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suppliers must meet in order to participate in the Medicare program and which are considered necessary to ensure the health and safety of patients.

§ 486.505 Definitions.

As used in §§ 486.520 and 486.525:

Applicable provider means a physician, a nurse practitioner, and a physician assistant.

Home means a place of residence used as the home of an individual, including an institution that is used as a home. An institution that is used as a home may not be a hospital, CAH, or SNF as defined in section 1861(e)(1), 1861(mm)(1), or 1819(a)(1) of the Act, respectively.

Home infusion drug means a parental drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment. The term does not include insulin pump systems or a self-administered drug or biological on a self-administered drug exclusion list.

Infusion drug administration calendar day means the day on which home infusion therapy services are furnished by skilled professionals in the individual's home on the day of infusion drug administration. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel.

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.

[83 FR 56630, Nov. 13, 2018, as amended at 84 FR 60646, Nov. 8, 2019]

STANDARDS FOR HOME INFUSION THERAPY

§ 486.520 Plan of care.

The qualified home infusion therapy supplier ensures the following:

(a) All patients must be under the care of an applicable provider.

(b) All patients must have a plan of care established by a physician that prescribes the type, amount, and duration of the home infusion therapy services that are to be furnished.

(c) The plan of care for each patient must be periodically reviewed by the physician.

§ 486.525 Required services.

(a) The qualified home infusion therapy supplier must provide the following services on a 7-day-a-week, 24-hour-a-day basis in accordance with the plan of care:

(1) Professional services, including nursing services.

(2) Patient training and education not otherwise paid for as durable medical equipment as described in § 424.57(c)(12) of this chapter.

(3) Remote monitoring and monitoring services for the provision of home infusion therapy services and home infusion drugs.

(b) All home infusion therapy suppliers must provide home infusion therapy services in accordance with nationally recognized standards of practice, and in accordance with all applicable state and federal laws and regulations.

[83 FR 56630, Nov. 13, 2018, as amended at 86 FR 61625, Nov. 5, 2021; 88 FR 36510, June 5, 2023]

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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, rural emergency 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; 88 FR 59335, Aug. 28, 2023]

§ 488.2 Statutory basis.

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

TABLE 1 TO § 488.2

Section	Subject
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 skilled nursing facilities (SNFs).
1820	Requirements for critical access hospitals (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 ambulatory surgical centers (ASCs).
1832(a)(2)(J)	Requirements for partial hospitalization services and intensive outpatient 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 rural health clinics (RHCs) and federally qualified health centers (FQHCs).
1861(cc)(2)	Requirements for comprehensive outpatient rehabilitation facilities (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.
1861(kkk)	Requirements for rural emergency hospitals (REHs).

TABLE 1 TO § 488.2—Continued

Section	Subject
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 end stage renal disease (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 nursing facility (NF) care.
1919	Medicaid requirements for NFs.

[88 FR 59335, Aug. 28, 2023, as amended at 88 FR 82183, Nov. 22, 2023]

§ 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.

(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 reapplication 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.

(f) *Change of ownership. What Constitutes Change of Ownership.* A description of what could constitute a change of ownership with respect to a national accrediting organization are those activities described in § 489.18(a)(1) through (3) of this chapter.

(1) *Notice to CMS.* Any CMS-approved accrediting organization that is contemplating or negotiating a change of ownership must notify CMS of the change of ownership.

(i) This notice requirement applies to any national accrediting organization with CMS-approved accreditation program(s) that is the subject of a potential or actual change of ownership transaction, including accrediting organizations for Advanced Diagnostic Imaging (ADI) suppliers; Home Infusion Therapy (HIT) suppliers; Diabetic Self-Management Training (DSMT) entities, and clinical laboratories.

(ii) This notice must be provided to CMS in writing.

(iii) This notice must be provided to CMS no less than 90 calendar days prior to the anticipated effective date of the change of ownership transaction.

(iv) CMS will complete their review of the AO's request for approval for the transfer of the existing CMS approval for the accreditation programs to be transferred in the change of ownership within 90 days from receipt of said AO's request.

(2) *Information submitted with the request for approval for change of ownership transaction.* The person(s) or organization(s) acquiring an existing CMS-approved accrediting organization or accreditation programs (that is, purchaser, buyer or transferee) through a

change of ownership transaction must do the following:

(i) Seek approval from CMS for the purchase or transfer of the existing CMS approval for the accreditation program(s) to be transferred in the change of ownership event; and

(ii) Meet the requirements of paragraphs (f)(2)(iii) through (f)(4) of this section to demonstrate that the entities that will be accredited with the transferred accrediting program(s) continue to meet or exceed the applicable Medicare conditions or requirements.

(iii) The following information must be submitted to CMS in the purchaser's/buyer's/transferee's request for approval of a transfer of the existing CMS approval for the accreditation program(s) to be transferred in the change or ownership transaction:

(A) The legal name and address of the new owner;

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

(C) A transition plan that summarizes the details of how the accreditation functions will be transitioned to the new owner, including:

(*1*) Changes to management and governance structures including current and proposed organizational charts;

(*2*) A list of the CMS-approved accreditation programs that will be transferred to the purchaser/buyer/transferee,

(*3*) Employee changes, if applicable,

(*4*) Anticipated timelines for action;

(*5*) Plans for notification to employees; and

(*6*) Any other relevant information that CMS finds necessary.

(D) The prospective new AO'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, as required by paragraph (a)(10) of this section.

(3) *Written acknowledgements.* The purchaser/buyer/transferee must provide a written acknowledgement to CMS, which states the following:

(i) If the application for the transfer of the existing CMS-approval for the accreditation program(s) to be transferred in the change of ownership transaction is approved by CMS, said purchaser/buyer/transferee must assume complete responsibility for the operations (that is, managerial, financial, and legal) of the CMS-approved accreditation programs transferred, immediately upon the finalization of the change of ownership transaction;

(ii) The purchaser/buyer/transferee agrees to operate the transferred CMS-approved accreditation program(s) under all of the CMS imposed terms and conditions, to include program reviews and probationary status terms, currently approved by CMS; and

(iii) The purchaser/buyer/transferee must not operate the accreditation program(s) it acquired in the change in ownership transaction as CMS approved accreditation programs, until the effective date set forth within the notice of approval from CMS.

(iv) The purchaser/buyer/transferee agrees to operate the transferred CMS-approved accreditation program(s) under all of the terms and conditions found at §§ 488.5 through 488.9.

(4) *Notification.* The following written notifications are required after the change of ownership transaction has been approved by CMS:

(i) All parties to the change of ownership transaction must notify the providers and suppliers affected by such change within 15 calendar days after being notified of CMS's approval of the transfer of the existing CMS-approval for the accreditation programs to be transferred in the change of ownership transaction.

(ii) If applicable, the purchaser/buyer/transferee must acknowledge in writing to CMS that the accrediting organization or accreditation program(s) being acquired through a purchase or transfer of ownership was under a performance review or under probationary status at the time the change of ownership notice was submitted.

(5) *Federal Register notice.* CMS will publish a notice of approval in the FEDERAL REGISTER of the transfer of the existing CMS approval for the accreditation program(s) to be transferred to the new owner, only after CMS receives written confirmation from the new

owner that the change of ownership has taken place.

(6) *Notification to parties in the event that CMS does not approve the transfer of the existing CMS approval.* In the event that CMS does not approve the transfer of the existing CMS approval for the accreditation program(s) to be transferred in the change of ownership transaction, CMS will notify all parties to the change of ownership transaction of such in writing.

(7) *Withdrawal of CMS approval for transferred accreditation programs due to failure to notify CMS of intent to transfer accreditation programs.* In the event that CMS was not made aware of or did not approve the transfer of the existing CMS-approval for the accreditation program(s) to be transferred under a change of ownership:

(i) The existing AO would be permitted to continue operating their existing CMS-approved accreditation programs, if the change of ownership transaction was not completed, unless our review of the transaction revealed issues with the AO that were the subject of the un-finalized change of ownership transaction that was previously unknown to CMS.

(ii) If a change of ownership transaction was completed without notice to CMS or the approval of CMS, CMS would be able to withdraw the existing approval of the AO's accreditation programs in accordance with § 488.8(c)(3)(ii) and (iii).

(8) *Withdrawal of CMS approval for accreditation programs which are transferred notwithstanding CMS' disapproval of the transfer.* In the event that the parties complete the change of ownership transaction, notwithstanding CMS disapproval and the purchaser/buyer/transferee attempts to operate the transferred accreditation program(s) under the CMS-approval granted to the previous owner, CMS will withdraw the existing approval of the transferred accreditation program(s) in accordance with the procedures set out at §§ 488.8(c)(3)(ii) and (iii).

(9) *Requirements for continuation of a deemed status accreditation of Medicare-certified providers and suppliers after CMS withdraws the existing approval of the transferred accreditation program(s).* If CMS withdraws the existing approval of the transferred accreditation program(s) because the change of ownership transaction was completed without notice to CMS or the approval of CMS, an affected Medicare-Certified provider or supplier's deemed status will continue in effect for 180 calendar days if the Medicare-Certified provider or supplier takes the following steps set forth is § 488.8(g).

(i) The Medicare-certified provider or supplier must submit 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; and

(ii) The Medicare-certified provider or supplier must 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 in accordance with § 488.8(g).

(iii) Failure to comply with the timeframe requirements specified in § 488.8(g) will place the provider or supplier under the SA's authority for continued participation in Medicare and on-going monitoring.

(10) *Requirements for continuation of accreditation for non-certified suppliers when CMS withdraws the existing approval of the transferred accreditation program(s).* If CMS withdraws its existing approval from a transferred non-certified accreditation program for Advanced Diagnostic Imaging (ADI) suppliers; Home Infusion Therapy (HIT) suppliers; or Diabetic Self-Management Training (DSMT) entities, because a change of ownership transaction was completed without notice to or the approval of CMS, such affected non-certified supplier's deemed status would continue in effect for 1 year after the removal of the existing CMS accreditation approval, if such non-certified supplier take the steps specified paragraphs (f)(10)(i) and (ii) of this section—

(i) The non-certified supplier must submit 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; and

(ii) The non-certified supplier must provide written notice to CMS stating that it has submitted an application

for accreditation under another CMS-approved accreditation program within the 60-calendar days from the date of publication of the removal notice in the FEDERAL REGISTER.

(iii) Failure to comply with the above-stated timeframe requirements will result in de-recognition of such provider or supplier's accreditation.

[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; 87 FR 25427, Apr. 29, 2022; 87 FR 36410, June 17, 2022]

§ 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 noncompliance.* (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) or a rural emergency hospital (as defined in section 1861(kkk)(2) 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; 88 FR 59335, Aug. 28, 2023]

§ 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]

§ 488.70 Special requirements for rural emergency hospitals (REHs).

