Displaying title 42, up to date as of 3/18/2022. Title 42 was last amended 3/08/2022.

Title 42 - Public Health
Chapter IV - Centers for Medicare & Medicaid Services, Department of Health and Human Services
Subchapter G - Standards and Certification

ENHANCED CONTENT - TABLE OF CONTENTS

PART 488 - SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

Authority: 42 U.S.C 1302 and 1395hh.

Source: 53 FR 22859, June 17, 1988, unless otherwise noted.

Subpart A - General Provisions

§ 488.1 Definitions.

As used in this part -

Act means the Social Security Act.

Certification means a determination made by the state survey agency that providers and suppliers are in compliance with the applicable conditions of participation, conditions for coverage, conditions for certification, or requirements.

Conditions for certification means the health and safety standards RHCs must meet to participate in the Medicare program.

Conditions for coverage means the requirements suppliers must meet to participate in the Medicare program.

Conditions of participation means the requirements providers other than skilled nursing facilities must meet to participate in the Medicare program and includes conditions of certification for rural health clinics.

Deemed status means that CMS has certified a provider or supplier for Medicare participation, based on all of the following criteria having been met: The provider or supplier has voluntarily applied for, and received, accreditation from a CMS-approved national accrediting organization under the applicable Medicare accreditation program; the accrediting organization has recommended the provider or supplier to CMS for Medicare participation; CMS has accepted the accrediting organization's recommendation; and CMS finds that all other participation requirements have been met.

Full review means a survey of a provider or supplier for compliance with all of the Medicare conditions or requirements applicable to that provider or supplier type.

Immediate jeopardy means a situation in which the provider's or supplier's non-compliance with one or more Medicare requirements, conditions of participation, conditions for coverage or certification has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident or patient.

Medicare condition means any condition of participation or for coverage, including any long term care requirements.

National accrediting organization means an organization that accredits provider entities, as that term is defined in section 1865(a)(4) of the Act, under a specific program and whose accredited provider entities under each program are widely located geographically across the United States.

Provider of services or provider refers to a hospital, critical access hospital, skilled nursing facility, nursing facility, home health agency, hospice, comprehensive outpatient rehabilitation facility, or a clinic, rehabilitation agency or public health agency that furnishes outpatient physical therapy or speech pathology services.

Rate of disparity means the percentage of all sample validation surveys for which a State survey agency finds noncompliance with one or more Medicare conditions and no comparable condition level deficiency was cited by the accreditation organization, where it is reasonable to conclude that the deficiencies were present at the time of the accreditation organization's most recent surveys of providers or suppliers of the same type.

Example: Assume that during a validation review period State survey agencies perform validation surveys at 200 facilities of the same type (for example, ambulatory surgical centers, home health agencies) accredited by the same accreditation organization. The State survey agencies find 60 of the facilities out of compliance with one or more Medicare conditions, and it is reasonable to conclude that these deficiencies were present at the time of the most recent survey by an accreditation organization. The accreditation organization, however, has found deficiencies comparable to the condition level deficiencies at only 22 of the 60 facilities. These validation results would yield ((60-22)/200) a rate of disparity of 19 percent.

Reasonable assurance means that an accrediting organization has demonstrated to CMS's satisfaction that its accreditation program requirements meet or exceed the Medicare program requirements.

State includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

State survey agency refers to the state health agency or other appropriate state or local agency CMS uses to perform survey and review functions provided for in sections 1864, 1819(g), and 1919(g) of the Act.

Substantial allegation of non-compliance means a complaint from any of a variety of sources (such as patient, relative, or third party), including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles, that would, if found to be present, adversely affect the health and safety of patients or residents and raises doubts as to a provider's or supplier's compliance with any Medicare condition of participation, condition for coverage, condition for certification, or requirements.

Supplier means any of the following: Independent laboratory; portable X-ray services; physical therapist in independent practice; ESRD facility; rural health clinic; Federally qualified health center; chiropractor; or ambulatory surgical center.

[53 FR 22859, June 17, 1988, as amended at 54 FR 5373, Feb. 2, 1989; 56 FR 48879, Sept. 26, 1991; 57 FR 24982, June 12, 1992; 58 FR 30676, May 26, 1993; 58 FR 61838, Nov. 23, 1993; 62 FR 46037, Aug. 29, 1997; 71 FR 68230, Nov. 24, 2006; 80 FR 29834, May 22, 2015]

§ 488.2 Statutory basis.

This part is based on the indicated provisions of the following sections of the Act:

1128 - Exclusion of entities from participation in Medicare.

1128A - Civil money penalties.

1138(b) - Requirements for organ procurement organizations and organ procurement agencies.

1814 - Conditions for, and limitations on, payment for Part A services.

1819 - Requirements for SNFs.

1820 - Requirements for CAHs.

1822 - Hospice Program survey and enforcement procedures.

1832(a)(2)(C) - Requirements for Organizations that provide outpatient physical therapy and speech language pathology services.

1832(a)(2)(F) - Requirements for ASCs.

1832(a)(2)(J) - Requirements for partial hospitalization services provided by CMHCs.

1861(e) - Requirements for hospitals.

1861(f) - Requirements for psychiatric hospitals.

1861(m) - Requirements for Home Health Services

1861(o) - Requirements for Home Health Agencies

1861(p)(4) - Requirements for rehabilitation agencies.

1861(z) - Institutional planning standards that hospitals and SNFs must meet.

1861(aa) - Requirements for RHCs and FQHCs.

1861(cc)(2) - Requirements for CORFs.

1861(dd) - Requirements for hospices.

1861(ee) - Discharge planning guidelines for hospitals.

1861(ff)(3)(A) - Requirements for CMHCs.

1861(ss)(2) - Accreditation of religious nonmedical health care institutions.

1863 - Consultation with state agencies, accrediting bodies, and other organizations to develop conditions of participation, conditions for coverage, conditions for certification, and requirements for providers or suppliers.

1864 - Use of State survey agencies.

1865 - Effect of accreditation.

1875(b) - Requirements for performance review of CMS-approved accreditation programs.

1880 - Requirements for hospitals and SNFs of the Indian Health Service.

1881 - Requirements for ESRD facilities.

1883 - Requirements for hospitals that furnish extended care services.

1891 - Conditions of participation for home health agencies; home health quality.

1902 - Requirements for participation in the Medicaid program.

1913 - Medicaid requirements for hospitals that provide NF care.

1919 - Medicaid requirements for NFs.

[60 FR 50443, Sept. 29, 1995, as amended at 64 FR 67052, Nov. 30, 1999; 77 FR 67164, Nov. 8, 2012; 80 FR 29834, May 22, 2015; 86 FR 62424, Nov. 9, 2021]

§ 488.3 Conditions of participation, conditions for coverage, conditions for certification and long term care requirements.

(a) ***Basic rules.*** To be approved for participation in, or coverage under, the Medicare program, a prospective provider or supplier must meet the following:

(1) Meet the applicable statutory definitions in section 1138(b), 1819, 1820, 1832(a)(2)(C), 1832(a)(2)(F), 1832(a)(2)(J), 1834(e), 1861, 1881, 1883, 1891, 1913 or 1919 of the Act.

(2) Be in compliance with the applicable conditions, certification requirements, or long term care requirements prescribed in part 405 subparts U or X, part 410 subpart E, part 416, part 418 subpart C, parts 482 through 486, part 491 subpart A, or part 494 of this chapter.

(b) ***Special conditions.*** The Secretary shall consult with state agencies and national AOs, as applicable, to develop CoP, CfC, conditions for certification and long term care requirements.

(1) The Secretary may, at a state's request, approve health and safety requirements for providers or suppliers in the state that exceed Medicare program requirements.

(2) If a state or political subdivision imposes requirements on institutions (that exceed the Medicare program requirements) as a condition for the purchase of health services under a state Medicaid plan approved under title XIX of the Act, (or if Guam, Puerto Rico, or the Virgin Islands does so under a state plan for Old Age Assistance under title I of the Act, or for Aid to the Aged, Blind, and Disabled under the original title XVI of the Act), the Secretary imposes similar requirements as a condition for payment under Medicare in that state or political subdivision.

[80 FR 29835, May 22, 2015]

§ 488.4 General rules for a CMS-approved accreditation program for providers and suppliers.

(a) The following requirements apply when a national accrediting organization has applied for CMS approval of a provider or supplier accreditation program and CMS has found that the program provides reasonable assurance for providers or suppliers accredited under the program:

(1) When a provider or supplier demonstrates full compliance with all of the accreditation program requirements of the accrediting organization's CMS-approved accreditation program, the accrediting organization may recommend that CMS grant deemed status to the provider or supplier.

(2) CMS may deem the provider or supplier, excluding kidney transplant centers within a hospital and ESRD facilities, to be in compliance with the applicable Medicare conditions or requirements. The deemed status provider or supplier is subject to validation surveys as provided at § 488.9.

(b) [Reserved]

[80 FR 29835, May 22, 2015]

§ 488.5 Application and re-application procedures for national accrediting organizations.

(a) ***Information submitted with application.*** A national accrediting organization applying to CMS for approval or re-approval of an accreditation program under § 488.4 must furnish CMS with all of the following information and materials to demonstrate that the program provides reasonable assurance that the entities accredited under the program meet or exceed the applicable Medicare conditions or requirements. This information must include the following:

(1) Documentation that demonstrates the organization meets the definition of a “national accrediting organization” under § 488.1 as it relates to the accreditation program.

(2) The type of provider or supplier accreditation program for which the organization is requesting approval or re-approval.

(3) A detailed crosswalk (in table format) that identifies, for each of the applicable Medicare conditions or requirements, the exact language of the organization's comparable accreditation requirements and standards.

(4) A detailed description of the organization's survey process to confirm that a provider or supplier meets or exceeds the Medicare program requirements. This description must include all of the following information:

(i) Frequency of surveys performed and an agreement by the organization to re-survey every accredited provider or supplier, through unannounced surveys, no later than 36 months after the prior accreditation effective date, including an explanation of how the accrediting organization will maintain the schedule it proposes. If there is a statutorily-mandated survey interval of less than 36 months, the organization must indicate how it will adhere to the statutory schedule.

(ii) Documentation demonstrating the comparability of the organization's survey process and surveyor guidance to those required for state survey agencies conducting federal Medicare surveys for the same provider or supplier type, in accordance with the applicable requirements or conditions of participation or conditions for coverage or certification.

(iii) Copies of the organization's survey forms, guidelines, and instructions to surveyors.

(iv) Documentation demonstrating that the organization's survey reports identify, for each finding of non-compliance with accreditation standards, the comparable Medicare CoP, CfC, conditions for certification, or requirements.

(v) Description of the organization's accreditation survey review process.

(vi) Description of the organization's procedures and timelines for notifying surveyed facilities of non-compliance with the accreditation program's standards.

(vii) Description of the organization's procedures and timelines for monitoring the provider's or supplier's correction of identified non-compliance with the accreditation program's standards.

(viii) A statement acknowledging that, as a condition for CMS approval of a national accrediting organization's accreditation program, the organization agrees to provide CMS with information extracted from each accreditation survey for a specified provider or supplier as part of its data submissions required under paragraph (a)(11)(ii) of this section, a copy of all survey reports and related information for applicants seeking initial participation in Medicare, and, upon request from CMS, a copy of the most recent accreditation survey for a specified provider or supplier, together with any other information related to the survey as CMS may require (including corrective action plans).

(ix) A statement acknowledging that the accrediting organization will provide timely notification to CMS when an accreditation survey or complaint investigation identifies an immediate jeopardy as that term is defined at § 489.3 of this chapter. Using the format specified by CMS, the accrediting organization must notify CMS within two business days from the date the accrediting organization identifies the immediate jeopardy.

(x) For accrediting organizations applying for approval or re-approval of CMS-approved hospice programs, a statement acknowledging that the accrediting organization (AO) will include a statement of deficiencies (that is, the Form CMS-2567 or a successor form) to document findings of the hospice Medicare conditions of participation in accordance with section 1822(a)(2)(A)(ii) of the Act and will submit such in a manner specified by CMS.

(5) The criteria for determining the size and composition of the organization's survey teams for the type of provider or supplier to be accredited, including variations in team size and composition for individual provider or supplier surveys.

(6) The overall adequacy of the number of the organization's surveyors, including how the organization will increase the size of the survey staff to match growth in the number of accredited facilities while maintaining re-accreditation intervals for existing accredited facilities.

(7) A description of the education and experience requirements surveyors must meet.

(8) A description of the content and frequency of the organization's in-service training it provides to survey personnel.

(9) A description of the organization's evaluation systems used to monitor the performance of individual surveyors and survey teams.

(10) The organization's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

(11) A description of the organization's data management and analysis system for its surveys and accreditation decisions, including all of the following:

(i) A detailed description of how the organization uses its data to assure the compliance of its accreditation program with the Medicare program requirements.

(ii) A statement acknowledging that the organization agrees to submit timely, accurate, and complete data to support CMS's evaluation of the accrediting organization's performance. Data to be submitted includes, but is not limited to, accredited provider or supplier identifying information, survey schedules, survey findings, and notices of accreditation decisions. The organization must submit necessary data according to the instructions and timeframes CMS specifies.

(12) The organization's procedures for responding to, and investigating, complaints against accredited facilities, including policies and procedures regarding referrals when applicable to appropriate licensing bodies and ombudsman programs.

(13) The organization's accreditation status decision-making process, including its policies and procedures for granting, withholding, or removing accreditation status for facilities that fail to meet the accrediting organization's standards or requirements, assignment of less than full accreditation status or other actions taken by the organization in response to non-compliance with its standards and requirements. The organization must furnish the following:

(i) A description of all types and categories of accreditation decisions associated with the program for which approval is sought, including the duration of each.

(ii) A statement acknowledging that the organization agrees to notify CMS (in a manner CMS specifies) of any decision to revoke, withdraw, or revise the accreditation status of a specific deemed status provider or supplier, within three business days from the date the organization takes an action.

(14) A list of all facilities currently accredited by the organization under the program for which CMS approval is sought, including the type and category of accreditation currently held by each provider or supplier, and the expiration date of each provider's or supplier's current accreditation.

(15) A schedule of all surveys expected to be conducted by the organization for the accreditation program under review during the 6-month period following submission of the application.

(16) The three most recent audited financial statements of the organization that demonstrate that the organization's staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(17) A statement that it will:

(i) Provide written notification to CMS and to all providers or suppliers accredited under a CMS-approved accreditation program at least 90 calendar days in advance of the effective date of a decision by the organization to voluntarily terminate its CMS-approved accreditation program, including the implications for their deemed status in accordance with § 488.8(g)(2);

(ii) Adhere to the requirements for written notice to its accredited providers or suppliers at § 488.8(e) in the case of an involuntary termination; and

(iii) Include a written statement that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program, the accrediting organization must continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

(18) A statement that it will provide written notification to CMS of any proposed changes in the organization's CMS-approved accreditation program and that it agrees not to implement the proposed changes without prior written notice of continued program approval from CMS except as provided for at § 488.8(b)(2).

(19) A statement that, in response to a written notice from CMS to the organization of a change in the applicable conditions or requirements or in the survey process, the organization will provide CMS with proposed corresponding changes in the organization's requirements for its CMS-approved accreditation program to ensure continued comparability with the CMS conditions or requirements or survey process. The organization must comply with the following requirements:

(i) The proposed changes must be submitted within 30 calendar days of the date of the written CMS notice to the organization or by a date specified in the notice, whichever is later. CMS will give due consideration to an organization's request for an extension of the deadline.

(ii) The proposed changes will not be implemented without prior written notice of continued program approval from CMS, except as provided for at § 488.8(b)(1)(iv).

(20) A statement acknowledging that, as a condition for CMS's approval of an accreditation program, the organization will agree to permit its surveyors to serve as witnesses in a legal proceeding if CMS takes an adverse action against a provider or supplier on the basis of the organization's accreditation survey findings, and will cooperate with CMS to make surveyors and other staff available when needed.

(21) A statement acknowledging that the organization agrees to make all Medicare cited deficiencies, both standard and condition level, immediate jeopardy situations, and dates of correction, for final accreditation survey reports publicly available on the organization's Web site within 90 days after the survey report is made available to those facilities for the most recent 3 years, on an ongoing basis in a manner specified by CMS. This acknowledgement includes all initial, triennial, full, follow-up, focused, and complaint surveys.

(b) ***Additional information needed.*** If CMS determines that additional information is necessary to make a determination for approval or denial of the organization's initial application or re-application for CMS's approval of an accreditation program, CMS will notify the organization and afford it an opportunity to provide the additional information.

(c)

(1) ***Withdrawing an application.*** An accrediting organization may withdraw its initial application for CMS's-approval of its accreditation program at any time before CMS publishes the final notice described in paragraph (e)(2) of this section.

(2) ***Voluntary termination of a CMS-approved accreditation program.*** An accrediting organization may voluntarily terminate its CMS-approved accreditation program at any time. The accrediting organization must notify CMS of its decision to voluntarily terminate its approved accreditation program at least 90 calendar days in advance of the effective date of the termination. In accordance with the requirement at § 488.4(a)(17)(i), the accrediting organization must also provide written notice at least 90 days in advance of the effective date of the termination to each of its deemed status providers or suppliers.

(d) ***Re-submitting a request.***

(1) Except as provided in paragraph (d)(2) of this section, an organization whose request for CMS's approval or re-approval of an accreditation program has been denied may resubmit its application if the organization satisfies all of the following requirements:

(i) Revises its accreditation program to address the issues related to the denial of its previous request.

(ii) Demonstrates that it can provide reasonable assurance.

(iii) Resubmits the application in its entirety.

(2) If an accrediting organization has requested, in accordance with subpart D of this part, a reconsideration of CMS's determination that its request for approval of an accreditation program is denied, it may not submit a new application for approval of an accreditation program for the type of provider or supplier at issue in the reconsideration until the reconsideration is administratively final.

(e) ***Public notice and comment.*** CMS publishes a notice in the Federal Register when the following conditions are met:

(1) ***Proposed notice.*** When CMS receives a complete application from a national accrediting organization seeking CMS's approval of an accreditation program, it publishes a proposed notice. The proposed notice identifies the organization and the type of providers or suppliers to be covered by the accreditation program and provides 30 calendar days for the public to submit comments to CMS.

(2) ***Final notice.*** When CMS decides to approve or disapprove a national accrediting organization's application, it publishes a final notice within 210 calendar days from the date CMS determines the AO's applications was complete, unless the application was for a skilled nursing facility accreditation program. There is no timeframe for publication of a final notice for a national accrediting organization's application for approval of a skilled nursing facility accreditation program. The final notice specifies the basis for the CMS decision.

(i) ***Approval or re-approval.*** If CMS approves or re-approves the accrediting organization's accreditation program, the final notices describes how the accreditation program provides reasonable assurance. The final notice specifies the effective date and term of the approval (which may not be later than the publication date of the notice and which will not exceed 6 years.

(ii) ***Disapproval.*** If CMS does not approve the accrediting organization's accreditation program, the final notice describes, except in the case of a skilled nursing facility accreditation program, how the organization fails to provide reasonable assurance. In the case of an application for a skilled nursing facility accreditation program, disapproval may be based on the program's failure to provide reasonable assurance, or on CMS's decision to exercise its discretion in accordance with section 1865(a)(1)(B) of the Act. The final notice specifies the effective date of the decision.

[80 FR 29835, May 22, 2015, as amended at 82 FR 38516, Aug. 14, 2017; 82 FR 46143, Oct. 4, 2017; 83 FR 56631, Nov. 13, 2018; 86 FR 62425, Nov. 9, 2021]

§ 488.6 Providers or suppliers that participate in the Medicaid program under a CMS-approved accreditation program.

A provider or supplier that has been granted "deemed status" by CMS by virtue of its accreditation from a CMS-approved accreditation program is eligible to participate in the Medicaid program if they are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements.

[80 FR 29837, May 22, 2015]

§ 488.7 Release and use of accreditation surveys.

A Medicare participating provider or supplier deemed to meet program requirements in accordance with § 488.4 must authorize its accrediting organization to release to CMS a copy of its most current accreditation survey and any information related to the survey that CMS may require (including, but not limited to, corrective action plans).

(a) CMS may determine that a provider or supplier does not meet the applicable Medicare conditions or requirements on the basis of its own investigation of the accreditation survey or any other information related to the survey.

(b) With the exception of home health agency and hospice program surveys, general disclosure of an accrediting organization's survey information is prohibited under section 1865(b) of the Act. CMS may publicly disclose an accreditation survey and information related to the survey, upon written request, to the extent that the accreditation survey and survey information are related to an enforcement action taken by CMS.

(c) CMS posts inspection reports from a State or local survey agency or accrediting organization conducted on or after October 1, 2022, for hospice programs, including copies of a hospice program's survey deficiencies, and enforcement actions (for example, involuntary terminations) taken as a result of such surveys, on its public website in a manner that is prominent, easily accessible, readily understandable, and searchable for the general public and allows for timely updates.

[80 FR 29837, May 22, 2015, as amended at 86 FR 62425, Nov. 9, 2021]

§ 488.8 Ongoing review of accrediting organizations.

(a) ***Performance review.*** In accordance with section 1875(b) of the Act, CMS evaluates the performance of each CMS-approved accreditation program on an ongoing basis. This review includes, but is not limited to the following:

(1) Review of the organization's survey activity.

(2) Analysis of the results of the validation surveys under § 488.9(a)(1), including the rate of disparity between certifications of the accrediting organization and certifications of the SA.

(3) Review of the organization's continued fulfillment of the requirements in § 488.5(a).

(b) ***Comparability review.*** CMS assesses the equivalency of an accrediting organization's CMS-approved program requirements to the comparable Medicare requirements if the following conditions exist:

(1) CMS imposes new Medicare certification requirements or changes its survey process.

(i) CMS provides written notice of the changes to the affected accrediting organization.

(ii) CMS specifies in its written notice a timeframe, not less than 30 calendar days from the date of the notice, for the accrediting organization to submit its proposed equivalent changes, including its implementation timeframe, for CMS review. CMS may extend the deadline after due consideration of a written request for extension by the accrediting organization, submitted prior to the original deadline.

(iii) After completing the comparability review CMS provides written notification to the organization whether or not the accreditation program, including the proposed revisions and implementation timeframe, continues to meet or exceed all applicable Medicare requirements.

(iv) If, no later than 60 calendar days after receipt of the organization's proposed changes, CMS does not provide the written notice to the organization required in paragraph (b)(1)(iii) of this section, then the revised program will be deemed to meet or exceed all applicable Medicare requirements and to have continued CMS approval.

(v) If an organization fails to submit its proposed changes within the required timeframe, or fails to implement the proposed changes that have been determined by CMS or deemed to be comparable, CMS may open an accreditation program review in accordance with paragraph (c) of this section.

(2) An accrediting organization proposes to adopt new requirements or to change its survey process.

(i) An accrediting organization must provide written notice to CMS of any proposed changes in its accreditation requirements or survey process and must not implement any changes before receiving CMS's approval, except as provided below.

(ii) If, no later than 60 calendar days after receipt of the organization's proposed changes, CMS does not provide written notice to the organization that the accreditation program, including the proposed revisions, continues or does not continue to meet or exceed all applicable Medicare requirements, then the revised program will be deemed to meet or exceed all applicable Medicare requirements and to have continued CMS approval.

(iii) If an organization implements changes that have neither been determined by CMS nor deemed to be comparable to the applicable Medicare requirements, CMS may open an accreditation program review in accordance with paragraph (c) of this section.

(c) ***CMS-approved accreditation program review.*** If a comparability or performance review reveals evidence of substantial non-compliance of an accrediting organization's CMS-approved accreditation program with the requirements of this subpart, CMS may initiate an accreditation program review.

(1) If an accreditation program review is initiated, CMS provides written notice to the organization indicating that its CMS-approved accreditation program approval may be in jeopardy and that an accreditation program review is being initiated. The notice provides all of the following information:

(i) A statement of the instances, rates or patterns of non-compliance identified, as well as other related information, if applicable.

(ii) A description of the process to be followed during the review, including a description of the opportunities for the accrediting organization to offer factual information related to CMS's findings.

(iii) A description of the possible actions that may be imposed by CMS based on the findings of the accreditation program review.

(iv) The actions the accrediting organization must take to address the identified deficiencies including a timeline for implementation not to exceed 180 calendar days after receipt of the notice that CMS is initiating an accreditation program review.

(2) CMS reviews the accrediting organization's plan of correction for acceptability.

(3) If CMS determines as a result of the accreditation program review or a review of an application for renewal of an existing CMS-approved accreditation program that the accrediting organization has failed to meet any of the requirements of this subpart, CMS may place the accrediting organization's CMS-approved accreditation program on probation for a period up to 180 calendar days to implement corrective actions, not to exceed the accrediting organization's current term of approval. In the case of a renewal application where CMS has placed the accreditation program on probation, CMS indicates that any approval of the application is conditional while the program is placed on probation.

(i) Within 60 calendar days after the end of any probationary period, CMS issues a written determination to the accrediting organization as to whether or not a CMS-approved accreditation program continues to meet the requirements of this subpart, including the reasons for the determination.

(ii) If CMS has determined that the accrediting organization does not meet the requirements, CMS withdraws approval of the CMS-approved accreditation program. The notice of determination provided to the accrediting organization includes notice of the removal of approval, reason for the removal, including the effective date determined in accordance with paragraph (c)(3)(iii) of this section.

(iii) CMS publishes in the Federal Register a notice of its decision to withdraw approval of a CMS-approved accreditation program, including the reasons for the withdrawal, effective 60 calendar days from the date of publication of the notice.

(d) ***Immediate jeopardy.*** If at any time CMS determines that the continued approval of a CMS-approved accreditation program of any accrediting organization poses an immediate jeopardy to the patients of the entities accredited under that program, or the continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of a CMS-approved accreditation program of that accrediting organization and publish a notice of the removal, including the reasons for it, in the Federal Register.

(e) ***Notification of providers or suppliers.*** An accrediting organization whose CMS approval of its accreditation program has been withdrawn must notify, in writing, each of its accredited providers or suppliers of the withdrawal of CMS approval and the implications in accordance with paragraph (g)(1) of this section for the providers' or suppliers' deemed status no later than 30 calendar days after the notice is published in the Federal Register.

(f) ***Request for reconsideration.*** Any accrediting organization dissatisfied with a determination to withdraw CMS approval of its accreditation program may request a reconsideration of that determination in accordance with subpart D of this part.

(g) ***Continuation of deemed status*** -

(1) ***Involuntary termination.*** After CMS removes approval of an accrediting organization's accreditation program, an affected provider's or supplier's deemed status continues in effect for 180 calendar days after the removal of the approval if the provider or supplier submits an application to another CMS-approved accreditation program within 60 calendar days from the date of publication of the removal notice in the Federal Register. The provider or supplier must also provide written notice to the SA that it has submitted an application for accreditation under another CMS-approved accreditation program within this same 60-calendar day timeframe. Failure to comply with the timeframe requirements specified in this section will place the provider or supplier under the SAs authority for continued participation in Medicare and on-going monitoring.

(2) ***Voluntary termination by accrediting organization.*** When an accrediting organization has voluntarily terminated its CMS-approved accreditation program and provides its accredited providers and suppliers the notice required at § 488.5(a)(17), an affected provider's or supplier's deemed status continues in effect for 180 calendar days after the termination effective date if the provider or supplier submits an application to another CMS-approved accreditation program within 60 calendar days from the date of the notice from the accrediting organization. The provider or supplier must also provide written notice to the SA that it has submitted an application for accreditation under another CMS-approved accreditation program within this same 60-calendar day timeframe. Failure to comply with the timeframe requirements specified in this section will place the provider or supplier under the SAs authority for continued participation in Medicare and on-going monitoring.

(h) ***Onsite observations of accrediting organization operations.*** As part of the application review process, the ongoing review process, or the continuing oversight of an accrediting organization's performance, CMS may conduct at any time an onsite inspection of the accrediting organization's operations and offices to verify the organization's representations and to assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, the review of documents, auditing meetings concerning the accreditation process, observation of surveys, the evaluation of survey results or the accreditation decision-making process, and interviews with the organization's staff.

[80 FR 29837, May 22, 2015]

§ 488.9 Validation surveys.

(a) ***Basis for survey.*** CMS may require a survey of an accredited provider or supplier to validate the accrediting organization's CMS-approved accreditation process. These surveys are conducted on a representative sample basis, or in response to substantial allegations of non-compliance.

(1) For a representative sample, the survey may be comprehensive and address all Medicare conditions or requirements, or it may be focused on a specific condition(s) as determined by CMS.

(2) For a substantial allegation of noncompliance, the SA surveys for any condition(s) or requirement(s) that CMS determines is related to the allegations.

(b) ***Selection for survey.***

(1) A provider or supplier selected for a validation survey must cooperate with the SA that performs the validation survey.

(2) If a provider or supplier selected for a validation survey fails to cooperate with the SA, it will no longer be deemed to meet the Medicare conditions or requirements, but will be subject to a review by the SA in accordance with § 488.10(a), and may be subject to termination of its provider agreement under § 489.53 of this chapter.

(c) ***Consequences of a finding of non-compliance.***

(1) If a CMS validation survey results in a finding that the provider or supplier is out of compliance with one or more Medicare conditions or requirements, the provider or supplier will no longer be deemed to meet the Medicare conditions or requirements and will be subject to ongoing review by the SA in accordance with § 488.10(a) until the provider or supplier demonstrates compliance.

(2) CMS may take actions for the deficiencies identified in the state validation survey in accordance with § 488.24, or may first direct the SA to conduct another survey of the provider's or supplier's compliance with specified Medicare conditions or requirements before taking the enforcement actions provided for at § 488.24.

(3) If CMS determines that a provider or supplier is not in compliance with applicable Medicare conditions or requirements, the provider or supplier may be subject to termination of the provider or supplier agreement under § 489.53 of this chapter or of the supplier agreement in accordance with the applicable supplier conditions and any other applicable intermediate sanctions and remedies.

(d) ***Re-instating deemed status.*** An accredited provider or supplier will be deemed to meet the applicable Medicare conditions or requirements in accordance with this section if all of the following requirements are met:

(1) It withdraws any prior refusal to authorize its accrediting organization to release a copy of the provider's or supplier's current accreditation survey.

(2) It withdraws any prior refusal to allow a validation survey, if applicable.

(3) CMS finds that the provider or supplier meets all applicable Medicare CoP, CfC, conditions of certification, or requirements.

(e) ***Impact of adverse actions.*** The existence of any performance review, comparability review, deemed status review, probationary period, or any other action by CMS, does not affect or limit conducting any validation survey.

[80 FR 29839, May 22, 2015]

§ 488.10 State survey agency review: Statutory provisions.

(a) Section 1864(a) of the Act requires the Secretary to enter into an agreement with any State that is able and willing to do so, under which appropriate State or local survey agencies will determine whether:

(1) Providers or prospective providers meet the Medicare conditions of participation or requirements (for SNFs and NFs);

(2) Suppliers meet the conditions for coverage; and

(3) Rural health clinics meet the conditions of certification.

(b) Section 1865(a) of the Act provides that if an institution is accredited by a national accrediting organization recognized by the Secretary, it may be deemed to have met the applicable conditions or requirements.

(c) Section 1864(c) of the Act authorizes the Secretary to enter into agreements with state survey agencies for the purpose of conducting validation surveys in institutions accredited by an accreditation program recognized by the Secretary.

(d) Section 1865(c) provides that an accredited institution that is found after a validation survey to have significant deficiencies related to health and safety of patients will no longer meet the applicable conditions or requirements.

[53 FR 22859, June 17, 1988, as amended at 56 FR 48879, Sept. 26, 1991; 58 FR 61842, Nov. 23, 1993; 62 FR 46037, Aug. 29, 1997; 80 FR 29839, May 22, 2015]

§ 488.11 State survey agency functions.

State and local agencies that have agreements under section 1864(a) of the Act perform the following functions:

(a) Survey and make recommendations regarding the issues listed in § 488.10.

(b) Conduct validation surveys of deemed status providers and suppliers as provided in § 488.9.

(c) Perform other surveys and carry out other appropriate activities and certify their findings to CMS.

(d) Make recommendations regarding the effective dates of provider agreements and supplier approvals in accordance with § 489.13 of this chapter.

[62 FR 43936, Aug. 18, 1997, as amended at 80 FR 29839, May 22, 2015]

§ 488.12 Effect of survey agency certification.

Certifications by the State survey agency represent recommendations to CMS.

(a) On the basis of these recommendations, CMS will determine whether:

(1) A provider or supplier is eligible to participate in or be covered under the Medicare program; or

(2) A provider or supplier accredited under a CMS-approved accreditation program remains deemed to meet the Medicare conditions or requirements, or will be placed under the jurisdiction of the SA and subject to further enforcement actions in accordance with the provisions at § 488.9.

(b) Notice of CMS's determination will be sent to the provider or supplier.

[53 FR 22859, June 17, 1988, as amended at 80 FR 29839, May 22, 2015]

§ 488.13 Loss of accreditation.

If an accrediting organization notifies CMS that it is terminating a provider or supplier due to non-compliance with its CMS-approved accreditation requirements, the SA will conduct a full review in a timely manner.

[80 FR 29839, May 22, 2015]

§ 488.14 Effect of QIO review.

When a QIO is conducting review activities under section 1154 of the Act and part 466 of this chapter, its activities are in lieu of the utilization review and evaluation activities required of health care institutions under sections 1861(e)(6), and 1861(k) of the Act.

[59 FR 56237, Nov. 10, 1994]

§ 488.18 Documentation of findings.

(a) The findings of the State agency with respect to each of the conditions of participation, requirements (for SNFs and NFs), or conditions for coverage must be adequately documented. When the State agency certifies to the Secretary that a provider or supplier is not in compliance with the conditions or requirements (for SNFs and NFs), and therefore not eligible to participate in the program, such documentation includes, in addition to the description of the specific deficiencies which resulted in the agency's recommendation, any provider or supplier response.

(b) If a provider or supplier is certified by the State agency as in compliance with the conditions or participation requirements (for SNFs and NFs) or as meeting the requirements for special certification (see § 488.54), with deficiencies not adversely affecting the health and safety of patients, the following information will be incorporated into the finding:

(1) A statement of the deficiencies that were found.

(2) A description of further action that is required to remove the deficiencies.

(3) A time-phased plan of correction developed by the provider and supplier and concurred with by the State agency.

(4) A scheduled time for a resurvey of the institution or agency to be conducted by the State agency within 90 days following the completion of the survey.

(c) If, on the basis of the State certification, the Secretary determines that the provider or supplier is eligible to participate, the information described in paragraph (b) of this section will be incorporated into a notice of eligibility to the provider or supplier.

(d) If the State agency receives information to the effect that a hospital or a critical access hospital (as defined in section 1861(mm)(1) of the Act) has violated § 489.24 of this chapter, the State agency is to report the information to CMS promptly.

[39 FR 2251, Jan. 17, 1974. Redesignated at 39 FR 11419, Mar. 28, 1974, and further redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 53 FR 23100, June 17, 1988; 59 FR 32120, June 22, 1994; 59 FR 56237, Nov. 10, 1994; 62 FR 46037, Aug. 29, 1997]

EFFECTIVE DATE NOTE

Effective Date Note: At 59 FR 32120, June 22, 1994, § 488.18(d) was added. This paragraph contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 488.20 Periodic review of compliance and approval.

(a) Determinations by CMS to the effect that a provider or supplier is in compliance with the conditions of participation, or requirements (for SNFs and NFs), or the conditions for coverage are made as often as CMS deems necessary and may be more or less than a 12-month period, except for SNFs, NFs and HHAs. (See § 488.308 for special rules for SNFs and NFs.)

(b) The responsibilities of State survey agencies in the review and certification of compliance are as follows:

(1) Resurvey providers or suppliers as frequently as necessary to ascertain compliance and confirm the correction of deficiencies;

(2) Review reports prepared by a Professional Standards Review Organization (authorized under Part B Title XI of the Act) or a State inspection of care team (authorized under Title XIX of the Act) regarding the quality of a facility's care;

(3) Evaluate reports that may pertain to the health and safety of patients; and

(4) Take appropriate actions that may be necessary to achieve compliance or certify noncompliance to CMS.

(c) A State survey agency certification to CMS that a provider or supplier is no longer in compliance with the conditions of participation or requirements (for SNFs and NFs) or conditions for coverage will supersede the State survey agency's previous certification.

