with the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).

(A) Chapter 7.8, 12 and 13 of the adopted Health Care Facilities Code does not apply to an ICF-IID.

(B) If application of the Health Care Facilities Code required under paragraph (j)(5)(iv) of this section would result in unreasonable hardship for the ICF-IID, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of clients.

(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.

(m) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy 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. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the FEDERAL REGISTER to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.

(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

(2) [Reserved]

[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; 81 FR 26900, May 4, 2016; 81 FR 64032, Sept. 16, 2016]

§ 483.475 Condition of participation: Emergency preparedness.

The Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID) must comply with all applicable Federal, State, and local emergency preparedness requirements. The ICF/IID must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The ICF/IID must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach, including missing clients.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address the special needs of its client population, including, but not limited to, persons at-risk; the type of services the ICF/IID has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the ICF/IID efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The ICF/IID must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and clients, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, medical, and pharmaceutical supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect client health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered clients in the ICF/IID's care during and after an emergency. If on-duty staff and sheltered clients are relocated during the emergency, the ICF/IID must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the ICF/IID, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for clients, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves client information, protects confidentiality of client information, and secures and maintains the availability of records.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other ICF/IIDs or other providers to receive clients in the event of limitations or cessation of operations to maintain the continuity of services to ICF/IID clients.

(8) The role of the ICF/IID under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The ICF/IID must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Clients' physicians.

(iv) Other ICF/IIDs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(iii) The State Licensing and Certification Agency.

(iv) The State Protection and Advocacy Agency.

(3) Primary and alternate means for communicating with the ICF/IID's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for clients under the ICF/IID's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release client information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of clients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the ICF/IID's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(8) A method for sharing information from the emergency plan that the facility has determined is appropriate with clients and their families or representatives.

(d) *Training and testing.* The ICF/IID must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually. The ICF/IID must meet the requirements for evacuation drills and training at § 483.470(h).

(1) *Training program.* The ICF/IID must do all the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and

volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Demonstrate staff knowledge of emergency procedures.

(2) *Testing.* The ICF/IID must conduct exercises to test the emergency plan at least annually. The ICF/IID must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the ICF/IID experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ICF/IID is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the ICF/IID's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the ICF/IID's emergency plan, as needed.

(e) *Integrated healthcare systems.* If an ICF/IID is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the ICF/IID may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility’s unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include all of the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

[81 FR 64032, Sept. 16, 2016]

EFFECTIVE DATE NOTE: At 84 FR 51824, Sept. 30, 2019, § 483.475 was amended by revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii); adding paragraph (d)(1)(v); and revising paragraph (d)(2), effective Nov. 29, 2019. For the convenience of the user, the added and revised text is set forth as follows:

§ 483.475 Condition of participation: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The ICF/IID must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do all of the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials’ efforts to maintain an integrated

response during a disaster or emergency situation.

(b) *Policies and procedures.* The ICF/IID must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The ICF/IID must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include the following:

* * * * *

(d) *Training and testing.* The ICF/IID must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years. The ICF/IID must meet the requirements for evacuation drills and training at § 483.470(i).

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the ICF/IID must conduct training on the updated policies and procedures.

(2) *Testing.* The ICF/IID must conduct exercises to test the emergency plan at least twice per year. The ICF/IID must do the following:

(i) Participate in an annual full-scale exercise that is community-based; or

(A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise; or

(B) If the ICF/IID experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ICF/IID is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional annual exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the ICF/IID's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the ICF/IID's emergency plan, as needed

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§ 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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484.335 Appeals process for the Home Health Value-Based Purchasing (HHVBP) Model.

AUTHORITY: 42 U.S.C. 1302 and 1395hh unless otherwise indicated.

SOURCE: 54 FR 33367, Aug. 14, 1989, unless otherwise noted.

Subpart A—General Provisions

SOURCE: 82 FR 4578, Jan. 13, 2017, unless otherwise noted.

§ 484.1 Basis and scope.

(a) *Basis*. This part is based on:

(1) Sections 1861(o) and 1891 of the Act, which establish the conditions that an HHA must meet in order to participate in the Medicare program and which, along with the additional requirements set forth in this part, are considered necessary to ensure the health and safety of patients; and

(2) Section 1861(z) of the Act, which specifies the institutional planning standards that HHAs must meet.

(b) *Scope*. The provisions of this part serve as the basis for survey activities for the purpose of determining whether an agency meets the requirements for participation in the Medicare program.