An eligible facility submitting an application for enrollment under section 1866(j) of the Act to become a rural emergency hospital (REH) (as defined in § 485.502 of this chapter) must also submit an action plan containing the following additional information:

(a) *Plan for provision of services.* The provider must submit an action plan for initiating rural emergency hospital (REH) services (as defined in § 485.502 of this chapter, and which must include the provision of emergency department services and observation care).

(b) *Transition plan.* The provider must submit a detailed transition plan that lists the specific services that the provider will retain, modify, add, and discontinue as an REH.

(c) *Other outpatient medical and health services.* The provider must submit a detailed description of the other medical and health services that it intends to furnish on an outpatient basis as an REH.

(d) *Use of additional facility payment.* The provider must submit information regarding how the provider intends to use the additional facility payment provided in accordance with section 1834(x)(2) of the Act, including a description of the services that the additional facility payment would be supporting, such as the operation and maintenance of the facility and the furnishing of covered services (for example, telehealth services, and ambulance services).

[88 FR 59335, Aug. 28, 2023]

Subpart C—Survey Forms and Procedures

§ 488.100 Long term care survey forms, Part A.

§ 488.100 Long term care survey forms, Part A.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

PART A — ADMINISTRATIVE AND PROCEDURAL REQUIREMENTS

MEDICARE / MEDICAID SKILLED NURSING FACILITY AND INTERMEDIATE CARE FACILITY SURVEY REPORT

PROVIDER NUMBER	FACILITY NAME AND ADDRESS (*City, State, Zip Code*)
VENDOR NUMBER	
SURVEY DATE	
SURVEYORS' NAMES	TITLES

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NAME OF FACILITY

CODE	COMPLIANCE WITH STATE AND LOCAL LAWS	YES	NO	N/A	EXPLANATORY STATEMENT
	Compliance with State and Local Laws *(Condition of Participation)*				
F500	SNF (405.1120) ☐ MET ☐ NOT MET				
	A. **Licensure**				
F501	SNF (405.1120(a)) (Standard) ☐ MET ☐ NOT MET				
F502	ICF (442.251) (Standard) ☐ MET ☐ NOT MET				
F503	The facility has a current State License (Number _____)				
	B. **Personnel Licensure**				
F504	SNF (405.1120(b)) (Standard) ☐ MET ☐ NOT MET				
F505	ICF (442.302) (Standard) ☐ MET ☐ NOT MET				
F506	Staff of the facility are licensed or registered in accordance with applicable State laws.				
	C. **Compliance with Other Laws**				
F507	SNF (405.1120(c)) (Standard) ☐ MET ☐ NOT MET				
F508	ICF (442.252) (Standard) ☐ MET ☐ NOT MET				
F509	ICF (442.315) (Standard) ☐ MET ☐ NOT MET				
F510	The facility is in compliance with applicable Federal, State and local laws and regulations relating to fire and safety, sanitation, communicable and reportable diseases, postmortem procedures and other relevant health and safety requirements.				

NAME OF FACILITY

CODE	COMPLIANCE WITH STATE AND LOCAL LAWS/ GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	The facility is in compliance with applicable regulations pertaining to:				
F511	Buying, dispensing, safeguarding, administering, and disposing of medications and controlled substances. **Exception: Not applicable to SNFs.**				
F512	Construction, maintenance and equipment. **Exception: Not applicable to SNFs.**				
F513	Current reports from all responsible governmental agencies are retained at the facility.				
	Governing Body and Management ***(Condition of Participation)***				
F514	SNF (405.1121) ☐ MET ☐ NOT MET The facility has a governing body with full legal authority and responsibility for operation of the facility.				
	A. **Disclosure**				
F515	SNF (405.1121(a)) (Standard) ☐ MET ☐ NOT MET Full disclosure of ownership has been made in accordance with requirements at 42 CFR 420.206.				
	B. **Administration**				
F516	SNF (405.1121(c)) (Standard) ☐ MET ☐ NOT MET				
F517	1. Written bylaws address the operation of the facility.				
F518	2. Written bylaws and policies address effective resident care.				
F519	3. Bylaws are reviewed and revised as necessary.				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F520	ICF (442.301) (Standard) ☐ MET ☐ NOT MET				
	C. **Independent Medical Review**				
F521	SNF (405.1121(d)) (Standard) ☐ MET ☐ NOT MET The facility has policies which ensure that the facility cooperates in an effective program for regular independent medical evaluation and audit of residents in the facility to the extent required by the programs in which the facility participates.				
	D. **Administrator**				
F522	SNF (405.1121(e)) (Standard) ☐ MET ☐ NOT MET				
F523	ICF (442.303) (Standard) ☐ MET ☐ NOT MET				
F524	The facility has a licensed administrator who has authority for the overall operation of the facility. (Administrator's license or registration number _____).				
	E. **Resident Care Director**				
F525	ICF (442.304) (Standard) ☐ MET ☐ NOT MET				
F526	1. The administrator or another professional staff member is the resident care director (RSD).				
F527	2. The RSD coordinates and monitors each resident's care.				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	F. **Institutional Planning**				
F528	SNF (405.1121(f)) (Standard) ☐ MET ☐ NOT MET				
F529	1. The facility has an overall plan and budget prepared by a committee of representatives from the governing body, administrative staff, and the organized medical staff (if any).				
F530	2. The overall plan and budget is reviewed and updated at least annually.				
F531	3. The plan includes a capital expenditures plan, if necessary.				
	G. **Personnel Policies and Procedures**				
F532	SNF (405.1121(g)) (Standard) ☐ MET ☐ NOT MET				
	1. The facility has written policies and procedures that support sound resident care and personnel practices and address, at least:				
F533	a. Control of communicable disease;				
F534	b. The review of employee incidents and accidents to identify health and safety hazards; and				
F535	c. The existence of a safe and sanitary environment.				
F536	2. Personnel records are current, available to each employee, and contain sufficient information to support placement in the position to which assigned.				
F537	3. Referral or provision for periodic health examinations to ensure freedom from communicable disease.				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	H. **Outside Resources/Consultant Agreements**				
F538	SNF (405.1121(i)) (Standard) ☐ MET ☐ NOT MET				
F539	ICF (442.317) (Standard) ☐ MET ☐ NOT MET				
F540	The facility has written agreements with qualified persons to render a service (if it does not employ a qualified professional person to do so). The agreements:				
F541	1. Address the responsibilities, functions, objectives, and terms (including financial arrangements and charges);				
F542	2. Are signed by an authorized representative of the facility and the outside resource; and				
F543	3. Specify that the facility retains ultimate responsibility for the services rendered.				
	I. **Notification of Change in Resident Status**				
F544	SNF (405.1121(j)) (Standard) ☐ MET ☐ NOT MET				
F545	The facility has policies and procedures to notify physicians and other responsible persons in the event of an accident involving the resident, or resident's physical, mental or emotional status, or resident charges, billings or related administrative matter.				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	J. Resident Rights				
F546	SNF (405.1121(k)) (Standard) ☐ MET ☐ NOT MET **Indicators 1 thru 12 apply to SNFs.**				
F547	ICF (442.311) (Standard) ☐ MET ☐ NOT MET				
	1. **Information**				
F548	a. The facility informs each resident, before or at the time of admission, of his rights and responsibilities.				
F549	b. The facility informs each resident, before or at the time of admission, of all rules governing resident conduct.				
F550	c. The facility informs each resident of amendments to their policies on residents' rights and responsibilities and rules governing conduct.				
F551	d. Each resident acknowledges in writing receipt of residents' rights information and any amendment to it.				
F552	e. The resident must be informed in writing of all services and charges for services.				
F553	f. The resident must be informed in writing of all changes in services and charges before or at the time of admission and on a continuing basis.				
F554	g. The resident must be informed of services not covered by Medicare or Medicaid in the basic rate.				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	2. Medical Condition and Treatment				
F555	a. Each resident is informed by a physician of his health and medical condition unless the physician decides that informing the resident is medically contraindicated.				
F556	b. Each resident is given an opportunity to participate in planning his total care and medical treatment.				
F557	c. Each resident is given an opportunity to refuse treatment.				
F558	d. Each resident gives informed, written consent before participating in experimental research.				
F559	e. If the physician decides that informing the resident of his health and medical condition is medically contraindicated, the physician has documented this decision in the resident's medical record.				
	3. Transfer and Discharge				
F560	Each resident is transferred or discharged only for: a. Medical reasons.				
F561	b. His/her welfare or that of other residents.				
F562	c. Nonpayment except as prohibited by the Medicare or Medicaid program.				
	4. Exercising Rights				
F563	a. Each resident is encouraged and assisted to exercise his/her rights as a resident of the facility and as a citizen.				
F564	b. Each resident is allowed to submit complaints and recommendations concerning the policies and services of the facility to staff or to outside representatives of the resident's choice or both.				
F565	c. Such complaints are submitted free from restraint, coercion, discrimination, or reprisal.				

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NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	5. **Financial Affairs**				
F566	a. Residents are allowed to manage their own personal financial affairs.				
F567	b. The facility establishes and maintains a system that assures full and complete accounting of residents' personal funds. An accounting report is made to residents in skilled nursing facilities at least on a quarterly basis.				
F568	c. The facility does not commingle resident funds with any other funds other than resident funds.				
F569	d. If a resident requests assistance from the facility in managing his personal financial affairs, resident's delegation is in writing.				
	e. The facility system of accounting includes written receipts for:				
F570	1. All personal possessions and funds received by or deposited with the facility.				
F571	2. All disbursement made to or for the resident.				
F572	f. The financial record must be available to the resident and his/her family.				
	6. **Freedom from Abuse and Restraints**				
F573	a. Each resident is free from mental and physical abuse.				
F574	b. Chemical and physical restraints are only used when authorized by a physician in writing for a specified period of time or in emergencies.				
F575	c. If used in emergencies, they are necessary to protect the resident from injury to himself or others.				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F576	d. The use is authorized by a professional staff member identified in the written policies and procedures of the facility.				
F577	e. The use is reported promptly to the resident's physician by the staff member.				
	7. **Privacy**				
F578	a. Each resident is treated with respect, consideration and full recognition of his/her dignity and individuality.				
F579	b. Each resident is given privacy during treatment and care of personal needs.				
F580	c. Each resident's records, including information in an automated data bank, are treated confidentially.				
F581	d. Each resident must give written consent before the facility releases information from his/her record to someone not otherwise authorized to receive it.				
F582	e. Married residents are given privacy during visits by their spouses.				
F583	f. Married residents are permitted to share a room.				
	8. **Work**				
F584	No resident may be required to perform services for the facility.				
	9. **Freedom of Association and Correspondence**				
F585	a. Each resident is allowed to communicate, associate and meet privately with individuals of his choice unless this infringes upon the rights of another resident.				
F586	b. Each resident is allowed to send and receive personal mail unopened.				