(Secs. 1102, 1814, 1861, 1863 through 1866, 1871, and 1881; 42 U.S.C. 1302, 1395f, 1395x, 1395z through 1395cc, 1395hh, and 1395rr)

[45 FR 74833, Nov. 12, 1981. Redesignated and amended at 53 FR 23100, June 17, 1988, and further amended at 54 FR 5373, Feb. 2, 1989; 56 FR 48879, Sept. 26, 1991; 59 FR 56237, Nov. 10, 1994]

§ 488.24 Certification of noncompliance.

(a) Special rules for certification of noncompliance for SNFs and NFs are set forth in § 488.330.

(b) The State agency will certify that a provider or supplier is not or is no longer in compliance with the conditions of participation or conditions for coverage where the deficiencies are of such character as to substantially limit the provider's or supplier's capacity to furnish adequate care or which adversely affect the health and safety of patients; or

(c) If CMS determines that an institution or agency does not qualify for participation or coverage because it is not in compliance with the conditions of participation or conditions for coverage, or if a provider's agreement is terminated for that reason, the institution or agency has the right to request that the determination be reviewed. (Appeals procedures are set forth in part 498 of this chapter.)

[59 FR 56237, Nov. 10, 1994]

§ 488.26 Determining compliance.

(a) Additional rules for certification of compliance for SNFs and NFs are set forth in § 488.330.

(b) The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition. Evaluation of a provider's or supplier's performance against these standards enables the State survey agency to document the nature and extent of deficiencies, if any, with respect to a particular function, and to assess the need for improvement in relation to the prescribed conditions.

(c) The State survey agency must adhere to the following principles in determining compliance with participation requirements:

(1) The survey process is the means to assess compliance with Federal health, safety and quality standards;

(2) The survey process uses resident and patient outcomes as the primary means to establish the compliance process of facilities and agencies. Specifically, surveyors will directly observe the actual provision of care and services to residents and/or patients, and the effects of that care, to assess whether the care provided meets the needs of individual residents and/or patients.

(3) Surveyors are professionals who use their judgment, in concert with Federal forms and procedures, to determine compliance;

(4) Federal procedures are used by all surveyors to ensure uniform and consistent application and interpretation of Federal requirements;

(5) Federal forms are used by all surveyors to ensure proper recording of findings and to document the basis for the findings.

(d) The State survey agency must use the survey methods, procedures, and forms that are prescribed by CMS.

(e) The State survey agency must ensure that a facility's or agency's actual provision of care and services to residents and patients and the effects of that care on such residents and patients are assessed in a systematic manner.

[59 FR 56237, Nov. 10, 1994, as amended at 77 FR 67164, Nov. 8, 2012]

§ 488.28 Providers or suppliers, other than SNFs, NFs, HHAs, and Hospice programs with deficiencies.

(a) If a provider or supplier is found to be deficient in one or more of the standards in the conditions of participation, conditions for coverage, or conditions for certification or requirements, it may participate in, or be covered under, the Medicare program only if the provider or supplier has submitted an acceptable plan of correction for achieving compliance within a reasonable period of time acceptable to CMS. In the case of an immediate jeopardy situation, CMS may require a shorter time period for achieving compliance.

(b) The existing deficiencies noted either individually or in combination neither jeopardize the health and safety of patients nor are of such character as to seriously limit the provider's capacity to render adequate care.

(c)

(1) If it is determined during a survey that a provider or supplier is not in compliance with one or more of the standards, it is granted a reasonable time to achieve compliance.

(2) The amount of time depends upon the -

(i) Nature of the deficiency; and

(ii) State survey agency's judgment as to the capabilities of the facility to provide adequate and safe care.

(d) Ordinarily a provider or supplier is expected to take the steps needed to achieve compliance within 60 days of being notified of the deficiencies but the State survey agency may recommend that additional time be granted by the Secretary in individual situations, if in its judgment, it is not reasonable to expect compliance within 60 days, for example, a facility must obtain the approval of its governing body, or engage in competitive bidding.

[59 FR 56237, Nov. 10, 1994, as amended at 77 FR 67164, Nov. 8, 2012; 80 FR 29839, May 22, 2015; 86 FR 62425, Nov. 9, 2021]

§ 488.30 Revisit user fee for revisit surveys.

(a) ***Definitions.*** As used in this section, the following definitions apply:

Certification (both initial and recertification) means those activities as defined in § 488.1.

Complaint surveys means those surveys conducted on the basis of a substantial allegation of noncompliance, as defined in § 488.1. The requirements of sections 1819(g)(4) and 1919(g)(4) of the Social Security Act and § 488.332 apply to complaint surveys.

Provider of services, provider, or supplier has the meaning defined in § 488.1, and ambulatory surgical centers, transplant programs, and religious nonmedical health care institutions subject to §§ 416.2, 482.70, and 403.702 [C8] of this chapter, respectively, will be subject to user fees unless otherwise exempted.

Revisit survey means a survey performed with respect to a provider or supplier cited for deficiencies during an initial certification, recertification, or substantiated complaint survey and that is designed to evaluate the extent to which previously-cited deficiencies have been corrected and the provider or supplier is in substantial compliance with applicable conditions of participation, requirements, or conditions for coverage. Revisit surveys include both offsite and onsite review.

Substantiated complaint survey means a complaint survey that results in the proof or finding of noncompliance at the time of the survey, a finding that noncompliance was proven to exist, but was corrected prior to the survey, and includes any deficiency that is cited during a complaint survey, whether or not the cited deficiency was the original subject of the complaint.

(b) ***Criteria for determining the fee.***

(1) The provider or supplier will be assessed a revisit user fee based upon one or more of the following:

(i) The average cost per provider or supplier type.

(ii) The type of revisit survey conducted (onsite or offsite).

(iii) The size of the provider or supplier.

(iv) The number of follow-up revisits resulting from uncorrected deficiencies.

(v) The seriousness and number of deficiencies.

(2) CMS may adjust the fees to account for any regional differences in cost.

(c) ***Fee schedule.*** CMS must publish in the Federal Register the proposed and final notices of a uniform fee schedule before it assesses revised revisit user fees. The notices must set forth which criteria will be used and how, as well as the amounts of the assessed fees based on the criteria as identified in paragraph (b) of this subpart.

(d) ***Collection of fees.***

(1) Fees for revisit surveys under this section may be deducted from amounts otherwise payable to the provider or supplier. As they are collected, fees will be deposited as an offset collection to be used exclusively for survey and certification activities conducted by State survey agencies pursuant to section 1864 of the Act or by CMS, and will be available for CMS until expended. CMS may devise other collection methods as it deems appropriate. In determining these methods, CMS will consider efficiency, effectiveness, and convenience for the providers, suppliers, and CMS. CMS may consider any method allowed by law, including: Credit card; electronic fund transfer; check; money order; and offset collections from claims submitted.

(2) Fees for revisit surveys under this section are not allowable items on a cost report, as identified in part 413, subpart B of this chapter, under title XVIII of the Act.

(3) Fees for revisit surveys will be due for any revisit surveys conducted during the time period for which authority to levy a revisit user fee exists.

(e) ***Reconsideration process for revisit user fees.***

(1) CMS will review a request for reconsideration of an assessed revisit user fee -

(i) If a provider or supplier believes an error of fact has been made in the application of the revisit user fee, such as clerical errors, billing for a fee already paid, or assessment of a fee when there was no revisit conducted, and

(ii) If the request for reconsideration is received by CMS within 14 calendar days from the date identified on the revisit user fee assessment notice.

(2) CMS will issue a credit toward any future revisit surveys conducted, if the provider or supplier has remitted an assessed revisit user fee and for which a reconsideration request is found in favor of the provider or supplier. If in the event that CMS judges that a significant amount of time has elapsed before such a credit is used, CMS will refund the assessed revisit user fee amount paid to the provider or supplier.

(3) CMS will not reconsider the assessment of revisit user fees that request reconsideration of the survey findings or deficiency citations that may have given rise to the revisit, the revisit findings, the need for the revisit itself, or other similarly identified basis for the assessment of the revisit user fee.

(f) ***Enforcement.*** If the full revisit user fee payment is not received within 30 calendar days from the date identified on the revisit user fee assessment notice, CMS may terminate the facility's provider agreement (pursuant to § 489.53(a)(16) of this chapter) and enrollment in the Medicare program or the supplier's enrollment and participation in the Medicare program (pursuant to § 424.535(a)(1) of this chapter).

[72 FR 53648, Sept. 19, 2007, as amended at 82 FR 36635, Aug. 4, 2017; 84 FR 51831, Sept. 30, 2019]

Subpart B - Special Requirements

§ 488.52 [Reserved]

§ 488.54 Temporary waivers applicable to hospitals.

(a) ***General provisions.*** If a hospital is found to be out of compliance with one or more conditions of participation for hospitals, as specified in part 482 of this chapter, a temporary waiver may be granted by CMS. CMS may extend a temporary waiver only if such a waiver would not jeopardize or adversely affect the health and safety of patients. The waiver may be issued for any one year period or less under certain circumstances. The waiver may be withdrawn earlier if CMS determines this action is necessary to protect the health and safety of patients. A waiver may be granted only if:

(1) The hospital is located in a rural area. This includes all areas not delineated as "urban" by the Bureau of the Census, based on the most recent census;

(2) The hospital has 50 or fewer inpatient hospital beds;

(3) The character and seriousness of the deficiencies do not adversely affect the health and safety of patients; and

(4) The hospital has made and continues to make a good faith effort to comply with personnel requirements consistent with any waiver.

(b) ***Minimum compliance requirements.*** Each case will have to be decided on its individual merits, and while the degree and extent of compliance will vary, the institution must, as a minimum, meet all of the statutory conditions in section 1861(e)(1)-(8), in addition to meeting such other requirements as the Secretary finds necessary under section 1861(e)(9). (For further information relating to the exception in section 1861(e)(5) of the Act, see paragraph (c) of this section.)

(c) ***Temporary waiver of 24-hour nursing requirement of 24-hour registered nurse requirement.*** CMS may waive the requirement contained in section 1861(e)(5) that a hospital must provide 24-hour nursing service furnished or supervised by a registered nurse. Such a waiver may be granted when the following criteria are met:

(1) The hospital's failure to comply fully with the 24-hour nursing requirement is attributable to a temporary shortage of qualified nursing personnel in the area in which the hospital is located.

(2) A registered nurse is present on the premises to furnish or supervise the nursing services during at least the daytime shift, 7 days a week.

(3) The hospital has in charge, on all tours of duty not covered by a registered nurse, a licensed practical (vocational) nurse.

(4) The hospital complies with all requirements specified in paragraph (a) of this section.

(d) ***Temporary waiver for technical personnel.*** CMS may waive technical personnel requirements, issued under section 1861(e)(9) of the Act, contained in the Conditions of Participation; Hospitals (part 482 of this chapter). Such a waiver must take into account the availability of technical personnel and the educational opportunities for technical personnel in the area in which the hospital is located. CMS may also limit the scope of services furnished by a hospital in conjunction with the waiver in order not to adversely affect the health and safety of the patients. In addition, the hospital must also comply with all requirements specified in paragraph (a) of this section.

[39 FR 2251, Jan. 17, 1974. Redesignated at 39 FR 11419, Mar. 28, 1974, and amended at 41 FR 27962, July 8, 1976. Further redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 47 FR 31531, July 20, 1982; 51 FR 22041, June 17, 1986. Redesignated at 53 FR 23100, June 17, 1988]

§ 488.56 Temporary waivers applicable to skilled nursing facilities.

(a) ***Waiver of 7-day registered nurse requirement.*** To the extent that § 483.35 of this chapter requires any skilled nursing facility to engage the services of a registered nurse more than 40 hours a week, the Secretary may waive such requirement for such periods as he deems appropriate if, based upon documented findings of the State agency, he determines that:

(1) Such facility is located in a rural area and the supply of skilled nursing facility services in such area is not sufficient to meet the needs of individual patients therein,

(2) Such facility has at least one fulltime registered nurse who is regularly on duty at such facility 40 hours a week, and

(3) Such facility

(i) has only patients whose attending physicians have indicated (through physicians' orders or admission notes) that each such patient does not require the services of a registered nurse for a 48-hour period, or

(ii) has made arrangements for a registered nurse or a physician to spend such time at the facility as is determined necessary by the patient's attending physician to provide necessary services on days when the regular fulltime registered nurse is not on duty.

(4) Such facility has made and continues to make a good faith effort to comply with the more than 40-hour registered nurse requirement, but such compliance is impeded by the unavailability of registered nurses in the area.

(b) ***Waiver of medical director requirement.*** To the extent that § 483.70(h) of this chapter requires any skilled nursing facility to engage the services of a medical director either part-time or full-time, the Secretary may waive such requirement for such periods as he deems appropriate if, based upon documented findings of the State agency, he determines that:

(1) Such facility is located in an area where the supply of physicians is not sufficient to permit compliance with this requirement without seriously reducing the availability of physician services within the area, and

(2) Such facility has made and continues to make a good faith effort to comply with § 483.70(h) of this chapter, but such compliance is impeded by the unavailability of physicians in the area.

[39 FR 35777, Oct. 3, 1974. Redesignated and amended at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 53 FR 23100, June 17, 1988, and further amended at 56 FR 48879, Sept. 26, 1991; 57 FR 43925, Sept. 23, 1992; 81 FR 68871, Oct. 4, 2016; 82 FR 32260, July 13, 2017]

§ 488.60 Special procedures for approving end stage renal disease facilities.

(a) ***Consideration for approval.*** An ESRD facility that wishes to be approved or that wishes an expansion of dialysis services to be approved for coverage, in accordance with part 494 of this chapter, must secure a determination by the Secretary. To secure a determination, the facility must submit the following documents and data for consideration by the Secretary:

(1) Certification by the State agency referred to in § 488.12 of this part.

(2) Data furnished by ESRD network organizations and recommendations of the Public Health Service concerning the facility's contribution to the ESRD services of the network.

(3) Data concerning the facility's compliance with professional norms and standards.

(4) Data pertaining to the facility's qualifications for approval or for any expansion of services.

(b) ***Determining compliance with minimal utilization rates: Time limitations*** -

(1) ***Unconditional status.*** A facility which meets minimal utilization requirements will be assigned this status as long as it continues to meet these requirements.

(2) ***Conditional status.*** A conditional status may be granted to a facility for not more than four consecutive calendar years and will not be renewable (see § 405.2122(b) of this chapter). Its status may be examined each calendar year to ascertain its compliance with Subpart U.

(3) ***Exception status.*** Under unusual circumstances (see § 405.2122 (b) of this chapter) the Secretary may grant a time-limited exception to a facility which is not in compliance with the minimal utilization rate(s) for either unconditional status or conditional status. This exception status may be granted, and may be renewed on an annual basis, under circumstances where rigid application of minimal utilization rate requirements would adversely affect the achievement of ESRD program objectives.

(c) ***New applicant.*** A facility which has not previously participated in the ESRD program must submit a plan detailing how it expects to meet the conditional minimal utilization rate status by the end of the second calendar year of its operation under the program and meet the unconditional minimal utilization rate status by the end of the fourth calendar year of its operation under the program.

(d) ***Notification.*** The Secretary will notify each facility and its network coordinating council of its initial and its subsequent minimal utilization rate classification.

(e) ***Failure to meet minimal utilization rate.*** A facility failing to meet standards for unconditional status or conditional status, or if applicable, for exception status, will be so notified at the time of such classification.

(f) ***Interim regulations participant.*** A facility previously participating under the interim regulations will not be approved under the program established by subpart U until it has demonstrated that it meets all the applicable requirements of this subpart, including the appropriate minimal utilization rate. It may continue under the interim program only for a period not to exceed 1 year from the effective date of these amendments (see § 405.2100(c) of this chapter). During this period it may demonstrate its ability to meet the appropriate minimal utilization rate. Failure to qualify under this subpart will automatically terminate coverage of such facility's services under the ESRD program at the end of such year.

[41 FR 22510, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and further amended at 45 FR 58124, Sept. 2, 1980. Redesignated and amended at 53 FR 23100, June 17, 1988; 73 FR 20474, Apr. 15, 2008]

§ 488.61 Special procedures for approval and re-approval of organ transplant programs.

For the purposes of this subpart, the survey, certification, and enforcement procedures described at 42 CFR part 488, subpart A apply to transplant programs, including the periodic review of compliance and approval described at § 488.20.

(a) ***Initial approval procedures for transplant programs that are not Medicare-approved as of June 28, 2007.*** A transplant program, including a kidney transplant program, may submit a request to CMS for Medicare approval at any time.

(1) The request, signed by a person authorized to represent the center (for example, a chief executive officer), must include:

(i) The hospital's Medicare provider I.D. number;

(ii) Name(s) of the designated primary transplant surgeon and primary transplant physician; and,

(iii) A statement from the OPTN that the center has complied with all data submission requirements.

(2) To determine compliance with the clinical experience and outcome requirements at §§ 482.80(b) and 482.80(c), CMS will review the data contained in the most recent OPTN Data Report and 1-year patient and graft survival data contained in the most recent Scientific Registry of Transplant Recipient (SRTR) program-specific report.

(3) If CMS determines that a transplant center has not met the data submission, clinical experience, or outcome requirements, CMS may deny the request for approval or may review the center's compliance with the conditions of participation at §§ 482.72 through 482.76 and §§ 482.90 through 482.104 of this chapter, using the procedures described at 42 CFR part 488, subpart A, to determine whether the center's request will be approved. CMS will notify the transplant center in writing whether it is approved and, if approved, of the effective date of its approval.

(4) CMS will consider mitigating factors in accordance with paragraphs (f), (g), and (h) of this section.

(5) If CMS determines that a transplant program has met the data submission, clinical experience, and outcome requirements, CMS will review the program's compliance with the conditions of participation contained at §§ 482.72 through 482.76 and §§ 482.90 through 482.104 of this chapter using the procedures described in subpart A of this part. If the transplant program is found to be in compliance with all the conditions of participation at §§ 482.72 through 482.104 of this chapter, CMS will notify the transplant program in writing of the effective date of its Medicare-approval. CMS will notify the transplant program in writing if it is not Medicare-approved.

(6) A kidney transplant center may submit a request for initial approval after performing at least 3 transplants over a 12-month period.

(b) ***Initial approval procedures for transplant centers, including kidney transplant centers, that are Medicare approved as of June 28, 2007.***

(1) A transplant center that wants to continue to be Medicare approved must be in compliance with the conditions of participation at §§ 482.72 through 482.104 as of June 28, 2007 and submit a request to CMS for Medicare approval under the conditions of participation no later than December 26, 2007, using the process described in paragraph (a)(1) of the section.

(2) CMS will determine whether to approve the transplant center, using the procedures described in paragraphs (a)(2) through (a)(5) of this section. Until CMS makes a determination whether to approve the transplant center under the conditions of participation at §§ 482.72 through 482.104, the transplant center will continue to be Medicare approved under the end stage renal disease (ESRD) conditions for coverage (CfCs) in part 405, subpart U of this chapter for kidney transplant centers or the pertinent national coverage decisions (NCDs) for extra-renal organ transplant centers, as applicable, and the transplant center will continue to be reimbursed for services provided to Medicare beneficiaries.

(3) Once CMS approves a kidney transplant center under the conditions of participation, the ESRD CfCs no longer apply to the center as of the date of its approval. Once CMS approves an extra-renal organ transplant center under the conditions of participation, the NCDs no longer apply to the center as of the date of its approval.

(4) If a transplant center that is Medicare approved as of June 28, 2007 submits a request for approval under the CoPs at §§ 482.72 through 482.104 of this chapter but CMS does not approve the transplant center, or if the transplant center does not submit its request to CMS for Medicare approval under the CoPs by December 26, 2007, CMS will revoke the transplant center's approval under the conditions for coverage for kidney transplant centers or the national coverage decisions for extra-renal transplant centers, as applicable, and the transplant center will no longer be reimbursed for services provided to Medicare beneficiaries. CMS will notify the transplant center in writing of the effective date of its loss of Medicare approval.

(c) ***Loss of Medicare approval.*** Programs that have lost their Medicare approval may seek re-entry into the Medicare program at any time. A program that has lost its Medicare approval must:

(1) Request initial approval using the procedures described in paragraph (a) of this section;

(2) Be in compliance with §§ 482.72 through 482.104 of this chapter at the time of the request for Medicare approval; and

(3) Submit a report to CMS documenting any changes or corrective actions taken by the program as a result of the loss of its Medicare approval status.

(d) ***Transplant program inactivity.*** A transplant program may remain inactive and retain its Medicare approval for a period not to exceed 12 months. A transplant program must notify CMS upon its voluntary inactivation as required by § 482.74(a)(3) of this chapter.

(e) ***Consideration of mitigating factors in initial approval survey, certification, and enforcement actions for transplant programs*** -

(1) ***Factors.*** Except for situations of immediate jeopardy or deficiencies other than failure to meet requirements at § 482.80 of this chapter, CMS will consider such mitigating factors as may be appropriate in light of the nature of the deficiency and circumstances, including (but not limited to) the following, in making a decision of initial approval of a transplant program that does not meet the data submission, clinical experience, or outcome requirements:

(i) The extent to which outcome measures are not met or exceeded;

(ii) Availability of Medicare-approved transplant centers in the area;

(iii) Extenuating circumstances (for example, natural disaster) that have a temporary effect on meeting the conditions of participation;

(iv) Program improvements that substantially address root causes of graft failures or patient deaths, that have been implemented and institutionalized on a sustainable basis, and that are supported by outcomes more recent than the latest available SRTR report, for which there is a sufficient post-transplant patient and graft survival period and a sufficient number of transplants such that CMS finds that the program demonstrates present-day compliance with the requirements at § 482.80(c)(2)(ii)(C) of this chapter;

(v) Whether the program has made extensive use of innovative transplantation practices relative to other transplant programs, such as a high rate of transplantation of individuals who are highly sensitized or children who have undergone a Fontan procedure compared to most other transplant programs, where CMS finds that the innovative practices are supported by evidence-based published research literature or nationally recognized standards or Institution Review Board (IRB) approvals, and the SRTR risk-adjustment methodology does not take the relevant key factors into consideration; and

(vi) Whether the program's performance, based on the OPTN method of calculating patient and graft survival, is within the OPTN's thresholds for acceptable performance and does not flag OPTN performance review under the applicable OPTN policy.

(2) ***Content.*** A request for consideration of mitigating factors must include sufficient information to permit an adequate review and understanding of the transplant program, the factors that have contributed to outcomes, program improvements or innovations that have been implemented or planned, and in the case of natural disasters, the recovery actions planned. Examples of information to be submitted with each request include (but are not limited to) the following:

(i) The name and contact information for the transplant hospital and the names and roles of key personnel of the transplant program;

(ii) The type of organ transplant program(s) for which approval is requested;

(iii) The conditions of participation that the program does not meet for which the transplant center is requesting CMS' review for mitigating factors;

(iv) The program's organizational chart with full-time equivalent levels, roles, and structure for reporting to hospital leadership;

(v) For applications involving substandard patient or graft survival, the rationale and supporting evidence for CMS' review includes, but is not limited to -

(A) Root Cause Analysis for patient deaths and graft failures, including factors the program has identified as likely causal or contributing factors for patient deaths and graft failures;

(B) Program improvements that have been implemented and improvements that are planned;

(C) Patient and donor/organ selection criteria and evaluation protocols, including methods for pre-transplant patient evaluation by cardiologists, hematologists, nephrologists, and psychiatrists or psychologists to the extent applicable;

(D) Waitlist management protocols and practices relevant to outcomes;

(E) Pre-operative management protocols and practices;

(F) Immunosuppression/infection prophylaxis protocols;

(G) Post-transplant monitoring and management protocols and practices;

(H) Quality Assessment and Performance Improvement (QAPI) Program meeting minutes from the most recent four meetings and attendance rosters from the most recent 12 months;

(I) Quality dashboard and other performance indicators; and

(J) The most recent data regarding transplants that have been made and for outcomes in terms of both patient survival and graft survival;

(vi) For mitigating factors requests based on innovative practice:

(A) A description of the innovations that have been implemented and identification of the specific cases for which the innovative practices are relevant so as to enable the patient and graft survival data for such cases to be compared with all other transplants for at least the period covered by the latest available SRTR report.

(B) The literature, research, or other evidentiary basis that supports consideration of the practice(s) as innovative.

(vii) For requests based on natural disasters or public health emergency:

(A) A description of the disaster or emergency, the specific impact on the program, the time periods of the event(s) and of its immediate recovery aftermath;

(B) Identification of the transplants that occurred during the period for which the request is being made; and

(C) The approximate date when the program believes it substantially recovered from the event(s), or believes it will recover if substantial recovery has not been accomplished at the time of the request.

(3) ***Timing.*** Within 14 calendar days after CMS has issued formal written notice of a condition-level deficiency to the program, CMS must receive notification of the program's intent to seek mitigating factors approval, and receive all information for consideration of mitigating factors within 120 calendar days of the CMS written notification for a deficiency due to data submission, clinical experience or outcomes at § 482.80 of this chapter. Failure to meet these timeframes may be the basis for denial of mitigating factors. CMS may permit an extension of the timeline for good cause, such as a declared public health emergency.

(f) ***Results of mitigating factors review*** -

(1) ***Actions.*** Upon review of the request to consider mitigating factors, CMS may take the following actions:

(i) Approve initial approval of a program's Medicare participation based upon approval of mitigating factors.

(ii) Deny the program's request for Medicare approval based on mitigating factors.

(iii) Offer a time-limited Systems Improvement Agreement, in accordance with paragraph (g) of this section, when a transplant program has waived its appeal rights, has implemented substantial program improvements that address root causes and are institutionally supported by the hospital's governing body on a sustainable basis, and has requested more time to design or implement additional improvements or demonstrate compliance with CMS outcome requirements. Upon completion of the Systems Improvement Agreement or a CMS finding that the hospital has failed to meet the terms of the Agreement, CMS makes a final determination of whether to approve or deny a program's request for Medicare approval based on mitigating factors. A Systems Improvement Agreement follows the process specified in paragraph (g) of this section.

(2) ***Limitation.*** CMS will not approve any program with a condition-level deficiency. However, CMS may approve a program with a standard-level deficiency upon receipt of an acceptable plan of correction.

(g) ***Transplant Systems Improvement Agreement.*** A Systems Improvement Agreement is a binding agreement, entered into voluntarily by the hospital and CMS, through which CMS extends a prospective Medicare termination date and offers the program additional time to achieve compliance with the conditions of participation, contingent on the hospital's agreement to participate in a structured regimen of quality improvement activities, demonstrate improved outcomes, and waive the right to appeal termination based on the identified deficiency or deficiencies (that led to the Agreement) in consideration for more time to demonstrate compliance. In some cases, transplant programs may enter a period of inactivity - voluntarily, or imposed as a condition of the Systems Improvement Agreement.

(1) ***Content.*** In exchange for the additional time to initiate or continue activities to achieve compliance with the conditions of participation, the hospital must agree to a regimen of specified activities, including (but not limited to) all of the following:

(i) Patient notification about the degree and type of noncompliance by the program, an explanation of what the program improvement efforts mean for patients, and financial assistance to defray the out-of-pocket costs of copayments and testing expenses for any wait-listed individual who wishes to be listed with another program;

(ii) An external independent peer review team that conducts an onsite assessment of the program. The peer review must include -

(A) Review of policies, staffing, operations, relationship to hospital services, and factors that contribute to program outcomes;

(B) Suggestions for quality improvements the hospital should consider;

(C) Both verbal and written feedback provided directly to the hospital;

(D) Verbal debriefing provided directly to CMS; neither the hospital nor the peer review team is required to provide a written report to CMS; and

(E) Onsite review by a multidisciplinary team that includes a transplant surgeon with expertise in the relevant organ type(s), a transplant administrator, an individual with expertise in transplant QAPI systems, a social worker or psychologist or psychiatrist, and a specialty physician with expertise in conditions particularly relevant to the applicable organ types(s) such as a cardiologist, nephrologist, or hepatologist. Except for the transplant surgeon, CMS may permit substitution of one type of expertise for another individual who has expertise particularly needed for the type of challenges experienced by the program, such as substitution of an infection control specialist in lieu of, or in addition to, a social worker;

(iii) An action plan that addresses systemic quality improvements and is updated after the onsite peer review;

(iv) An onsite consultant whose qualifications are approved by CMS, and who provides services for 8 days per month on average for the duration of the agreement, except that CMS may permit a portion of the time to be spent offsite and may agree to fewer consultant days each month after the first 3 months of the Systems Improvement Agreement;

(v) A comparative effectiveness analysis that compares policies, procedures, and protocols of the transplant program with those of other programs in areas of endeavor that are relevant to the center's current quality improvement needs;

(vi) Development of increased proficiency, or demonstration of current proficiency, with patient-level data from the Scientific Registry of Transplant Recipients and the use of registry data to analyze outcomes and inform quality improvement efforts;

(vii) A staffing analysis that examines the level, type, training, and skill of staff in order to inform transplant center efforts to ensure the engagement and appropriate training and credentialing of staff;

(viii) Activities to strengthen performance of the Quality Assessment and Performance Improvement Program to ensure full compliance with the requirements of § 482.96 and § 482.21 of this chapter;

(ix) Monthly (unless otherwise specified) reporting and conference calls with CMS regarding the status of programmatic improvements, results of the deliverables in the Systems Improvement Agreement, and the number of transplants, deaths, and graft failures that occur within 1 year post-transplant; and

(x) Additional or alternative requirements specified by CMS, tailored to the transplant program type and circumstances. CMS may waive the content elements at paragraph (g)(1)(v), (vi), (vii) or (viii) of this section if it finds that the program has already adequately conducted the activity, the program is already proficient in the function, or the activity is clearly inapplicable to the deficiencies that led to the Agreement.

(2) ***Timeframe.*** A Systems Improvement Agreement will be established for up to a 12-month period, subject to CMS' discretion to determine if a shorter timeframe may suffice. At the hospital's request, CMS may extend the agreement for up to an additional 6-month period. A signed Systems Improvement Agreement remains in force even if a subsequent SRTR report indicates that the program has restored compliance with the CMS conditions of participation, except that CMS in its sole discretion may shorten the timeframe or allow modification to any portion of the elements of the Agreement in such a case.

[72 FR 15278, Mar. 30, 2007, as amended at 79 FR 27156, May 12, 2014; 79 FR 50359, Aug. 22, 2014; 81 FR 79881, Nov. 14, 2016; 84 FR 51831, Sept. 30, 2019]

§ 488.64 Remote facility variances for utilization review requirements.

(a) As used in this section:

(1) An “available” individual is one who:

(i) Possesses the necessary professional qualifications;

(ii) Is not precluded from participating by reason of financial interest in any such facility or direct responsibility for the care of the patients being reviewed or, in the case of a skilled nursing facility, employment by the facility; and

(iii) Is not precluded from effective participation by the distance between the facility and his residence, office, or other place of work. An individual whose residence, office, or other place of work is more than approximately one hour's travel time from the facility shall be considered precluded from effective participation.

(2) “Adjacent facility” means a health care facility located within a 50-mile radius of the facility which requests a variance.

(b) The Secretary may grant a requesting facility a variance from the time frames set forth in §§ 405.1137(d) of this chapter and 482.30 as applicable, within which reviews all of cases must be commenced and completed, upon a showing satisfactory to the Secretary that the requesting facility has been unable to meet one or more of the requirements of § 405.1137 of this chapter or § 482.30 of this chapter, as applicable, by reason of insufficient medical and other professional personnel available to conduct the utilization review required by § 405.1137 of this chapter or § 482.30 of this chapter, as applicable.

(c) The request for variance shall document the requesting facility's inability to meet the requirements for which a variance is requested and the facility's good faith efforts to comply with the requirements contained in § 405.1137 of this chapter or § 482.30 of this chapter, as applicable.

(d) The request shall include an assurance by the requesting facility that it will continue its good faith efforts to meet the requirements contained in § 405.1137 of this chapter or § 482.30 of this chapter, as applicable.

(e) A revised utilization review plan for the requesting facility shall be submitted concurrently with the request for a variance. The revised plan shall specify the methods and procedures which the requesting facility will use, if a variance is granted, to assure:

(1) That effective and timely control will be maintained over the utilization of services; and

(2) That reviews will be conducted so as to improve the quality of care provided to patients.

(f) The request for a variance shall include:

(1) The name, location, and type (e.g., hospital, skilled nursing facility) of the facility for which the variance is requested;

(2) The total number of patient admissions and average daily patient census at the facility within the previous six months;

(3) The total number of title XVIII and title XIX patient admissions and the average daily patient census of title XVIII and title XIX patients in the facility within the previous six months;

(4) As relevant to the request, the names of all physicians on the active staff of the facility and the names of all other professional personnel on the staff of the facility, or both;

(5) The name, location, and type of each adjacent facility (e.g., hospital, skilled nursing facility);

(6) The distance and average travel time between the facility and each adjacent facility;

(7) As relevant to the request, the location of practice of available physicians and the estimated number of other available professional personnel, or both (see paragraph (a)(1)(iii) of this section);

(8) Documentation by the facility of its attempt to obtain the services of available physicians or other professional personnel, or both; and

(9) A statement of whether a QIO exists in the area where the facility is located.

(g) The Secretary shall promptly notify the facility of the action taken on the request. Where a variance is in effect, the validation of utilization review pursuant to § 405.1137 of this chapter or § 482.30 shall be made with reference to the revised utilization review plan submitted with the request for variance.

(h) The Secretary, in granting a variance, will specify the period for which the variance has been granted; such period will not exceed one year. A request for a renewal shall be submitted not later than 30 days prior to the expiration of the variance and shall contain all information required by paragraphs (c), (d), and (f) of this section. Renewal of the variance will be contingent upon the facility's continuing to meet the provisions of this section.

[40 FR 30818, July 23, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977; 51 FR 22041, June 17, 1986; 51 FR 27847, Aug. 4, 1986; 51 FR 43197, Dec. 1, 1986. Redesignated and amended at 53 FR 23100, June 17, 1988]

§ 488.68 State Agency responsibilities for OASIS collection and data base requirements.

As part of State agency survey responsibilities, the State agency or other entity designated by CMS has overall responsibility for fulfilling the following requirements for operating the OASIS system:

(a) ***Establish and maintain an OASIS database.*** The State agency or other entity designated by CMS must -

(1) Use a standard system developed or approved by CMS to collect, store, and analyze data;

(2) Conduct basic system management activities including hardware and software maintenance, system back-up, and monitoring the status of the database; and

(3) Obtain CMS approval before modifying any parts of the CMS standard system including, but not limited to, standard CMS-approved -

(i) OASIS data items;

(ii) Record formats and validation edits; and

(iii) Agency encoding and transmission methods.

(b) ***Analyze and edit OASIS data.*** The State agency or other entity designated by CMS must -

(1) Upon receipt of data from an HHA, edit the data as specified by CMS and ensure that the HHA resolves errors within the limits specified by CMS;

(2) At least monthly, make available for retrieval by CMS all edited OASIS records received during that period, according to formats specified by CMS, and correct and retransmit previously rejected data as needed; and

(3) Analyze data and generate reports as specified by CMS.

(c) ***Ensure accuracy of OASIS data.*** The State agency must audit the accuracy of the OASIS data through the survey process.

(d) ***Restrict access to OASIS data.*** The State agency or other entity designated by CMS must do the following:

(1) Ensure that access to data is restricted except for the transmission of data and reports to -

(i) CMS;

(ii) The State agency component that conducts surveys for purposes related to this function; and

(iii) Other entities if authorized by CMS.

(2) Ensure that patient identifiable OASIS data is released only to the extent that it is permitted under the Privacy Act of 1974.

(e) ***Provide training and technical support for HHAs.*** The State agency or other entity designated by CMS must -

(1) Instruct each HHA on the administration of the data set, privacy/confidentiality of the data set, and integration of the OASIS data set into the facility's own record keeping system;

(2) Instruct each HHA on the use of software to encode and transmit OASIS data to the State;

(3) Specify to a facility the method of transmission of data to the State, and instruct the facility on this method.

(4) Monitor each HHA's ability to transmit OASIS data.

(5) Provide ongoing technical assistance and general support to HHAs in implementing the OASIS reporting requirements specified in the conditions of participation for home health agencies; and

(6) Carry out any other functions as designated by CMS necessary to maintain OASIS data on the standard State system.

[64 FR 3763, Jan. 25, 1999]

Subpart C - Survey Forms and Procedures

§ 488.100 Long term care survey forms, Part A.

§ 488.105 Long term care survey forms, Part B.

§ 488.110 Procedural guidelines.

