

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 431, 447, 482, 483, 485, 488, and 489

[CMS–3260–F]

RIN 0938–AR61

Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule will revise the requirements that Long-Term Care facilities must meet to participate in the Medicare and Medicaid programs. These changes are necessary to reflect the substantial advances that have been made over the past several years in the theory and practice of service delivery and safety. These revisions are also an integral part of our efforts to achieve broad-based improvements both in the quality of health care furnished through federal programs, and in patient safety, while at the same time reducing procedural burdens on providers.

DATES: *Effective date:* These regulations are effective on November 28, 2016.

Implementation date: The regulations included in Phase 1 must be implemented by November 28, 2016.

The regulations included in Phase 2 must be implemented by November 28, 2017.

The regulations included in Phase 3 must be implemented by November 28, 2019.

A detailed discussion regarding the different phases of the implementation timeline can be found in Section B. II “Implementation Date.”

FOR FURTHER INFORMATION CONTACT:

LTC Regulations Team, (410) 786–6633; Sheila Blackstock, Ronisha Blackstone, Diane Corning, Lisa Parker.

SUPPLEMENTARY INFORMATION:

Acronyms

Because of the many terms to which we refer by acronym in this final rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

AAA Area Agencies on Aging
 ACL Administration for Community Living
 ADL Activities of Daily Living
 AHCA American Health Care Association
 AHLA American Health Lawyers Association
 ANSI American National Standards Institute

ASPE Assistant Secretary for Planning and Evaluation
 BSPD Behavioral and Psychological Symptoms of Dementia
 CASPER Certification and Survey Provider Enhanced Reports
 CIL Centers for Independent Living
 CLIA Clinical Laboratory Improvement Amendment
 CMS Centers for Medicare & Medicaid Services
 CNS Clinical Nurse Specialist
 CPR Cardiopulmonary Resuscitation
 DoN Director of Nursing
 EHR Electronic Health Records
 FDA Food and Drug Administration
 GAO Government Accountability Office
 HACCP Hazard Analysis and Critical Control Point
 HAI Healthcare-Associated Infection
 HHS U.S. Department of Health and Human Services
 HIPAA Health Insurance Portability and Accountability Act of 1996
 ICN International Council of Nurses
 IDT Interdisciplinary Team
 IG Interpretive Guidance
 IP Infection Preventionist
 IPCP Infection Prevention and Control Program
 LSC Life Safety Code
 LTC Long-Term Care
 NATCEP Nurse Aide Training Competency Evaluation Program
 MAR Medication Administration Record
 MDS Minimum Data Set
 NA Nurse Aide
 NF Nursing Facility
 NP Nurse Practitioner
 OIG Office of the Inspector General
 OMB Office of Management and Budget
 ONC Office of the National Coordinator
 PA Physician Assistant
 PASARR Preadmission Screening and Resident Review
 PIPs Performance Improvement Projects
 PEU Protein-Energy under Nutrition
 QA Quality Assurance
 QAA Quality Assessment and Assurance
 QAPI Quality Assurance and Performance Improvement
 QIO Quality Improvement Organization
 RFA Regulatory Flexibility Act
 RN Registered Nurse
 SNF Skilled Nursing Facility
 WHO World Health Organization

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I. Background

A. Executive Summary

1. Purpose

Consolidated Medicare and Medicaid requirements for participation (requirements) for long term care (LTC) facilities (42 CFR part 483, subpart B) were first published in the **Federal Register** on February 2, 1989 (54 FR 5316). These regulations have been revised and added to since that time, principally as a result of legislation or a need to address a specific issue. However, they have not been comprehensively reviewed and updated since 1991 (56 FR 48826, September 26, 1991), despite substantial changes in service delivery in this setting.

Since the current requirements were developed, significant innovations in resident care and quality assessment practices have emerged. In addition, the population of LTC facilities has changed, and has become more diverse and more clinically complex. Over the last two to three decades, extensive, evidence-based research has been conducted and has enhanced our knowledge about resident safety, health outcomes, individual choice, and quality assurance and performance improvement. In light of these changes, we recognized the need to evaluate the regulations on a comprehensive basis, from both a structural and a content perspective. Therefore, we reviewed regulations in an effort to improve the quality of life, care, and services in LTC

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 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.

■ 14. Section 483.12 is revised to read as follows:

§ 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 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.

§ 483.13 [Removed]

■ 15. Remove § 483.13.

■ 16. Section 483.15 is revised to read as follows:

§ 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 (b)(10) of this section.

(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)(3) 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 (b)(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 residents 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 (b)(5) of this section.

(4) *Timing of the notice.* (i) Except as specified in paragraphs (b)(4)(ii) and (b)(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 (b)(1)(ii)(C) of this section;

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

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

(D) An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (b)(1)(ii)(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 (b)(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(l).

(9) *Room changes in a composite distinct part.* Room changes in a facility 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 (c)(3) of this section, permitting a resident to return; and

(iv) The information specified in paragraph (c)(3) 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 (c)(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.

§ 483.20 [Amended]

■ 17. In § 483.20—

■ a. Revise paragraph (b)(1) introductory text.

■ b. Revise paragraphs (b)(1)(xvi) and (xviii).

■ c. Revise paragraph (e).

■ d. Remove paragraphs (k) and (l).

■ e. Redesignate paragraph (m) as paragraph (k).

■ f. Revise newly designated paragraph (k).

The revisions read as follows:

§ 483.20 Resident assessment.

* * * * *

(b) * * *

(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:

* * * * *

(xvi) Discharge planning.

* * * * *

(xviii) Documentation of participation in assessment. The assessment process must include direct observation and communication with the resident, as