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NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	10. **Activities**				
F587	Each resident is allowed to participate in social, religious, and community group activities.				
	11. **Personal Possessions**				
F588	Each resident is allowed to retain and use his personal possessions and clothing as space permits.				
	12. **Written Policies and Procedures: Delegation of Rights and Responsibilities**				
F589	ICF (442.312) (Standard) ☐ MET ☐ NOT MET				
F590	a. The facility has written policies and procedures that provide that all the rights and responsibilities of a resident pass to the resident's guardian, next of kin or sponsoring agency or agencies if the resident is adjudicated incompetent under State law or is determined by his physician to be incapable of understanding his rights and responsibilities.				
F591	b. Physician determinations of incapability and the specific reasons thereof are recorded by the physician in the resident's record.				
	K. **Resident Care Policies**				
F592	SNF (405.1121(l)) (Standard) ☐ MET ☐ NOT MET				
F593	1. The facility has written policies to govern the continuing skilled nursing care and related medical or other services provided.				
F594	2. These policies reflect awareness of and provision for meeting the total medical and psychosocial needs of residents including admission, transfer, discharge planning, and the range of services available to residents; and				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F595	3. The protection of residents' personal and property rights.				
F596	4. The policies are developed by a group of professional personnel, including the Medical Director or the organized medical staff, and are periodically reviewed and revised (if necessary).				
F597	5. These policies are available to admitting physicians, sponsoring agencies, residents, and the public.				
F598	6. The Medical Director or a registered nurse is designated as responsible for the execution of the policies.				
	L. **Public Availability**				
F599	ICF (442.305) (Standard) ☐ MET ☐ NOT MET				
F600	1. The facility has written policies and procedures governing all the services it provides.				
F601	2. The policies and procedures are available to the staff and residents, members of the family, the public, and legal representatives of residents.				
	M. **Admissions**				
F602	ICF (442.306) (Standard) ☐ MET ☐ NOT MET				
	The facility has written policies and procedures that ensure that it admits as residents only those residents whose needs can be met by:				
F603	1. the facility itself.				
F604	2. the facility in cooperation with community resources.				
F605	3. the facility in cooperation with other providers of care affiliated with or under contract to the facility.				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	N. Transfers				
F606	ICF (442.307) (Standard) ☐ MET ☐ NOT MET				
F607	1. The facility has written policies and procedures to ensure that residents are transferred promptly to a hospital, SNF or other appropriate facility when a change is necessary.				
F608	2. Except in emergencies, the facility consults the resident, his next of kin, the attending physician, and the responsible agency, if any, at least five days before discharge.				
F609	3. The facility uses casework services and other means to ensure that adequate arrangements are made to meet resident's needs through other resources.				
	O. Restraints				
F610	ICF (442.308) (Standard) ☐ MET ☐ NOT MET				
	The facilty has written policies and procedures that:				
F611	1. Define the uses of chemical and physical restraints.				
F612	2. Identify the professional personnel who may authorize the use of restraints in emergencies under 442.311(f).				
F613	3. Describe procedures for monitoring and controlling the use of these restraints.				
	P. Complaints				
F614	ICF (442.309) (Standard) ☐ MET ☐ NOT MET				
	The facility has written policies and procedures that:				
F615	1. Describe the procedures the facility uses to receive complaints and recommendations from residents.				
F616	2. Ensure that the facility responds to complaints and recommendations.				

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NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	Q. Staff Development				
F617	SNF (405.1121(h)) (Standard) ☐ MET ☐ NOT MET				
F618	ICF (442.314) (Standard) ☐ MET ☐ NOT MET				
F619	1. The facility conducts an orientation program for all new employees that includes a review of all its policies.				
F620	2. The facility plans and conducts an inservice staff development program for all personnel to assist them in developing and improving their skills.				
F621	3. The facility maintains a record of the orientation and staff development programs it conducts.				
F622	4. The record includes the content of the program and the names of participants.				
F623	5. Inservice training includes at least prevention and control of infections, fire prevention and safety, confidentiality of resident information, and preservation of resident dignity including protection of resident's privacy and personal and property rights.				

NAME OF FACILITY

CODE	MEDICAL DIRECTION	YES	NO	N/A	EXPLANATORY STATEMENT
	Medical Direction *(Condition of Participation)*				
F624	SNF (405.1122) ☐ MET ☐ NOT MET The facility has a written agreement with a licensed physician to serve as Medical Director on a part-time or full-time basis as is appropriate to the needs of the residents and the facility. (See 405.1911(b) regarding waiver of this requirement.)				
	A. **Coordination of Medical Care**				
F625	SNF (405.1122(a)) (Standard) ☐ MET ☐ NOT MET				
F626	1. Medical direction and coordination of medical care in the facility are provided by a Medical Director.				
F627	2. The Medical Director is responsible for development of policies approved by the governing body.				
F628	3. Coordination of medical care includes liaison with attending physicians to ensure their writing orders promptly upon admission of a resident, and periodic evaluation of the adequacy and appropriateness of health professional and supportive staff and services.				
	B. **Responsibilities to the Facility**				
F629	SNF (405.1122(b)) (Standard) ☐ MET ☐ NOT MET				
F630	1. The Medical Director is responsible for surveillance of the health status of the facility's employees.				
F631	2. Incidents and accidents that occur on the premises are reviewed by the Medical Director to identify hazards to health and safety.				

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NAME OF FACILITY

CODE	PHYSICIAN SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	Physician Services *(Condition of Participation)*				
F632	SNF (405.1123) ☐ MET ☐ NOT MET Residents in need of skilled or rehabilitative care are admitted to the facility only upon the recommendation of, and remain under the care of, a physician. To the extent feasible, each resident designates a personal physician.				
	A. **Physician Supervision**				
F633	SNF (405.1123(b)) (Standard) ☐ MET ☐ NOT MET				
F634	ICF (442.346) (Standard) ☐ MET ☐ NOT MET				
F635	1. The facility has a policy that the health care of every resident must be under the supervision of a physician.				
F636	2. All attending physicians must make arrangements for the medical care of their residents in their absence.				
	B. **Emergency Services**				
F637	SNF (405.1123(c)) (Standard) ☐ MET ☐ NOT MET The facility has written procedures available at each nurses' station, that provide for having a physician available to furnish necessary medical care in case of emergency.				

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	Nursing Services *(Condition of Participation)*				
F638	SNF (405.1124) ☐ MET ☐ NOT MET The facility provides 24-hour service by licensed nurses, including the services of a registered nurse at least during the day tour of duty, 7 days a week. There is an organized nursing service with a sufficient number of qualified nursing personnel to meet the total nursing needs of all residents (See 405.1911(a) regarding waiver of the 7-day registered nurse requirement).				
F639	ICF (442.342) (Standard) ☐ MET ☐ NOT MET The facility provides nursing care as needed including restorative nursing care.				
	A. **Director of Nursing Services**				
F640	SNF (405.1124(a)) (Standard) ☐ MET ☐ NOT MET				
F641	1. The director of nursing services is a qualified registered nurse employed full-time.				
F642	2. The director of nursing services has, in writing, administrative authority, responsibility, and accountability for the functions, activities, and training of the nursing services staff, and serves only one facility in this capacity.				
F643	3. If the director of nursing services has other institutional responsibilities, a qualified registered nurse serves as assistant so that there is the equivalent of a full-time director of nursing services on duty.				

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	B. Health Services Supervision				
F644	ICF (442.339) (Standard) ☐ MET ☐ NOT MET				
F645	1. The facility has a full-time registered nurse, or a licensed practical or vocational nurse to supervise the health services 7 days a week on the day shift.				
F646	2. The nurse has a current State license.				
F647	3. If the supervisor of health services is a licensed practical or vocational nurse, the facilty has a formal contract with a registered nurse to serve as a consultant no less than 4 hours a week.				
F648	4. To qualify to serve as a health services supervisor, a licensed practical or vocational nurse must: a. Have graduated from a State-approved school of practical nursing, or				
F649	b. Have education or other training that the State authority responsible for licensing practical nurses considered equal to graduation from a State-approved school of practical nursing, or				
F650	c. Have passed the Public Health Service examination for waivered licensed practical or vocational nurses.				
F651	5. If the nurse in charge is licensed by the State in a category other than registered nurse or licensed practical or vocational nurse: a. The individual has completed a training program to get the license that includes at least the same number of classroom and practice hours in all nursing subjects as in the program of a State-approved school of practical or vocational nursing, and				

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NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F652	b. The State agency responsible for licensing the individual submits a report to the Medicaid agency comparing State-licensed practical nurse or vocational nurse course requirements with those for the program completed by the individual.				
	C. **Twenty-four Hour Nursing Service**				
F653	SNF (405.1124(c)) (Standard) ☐ MET ☐ NOT MET				
F654	ICF (442.338) (Standard) ☐ MET ☐ NOT MET				
F655	1. 24-Hour Nursing Nursing policies and procedures address the total nursing needs of the residents.				
F656	The policies are designed to ensure that each resident receives: Treatment.				
F657	Medications as prescribed.				
F658	Diet as prescribed.				
F659	Rehabilitative nursing care as needed.				
F660	Proper care to prevent decubitus ulcers and deformities.				
F661	Proper care to ensure that residents are clean, well-groomed and comfortable.				
F662	Protection from accident and injury.				
F663	Protection from infection.				
F664	Encouragement, assistance, and training in self-care and group activities.				

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F665	2. Weekly time schedules are maintained and indicate the number and classifications of nursing personnel including relief personnel, who worked on each unit for each tour of duty.				
	D. **Rehabilitative Nursing Care**				
F666	SNF (405.1124(e)) (Standard) ☐ MET ☐ NOT MET				
F667	Nursing personnel are trained in rehabilitative nursing.				
	E. **Supervision of Resident Nutrition**				
F668	SNF (405.1124(f)) (Standard) ☐ MET ☐ NOT MET				
F669	A procedure is established to inform dietetic service of physicians' diet orders and of residents' dietetic problems.				
	F. **Administration of Drugs**				
F670	SNF (405.1124(g)) (Standard) ☐ MET ☐ NOT MET				
F671	Procedures are established by the Pharmaceutical Services Committee (see 405.1127(d)) to ensure that drugs are checked against physicians' orders.				
	G. **Conformance with Physicians' Drug Orders**				
F672	SNF (405.1124(h)) (Standard) ☐ MET ☐ NOT MET **Indicators 1 thru 4 apply to SNFs.**				
F673	ICF (442.335) (Standard) ☐ MET ☐ NOT MET				
F674	1. Drugs not specifically limited as to time or number of doses when ordered are controlled by automatic stop orders or other methods in accordance with written policies.				