SNF/ICF Survey Process. The purpose for implementing a new SNF/ICF survey process is to assess whether the quality of care, as intended by the law and regulations, and as needed by the resident, is actually being provided in nursing homes. Although the onsite review procedures have been changed, facilities must continue to meet all applicable Conditions/Standards, in order to participate in Medicare/Medicaid programs. That is, the methods used to compile information about compliance with law and regulations are changed; the law and regulations themselves are not changed. The new process differs from the traditional process, principally in terms of its emphasis on resident outcomes. In ascertaining whether residents grooming and personal hygiene needs are met, for example, surveyors will no longer routinely evaluate a facility's written policies and procedures. Instead, surveyors will observe residents in order to make that determination. In addition, surveyors will confirm, through interviews with residents and staff, that such needs are indeed met on a regular basis. In most reviews, then, surveyors will ascertain whether the facility is actually providing the required and needed care and services, rather than whether the facility is capable of providing the care and services.

The Outcome-Oriented Survey Process - Skilled Nursing Facilities (SNFs) and Intermediate Care Facilities (ICFs)

(a) General.

(b) The Survey Tasks.

(c) Task 1 - Entrance Conference.

(d) Task 2 - Resident Sample - Selection Methodology.

(e) Task 3 - Tour of the Facility.

(f) Task 4 - Observation/Interview/Medical Record Review (including drug regimen review).

(g) Task 5 - Drug Pass Observation.

(h) Task 6 - Dining Area and Eating Assistance Observation.

(i) Task 7 - Forming the Deficiency Statement.

(j) Task 8 - Exit Conference.

(k) Plan of Correction.

(l) Followup Surveys.

(m) Role of Surveyor.

(n) Confidentiality and Respect for Resident Privacy.

(o) Team Composition.

(p) Type of Facility-Application of SNF or ICF Regulations.

(q) Use of Part A and Part B of the Survey Report.

(a) ***General.*** A complete SNF/ICF facility survey consists of three components:

• Life Safety Code requirements;

• Administrative and structural requirements (Part A of the Survey Report, Form CMS-525); and

• Direct resident care requirements (Part B of the Survey Report, Form CMS-519), along with the related worksheets (CMS-520 through 524).

Use this survey process for all surveys of SNFs and ICFs - whether freestanding, distinct parts, or dually certified. Do not use this process for surveys of Intermediate Care Facilities for Mentally Retarded (ICFs/IID), swing-bed hospitals or skilled nursing sections of hospitals that are not separately certified as SNF distinct parts. Do not announce SNF/ICF surveys ahead of time.

(b) ***The Survey Tasks.*** Listed below are the survey tasks for easy reference:

• Task 1. Entrance Conference.

• Task 2. Resident Sample - Selection Methodology.

• Task 3. Tour of the Facility. Resident Needs. Physical Environment. Meeting with Resident Council Representatives. Tour Summation and Focus of Remaining Survey Activity.

• Task 4. Observation/Interview/Medical Record. Review of Each Individual in the Resident Sample (including drug regimen review).

• Task 5. Drug Pass Observation.

• Task 6. Dining Area and Eating Assistance Observation.

• Task 7. Forming the Deficiency Statement (if necessary).

• Task 8. Exit Conference.

(c) ***Task 1*** - *Entrance Conference.* Perform these activities during the entrance conference in every certification and recertification survey:

• Introduce all members of the team to the facility staff, if possible, even though the whole team may not be present for the entire entrance conference. (All surveyors wear identification tags.)

• Explain the SNF/ICF survey process as resident centered in focus, and outline the basic steps.

• Ask the facility for a list showing names of residents by room number with each of the following care needs/treatments identified for each resident to whom they apply:

- Decubitus care

- Restraints

- Catheters

- Injections

- Parenteral fluids

- Rehabilitation service

- Colostomy/ileostomy care

- Respiratory care

- Tracheostomy care

- Suctioning

- Tube feeding

Use this list for selecting the resident sample.

• Ask the facility to complete page 2 of Form CMS-519 (Resident Census) as soon as possible, so that the information can further orient you to the facility's population. In a survey of a SNF with a distinct part ICF, you may collect two sets of census data. However, consolidate the information when submitting it to the regional office. You may modify the Resident Census Form to include the numbers of licensed and certified beds, if necessary.

• Ask the facility to post signs on readily viewed areas (at least one on each floor) announcing that State surveyors are in the facility performing an "inspection," and are available to meet with residents in private. Also indicate the name and telephone number of the State agency. Hand-printed signs with legible, large letters are acceptable.

• If the facility has a Resident Council, make mutually agreeable arrangements to meet privately with the president and officers and other individuals they might invite.

• Inform the facility that interviews with residents and Resident Councils are conducted privately, unless they independently request otherwise, in order to enhance the development of rapport as well as to allay any resident anxiety. Tell the facility that information is gathered from interviews, the tour, observations, discussions, record review, and facility officials. Point out that the facility will be given an opportunity to respond to all findings.

(d) ***Task 2*** - *Resident Sample - Selection Methodology.* This methodology is aimed at formulating a sample that reflects the actual distribution of care needs/treatments in the facility population.

Primarily performed on a random basis, it also ensures representation in the sample of certain care needs and treatments that are assessed during the survey.

(1) ***Sample Size.*** Calculate the size of the sample according to the following guide:

Number of residents in facility	Number of residents in sample[1]
0-60 residents	25% of residents (minimum - 10).
61-120 residents	20% of residents (minimum - 15).
121-200 residents	15% of residents (minimum - 24).
201 + residents	10% of residents (minimum - 30).

[1] Maximum - 50.

Note that the calculation is based on the resident census, not beds. After determining the appropriate sample size, select residents for the sample in a random manner. You may, for example, select every fifth resident from the resident census, beginning at a random position on the list. For surveys of dually certified facilities or distinct part SNFs/ICFs, first use the combined SNF/ICF population to calculate the size of the sample, and then select a sample that reflects the proportions of SNF and ICF residents in the facility's overall population.

(2) ***Special Care Needs/Treatments.*** The survey form specifies several care needs/treatments that must always be reviewed when they apply to any facility residents. These include:

• Decubitus Care

• Restraints

• Catheters

• Injections, Parenteral Fluids, Colostomy/Ileostomy, Respiratory Care, Tracheostomy Care, Suctioning, Tube Feeding

• Rehabilitative Services (physical therapy, speech pathology and audiology services, occupational therapy)

Due to the relatively low prevalence of these care needs/treatments, appropriate residents may be either under-

represented or entirely omitted from the sample. Therefore, determine during the tour how many residents in the random selection fall into each of these care categories. Then, compare the number of such residents in the random selection with the total number of residents in the facility with each specified care need/treatment (based on either the resident census or other information provided by the facility).

Review no less than 25 percent of the residents in each of these special care needs/treatments categories. For example, if the facility has 10 residents with decubitus ulcers, but only one of these residents is selected randomly, review two more residents with decubitis ulcers (25% of 10 equals 2.5, so review a total of 3). Or, if the facility has two residents who require tube feeding, neither of whom is in the random selection, review the care of at least one of the these residents. This can be accomplished in the following manner:

Conduct in-depth reviews of the randomly selected residents and then perform limited reviews of additional residents as needed to cover the specified care categories. Such reviews are limited to the care and services related to the pertinent care areas only, e.g., catheters, restraints, or colostomy. Utilize those worksheets or portions of worksheets which are appropriate to the limited review. Refer to the Care Guidelines, as a resource document, when appropriate.

Always keep in mind that neither the random selection approach nor the review of residents within the specified care categories precludes investigation of other resident care situations that you believe might pose a serious threat to a resident's health or safety. Add to the sample, as appropriate.

(e) ***Task 3*** - *Tour of the Facility* -

(1) ***Purpose.*** Conduct the tour in order to:

• Develop an overall picture of the types and patterns of care delivery present within the facility;

• View the physical environment; and

• Ascertain whether randomly selected residents are communicative and willing to be interviewed.

(2) ***Protocol.*** You may tour the entire facility as a team or separately, as long as all areas of the facility are examined by at least one team member. Success of the latter approach, however, is largely dependent on open intra-team communication and the ability of each team member to identify situations for further review by the team member of the appropriate discipline. You may conduct the tour with or without facility staff accompanying you, as you prefer. Facilities, however, vary in staff member availability. Record your notes on the Tour Notes Worksheet, Form CMS-521.

Allow approximately three hours for the tour. Converse with residents, family members/significant others (if present), and staff, asking open-ended questions in order to confirm observations, obtain additional information, or corroborate information, (e.g., accidents, odors, apparent inappropriate dress, adequacy and appropriateness of activities). Converse sufficiently with residents selected for in-depth review to ascertain whether they are willing to be interviewed and are communicative. Observe staff interactions with other staff members as well as with residents for insight into matters such as resident rights and assignments of staff responsibilities.

Always knock and/or get permission before entering a room or interrupting privacy. If you wish to inspect a resident's skin, observe a treatment procedure, or observe a resident who is exposed, courteously ask permission from the resident if she/he comprehends, or ask permission from the staff nurse if the resident cannot communicate. Do not do “hands-on” monitoring such as removal of dressings; ask staff to remove a dressing or handle a resident.

(3) ***Resident Needs.*** While touring, focus on the residents' needs - physical, emotional, psychosocial, or spiritual - and whether those needs are being met. Refer to the following list as needed:

- Personal hygiene, grooming, and appropriate dress

- Position

- Assistive and other restorative devices

- Rehabilitation issues

- Functional limitations in ADL

- Functional limitations in gait, balance and coordination

- Hydration and nutritional status

- Resident rights

- Activity for time of day (appropriate or inappropriate)

- Emotional status

- Level of orientation

- Awareness of surroundings

- Behaviors

- Cleanliness of immediate environment (wheelchair, bed, bedside table, etc.)

- Odors

- Adequate clothing and care supplies as well as maintenance and cleanliness of same

(4) ***Review of the Physical Environment.*** As you tour each resident's room and auxiliary rooms, also examine them in connection with the physical environment requirements. You need not document physical environment on the Tour Notes Worksheet. Instead, you may note any negative findings directly on the Survey Report Form in the remarks section.

(5) ***Meeting With Resident Council Representatives.*** If a facility has a Resident Council, one or more surveyors meet with the respresentatives in a private area. Facility staff members do not attend unless specifically requested by the Council. Explain the purpose of the survey and briefly outline the steps in the survey process, i.e., entrance conference * * * exit conference. Indicate your interest in learning about the strengths of the facility in addition to any complaints or shortcomings. State that this meeting is one part of the information gathering; the findings have not yet been completed nor the conclusions formulated. Explain further, however, that the official survey findings are usually available within three months after the completion of the survey, and give the telephone number of the State agency office.

Use this meeting to ascertain strengths and/or problems, if any, from the consumer's perspective, as well as to develop additional information about aspects of care and services gleaned during the tour that were possibly substandard.

Conduct the meeting in a manner that allows for comments about any aspect of the facility. (See the section on Interview Procedures.) Use open-ended questions such as:

• “What is best about this home?”

• "What is worst?"

• "What would you like to change?"

In order to get more detail, use questions such as:

• "Can you be more specific?"

• "Can you give me an example?"

• "What can anyone else tell me about this?"

If you wish to obtain information about a topic not raised by the residents, use an approach like the following:

• "Tell me what you think about the food/staff/cleanliness here."

• "What would make it better?"

• "What don't you like? What do you like?"

(6) ***Tour Summation and Focus of Remaining Survey Activity.*** When the tour is completed, review the resident census data provided by the facility. Determine if the care categories specified in the section on Resident Sample are sufficiently represented in the random selection, make adjustments as needed, and complete the listing of residents on the worksheet labeled "Residents Selected for In-depth Review", Form CMS-520.

Transcribe notes of a negative nature onto the SRF in the "Remarks" column under the appropriate rule. Findings from a later segment in the survey or gathered by another surveyor may combine to substantiate a deficiency. You need not check "met" or "not met" at this point in the survey. Discuss significant impressions/conclusions at the completion of each subsequent survey task, and transfer any negative findings onto the Survey Report Form in the Remarks section.

(f) ***Task 4*** - *Observation/Interview/Medical Record Review (including drug regimen review).* Perform the in-depth review of each individual in the resident sample in order to ascertain whether the facility is meeting resident needs. Evaluate specific indicators for each resident, utilizing the front and back of the "Observation/Interview/Record Review (OIRR)" worksheet, Form CMS-524. You may prefer to perform the record review first, complete resident/staff/family observations and interviews, and finally, return to the record for any final unresolved issues. On the other hand, you may prefer to do the interviews first. Either method is acceptable. Whenever possible, however, complete one resident's observation/interview/medical record review and document the OIRR before moving onto another resident. If because of the facility layout, it is more efficient to do more than one record review at a time, limit such record review to two or three residents so your familiarity with the particular resident and continuity of the OIRR are not compromised.

(1) ***Observation.*** Conduct observations concurrently with interviews of residents, family/significant others, and discussions with direct care staff [of the various disciplines involved. In multi-facility operations, whenever possible, observe staff that is regularly assigned to the facility in order to gain an understanding of the care and services usually provided.] Maintain respect for resident privacy. Minimize disruption of the operations of the facility or impositions upon any resident as much as possible. Based upon your observations of the residents' needs, gather information about any of the following areas, as appropriate:

Bowel and bladder training

Catheter care

Restraints

Injections

Parenteral fluids

Tube feeding/gastrostomy

Colostomy/ileostomy

Respiratory therapy

Tracheostomy care

Suctioning

(2) ***Interviews.*** Interview each resident in private unless he/she independently requests that a facility staff member or other individual be present. Conduct the in-depth interview in a nonthreatening and noninvasive fashion so as to decrease anxiety and defensiveness. The open-ended approach described in the section on the Resident Council is also appropriate for the in-depth interview. While prolonged time expenditure is not usually a worthwhile use of resources or the resident's time, do allow time initially to establish rapport.

At each interview:

• Introduce yourself.

• Address the resident by name.

• Explain in simple terms the reason for your visit (e.g., to assure that the care and services are adequate and appropriate for each resident).

• Briefly outline the process - entrance conference, tour, interviews, observations, review of medical records, resident interviews, and exit conference.

• Mention that the selection of a particular resident for an interview is not meant to imply that his/her care is substandard or that the facility provides substandard care. Also mention that most of those interviewed are selected randomly.

• Assure that you will strive for anonymity for the resident and that the interview is used in addition to medical records, observations, discussions, etc., to capture an accurate picture of the treatment and care provided by the facility. Explain that the official findings of the survey are usually available to the public about three months after completion of the survey, but resident names are not given to the public.

• When residents experience difficulty expressing themselves:

- Avoid pressuring residents to verbalize

- Accept and respond to all communication

- Ignore mistakes in word choice

- Allow time for recollection of words

- Encourage self-expression through any means available

• When interviewing residents with decreased receptive capacity:

- Speak slowly and distinctly

- Speak at conversational voice level

- Sit within the resident's line of vision

• Listen to all resident information/allegations without judgment. Information gathered subsequently may substantiate or repudiate an allegation.

The length of the interview varies, depending on the condition and wishes of the resident and the amount of information supplied. Expect the average interview, however, to last approximately 15 minutes. Courteously terminate an interview whenever the resident is unable or unwilling to continue, or is too confused or disoriented to continue. Do, however, perform the other activities of this task (observation and record review). If, in spite of your conversing during the tour, you find that less than 40 percent of the residents in your sample are sufficiently alert and willing to be interviewed, try to select replacements so that a complete OIRR is performed for a group this size, if possible. There may be situations, however, where the resident population has a high percentage of confused individuals and this percentage is not achievable. Expect that the information from confused individuals can be, but is not necessarily, less reliable than that from more alert individuals.

Include the following areas in the interview of each resident in the sample:

Activities of daily living

Grooming/hygiene

Nutrition/dietary

Restorative/rehabilitation care and services

Activities

Social services

Resident rights

Refer to the Care Guidelines “evaluation factors” as a resource for possible elements to consider when focusing on particular aspects of care and resident needs.

Document information obtained from the interviews/observations on the OIRR Worksheet. Record in the “Notes” section any additional information you may need in connection with substandard care or services. Unless the resident specifically requests that he/she be identified, do not reveal the source of the information gleaned from the interview.

(3) ***Medical Record Review.*** The medical record review is a three-part process, which involves first reconciling the observation/interview findings with the record, then reconciling the record against itself, and lastly performing the drug regimen review.

Document your findings on the OIRR Worksheet, as appropriate, and summarize on the Survey Report Form the findings that are indicative of problematic or substandard care. Be alert for repeated similar instances of substandard care developing as the number of completed OIRR Worksheets increases.

Note:
The problems related to a particular standard or condition could range from identical (e.g., meals not in accordance with dietary plan) to different but related (e.g., nursing services - lapse in care provided to residents with catheters, to residents with contractures, to residents needing assistance for personal hygiene and residents with improperly applied restraints).

(i) ***Reconciling the observation/interview findings with the record.*** Determine if:

• An assessment has been performed.

• A plan with goals has been developed.

• The interventions have been carried out.

• The resident has been evaluated to determine the effectiveness of the interventions.

For example, if a resident has developed a decubitus ulcer while in the facility, record review can validate staff and resident interviews regarding the facility's attempts at prevention. Use your own judgment; review as much of the record(s) as necessary to evaluate the care planning. Note that facilities need not establish specific areas in the record stating “Assessment,” “Plan,” “Intervention,” or “Evaluation” in order for the documentation to be considered adequate.

(ii) ***Reconciling the record with itself.*** Determine:

• If the resident has been properly assessed for all his/her needs.

• That normal and routine nursing practices such as periodic weights, temperatures, blood pressures, etc., are performed as required by the resident's conditions.

(iii) ***Performing the drug regimen review.*** The purpose of the drug regimen review is to determine if the pharmacist has reviewed the drug regimen on a monthly basis. Follow the procedures in Part One of Appendix N, Surveyor Procedures for Pharmaceutical Service Requirements in Long-Term Care Facilities. Fill in the appropriate boxes on the top left hand corner of the reverse side of the OIRR Worksheet, Form CMS-524. Appendix N lists many irregularities that can occur. Review at least six different indicators on each survey. However, the same six indicators need not be reviewed on every survey.

Note:
If you detect irregularities and the documentation demonstrates that the pharmacist has notified the attending physician, do not cite a deficiency. Do, however, bring the irregularity to the attention of the medical director or other facility official, and note the official's name and date of notification on the Survey Report Form.

(g) ***Task 5 - Drug Pass Observation.*** The purpose of the drug pass observation is to observe the actual preparation and administration of medications to residents. With this approach, there is no doubt that the errors detected, if any, are errors in drug administration, not documentation. Follow the procedure in Part Two of Appendix N, Surveyor Procedures for Pharmaceutical Service Requirements in Long-Term Care Facilities, and complete the Drug Pass Worksheet, Form CMS-522. Be as neutral and unobtrusive as possible during the drug pass observation. Whenever possible, select one surveyor, who is a Registered Nurse or a pharmacist, to observe the drug pass of approximately 20 residents. In facilities where fewer than 20 residents are receiving medications, review as many residents receiving medications as possible. Residents selected for the in-depth review need not be included in the group chosen for the drug pass; however, their whole or partial inclusion is acceptable. In order to get a balanced view of a facility's practices, observe more than one person administering a drug pass, if feasible. This might involve observing the morning pass one day in Wing A, for example, and the morning pass the next day in Wing B.

Transfer findings noted on the “Drug Pass” worksheet to the SRF under the appropriate rule. If your team concludes that the facility's medication error rate is 5 percent or more, cite the deficiency under Nursing Services/Administration of Drugs. Report the error rate under F209. If the deficiency is at the standard level, cite it in Nursing Services, rather than Pharmacy.

(h) ***Task 6 - Dining Area and Eating Assistance Observation.*** The purpose of this task is to ascertain the extent to which the facility meets dietary needs, particularly for those who require eating assistance. This task also yields information about staff interaction with residents, promptness and appropriateness of assistance, adaptive equipment usage and availability, as well as appropriateness of dress and hygiene for meals.

For this task, use the worksheet entitled “Dining Area and Eating Assistance Observation” (Form CMS-523). Observe two meals; for a balanced view, try to observe meals at different times of the day. For example, try to observe a breakfast and a dinner rather than two breakfasts. Give particular care to performing observations as unobtrusively as possible. Chatting with residents and sitting down nearby may help alleviate resident anxiety over the observation process.

Select a minimum of five residents for each meal observation and include residents who have their meals in their rooms. Residents selected for the in-depth review need not be included in the dining and eating assistance observation; however, their whole or partial inclusion is acceptable. Ascertain the extent to which the facility assesses, plans, and evaluates the nutritional care of residents and eating assistance needs by reviewing the sample of 10 or more residents. If you are unable to determine whether the facility meets the standards from the sample reviewed, expand the sample and focus on the specific area(s) in question, until you can formulate a conclusion about the extent of compliance. As with the other survey tasks, transfer the findings noted on the “Dining & Eating Assistance Observation” worksheet to the Survey Report Form.

(i) ***Task 7 - Forming the Deficiency Statement*** -

(1) ***General.*** The Survey Report Form contains information about all of the negative findings of the survey. Be sure to transfer to the Survey Report Form data from the tour, drug pass observation, dining area and eating assistance observation, as well as in-depth review of the sample of residents. Transfer only those findings which could possibly contribute to a determination that the facility is deficient in a certain area.

Meet as a group in a pre-exit conference to discuss the findings and make conclusions about the deficiencies, subject to information provided by facility officials that may further explain the situation. Review the summaries/conclusions from each task and decide whether any further information and/or documentation is necessary to substantiate a deficiency. As the facility for additional information for clarification about particular findings, if necessary. Always consider information provided by the facility. If the facility considers as acceptable, practices which you believe are not acceptable, ask the facility to backup its contention with suitable reference material or sources and submit them for your consideration.

(2) ***Analysis.*** Analyze the findings on the Survey Report Form for the degree of severity, frequency of occurrence and impact on delivery of care or quality of life. The threshold at which the frequency of occurrences amounts to a deficiency varies from situation to situation. One occurrence directly related to a life-threatening or fatal outcome can be cited as a deficiency. On the other hand, a few sporadic occurrences may have so slight an impact on delivery of care or quality of life that they do not warrant a deficiency citation. Review carefully all the information gathered. What may appear during observation as a pattern, may or may not be corroborated by records, staff, and residents. For example, six of the 32 residents in the sample are dressed in mismatched, poorly buttoned clothes. A few of the six are wearing slippers without socks. A few others are wearing worn clothes. Six occurrences might well be indicative of a pattern of susbstandard care. Close scrutiny of records, discussions with staff, and interviews reveal, however, that the six residents are participating in dressing retraining programs. Those residents who are without socks, chose to do so. The worn clothing items were also chosen - they are favorites.

Combinations of substandard care such as poor grooming of a number of residents, lack of ambulation of a number of residents, lack of attention to positioning, poor skin care, etc., can yield a deficiency in nursing services just as 10 out of 10 residents receiving substandard care for decubiti yields a deficiency.

(3) ***Deficiencies Alleged by Staff or Residents.*** If staff or residents allege deficiencies, but records, interviews, and observation fail to confirm the situation, it is unlikely that a deficiency exists. Care and services that are indeed confirmed by the survey to be in compliance with the regulatory requirements, but considered deficient by residents or staff, cannot be cited as deficient for certification purposes. On the other hand, if an allegation is of a very serious nature (e.g., resident abuse) and the tools of record review and observation are not effective because the problem is concealed, obtain as much information as possible or necessary to ascertain compliance, and cite accordingly. Residents, family, or former employees may be helpful for information gathering.

(4) ***Composing the Deficiency Statement.*** Write the deficiency statement in terms specific enough to allow a reasonably knowledgeable person to understand the aspect(s) of the requirement(s) that is (are) not met. Do not delve into the facility's policies and procedures to determine or speculate on the root cause of a deficiency, or sift through various alternatives in an effort to prescribe an acceptable remedy. Indicate the data prefix tag and regulatory citation, followed by a summary of the deficiency and supporting findings using resident identifiers, not resident names, as in the following example.

> *F102 SNF 405.1123(b).* - Each resident has not had a physician's visit at least once every 30 days for the first 90 days after admission. Resident #1602 has not been seen by a physician since she was admitted 50 days ago. Her condition has deteriorated since that time (formulation of decubiti, infections).

When the data prefix tag does not repeat the regulations, also include a short phrase that describes the prefix tag (e.g., F117 decubitus ulcer care). List the data tags in numerical order, whenever possible.

(j) ***Task 8 - Exit Conference.*** The purpose of the exit conference is to inform the facility of survey findings and to arrange for a plan of correction, if needed. Keep the tone of the exit conference consistent with the character of the survey process - inspection and enforcement. Tactful, business-like, professional presentation of the findings is of paramount importance. Recognize that the facility may wish to respond to various findings. Although deficiency statements continue to depend, in part, on surveyor professional judgment, support your conclusions with resident-specific examples (identifiers other than names) whenever you can do so without compromising confidentiality. Before formally citing deficiencies, discuss any allegations or findings that could not be substantiated during earlier tasks in the process. For example, if information is gathered that suggests a newly hired R.N. is not currently licensed, ask the facility officials to present current licensure information for the nurse in question. Identify residents when the substandard care is readily observed or discerned through record review. Ensure that the facility improves the care provided to all affected residents, not only the identified residents. Make clear to the facility that during a follow-up visit the surveyors may review residents other than those with significant problems from the original sample, in order to see that the facility has corrected the problems overall. Do not disclose the source of information provided during interviews, unless the resident has specifically requested you to inform the facility of his/her comments or complaints. In accordance with your Agency's policy, present the Statement of Deficiencies, form CMS-2567, on site or after supervisory review, no later than 10 calendar days following the survey.

(k) ***Plan of Correction.*** Explain to the facility that your role is to identify care and services which are not consistent with the regulatory requirements, rather than to ascertain the root causes of deficiencies. Each facility is expected to review its own care delivery. Subsequent to the exit conference, each facility is required to submit a plan of correction that identifies necessary changes in operation that will assure correction of the cited deficiencies. In reviewing and accepting a proposed plan of correction, apply these criteria:

• Does the facility have a reasonable approach for correcting the deficiencies?

• Is there a high probability that the planned action will result in compliance?

• Is compliance expected timely?

Plans of correction specific to residents identified on the deficiency statement are acceptable only where the deficiency is determined to be unique to that resident and not indicative of a possible systemic problem. For example, as a result of an aide being absent, two residents are not ambulated three times that day as called for in their care plans. A plan of correction that says “Ambulate John Jones and Mary Smith three times per day,” is not acceptable. An acceptable plan of correction would explain changes made to the facility's staffing and scheduling in order to gurantee that staff is available to provide all necessary services for all residents.

Acceptance of the plan of correction does not absolve the facility of the responsibility for compliance should the implementation not result in correction and compliance. Acceptance indicates the State agency's acknowledgement that the facility indicated a willingness and ability to make corrections adequately and timely.

Allow the facility up to 10 days to prepare and submit the plan of correction to the State agency, however, follow your SA policy if the timeframe is shorter. Retain the various survey worksheets as well as the Survey Report Form at the State agency. Forward the deficiency statement to the CMS regional office.

(l) ***Follow-up Surveys.*** The purpose of the follow-up survey is to re-evaluate the specific types of care or care delivery patterns that were cited as deficient during the original survey. Ascertain the corrective status of all deficiencies cited on the CMS-2567. Because this survey process focuses on the actual provision of care and services, revisits are almost always necessary to ascertain whether the deficienicies have indeed been corrected. The nature of the deficiencies dictates the scope of the follow-up visit. Use as many tasks or portions of the Survey Report Form(s) as needed to ascertain compliance status. For example, you need not perform another drug pass if no drug related deficiencies were cited on the initial survey. Similarly, you need not repeat the dining area and eating assistance observations if no related problems were identified. All or some of the aspects of the observation/interview/medical record review, however, are likely to be appropriate for the follow-up survey.

When selecting the resident sample for the follow-up, determine the sample size using the same formula as used earlier in the survey, with the following exceptions:

• The maximum sample size is 30 residents, rather than 50.

• The minimum sample size of 10 residents does not apply if only one care category was cited as deficient and the total number of residents in the facility in that category was less than 10 (e.g., deficiency cited under catheter care and only five residents have catheters).

Include in the sample those residents who, in your judgment, are appropriate for reviewing vis-a-vis the cited substandard care. If possible, include some residents identified as receiving substandard care during the initial survey. If after completing the follow-up activities you determine that the cited deficiencies were not corrected, initiate adverse action procedures, as appropriate.

(m) ***Role of Surveyor.*** The survey and certification process is intended to determine whether providers and suppliers meet program participation requirements. The primary role of the surveyor, then, is to assess the quality of care and services and to relate those findings to statutory and regulatory requirements for program participation.

When you find substandard care or services in the course of a survey, carefully document your findings. Explain the deficiency in sufficient detail so that the facility officials understand your rationale. If the cause of the deficiency is obvious, share the information with the provider. For example, if you cite a deficiency for restraints (F118), indicate that restraints were applied backwards on residents 1621, 1634, 1646, etc.

In those instances where the cause is not obvious, do not delve into the facility's policies and procedures to determine the root cause of any deficiency. Do not recommend or prescribe an acceptable remedy. The provider is responsible for deciding on and implementing the action(s) necessary for achieving compliance. For the restraint situation in the example above, you would not ascertain whether the improper application was due to improper training or lack of training, nor would you attempt to identify the staff member who applied the restraints. It is the provider's responsibility to make the necessary changes or corrections to ensure that the restriants are applied properly.

A secondary role for the surveyor is to provide general consultation to the provider/consumer community. This includes meeting with provider/consumer associations and other groups as well as participating in seminars. It also includes informational activities, whereby you respond to oral or written inquiries about required outcomes in care and services.

(n) ***Confidentiality and Respect for Resident Privacy.*** Conduct the survey in a manner that allows for the greatest degree of confidentiality for residents, particularly regarding the information gathered during the in-depth interviews. When recording observations about care and resident conditions, protect the privacy of all residents. Use a code such as resident identifier number rather than names on worksheets whenever possible. Never use a resident's name on the Deficiency Statement, Form CMS-2567. Block out resident names, if any, from any document that is disclosed to the facility, individual or organization.

When communicating to the facility about substandard care, fully identify the resident(s) by name if the situation was identified through observation or record review. Improperly applied restraints, expired medication, cold food, gloves not worn for a sterile procedure, and diet inconsistent with order, are examples of problems which can be identified to the facility by resident name. Information about injuries due to broken equipment, prolonged use of restraints, and opened mail is less likely to be obtained through observation or record review. Do not reveal the source of information unless actually observed, discovered in the record review, or requested by the resident or family.

(o) ***Team Composition.*** Whenever possible, use the following survey team model:

SNF/ICF Survey Team Model

In facilities with 200 beds or less, the team size may range from 2 to 4 members. If the team size is:

• *2 members:* The team has at least one RN plus another RN or a dietitian or a pharmacist.

• *3-4 member:* In addition to the composition described above, the team has one or two members of any discipline such as a social worker, sanitarian, etc.

If the facility has over 200 beds *and* the survey will last more than 2 days, the team size may be greater than 4 members. Select additional disciplines as appropriate to the facility's compliance history.

Average onsite time per survey: 60 person hours (Number of surveyors multiplied by the number of hours on site)

Preferably, team members have gerontological training and experience. Any member may serve as the team leader, consistent with State agency procedures. In followup surveys, select disciplines based on major areas of correction. Include a social worker, for example, if the survey revealed major psychosocial problems. This model does not consider integrated survey and Inspection of Care review teams, which typically would be larger.

(p) ***Type of Facility*** - *Application of SNF or ICF Regulations.* Apply the regulations to the various types of facilities in the following manner:

• Freestanding Skilled Nursing Facility (SNF)	Apply SNF regulations.

• Freestanding Intermediate Care Facility (ICF)	Apply ICF regulations.
• SNF Distinct Part of a Hospital	Apply SNF regulations.
• ICF Distinct Part of a Hospital	Apply ICF regulations.
• Dually Certified SNF/ICF	Apply SNF regulations and 442.346(b).
• Freestanding SNF with ICF Distinct Part (Regardless of the proportion of SNF and ICF beds, the facility type is determined by the higher level of care. Therefore, LTC facilities with distinct parts are defined as SNFs with ICF distinct parts.)	Apply SNF regulations for SNF unit. Apply ICF regulations for ICF distinct part. Apply both SNF and ICF regulations for shared services (e.g., dietary). If the same deficiency occurs in both the SNF and ICF components of the facility, cite both SNF and ICF regulations. If the deficiency occurs in the SNF part only, cite only the SNF regulation. If the deficiency occurs in the ICF part only, cite only the ICF regulation.

(q) ***Use of Part A and Part B of the Survey Report*** -

(1) ***Use of Part A (CMS-525).*** Use Part A for initial certification surveys only, except under the following circumstances:

• When a terminated facility requests program participation 60 days or more after termination. Treat this situation as a request for initial certification and complete Part A of the survey report in addition to Part B.

• If an ICF with a favorable compliance history requests to covert a number of beds to SNF level, complete both Part A and Part B for compliance with the SNF requirements. If distinct part status is at issue, also examine whether it meets the criteria for certification as a distinct part.

(i) ***Addendum for Outpatient Physical Therapy (OPT) or Speech Pathology Services.*** Use the Outpatient Physical Therapy - Speech Pathology SRF (CMS-1893) as an addendum to Part A.

(ii) ***Resurvey of Participating Facilities.*** Do not use Part A for resurveys of participating SNFs and ICFs. A determination of compliance, based on documented examination of the written policies and procedures and other pertinent documents during the initial survey, establishes the facility's compliance status with Part A requirements. This does not preclude citing deficiencies if they pertain to administrative or structural requirements from Part A that are uncovered incidental to a Part B survey. As an assurance measure, however, each facility at the time of recertification must complete an affidavit (on the CMS-1516) attesting that no substantive changes have occurred that would affect compliance. Each facility must also agree to notify the State agency immediately of any upcoming changes in its organization or management which may affect its compliance status. If a new administrator is unable to complete the affidavit, proceed with the survey using the Part B form and worksheets; do not use the Part A form. The survey cannot be considered complete, however, until the affidavit is signed. If the facility fails to complete the affidavit, it cannot participate in the program.

(iii) ***Substantial Changes in a Facility's Organization and Management.*** If you receive such information, review the changes to ensure compliance with the regulations. Request copies of the appropriate documents (e.g., written policies and procedures, personnel qualifications, or agreements) if they were not submitted. If the changes have made continued compliance seem doubtful, determine through a Part B survey whether deficiencies have resulted. Cite any deficiencies on the CMS-2567 and follow the usual procedures.

(2) ***Use of Part B (CMS-519).*** Use Part B and the worksheets for all types of SNF and ICF surveys - initials, recertifications, followup, complaints, etc.

The worksheets are:

• CMS-520 - Residents Selected for Indepth Review

• CMS-521 - Tour Notes Worksheet

• CMS-522 - Drug Pass Worksheet

• CMS-523 - Dining Area and Eating Assistance Worksheet

• CMS-5245 - Observation/Interview/Record Review Worksheet

For complaint investigations, perform a full or partial Part B survey based on the extent of the allegations. If the complaint alleges substandard care in a general fashion or in a variety of services and care areas, perform several tasks or a full Part B survey, as needed. If the complaint is of a more specific nature, such as an allegation of improper medications, perform an appropriate partial Part B survey, such as a drug pass review and a review of selected medical records.

§ 488.115 Care guidelines.

Subpart D - Reconsideration of Adverse Determinations - Deeming Authority for Accreditation Organizations and CLIA Exemption of Laboratories Under State Programs

Source: 57 FR 34012, July 31, 1992, unless otherwise noted.

§ 488.201 Reconsideration.

(a) ***Right to reconsideration.***

(1) A national accreditation organization dissatisfied with a determination that its accreditation requirements do not provide (or do not continue to provide) reasonable assurance that the entities accredited by the accreditation organization meet the applicable long-term care requirements, conditions for coverage, conditions of certification, conditions of participation, or CLIA condition level requirements is entitled to a reconsideration as provided in this subpart.

(2) A State dissatisfied with a determination that the requirements it imposes on laboratories in that State and under the laws of that State do not provide (or do not continue to provide) reasonable assurance that laboratories licensed or approved by the State meet applicable CLIA requirements is entitled to a reconsideration as provided in this subpart.

(b) ***Eligibility for reconsideration.*** CMS will reconsider any determination to deny, remove or not renew the approval of deeming authority to private accreditation organizations, or any determination to deny, remove or not renew the approval of a State laboratory program for the purpose of exempting the State's laboratories from CLIA requirements, if the accreditation organization or State files a written request for a reconsideration in accordance with paragraphs (c) and (d) of this section.