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NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F675	2. The attending physician is notified of an automatic stop order prior to the last dose so that the physician may decide if the administration of the drug or biological is to be continued or altered.				
F676	ICF (442.334) (Standard) ☐ MET ☐ NOT MET				
F677	3. Physicians' verbal orders for drugs are given only to a licensed nurse, pharmacist, or physician and are immediately recorded and signed by the person receiving the order. (Verbal orders for Schedule II drugs are permitted only in the case of a bona fide emergency situation.)				
F678	4. Such orders are countersigned by the attending physician within a reasonable time.				
	H. **Storage of Drugs and Biologicals**				
F679	SNF (405.1124(i)) (Standard) ☐ MET ☐ NOT MET				
F680	1. Procedures for storing and disposing of drugs and biologicals are established by the pharmaceutical services committee.				
F681	2. In accordance with State and Federal laws, all drugs and biologicals are stored in locked compartments under proper temperature controls.				
F682	3. Only authorized personnel have access to the keys.				
F683	4. Separately locked, permanently affixed compartments are provided for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention & Control Act of 1970 and other drugs subject to abuse, except under single unit dosage distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.				
F684	5. An emergency medication kit approved by the pharmaceutical services committee is kept readily available.				

NAME OF FACILITY

CODE	DIETETIC SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	Dietetic Services *(Condition of Participation)*				
F685	SNF (405.1125) ☐ MET ☐ NOT MET The facility provides a hygienic dietetic service that meets the daily nutritional needs of patients, ensures that special dietary needs are met, and provides palatable and attractive meals. A facility that has a contract with an outside food management company may be found to be in compliance with this condition provided the facility and/or company meets the standards listed herein.				
	A. **Staffing**				
F686	SNF (405.1125(a)) (Standard) ☐ MET ☐ NOT MET				
F687	1. Overall supervisory responsibility for the dietetic service is assigned to a full-time qualified dietetic service supervisor.				
F688	2. If the dietetic service supervisor is not a qualified dietitian, the dietetic service supervisor functions with frequent, regularly scheduled consultation from a person so qualified. (§405.1101(e).)				
F689	3. In addition, the facility employs sufficient supportive personnel competent to carry out the functions of the dietetic service.				
F690	4. If consultant dietetic services are used, the consultant's visits are at appropriate times, and of sufficient duration and frequency to provide continuing liaison with medical and nursing staffs, advice to the administrator, resident counseling, guidance to the supervisor and staff of the dietetic service, approval of all menus, and participation in the development or revisions of dietetic policies and procedures. (See §405.1121(i).)				

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NAME OF FACILITY

CODE	DIETETIC SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	B. Staffing				
F691	ICF (442.332) (Standard) ☐ MET ☐ NOT MET				
F692	1. The facility has a staff member trained or experienced in food management or nutrition who is responsible for: a. Planning meals that meet the nutritional needs of each resident.				
F693	b. Following the orders of the resident's physician.				
F694	c. To the extent medically possible, following the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences (Recommended Dietary Allowances, 8th Ed., 1974).				
F695	d. Supervising the meal preparation and service to ensure that the menu plan is followed.				
F696	2. For residents who required medically prescribed special diets, the facility: a. Has menus for those residents planned by a professionally qualified dietitian or reviewed and approved by the attending physician; and				
F697	b. Supervises the preparation and serving of meals to ensure that the resident accepts the special diet.				
F698	3. The facility keeps for 30 days a record of each menu as served.				

NAME OF FACILITY

CODE	DIETETIC SERVICES/ SPECIALIZED REHABILITATION SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	C. **Hygiene of Staff**				
F699	SNF (405.1125(f)) (Standard) ☐ MET ☐ NOT MET				
F700	In the event food service employees are assigned duties outside the dietetic service, these duties do not interfere with the sanitation, safety, or the time required for dietetic work assignments. (See §405.1121(g).)				
	D. **Sanitary Conditions**				
F701	SNF (405.1125(g)) (Standard) ☐ MET ☐ NOT MET				
F702	Written reports of inspections by State and local health authorities are on file at the facility, with notation made of action taken by the facility to comply with any recommendations.				
	Specialized Rehabilitation Services *(Condition of Participation)*				
F703	SNF (405.1126) ☐ MET ☐ NOT MET The facility provides, or arranges for, under written agreement, specialized rehabilitative services by qualified personnel (i.e., physical therapy, speech pathology and audiology, and occupational therapy) as needed by residents to improve and maintain functioning. Safe and adequate space and equipment are available, commensurate with the services offered. If the facility does not offer such services directly, it does not admit nor retain residents in need of this care unless provision is made for such services under arrangement with qualified outside resources under which the facility assumes professional responsibility for the services rendered. (See §405.1121(i).)				

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NAME OF FACILITY

CODE	SPECIALIZED REHABILITATION SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	A. Staffing and Organization				
F704	SNF (405.1126(a)) (Standard) ☐ MET ☐ NOT MET				
	Indicators 1 thru 3 apply to SNFs				
F705	ICF (442.343) (Standard) ☐ MET ☐ NOT MET				
F706	1. Specialized rehabilitative services are provided, in accordance with accepted professional practices, by qualified therapists or by qualified assistants or other supportive personnel under the supervision of qualified therapists.				
F707	2. Other rehabilitative services also may be provided, but must be in a facility where all rehabilitative services are provided through an organized rehabilitative service under the supervision of a physician qualified in physical medicine who determines the goals and limitations of these services and assigns duties appropriate to the training and experience of those providing such services. **Exception: Does not apply to ICFs.**				
F708	3. Written administrative and resident care policies and procedures are developed for rehabilitative services by appropriate therapists and representatives of the medical, administrative, and nursing staffs. **Exception: Does not apply to ICF's See General Requirements 442.305**				

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NAME OF FACILITY

CODE	SPECIALIZED REHABILITATION SERVICES/ PHARMACEUTICAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	B. Documentation of Services				
F709	SNF (405.1126(c)) (Standard) ☐ MET ☐ NOT MET The physician's order, the plan of rehabilitative care, services rendered, evaluations of progress, and other pertinent information are recorded in the patient's medical record, and are dated and signed by the physician ordering the service and the person who provided the service.				
	C. Qualifying to Provide Outpatient Physical Therapy Services				
F710	SNF (405.1126(d)) (Standard) ☐ MET ☐ NOT MET If the facility provides outpatient physical therapy services, it meets the applicable health and safety regulations pertaining to such services as are included in Subpart Q of this part. (See §405.1719, 405.1720, 405.1722(a) and (b)(1)(2)(3)(i), (4), (5), (6), (7), and (8); and 405.1725.)				
	Pharmaceutical Services (Condition of Participation)				
F711	SNF (405.1127) ☐ MET ☐ NOT MET The facility has appropriate methods and procedures for the dispensing and administering of drugs and biologicals. The facility is responsible for providing such drugs and biologicals for its residents, insofar as they are covered under the programs, and for ensuring that pharmaceutical services are provided in accordance with accepted professional principles.				

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NAME OF FACILITY

CODE	PHARMACEUTICAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	A. Supervision of Services				
F712	SNF (405.1127(a)) (Standard) ☐ MET ☐ NOT MET				
F713	1. The pharmaceutical services are under the general supervision of a qualified pharmacist.				
F714	2. The pharmacist is responsible to the administrative staff for developing coordinating, and supervising all pharmaceutical services.				
F715	3. The pharmacist (if not a full-time employee) devotes a sufficient number of hours, based upon the needs of the facility, during regularly scheduled visits to carry out these responsibilities.				
F716	ICF (442.333) (Standard) ☐ MET ☐ NOT MET				
F717	1. The facility employs a licensed pharmacist, or				
F718	2. The facility has formal arrangements with a licensed pharmacist to advise the facility on ordering, storage, administration, disposal and recordkeeping of drugs and biologicals.				
	B. Control and Accountability				
F719	SNF (405.1127(b)) (Standard) ☐ MET ☐ NOT MET				
F720	1. The pharmaceutical service has procedures for control and accountability of all drugs and biologicals throughout the facility.				
F721	2. Only approved drugs and biologicals are used in the facility.				
F722	3. Records of receipt and disposition of all controlled drugs are maintained in sufficient detail to enable an accurate reconciliation.				

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NAME OF FACILITY

CODE	PHARMACEUTICAL SERVICES/ LABORATORY AND RADIOLOGIC SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	C. **Pharmaceutical Services Committee**				
F723	SNF (405.1127(d)) (Standard) ☐ MET ☐ NOT MET				
F724	1. A pharmaceutical services committee or its equivalent develops written policies and procedures for safe and effective drug therapy, distribution, control and use.				
F725	2. The committee is comprised of at least the pharmacist, the director of nursing services, the administrator, and one physician.				
F726	3. The committee oversees pharmaceutical services in the facility, makes recommendations for improvement, and monitors the service to ensure its accuracy and adequacy.				
	Laboratory and Radiologic Services *(Condition of Participation)*				
F727	SNF (405.1128) ☐ MET ☐ NOT MET The facility has provision for promptly obtaining required laboratory, X-ray, and other diagnostic services.				
	A. **Provision for Services**				
F728	SNF (405.1128(a)) (Standard) ☐ MET ☐ NOT MET				
F729	1. If the facility provides its own laboratory and X-ray services, these meet the applicable conditions established for certification of hospitals that are contained in 405.1028 and 405.1029, respectively.				

NAME OF FACILITY

CODE	LABORATORY AND RADIOLOGIC SERVICES/ DENTAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F730	2. If the facility itself does not provide such services, arrangements are made for obtaining these services from a physician's office, a participating hospital or skilled nursing facility, or a portable X-ray supplier or independent laboratory which is approved to provide these services under the program.				
F731	3. The facility assists the resident, if necessary, in arranging for transportation to and from the source of service.				
	B. **Blood and Blood Products**				
F732	SNF (405.1128(b)) (Standard) ☐ MET ☐ NOT MET				
F733	1. Blood handling and storage facilities are safe, adequate, and properly supervised.				
F734	2. If the facility provides for maintaining and transfusing blood and blood products, it meets the conditions established for certification of hospitals that are contained in §405.1028(j).				
F735	3. If the facility does not provide its own facility but does provide transfusion services alone, it meets at least the requirements of §405.1028(j)(1), (3), (4), (6), and (9).				
	Dental Services *(Condition of Participation)*				
F736	SNF (405.1129) ☐ MET ☐ NOT MET The facility has satisfactory arrangements to assist residents to obtain routine and emergency dental care (See §405.1121(i). (The basic Hospital Insurance Program does not cover the services of a dentist in a skilled nursing facility in connection with the care, treatment, filling, removal, or replacement of teeth or structures supporting the teeth; and only certain oral surgery is included in the Supplemental Medical Insurance Program.)				