(c) ***Manner and timing of request for reconsideration.***

(1) A national accreditation organization or a State laboratory program described in paragraph (b), dissatisfied with a determination with respect to its deeming authority, or, in the case of a State, a determination with respect to the exemption of the laboratories in the State from CLIA requirements, may request a reconsideration of the determination by filing a request with CMS either directly by its authorized officials or through its legal representative. The request must be filed within 60 days of the receipt of notice of an adverse determination or nonrenewal as provided in subpart A of part 488 or subpart E of part 493, as applicable.

(2) Reconsideration procedures are available after the effective date of the decision to deny, remove, or not renew the approval of an accreditation organization or State laboratory program.

(d) ***Content of request.*** The request for reconsideration must specify the findings or issues with which the accreditation organization or State disagrees and the reasons for the disagreement.

[57 FR 34012, July 31, 1992, as amended at 58 FR 61843, Nov. 23, 1993]

§ 488.203 Withdrawal of request for reconsideration.

A requestor may withdraw its request for reconsideration at any time before the issuance of a reconsideration determination.

§ 488.205 Right to informal hearing.

In response to a request for reconsideration, CMS will provide the accreditation organization or the State laboratory program the opportunity for an informal hearing as described in § 488.207 that will -

(a) Be conducted by a hearing officer appointed by the Administrator of CMS; and

(b) Provide the accreditation organization or State laboratory program the opportunity to present, in writing or in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew deeming authority or the exemption of a State's laboratories from CLIA requirements.

§ 488.207 Informal hearing procedures.

(a) CMS will provide written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(b) The informal reconsideration hearing will be conducted in accordance with the following procedures -

(1) The hearing is open to CMS and the organization requesting the reconsideration, including -

(i) Authorized representatives;

(ii) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts); and

(iii) Legal counsel;

(2) The hearing is conducted by the hearing officer who receives testimony and documents related to the proposed action;

(3) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissable under the usual rules of court procedures;

(4) Either party may call witnesses from among those individuals specified in paragraph (b)(1) of this section; and

(5) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

§ 488.209 Hearing officer's findings.

(a) Within 30 days of the close of the hearing, the hearing officer will present the findings and recommendations to the accreditation organization or State laboratory program that requested the reconsideration.

(b) The written report of the hearing officer will include -

(1) Separate numbered findings of fact; and

(2) The legal conclusions of the hearing officer.

§ 488.211 Final reconsideration determination.

(a) The hearing officer's decision is final unless the Administrator, within 30 days of the hearing officer's decision, chooses to review that decision.

(b) The Administrator may accept, reject or modify the hearing officer's findings.

(c) Should the Administrator choose to review the hearing officer's decision, the Administrator will issue a final reconsideration determination to the accreditation organization or State laboratory program on the basis of the hearing officer's findings and recommendations and other relevant information.

(d) The reconsideration determination of the Administrator is final.

(e) A final reconsideration determination against an accreditation organization or State laboratory program will be published by CMS in the Federal Register.

Subpart E - Survey and Certification of Long-Term Care Facilities

Source: 59 FR 56238, Nov. 10, 1994, unless otherwise noted.

§ 488.300 Statutory basis.

Sections 1819 and 1919 of the Act establish requirements for surveying SNFs and NFs to determine whether they meet the requirements for participation in the Medicare and Medicaid programs.

---

§ 488.301 Definitions.

As used in this subpart -

Abbreviated standard survey means a survey other than a standard survey that gathers information primarily through resident-centered techniques on facility compliance with the requirements for participation. An abbreviated standard survey may be premised on complaints received; a change of ownership, management, or director of nursing; or other indicators of specific concern. Abbreviated standard surveys conducted to investigate a complaint or to conduct on-site monitoring to verify compliance with participation requirements are subject to the requirements of § 488.332. Other premises for abbreviated standard surveys would follow the requirements of § 488.314.

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.

Deficiency means a SNF's or NF's failure to meet a participation requirement specified in the Act or in part 483, subpart B of this chapter.

Dually participating facility means a facility that has a provider agreement in both the Medicare and Medicaid programs.

Extended survey means a survey that evaluates additional participation requirements subsequent to finding substandard quality of care during a standard survey.

Facility means a SNF or NF, or a distinct part SNF or NF, in accordance with § 483.5 of this chapter.

Immediate family means husband or wife; natural or adoptive parent, child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild.

Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.

Misappropriation of resident property means the deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a resident's belongings or money without the resident's consent.

Neglect 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.

Noncompliance means any deficiency that causes a facility to not be in substantial compliance.

Nurse aide means an individual, as defined in § 483.5 of this chapter.

Nursing facility (NF) means a Medicaid nursing facility.

Paid feeding assistant means an individual who meets the requirements specified in § 483.60(h)(1) of this chapter and who is paid to feed residents by a facility, or who is used under an arrangement with another agency or organization.

Partial extended survey means a survey that evaluates additional participation requirements subsequent to finding substandard quality of care during an abbreviated standard survey.

Skilled nursing facility (SNF) means a Medicare nursing facility.

Standard survey means a periodic, resident-centered inspection which gathers information about the quality of service furnished in a facility to determine compliance with the requirements for participation.

Substandard quality of care means one or more deficiencies related to participation requirements under § 483.10 "Resident rights", paragraphs (a)(1) through (a)(2), (b)(1) through (b)(2), (e) (except for (e)(2), (e)(7), and (e)(8)), (f)(1) through (f)(3), (f)(5) through (f)(8), and (i) of this chapter; § 483.12 of this chapter "Freedom from abuse, neglect, and exploitation"; § 483.24 of this chapter "Quality of life"; § 483.25 of this chapter "Quality of care"; § 483.40 "Behavioral health services", paragraphs (b) and (d) of this chapter; § 483.45 "Pharmacy services", paragraphs (d), (e), and (f) of this chapter; § 483.70 "Administration", paragraph (p) of this chapter, and § 483.80 "Infection control", paragraph (d) of this chapter, which constitute either immediate jeopardy to resident health or safety; a pattern of or widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm.

Substantial compliance means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm.

Validation survey means a survey conducted by the Secretary within 2 months following a standard survey, abbreviated standard survey, partial extended survey, or extended survey for the purpose of monitoring State survey agency performance.

[59 FR 56238, Nov. 10, 1994, as amended at 68 FR 55539, Sept. 26, 2003; 81 FR 68871, Oct. 4, 2016; 82 FR 36635, Aug. 4, 2017]

---

§ 488.303 State plan requirement.

(a) A State plan must provide that the requirements of this subpart and subpart F of this part are met, to the extent that those requirements apply to the Medicaid program.

(b) A State may establish a program to reward, through public recognition, incentive payments, or both, nursing facilities that provide the highest quality care to Medicaid residents. For purposes of section 1903(a)(7) of the Social Security Act, proper expenses incurred by a State in carrying out such a program are considered to be expenses necessary for the proper and efficient administration of the State plan.

(c) A State must conduct periodic educational programs for the staff and residents (and their representatives) of NFs in order to present current regulations, procedures, and policies under this subpart and subpart F of this part.

(d) Required remedies for a non-State operated NF. A State must establish, in addition to termination of the provider agreement, the following remedies or an approved alternative to the following remedies for imposition against a non-State operated NF:

(1) Temporary management.

(2) Denial of payment for new admissions.

(3) Civil money penalties.

(4) Transfer of residents.

(5) Closure of the facility and transfer of residents.

(6) State monitoring.

(e) Optional remedies for a non-State operated NF. A State may establish the following remedies for imposition against a non-State operated NF:

(1) Directed plan of correction.

(2) Directed in-service training.

(3) Alternative or additional State remedies.

(f) Alternative or additional State remedies. If a State uses remedies that are in addition to those specified in paragraph (d) or (e) of this section, or alternative to those specified in paragraph (d) of this section (other than termination of participation), it must -

(1) Specify those remedies in the State plan; and

(2) Demonstrate to CMS's satisfaction that those alternative remedies are as effective in deterring noncompliance and correcting deficiencies as the remedies listed in paragraphs (d) and (e) of this section.

[59 FR 56238, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.305 Standard surveys.

(a) For each SNF and NF, the State survey agency must conduct standard surveys that include all of the following:

(1) A case-mix stratified sample of residents;

(2) A survey of the quality of care furnished, as measured by indicators of medical, nursing, and rehabilitative care, dietary and nutrition services, activities and social participation, and sanitation, infection control, and the physical environment;

(3) An audit of written plans of care and residents' assessments to determine the accuracy of such assessments and the adequacy of such plans of care; and

(4) A review of compliance with residents' rights requirements set forth in sections 1819(c) and 1919(c) of the Act.

(b) The State survey agency's failure to follow the procedures set forth in this section will not invalidate otherwise legitimate determinations that a facility's deficiencies exist.

§ 488.307 Unannounced surveys.

(a) ***Basic rule.*** All standard surveys must be unannounced.

(b) ***Review of survey agency's scheduling and surveying procedures.***

(1) CMS reviews on an annual basis each State survey agency's scheduling and surveying procedures and practices to ensure that survey agencies avoid giving notice of a survey through the scheduling procedures and the conduct of the surveys.

(2) CMS takes corrective action in accordance with the nature and complexity of the problem when survey agencies are found to have notified a SNF or NF through their scheduling or procedural policies. Sanctions for inadequate survey performance are in accordance with § 488.320.

(c) ***Civil money penalties.*** An individual who notifies a SNF or NF, or causes a SNF or NF to be notified, of the time or date on which a standard survey is scheduled to be conducted is subject to a Federal civil money penalty not to exceed $2,000 as adjusted annually under 45 CFR part 102.

[59 FR 56238, Nov. 10, 1994, as amended at 81 FR 61563, Sept. 6, 2016]

§ 488.308 Survey frequency.

(a) ***Basic period.*** The survey agency must conduct a standard survey of each SNF and NF not later than 15 months after the last day of the previous standard survey.

(b) ***Statewide average interval.***

(1) The statewide average interval between standard surveys must be 12 months or less, computed in accordance with paragraph (d) of this section.

(2) CMS takes corrective action in accordance with the nature of the State survey agency's failure to ensure that the 12-month statewide average interval requirement is met. CMS's corrective action is in accordance with § 488.320.

(c) ***Other surveys.*** The survey agency may conduct a survey as frequently as necessary to -

(1) Determine whether a facility complies with the participation requirements; and

(2) Confirm that the facility has corrected deficiencies previously cited.

(d) ***Computation of statewide average interval.*** The statewide average interval is computed at the end of each Federal fiscal year by comparing the last day of the most recent standard survey for each participating facility to the last day of each facility's previous standard survey.

(e) ***Special surveys.***

(1) The survey agency may conduct a standard or an abbreviated standard survey to determine whether certain changes have caused a decline in the quality of care furnished by a SNF or a NF, within 60 days of a change in the following:

(i) Ownership;

(ii) Entity responsible for management of a facility (management firm);

(iii) Nursing home administrator; or

(iv) Director of nursing.

(2) [Reserved]

(f) ***Investigation of complaints.***

(1) The survey agency must review all complaint allegations and conduct a standard or an abbreviated survey to investigate complaints of violations of requirements by SNFs and NFs if its review of the allegation concludes that -

(i) A deficiency in one or more of the requirements may have occurred; and

(ii) Only a survey can determine whether a deficiency or deficiencies exist.

(2) The survey agency does not conduct a survey if the complaint raises issues that are outside the purview of Federal participation requirements.

[53 FR 22859, June 17, 1988, as amended at 82 FR 36635, Aug. 4, 2017]

§ 488.310 Extended survey.

(a) ***Purpose of survey.*** The purpose of an extended survey is to identify the policies and procedures that caused the facility to furnish substandard quality of care.

(b) ***Scope of extended survey.*** An extended survey includes all of the following:

(1) Review of a larger sample of resident assessments than the sample used in a standard survey.

(2) Review of the staffing and in-service training.

(3) If appropriate, examination of the contracts with consultants.

(4) A review of the policies and procedures related to the requirements for which deficiencies exist.

(5) Investigation of any participation requirement at the discretion of the survey agency.

(c) ***Timing and basis for survey.*** The survey agency must conduct an extended survey not later than 14 calendar days after completion of a standard survey which found that the facility had furnished substandard quality of care.

§ 488.312 Consistency of survey results.

CMS does and the survey agency must implement programs to measure accuracy and improve consistency in the application of survey results and enforcement remedies.

§ 488.314 Survey teams.

(a) ***Team composition.***

(1) Surveys under sections 1819(g)(2) and 1919(g)(2) of the Social Security Act must be conducted by an interdisciplinary team of professionals, which must include a registered nurse.

(2) Examples of professionals include, but are not limited to, physicians, physician assistants, nurse practitioners, physical, speech, or occupational therapists, registered professional nurses, dieticians, sanitarians, engineers, licensed practical nurses, or social workers.

(3) The State determines what constitutes a professional, subject to CMS approval.

(4) Any of the following circumstances disqualifies a surveyor for surveying a particular facility:

(i) The surveyor currently works, or, within the past two years, has worked as an employee, as employment agency staff at the facility, or as an officer, consultant, or agent for the facility to be surveyed.

(ii) The surveyor has any financial interest or any ownership interest in the facility.

(iii) The surveyor has an immediate family member who has a relationship with a facility described in paragraphs (a)(4)(i) or paragraph (a)(4)(ii) of this section.

(iv) The surveyor has an immediate family member who is a resident in the facility to be surveyed. For purposes of this section, an immediate family member is defined at § 488.301 of this part.

(b) ***CMS training.*** CMS provides comprehensive training to surveyors, including at least the following:

(1) Application and interpretation of regulations for SNFs and NFs.

(2) Techniques and survey procedures for conducting standard and extended surveys.

(3) Techniques for auditing resident assessments and plans of care.

(c) ***Required surveyor training.***

(1) Except as specified in paragraph (c)(3) of this section, the survey agency may not permit an individual to serve as a member of a survey team unless the individual has successfully completed a training and testing program prescribed by the Secretary.

(2) The survey agency must have a mechanism to identify and respond to in-service training needs of the surveyors.

(3) The survey agency may permit an individual who has not completed a training program to participate in a survey as a trainee if accompanied on-site by a surveyor who has successfully completed the required training and testing program.

[59 FR 56238, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995 as amended at 82 FR 36636, Aug. 4, 2017]

§ 488.318 Inadequate survey performance.

(a) CMS considers survey performance to be inadequate if the State survey agency -

(1) Indicates a pattern of failure to -

(i) Identify deficiencies and the failure cannot be explained by changed conditions in the facility or other case specific factors;

(ii) Cite only valid deficiencies;

(iii) Conduct surveys in accordance with the requirements of this subpart; or

(iv) Use Federal standards, protocols, and the forms, methods and procedures specified by CMS in manual instructions; or

(2) Fails to identify an immediate jeopardy situation.

(b) Inadequate survey performance does not -

(1) Relieve a SNF or NF of its obligation to meet all requirements for program participation; or

(2) Invalidate adequately documented deficiencies.

§ 488.320 Sanctions for inadequate survey performance.

(a) ***Annual assessment of survey performance.*** CMS assesses the performance of the State's survey and certification program annually.

(b) ***Sanctions for inadequate survey performance.*** When a State demonstrates inadequate survey performance, as specified in § 488.318, CMS notifies the survey agency of the inadequacy and takes action in accordance with paragraphs (c) and (d) of this section.

(c) ***Medicaid facilities.***

(1) For a pattern of failure to identify deficiencies in Medicaid facilities, CMS -

(i) Reduces FFP, as specified in paragraph (e) of this section, and if appropriate;

(ii) Provides for training of survey teams.

(2) For other survey inadequacies in Medicaid facilities, CMS provides for training of survey teams.

(d) ***Medicare facilities.*** For all survey inadequacies in Medicare facilities, CMS -

(1) Requires that the State survey agency submit a plan of correction;

(2) Provides for training of survey teams;

(3) Provides technical assistance on scheduling and procedural policies;

(4) Provides CMS-directed scheduling; or

(5) Initiates action to terminate the agreement between the Secretary and the State under section 1864 of the Act, either in whole or in part.

(e) ***Reduction of FFP.*** In reducing FFP for inadequate survey performance, CMS uses the formula specified in section 1919(g)(3)(C) of the Act, that is 33 percent multiplied by a fraction -

(1) The numerator of which is equal to the total number of residents in the NFs that CMS found to be noncompliant during validation surveys for that quarter; and

(2) The denominator of which is equal to the total number of residents in the NFs in which CMS conducted validation surveys during that quarter.

(f) ***Appeal of FFP reduction.*** When a State is dissatisfied with CMS's determination to reduce FFP, the State may appeal the determination to the Departmental Appeals Board, using the procedures specified in 45 CFR part 16.

§ 488.325 Disclosure of results of surveys and activities.

(a) ***Information which must be provided to public.*** As provided in sections 1819(g)(5) and 1919(g)(5) of the Act, the following information must be made available to the public, upon the public's request, by the State or CMS for all surveys and certifications of SNFs and NFs:

(1) Statements of deficiencies and providers' comments.

(2) A list of isolated deficiencies that constitute no actual harm, with the potential for minimal harm.

(3) Approved plans of correction.

(4) Statements that the facility did not submit an acceptable plan of correction or failed to comply with the conditions of imposed remedies.

(5) Final appeal results.

(6) Notice of termination of a facility.

(7) Medicare and Medicaid cost reports.

(8) Names of individuals with direct or indirect ownership interest in a SNF or NF, as defined in § 420.201 of this chapter.

(9) Names of individuals with direct or indirect ownership interest in a SNF or NF, as defined in § 420.201 of this chapter, who have been found guilty by a court of law of a criminal offense in violation of Medicare or Medicaid law.

(b) ***Charge to public for information.*** CMS and the State may charge the public for specified services with respect to requests for information in accordance with -

(1) Section 401.140 of this chapter, for Medicare; or

(2) State procedures, for Medicaid.

(c) ***How public can request information.*** The public may request information in accordance with disclosure procedures specified in 45 CFR part 5.

(d) ***When information must be disclosed.*** The disclosing agency must make available to the public, upon the public's request, information concerning all surveys and certifications of SNFs and NFs, including statements of deficiencies, separate listings of any isolated deficiencies that constitute no actual harm, with the potential for minimal harm, and plans of correction (which contain any provider response to the deficiency statement) within 14 calendar days after each item is made available to the facility.

(e) ***Procedures for responding to requests.*** The procedures and time periods for responding to requests are in accordance with -

(1) Section 401.136 of this chapter for documents maintained by CMS; and

(2) State procedures for documents maintained by the State.

(f) ***Information that must be provided to the State's long-term care ombudsman.*** The State must provide the State's long-term care ombudsman with the following:

(1) A statement of deficiencies reflecting facility noncompliance, including a separate list of isolated deficiencies that constitute no harm with the potential for minimal harm.

(2) Reports of adverse actions specified at § 488.406 imposed on a facility.

(3) Written response by the provider.

(4) A provider's request for an appeal and the results of any appeal.

(g) ***Information which must be provided to State by a facility with substandard quality of care.***

(1) To provide for the notice to physicians required under sections 1819(g)(5)(C) and 1919(g)(5)(C) of the Act, not later than 10 working days after receiving a notice of substandard quality of care, a SNF or NF must provide the State with a list of -

(i) Each resident in the facility with respect to which such finding was made; and

(ii) The name and address of his or her attending physician.

(2) Failure to disclose the information timely will result in termination of participation or imposition of alternative remedies.

(h) ***Information the State must provide to attending physician and State board.*** Not later than 20 calendar days after a SNF or NF complies with paragraph (g) of this section, the State must provide written notice of the noncompliance to -

(1) The attending physician of each resident in the facility with respect to which a finding of substandard quality of care was made; and

(2) The State board responsible for licensing the facility's administrator.

(i) ***Access to information by State Medicaid fraud control unit.*** The State must provide access to any survey and certification information incidental to a SNF's or NF's participation in Medicare or Medicaid upon written request by the State Medicaid fraud control unit established under part 1007, of this title, consistent with current State laws.

[59 FR 56238, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.330 Certification of compliance or noncompliance.

(a) ***General rules*** -

(1) ***Responsibility for certification.***

(i) The State survey agency surveys all facilities for compliance or noncompliance with requirements for long term care facilities. The survey by the State survey agency may be followed by a Federal validation survey.

(A) The State certifies the compliance or noncompliance of non-State operated NFs. Regardless of the State entity doing the certification, it is final, except in the case of a complaint or validation survey conducted by CMS, or CMS review of the State's findings.

(B) CMS certifies the compliance or noncompliance of all State-operated facilities.

(C) The State survey agency certifies the compliance or noncompliance of a non-State operated SNF, subject to the approval of CMS.

(D) The State survey agency certifies compliance or noncompliance for a dually participating SNF/NF. In the case of a disagreement between CMS and the State survey agency, a finding of noncompliance takes precedence over that of compliance.

(ii) In the case of a validation survey, the Secretary's determination as to the facility's noncompliance is binding, and takes precedence over a certification of compliance resulting from the State survey.

(2) ***Basis for certification.***

(i) Certification by the State is based on the survey agency findings.

(ii) Certification by CMS is based on either the survey agency findings (in the case of State-operated facilities), or, in the case of a validation survey, on CMS's own survey findings.

(b) ***Effect of certification*** -

(1) ***Certification of compliance.*** A certification of compliance constitutes a determination that the facility is in substantial compliance and is eligible to participate in Medicaid as a NF, or in Medicare as a SNF, or in Medicare and Medicaid as a dually participating facility.

(2) ***Certification of noncompliance.*** A certification of noncompliance requires denial of participation for prospective providers and enforcement action for current providers in accordance with subpart F of this part. Enforcement action must include one of the following:

(i) Termination of any Medicare or Medicaid provider agreements that are in effect.

(ii) Application of alternative remedies instead of, or in addition to, termination procedures.

(c) ***Notice of certification of noncompliance and resulting action.*** The notice of certification of noncompliance is sent in accordance with the timeframes specified in § 488.402(f), and resulting action is issued by CMS, except when the State is taking the action for a non-State operated NF.

(d) ***Content of notice of certification of noncompliance.*** The notice of certification of noncompliance is sent in accordance with the timeframes specified in § 488.402(f) and includes information on all of the following:

(1) Nature of noncompliance.

(2) Any alternative remedies to be imposed under subpart F of this part.

(3) Any termination or denial of participation action to be taken under this part.

(4) The appeal rights available to the facility under this part.

(5) Timeframes to be met by the provider and certifying agency with regard to each of the enforcement actions or appeal procedures addressed in the notice.

(e) ***Appeals.***

(1) Notwithstanding any provision of State law, the State must impose remedies promptly on any provider of services participating in the Medicaid program -

(i) After promptly notifying the facility of the deficiencies and impending remedy or remedies; and

(ii) Except for civil money penalties, during any pending hearing that may be requested by the provider of services.

(2) CMS imposes remedies promptly on any provider of services participating in the Medicare or Medicaid program or any provider of services participating in both the Medicare and Medicaid programs -

(i) After promptly notifying the facility of the deficiencies and impending remedy or remedies; and

(ii) Except for civil money penalties imposed on NFs-only by the State, during any pending hearing that may be requested by the provider of services.

(3) The provisions of part 498 of this chapter apply when the following providers request a hearing on a denial of participation, or certification of noncompliance leading to an enforcement remedy (including termination of the provider agreement), except State monitoring:

(i) All State-operated facilities;

(ii) SNFs and dually participating SNF/NFs; and

(iii) Any other facilities subject to a CMS validation survey or CMS review of the State's findings.

(4) The provisions of part 431 of this chapter apply when a non-State operated Medicaid NF, which has not received a CMS validation survey or CMS review of the State's findings, requests a hearing on the State's denial of participation, termination of provider agreement, or certification of noncompliance leading to an alternative remedy, except State monitoring.

(f) ***Provider agreements.*** CMS or the Medicaid agency may execute a provider agreement when a prospective provider is in substantial compliance with all the requirements for participation for a SNF or NF, respectively.

(g) ***Special rules for Federal validation surveys.***

(1) CMS may make independent certifications of a NF's, SNF's, or dually participating facility's noncompliance based on a CMS validation survey.

(2) CMS issues the notice of actions affecting facilities for which CMS did validation surveys.

(3) For non-State-operated NFs and non-State-operated dually participating facilities, any disagreement between CMS and the State regarding the timing and choice of remedies is resolved in accordance with § 488.452.

(4) Either CMS or the survey agency, at CMS's option, may revisit the facility to ensure that corrections are made.

[59 FR 56238, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995; 76 FR 15126, Mar. 18, 2011]

§ 488.331 Informal dispute resolution.

(a) ***Opportunity to refute survey findings.***

(1) For non-Federal surveys, the State must offer a facility an informal opportunity, at the facility's request, to dispute survey findings upon the facility's receipt of the official statement of deficiencies.

(2) For Federal surveys, CMS offers a facility an informal opportunity, at the facility's request, to dispute survey findings upon the facility's receipt of the official statement of deficiencies.

(3) For SNFs, dually-participating SNF/NFs, and NF-only facilities that have civil money penalties imposed by CMS that will be placed in a CMS escrow account, CMS also offers the facility an opportunity for independent informal dispute resolution, subject to the terms of paragraphs (b), (c), and (d) of this section and of § 488.431. The facility must request independent informal dispute resolution in writing within 10 days of receipt of CMS's offer. However, a facility may not use the dispute resolution processes at both §§ 488.331 and 488.431 for the same deficiency citation arising from the same survey unless the informal dispute resolution process at § 488.331 was completed prior to the imposition of the civil money penalty.

(b)

(1) Failure of the State or CMS, as appropriate, to complete informal dispute resolution timely cannot delay the effective date of any enforcement action against the facility.

(2) A facility may not seek a delay of any enforcement action against it on the grounds that informal dispute resolution has not been completed before the effective date of the enforcement action.

(c) If a provider is subsequently successful, during the informal dispute resolution process, at demonstrating that deficiencies should not have been cited, the deficiencies are removed from the statement of deficiencies and any enforcement actions imposed solely as a result of those cited deficiencies are rescinded.

(d) ***Notification.*** Upon request, CMS does and the State must provide the facility with written notification of the informal dispute resolution process.

[59 FR 56238, Nov. 10, 1994, as amended at 76 FR 15126, Mar. 18, 2011]

§ 488.332 Investigation of complaints of violations and monitoring of compliance.

(a) ***Investigation of complaints.***

(1) The State survey agency must establish procedures and maintain adequate staff to investigate complaints of violations of participation requirements.

(2) The State survey agency takes appropriate precautions to protect a complainant's anonymity and privacy, if possible.

(3) If arrangements have been made with other State components for investigation of complaints, the State must have a means of communicating information among appropriate entities, and the State survey agency retains responsibility for the investigation process.

(4) If, after investigating a complaint, the State has reason to believe that an identifiable individual neglected or abused a resident, or misappropriated a resident's property, the State survey agency must act on the complaint in accordance with § 488.335.

(b) ***On-site monitoring.*** The State survey agency conducts on-site monitoring on an as necessary basis when -

(1) A facility is not in substantial compliance with the requirements and is in the process of correcting deficiencies;

(2) A facility has corrected deficiencies and verification of continued substantial compliance is needed; or

(3) The survey agency has reason to question the substantial compliance of the facility with a requirement of participation.

(c) ***Composition of the investigative team.*** A State may use a specialized team, which may include an attorney, auditor and appropriate health professionals, to identify, survey, gather and preserve evidence, and administer remedies to noncompliant facilities.

§ 488.334 Educational programs.

A State must conduct periodic educational programs for the staff and residents (and their representatives) of SNFs and NFs in order to present current regulations, procedures, and policies on the survey, certification and enforcement process under this subpart and subpart F of this part.

§ 488.335 Action on complaints of resident neglect and abuse, and misappropriation of resident property.

(a) ***Investigation.***

(1) The State must review all allegations of resident neglect and abuse, and misappropriation of resident property and follow procedures specified in § 488.332.

(2) If there is reason to believe, either through oral or written evidence that an individual used by a facility to provide services to residents could have abused or neglected a resident or misappropriated a resident's property, the State must investigate the allegation.

(3) The State must have written procedures for the timely review and investigation of allegations of resident abuse and neglect, and misappropriation of resident property.

(b) ***Source of complaints.*** The State must review all allegations regardless of the source.

(c) ***Notification*** -

(1) ***Individuals to be notified.*** If the State makes a preliminary determination, based on oral or written evidence and its investigation, that the abuse, neglect or misappropriation of property occurred, it must notify in writing -

(i) The individuals implicated in the investigation; and

(ii) The current administrator of the facility in which the incident occurred.

(2) ***Timing of the notice.*** The State must notify the individuals specified in paragraph (c)(1) of this section in writing within 10 working days of the State's investigation.

(3) ***Contents of the notice.*** The notice must include the -

(i) Nature of the allegation(s);

(ii) Date and time of the occurrence;

(iii) Right to a hearing;

(iv) Intent to report the substantiated findings in writing, once the individual has had the opportunity for a hearing, to the nurse aide registry or appropriate licensure authority;

(v) Fact that the individual's failure to request a hearing in writing within 30 days from the date of the notice will result in reporting the substantiated findings to the nurse aide registry or appropriate licensure authority.

(vi) Consequences of waiving the right to a hearing;

(vii) Consequences of a finding through the hearing process that the alleged resident abuse or neglect, or misappropriation of resident property did occur; and

(viii) Fact that the individual has the right to be represented by an attorney at the individual's own expense.

(d) ***Conduct of hearing.***

(1) The State must complete the hearing and the hearing record within 120 days from the day it receives the request for a hearing.

(2) The State must hold the hearing at a reasonable place and time convenient for the individual.

(e) ***Factors beyond the individual's control.*** A State must not make a finding that an individual has neglected a resident if the individual demonstrates that such neglect was caused by factors beyond the control of the individual.

(f) ***Report of findings.*** If the finding is that the individual has neglected or abused a resident or misappropriated resident property or if the individual waives the right to a hearing, the State must report the findings in writing within 10 working days to -

(1) The individual;

(2) The current administrator of the facility in which the incident occurred; and

(3) The administrator of the facility that currently employs the individual, if different than the facility in which the incident occurred;

(4) The licensing authority for individuals used by the facility other than nurse aides, if applicable; and

(5) The nurse aide registry for nurse aides. Only the State survey agency may report the findings to the nurse aide registry, and this must be done within 10 working days of the findings, in accordance with § 483.156(c) of this chapter. The State survey agency may not delegate this responsibility.

(g) ***Contents and retention of report of finding to the nurse aide registry.***

(1) The report of finding must include information in accordance with § 483.156(c) of this chapter.

(2) The survey agency must retain the information as specified in paragraph (g)(1) of this section, in accordance with the procedures specified in § 483.156(c) of this chapter.

(h) ***Survey agency responsibility.***

(1) The survey agency must promptly review the results of all complaint investigations and determine whether or not a facility has violated any requirements in part 483, subpart B of this chapter.

(2) If a facility is not in substantial compliance with the requirements in part 483, subpart B of this chapter, the survey agency initiates appropriate actions, as specified in subpart F of this part.

[59 FR 56238, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

Subpart F - Enforcement of Compliance for Long-Term Care Facilities with Deficiencies

Source: 59 FR 56243, Nov. 10, 1994, unless otherwise noted.

§ 488.400 Statutory basis.

Sections 1819(h) and 1919(h) of the Act specify remedies that may be used by the Secretary or the State respectively when a SNF or a NF is not in substantial compliance with the requirements for participation in the Medicare and Medicaid programs. These sections also provide for ensuring prompt compliance and specify that these remedies are in addition to any other available under State or Federal law, and, except, for civil money penalties imposed on NFs-only by the State, are imposed prior to the conduct of a hearing.

[76 FR 15126, Mar. 18, 2011]

§ 488.401 Definitions.

As used in this subpart -

New admission means a resident who is admitted to the facility on or after the effective date of a denial of payment remedy and, if previously admitted, has been discharged before that effective date. Residents admitted before the effective date of the denial of payment, and taking temporary leave, are not considered new admissions, nor subject to the denial of payment.

Plan of correction means a plan developed by the facility and approved by CMS or the survey agency that describes the actions the facility will take to correct deficiencies and specifies the date by which those deficiencies will be corrected.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.402 General provisions.

(a) ***Purpose of remedies.*** The purpose of remedies is to ensure prompt compliance with program requirements.

(b) ***Basis for imposition and duration of remedies.*** When CMS or the State chooses to apply one or more remedies specified in § 488.406, the remedies are applied on the basis of noncompliance found during surveys conducted by CMS or by the survey agency.

(c) ***Number of remedies.*** CMS or the State may apply one or more remedies for each deficiency constituting noncompliance or for all deficiencies constituting noncompliance.

(d) ***Plan of correction requirement.***

(1) Except as specified in paragraph (d)(2) of this section, regardless of which remedy is applied, each facility that has deficiencies with respect to program requirements must submit a plan of correction for approval by CMS or the survey agency.

(2) ***Isolated deficiencies.*** A facility is not required to submit a plan of correction when it has deficiencies that are isolated and have a potential for minimal harm, but no actual harm has occurred.

(e) ***Disagreement regarding remedies.*** If the State and CMS disagree on the decision to impose a remedy, the disagreement is resolved in accordance with § 488.452.

(f) ***Notification requirements*** -

(1) Except when the State is taking action against a non-State operated NF, CMS or the State (as authorized by CMS) gives the provider notice of the remedy, including the -

(i) Nature of the noncompliance;

(ii) Which remedy is imposed;

(iii) Effective date of the remedy; and

(iv) Right to appeal the determination leading to the remedy.

(2) When a State is taking action against a non-State operated NF, the State's notice must include the same information required by CMS in paragraph (f)(1) of this section.

(3) ***Immediate jeopardy - 2 day notice.*** Except for civil money penalties and State monitoring imposed when there is immediate jeopardy, for all remedies specified in § 488.406 imposed when there is immediate jeopardy, the notice must be given at least 2 calendar days before the effective date of the enforcement action.

(4) ***No immediate jeopardy - 15 day notice.*** Except for civil money penalties and State monitoring, notice must be given at least 15 calendar days before the effective date of the enforcement action in situations in which there is no immediate jeopardy.

(5) ***Date of enforcement action.*** The 2-and 15-day notice periods begin when the facility receives the notice.

(6) ***Civil money penalties.*** For civil money penalties, the notices must be given in accordance with the provisions of §§ 488.434 and 488.440.

(7) ***State monitoring.*** For State monitoring, no prior notice is required.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995, as amended at 64 FR 13360, Mar. 18, 1999]

§ 488.404 Factors to be considered in selecting remedies.

(a) ***Initial assessment.*** In order to select the appropriate remedy, if any, to apply to a facility with deficiencies, CMS and the State determine the seriousness of the deficiencies.

(b) ***Determining seriousness of deficiencies.*** To determine the seriousness of the deficiency, CMS considers and the State must consider at least the following factors:

(1) Whether a facility's deficiencies constitute -

(i) No actual harm with a potential for minimal harm;

(ii) No actual harm with a potential for more than minimal harm, but not immediate jeopardy;

(iii) Actual harm that is not immediate jeopardy; or

(iv) Immediate jeopardy to resident health or safety.

(2) Whether the deficiencies -

(i) Are isolated;

(ii) Constitute a pattern; or

(iii) Are widespread.

(c) ***Other factors which may be considered in choosing a remedy within a remedy category.*** Following the initial assessment, CMS and the State may consider other factors, which may include, but are not limited to the following:

(1) The relationship of the one deficiency to other deficiencies resulting in noncompliance.

(2) The facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

§ 488.406 Available remedies.

(a) ***General.*** In addition to the remedy of termination of the provider agreement, the following remedies are available:

(1) Temporary management.

(2) Denial of payment including -

(i) Denial of payment for all individuals, imposed by CMS, to a -

(A) Skilled nursing facility, for Medicare;

(B) State, for Medicaid; or

(ii) Denial of payment for all new admissions.

(3) Civil money penalties.

(4) State monitoring.

(5) Transfer of residents.

(6) Closure of the facility and transfer of residents.

(7) Directed plan of correction.

(8) Directed in-service training.

(9) Alternative or additional State remedies approved by CMS.

(b) ***Remedies that must be established.*** At a minimum, and in addition to termination of the provider agreement, the State must establish the following remedies or approved alternatives to the following remedies:

(1) Temporary management.

(2) Denial of payment for new admissions.

(3) Civil money penalties.

(4) Transfer of residents.

(5) Closure of the facility and transfer of residents.

(6) State monitoring.

(c) ***State plan requirement.*** If a State wishes to use remedies for noncompliance that are either additional or alternative to those specified in paragraphs (a) or (b) of this section, it must -

(1) Specify those remedies in the State plan; and

(2) Demonstrate to CMS's satisfaction that those remedies are as effective as the remedies listed in paragraph (a) of this section, for deterring noncompliance and correcting deficiencies.

(d) ***State remedies in dually participating facilities.*** If the State's remedy is unique to the State plan and has been approved by CMS, then that remedy, as imposed by the State under its Medicaid authority, may be imposed by CMS against the Medicare provider agreement of a dually participating facility.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.408 Selection of remedies.

(a) ***Categories of remedies.*** In this section, the remedies specified in § 488.406(a) are grouped into categories and applied to deficiencies according to how serious the noncompliance is.

(b) ***Application of remedies.*** After considering the factors specified in § 488.404, as applicable, if CMS and the State choose to impose remedies, as provided in paragraphs (c)(1), (d)(1) and (e)(1) of this section, for facility noncompliance, instead of, or in addition to, termination of the provider agreement, CMS does and the State must follow the criteria set forth in paragraphs (c)(2), (d)(2), and (e)(2) of this section, as applicable.

(c) ***Category 1.***

(1) Category 1 remedies include the following:

(i) Directed plan of correction.

(ii) State monitoring.

(iii) Directed in-service training.

(2) CMS does or the State must apply one or more of the remedies in Category 1 when there -

(i) Are isolated deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

(ii) Is a pattern of deficiencies that constitutes no actual harm with a potential for more than minimal harm but not immediate jeopardy.

(3) Except when the facility is in substantial compliance, CMS or the State may apply one or more of the remedies in Category 1 to any deficiency.

(d) ***Category 2.***

(1) Category 2 remedies include the following:

(i) Denial of payment for new admissions.

(ii) Denial of payment for all individuals imposed only by CMS.

(iii) Civil money penalties of $50-3,000 as adjusted annually under 45 CFR part 102 per day.

(iv) Civil money penalty of $1,000-$10,000 as adjusted annually under 45 CFR part 102 per instance of noncompliance.

(2) CMS applies one or more of the remedies in Category 2, or, except for denial of payment for all individuals, the State must apply one or more of the remedies in Category 2 when there are -

(i) Widespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

(ii) One or more deficiencies that constitute actual harm that is not immediate jeopardy.

(3) CMS or the State may apply one or more of the remedies in Category 2 to any deficiency except when -

(i) The facility is in substantial compliance; or

(ii) CMS or the State imposes a civil money penalty for a deficiency that constitutes immediate jeopardy, the penalty must be in the upper range of penalty amounts, as specified in § 488.438(a).

(e) ***Category 3.***

(1) Category 3 remedies include the following:

(i) Temporary management.

(ii) Immediate termination.

(iii) Civil money penalties of $3,050-$10,000 as adjusted annually under 45 CFR part 102 per day.

(iv) Civil money penalty of $1,000-$10,000 as adjusted annually under 45 CFR part 102 per instance of noncompliance.

(2) When there are one or more deficiencies that constitute immediate jeopardy to resident health or safety -

(i) CMS does and the State must do one or both of the following:

(A) Impose temporary management; or

(B) Terminate the provider agreement;

(ii) CMS and the State may impose a civil money penalty of $3,050-$10,000 as adjusted annually under 45 CFR part 102 per day or $1,000-$10,000 as adjusted annually under 45 CFR part 102 per instance of noncompliance, in addition to imposing the remedies specified in paragraph (e)(2)(i) of this section.

(3) When there are widespread deficiencies that constitute actual harm that is not immediate jeopardy, CMS and the State may impose temporary management, in addition to Category 2 remedies.

(f) ***Plan of correction.***

(1) Except as specified in paragraph (f)(2) of this section, each facility that has a deficiency with regard to a requirement for long term care facilities must submit a plan of correction for approval by CMS or the State, regardless of -

(i) Which remedies are imposed; or

(ii) The seriousness of the deficiencies.

(2) When there are only isolated deficiencies that CMS or the State determines constitute no actual harm with a potential for minimal harm, the facility need not submit a plan of correction.

(g) ***Appeal of a certification of noncompliance.***

(1) A facility may appeal a certification of noncompliance leading to an enforcement remedy.

(2) A facility may not appeal the choice of remedy, including the factors considered by CMS or the State in selecting the remedy, specified in § 488.404.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995, as amended at 64 FR 13360, Mar. 18, 1999; 81 FR 61563, Sept. 6, 2016]

§ 488.410 Action when there is immediate jeopardy.

(a) If there is immediate jeopardy to resident health or safety, the State must (and CMS does) either terminate the provider agreement within 23 calendar days of the last date of the survey or appoint a temporary manager to remove the immediate jeopardy. The rules for appointment of a temporary manager in an immediate jeopardy situation are as follows:

(1) CMS does and the State must notify the facility that a temporary manager is being appointed.

(2) If the facility fails to relinquish control to the temporary manager, CMS does and the State must terminate the provider agreement within 23 calendar days of the last day of the survey, if the immediate jeopardy is not removed. In these cases, State monitoring may be imposed pending termination.

(3) If the facility relinquishes control to the temporary manager, the State must (and CMS does) notify the facility that, unless it removes the immediate jeopardy, its provider agreement will be terminated within 23 calendar days of the last day of the survey.

(4) CMS does and the State must terminate the provider agreement within 23 calendar days of the last day of survey if the immediate jeopardy has not been removed.

(b) CMS or the State may also impose other remedies, as appropriate.

(c)

(1) In a NF or dually participating facility, if either CMS or the State finds that a facility's noncompliance poses immediate jeopardy to resident health or safety, CMS or the State must notify the other of such a finding.

(2) CMS will or the State must do one or both of the following:

(i) Take immediate action to remove the jeopardy and correct the noncompliance through temporary management.

(ii) Terminate the facility's participation under the State plan. If this is done, CMS will also terminate the facility's participation in Medicare if it is a dually participating facility.

(d) The State must provide for the safe and orderly transfer of residents when the facility is terminated.

(e) If the immediate jeopardy is also substandard quality of care, the State survey agency must notify attending physicians and the State board responsible for licensing the facility administrator of the finding of substandard quality of care, as specified in § 488.325(h).

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.412 Action when there is no immediate jeopardy.

(a) If a facility's deficiencies do not pose immediate jeopardy to residents' health or safety, and the facility is not in substantial compliance, CMS or the State may terminate the facility's provider agreement or may allow the facility to continue to participate for no longer than 6 months from the last day of the survey if -

(1) The State survey agency finds that it is more appropriate to impose alternative remedies than to terminate the facility's provider agreement;

(2) The State has submitted a plan and timetable for corrective action approved by CMS; and

(3) The facility in the case of a Medicare SNF or the State in the case of a Medicaid NF agrees to repay to the Federal government payments received after the last day of the survey that first identified the deficiencies if corrective action is not taken in accordance with the approved plan of correction.

(b) If a facility does not meet the criteria for continuation of payment under paragraph (a) of this section, CMS will and the State must terminate the facility's provider agreement.

(c) CMS does and the State must deny payment for new admissions when a facility is not in substantial compliance 3 months after the last day of the survey.

(d) CMS terminates the provider agreement for SNFs and NFs, and stops FFP to a State for a NF for which participation was continued under paragraph (a) of this section, if the facility is not in substantial compliance within 6 months of the last day of the survey.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.414 Action when there is repeated substandard quality of care.

(a) ***General.*** If a facility has been found to have provided substandard quality of care on the last three consecutive standard surveys, as defined in § 488.305, regardless of other remedies provided -

(1) CMS imposes denial of payment for all new admissions, as specified in § 488.417, or denial of all payments, as specified in § 488.418;

(2) The State must impose denial of payment for all new admissions, as specified in § 488.417; and

(3) CMS does and the State survey agency must impose State monitoring, as specified in § 488.422, until the facility has demonstrated to the satisfaction of CMS or the State, that it is in substantial compliance with all requirements and will remain in substantial compliance with all requirements.

(b) ***Repeated noncompliance.*** For purposes of this section, repeated noncompliance is based on the repeated finding of substandard quality of care and not on the basis that the substance of the deficiency or the exact tag number for the deficiency was repeated.

(c) ***Standard surveys to which this provision applies.*** Standard surveys completed by the State survey agency on or after October 1, 1990, are used to determine whether the threshold of three consecutive standard surveys is met.

(d) ***Program participation.***

(1) The determination that a certified facility has repeated instances of substandard quality of care is made without regard to any variances in the facility's program participation (that is, any standard survey completed for Medicare, Medicaid or both programs will be considered).

(2) Termination would allow the count of repeated substandard quality of care surveys to start over.

(3) Change of ownership.

(i) A facility may not avoid a remedy on the basis that it underwent a change of ownership.

(ii) In a facility that has undergone a change of ownership, CMS does not and the State may not restart the count of repeated substandard quality of care surveys unless the new owner can demonstrate to the satisfaction of CMS or the State that the poor past performance no longer is a factor due to the change in ownership.

(e) ***Facility alleges corrections or achieves compliance after repeated substandard quality of care is identified.***

(1) If a penalty is imposed for repeated substandard quality of care, it will continue until the facility has demonstrated to the satisfaction of CMS or the State that it is in substantial compliance with the requirements and that it will remain in substantial compliance with the requirements for a period of time specified by CMS or the State.

(2) A facility will not avoid the imposition of remedies or the obligation to demonstrate that it will remain in compliance when it -

(i) Alleges correction of the deficiencies cited in the most recent standard survey; or

(ii) Achieves compliance before the effective date of the remedies.

§ 488.415 Temporary management.

(a) ***Definition.*** Temporary management means the temporary appointment by CMS or the State of a substitute facility manager or administrator with authority to hire, terminate or reassign staff, obligate facility funds, alter facility procedures, and manage the facility to correct deficiencies identified in the facility's operation.

(b) ***Qualifications.*** The temporary manager must -

(1) Be qualified to oversee correction of deficiencies on the basis of experience and education, as determined by the State;

(2) Not have been found guilty of misconduct by any licensing board or professional society in any State;

(3) Have, or a member of his or her immediate family have, no financial ownership interest in the facility; and

(4) Not currently serve or, within the past 2 years, have served as a member of the staff of the facility.

(c) ***Payment of salary.*** The temporary manager's salary -

(1) Is paid directly by the facility while the temporary manager is assigned to that facility; and

(2) Must be at least equivalent to the sum of the following -

(i) The prevailing salary paid by providers for positions of this type in what the State considers to be the facility's geographic area;

(ii) Additional costs that would have reasonably been incurred by the provider if such person had been in an employment relationship; and

(iii) Any other costs incurred by such a person in furnishing services under such an arrangement or as otherwise set by the State.

(3) May exceed the amount specified in paragraph (c)(2) of this section if the State is otherwise unable to attract a qualified temporary manager.

(d) ***Failure to relinquish authority to temporary management*** -

(1) ***Termination of provider agreement.*** If a facility fails to relinquish authority to the temporary manager as described in this section, CMS will or the State must terminate the provider agreement in accordance with § 488.456.

(2) ***Failure to pay salary of temporary manager.*** A facility's failure to pay the salary of the temporary manager is considered a failure to relinquish authority to temporary management.

(e) ***Duration of temporary management.*** Temporary management ends when the facility meets any of the conditions specified in § 488.454(c).

§ 488.417 Denial of payment for all new admissions.

(a) ***Optional denial of payment.*** Except as specified in paragraph (b) of this section, CMS or the State may deny payment for all new admissions when a facility is not in substantial compliance with the requirements, as defined in § 488.401, as follows:

(1) ***Medicare facilities.*** In the case of Medicare facilities, CMS may deny payment to the facility.

(2) ***Medicaid facilities.*** In the case of Medicaid facilities -

(i) The State may deny payment to the facility; and

(ii) CMS may deny payment to the State for all new Medicaid admissions to the facility.

(b) ***Required denial of payment.*** CMS does or the State must deny payment for all new admissions when -

(1) The facility is not in substantial compliance, as defined in § 488.401, 3 months after the last day of the survey identifying the noncompliance; or

(2) The State survey agency has cited a facility with substandard quality of care on the last three consecutive standard surveys.

(c) ***Resumption of payments: Repeated instances of substandard quality of care.*** When a facility has repeated instances of substandard quality of care, payments to the facility or, under Medicaid, CMS payments to the State on behalf of the facility, resume on the date that -

(1) The facility achieves substantial compliance as indicated by a revisit or written credible evidence acceptable to CMS (for all facilities except non-State operated NFs against which CMS is imposing no remedies) or the State (for non-State operated NFs against which CMS is imposing no remedies); and

(2) CMS (for all facilities except non-State operated NFs against which CMS is imposing no remedies) or the State (for non-State operated NFs against which CMS is imposing no remedies) believes that the facility is capable of remaining in substantial compliance.

(d) ***Resumption of payments: No repeated instances of substandard quality of care.*** When a facility does not have repeated instances of substandard quality of care, payments to the facility or, under Medicaid, CMS payments to the State on behalf of the facility, resume prospectively on the date that the facility achieves substantial compliance, as indicated by a revisit or written credible evidence acceptable to CMS (under Medicare) or the State (under Medicaid).

(e) ***Restriction.*** No payments to a facility or, under Medicaid, CMS payments to the State on behalf of the facility, are made for the period between the date that the -

(1) Denial of payment remedy is imposed; and

(2) Facility achieves substantial compliance, as determined by CMS or the State.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.418 Secretarial authority to deny all payments.

(a) ***CMS option to deny all payment.*** If a facility has not met a requirement, in addition to the authority to deny payment for all new admissions as specified in § 488.417, CMS may deny any further payment for all Medicare residents in the facility and to the State for all Medicaid residents in the facility.

(b) ***Prospective resumption of payment.*** Except as provided in paragraphs (d) and (e) of this section, if the facility achieves substantial compliance, CMS resumes payment prospectively from the date that it verifies as the date that the facility achieved substantial compliance.

(c) ***Restriction on payment after denial of payment is imposed.*** If payment to the facility or to the State resumes after denial of payment for all residents, no payment is made for the period between the date that -

(1) Denial of payment was imposed; and

(2) CMS verifies as the date that the facility achieved substantial compliance.

(d) ***Retroactive resumption of payment.*** Except when a facility has repeated instances of substandard quality of care, as specified in paragraph (e) of this section, when CMS or the State finds that the facility was in substantial compliance before the date of the revisit, or before CMS or the survey agency received credible evidence of such compliance, payment is resumed on the date that substantial compliance was achieved, as determined by CMS.

(e) ***Resumption of payment - repeated instances of substandard care.*** When CMS denies payment for all Medicare residents for repeated instances of substandard quality of care, payment is resumed when -

(1) The facility achieved substantial compliance, as indicated by a revisit or written credible evidence acceptable to CMS; and

(2) CMS believes that the facility will remain in substantial compliance.

§ 488.422 State monitoring.

(a) A State monitor -

(1) Oversees the correction of deficiencies specified by CMS or the State survey agency at the facility site and protects the facility's residents from harm;

(2) Is an employee or a contractor of the survey agency;

(3) Is identified by the State as an appropriate professional to monitor cited deficiencies;

(4) Is not an employee of the facility;

(5) Does not function as a consultant to the facility; and

(6) Does not have an immediate family member who is a resident of the facility to be monitored.

(b) A State monitor must be used when a survey agency has cited a facility with substandard quality of care deficiencies on the last 3 consecutive standard surveys.

(c) State monitoring is discontinued when -

(1) The facility has demonstrated that it is in substantial compliance with the requirements, and, if imposed for repeated instances of substandard quality of care, will remain in compliance for a period of time specified by CMS or the State; or

(2) Termination procedures are completed.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.424 Directed plan of correction.

CMS, the State survey agency, or the temporary manager (with CMS or State approval) may develop a plan of correction and CMS, the State, or the temporary manager require a facility to take action within specified timeframes.

§ 488.425 Directed inservice training.

(a) ***Required training.*** CMS or the State agency may require the staff of a facility to attend an inservice training program if -

(1) The facility has a pattern of deficiencies that indicate noncompliance; and

(2) Education is likely to correct the deficiencies.

(b) ***Action following training.*** After the staff has received inservice training, if the facility has not achieved substantial compliance, CMS or the State may impose one or more other remedies specified in § 488.406.

(c) ***Payment.*** The facility pays for directed inservice training.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.426 Transfer of residents, or closure of the facility and transfer of residents.

(a) ***Transfer of residents, or closure of the facility and transfer of residents in an emergency.*** In an emergency, the State has the authority to -

(1) Transfer Medicaid and Medicare residents to another facility; or

(2) Close the facility and transfer the Medicaid and Medicare residents to another facility.

(b) ***Required transfer when a facility's provider agreement is terminated.*** When the State or CMS terminates a facility's provider agreement, the State will arrange for the safe and orderly transfer of all Medicare and Medicaid residents to another facility, in accordance with § 483.70(l) of this chapter.

(c) ***Required notifications when a facility's provider agreement is terminated.*** When the State or CMS terminates a facility's provider agreement, CMS determines the appropriate date for notification, in accordance with § 483.70(l) of this chapter.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995, as amended at 76 FR 9511, Feb. 18, 2011; 81 FR 68872, Oct. 4, 2016]

§ 488.430 Civil money penalties: Basis for imposing penalty.

(a) CMS or the State may impose a civil money penalty for either the number of days a facility is not in substantial compliance with one or more participation requirements or for each instance that a facility is not in substantial compliance, regardless of whether or not the deficiencies constitute immediate jeopardy.

(b) CMS or the State may impose a civil money penalty for the number of days of past noncompliance since the last standard survey, including the number of days of immediate jeopardy.

[59 FR 56243, Nov. 10, 1994, as amended at 64 FR 13360, Mar. 18, 1999]

§ 488.431 Civil money penalties imposed by CMS and independent informal dispute resolution: for SNFS, dually-participating SNF/NFs, and NF-only facilities.

(a) ***Opportunity for independent review.*** CMS retains ultimate authority for the survey findings and imposition of civil money penalties, but provides an opportunity for independent informal dispute resolution within 30 days of notice of imposition of a civil money penalty that will be placed in escrow in accordance with paragraph (b) of this section. An independent informal dispute resolution will -

(1) Be completed within 60 days of facility's request if an independent informal dispute resolution is timely requested by the facility.

(2) Generate a written record prior to the collection of the penalty.

(3) Include notification to an involved resident or resident representative, as well as the State's long term care ombudsman, to provide opportunity for written comment.

(4) Be approved by CMS and conducted by the State under section 1864 of the Act, or by an entity approved by the State and CMS, or by CMS or its agent in the case of surveys conducted only by federal surveyors where the State independent dispute resolution process is not used, and which has no conflict of interest, such as:

(i) A component of an umbrella State agency provided that the component is organizationally separate from the State survey agency.

(ii) An independent entity with a specific understanding of Medicare and Medicaid program requirements selected by the State and approved by CMS.

(5) Not include the survey findings that have already been the subject of an informal dispute resolution under § 488.331 for the particular deficiency citations at issue in the independent process under § 488.431, unless the informal dispute resolution under § 488.331 was completed prior to the imposition of the civil money penalty.

(b) ***Collection and placement in escrow account.***

(1) For both per day and per instance civil money penalties, CMS may collect and place the imposed civil money penalties in an escrow account on whichever of the following occurs first:

(i) The date on which the independent informal dispute resolution process is completed under paragraph (a) of this section.

(ii) The date that is 90 days after the date of the notice of imposition of the penalty.

(2) For collection and placement in escrow accounts of per day civil money penalties, CMS may collect the portion of the per day civil money penalty that has accrued up to the time of collection as specified in paragraph (b)(1) of this section. CMS may make additional collections periodically until the full amount is collected, except that the full balance must be collected once the facility achieves substantial compliance or is terminated from the program and CMS determines the final amount of the civil money penalty imposed.

(3) CMS may provide for an escrow payment schedule that differs from the collection times of paragraph (1) of this subsection in any case in which CMS determines that more time is necessary for deposit of the total civil money penalty into an escrow account, not to exceed 12 months, if CMS finds that immediate payment would create substantial and undue financial hardship on the facility.

(4) If the full civil money penalty is not placed in an escrow account within 30 calendar days from the date the provider receives notice of collection, or within 30 calendar days of any due date established pursuant to a hardship finding under paragraph (b)(3), CMS may deduct the amount of the civil money penalty from any sum then or later owed by CMS or the State to the facility in accordance with § 488.442(c).

(5) For any civil money penalties that are not collected and placed into an escrow account under this section, CMS will collect such civil money penalties in the same manner as the State in accordance with § 488.432.

(c) ***Maintenance of escrowed funds.*** CMS will maintain collected civil money penalties in an escrow account pending the resolution of any administrative appeal of the deficiency findings that comprise the basis for the civil monetary penalty imposition. CMS will retain the escrowed funds on an on-going basis and, upon a final administrative decision, will either return applicable funds in accordance with

paragraph (d)(2) of this section or, in the case of an unsuccessful administrative appeal, will periodically disburse the funds to States or other entities in accordance with § 488.433.

(d) ***When a facility requests a hearing.***

(1) A facility must request a hearing on the determination of the noncompliance that is the basis for imposition of the civil money penalty as specified in § 498.40 of this chapter.

(2) If the administrative law judge reverses deficiency findings that comprise the basis of a civil money penalty in whole or in part, the escrowed amounts continue to be held pending expiration of the time for CMS to appeal the decision or, where CMS does appeal, a Departmental Appeals Board decision affirming the reversal of the pertinent deficiency findings. Any collected civil money penalty amount owed to the facility based on a final administrative decision will be returned to the facility with applicable interest as specified in section 1878(f)(2) of the Act.

[76 FR 15126, Mar. 18, 2011]

§ 488.432 Civil money penalties imposed by the State: NF-only.

(a) ***When a facility requests a hearing.***

(1) When the State imposes a civil money penalty against a non-State operated NF that is not subject to imposition of remedies by CMS, the facility must request a hearing on the determination of noncompliance that is the basis for imposition of the civil money penalty within the time specified in § 431.153 of this chapter.

(2)

(i) If a facility requests a hearing within the time frame specified in paragraph (a)(1) of this section, for a civil money penalty imposed per day, the State initiates collection of the penalty when there is a final administrative decision that upholds the State's determination of noncompliance after the facility achieves substantial compliance or is terminated.

(ii) If a facility requests a hearing for a civil money penalty imposed per instance of noncompliance within the time specified in paragraph (a)(1) of this section, the State initiates collection of the penalty when there is a final administrative decision that upholds the State's determination of noncompliance.

(b) When a facility does not request a hearing for a civil money penalty imposed per day.

(1) If a facility does not request a hearing in accordance with paragraph (a) of this section, the State initiates collection of the penalty when the facility -

(i) Achieves substantial compliance; or

(ii) Is terminated.

(2) ***When a facility does not request a hearing for a civil money penalty imposed per instance of noncompliance.*** If a facility does not request a hearing in accordance with paragraph (a) of this section, the State initiates collection of the penalty when the time frame for requesting a hearing expires.

(c) When a facility waives a hearing.

(1) If a facility waives, in writing, its right to a hearing as specified in § 488.436, for a civil money penalty imposed per day, the State initiates collection of the penalty when the facility -

(i) Achieves substantial compliance; or

(ii) Is terminated.

(2) If a facility waives, in writing, its right to a hearing as specified in § 488.436, the State initiates collection of civil money penalty imposed per instance of noncompliance upon receipt of the facility's notification.

(d) Accrual and computation of penalties for a facility that -

(1) Requests a hearing or does not request a hearing are specified in § 488.440;

(2) Waives its right to a hearing in writing, are specified in §§ 488.436(b) and 488.440.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995, as amended at 64 FR 13360, Mar. 18, 1999; 76 FR 15127, Mar. 18, 2011]

§ 488.433 Civil money penalties: Uses and approval of civil money penalties imposed by CMS.

(a) Ten percent of the collected civil money penalty funds that are required to be held in escrow pursuant to § 488.431 and that remain after a final administrative decision will be deposited with the Department of the Treasury in accordance with § 488.442(f). The remaining ninety percent of the collected civil money penalty funds that are required to be held in escrow pursuant to § 488.431 and that remain after a final administrative decision must be used entirely for activities that protect or improve the quality of care or quality of life for residents consistent with paragraph (b) of this section and may not be used for survey and certification operations or State expenses, except that reasonable expenses necessary to administer, monitor, or evaluate the effectiveness of projects utilizing civil money penalty funds may be permitted.

(b) All activities and plans for utilizing civil money penalty funds, including any expense used to administer grants utilizing civil money penalty funds, must be approved in advance by CMS and may include, but are not limited to:

(1) Support and protection of residents of a facility that closes (voluntarily or involuntarily).

(2) Time-limited expenses incurred in the process of relocating residents to home and community-based settings or another facility when a facility is closed (voluntarily or involuntarily) or downsized pursuant to an agreement with the State Medicaid agency.

(3) Projects that support resident and family councils and other consumer involvement in assuring quality care in facilities.

(4) Facility improvement initiatives, such as joint training of facility staff and surveyors or technical assistance for facilities implementing quality assurance and performance improvement programs.

(5) Development and maintenance of temporary management or receivership capability such as but not limited to, recruitment, training, retention or other system infrastructure expenses. However, as specified in § 488.415(c), a temporary manager's salary must be paid by the facility. In rare situations, if the facility is closing, CMS plans to stop or suspend continued payments to the facility under § 489.55 of this chapter during the temporary manager's duty period, and CMS determines that extraordinary action is necessary to protect the residents until relocation efforts are successful, civil money penalty funds may be used to pay the manager's salary.

(c) At a minimum, proposed activities submitted to CMS for prior approval must include a description of the intended outcomes, deliverables, and sustainability; and a description of the methods by which the activity results will be assessed, including specific measures.

(d) Civil money penalty funds may not be used for activities that have been disapproved by CMS.

(e) The State must maintain an acceptable plan, approved by CMS, for the effective use of civil money funds, including a description of methods by which the State will:

(1) Solicit, accept, monitor, and track projects utilizing civil money penalty funds including any funds used for state administration.

(2) Make information about the use of civil money penalty funds publicly available, including about the dollar amount awarded for approved projects, the grantee or contract recipients, the results of projects, and other key information.

(3) Ensure that:

(i) A core amount of civil money penalty funds will be held in reserve for emergencies, such as relocation of residents pursuant to an involuntary termination from Medicare and Medicaid.

(ii) A reasonable amount of funds, beyond those held in reserve under paragraph (e)(3)(i) of this section, will be awarded or contracted each year for the purposes specified in this section.

(f) If CMS finds that a State has not spent civil money penalty funds in accordance with this section, or fails to make use of funds to benefit the quality of care or life of residents, or fails to maintain an acceptable plan for the use of funds that is approved by CMS, then CMS may withhold future disbursements of civil money penalty funds to the State until the State has submitted an acceptable plan to comply with this section.

[79 FR 45658, Aug. 5, 2014]

§ 488.434 Civil money penalties: Notice of penalty.

(a) ***CMS notice of penalty.***

(1) CMS sends a written notice of the penalty to the facility for all facilities except non-State operated NFs when the State is imposing the penalty.

(2) ***Content of notice.*** The notice that CMS sends includes -

(i) The nature of the noncompliance;

(ii) The statutory basis for the penalty;

(iii) The amount of penalty per day of noncompliance or the amount of the penalty per instance of noncompliance;

(iv) Any factors specified in § 488.438(f) that were considered when determining the amount of the penalty;

(v) The date of the instance of noncompliance or the date on which the penalty begins to accrue;

(vi) When the penalty stops accruing, if applicable;

(vii) When the penalty is collected; and

(viii) Instructions for responding to the notice, including a statement of the facility's right to a hearing, and the implication of waiving a hearing, as provided in § 488.436.

(b) ***State notice of penalty.***

(1) The State must notify the facility in accordance with State procedures for all non-State operated NFs when the State takes the action.

(2) The State's notice must -

(i) Be in writing; and

(ii) Include, at a minimum, the information specified in paragraph (a)(2) of this section.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995, as amended at 64 FR 13360, Mar. 18, 1999]

§ 488.436 Civil money penalties: Waiver of hearing, reduction of penalty amount.

(a) ***Waiver of a hearing.*** The facility may waive the right to a hearing, in writing, within 60 days from the date of the notice imposing the civil money penalty.

(b) ***Reduction of penalty amount.***

(1) If the facility waives its right to a hearing in accordance with the procedures specified in paragraph (a) of this section, CMS or the State reduces the civil money penalty by 35 percent, as long as the civil money penalty has not also been reduced by 50 percent under § 488.438.

(2) If the facility does not waive its right to a hearing in accordance with the procedures specified in paragraph (a) of this section, the civil money penalty is not reduced by 35 percent.

[59 FR 56243, Nov. 10, 1994; 62 FR 44221, Aug. 20, 1997; 76 FR 15127, Mar. 18, 2011]

§ 488.438 Civil money penalties: Amount of penalty.

(a) ***Amount of penalty.***

(1) The penalties are within the following ranges, set at $50 increments:

(i) ***Upper range.*** Penalties in the range of $3,050-$10,000 as adjusted annually under 45 CFR part 102 per day are imposed for deficiencies constituting immediate jeopardy, and as specified in paragraph (d)(2) of this section.

(ii) ***Upper range.*** Penalties in the range of $50-$3,000 as adjusted annually under 45 CFR part 102 per day are imposed for deficiencies that do not constitute immediate jeopardy, but either caused actual harm, or caused no actual harm, but have the potential for more than minimal harm.

(2) ***Per instance penalty.*** When penalties are imposed for an instance of noncompliance, the penalties will be in the range of $1,000-$10,000 as adjusted annually under 45 CFR part 102 per instance.

(b) ***Basis for penalty amount.*** The amount of penalty is based on CMS's or the State's assessment of factors listed in paragraph (f) of this section.

(c) ***Decreased penalty amounts.***

(1) Except as specified in paragraph (d)(2) of this section, if immediate jeopardy is removed, but the noncompliance continues, CMS or the State will shift the penalty amount imposed per day to the lower range.

(2) When CMS determines that a SNF, dually-participating SNF/NF, or NF-only facility subject to a civil money penalty imposed by CMS self-reports and promptly corrects the noncompliance for which the civil money penalty was imposed, CMS will reduce the amount of the penalty by 50 percent, provided that all of the following apply -

(i) The facility self-reported the noncompliance to CMS or the State before it was identified by CMS or the State and before it was reported to CMS or the State by means of a complaint lodged by a person other than an official representative of the nursing home;

(ii) Correction of the self-reported noncompliance occurred on whichever of the following occurs first:

(A) 15 calendar days from the date of the circumstance or incident that later resulted in a finding of noncompliance; or

(B) 10 calendar days from the date the civil money penalty was imposed;

(iii) The facility waives its right to a hearing under § 488.436;

(iv) The noncompliance that was self-reported and corrected did not constitute a pattern of harm, widespread harm, immediate jeopardy, or result in the death of a resident;

(v) The civil money penalty was not imposed for a repeated deficiency, as defined in paragraph (d)(3) of this section, that was the basis of a civil money penalty that previously received a reduction under this section; and

(vi) The facility has met mandatory reporting requirements for the incident or circumstance upon which the civil money penalty is based, as required by Federal and State law.

(3) Under no circumstances will a facility receive both the 50 percent civil money penalty reduction for self-reporting and correcting under this section and the 35 percent civil money penalty reduction for waiving its right to a hearing under § 488.436.

(d) ***Increased penalty amounts.***

(1) Before a hearing requested in accordance with § 488.431(d) or § 488.432(a), CMS or the State may propose to increase the per day penalty amount for facility noncompliance which, after imposition of a lower level penalty amount, becomes sufficiently serious to pose immediate jeopardy.

(2) CMS does and the State must increase the per day penalty amount for any repeated deficiencies for which a lower level penalty amount was previously imposed, regardless of whether the increased penalty amount would exceed the range otherwise reserved for nonimmediate jeopardy deficiencies.

(3) Repeated deficiencies are deficiencies in the same regulatory grouping of requirements found at the last survey, subsequently corrected, and found again at the next survey.

(e) ***Review of the penalty.*** When an administrative law judge or State hearing officer (or higher administrative review authority) finds that the basis for imposing a civil money penalty exists, as specified in § 488.430, the administrative law judge or State hearing officer (or higher administrative review authority) may not -

(1) Set a penalty of zero or reduce a penalty to zero;

(2) Review the exercise of discretion by CMS or the State to impose a civil money penalty; and

(3) Consider any factors in reviewing the amount of the penalty other than those specified in paragraph (f) of this section.

(f) ***Factors affecting the amount of penalty.*** In determining the amount of penalty, CMS does or the State must take into account the following factors:

(1) The facility's history of noncompliance, including repeated deficiencies.

(2) The facility's financial condition.

(3) The factors specified in § 488.404.

(4) ***The facility's degree of culpability. Culpability*** for purposes of this paragraph includes, but is not limited to, neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating circumstance in reducing the amount of the penalty.

[59 FR 56243, Nov. 10, 1994, as amended at 64 FR 13360, Mar. 18, 1999; 68 FR 46072, Aug. 4, 2003; 76 FR 15127, Mar. 18, 2011; 81 FR 61563, Sept. 6, 2016]

§ 488.440 Civil money penalties: Effective date and duration of penalty.

(a)

(1) The per day civil money penalty may start accruing as early as the date that the facility was first out of compliance, as determined by CMS or the State.

(2) A civil money penalty for each instance of noncompliance is imposed in a specific amount for that particular deficiency .

(b) The per day civil money penalty is computed and collectible, as specified in §§ 488.431, 488.432, and 488.442 for the number of days of noncompliance until the date the facility achieves substantial compliance, or, if applicable, the date of termination when -

(1) The determination of noncompliance is upheld after a final administrative decision for NFs-only subject to civil money penalties imposed by the state or for civil money penalties imposed by CMS that are not collected and placed into an escrow account;

(2) The facility waives its right to a hearing in accordance with § 488.436; or

(3) The time for requesting a hearing has expired and CMS or the State has not received a hearing request from the facility.

(c)

(1) For NFs-only subject to civil money penalties imposed by the State and for civil money penalties imposed by CMS that may not be placed in an escrow account, the entire penalty, whether imposed on a per day or per instance basis, is due and collectible as specified in the notice sent to the provider under paragraphs (d) and (e) of this section.

(2) For SNFs, dually-participating SNF/NFs, or NFs subject to civil money penalties imposed by CMS, collection is made in accordance with § 488.431.

(d)

(1) When a civil money penalty is imposed on a per day basis and the facility achieves substantial compliance, CMS does or the State must send a separate notice to the facility containing the following information:

(i) The amount of penalty per day.

(ii) The number of days involved.

(iii) The total amount due.

(iv) The due date of the penalty.

(v) The rate of interest assessed on the unpaid balance beginning on the due date, as provided in § 488.442.

(2) When a civil money penalty is imposed for an instance of noncompliance, CMS does or the State must send a separate notice to the facility containing the following information:

(i) The amount of the penalty.

(ii) The total amount due.

(iii) The due date of the penalty.

(iv) The rate of interest assessed on the unpaid balance beginning on the due date, as provided in § 488.442.

(e) In the case of a facility for which the provider agreement has been terminated and on which a civil money penalty was imposed on a per day basis, CMS does or the State must send this penalty information after the -

(1) Final administrative decision is made;

(2) Facility has waived its right to a hearing in accordance with § 488.436; or

(3) Time for requesting a hearing has expired and CMS or the state has not received a hearing request from the facility.

(f) ***Accrual of penalties when there is no immediate jeopardy.***

(1) In the case of noncompliance that does not pose immediate jeopardy, the daily accrual of per day civil money penalties is imposed for the days of noncompliance prior to the notice specified in § 488.434 and an additional period of no longer than 6 months following the last day of the survey.

(2) After the period specified in paragraph (f)(1) of this section, if the facility has not achieved substantial compliance, CMS terminates the provider agreement and the State may terminate the provider agreement.

(g)

(1) In a case when per day civil money penalties are imposed, when a facility has deficiencies that pose immediate jeopardy, CMS does or the State must terminate the provider agreement within 23 calendar days after the last day of the survey if the immediate jeopardy remains.

(2) The accrual of the civil money penalty imposed on a per day basis stops on the day the provider agreement is terminated.

(h)

(1) If an on-site revisit is necessary to confirm substantial compliance and the provider can supply documentation acceptable to CMS or the State agency that substantial compliance was achieved on a date preceding the revisit, penalties imposed on a per day basis only accrue until that date of correction for which there is written credible evidence.

(2) If an on-site revisit is not necessary to confirm substantial compliance, penalties imposed on a per day basis only accrue until the date of correction for which CMS or the State receives and accepts written credible evidence.

[59 FR 56243, Nov. 10, 1994, as amended at 64 FR 13361, Mar. 18, 1999; 76 FR 15128, Mar. 18, 2011]

§ 488.442 Civil money penalties: Due date for payment of penalty.