NAME OF FACILITY

CODE	DENTAL SERVICES/SOCIAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	A. Advisory Dentist				
F737	SNF (405.1129(a)) (Standard) ☐ MET ☐ NOT MET				
F738	A dentist recommends oral hygiene policies and practices for the care of residents. (§405.1121(h).				
	B. Arrangements of Outside Services				
F739	SNF (405.1129(b)) (Standard) ☐ MET ☐ NOT MET				
F740	1. The facility has a cooperative agreement with a dentist, and				
F741	2. Maintains a list of dentists in the community for residents who do not have a private dentist.				
F742	3. The facility assists the resident, if necessary, in arranging for transportation to and from the dentist's office.				
	Social Services *(Condition of Participation)*				
F743	SNF (405.1130) ☐ MET ☐ NOT MET The facility has satisfactory arrangements for identifying the medically related social and emotional needs of the resident. It is not mandatory that the skilled nursing facility itself provide social services in order to participate in the program. If the facility does not provide social services, it has written procedures for referring residents in need of social services to appropriate social agencies. If social services are offered by the facility, they are provided under a clearly defined plan, by qualified persons, to assist each resident to adjust to the social and emotional aspects of the resident's illness, treatment, and stay in the facility.				

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NAME OF FACILITY

CODE	SOCIAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	A. Social Service Functions				
F744	SNF (405.1130(a)) (Standard) ☐ MET ☐ NOT MET				
F745	Services are provided to meet the social and emotional needs of residents by qualified staff of the facility, or by referral, based on established procedures, to appropriate social agencies.				
F746	ICF (442.344(b)) ☐ MET ☐ NOT MET The facility either provides these services itself or arranges for them with qualified outside resources.				
	B. Staffing				
F747	SNF (405.1130(b)) (Standard) ☐ MET ☐ NOT MET				
F748	1. If the facility offers social services, a member of the staff of the facility is designated as responsible for social services.				
F749	2. If the designated person is not a qualified social worker, the facility has a written agreement with a qualified social worker or recognized social agency for consultation and assistance on a regularly scheduled basis. (See §405.1101(s).)				
F750	3. The social service also has sufficient supportive personnel to meet resident needs.				
F751	4. Facilities are adequate for social service personnel, easily accessible to residents and medical and other staff, and ensure privacy for interviews.				

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NAME OF FACILITY

CODE	SOCIAL SERVICES/ACTIVITIES	YES	NO	N/A	EXPLANATORY STATEMENT
F752	ICF (442.344(c)) ☐ MET ☐ NOT MET				
F753	The facility designates one staff member, qualified by training or experience, to be responsible for: a. Arranging for social services; and				
F754	b. Integrating social services with other elements of the plan of care.				
	C. Records and Confidentiality				
F755	SNF (405.1130(c)) (Standard) ☐ MET ☐ NOT MET				
F756	Records of pertinent social data about personal and family problems medically related to the resident's illness and care, and of action taken to meet the resident's needs, are maintained in the resident's medical records.				
F757	If social services are provided by an outside resource, a record is maintained of each referral to such resource.				
	Activities (Condition of Participation)				
F758	SNF (405.1131) ☐ MET ☐ NOT MET The facility provides for an activities program, appropriate to the needs and interests of each resident, to encourage self care, resumption of normal activities, and maintenance of an optimal level of psychosocial functioning.				

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NAME OF FACILITY

CODE	ACTIVITIES/MEDICAL RECORDS	YES	NO	N/A	EXPLANATORY STATEMENT
	A. Staffing				
F759	SNF (405.1131(a)) (Standard) ☐ MET ☐ NOT MET				
F760	A member of the facility's staff is designated as responsible for the activities program.				
F761	If not a qualified activities coordinator, this staff member functions with frequent, regularly scheduled consultation from a person so qualified. (See §405.1101(o).)				
F762	ICF (442.345(b)) ☐ MET ☐ NOT MET The facility designates one staff member, qualified by training or experience in directing group activity, to be responsible for activity service.				
	Medical Records *(Condition of Participation)*				
F763	SNF (405.1132) ☐ MET ☐ NOT MET The facility maintains clinical (medical) records on all residents in accordance with accepted professional standards and practices. The medical record service has sufficient staff, facilities, and equipment to provide medical records that are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.				
F764	ICF (442.318(a)) ☐ MET ☐ NOT MET The facility maintains an organized resident record system that contains a record for each resident.				

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NAME OF FACILITY

CODE	MEDICAL RECORDS	YES	NO	N/A	EXPLANATORY STATEMENT
	A. Staffing				
F765	SNF (405.1132(a)) (Standard) ☐ MET ☐ NOT MET				
F766	1. Overall supervisory responsibility for the medical record service is assigned to a full-time employee of the facility.				
F767	2. The facility also employs sufficient supportive personnel competent to carry out the functions of the medical record service.				
F768	3. If the medical record supervisor is not a qualified medical record practitioner, this person functions with consultation from a person qualified. (See §405.1101(i).)				
	B. Protection of Medical Record Information				
F769	SNF (405.1132(b)) (Standard) ☐ MET ☐ NOT MET				
F770	ICF (442.318(d)) ☐ MET ☐ NOT MET				
F771	The facility safeguards medical record information against loss, destruction, or unauthorized use.				
	C. Physician Documentation				
F772	SNF (405.1132(d)) (Standard) ☐ MET ☐ NOT MET				
F773	1. Only physicians enter or authenticate in medical records opinions that require medical judgment (in accordance with medical staff bylaws, rules, and regulations, if applicable).				
F774	2. All physicians sign their entries into the medical record.				

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NAME OF FACILITY

CODE	MEDICAL RECORDS	YES	NO	N/A	EXPLANATORY STATEMENT
	D. **Completion of Records and Centralization of Reports**				
F775	SNF (405.1132(e)) (Standard) ☐ MET ☐ NOT MET				
F776	1. Current medical records and those of discharged residents are completed promptly.				
F777	2. All clinical information pertaining to a resident's stay is centralized in the resident's medical record.				
	E. **Retention and Preservation**				
F778	SNF (405.1132(f)) (Standard) ☐ MET ☐ NOT MET Medical records are retained for a period of time not less than that determined by the respective State statute, the statue of limitations in the State, or 5 years from the date of discharge in the absence of a State statute, or, in the case of a minor, 3 years after the resident becomes of age under State law.				
F779	ICF (442.318(e)) ☐ MET ☐ NOT MET The facility must keep a resident's record for at least 3 years after the resident is discharged.				
	F. **Location and Facilities**				
F780	SNF (405.1132(h)) (Standard) ☐ MET ☐ NOT MET The facility maintains adequate facilities and equipment, conveniently located to provide efficient processing of medical records (reviewing, indexing, filing, and prompt retrieval).				

NAME OF FACILITY

CODE	TRANSFER AGREEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	Transfer Agreement *(Condition of Participation)*				
F781	SNF (405.1133) ☐ MET ☐ NOT MET				
F782	ICF (442.316) (Standard) ☐ MET ☐ NOT MET				
F783	The facility has in effect a transfer agreement with one or more hospitals approved for participation under the programs, which provides the basis for effective working arrangements under which inpatient hospital care or other hospital services are available promptly to the facility's residents when needed. (A facility that has been unable to establish a transfer agreement with the hospital(s) in the community or service area after documented attempts to do so is considered to have such an agreement in effect.) Exception: A facility that has been unable to establish a written agreement after documented attempts to do so, is considered to have such an agreement.				
	Resident Transfer				
F784	SNF (405.1133(a)) (Standard) ☐ MET ☐ NOT MET				
F785	A hospital and a skilled nursing facility shall be considered to have a transfer agreement in effect if, by reason of a written agreement between them or (in case of two institutions are under common control) by resaon of a written undertaking by the person or body which controls them, there is reasonable assurance that: 1. Transfer of patients will be effected between the hospital and the skilled nursing facility, ensuring timely admission, whenever such transfer is medically appropriate as determined by the attending physician.				

NAME OF FACILITY

CODE	TRANSFER AGREEMENT/PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F786	2. There will be interchange of medical and other information necessary or useful in the care and treatment of individuals transferred between institutions, or in determining whether such individuals can be adequately cared for otherwise than in either of such institutions.				
F787	3. Security and accountability for residents' personal effects are provided on transfer.				
	Physical Environment *(Condition of Participation)*				
F788	SNF (405.1134) ☐ MET ☐ NOT MET The facility is constructed, equipped, and maintained to protect the health and safety or residents, personnel, and the public.				
	A. **Life Safety from Fire** SNF (405.1134(a)) (Standard) ☐ MET ☐ NOT MET				
	ICF (442.321) (Standard) ☐ MET ☐ NOT MET				
	(See appropriate HCFA Fire Safety survey form.)				
	B. **Maintenance of Equipment, Building, and Grounds**				
F789	SNF (405.1134(i)) (Standard) ☐ MET ☐ NOT MET				
F790	The facility establishes a written preventative maintenance program to ensure that all equipment is operative.				

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NAME OF FACILITY

CODE	INFECTION CONTROL	YES	NO	N/A	EXPLANATORY STATEMENT
	Infection Control *(Condition of Participation)*				
F791	SNF (405.1135) ☐ MET ☐ NOT MET The facility establishes an infection control committee of representative professional staff with responsibility for overall infection control in the facility. All necessary housekeeping and maintenance services are provided to maintain a sanitary and comfortable environment and to help prevent the development and transmission of infection.				
	A. **Infection Control Committee**				
F792	SNF (405.1135(a)) (Standard) ☐ MET ☐ NOT MET				
F793	1. The infection control committee is composed of members of the medical and nursing staffs, administration, and the dietetic, pharmacy, housekeeping, maintenance, and other services.				
F794	2. The committee establishes policies and procedures for investigating, controlling, and preventing infection in the facility.				
F795	3. The committee monitors staff performance to ensure that the policies and procedures are executed.				
	B. **Aseptic and Isolation Techniques**				
F796	SNF (405.1135(b)) (Standard) ☐ MET ☐ NOT MET				
F797	1. The facility has written procedures for aseptic and isolation techniques.				
F798	2. These procedures are reviewed and revised for effectiveness and improvement as necessary.				

NAME OF FACILITY

CODE	INFECTION CONTROL	YES	NO	N/A	EXPLANATORY STATEMENT
	C. **Housekeeping**				
F799	SNF (405.1135(c)) (Standard) ☐ MET ☐ NOT MET				
F800	1. The facility employs sufficient housekeeping personnel.				
F801	2. Provides all necessary equipment to maintain a safe, clean and orderly interior.				
F802	3. A full-time employee is designated responsible for the services and for supervision and training of personnel.				
F803	4. If a facility has a contract with an outside resource for housekeeping services, the facility and/or outside resource meets the requirements of the standards.				
	D. **Pest Control**				
F804	SNF (405.1135(e)) (Standard) ☐ MET ☐ NOT MET The facility has an ongoing pest control program.				

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NAME OF FACILITY

CODE	DISASTER PREPAREDNESS	YES	NO	N/A	EXPLANATORY STATEMENT
	Disaster Preparedness *(Condition of Participation)*				
F805	SNF (405.1136) ☐ MET ☐ NOT MET The facility has a written plan, periodically rehearsed, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (residents and personnel) arising from such disasters.				
	A. **Plan**				
F806	ICF (442.313) (Standard) ☐ MET ☐ NOT MET				
F807	1. The facility has a written plan for staff and residents to follow in case of emergencies such as fire or explosion.				
F808	2. The facility rehearses the plan regularly.				
F809	3. The facility has written procedures for the staff to follow in case of an emergency involving an individual resident.				
F810	4. These procedures include: a. Caring for the resident.				
F811	b. Notifying the attending physician and other individuals responsible for the resident.				
F812	c. Arranging for transportation, hospitalization, and other appropriate services.				
F813	SNF (405.1136(a)) (Standard) ☐ MET ☐ NOT MET				
F814	1. The facility has an acceptable written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster.				
F815	2. The plan is developed and maintained with the assistance of qualified fire, safety, and other appropriate experts.				

NAME OF FACILITY

CODE	DISASTER PREPAREDNESS/UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F816	3. Includes procedures for prompt transfer of casualties and records.				
F817	4. Instructions regarding the location and use of alarm systems and signals and of fire-fighting equipment.				
F818	5. Information regarding methods of containing fire.				
F819	6. Procedures for notification of appropriate persons.				
F820	7. Specifications of evacuation routes and procedures. (See §405.1134(a).)				
	B. Orientation and training				
F821	SNF (405.1136(b)) (Standard) ☐ MET ☐ NOT MET				
F822	The disaster program includes orientation and ongoing training and drills for all personnel in all procedures so that each employee promptly and correctly carries out a specific role in case of a disaster (See §405.1121(h).)				
	Utilization Review *(Condition of Participation)*				
F823	SNF (405.1137) ☐ MET ☐ NOT MET The facility carries out utilization review of the services provided in the facility to residents who are entitled to benefits under the program(s). Utilization review assures the maintenance of high quality care and appropriate and efficient utilization of facility services. There are two elements to utilization review: medical care evaluation studies and review of extended duration cases.				

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NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
	A. Plan				
F824	SNF (405.1137(a)) (Standard) ☐ MET ☐ NOT MET				
F825	1. The facility has a currently applicable written description of its utilization review plan.				
F826	2. Such description includes:				
	a. The organization and composition of the committee or group which will be responsible for the utilization review function.				
F827	b. Methods of criteria (including norms where available) to be used to define periods of continuous extended duration and to assign or select subsequent dates for continued stay review.				
F828	c. Methods for selection and conduct of medical care evaluation studies.				
	B. Organization and Composition of Utilization Review Committees				
F829	SNF (405.1137(b)) (Standard) ☐ MET ☐ NOT MET				
F830	1. The utilization review (UR) function is conducted by:				
	a. A staff committee of the skilled nursing facility which is composed of two or more physicians, with participation of other professional personnel; or,				

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NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F831	b. A group outside the facility which is similarly composed and which is established by the local medical or osteopathic society and some or all of the hospitals and skilled nursing facilities in the locality; or (indicate name of the outside group and briefly describe the organization.)				
F832	c. A group established and organized in a manner approved by the Secretary that is capable of performing such function.				
F833	2. The medical care evaluation studies, educational duties of the review program, and the review of admissions and long-stay cases are performed by: a. the same committee or group;				
F834	b. or more committees or groups. Briefly explain who performs these functions.				
	C. Medical Care Evaluation Studies				
F835	**SNF (405.1137(c))** (Standard) ☐ MET ☐ NOT MET				
F836	1. Medical care evaluation studies are performed to promote the most effective and efficient use of available health facilities and services consistent with resident needs and professionally recognized standards of health care.				
F837	2. Studies emphasize identification and analysis of patterns of resident care and suggest, where appropriate, possible changes for maintaining consistently high quality care and effective and efficient use of services.				

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NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F838	3. Each medical care evaluation study identifies and analyzes factors related to the care rendered in the facility and where indicated, results in recommendations for change beneficial to residents, staff, the facility, and the community.				
F839	4. Studies, on a sample or other basis, include, but need not be limited to, admissions, durations of stay, ancillary services furnished (including drugs and biologicals), and professional services performed on premises.				
F840	At least one study was completed during the last year. Type of study last completed: _____				
	D. **Extended Stay Review**				
F841	SNF (405.1137(d)) (Standard) ☐ MET ☐ NOT MET				
F842	1. Periodic review is made of each current inpatient skilled nursing facility beneficiary case of continuous extended duration, and the length of which is defined in the utilization review plan to determine whether further inpatient stay is necessary.				
F843	2. The review is based on the attending physician's reasons for and plan for continued stay and any other documentation the committee or group deems appropriate.				
F844	3. Cases are screened by: a. A qualified non-physician representative of the committee.				
F845	b. The group.				
F846	c. The reviewer uses criteria established by the physician members of the committee.				

NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F847	4. In instances when non-physician members are utilized, those cases are referred to a physician member for further review when it appears that the resident no longer requires further inpatient care.				
F848	5. Non-physician representatives used to screen extended stay review cases, have experience in such screening or appropriate training in the application of the screening criteria used, or both.				
F849	6. Before the expiration of each new period, the case must be reviewed again in like manner with such reviews being repeated as long as the stay continues beyond the scheduled review dates and notice has not been given pursuant to paragraph (e) of this section.				
	E. **Further Stay Not Medically Necessary**				
F850	SNF (405.1137(e)) (Standard) ☐ MET ☐ NOT MET				
F851	1. A final determination of the committee or group that continued stay is not medically necessary is made by at least two physician members of the committee or group, except that the final determination may be made by one physician where the attending physician, when given an opportunity to express his views, does not do so, or does not contest the finding that the continued stay is not medically necessary.				
F852	2. If the committee or group, or its nonphysician representative where a physician member concurs, has reason to believe from the review of an extended duration case or a case reviewed as part of a medical care evaluation study that further stay is no longer medically necessary, the committee or group shall notify the individual's attending physician and afford him an opportunity to present his views before it makes a final determination.				

NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F853	3. If the final determination of the committee or group is that further stay is no longer medically necessary, written notification of the finding is given to the facility, the attending physician, and the individual (or where appropriate, his next of kin) no later than 2 days after such final determination is made and, in no event in the case of an extended duration case, later than 3 working days after the end of the extended duration period specified pursuant to paragraph (d) of this section.				
	F. Administrative Responsibilities				
F854	SNF (405.1137(f)) (Standard) ☐ MET ☐ NOT MET				
F855	The administrative staff of the facility is kept directly and fully informed of committee activities to facilitate support and assistance. (Explain)				
	G. Utilization Review Records				
F856	SNF (405.1137(g)) (Standard) ☐ MET ☐ NOT MET				
F857	1. Written records of committee activities are maintained.				
F858	2. Appropriate reports, signed by the committee chairman, are made regularly to the medical staff, administrative staff, governing body, and sponsors (if any).				
F859	3. Minutes of each committee meeting is maintained and include at least: a. Name of committee.				
F860	b. Date and duration of meeting.				
F861	c. Names of committee members present and absent.				

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NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F862	4. Description of activities presently in progress to satisfy the requirements for medical care evaluation studies, including the subject, reason for study, dates of commencement and expected completion, summary of studies completed since the last meeting, conclusions and follow-up on implementation of recommendations made from previous studies.				
F863	5. Summary of extended duration cases reviewed including the number of cases, identification number, admission and review dates, and decision reached, including the basis for each determination and action taken for each case not approved for extended care.				
	H. **Discharge Planning**				
F864	SNF (405.1137(h)) (Standard) ☐ MET ☐ NOT MET The facility maintains a centralized, coordinated program to ensure that each resident has a planned program of continuing care which meets his postdischarge needs.				
F865	1. The facility has in operation an organized discharge planning program.				
F866	The utilization review committee, in its evaluation of the current status of each extended duration case, has available to it the results of such discharge planning and information on alternative available community resources to which the resident may be referred.				
F867	2. The facility maintains written discharge planning procedures which describe: a. How the discharge coordinator will function, and his authority and relationships with the facility's staff.				
F868	b. The maximum time period after which reevaluation of each resident's discharge plan is made.				

NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F869	c. Local resources available to the facility, the resident, and the attending physician to assist in developing and implementing individual discharge plans; and				
F870	d. Provisions for periodic review and reevaluation of the facility's discharge planning program.				
F871	3. At the time of discharge, the facility provides those responsible for the resident's post discharge care with appropriate summary of information about the discharged resident to ensure the optimal continuity of care.				
	The discharge summary includes at least the following:				
F872	a. Current information relative to diagnoses.				
F873	b. Rehabilitation potential.				
F874	c. A summary of the course of prior treatment.				
F875	d. Physician orders for the immediate care of the resident.				
F876	e. Pertinent social information.				