(a) ***When payments are due for a civil money penalty.***

(1) Payment for a civil money penalty is due in accordance with § 488.431 of this chapter for CMS-imposed penalties and 15 days after the State initiates collection pursuant to § 488.432 of this chapter for State-imposed penalties, except as provided in paragraphs (a)(2) and (3) of this section.

(2) ***After a request to waive a hearing or when a hearing was not requested.*** Except as provided for in § 488.431, a civil money penalty is due 15 days after receipt of a written request to waive a hearing in accordance with § 488.436 or 15 days after the time period for requesting a hearing has expired and a hearing request was not received when:

(i) The facility achieved substantial compliance before the hearing request was due; or

(ii) The effective date of termination occurs before the hearing request was due.

(3) ***After the effective date of termination.*** A civil money penalty payment is due 15 days after the effective date of termination, if that date is earlier than the date specified in paragraph (a)(1)of this section.

(b) [Reserved]

(c) ***Deduction of penalty from amount owed.*** The amount of the penalty, when determined, may be deducted from any sum then or later owing by CMS or the State to the facility.

(d) ***Interest*** -

(1) ***Assessment.*** Interest is assessed on the unpaid balance of the penalty, beginning on the due date.

(2) ***Medicare interest.*** Medicare rate of interest is the higher of -

(i) The rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of the notice of the penalty amount due (published quarterly in the Federal Register by HHS under 45 CFR 30.13(a)); or

(ii) The current value of funds (published annually in the Federal Register by the Secretary of the Treasury, subject to quarterly revisions).

(3) ***Medicaid interest.*** The interest rate for Medicaid is determined by the State.

(e) ***Penalties collected by CMS.*** Civil money penalties and corresponding interest collected by CMS from -

(1) Medicare-participating facilities are deposited and disbursed in accordance with § 488.433; and

(2) Medicaid-participating facilities are returned to the State.

(f) ***Collection from dually participating facilities.*** Civil money penalties collected from dually participating facilities are deposited and disbursed in accordance with § 488.433 and returned to the State in proportion commensurate with the relative proportions of Medicare and Medicaid beds at the facility actually in use by residents covered by the respective programs on the date the civil money penalty begins to accrue.

(g) ***Penalties collected by the State.*** Civil money penalties collected by the State must be applied to the protection of the health or property of residents of facilities that the State or CMS finds noncompliant, such as -

(1) Payment for the cost of relocating residents to other facilities;

(2) State costs related to the operation of a facility pending correction of deficiencies or closure; and

(3) Reimbursement of residents for personal funds or property lost at a facility as a result of actions by the facility or by individuals used by the facility to provide services to residents.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995, as amended at 64 FR 13361, Mar. 18, 1999; 76 FR 15128, Mar. 18, 2011]

§ 488.444 Civil money penalties: Settlement of penalties.

(a) CMS has authority to settle cases at any time prior to a final administrative decision for Medicare-only SNFs, State-operated facilities, or other facilities for which CMS's enforcement action prevails, in accordance with § 488.330.

(b) The State has the authority to settle cases at any time prior to the evidentiary hearing decision for all cases in which the State's enforcement action prevails.

§ 488.446 Administrator sanctions: long-term care facility closures.

Any individual who is or was the administrator of a facility and fails or failed to comply with the requirements at § 483.70(l) of this chapter -

(a) Will be subject to a civil monetary penalty as follows:

(1) A minimum of $500 as adjusted annually under 45 CFR part 102 for the first offense.

(2) A minimum of $1,500 as adjusted annually under 45 CFR part 102 for the second offense.

(3) A minimum of $3,000 as adjusted annually under 45 CFR part 102 for the third and subsequent offenses.

(b) May be subject to exclusion from participation in any Federal health care program (as defined in section 1128B(f) of the Act); and

(c) Will be subject to any other penalties that may be prescribed by law.

[76 FR 9511, Feb. 18, 2011, as amended at 81 FR 61563, Sept. 6, 2016; 81 FR 68872, Oct. 4, 2016]

§ 488.447 Civil Money Penalties imposed for failure to comply with 42 CFR 483.80(g)(1) and (2).

(a) CMS may impose a civil money penalty for noncompliance with the requirements at § 483.80(g)(1) and (2) of this chapter as follows:

(1) ***Minimum.*** A minimum of $1,000 for the first occurrence.

(2) ***Increased amount.*** An amount equal to $500 added to the previously imposed civil money penalty amount for each subsequent occurrence, not to exceed the maximum amount set forth in § 488.408(d)(1)(iii).

(b) The penalty amounts in this section will be adjusted annually under 45 CFR part 102.

(c) Compliance with the requirements at § 483.80(g)(1) and (2) of this chapter will be assessed weekly. Facilities found out of compliance with § 483.80(g)(1) and (2) of this chapter are not required to submit a plan of correction as indicated in § 488.408(f)(1).

(d) This section is in effect during and the Public Health Emergency (PHE), as defined in § 400.200 of this chapter, and will continue for up to one year after the end of the PHE.

[85 FR 54873, Sept. 2, 2020]

§ 488.450 Continuation of payments to a facility with deficiencies.

(a) ***Criteria.***

(1) CMS may continue payments to a facility not in substantial compliance for the periods specified in paragraph (c) of this section if the following criteria are met:

(i) The State survey agency finds that it is more appropriate to impose alternative remedies than to terminate the facility;

(ii) The State has submitted a plan and timetable for corrective action approved by CMS; and

(iii) The facility, in the case of a Medicare SNF, or the State, in the case of a Medicaid NF, agrees to repay the Federal government payments received under this provision if corrective action is not taken in accordance with the approved plan and timetable for corrective action.

(2) CMS or the State may terminate the SNF or NF agreement before the end of the correction period if the criteria in paragraph (a)(1) of this section are not met.

(b) ***Cessation of payments.*** If termination is not sought, either by itself or along with another remedy or remedies, or any of the criteria set forth in paragraph (a)(1) of this section are not met or agreed to by either the facility or the State, the facility or State will receive no Medicare or Federal Medicaid payments, as applicable, from the last day of the survey.

(c) ***Period of continued payments*** -

(1) ***Non-compliance.*** If the conditions in paragraph (a)(1) of this section are met, CMS may continue payments to a Medicare facility or the State for a Medicaid facility with noncompliance that does not constitute immediate jeopardy for up to 6 months from the last day of the survey.

(2) ***Facility closure.*** In the case of a facility closure, the Secretary may, as the Secretary determines appropriate, continue to make payments with respect to residents of a long-term care facility that has submitted a notification of closure during the period beginning on the date such notification is submitted to CMS and ending on the date on which the residents are successfully relocated.

(d) ***Failure to achieve substantial compliance.*** If the facility does not achieve substantial compliance by the end of the period specified in paragraph (c) of this section,

(1) CMS will -

(i) Terminate the provider agreement of the Medicare SNF in accordance with § 488.456; or

(ii) Discontinue Federal funding to the SNF for Medicare; and

(iii) Discontinue FFP to the State for the Medicaid NF.

(2) The State may terminate the provider agreement for the NF.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995, as amended at 76 FR 9511, Feb. 18, 2011; 78 FR 16805, Mar. 19, 2013]

§ 488.452 State and Federal disagreements involving findings not in agreement in non-State operated NFs and dually participating facilities when there is no immediate jeopardy.

The following rules apply when CMS and the State disagree over findings of noncompliance or application of remedies in a non-State operated NF or dually participating facility:

(a) ***Disagreement over whether facility has met requirements.***

(1) The State's finding of noncompliance takes precedence when -

(i) CMS finds that a NF or a dually participating facility is in substantial compliance with the participation requirements; and

(ii) The State finds that a NF or dually participating facility has not achieved substantial compliance.

(2) CMS's findings of noncompliance take precedence when -

(i) CMS finds that a NF or a dually participating facility has not achieved substantial compliance; and

(ii) The State finds that a NF or a dually participating facility is in substantial compliance with the participation requirements.

(3) When CMS's survey findings take precedence, CMS may -

(i) Impose any of the alternative remedies specified in § 488.406;

(ii) Terminate the provider agreement subject to the applicable conditions of § 488.450; and

(iii) Stop FFP to the State for a NF.

(b) ***Disagreement over decision to terminate.***

(1) CMS's decision to terminate the participation of a facility takes precedence when -

(i) Both CMS and the State find that the facility has not achieved substantial compliance; and

(ii) CMS, but not the State, finds that the facility's participation should be terminated. CMS will permit continuation of payment during the period prior to the effective date of termination not to exceed 6 months, if the applicable conditions of § 488.450 are met.

(2) The State's decision to terminate a facility's participation and the procedures for appealing such termination, as specified in § 431.153(c) of this chapter, takes precedence when -

(i) The State, but not CMS, finds that a NF's participation should be terminated; and

(ii) The State's effective date for the termination of the NF's provider agreement is no later than 6 months after the last day of survey.

(c) ***Disagreement over timing of termination of facility.*** The State's timing of termination takes precedence if it does not occur later than 6 months after the last day of the survey when both CMS and the State find that -

(1) A facility is not in substantial compliance; and

(2) The facility's participation should be terminated.

(d) ***Disagreement over remedies.***

(1) When CMS or the State, but not both, establishes one or more remedies, in addition to or as an alternative to termination, the additional or alternative remedies will also apply when -

(i) Both CMS and the State find that a facility has not achieved substantial compliance; and

(ii) Both CMS and the State find that no immediate jeopardy exists.

(2) ***Overlap of remedies.*** When CMS and the State establish one or more remedies, in addition to or as an alternative to termination, only the CMS remedies apply when both CMS and the State find that a facility has not achieved substantial compliance.

(e) Regardless of whether CMS's or the State's decision controls, only one noncompliance and enforcement decision is applied to the Medicaid agreement, and for a dually participating facility, that same decision will apply to the Medicare agreement.

§ 488.454 Duration of remedies.

(a) Except as specified in paragraphs (b) and (d) of this section, alternative remedies continue until -

(1) The facility has achieved substantial compliance, as determined by CMS or the State based upon a revisit or after an examination of credible written evidence that it can verify without an on-site visit; or

(2) CMS or the State terminates the provider agreement.

(b) In the cases of State monitoring and denial of payment imposed for repeated substandard quality of care, remedies continue until -

(1) CMS or the State determines that the facility has achieved substantial compliance and is capable of remaining in substantial compliance; or

(2) CMS or the State terminates the provider agreement.

(c) In the case of temporary management, the remedy continues until -

(1) CMS or the State determines that the facility has achieved substantial compliance and is capable of remaining in substantial compliance;

(2) CMS or the State terminates the provider agreement; or

(3) The facility which has not achieved substantial compliance reassumes management control. In this case, CMS or the State initiates termination of the provider agreement and may impose additional remedies.

(d) In the case of a civil money penalty imposed for an instance of noncompliance, the remedy is the specific amount of the civil money penalty imposed for the particular deficiency.

(e) If the facility can supply documentation acceptable to CMS or the State survey agency that it was in substantial compliance and was capable of remaining in substantial compliance, if necessary, on a date preceding that of the revisit, the remedies terminate on the date that CMS or the State can verify as the date that substantial compliance was achieved and the facility demonstrated that it could maintain substantial compliance, if necessary.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995, as amended at 64 FR 13361, Mar. 18, 1999]

§ 488.456 Termination of provider agreement.

(a) ***Effect of termination.*** Termination of the provider agreement ends -

(1) Payment to the facility; and

(2) Any alternative remedy.

(b) ***Basis for termination.***

(1) CMS and the State may terminate a facility's provider agreement if a facility -

(i) Is not in substantial compliance with the requirements of participation, regardless of whether or not immediate jeopardy is present; or

(ii) Fails to submit an acceptable plan of correction within the timeframe specified by CMS or the State.

(2) CMS and the State terminate a facility's provider agreement if a facility -

(i) Fails to relinquish control to the temporary manager, if that remedy is imposed by CMS or the State; or

(ii) Does not meet the eligibility criteria for continuation of payment as set forth in § 488.412(a)(1).

(c) ***Notice of termination.*** Before terminating a provider agreement, CMS does and the State must notify the facility and the public -

(1) At least 2 calendar days before the effective date of termination for a facility with immediate jeopardy deficiencies; and

(2) At least 15 calendar days before the effective date of termination for a facility with non-immediate jeopardy deficiencies that constitute noncompliance.

(d) ***Procedures for termination.***

(1) CMS terminates the provider agreement in accordance with procedures set forth in § 489.53 of this chapter; and

(2) The State must terminate the provider agreement of a NF in accordance with procedures specified in parts 431 and 442 of this chapter.

Subpart G [Reserved]

Subpart H - Termination of Medicare Coverage and Alternative Sanctions for End-Stage Renal Disease (ESRD) Facilities

Source: 73 FR 20475, Apr. 15, 2008, unless otherwise noted.

§ 488.604 Termination of Medicare coverage.

(a) Except as otherwise provided in this subpart, failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in part 494 of this chapter will result in termination of Medicare coverage of the services furnished by the supplier.

(b) If termination of coverage is based solely on a supplier's failure to participate in network activities and pursue network goals, as required at § 494.180(i) of this chapter, coverage may be reinstated when CMS determines that the supplier is making reasonable and appropriate efforts to meet that condition.

(c) If termination of coverage is based on failure to meet any of the other conditions specified in part 494 of this chapter, coverage will not be reinstated until CMS finds that the reason for termination has been removed and there is reasonable assurance that it will not recur.

§ 488.606 Alternative sanctions.

(a) ***Basis for application of alternative sanctions.*** CMS may, as an alternative to termination of Medicare coverage, impose one of the sanctions specified in paragraph (b) of this section if CMS finds that -

(1) The supplier fails to participate in the activities and pursue the goals of the ESRD network that is designated to encompass the supplier's geographic area; and

(2) This failure does not jeopardize patient health and safety.

(b) ***Alternative sanctions.*** The alternative sanctions that CMS may apply in the circumstances specified in paragraph (a) of this section include the following:

(1) Denial of payment for services furnished to patients first accepted for care after the effective date of the sanction as specified in the sanction notice.

(2) Reduction of payments, for all ESRD services furnished by the supplier, by 20 percent for each 30-day period after the effective date of the sanction.

(3) Withholding of all payments, without interest, for all ESRD services furnished by the supplier to Medicare beneficiaries.

(c) ***Duration of alternative sanction.*** An alternative sanction remains in effect until CMS finds that the supplier is in substantial compliance with the requirement to cooperate in the network plans and goals, or terminates coverage of the supplier's services for lack of compliance.

§ 488.608 Notice of alternative sanction and appeal rights: Termination of coverage.

(a) ***Notice of alternative sanction.*** CMS gives the supplier and the general public notice of the alternative sanction and of the effective date of the sanction. The effective date of the alternative sanction is at least 30 days after the date of the notice.

(b) ***Appeal rights.*** Termination of Medicare coverage of a supplier's ESRD services because the supplier no longer meets the conditions for coverage of its services is an initial determination appealable under part 498 of this chapter.

§ 488.610 Notice of appeal rights: Alternative sanctions.

If CMS proposes to apply an alternative sanction specified in § 488.606(b), the following rules apply:

(a) CMS gives the facility notice of the proposed alternative sanction and 15 days in which to request a hearing.

(b) If the facility requests a hearing, CMS provides an informal hearing by a CMS official who was not involved in making the appealed decision.

(c) During the informal hearing, the facility -

(1) May be represented by counsel;

(2) Has access to the information on which the allegation was based; and

(3) May present, orally or in writing, evidence and documentation to refute the finding of failure to participate in network activities and pursue network goals.

(d) If the written decision of the informal hearing supports application of the alternative sanction, CMS provides the facility and the public, at least 30 days before the effective date of the alternative sanction, a written notice that specifies the effective date and the reasons for the alternative sanction.

Subpart I - Survey and Certification of Home Health Agencies

Source: 77 FR 67164, Nov. 8, 2012, unless otherwise noted.

§ 488.700 Basis and scope.

Section 1891 of the Act establishes requirements for surveying HHAs to determine whether they meet the Medicare conditions of participation.

§ 488.705 Definitions.

As used in this subpart -

Abbreviated standard survey means a focused survey other than a standard survey that gathers information on an HHA's compliance with fewer specific standards or conditions of participation. An abbreviated standard survey may be based on complaints received, a change of ownership or management, or other indicators of specific concern such as reapplication for Medicare billing privileges following a deactivation.

Complaint survey means a survey that is conducted to investigate specific allegations of noncompliance.

Condition-level deficiency means noncompliance as described in § 488.24 of this part.

Deficiency is a violation of the Act and regulations contained in part 484, subparts A through C of this chapter, is determined as part of a survey, and can be either standard or condition-level.

Extended survey means a survey that reviews additional conditions of participation not examined during a standard survey. It may be conducted at any time but must be conducted when substandard care is identified.

Noncompliance means any deficiency found at the condition-level or standard-level.

Partial extended survey means a survey conducted to determine if deficiencies and/or deficient practice(s) exist that were not fully examined during the standard survey. The surveyors may review any additional requirements which would assist in making a compliance finding.

Standard-level deficiency means noncompliance with one or more of the standards that make up each condition of participation for HHAs.

Standard survey means a survey conducted in which the surveyor reviews the HHA's compliance with a select number of standards and/or conditions of participation in order to determine the quality of care and services furnished by an HHA as measured by indicators related to medical, nursing, and rehabilitative care.

Substandard care means noncompliance with one or more conditions of participation identified on a standard survey, including deficiencies which could result in actual or potential harm to patients of an HHA.

Substantial compliance means compliance with all condition-level requirements, as determined by CMS or the State.

§ 488.710 Standard surveys.

(a) For each HHA, the survey agency must conduct a standard survey not later than 36 months after the date of the previous standard survey that includes, but is not limited to, all of the following (to the extent practicable):

(1) A case-mix stratified sample of individuals furnished items or services by the HHA.

(2) Visits to the homes of patients, (the purpose of the home visit is to evaluate the extent to which the quality and scope of services furnished by the HHA attained and maintained the highest practicable functional capacity of each patient as reflected in the patient's written plan of care and clinical records), but only with their consent, and, if determined necessary by CMS or the survey team, other forms of communication with patients including telephone calls.

(3) Review of indicators that include the outcomes of quality care and services furnished by the agency as indicated by medical, nursing, and rehabilitative care.

(4) Review of compliance with a select number of regulations most related to high-quality patient care.

(b) The survey agency's failure to follow the procedures set forth in this section will not invalidate otherwise legitimate determinations that deficiencies exist at an HHA.

§ 488.715 Partial extended surveys.

A partial extended survey is conducted to determine if standard or condition-level deficiencies are present in the conditions of participation not fully examined during the standard survey and there are indications that a more comprehensive review of conditions of participation would determine if a deficient practice exists.

§ 488.720 Extended surveys.

(a) ***Purpose of survey.*** The purpose of an extended survey is:

(1) To review and identify the policies and procedures that caused an HHA to furnish substandard care.

(2) To determine whether the HHA is in compliance with one or more or all additional conditions of participation not examined during the standard survey.

(b) ***Timing and basis for survey.*** An extended survey must be conducted not later than 14 calendar days after completion of a standard survey which found that a HHA was out of compliance with a condition of participation.

§ 488.725 Unannounced surveys.

(a) ***Basic rule.*** All HHA surveys must be unannounced and conducted with procedures and scheduling that renders the onsite surveys as unpredictable in their timing as possible.

(b) ***State survey agency's scheduling and surveying procedures.*** CMS reviews each survey agency's scheduling and surveying procedures and practices to assure that the survey agency has taken all reasonable steps to avoid giving notice of a survey through the scheduling procedures and conduct of the surveys.

(c) ***Civil money penalties.*** Any individual who notifies an HHA, or causes an HHA to be notified, of the time or date on which a standard survey is scheduled to be conducted is subject to a Federal civil money penalty not to exceed $2,000 as adjusted annually under 45 CFR part 102.

[77 FR 67164, Nov. 8, 2012, as amended at 81 FR 61563, Sept. 6, 2016]

§ 488.730 Survey frequency and content.

(a) ***Basic period.*** Each HHA must be surveyed not later than 36 months after the last day of the previous standard survey. Additionally, a survey may be conducted as frequently as necessary to -

(1) Assure the delivery of quality home health services by determining whether an HHA complies with the Act and conditions of participation; and

(2) Confirm that the HHA has corrected deficiencies that were previously cited.

(b) ***Change in HHA information.*** A standard survey or an abbreviated standard survey may be conducted within 2 months of a change, or knowledge of a change, in any of the following:

(1) Ownership;

(2) Administration; or,

(3) Management of the HHA.

(c) ***Complaints.*** A standard survey, or abbreviated standard survey -

(1) Must be conducted of an HHA within 2 months of when a significant number of complaints against the HHA are reported to CMS, the State, the State or local agency responsible for maintaining a toll-free hotline and investigative unit, or any other appropriate Federal, State, or local agency; or

(2) As otherwise required to determine compliance with the conditions of participation such as the investigation of a complaint.

§ 488.735 Surveyor qualifications.

(a) ***Minimum qualifications.*** Surveys must be conducted by individuals who meet minimum qualifications prescribed by CMS. In addition, before any State or Federal surveyor may serve on an HHA survey team (except as a trainee), he/she must have successfully completed the relevant CMS-sponsored Basic HHA Surveyor Training Course and any associated course prerequisites. All surveyors must follow the principles set forth in § 488.24 through § 488.28 according to CMS policies and procedures for determining compliance with the conditions of participation.

(b) ***Disqualifications.*** Any of the following circumstances disqualifies a surveyor from surveying a particular agency:

(1) The surveyor currently works for, or, within the past two years, has worked with the HHA to be surveyed as:

(i) A direct employee;

(ii) An employment agency staff at the agency; or

(iii) An officer, consultant, or agent for the agency to be surveyed concerning compliance with conditions of participation specified in or pursuant to sections 1861(o) or 1891(a) of the Act.

(2) The surveyor has a financial interest or an ownership interest in the HHA to be surveyed.

(3) The surveyor has a family member who has a relationship with the HHA to be surveyed.

(4) The surveyor has an immediate family member who is a patient of the HHA to be surveyed.

§ 488.740 Certification of compliance or noncompliance.

Rules to be followed for certification, documentation of findings, periodic review of compliance and approval, certification of noncompliance, and determining compliance of HHAs are set forth, respectively, in §§ 488.12, 488.18, 488.20, 488.24, and 488.26 of this part.

§ 488.745 Informal Dispute Resolution (IDR).

(a) ***Opportunity to refute survey findings.*** Upon the provider's receipt of an official statement of deficiencies, HHAs are afforded the option to request an informal opportunity to dispute condition-level survey findings.

(b) ***Failure to conduct IDR timely.*** Failure of CMS or the State, as appropriate, to complete IDR shall not delay the effective date of any enforcement action.

(c) ***Revised statement of deficiencies as a result of IDR.*** If any findings are revised or removed by CMS or the State based on IDR, the official statement of deficiencies is revised accordingly and any enforcement actions imposed solely as a result of those cited deficiencies are adjusted accordingly.

(d) ***Notification.*** When the survey findings indicate a condition-level deficiency, CMS or the State, as appropriate, must provide the agency with written notification of the opportunity for participating in an IDR process at the time the official statement of deficiencies is issued. The request for IDR must be submitted in writing to the State or CMS, must include the specific deficiencies that are disputed, and must be made within the same 10 calendar day period that the HHA has for submitting an acceptable plan of correction.

Subpart J - Alternative Sanctions for Home Health Agencies With Deficiencies

Source: 77 FR 67165, Nov. 8, 2012, unless otherwise noted.

§ 488.800 Statutory basis.

Section 1891(e) through (f) of the Act authorizes the Secretary to take actions to remove and correct deficiencies in an HHA through an alternative sanction or termination or both. Furthermore, this section specifies that these sanctions are in addition to any others available under State or Federal law, and, except for the final determination of civil money penalties, are imposed prior to the conduct of a hearing.

§ 488.805 Definitions.

As used in this subpart -

Directed plan of correction means CMS or the temporary manager (with CMS/SA approval) may direct the HHA to take specific corrective action to achieve specific outcomes within specific timeframes.

Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause serious injury, harm, impairment, or death to a patient(s).

New admission means an individual who becomes a patient or is readmitted to the HHA on or after the effective date of a suspension of payment sanction.

Per instance means a single event of noncompliance identified and corrected through a survey, for which the statute authorizes CMS to impose a sanction.

Plan of correction means a plan developed by the HHA and approved by CMS that is the HHA's written response to survey findings detailing corrective actions to cited deficiencies and specifies the date by which those deficiencies will be corrected.

Repeat deficiency means a condition-level citation that is cited on the current survey and is substantially the same as or similar to, a finding of a standard-level or condition-level deficiency citation cited on the most recent previous standard survey or on any intervening survey since the most recent standard survey.

Temporary management means the temporary appointment by CMS or by a CMS authorized agent, of a substitute manager or administrator based upon qualifications described in §§ 484.105(b) and 484.115 of this chapter. The HHA's governing body must ensure that the temporary manager has authority to hire, terminate or reassign staff, obligate funds, alter procedures, and manage the HHA to correct deficiencies identified in the HHA's operation.

[77 FR 67165, Nov. 8, 2012, as amended at 82 FR 4591, Jan. 13, 2017]

§ 488.810 General provisions.

(a) ***Purpose of sanctions.*** The purpose of sanctions is to ensure prompt compliance with program requirements in order to protect the health and safety of individuals under the care of an HHA.

(b) ***Basis for imposition of sanctions.*** When CMS chooses to apply one or more sanctions specified in § 488.820, the sanctions are applied on the basis of noncompliance with one or more conditions of participation found through a survey and may be based on failure to correct previous deficiency findings as evidenced by repeat deficiencies.

(c) ***Number of sanctions.*** CMS may apply one or more sanctions for each deficiency constituting noncompliance or for all deficiencies constituting noncompliance.

(d) ***Extent of sanctions imposed.*** When CMS imposes a sanction, the sanction applies to the parent HHA and its respective branch offices.

(e) ***Plan of correction requirement.*** Regardless of which sanction is applied, a non-compliant HHA must submit a plan of correction for approval by CMS.

(f) ***Notification requirements*** -

(1) ***Notice.*** CMS provides written notification to the HHA of the intent to impose the sanction.

(2) ***Date of enforcement action.*** The notice periods specified in § 488.825(b) and § 488.830(b) begin the day after the HHA receives the notice.

(g) ***Appeals.***

(1) The provisions of part 498 of this chapter apply when the HHA requests a hearing on a determination of noncompliance leading to the imposition of a sanction, including termination of the provider agreement.

(2) A pending hearing does not delay the effective date of a sanction, including termination, against an HHA. Sanctions continue to be in effect regardless of the timing of any appeals proceedings.

§ 488.815 Factors to be considered in selecting sanctions.

CMS bases its choice of sanction or sanctions on consideration of one or more factors that include, but are not limited to, the following:

(a) The extent to which the deficiencies pose immediate jeopardy to patient health and safety.

(b) The nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.

(c) The presence of repeat deficiencies, the HHA's overall compliance history and any history of repeat deficiencies at either the parent or branch location.

(d) The extent to which the deficiencies are directly related to a failure to provide quality patient care.

(e) The extent to which the HHA is part of a larger organization with performance problems.

(f) An indication of any system-wide failure to provide quality care.

§ 488.820 Available sanctions.

In addition to termination of the provider agreement, the following alternative sanctions are available:

(a) Civil money penalties.

(b) Suspension of payment for all new admissions.

(c) Temporary management of the HHA.

(d) Directed plan of correction, as set out at § 488.850.

(e) Directed in-service training, as set out at § 488.855.

§ 488.825 Action when deficiencies pose immediate jeopardy.

(a) ***Immediate jeopardy.*** If there is immediate jeopardy to the HHA's patient health or safety -

(1) CMS immediately terminates the HHA provider agreement in accordance with § 489.53 of this chapter.

(2) CMS terminates the HHA provider agreement no later than 23 days from the last day of the survey, if the immediate jeopardy has not been removed by the HHA.

(3) In addition to a termination, CMS may impose one or more alternative sanctions, as appropriate.

(b) ***2-day notice.*** Except for civil money penalties, for all sanctions specified in § 488.820 that are imposed when there is immediate jeopardy, notice must be given at least 2 calendar days before the effective date of the enforcement action.

(c) ***Transfer of care.*** An HHA, if its provider agreement terminated, is responsible for providing information, assistance, and arrangements necessary for the proper and safe transfer of patients to another local HHA within 30 days of termination. The State must assist the HHA in the safe and orderly transfer of care and services for the patients to another local HHA.

§ 488.830 Action when deficiencies are at the condition-level but do not pose immediate jeopardy.

(a) ***Noncompliance.*** If the HHA is no longer in compliance with the conditions of participation, either because the deficiency or deficiencies substantially limit the provider's capacity to furnish adequate care but do not pose immediate jeopardy, have a condition-level deficiency or deficiencies that do not pose immediate jeopardy, or because the HHA has repeat noncompliance that results in a condition-level deficiency based on the HHA's failure to correct and sustain compliance, CMS will:

(1) Terminate the HHA's provider agreement; or

(2) Impose one or more alternative sanctions set forth in § 488.820(a) through (f) of this part as an alternative to termination, for a period not to exceed 6 months.

(b) ***15-day notice.*** Except for civil money penalties, for all sanctions specified in § 488.820 imposed when there is no immediate jeopardy, notice must be given at least 15 calendar days before the effective date of the enforcement action. The requirements of the notice are set forth in § 488.810(f) of this part.

(c) ***Not meeting criteria for continuation of payment.*** If an HHA does not meet the criteria for continuation of payment under § 488.860(a) of this part, CMS will terminate the HHA's provider agreement in accordance with § 488.865 of this part.

(d) ***Termination time frame when there is no immediate jeopardy.*** CMS terminates an HHA within 6 months of the last day of the survey, if the HHA is not in compliance with the conditions of participation, and the terms of the plan of correction have not been met.

(e) ***Transfer of care.*** An HHA, if its provider agreement terminated, is responsible for providing information, assistance, and arrangements necessary for the proper and safe transfer of patients to another local HHA within 30 days of termination. The State must assist the HHA in the safe and orderly transfer of care and services for the patients to another local HHA.

§ 488.835 Temporary management.

(a) ***Application.***

(1) CMS may impose temporary management of an HHA if it determines that an HHA has a condition-level noncompliance and CMS determines that management limitations or the deficiencies are likely to impair the HHA's ability to correct deficiencies and return the HHA to full compliance with the conditions of participation within the timeframe required.

(2) [Reserved]

(b) ***Procedures.***

(1) CMS notifies the HHA that a temporary manager is being appointed.

(2) If the HHA fails to relinquish authority and control to the temporary manager, CMS terminates the HHA's provider agreement in accordance with § 488.865.

(c) ***Duration and effect of sanction.*** Temporary management continues until -

(1) CMS determines that the HHA has achieved substantial compliance and has the management capability to ensure continued compliance with all the conditions of participation;

(2) CMS terminates the provider agreement; or

(3) The HHA reassumes management control without CMS approval. In such case, CMS initiates termination of the provider agreement and may impose additional sanctions.

(4) Temporary management will not exceed a period of 6 months from the date of the survey identifying noncompliance.

(d) ***Payment of salary.***

(1) The temporary manager's salary -

(i) Is paid directly by the HHA while the temporary manager is assigned to that HHA; and

(ii) Must be at least equivalent to the sum of the following:

(A) The prevailing salary paid by providers for positions of this type in what the State considers to be the HHA's geographic area (prevailing salary based on the Geographic Guide by the Department of Labor (BLS Wage Data by Area and Occupation);

(B) Any additional costs that would have reasonably been incurred by the HHA if such person had been in an employment relationship; and

(C) Any other costs incurred by such a person in furnishing services under such an arrangement or as otherwise set by the State.

(2) An HHA's failure to pay the salary and other costs of the temporary manager described in paragraph (d)(1) of this section is considered a failure to relinquish authority and control to temporary management.

§ 488.840 Suspension of payment for all new patient admissions.

(a) ***Application.***

(1) CMS may suspend payment for all new admissions if an HHA is found to have condition-level deficiencies, regardless of whether those deficiencies pose immediate jeopardy.

(2) CMS will consider this sanction for any deficiency related to poor patient care outcomes, regardless of whether the deficiency poses immediate jeopardy.

(b) ***Procedures*** -

(1) ***Notices.***

(i) Before suspending payments for new admissions, CMS provides the HHA notice of the suspension of payment for all new admissions as set forth in § 488.810(f). The CMS notice of suspension will include the nature of the noncompliance; the effective date of the sanction; and the right to appeal the determination leading to the sanction.

(ii) The HHA may not charge a newly admitted HHA patient who is a Medicare beneficiary for services for which Medicare payment is suspended unless the HHA can show that, before initiating care, it gave the patient or his or her representative oral and written notice of the suspension of Medicare payment in a language and manner that the beneficiary or representative can understand.

(2) ***Restriction.***

(i) Suspension of payment for all new admissions sanction may be imposed anytime an HHA is found to be out of substantial compliance.

(ii) Suspension of payment for patients with new admissions will remain in place until CMS determines that the HHA has achieved substantial compliance or is involuntarily terminated with the conditions of participation, as determined by CMS.

(3) ***Resumption of payments.*** Payments to the HHA resume prospectively on the date that CMS determines that the HHA has achieved substantial compliance with the conditions of participation.

(c) ***Duration and effect of sanction.*** This sanction ends when -

(1) CMS determines that the HHA is in substantial compliance with all of the conditions of participation; or

(2) When the HHA is terminated or CMS determines that the HHA is not in compliance with the conditions of participation at a maximum of 6 months from the date noncompliance was determined.

§ 488.845 Civil money penalties.

(a) ***Application.***

(1) CMS may impose a civil money penalty against an HHA for either the number of days the HHA is not in compliance with one or more conditions of participation or for each instance that an HHA is not in compliance, regardless of whether the HHA's deficiencies pose immediate jeopardy.

(2) CMS may impose a civil money penalty for the number of days of immediate jeopardy.

(3) A per-day and a per-instance CMP may not be imposed simultaneously for the same deficiency.

(b) ***Amount of penalty*** -

(1) ***Factors considered.*** CMS takes into account the following factors in determining the amount of the penalty:

(i) The factors set out at § 488.815.

(ii) The size of an agency and its resources.

(iii) Accurate and credible resources, such as PECOS, Medicare cost reports and Medicare/Medicaid claims information that provide information on the operation and resources of the HHA.

(iv) Evidence that the HHA has a built-in, self-regulating quality assessment and performance improvement system to provide proper care, prevent poor outcomes, control patient injury, enhance quality, promote safety, and avoid risks to patients on a sustainable basis that indicates the ability to meet the conditions of participation and to ensure patient health and safety.

(2) ***Adjustments to penalties.*** Based on revisit survey findings, adjustments to penalties may be made after a review of the provider's attempted correction of deficiencies.

(i) CMS may increase a CMP in increments based on a HHA's inability or failure to correct deficiencies, the presence of a system-wide failure in the provision of quality care, or a determination of immediate jeopardy with actual harm versus immediate jeopardy with potential for harm.

(ii) CMS may also decrease a CMP in increments to the extent that it finds, pursuant to a revisit, that substantial and sustainable improvements have been implemented even though the HHA is not yet in full compliance with the conditions of participation.

(iii) No penalty assessment will exceed $10,000 as adjusted annually under 45 CFR part 102 for each day of noncompliance.

(3) ***Upper range of penalty.*** Penalties in the upper range of $8,500 to $10,000 as adjusted under 45 CFR part 102 per day of noncompliance are imposed for a condition-level deficiency that is immediate jeopardy. The penalty in this range will continue until compliance can be determined based on a revisit survey.

(i) $10,000 as adjusted annually under 45 CFR part 102 per day for a deficiency or deficiencies that are immediate jeopardy and that result in actual harm.

(ii) $9,000 as adjusted annually under 45 CFR part 102 per day for a deficiency or deficiencies that are immediate jeopardy and that result in a potential for harm.

(iii) $8,500 as adjusted annually under 45 CFR part 102 per day for an isolated incident of noncompliance in violation of established HHA policy.

(4) ***Middle range of penalty.*** Penalties in the range of $1,500-$8,500 as adjusted annually under 45 CFR part 102 per day of noncompliance are imposed for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy, but is directly related to poor quality patient care outcomes.

(5) ***Lower range of penalty.*** Penalties in this range of $500-$4,000 as adjusted annually under 45 CFR part 102 are imposed for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy and that are related predominately to structure or process-oriented conditions (such as OASIS submission requirements) rather than directly related to patient care outcomes.