Form HCFA-525 (2-86)

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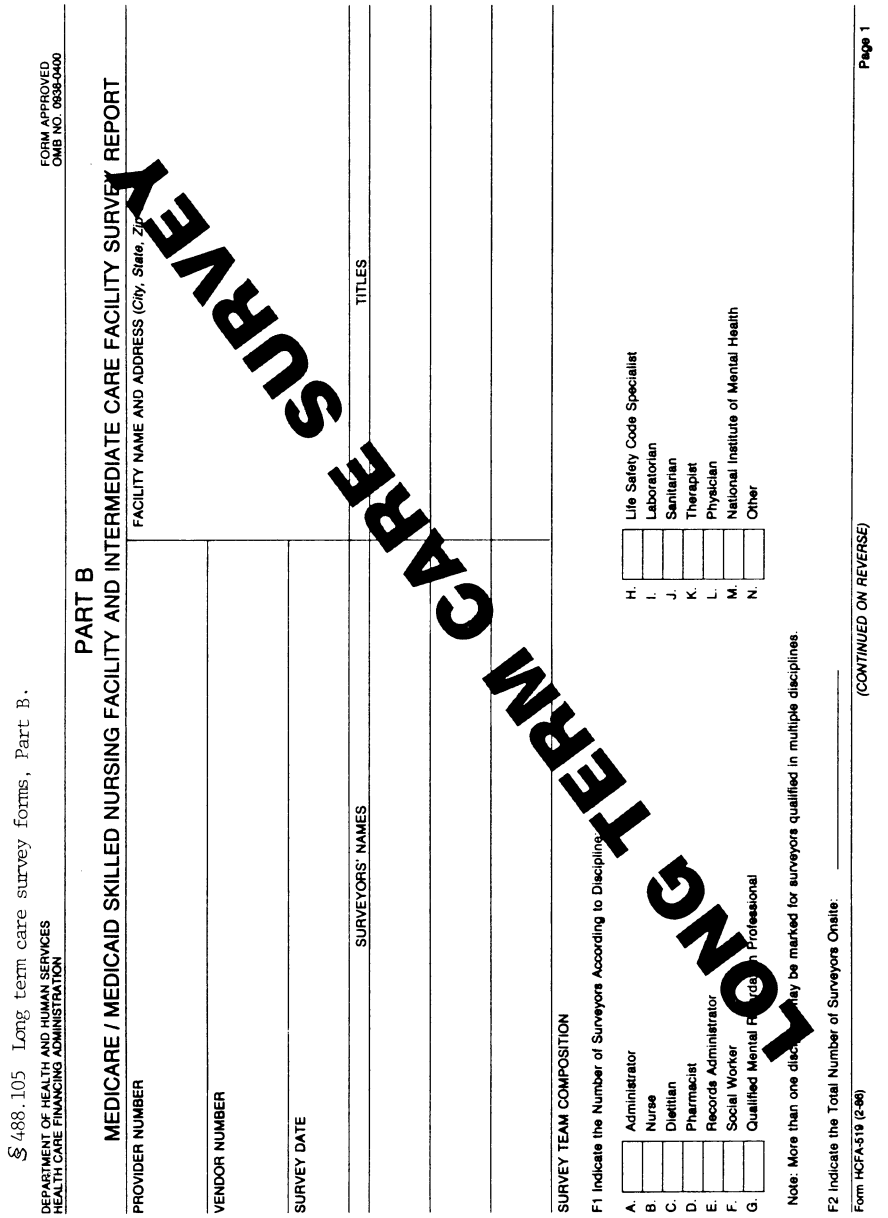
§ 488.105 Long term care survey forms, Part B.



RESIDENT CENSUS AND CONDITIONS OF RESIDENTS

PROVIDER NO. _____ | F3 ☐ MEDICARE _____ | F4 ☐ MEDICAID _____ | F5 ☐ OTHER _____ | F6 TOTAL RESIDENTS _____

CODE		
	BATHING	
F7	___	Number of residents requiring assistance in bathing more than one part of body—or does not bathe self.
F8	___	Number of residents requiring assistance in bathing only a single part (as back or disabled extremity) or bathes self completely.
F9	___	**TOTAL***
	DRESSING	
F10	___	Number of residents totally dressed by another person.
F11	___	Number of residents needing assistance to dress self or remain partly dressed. (Exclude those residents totally dressed.)
F12	___	Number of residents able to get clothes from closets and drawers-puts on clothes, outer garments, braces-manages fasteners. Act of tying shoes is excluded.
F13	___	**TOTAL***
	TOILETING	
F14	___	Number of residents not toileted. (Use protective padding, catheter.)
F15	___	Number of residents who must use a bedpan or commode and/or receive assistance in getting to and using a toilet.
F16	___	Number of residents able to get to toilet—gets on and off toilet—cleans self—arranges clothes.
F17	___	**TOTAL***
	TRANSFERRING	
F18	___	Number of residents needing assistance in all transfers (moving in or out of bed and/or chair, toilet, tub transfers).
F19	___	Number of residents needing assistance in transferring to toilet and tub only.
F20	___	Number of residents able to complete all transfers independently (may or may not be using mechanical supports).
F21	___	Total*

CODE		
	CONTINENCE	
F22	___	Number of residents with indwelling or external catheters.
F23	___	Number of residents with partial or total incontinence in urination or defecation—partial or total control by suppositories or enemas, regulated use of urinals and/or bedpans.
F24	___	Number of residents with urination and defecation entirely self-controlled.
F25	___	**TOTAL***
	FEEDING	
F26	___	Number of residents who receive enteral/parenteral feedings.
F27	___	Number of residents who receive NG tube feedings.
F28	___	Number of residents who require assistance in act of eating.
F29	___	Number of residents who get food from plate or its equivalent into mouth—(pre-cutting of meat and preparation of food, buttering bread, opening cartons, removing plate covers, etc., are *excluded* from evaluation).
F30	___	**TOTAL***
F31	___	Number of completely bedfast residents.
F32	___	Number of chairbound residents.
F33	___	Number of ambulatory residents (may use cane, walker, or crutches).
F34	___	Number of physically restrained residents (belt, vest, cuffs).
F35	___	Number of residents receiving psychotropic drugs.
F36	___	Number of confused or disoriented residents.
F37	___	Number of residents with decubiti.
F38	___	Number of residents on individually written bowel and bladder retraining program.
F39	___	Number of residents receiving special skin care.
F40	___	Number of residents receiving intravenous therapy and/or blood transfusion.
F41	___	Number of residents requiring no assistance in ADLs.
F42	___	Number of residents on self-administration of drugs.
F43	___	Number of residents with contractures.
F44	___	Number of residents receiving respiratory care.
F45	___	Number of residents receiving tracheostomy care.
F46	___	Number of residents receiving suctioning.
F47	___	Number of residents receiving rehabilitative services (physical therapy, speech pathology and audiology, occupational therapy)
F48	___	Number of residents receiving injections.
F49	___	Number of residents receiving colostomy care.

Form HCFA-519 (2-86) *MUST EQUAL TOTAL NUMBER OF RESIDENTS IN FACILITY Page 2

NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
	GOVERNING BODY *(CONDITION OF PARTICIPATION)*				
F50	SNF (405.1121) ☐ MET ☐ NOT MET				
	RESIDENT RIGHTS				
F51	SNF (405.1121(k)) (Standard) ☐ MET ☐ NOT MET Indicators A thru K apply to this standard for SNFs.				
F52	ICF (442.311) (Standard) ☐ MET ☐ NOT MET Indicators A thru K apply to this standard for ICFs.				
	A. Information				
F53	1. The facility informs each resident, before or at the time of admission, of his/her rights and responsibilities.				
F54	2. The facility informs each resident, before or at the time of admission, of all rules governing resident conduct.				
F55	3. The facility informs each resident of amendments to their policies on residents' rights and responsibilities and rules governing conduct.				
F56	4. Each resident acknowledges in writing receipt of residents' rights information and any amendment to it.				
F57	5. The resident must be informed in writing of all services and charges for services.				
F58	6. The resident must be informed in writing of all changes in services and charges before or at the time of admission and on a continuing basis.				
F59	7. The resident must be informed of services not covered by Medicare or Medicaid and not covered in the basic rate.				

NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
	B. Medical Condition and Treatment				
F60	1. Each resident is informed by a physician of his/her health and medical condition unless the physician decides that informing the resident is medically contraindicated.				
F61	2. Each resident is given an opportunity to participate in planning his/her total care and medical treatment.				
F62	3. Each resident is given an opportunity to refuse treatment.				
F63	4. Each resident gives informed, written consent before participating in experimental research.				
F64	5. If the physician decides that informing the resident of his/her health and medical condition is medically contraindicated, the physician has documented this decision in the resident's medical record.				
	C. Transfer and Discharge				
	Each resident is transferred or discharged only for:				
F65	1. Medical reasons.				
F66	2. His/her welfare or that of other residents.				
F67	3. Nonpayment except as prohibited by the Medicare or Medicaid program.				
F68	4. Each resident is given reasonable advance notice to ensure orderly transfer or discharge. EXCEPTION: Not required for ICF residents.				
	D. Exercising Rights				
F69	1. Each resident is encouraged and assisted to exercise his/her rights as a resident of the facility and as a citizen.				
F70	2. Each resident is allowed to submit complaints and recommendations concerning the policies and services of the facility to staff or to outside representatives of the resident's choice or both.				

NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
F71	3. Such complaints are submitted free from restraint, coercion, discrimination, or reprisal.				
	E. Financial Affairs				
F72	1. Residents are allowed to manage their own personal financial affairs.				
F73	2. The facility establishes and maintains a system that assures full and complete accounting of residents' personal funds. An accounting report is made to each resident in a skilled nursing facility at least on a quarterly basis.				
F74	3. The facility does not commingle resident funds with any other funds.				
F75	4. If a resident requests assistance from the facility in managing his/her personal financial affairs, resident's delegation is in writing.				
F76	5. The facility system of accounting includes written receipts for: All personal possessions and funds received by or deposited with the facility.				
F77	All disbursements made to or for the resident.				
F78	6. The financial record must be available to the resident and his/her family.				
	F. Freedom from Abuse and Restraints				
F79	1. Each resident is free from mental and physical abuse.				
F80	2. Chemical and physical restraints are only used when authorized by a physician in writing for a specified period of time or in emergencies.				

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NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
F81	3. If used in emergencies, they are necessary to protect the resident from injury to himself/herself or others.				
F82	4. The emergency use is authorized by a professional staff member identified in the written policies and procedures of the facility.				
F83	5. The emergency use is reported promptly to the resident's physician by the staff member.				
	G. Privacy				
F84	1. Each resident is treated with respect, consideration and full recognition of his/her dignity and individuality.				
F85	2. Each resident is given privacy during treatment and care of personal needs.				
F86	3. Each resident's records, including information in an automated data bank, are treated confidentially.				
F87	4. Each resident must give written consent before the facility releases information from his/her record to someone not otherwise authorized to receive it.				
F88	5. Married residents are given privacy during visits by their spouses.				
F89	6. Married residents are permitted to share a room.				
	H. Work				
F90	No resident may be required to perform services for the facility.				

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NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
	I. Freedom of Association and Correspondence				
F91	1. Each resident is allowed to communicate, associate and meet privately with individuals of his/her choice unless this infringes upon the rights of another resident.				
F92	2. Each resident is allowed to send and receive personal mail unopened.				
	J. Activities				
F93	Each resident is allowed to participate in social, religious, and community group activities.				
	K. Personal Possessions				
F94	Each resident is allowed to retain and use his/her personal possessions and clothing as space permits.				
	L. Delegation of Rights and Responsibilities				
F95	ICF (442.312) (Standard) ☐ MET ☐ NOT MET				
F96	1. All the rights and responsibilities of a resident pass to the resident's guardian, next of kin or sponsoring agency or agencies if the resident is adjudicated incompetent under State law or is determined by his/her physician to be incapable of understanding his/her rights and responsibilities.				
F97	2. Physician determinations of incapability and the specific reasons thereof are recorded by the physician in the resident's record.				