(6) ***Per instance penalty.*** Penalty imposed per instance of noncompliance may be assessed for one or more singular events of condition-level noncompliance that are identified and where the noncompliance was corrected during the onsite survey. When penalties are imposed for per instance of noncompliance, or more than one per instance of noncompliance, the penalties will be in the range of $1,000 to $10,000 as adjusted annually under 45 CFR part 102 per instance, not to exceed $10,000 as adjusted annually under 45 CFR part 102 each day of noncompliance.

(7) ***Decreased penalty amounts.*** If the immediate jeopardy situation is removed, but condition-level noncompliance continues, CMS will shift the penalty amount imposed per day from the upper range to the middle or lower range. An earnest effort to correct any systemic causes of deficiencies and sustain improvement must be evident.

(8) ***Increased penalty amounts.***

(i) In accordance with paragraph (b)(2) of this section, CMS will increase the per day penalty amount for any condition-level deficiency or deficiencies which, after imposition of a lower-level penalty amount, become sufficiently serious to pose potential harm or immediate jeopardy.

(ii) CMS increases the per day penalty amount for deficiencies that are not corrected and found again at the time of revisit survey(s) for which a lower-level penalty amount was previously imposed.

(iii) CMS may impose a more severe amount of penalties for repeated noncompliance with the same condition-level deficiency or uncorrected deficiencies from a prior survey.

(c) ***Procedures*** -

(1) ***Notice of intent.*** CMS provides the HHA with written notice of the intent to impose a civil money penalty. The notice includes the amount of the CMP being imposed, the basis for such imposition and the proposed effective date of the sanction.

(2) ***Appeals.***

(i) ***Appeals procedures.*** An HHA may request a hearing on the determination of the noncompliance that is the basis for imposition of the civil money penalty. The request must meet the requirements in § 498.40 of this chapter.

(ii) ***Waiver of a hearing.*** An HHA may waive the right to a hearing, in writing, within 60 days from the date of the notice imposing the civil money penalty. If an HHA timely waives its right to a hearing, CMS reduces the penalty amount by 35 percent, and the amount is due within 15 days of the HHAs agreeing in writing to waive the hearing. If the HHA does not waive its right to a hearing in accordance to the procedures specified in this subsection, the civil money penalty is not reduced by 35 percent.

(d) ***Accrual and duration of penalty.***

(1)

(i) The per day civil money penalty may start accruing as early as the beginning of the last day of the survey that determines that the HHA was out of compliance, as determined by CMS.

(ii) A civil money penalty for each per instance of noncompliance is imposed in a specific amount for that particular deficiency, with a maximum of $10,000 as adjusted annually under 45 CFR part 102 per day per HHA.

(2) A penalty that is imposed per day and per instance of noncompliance may not be imposed simultaneously.

(3) ***Duration of per day penalty when there is immediate jeopardy.***

(i) In the case of noncompliance that poses immediate jeopardy, CMS must terminate the provider agreement within 23 calendar days after the last day of the survey if the immediate jeopardy is not removed.

(ii) A penalty imposed per day of noncompliance will stop accruing on the day the provider agreement is terminated or the HHA achieves substantial compliance, whichever occurs first.

(4) ***Duration of penalty when there is no immediate jeopardy.***

(i) In the case of noncompliance that does not pose immediate jeopardy, the daily accrual of per day civil money penalties is imposed for the days of noncompliance prior to the notice specified in paragraph (c)(1) of this section and an additional period of no longer than 6 months following the last day of the survey.

(ii) If the HHA has not achieved compliance with the conditions of participation, CMS terminates the provider agreement. The accrual of civil money penalty stops on the day the HHA agreement is terminated or the HHA achieves substantial compliance, whichever is earlier.

(e) ***Computation and notice of total penalty amount.***

(1) When a civil money penalty is imposed on a per day basis and the HHA achieves compliance with the conditions of participation as determined by a revisit survey, CMS sends a final notice to the HHA containing all of the following information:

(i) The amount of penalty assessed per day.

(ii) The total number of days of noncompliance.

(iii) The total amount due.

(iv) The due date of the penalty.

(v) The rate of interest to be assessed on any unpaid balance beginning on the due date, as provided in paragraph (f)(4) of this section.

(2) When a civil money penalty is imposed for per instance of noncompliance, CMS sends a notice to the HHA containing all of the following information:

(i) The amount of the penalty that was assessed.

(ii) The total amount due.

(iii) The due date of the penalty.

(iv) The rate of interest to be assessed on any unpaid balance beginning on the due date, as provided in paragraph (f)(6) of this section.

(3) In the case of an HHA for which the provider agreement has been involuntarily terminated and for which a civil money penalty was imposed on a per day basis, CMS sends this penalty information after one of the following actions has occurred:

(i) Final administrative decision is made.

(ii) The HHA has waived its right to a hearing in accordance with paragraph (c)(2)(ii) of this section.

(iii) Time for requesting a hearing has expired and CMS has not received a hearing request from the HHA.

(f) ***Due date for payment of penalty.*** A penalty is due and payable 15 days from notice of the final administrative decision.

(1) Payments are due for all civil money penalties within 15 days:

(i) After a final administrative decision when the HHA achieves substantial compliance before the final decision or the effective date of termination before final decision,

(ii) After the time to appeal has expired and the HHA does not appeal or fails to timely appeal the initial determination,

(iii) After CMS receives a written request from the HHA requesting to waive its right to appeal the determinations that led to the imposition of a sanction,

(iv) After substantial compliance is achieved, or

(v) After the effective date of termination.

(2) A request for hearing does not delay the imposition of any penalty; it only potentially delays the collection of the final penalty amount.

(3) If an HHA waives its right to a hearing according to paragraph (c)(2)(ii) of this section, CMS will apply a 35 percent reduction to the CMP amount when:

(i) The HHA achieved compliance with the conditions of participation before CMS received the written waiver of hearing; or

(ii) The effective date of termination occurs before CMS received the written waiver of hearing.

(4) The period of noncompliance may not extend beyond 6 months from the last day of the survey.

(5) The amount of the penalty, when determined, may be deducted (offset) from any sum then or later owing by CMS or State Medicaid to the HHA.

(6) Interest is assessed and accrues on the unpaid balance of a penalty, beginning on the due date. Interest is computed at the rate specified in § 405.378(d) of this chapter.

(g) ***Penalties collected by CMS*** -

(1) ***Disbursement of CMPs.*** Civil money penalties and any corresponding interest collected by CMS from Medicare and Medicaid participating HHAs are disbursed in proportion to average dollars spent by Medicare and Medicaid at the national level based on MSIS and HHA PPS data for a three year fiscal period.

(i) Based on expenditures for the FY 2007-2009 period, the initial proportions to be disbursed are 63 percent returned to the U.S. Treasury and 37 percent returned to the State Medicaid agency.

(ii) Beginning one year after the effective date of this section, CMS shall annually update these proportions based on the most recent 3-year fiscal period, prior to the year in which the CMP is imposed, for which CMS determines that the relevant data are essentially complete.

(iii) The portion corresponding to the Medicare payments is returned to the U.S. Department of Treasury as miscellaneous receipts.

(iv) The portion corresponding to the Medicaid payments is returned to the State Medicaid agency.

(2) Penalties may not be used for Survey and Certification operations nor as the State's Medicaid non-Federal medical assistance or administrative match.

(h) ***Review of the penalty.*** When an administrative law judge or state hearing officer (or higher administrative review authority) finds that the basis for imposing a civil monetary penalty exists, as specified in this part, the administrative law judge, State hearing officer (or higher administrative review authority) may not -

(1) Set a penalty of zero or reduce a penalty to zero;

(2) Review the exercise of discretion by CMS to impose a civil monetary penalty; and

(3) Consider any factors in reviewing the amount of the penalty other than those specified in paragraph (b) of this section.

[77 FR 67165, Nov. 8, 2012, as amended at 79 FR 66118, Nov. 6, 2014; 81 FR 61563, Sept. 6, 2016]

§ 488.850 Directed plan of correction.

(a) ***Application.*** CMS may impose a directed plan of correction when an HHA:

(1) Has one or more deficiencies that warrant directing the HHA to take specific actions; or

(2) Fails to submit an acceptable plan of correction.

(b) ***Procedures.***

(1) Before imposing this sanction, CMS provides the HHA notice of the impending sanction.

(2) CMS or the temporary manager (with CMS approval) may direct the HHA to take corrective action to achieve specific outcomes within specific timeframes.

(c) ***Duration and effect of sanction.*** If the HHA fails to achieve compliance with the conditions of participation within the timeframes specified in the directed plan of correction, CMS:

(1) May impose one or more other sanctions set forth in § 488.820; or

(2) Terminates the provider agreement.

§ 488.855 Directed in-service training.

(a) ***Application.*** CMS may require the staff of an HHA to attend in-service training program(s) if CMS determines that -

(1) The HHA has deficiencies that indicate noncompliance;

(2) Education is likely to correct the deficiencies; and

(3) The programs are conducted by established centers of health education and training or consultants with background in education and training with Medicare Home Health Providers, or as deemed acceptable by CMS and/or the State (by review of a copy of curriculum vitas and/or resumes/references to determine the educator's qualifications).

(b) ***Procedures*** -

(1) ***Action following training.*** After the HHA staff has received in-service training, if the HHA has not achieved compliance, CMS may impose one or more other sanctions specified in § 488.820.

(2) ***Payment.*** The HHA pays for the directed in-service training for its staff.

§ 488.860 Continuation of payments to an HHA with deficiencies.

(a) ***Continued payments.*** CMS may continue payments to an HHA with condition-level deficiencies that do not constitute immediate jeopardy for up to 6 months from the last day of the survey if the criteria in paragraph (a)(1) of this section are met.

(1) ***Criteria.*** CMS may continue payments to an HHA not in compliance with the conditions of participation for the period specified in paragraph (a) of this section if all of the following criteria are met:

(i) The HHA has been imposed an alternative sanction or sanctions and termination has not been imposed.

(ii) The HHA has submitted a plan of correction approved by CMS.

(iii) The HHA agrees to repay the Federal government payments received under this provision if corrective action is not taken in accordance with the approved plan and timetable for corrective action.

(2) CMS may terminate the HHA's provider agreement any time if the criteria in paragraph (a)(1) of this section are not met.

(b) ***Cessation of payments for new admissions.*** If termination is imposed, either on its own or in addition to an alternative sanction or sanctions, or if any of the criteria set forth in paragraph (a)(1) of this section are not met, the HHA will receive no Medicare payments, as applicable, for new admissions following the last day of the survey.

(c) ***Failure to achieve compliance with the conditions of participation.*** If the HHA does not achieve compliance with the conditions of participation by the end of the period specified in paragraph (a) of this section, CMS will terminate the provider agreement of the HHA in accordance with § 488.865.

§ 488.865 Termination of provider agreement.

(a) ***Effect of termination by CMS.*** Termination of the provider agreement ends -

(1) Payment to the HHA; and

(2) Any alternative sanction(s).

(b) ***Basis for termination.*** CMS terminates an HHA's provider agreement under any one of the following conditions -

(1) The HHA is not in compliance with the conditions of participation.

(2) The HHA fails to submit an acceptable plan of correction within the timeframe specified by CMS.

(3) The HHA fails to relinquish control to the temporary manager, if that sanction is imposed by CMS.

(4) The HHA fails to meet the eligibility criteria for continuation of payment as set forth in § 488.860(a)(1).

(c) ***Notice.*** CMS notifies the HHA and the public of the termination, in accordance with procedures set forth in § 489.53 of this chapter.

(d) ***Procedures for termination.*** CMS terminates the provider agreement in accordance with procedures set forth in § 489.53 of this chapter.

(e) ***Appeal.*** An HHA may appeal the termination of its provider agreement by CMS in accordance with part 498 of this chapter.

Subpart K - [Reserved]

Subpart L - Accreditation of Home Infusion Therapy Suppliers

Source: 83 FR 56631, Nov. 13, 2018, unless otherwise noted.

General Provisions

§ 488.1000 Basis and scope.

(a) ***Regulatory basis for home infusion therapy services.*** The home infusion therapy health and safety regulations are codified at part 486, subpart I, of this chapter.

(b) ***Statutory basis for the accreditation of home infusion therapy suppliers.***

(1) Sections 1102 and 1871 of the Act require that the Secretary prescribe such regulations as may be necessary to carry out the administration of the Medicare program.

(2) Section 1834(u)(5) of the Act require the Secretary to designate and approve independent organizations for the purposes of accrediting qualified home infusion therapy suppliers.

(c) ***Scope.*** This subpart sets forth the following:

(1) Application and reapplication procedures for national accrediting organizations seeking approval or re-approval of authority to accredit qualified home infusion therapy suppliers.

(2) Ongoing CMS oversight processes for approved accrediting organizations that accredit qualified home infusion therapy suppliers.

(3) Appeal procedures for accrediting organizations that accredit qualified home infusion therapy suppliers.

§ 488.1005 Definitions.

As used in this subpart -

Immediate jeopardy means a situation in which the provider's or supplier's non-compliance with one or more Medicare accreditation requirements has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient.

National accrediting organization means an organization that accredits provider or supplier entities under a specific program and whose accredited provider or supplier entities under each program are widely dispersed geographically across the United States. In addition, the specific program is active, fully implemented, and operational.

National in scope means a program is fully implemented, operational, and widely dispersed geographically throughout the country.

Qualified home infusion therapy supplier means a supplier of home infusion therapy that meets the all of the following criteria which are set forth at section 1861(iii)(3)(D)(i) of the Act:

(1) Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs.

(2) Ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis.

(3) Is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act.

(4) Meets such other requirements as the Secretary determines appropriate.

Reasonable assurance means an accrediting organization has demonstrated to CMS' satisfaction that its accreditation program requirements meet or exceed the Medicare program requirements.

Rural area as defined at section 1886(d)(2)(D) of the Act.

Substantial allegation of non-compliance means a complaint from any of a variety of sources (such as patient, relative, or third party), including complaints submitted in person, by telephone, through written correspondence, or in the newspaper, magazine articles or other media, that would, if found to be present, adversely affect the health and safety of patients and raises doubts as to a qualified home

infusion therapy supplier's compliance with the applicable Medicare accreditation requirements.

APPROVAL AND OVERSIGHT OF HOME INFUSION THERAPY SUPPLIER ACCREDITING ORGANIZATIONS

§ 488.1010 Application and reapplication procedures for national home infusion therapy accrediting organizations.

(a) ***Information submitted with application.*** A national home infusion therapy accrediting organization applying to CMS for approval or re-approval of a designated home infusion therapy accreditation program must furnish CMS with information and materials that demonstrate that its home infusion therapy accreditation program requirements meet or exceed the applicable Medicare requirements for accrediting organizations, including the following:

(1) Documentation that demonstrates the organization meets the definition of a national accrediting organization under § 488.1005 as it relates to the accreditation program.

(2) The Medicare provider or supplier type for which the organization is requesting approval or reapproval.

(3) Documentation that demonstrates the home infusion therapy accrediting organization's ability to take into account the capacities of rural home infusion therapy suppliers (as required by section 1834(u)(5)(A)(ii) of the Act).

(4) Information that demonstrates the home infusion therapy accrediting organization's knowledge, expertise, and experience in home infusion therapy.

(5) A detailed crosswalk (in table format) that identifies, for each of the applicable Medicare requirements, the exact language of the organization's comparable accreditation requirements and standards.

(6) A detailed description of the home infusion therapy accrediting organization's survey processes to confirm that a home infusion therapy supplier's processes are comparable to those of Medicare. This description must include all of the following:

(i) The types and frequency of surveys performed, and a rationale for which accreditation requirements will be evaluated via onsite surveys and which will be evaluated via offsite audits, or other strategies for ensuring accredited home infusion therapy suppliers maintain adherence to the home infusion therapy accreditation program requirements, including an explanation of how the accrediting organization will maintain the schedule it proposes.

(ii) Copies of the home infusion therapy accrediting organizations survey and audit forms, guidelines, and instructions to surveyors.

(iii) Documentation demonstrating that the home infusion therapy accrediting organization's onsite survey or offsite audit reports identify, for each finding of non-compliance with accreditation standards, the comparable Medicare home infusion therapy accreditation requirements, as applicable.

(iv) A description of the home infusion therapy accrediting organization's accreditation survey review process.

(v) A description of the home infusion therapy accrediting organization's procedures and timelines for notifying a surveyed or audited home infusion therapy supplier of non-compliance with the home infusion therapy accreditation program's standards.

(vi) A description of the home infusion therapy accrediting organization's procedures and timelines for monitoring the home infusion therapy supplier's correction of identified non-compliance with the accreditation program's standards.

(vii) The ability of the home infusion therapy accrediting organization to conduct timely reviews of accreditation applications.

(viii) A statement acknowledging that, as a condition for CMS approval of a national accrediting organization's accreditation program, the home infusion therapy accrediting organization agrees to provide CMS with information extracted from each home infusion therapy accreditation onsite survey, offsite audit or other evaluation strategies as part of its data submissions required under paragraph (a)(19) of this section, and, upon request from CMS, a copy of the most recent accreditation onsite survey, offsite audit, or other evaluation strategy together with any other information related to the survey as CMS may require (including corrective action plans).

(ix) A statement acknowledging that the home infusion therapy accrediting organization will provide timely notification to CMS when an accreditation survey or complaint investigation identifies an immediate jeopardy as that term is defined at § 488.1005. Using the format specified by CMS, the home infusion therapy accrediting organization must notify CMS within 2 business days from the date the accrediting organization identifies the immediate jeopardy.

(7) Procedures to ensure that -

(i) Unannounced onsite surveys, as appropriate, will be conducted periodically, including procedures that protect against unannounced surveys becoming known to the provider or supplier in advance of the visit; or

(ii) Offsite survey audits are performed to evaluate the quality of services provided which may be followed up with periodic onsite visits.

(8) The criteria for determining the size and composition of the home infusion therapy accrediting organization's survey, audit and other evaluation strategy teams for individual supplier onsite surveys. The home infusion therapy accrediting organization's criteria should include, but not be limited to the following information:

(i) The expected number of individual home infusion therapy supplier locations to be surveyed using an onsite survey.

(ii) The number of home infusion therapy suppliers to be surveyed using off-site audits.

(iii) A description of other types of home infusion therapy accreditation review activities to be used.

(iv) The reasons for each type of survey (that is, initial accreditation survey, reaccreditation survey, and complaint survey).

(9) The overall adequacy of the number of the home infusion therapy accrediting organization's surveyors, auditors, and other staff available to perform survey related activities, including how the organization will increase the size of the survey, audit, and other evaluation staff to match growth in the number of accredited facilities or programs while maintaining re-accreditation intervals for

existing accredited facilities or programs.

(10) Detailed information about the individuals who perform onsite surveys, offsite audits or other strategies for ensuring accredited home infusion therapy suppliers maintain adherence to the home infusion therapy accreditation program requirements, including all of the following information:

(i) The number and types of professional and technical staff available for conducting onsite surveys, offsite audits, or other strategies for ensuring accredited home infusion therapy suppliers maintain adherence to the home infusion therapy accreditation program requirements.

(ii) The education, employment, and experience requirements surveyors and auditors must meet.

(iii) The content and length of the orientation program.

(11) The content, frequency and types of in-service training provided to survey and audit personnel.

(12) The evaluation systems used to monitor the performance of individual surveyors, auditors and survey teams.

(13) The home infusion therapy accrediting organization's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys, audits or participate in accreditation decisions.

(14) The policies and procedures used when a home infusion therapy supplier has a dispute regarding survey or audit findings, or an adverse decision.

(15) Procedures for the home infusion therapy supplier to use to notify the home infusion therapy accrediting organization when the accredited home infusion therapy supplier does the either of the following:

(i) Removes or ceases furnishing services for which they are accredited.

(ii) Adds services for which they are not accredited.

(16) The home infusion therapy accrediting organization's procedures for responding to, and investigating complaints against accredited facilities, including policies and procedures regarding referrals, when applicable, to appropriate licensing bodies, ombudsmen offices, and CMS.

(17) A description of the home infusion therapy accrediting organization's accreditation status decision-making process. The home infusion therapy accrediting organization must furnish the following:

(i) Its process for addressing deficiencies identified with accreditation program requirements, and the procedures used to monitor the correction of deficiencies identified during an accreditation survey and audit process.

(ii) A description of all types and categories of accreditation decisions associated with the program, including the duration of each of the organization's accreditation decisions.

(iii) Its policies and procedures for the granting, withholding or removal of accreditation status for facilities that fail to meet the accrediting organization's standards or requirements, assignment of less than full accreditation status or other actions taken by the organization in response to non-compliance with its standards and requirements.

(iv) A statement acknowledging that the home infusion therapy accrediting organization agrees to notify CMS (in a manner CMS specifies) of any decision to revoke, terminate, or revise the accreditation status of a home infusion therapy supplier, within 3 business days from the date the organization takes an action.

(18) A list of all currently accredited home infusion therapy suppliers, the type and category of accreditation, currently held by each, and the expiration date for each home infusion therapy supplier's current accreditation.

(19) A schedule of all survey activity (such as onsite surveys, offsite audits and other types if survey strategies) expected to be conducted by the organization during the 6-month period following submission of an initial or renewal application.

(20) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data.

(21) A description of the home infusion therapy accrediting organization's data management and analysis system with respect to its surveys and accreditation decisions, including all of the following:

(i) A detailed description of how the home infusion therapy accrediting organization uses its data to assure the compliance of its home infusion therapy accreditation program with the Medicare home infusion therapy accreditation program requirements.

(ii) A written statement acknowledging that the home infusion therapy accrediting organization agrees to submit timely, accurate, and complete data that CMS has determined is both necessary to evaluate the accrediting organization's performance and is not unduly burdensome for the accrediting organization to submit.

(A) The organization must submit necessary data according to the instructions and timeframes CMS specifies.

(B) Data to be submitted includes the following:

(*1*) Accredited home infusion therapy supplier identifying information.

(*2*) Survey findings.

(*3*) Quality measures.

(*4*) Notices of accreditation decisions.

(22) The three most recent annual audited financial statements of the home infusion therapy accrediting organization that demonstrate that the organization's staffing, funding, and other resources are adequate to perform the required surveys, audits, and related activities to maintain the accreditation program.

(23) A written statement acknowledging that, as a condition for approval, the home infusion therapy accrediting organization agrees to the following:

(i) ***Voluntary termination.*** Provide written notification to CMS and all home infusion therapy suppliers accredited under its CMS-approved home infusion therapy accreditation program at least 180 calendar days in advance of the effective date of a decision by the home infusion therapy accrediting organization to voluntarily terminate its CMS-approved home infusion therapy accreditation program and the implications for the suppliers' payment status once their current term of accreditation expires in accordance with the requirements at § 488.1045(a).

(ii) ***Involuntary termination.*** Provide written notification to all accredited home infusion therapy suppliers accredited under its CMS-approved home infusion therapy accreditation program no later than 30 calendar days after the notice is published in the Federal Register announcing that CMS is withdrawing its approval of its accreditation program and the implications for the home infusion therapy supplier's payment status in accordance with the requirements at § 488.1045(b) once their current term of accreditation expires.

(A) For both voluntary and involuntary terminations, provide a second written notification to all accredited home infusion therapy suppliers 10 calendar days prior to the organization's accreditation program effective date of termination.

(B) Notify CMS, in writing (electronically or hard copy), within 2 business days of a deficiency identified in any accredited home infusion therapy supplier from any source where the deficiency poses an immediate jeopardy to the home infusion therapy supplier's beneficiaries or a hazard to the general public.

(iii) ***Summary accreditation activity data and trends.*** Provide, on an annual basis, summary accreditation activity data and trends including the following:

(A) Deficiencies.

(B) Complaints.

(C) Terminations.

(D) Withdrawals.

(E) Denials.

(F) Accreditation decisions.

(G) Other survey-related activities as specified by CMS.

(iv) ***Termination of an accreditation organization.*** If CMS terminates a home infusion therapy accrediting organization's approved status, the home infusion therapy accrediting organization must work collaboratively with CMS to direct its accredited home infusion therapy suppliers to the remaining CMS-approved accrediting organizations within a reasonable period of time.

(v) ***Notification of proposed changes.*** Notify CMS at least 60 days in advance of the implementation date of any significant proposed changes in its CMS-approved home infusion therapy accreditation program and that it agrees not to implement the proposed changes without prior written notice of continued program approval from CMS, except as provided for at § 488.1040(b)(2).

(vi) ***Response to a written notice from CMS.*** A statement acknowledging that, in response to a written notice from CMS to the home infusion therapy accrediting organization of a change in the applicable home infusion therapy accreditation requirements or survey process, the organization will provide CMS with proposed corresponding changes in the accrediting organization's home infusion therapy accreditation requirements for its CMS-approved home infusion therapy accreditation program to ensure that its accreditation standards continue to meet or exceed those of Medicare, or survey process remains comparable with that of Medicare. The home infusion therapy accrediting organization must comply with the following requirements:

(A) The proposed changes must be submitted within 30 calendar days of the date of the written CMS notice to the home infusion therapy accrediting organization or by a date specified in the notice, whichever is later. CMS gives due consideration to a home infusion therapy accrediting organization's request for an extension of the deadline as long as it is submitted prior to the due date.

(B) The proposed changes are not to be implemented without prior written notice of continued program approval from CMS, except as provided for at § 488.1040(b)(2)(ii).

(24) The organization's proposed fees for accreditation, including any plans for reducing the burden and cost of accreditation to small and rural suppliers.

(b) ***Additional information needed.*** If CMS determines that additional information is necessary to make a determination for approval or denial of the home infusion therapy accrediting organization's initial application or re-application for CMS-approval of an accreditation program, CMS requires that the home infusion therapy accrediting organization s submit any specific documentation requirements and attestations as a condition of approval of accreditation status. CMS notifies the home infusion therapy accrediting organization and afford it an opportunity to provide the additional information.

(c) ***Withdrawing an application.*** A home infusion therapy accrediting organization may withdraw its initial application for CMS' approval of its home infusion therapy accreditation program at any time before CMS publishes the final notice described in § 488.1025(b).

(d) ***Notice of approval or disapproval of application.*** CMS sends a notice of its decision to approve or disapprove the home infusion therapy accrediting organization's application within 210 calendar days from the date CMS determines the home infusion therapy accrediting organization's application is complete. The final notice specifies the following:

(1) The basis for the decision.

(2) The effective date.

(3) The term of the approval (not exceed 6 years).

§ 488.1015 Resubmitting a request for reapproval.

(a) Except as provided in paragraph (b) of this section, a home infusion therapy accrediting organization whose request for CMS's approval or re-approval of an accreditation program has been denied, or a home infusion therapy accrediting organization that has voluntarily withdrawn an initial application, may resubmit its application if the home infusion therapy accrediting organization satisfies all of the following requirements:

(1) Revises its home infusion therapy accreditation program to address the issues related to the denial of its previous request or its voluntary withdrawal.

(2) Resubmits the application in its entirety.

(b) If a home infusion therapy accrediting organization has requested, in accordance with § 488.1050, a reconsideration of CMS's disapproval, it may not submit a new application for approval of a home infusion therapy accreditation program until such reconsideration is administratively final.

§ 488.1020 Public notice and comment.

CMS publishes a notice in the Federal Register when the following conditions are met:

(a) ***Proposed notice.*** CMS publishes a notice after the receipt of a completed application from a national home infusion therapy accrediting organization seeking CMS's approval of a home infusion therapy accreditation program. The notice identifies the home infusion therapy accrediting organization, the type of suppliers covered by the home infusion therapy accreditation program, and provides at least a 30 day public comment period (beginning on the date of publication).

(b) ***Final notice.*** The final notice announces CMS decision to approve or deny a national accrediting organization application. The notice specifies the basis for the CMS decision.

(1) ***Approval or re-approval.*** If CMS approves or re-approves the home infusion therapy accrediting organization's home infusion therapy accreditation program, the final notice at a minimum includes the following information:

(i) A description of how the home infusion therapy accreditation program meets or exceeds Medicare home infusion therapy accreditation program requirements.

(ii) The effective date of approval (no later than the publication date of the notice).

(iii) The term of the approval (6 years or less).

(2) ***Denial.*** If CMS does not approve the home infusion therapy accrediting organization's accreditation program, the final notice describes the following:

(i) How the home infusion therapy accrediting organization fails to meet Medicare home infusion therapy accreditation program requirements.

(ii) The effective date of the decision.

§ 488.1025 Release and use of home infusion therapy accreditation surveys.

The home infusion therapy accrediting organization must include, in its accreditation agreement with each supplier, an acknowledgement that the supplier agrees to release to CMS a copy of its most current accreditation survey and any information related to the survey that CMS may require, corrective action plans.

(a) CMS may determine that a home infusion therapy supplier does not meet the applicable Medicare conditions or requirements on the basis of its own investigation of the accreditation survey or any other information related to the survey.

(b) With the exception of home health agency surveys, general disclosure of an accrediting organization's survey information is prohibited under section 1865(b) of the Act. CMS may publically disclose an accreditation survey and information related to the survey, upon written request, to the extent that the accreditation survey and survey information are related to an enforcement action taken by CMS.

§ 488.1030 Ongoing review of home infusion therapy accrediting organizations.

(a) ***Performance review.*** CMS evaluates the performance of each CMS-approved home infusion therapy accreditation program on an ongoing basis. This review includes the review of the following:

(1) The home infusion therapy accrediting organization's survey activity.

(2) The home infusion therapy accrediting organization's continued fulfillment of the requirements at §§ 488.1010 and 488.1035.

(b) ***Comparability review.*** CMS assesses the equivalency of a home infusion therapy accrediting organization's CMS-approved program requirements with the comparable Medicare home infusion therapy accreditation requirements after CMS imposes new or revised Medicare accreditation requirements. When this occurs, the following takes place:

(1) CMS provides the home infusion therapy accrediting organizations with written notice of the changes to the to the Medicare home infusion therapy accreditation requirements.

(2) The home infusion therapy accrediting organization must make revisions to its home infusion therapy accreditation standards or survey processes which incorporate the new or revised Medicare accreditation requirements.

(3) In the written notice, CMS specifies the deadline (no less than 30 calendar days) by which the home infusion therapy accrediting organization must submit its proposed revised home infusion therapy accreditation standard or survey process revisions, and the timeframe(s) for implementation of these revised home infusion therapy accreditation standards.

(4) CMS may extend the submission deadline by which the accrediting organization must submit its proposed revised home infusion therapy accreditation standards and survey processes, if both of the following occur:

(i) The accrediting organization submits a written request for an extension of the submission deadline.

(ii) The request for extension is submitted prior to the original submission deadline.

(5) After completing the comparability review of the home infusion therapy accrediting organizations revised home infusion therapy accreditation standards and survey processes, CMS shall provide written notification to the home infusion therapy accrediting organization regarding whether or not its home infusion therapy accreditation program, including the proposed revised home infusion therapy accreditation standards and implementation timeframe(s), continues to meet or exceed all applicable Medicare requirements.

(6) If, no later than 60 calendar days after receipt of the home infusion therapy accrediting organization's proposed changes, CMS does not provide the written notice to the home infusion therapy accrediting organization required, then the revised home infusion therapy accreditation standards and program is deemed to meet or exceed all applicable Medicare requirements and to have continued CMS-approval.

(7) If a home infusion therapy accrediting organization is required to submit a new application because CMS imposes new home infusion therapy regulations or makes significant substantive revisions to the existing home infusion therapy regulations, CMS provides notice of the decision to approve or disapprove the new application submitted by the home infusion therapy accrediting organization within the time period specified in § 488.1010(d).

(8) If a home infusion therapy accrediting organization fails to submit its proposed changes to its home infusion therapy accreditation standards and survey processes within the required timeframe, or fails to implement the proposed changes that have been determined or deemed by CMS to be comparable, CMS may open an accreditation program review in accordance with paragraph (d) of this section.

(c) ***Review of revised home infusion therapy accreditation standards submitted to CMS by an accrediting organization.*** When a home infusion therapy accrediting organization proposes to adopt new or revised accreditation standards, requirements or changes in its survey process, the home infusion therapy accrediting organization must do the following:

(1) Provide CMS with written notice of any proposed changes in home infusion therapy accreditation standards, requirements or survey process at least 60 days prior to the proposed implementation date of the proposed changes.

(2) Not implement any of the proposed changes before receiving CMS's approval, except as provided in paragraph (c)(4) of this section.

(3) Provide written notice to CMS that includes all of the following:

(i) A detailed description of the changes that are to be made to the organization's home infusion therapy accreditation standards, requirements and survey processes.

(ii) A detailed crosswalk (in table format) that states the exact language of the organization's revised accreditation requirements and the applicable Medicare requirements for each.

(4) CMS must provide a written notice to the home infusion therapy accrediting organization which states whether the home infusion therapy accreditation program, including the proposed revisions, continues or does not continue to meet or exceed all applicable Medicare home infusion therapy requirements within 60 days of receipt of the home infusion therapy accrediting organization's proposed changes. If CMS has made a finding that the home infusion therapy accrediting organization's home infusion therapy accreditation program, accreditation requirements and survey processes, including the proposed revisions does not continue to meet or exceed all applicable Medicare home infusion therapy requirements. CMS must state the reasons for these findings.

(5) If, no later than 60 calendar days after receipt of the home infusion therapy accrediting organization's proposed changes, CMS does not provide written notice to the home infusion therapy accrediting organization that the home infusion therapy accreditation program, including the proposed revisions, continues or does not continue to meet or exceed all applicable Medicare home infusion therapy requirements, then the revised home infusion therapy accreditation program is deemed to meet or exceed all applicable Medicare home infusion therapy requirements and to have continued CMS approval.

(6) If a home infusion therapy accrediting organization implements changes that have neither been determined nor deemed by CMS to be comparable to the applicable Medicare home infusion therapy requirements, CMS may open a home infusion therapy accreditation program review in accordance with paragraph (d) of this section.

(d) ***CMS-approved home infusion therapy accreditation program review.*** If a comparability, performance, or standards review reveals evidence of substantial non-compliance of a home infusion therapy accrediting organization's CMS-approved home infusion therapy accreditation program with the requirements of this subpart, CMS may initiate a home infusion therapy accreditation program review.

(1) If a home infusion therapy accreditation program review is initiated, CMS will provide written notice to the home infusion therapy accrediting organization indicating that its CMS-approved accreditation program approval may be in jeopardy and that a home infusion therapy accreditation program review is being initiated. The notice will provide all of the following information:

(i) A statement of the instances, rates or patterns of non-compliance identified, as well as other related information, if applicable.

(ii) A description of the process to be followed during the review, including a description of the opportunities for the home infusion therapy accrediting organization to offer factual information related to CMS' findings.

(iii) A description of the possible actions that may be imposed by CMS based on the findings of the home infusion therapy accreditation program review.

(iv) The actions the home infusion therapy accrediting organization must take to address the identified deficiencies

(v) The length of the accreditation program review probation period, which will include monitoring of the home infusion therapy accrediting organization's performance and implementation of the corrective action plan. The probation period is not to exceed 180 calendar days from the date that CMS approves the AOs corrective action plan.

(2) CMS will review and approve the home infusion therapy accrediting organization's plan of correction for acceptability within 30 days after receipt.

(3) CMS will monitor the AO's performance and implementation of the plan of correction during the probation period which is not to exceed 180 days from the date of approval of the plan of correction.

(4) If CMS determines, as a result of the home infusion therapy accreditation program review or a review of an application for renewal of the accrediting organizations existing CMS-approved home infusion therapy accreditation program, that the home infusion therapy accrediting organization has failed to meet any of the requirements of this subpart, CMS may place the home infusion therapy accrediting organization's CMS-approved home infusion therapy accreditation program on an additional probation period of up to 180 calendar days subsequent to the 180-day probation period described in paragraph (d)(1)(v) of this section to implement additional corrective actions or demonstrate sustained compliance, not to exceed the home infusion therapy accrediting organization's current term of approval. In the case of a renewal application where CMS has already placed the home infusion therapy accreditation program on probation, CMS indicates that any approval of the application is conditional while the program is placed on probation.

(i) Within 60 calendar days after the end of any probationary period, CMS issues a written determination to the home infusion therapy accrediting organization as to whether or not its CMS-approved home infusion therapy accreditation program continues to meet the requirements of this subpart, including the reasons for the determination.

(ii) If CMS determines that the home infusion therapy accrediting organization does not meet the requirements, CMS may withdraw approval of the CMS-approved home infusion therapy accreditation program. The notice of determination provided to the home infusion therapy accrediting organization includes notice of the removal of approval, reason for the removal, including the effective date determined in accordance with paragraph (d)(4)(iii) of this section.

(iii) CMS publishes in the Federal Register a notice of its decision to withdraw approval of a CMS-approved accreditation program, including the reasons for the withdrawal, effective 60 calendar days after the date of publication of the notice.

(e) ***Immediate jeopardy.*** If at any time CMS determines that the continued approval of a CMS-approved home infusion therapy accreditation program of any home infusion therapy accrediting organization poses an immediate jeopardy to the patients of the suppliers accredited under the program, or the continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of a CMS-approved home infusion therapy accreditation program of that home infusion therapy accrediting organization and publish a notice of the removal, including the reasons for it, in the Federal Register.

(f) ***Notification to home infusion therapy suppliers of withdrawal of CMS approval status.*** A home infusion therapy accrediting organization whose CMS approval of its home infusion therapy accreditation program has been withdrawn must notify each of its accredited home infusion therapy suppliers, in writing, of the withdrawal of CMS approval status no later than 30 calendar days after the notice is published in the Federal Register. The notification to the accredited home infusion therapy suppliers must inform them of the implications for their payment status once their current term of accreditation expires.

§ 488.1035 Ongoing responsibilities of a CMS-approved home infusion therapy accrediting organization.

A home infusion therapy accreditation organization approved by CMS must carry out the following activities on an ongoing basis:

(a) Provide CMS with all of the following in written format (either electronic or hard copy):

(1) Copies of all home infusion therapy accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of findings with respect to unmet CMS requirements).

(2) Notice of all accreditation decisions.

(3) Notice of all complaints related to providers or suppliers.

(4) Information about all home infusion therapy accredited suppliers against which the home infusion therapy accreditation organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the providers or suppliers accreditation.

(5) The home infusion therapy accrediting organization must provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(6) Notice of any proposed changes in the home infusion therapy accrediting organization's accreditation standards or requirements or survey process. If the home infusion therapy accrediting organization implements the changes before or without CMS' approval, CMS may withdraw its approval of the accrediting organization.

(b) Within 30 calendar days after a change in CMS requirements, the home infusion therapy accrediting organization must submit an acknowledgment of receipt of CMS' notification to CMS.

(c) The home infusion therapy accrediting organization must permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(d) Within 2 business days of identifying a deficiency of an accredited home infusion therapy supplier that poses immediate jeopardy to a beneficiary or to the general public, the home infusion therapy accrediting organization must provide CMS with written notice of the deficiency and any adverse action implemented by the accrediting organization.

(e) Within 10 calendar days after CMS' notice to a CMS-approved home infusion therapy accrediting organization that CMS intends to withdraw approval of the home infusion therapy accrediting organization, the home infusion therapy accrediting organization must provide written notice of the withdrawal to all of the home infusion therapy accrediting organization's accredited suppliers.

§ 488.1040 Onsite observations of home infusion therapy accrediting organization operations.

(a) As part of the application review process, the ongoing review process, or the continuing oversight of a home infusion therapy accrediting organization's performance, CMS may conduct onsite inspections of the home infusion therapy accrediting organization's operations and offices at any time to verify the home infusion therapy accrediting organization's representations and to assess the home infusion therapy accrediting organization's compliance with its own policies and procedures.

(b) Activities to be performed by CMS staff during the onsite inspections may include, but are not limited to the following:

(1) Interviews with various accrediting organization staff.

(2) Review of documents, survey files, audit tools, and related records.

(3) Observation of meetings concerning the home infusion therapy accreditation process.

(4) Auditing meetings concerning the accreditation process.

(5) Observation of in-progress surveys and audits.

(6) Evaluation of the accrediting organization's survey results and accreditation decision-making process.

§ 488.1045 Voluntary and involuntary termination.

(a) ***Voluntary termination by a CMS-approved accrediting program.*** In accordance with § 488.1010(a)(23), a home infusion therapy accrediting organization that decides to voluntarily terminate its CMS-approved home infusion therapy accreditation program must provide written notice at least 180 days in advance of the effective date of the termination to CMS and each of its accredited home infusion therapy suppliers.

(b) ***Involuntary termination of an accrediting organization's approval by CMS.*** Once CMS publishes the notice in the Federal Register announcing its decision terminate the home infusion therapy accrediting organization's home infusion therapy accreditation program, the home infusion therapy accrediting organization must provide written notification to all suppliers accredited under its CMS-approved home infusion therapy accreditation program no later than 30 calendar days after the notice is published in the Federal Register announcing that CMS is withdrawing its approval of its home infusion therapy accreditation program and the implications for the home infusion therapy suppliers payment status in accordance with the requirements at § 488.1010(f) once their current term of accreditation expires.

(c) ***Voluntary and involuntary terminations.*** For both voluntary and involuntary terminations -

(1) The accreditation status of affected home infusion therapy suppliers is considered to remain in effect until their current term of accreditation expires;

(2) If the home infusion therapy supplier wishes to avoid a suspension of payment, it must provide written notice to CMS at least 60-calendar days prior to its accreditation expiration date that it has submitted an application for home infusion therapy accreditation under another CMS-approved home infusion therapy accreditation program. Failure to comply with this 60-calendar day requirement prior to expiration of their current home infusion therapy accreditation stations within could result in a suspension of payment; and

(3) The home infusion therapy accrediting organization provides a second written notification to all accredited home infusion therapy suppliers ten calendar days prior to the organization's accreditation program effective date of termination.

(d) ***Voluntary withdrawal from accreditation requested by a home infusion therapy supplier.*** If a voluntary withdrawal from accreditation is requested by the home infusion therapy supplier, the withdrawal may not become effective until the accrediting organization completes all of the following steps:

(1) The accrediting organization must contact the home infusion therapy supplier to seek written confirmation that the home infusion therapy supplier intends to voluntarily withdraw from the home infusion therapy accreditation program.

(2) The home infusion therapy accrediting organization must advise the home infusion therapy supplier, in writing, of the statutory requirement for accreditation for all home infusion therapy suppliers and the possible payment consequences for a lapse in accreditation status.

(3) The home infusion therapy accrediting organization must submit their final notice of the voluntary withdrawal of accreditation by the home infusion therapy supplier to CMS by 5 business days after the request for voluntary withdrawal is ultimately processed and effective.

§ 488.1050 Reconsideration.

(a) ***General rule.*** A home infusion therapy accrediting organization dissatisfied with a determination that its home infusion therapy accreditation requirements do not provide or do not continue to provide reasonable assurance that the suppliers accredited by the home infusion therapy accrediting organization meet the applicable quality standards is entitled to reconsideration.

(b) ***Filing requirements.***

(1) A written request for reconsideration must be filed within 30 calendar days of the receipt of CMS notice of an adverse determination or non-renewal.

(2) The written request for reconsideration must specify the findings or issues with which the home infusion therapy accrediting organization disagrees and the reasons for the disagreement.

(3) A requestor may withdraw its written request for reconsideration at any time before the issuance of a reconsideration determination.

(c) ***CMS response to a request for reconsideration.*** In response to a request for reconsideration, CMS provides the accrediting organization with -

(1) The opportunity for a hearing to be conducted by a hearing officer appointed by the Administrator of CMS and provide the accrediting organization the opportunity to present, in writing and in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew designation; and

(2) Written notice of the time and place of the hearing at least 10 business days before the scheduled date.

(d) ***Hearing requirements and rules.***

(1) The reconsideration hearing is a public hearing open to all of the following:

(i) Authorized representatives and staff from CMS, including, but not limited to, the following:

(A) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts).

(B) Legal counsel.

(C) Non-technical witnesses with personal knowledge of the facts of the case.

(ii) Representatives from the accrediting organization requesting the reconsideration including, but not limited to, the following:

(A) Authorized representatives and staff from the accrediting organization.

(B) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts).

(C) Legal counsel.

(D) Non-technical witnesses, such as patients and family members that have personal knowledge of the facts of the case.

(2) The hearing is conducted by the hearing officer who receives testimony and documents related to the proposed action.

(3) Testimony and other evidence may be accepted by the hearing officer even though such evidence may be inadmissible under the Federal Rules of Civil Procedure.

(4) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(5) Within 45 calendar days after the close of the hearing, the hearing officer will present the findings and recommendations to the accrediting organization that requested the reconsideration.

(6) The written report of the hearing officer will include separate numbered findings of fact and the legal conclusions of the hearing officer.

(7) The hearing officer's decision is final.

Subpart M - Survey and Certification of Hospice Programs

Source: 86 FR 62425, Nov. 9, 2021, unless otherwise noted.

§ 488.1100 Basis and scope.

Sections 1812, 1814, 1822, 1861, 1864, and 1865 of the Act establish requirements for Hospice programs and to authorize surveys to determine whether they meet the Medicare conditions of participation.

§ 488.1105 Definitions.

As used in this subpart -

Abbreviated standard survey means a focused survey other than a standard survey that gathers information on hospice program's compliance with specific standards or conditions of participation. An abbreviated standard survey may be based on complaints received or other indicators of specific concern.

Complaint survey means a survey that is conducted to investigate substantial allegations of noncompliance as defined in § 488.1.

Condition-level deficiency means noncompliance as described in § 488.24.

Deficiency is a violation of the Act and regulations contained in part 418, subparts C and D, of this chapter, is determined as part of a survey, and can be either standard or condition-level.

Noncompliance means any deficiency found at the condition-level or standard-level.

Standard-level deficiency means noncompliance with one or more of the standards that make up each condition of participation for hospice programs.

Standard survey means a survey conducted in which the surveyor reviews the hospice program's compliance with a select number of standards or conditions of participation or both to determine the quality of care and services furnished by a hospice program.

Substantial compliance means compliance with all condition-level requirements, as determined by CMS or the State.

§ 488.1110 Hospice program: surveys and hotline.

(a) ***Basic period.*** Each hospice program as defined in section 1861(dd) of the Act is subject to a standard survey by an appropriate State or local survey agency, or an approved accreditation agency, as determined by the Secretary, not less frequently than once every 36 months. Additionally, a survey may be conducted as frequently as necessary to -

(1) Assure the delivery of quality hospice program services by determining whether a hospice program complies with the Act and conditions of participation; and

(2) Confirm that the hospice program has corrected deficiencies that were previously cited.

(b) ***Complaints.*** A standard survey, or abbreviated standard survey-

(1) Must be conducted of a hospice program when complaints against the hospice program are reported to CMS, the State, or local agency.

(2) The State, or local agency is responsible for maintaining a toll-free hotline to collect, maintain, and continually update information on Medicare-participating hospice programs including significant deficiencies found regarding patient care, corrective actions, and remedy activity during its most recent survey, and to receive complaints and answer questions about hospice programs. The State or local agency is also responsible for maintaining a unit for investigating such complaints.

§ 488.1115 Surveyor qualifications and prohibition of conflicts of interest.

(a) ***Minimum qualifications.*** Surveyors must meet minimum qualifications prescribed by CMS. Before any accrediting organization, State or Federal surveyor may serve on a hospice survey team (except as a trainee), he/she must have successfully completed the relevant CMS-sponsored Basic Hospice Surveyor Training Course, and additional training as specified by CMS.

(b) ***Disqualifications.*** Surveyor(s) must disclose actual or perceived conflicts of interest prior to participating in a hospice program survey and be provided the opportunity to recuse themselves as necessary. Any of the following circumstances disqualifies a surveyor from surveying a particular hospice program:

(1) The surveyor currently serves, or, within the previous 2 years has served, with the hospice program to be surveyed as one of the following:

(i) A direct employee.

(ii) An employment agency staff at the hospice program.

(iii) An officer, consultant, or agent for the hospice program to be surveyed concerning compliance with conditions of participation specified in or in accordance with sections 1861(dd) of the Act.

(2) The surveyor has a financial interest or an ownership interest in the hospice program to be surveyed.

(3) The surveyor has an immediate family member, as defined at § 411.351 of this chapter, who has a financial interest or an ownership interest with the hospice program to be surveyed.

(4) The surveyor has an immediate family member, as defined at § 411.351 of this chapter, who is a patient of the hospice program to be surveyed.

§ 488.1120 Survey teams.

Standard surveys conducted by more than one surveyor must be conducted by a multidisciplinary team of professionals typically involved in hospice care and identified as professionals providing hospice core services at § 418.64 of this chapter. The multidisciplinary team must include a registered nurse. Surveys conducted by a single surveyor, must be conducted by a registered nurse.

§ 488.1125 Consistency of survey results.

A survey agency or accrediting organization must provide a corrective action plan to CMS for any disparity rates that are greater than the threshold established by CMS.

Subpart N - Enforcement Remedies for Hospice Programs With Deficiencies

Source: 86 FR 62425, Nov. 9, 2021, unless otherwise noted.

§ 488.1200 Statutory basis.

Section 1822 of the Act authorizes the Secretary to take actions to remove and correct deficiencies in a hospice program through an enforcement remedy or termination or both. This section specifies that these remedies are in addition to any others available under State or Federal law, and, except for the final determination of civil money penalties, are imposed prior to the conduct of a hearing.

§ 488.1205 Definitions.

As used in this subpart -

Directed plan of correction means CMS or the temporary manager (with CMS/survey agency (SA) approval) may direct the hospice program to take specific corrective action to achieve specific outcomes within specific timeframes.

Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient(s).

New admission means an individual who becomes a patient or is readmitted to the hospice program on or after the effective date of a suspension of payment remedy.

Per instance means a single event of noncompliance identified and corrected during a survey, for which the statute authorizes CMS to impose a remedy.

Plan of correction means a plan developed by the hospice program and approved by CMS that is the hospice program's written response to survey findings detailing corrective actions to cited deficiencies and specifies the date by which those deficiencies will be corrected.

Repeat deficiency means a condition-level deficiency that is cited on the current survey and is substantially the same as or similar to, a finding of a standard-level or condition-level deficiency cited on the most recent previous standard survey or on any intervening survey since the most recent standard survey. Repeated non-compliance is not on the basis that the exact regulation (that is, tag number) for the deficiency was repeated.

Temporary management means the temporary appointment by CMS or by a CMS authorized agent, of a substitute manager or administrator. The hospice program's governing body must ensure that the temporary manager has authority to hire, terminate or reassign staff, obligate funds, alter procedures, and manage the hospice program to correct deficiencies identified in the hospice program's operation.

§ 488.1210 General provisions.

(a) ***Purpose of remedies.*** The purpose of remedies is to ensure prompt compliance with program requirements in order to protect the health and safety of individuals under the care of a hospice program.

(b) ***Basis for imposition of remedies.*** When CMS chooses to apply one or more remedies specified in § 488.1220, the remedies are applied on the basis of noncompliance with one or more conditions of participation and may be based on failure to correct previous deficiency findings as evidenced by repeat condition-level deficiencies.

(c) ***Number of remedies.*** CMS may impose one or more remedies specified in § 488.1220 for each condition-level deficiency constituting noncompliance.

(d) ***Plan of correction requirement.*** Regardless of which remedy is applied, a non-compliant hospice program must submit a plan of correction for approval by CMS or the State Survey Agency.

(e) ***Notification requirements*** -

(1) ***Notice of intent.*** CMS provides written notification to the hospice program of the intent to impose the remedy, the statutory basis for the remedy, the nature of the noncompliance, the proposed effective date of the sanction, and the appeal rights. For civil money penalties, the notice of intent would also include the amount being imposed.

(2) ***Final notice.*** With respect to civil money penalties, CMS provides a written final notice to the hospice program, as set forth in § 488.1245(e), once the administrative determination is final.

(3) ***Date of enforcement action.*** The notice periods specified in §§ 488.1225(b) and 488.1230(b) begin the day after the hospice receives the notice of intent.

(f) ***Appeals.***

(1) The hospice program may request a hearing on a determination of noncompliance leading to the imposition of a remedy, including termination of the provider agreement, under the provisions of part 498 of this chapter.

(2) A pending hearing does not delay the effective date of a remedy, including termination, against a hospice program. Remedies continue to be in effect regardless of the timing of any appeals proceedings.

§ 488.1215 Factors to be considered in selecting remedies.

CMS bases its choice of remedy or remedies on consideration of one or more factors that include, but are not limited to, the following:

(a) The extent to which the deficiencies pose immediate jeopardy to patient health and safety.

(b) The nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.

(c) The presence of repeat deficiencies, the hospice program's overall compliance history and any history of repeat deficiencies at either the parent hospice program or any of its multiple locations.

(d) The extent to which the deficiencies are directly related to a failure to provide quality patient care.

(e) The extent to which the hospice program is part of a larger organization with performance problems.

(f) An indication of any system-wide failure to provide quality care.

§ 488.1220 Available remedies.

The following enforcement remedies are available instead of, or in addition to, termination of the hospice program's provider agreement under § 489.53 of this chapter, for a period not to exceed 6 months:

(a) Civil money penalties.

(b) Suspension of payment for all new patient admissions.

(c) Temporary management of the hospice program.

(d) Directed plan of correction.

(e) Directed in-service training.

§ 488.1225 Action when deficiencies pose immediate jeopardy.

(a) ***Immediate jeopardy.*** If there is immediate jeopardy to the hospice program's patient health or safety, the following rules apply:

(1) CMS immediately terminates the hospice program provider agreement in accordance with § 489.53 of this chapter.

(2) CMS terminates the hospice program provider agreement no later than 23 calendar days from the last day of the survey, if the immediate jeopardy has not been removed by the hospice program.

(3) In addition to a termination, CMS may impose one or more enforcement remedies, as appropriate.

(b) ***2-calendar day notice.*** Except for civil money penalties, for all remedies specified in § 488.1220 imposed when there is immediate jeopardy, notice must be given at least 2 calendar days before the effective date of the enforcement action. The requirements of the notice are set forth in § 488.1210(e).

(c) ***Transfer of care.*** A hospice program, if its provider agreement is terminated, is responsible for providing information, assistance, and arrangements necessary for the proper and safe transfer of patients to another local hospice program within 30 calendar days of termination.

§ 488.1230 Action when deficiencies are at the condition-level but do not pose immediate jeopardy.

(a) ***Noncompliance with conditions of participation.*** If the hospice program is no longer in compliance with the conditions of participation, either because the condition-level deficiency or deficiencies substantially limit the provider's capacity to furnish adequate care but do not pose immediate jeopardy, or the hospice program has repeat condition-level deficiencies based on the hospice program's failure to correct and sustain compliance, CMS does either of the following.

(1) Terminates the hospice program's provider agreement.

(2) Imposes one or more enforcement remedies set forth in § 488.1220(a) through (e) in lieu of termination, for a period not to exceed 6 months.

(b) ***15-calendar day notice.*** Except for civil money penalties, for all remedies specified in § 488.1220 imposed when there is no immediate jeopardy, notice must be given at least 15 calendar days before the effective date of the enforcement action. The requirements of the notice are set forth in § 488.1210(e).

(c) ***Not meeting criteria for continuation of payment.*** If a hospice program does not meet the criteria for continuation of payment under § 488.1260(a), CMS terminates the hospice program's provider agreement in accordance with § 488.1265.

(d) ***Termination timeframe when there is no immediate jeopardy.*** CMS terminates a hospice program within 6 months of the last day of the survey, if the hospice program is not in compliance with the conditions of participation, and the terms of the plan of correction have not been met.

(e) ***Transfer of care.*** A hospice program, if its provider agreement terminated, is responsible for providing information, assistance, and arrangements necessary for the proper and safe transfer of patients to another local hospice program within 30 calendar days of termination. The State must assist the hospice program in the safe and orderly transfer of care and services for the patients to another local hospice program.

§ 488.1235 Temporary management.

(a) ***Application.*** CMS may impose temporary management of a hospice program if it determines that a hospice program has a condition-level deficiency and CMS determines that management limitations or the deficiencies are likely to impair the hospice program's ability to correct the noncompliance and return the hospice program to compliance with all of the conditions of participation within the timeframe required.

(b) ***Procedures*** -

(1) ***Notice of intent.*** Before imposing the remedy in paragraph (a) of this section, CMS notifies the hospice program in accordance with § 488.1210(e) that a temporary manager is being appointed.

(2) ***Termination.*** If the hospice program fails to relinquish authority and control to the temporary manager, CMS terminates the hospice program's provider agreement in accordance with § 488.1265.

(c) ***Duration and effect of remedy.*** Temporary management continues until one of the following occur:

(1) CMS determines that the hospice program has achieved substantial compliance and has the management capability to ensure continued compliance with all the conditions of participation.

(2) CMS terminates the provider agreement.

(3) The hospice program resumes management control without CMS approval. In this case, CMS initiates termination of the provider agreement and may impose additional remedies.

(4) Temporary management will not exceed a period of 6 months from the date of the survey identifying noncompliance.

(d) ***Payment of salary.***

(1) The temporary manager's salary must meet the following:

(i) Is paid directly by the hospice program while the temporary manager is assigned to that hospice program.

(ii) Must be at least equivalent to the sum of the following:

(A) The prevailing salary paid by providers for positions of this type in what the State considers to be the hospice program's geographic area (prevailing salary based on the Bureau of Labor Statistics, National Occupational Employment and Wage Estimates).

(B) Any additional costs that would have reasonably been incurred by the hospice program if such person had been in an employment relationship.

(C) Any other costs incurred by such a person in furnishing services under such an arrangement or as otherwise set by the State.

(2) A hospice program's failure to pay the salary and other costs of the temporary manager described in paragraph (d)(1) of this section is considered a failure to relinquish authority and control to temporary management.

§ 488.1240 Suspension of payment for all new patient admissions.

(a) ***Application.***

(1) CMS may suspend payment for all new admissions to a hospice program on or after the date on which the Secretary determines that remedies should be imposed.

(2) CMS considers the remedy in paragraph (a)(1) of this section for any deficiency related to poor patient care outcomes, regardless of whether the deficiency poses immediate jeopardy.

(b) ***Procedures*** -

(1) ***Notice of intent.***

(i) Before suspending payments for all new admissions, CMS provides the hospice program notice of the suspension of payment in accordance with § 488.1210(e).

(ii) The hospice program may not charge a newly admitted hospice patient who is a Medicare beneficiary for services for which Medicare payment is suspended unless the hospice program can show that, before initiating care, it gave the patient or his or her representative oral and written notice of the suspension of Medicare payment in a language and manner that the beneficiary or representative can understand.

(2) ***Restriction.***

(i) The suspension of payment for all new admissions remedy may be imposed anytime a hospice program is found to be out of substantial compliance with the conditions of participation.

(ii) The suspension of payment for all new admissions remains in place until CMS determines that the hospice program has achieved substantial compliance with the conditions of participation or is terminated, as determined by CMS.

(3) ***Resumption of payments.*** Payments for all new admissions to the hospice program resume prospectively on the date that CMS determines that the hospice program has achieved substantial compliance with the conditions of participation.

(c) ***Duration and effect of remedy.*** The remedy in paragraph (a) of this section ends when any of the following occur -

(1) CMS determines that the hospice program has achieved substantial compliance with all of the conditions of participation.

(2) When the hospice program is terminated or CMS determines that the hospice program is not in compliance with the conditions of participation at a maximum of 6 months from the date of the survey identifying the noncompliance.

§ 488.1245 Civil money penalties.

(a) ***Application.***

(1) CMS may impose a civil money penalty against a hospice program for either the number of days the hospice program is not in compliance with one or more conditions of participation or for each instance that a hospice program is not in compliance, regardless of whether the hospice program's deficiencies pose immediate jeopardy.

(2) CMS may impose a civil money penalty for the number of days of immediate jeopardy.

(3) A per-day and a per-instance civil money penalty (CMP) may not be imposed simultaneously for the same deficiency in conjunction with a survey.

(4) CMS may impose a civil money penalty for the number of days of noncompliance since the last standard survey, including the number of days of immediate jeopardy.

(b) ***Amount of penalty*** -

(1) ***Factors considered.*** CMS takes into account the following factors in determining the amount of the penalty:

(i) The factors set out at § 488.1215.

(ii) The size of a hospice program and its resources.

(iii) Evidence that the hospice program has a built-in, self-regulating quality assessment and performance improvement system to provide proper care, prevent poor outcomes, control patient injury, enhance quality, promote safety, and avoid risks to patients on a sustainable basis that indicates the ability to meet the conditions of participation and to ensure patient health and safety.

(2) ***Adjustments to penalties.*** Based on revisit survey findings, adjustments to penalties may be made after a review of the provider's attempted correction of deficiencies.

(i) CMS may increase a CMP in increments based on a hospice program's inability or failure to correct deficiencies, the presence of a system-wide failure in the provision of quality care, or a determination of immediate jeopardy with actual harm versus immediate jeopardy with potential for harm.

(ii) CMS may also decrease a CMP in increments to the extent that it finds, in accordance with a revisit, that substantial and sustainable improvements have been implemented even though the hospice program is not yet in compliance with the conditions of participation.

(iii) No penalty assessment exceeds $10,000, as adjusted annually under 45 CFR part 102, for each day a hospice program is not in substantial compliance with one or more conditions of participation.

(3) ***Upper range of penalty.*** Penalties in the upper range of $8,500 to $10,000 per day, as adjusted annually under 45 CFR part 102, are imposed for a condition-level deficiency that is immediate jeopardy. The penalty in this range continues until substantial compliance can be determined based on a revisit survey.

(i) $10,000, as adjusted annually under 45 CFR part 102, per day for a deficiency or deficiencies that are immediate jeopardy and that result in actual harm.

(ii) $9,000, as adjusted annually under 45 CFR part 102, per day for a deficiency or deficiencies that are immediate jeopardy and that result in a potential for harm.

(iii) $8,500, as adjusted annually under 45 CFR part 102, per day for a deficiency based on an isolated incident in violation of established hospice policy.

(4) ***Middle range of penalty.*** Penalties in the range of $1,500 up to $8,500, as adjusted annually under 45 CFR part 102, per day of noncompliance are imposed for a repeat or condition-level deficiency or both that does not constitute immediate jeopardy but is directly related to poor quality patient care outcomes.

(5) ***Lower range of penalty.*** Penalties in this range of $500 to $4,000, as adjusted annually under 45 CFR part 102, are imposed for a repeat or condition-level deficiency or both that does not constitute immediate jeopardy and that are related predominately to structure or process-oriented conditions rather than directly related to patient care outcomes.

(6) ***Per instance penalty.*** Penalty imposed per instance of noncompliance may be assessed for one or more singular events of condition-level deficiency that are identified and where the noncompliance was corrected during the onsite survey. When penalties are imposed for per instance of noncompliance, or more than one per instance of noncompliance, the penalties will be in the range of $1,000 to $10,000 per instance, not to exceed $10,000 each day of noncompliance, as adjusted annually under 45 CFR part 102.

(7) ***Decreased penalty amounts.*** If the immediate jeopardy situation is removed, but a condition-level deficiency exists, CMS shifts the penalty amount imposed per day from the upper range to the middle or lower range. An earnest effort to correct any systemic causes of deficiencies and sustain improvement must be evident.

(8) ***Increased penalty amounts.***

(i) In accordance with paragraph (b)(2) of this section, CMS increases the per day penalty amount for any condition-level deficiency or deficiencies which, after imposition of a lower-level penalty amount, become sufficiently serious to pose potential harm or immediate jeopardy.

(ii) CMS increases the per day penalty amount for deficiencies that are not corrected and found again at the time of revisit survey(s) for which a lower-level penalty amount was previously imposed.

(iii) CMS may impose a more severe amount of penalties for repeated noncompliance with the same condition-level deficiency or uncorrected deficiencies from a prior survey.

(c) ***Procedures*** -

(1) ***Notice of intent.*** CMS provides the hospice program with written notice of the intent to impose a civil money penalty in accordance with § 488.1210(e).

(2) ***Appeals*** -

(i) ***Appeals procedures.*** A hospice program may request a hearing on the determination of the noncompliance that is the basis for imposition of the civil money penalty. The request must meet the requirements in § 498.40 of this chapter.

(ii) ***Waiver of a hearing.*** A hospice program may waive the right to a hearing, in writing, within 60 calendar days from the date of the notice imposing the civil money penalty. If a hospice program timely waives its right to a hearing, CMS reduces the penalty amount by 35 percent, and the amount is due within 15 calendar days of the hospice program agreeing in writing to waive the hearing. If the hospice program does not waive its right to a hearing in accordance to the procedures specified in this section, the civil money penalty is not reduced by 35 percent.

(d) ***Accrual and duration of penalty*** -

(1) ***Accrual of per day penalty.***

(i) The per day civil money penalty may start accruing as early as the beginning of the last day of the survey that determines that the hospice program was out of compliance, as determined by CMS.

(ii) A civil money penalty for each per instance of noncompliance is imposed in a specific amount for that particular deficiency, with a maximum of $10,000 per day per hospice program.

(2) ***Duration of per day penalty when there is immediate jeopardy.***

(i) In the case of noncompliance that poses immediate jeopardy, CMS must terminate the provider agreement within 23 calendar days after the last day of the survey if the immediate jeopardy is not removed.

(ii) A penalty imposed per day of noncompliance will stop accruing on the day the provider agreement is terminated or the hospice program achieves substantial compliance, whichever occurs first.

(3) ***Duration of penalty when there is no immediate jeopardy.***

(i) In the case of noncompliance that does not pose immediate jeopardy, the daily accrual of per day civil money penalties is imposed for the days of noncompliance prior to the notice of intent specified in paragraph (c)(1) of this section and an additional period of no longer than 6 months following the last day of the survey.

(ii) If the hospice program has not achieved compliance with the conditions of participation within 6 months following the last day of the survey, CMS terminates the provider agreement. The accrual of civil money penalty stops on the day the hospice program agreement is terminated or the hospice program achieves substantial compliance, whichever is earlier.

(e) ***Computation and notice of total penalty amount.***

(1) When a civil money penalty is imposed on a per day basis and the hospice program achieves compliance with the conditions of participation as determined by a revisit survey, once the administrative determination is final, CMS sends a final notice to the hospice program containing of the following information:

(i) The amount of penalty assessed per day.

(ii) The total number of days of noncompliance.

(iii) The total amount due.

(iv) The due date of the penalty.

(v) The rate of interest to be assessed on any unpaid balance beginning on the due date, as provided in paragraph (f)(6) of this section.

(2) When a civil money penalty is imposed per instance of noncompliance, once the administrative determination is final, CMS sends a final notice to the hospice program containing all of the following information:

(i) The amount of the penalty that was assessed.

(ii) The total amount due.

(iii) The due date of the penalty.

(iv) The rate of interest to be assessed on any unpaid balance beginning on the due date, as provided in paragraph (f)(6) of this section.

(3) In the case of a hospice program for which the provider agreement has been involuntarily terminated, CMS sends the final notice after one of the following actions has occurred:

(i) The administrative determination is final.

(ii) The hospice program has waived its right to a hearing in accordance with paragraph (c)(2)(ii) of this section.

(iii) Time for requesting a hearing has expired and the hospice program has not requested a hearing.

(f) ***Due date for payment of penalty.*** A penalty is due and payable 15 calendar days from notice of the final administrative decision.

(1) Payments are due for all civil money penalties within 15 calendar days of any of the following:

(i) After a final administrative decision when the hospice program achieves substantial compliance before the final decision or the effective date of termination occurs before the final decision.

(ii) After the time to appeal has expired and the hospice program does not appeal or fails to timely appeal the initial determination.

(iii) After CMS receives a written request from the hospice program requesting to waive its right to appeal the determinations that led to the imposition of a remedy.

(iv) After the effective date of termination.

(2) A request for hearing does not delay the imposition of any penalty; it only potentially delays the collection of the final penalty amount.

(3) If a hospice program waives its right to a hearing according to paragraph (c)(2)(ii) of this section, CMS applies a 35 percent reduction to the CMP amount for any of the following:

(i) The hospice program achieved compliance with the conditions of participation before CMS received the written waiver of hearing.

(ii) The effective date of termination occurs before CMS received the written waiver of hearing.

(4) The period of noncompliance may not extend beyond 6 months from the last day of the survey.

(5) The amount of the penalty, when determined, may be deducted (offset) from any sum then or later owing by CMS or State Medicaid to the hospice program.

(6) Interest is assessed and accrues on the unpaid balance of a penalty, beginning on the due date. Interest is computed at the rate specified in § 405.378(d) of this chapter.

(g) ***Review of the penalty.*** When an administrative law judge finds that the basis for imposing a civil monetary penalty exists, as specified in this part, the administrative law judge, may not do any of the following:

(1) Set a penalty of zero or reduce a penalty to zero.

(2) Review the exercise of discretion by CMS to impose a civil monetary penalty.

(3) Consider any factors in reviewing the amount of the penalty other than those specified in paragraph (b) of this section.

§ 488.1250 Directed plan of correction.

(a) ***Application.*** CMS may impose a directed plan of correction when a hospice program -

(1) Has one or more condition-level deficiencies that warrant directing the hospice program to take specific actions; or

(2) Fails to submit an acceptable plan of correction.

(b) ***Procedures.***

(1) Before imposing the remedy in paragraph (a) of this section, CMS notifies the hospice program in accordance with § 488.1210(e).

(2) CMS or the temporary manager (with CMS approval) may direct the hospice program to take corrective action to achieve specific outcomes within specific timeframes.

(c) ***Duration and effect of remedy.*** If the hospice program fails to achieve compliance with the conditions of participation within the timeframes specified in the directed plan of correction, which may not to exceed 6 months, CMS does one of the following:

(1) May impose one or more other remedies set forth in § 488.1220.

(2) Terminates the provider agreement.

§ 488.1255 Directed in-service training.

(a) ***Application.*** CMS may require the staff of a hospice program to attend in-service training program(s) if CMS determines all of the following:

(1) The hospice program has condition-level deficiencies.

(2) Education is likely to correct the deficiencies.

(3) The programs are conducted by established centers of health education and training or consultants with background in education and training with Medicare hospice providers, or as deemed acceptable by CMS or the State (by review of a copy of curriculum vitas or resumes and references to determine the educator's qualifications).

(b) ***Procedures*** -

(1) ***Notice of intent.*** Before imposing the remedy in paragraph (a) of this section, CMS notifies the hospice program in accordance with § 488.1210(e).

(2) ***Action following training.*** After the hospice program staff has received in-service training, if the hospice program has not achieved substantial compliance, CMS may impose one or more other remedies specified in § 488.1220.

(3) ***Payment.*** The hospice program pays for the directed in-service training for its staff.

§ 488.1260 Continuation of payments to a hospice program with deficiencies.

(a) ***Continued payments.*** CMS may continue payments to a hospice program with condition-level deficiencies that do not constitute immediate jeopardy for up to 6 months from the last day of the survey if the criteria in paragraph (a)(1) of this section are met.

(1) ***Criteria.*** CMS may continue payments to a hospice program not in compliance with the conditions of participation for the period specified in paragraph (a) of this section if all of the following criteria are met:

(i) An enforcement remedy, or remedies, has been imposed on the hospice program and termination has not been imposed.

(ii) The hospice program has submitted a plan of correction approved by CMS.

(iii) The hospice program agrees to repay the Federal Government payments received under this paragraph (a) if corrective action is not taken in accordance with the approved plan and timetable for corrective action.

(2) ***Termination.*** CMS may terminate the hospice program's provider agreement any time if the criteria in paragraph (a)(1) of this section are not met.

(b) ***Cessation of payments for new admissions.*** If termination is imposed, either on its own or in addition to an enforcement remedy or remedies, or if any of the criteria set forth in paragraph (a)(1) of this section are not met, the hospice program will receive no Medicare payments, as applicable, for new admissions following the last day of the survey.

(c) ***Failure to achieve compliance with the conditions of participation.*** If the hospice program does not achieve compliance with the conditions of participation by the end of the period specified in paragraph (a) of this section, CMS terminates the provider agreement of the hospice program in accordance with § 488.1265.

§ 488.1265 Termination of provider agreement.

(a) ***Effect of termination by CMS.*** Termination of the provider agreement ends -

(1) Payment to the hospice program; and

(2) Any enforcement remedy.

(b) ***Basis for termination.*** CMS terminates a hospice program's provider agreement under any one of the following conditions:

(1) The hospice program is not in compliance with the conditions of participation.

(2) The hospice program fails to submit an acceptable plan of correction within the timeframe specified by CMS.

(3) The hospice program fails to relinquish control to the temporary manager, if that remedy is imposed by CMS.

(4) The hospice program fails to meet the eligibility criteria for continuation of payment as set forth in § 488.1260(a)(1).

(c) ***Notice.*** CMS notifies the hospice program and the public of the termination, in accordance with procedures set forth in § 489.53 of this chapter.

(d) ***Procedures for termination.*** CMS terminates the provider agreement in accordance with procedures set forth in § 489.53 of this chapter.

(e) ***Payment post termination.*** Payment is available for up to 30 calendar days after the effective date of termination for hospice care furnished under a plan established before the effective date of termination as set forth in § 489.55 of this chapter.

(f) ***Appeal.*** A hospice program may appeal the termination of its provider agreement by CMS in accordance with part 498 of this chapter.