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NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
F98	STAFF DEVELOPMENT SNF (405.1121(h)) (Standard) ☐ MET ☐ NOT MET				
F99	ICF (442.314) (Standard) ☐ MET ☐ NOT MET				
F100	1. Facility staff are knowledgeable about the problems and needs of the aged, ill, and disabled.				
F101	2. Facility staff practices proper techniques in providing care to the aged, ill, and disabled.				
F102	3. Facility staff practice proper technique for prevention and control of infection, fire prevention and safety, accident prevention, confidentiality of resident information, and preservation of resident dignity, including protection of privacy and personal and property rights.				
	STATUS CHANGE NOTIFICATIONS				
F103	SNF (405.1121(j)) (Standard) ☐ MET ☐ NOT MET				
F104	ICF (442.307) (Standard) ☐ Met ☐ Not Met				
F105	1. The facility notifies the resident's attending physician and other responsible persons in the event of an accident involving the resident, or other significant change in the resident's physical, mental, or emotional status, or resident charges, billings, and related administrative matters.				
F106	2. Except in a medical emergency, a resident is not transferred or discharged, nor is treatment altered radically, without consultation with the resident or, if the resident is incompetent, without prior notification of next of kin or sponsor.				

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NAME OF FACILITY

CODE	PHYSICIANS' SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	PHYSICIANS' SERVICES *(CONDITION OF PARTICIPATION)*				
F107	SNF (405.1123) ☐ MET ☐ NOT MET				
	A. Medical Findings and Orders at Time of Admission				
F108	SNF (405.1123(a)) (Standard) ☐ MET ☐ NOT MET				
F109	1. There is made available to the facility prior to or at the time of admission, resident information which includes current medical findings, diagnoses, and orders from a physician for immediate care of the resident.				
F110	2. Information about the rehabilitation potential of the resident and a summary of prior treatment are made available to the facility at the time of admission or within 48 hours thereafter.				

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NAME OF FACILITY

CODE	PHYSICIANS' SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	B. Resident Supervision by Physician				
F111	SNF (405.1123(b)) (Standard) ☐ MET ☐ NOT MET				
F112	ICF (442.346) (Standard) ☐ MET ☐ NOT MET **Indicators B and C apply to** this standard for ICFS.				
F113	1. Every resident must be under the supervision of a physician.				
F114	2. A physician prescribes a planned regimen of care based on a medical evaluation of each resident's immediate and long-term care needs. **Exception: Not required for ICF residents**				
F115	3. A physician is available to provide care in the absence of any resident's attending physician.				
F116	4. Medical evaluation is done within 48 hours of admission unless done within 5 days prior to admission. **Exception: Not required for ICF residents.**				
F117	5. Each resident is seen by their attending physician at least once every 30 days for the first 90 days after admission. **Exception: ICF residents must be seen every 60 days unless otherwise justified and documented by the attending physician.**				
F118	6. Each resident's total program of care including medications and treatments is reviewed during a visit by the attending physician at least once every 30 days for the first 90 days and revised as necessary. **Exception: Only medications must be reviewed quarterly for ICF residents.**				

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NAME OF FACILITY

CODE	PHYSICIANS' SERVICES/NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F119	7. Progress notes are written and signed by the physician at the time of each visit, and all orders are signed by the physician.				
F120	8. Alternate physician visit schedules that exceed a 30-day schedule adopted after the 90th day following admission are justified by the attending physician in the medical record. These visits cannot exceed 60 days or apply to residents who require specialized rehabilitation schedules. EXCEPTION: Not required for ICF residents.				
	C. **Emergency Services**				
F121	SNF (405.1123(c)) (Standard) ☐ MET ☐ NOT MET				
F122	Emergency services from a physician are available and provided to each resident who requires emergency care.				
	NURSING SERVICES *(CONDITION OF PARTICIPATION)*				
F123	SNF (405.1124) ☐ MET ☐ NOT MET				
F124	SNF (405.1124(c)) (Standard) ☐ Met ☐ Not Met Indicators A and B apply to this standard for SNFs.				
F125	ICF (442.338) ☐ Met ☐ Not Met Indicators A thru E apply to this standard for ICFs except where noted.				
F126	A. The facility provides nursing services which are sufficient to meet nursing needs of all residents all hours of each day. 1. Each resident receives all treatments, medications and diet as prescribed. Deviations are reported and appropriate action is taken.				

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NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F127	2. Each resident receives daily personal hygiene as needed to assure cleanliness, good skin care, good grooming, and oral hygiene taking into account individual preferences. Residents are encouraged to engage in self care activity.				
F128	3. Each resident receives care necessary to prevent skin breakdown.				
F129	4. Each resident with a decubitus receives care necessary to promote the healing of the decubitus including proper dressing.				
F130	5. When residents require restraints the application is ordered by the physician, applied properly, and released at least every 2 hours.				
F131	6. Each resident with incontinence is provided with care necessary to encourage continence including frequent toileting and opportunities for rehabilitative training.				
F132	7. Each resident with a urinary catheter receives proper routine care including periodic evaluation.				
F133	8. Each resident receives proper care for the following needs: Injections Parenteral Fluids Colostomy/Ileostomy Respiratory Care Tracheostomy Care Suctioning Tube Feeding				
F134	9. Infection Control Techniques are properly carried out in the provision of care to each resident.				

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NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F135	10. Proper nursing and sanitary procedures and techniques are used when medications are given to residents.				
F136	11. Adequate resident care supplies are available for providing treatments.				
	B. **Twenty-Four Hour Nursing Service**				
F137	1. Nursing personnel,including registered nurses, licensed practical (vocational) nurses, nurse aides, orderlies, and ward clerks, are assigned duties consistent with their education and experience, and based on the characteristics of the resident load. EXCEPTION: Not required for ICFs.				
F138	2. Weekly time schedules are maintained and indicate the number and classifications of nursing personnel including relief personnel, who worked on each unit for each tour of duty. (If a distinct part certification, show the staffing for the DP and, if appropriate, any nonparticipating remainder and explain any sharing of nursing personnel.) **Exception: Not required for Freestanding ICFs.**				
F139	3. There is a sufficient number of nursing staff available to meet the total needs of all residents.				
F140	4. There is a registered nurse on the day tour of duty 7 days a week. **Exception: Not required for ICF residents.**				

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	C. Charge Nurse				
F141	SNF (405.1124(b)) (Standard) ☐ MET ☐ NOT MET				
F142	1. A registered nurse or a qualified licensed practical (or vocational) nurse is designated as charge nurse by the director of nursing for each tour of duty. **Exception: Not required for ICFs.**				
F143	2. The director of nursing services does not serve as charge nurse in a facility with an average daily total occupancy of 60 or more residents. **Exception: Not required for ICFs.**				
F144	3. The ICF must have a registered nurse, or a licensed practical or vocational nurse full-time, 7 days a week, on the day shift. **Exception: Not required for SNFs.**				

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NAME OF FACILITY

List the number of full-time equivalents of RN's, LPN's, Aides/Orderlies assigned to nursing duty from the last 3 complete weeks. (Note only actual staff on duty.)

Shift		CODE	Day 1			Day 2			Day 3			Day 4			Day 5			Day 6			Day 7		
			RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A
DAY	DP	F145																					
	Entire Facility	F146																					
EVENING	DP	F147																					
	Entire Facility	F148																					
NIGHT	DP	F149																					
	Entire Facility	F150																					

Shift		CODE	Day 1			Day 2			Day 3			Day 4			Day 5			Day 6			Day 7		
			RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A
DAY	DP																						
	Entire Facility																						
EVENING	DP																						
	Entire Facility																						
NIGHT	DP																						
	Entire Facility																						

NAME OF FACILITY

Shift		CODE	Day 1			Day 2			Day 3			Day 4			Day 5			Day 6			Day 7		
			RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A
DAY	DP	F151																					
	Entire Facility	F152																					
EVENING	DP	F153																					
	Entire Facility	F154																					
NIGHT	DP	F155																					
	Entire Facility	F156																					

STAFFING PATTERN WORKSHEETS DAY OF SURVEY (OPTIONAL)

ENTIRE FACILITY STAFFING PATTERN (DAY OF SURVEY)

	CODE		RN	PN	A
DAY	F157	REPORT			
	F158	ACTUAL			
EVENING	F159	REPORT			
	F160	ACTUAL			
NIGHT	F161	REPORT			
	F162	ACTUAL			

UNIT STAFFING PATTERN WORKSHEET (DAY OF SURVEY)

	CODE	Unit			Unit			Unit			Unit			Unit			Unit			Unit		
		RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A
DAY	F163																					
EVENING	F164																					
NIGHT	F165																					
CENSUS	F166																					

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	D PATIENT CARE MANAGEMENT				
F167	SNF (405.1124(d)) (Standard) ☐ MET ☐ NOT MET				
F168	ICF (442.341) (Standard) ☐ MET ☐ NOT MET				
F169	1. Each resident's needs are addressed in a written plan of care which demonstrates that the plans of all services are integrated, consonant with the physician's plan of medical care, and implemented shortly after admission.				
F170	2. Each professional service identifies needs, goals, plans, and evaluates the effectiveness of interventions, plus institutes changes in the plan of care in a timely manner.				
	E. Rehabilitative Nursing Services are performed daily, and recorded for those residents who require such service.				
F171	SNF (405.1124(e)) (Standard) ☐ MET ☐ NOT MET				
F172	ICF (442.342) (Standard) ☐ Met ☐ Not Met				
F173	1. Each resident receives rehabilitative nursing care to promote maximum physical functioning to prevent immobility, deformities, and contractures.				
F174	2. There is an ongoing evaluation of each resident's rehabilitative nursing needs. This may include;				
F175	(a) Range of motion, ambulation, turning and positioning and other activities;				
F176	(b) Assistance and instruction in the activities of daily living such as feeding, dressing, grooming, oral hygiene and toilet activities;				
F177	(c) Remotivation therapy and/or reality orientation when appropriate.				
F178	3. These activities are coordinated with other resident care services.				

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NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	F. The facility has an awareness of nutritional needs and fluid intake of residents and provides prompt assistance where necessary in feeding residents.				
F179	SNF (405.1124(f)) (Standard) ☐ MET ☐ NOT MET				
F180	1. Each resident is provided with the amount of food and fluid on a daily basis necessary to maintain their appropriate minimum average weight. Between meal feedings are offered and the amount consumed is observed. Daily food and fluid intake is observed and encouraged.				
F181	2. Each resident needing assistance in eating or drinking is provided prompt assistance. Specific self-help devices are available when necessary.				
F182	3. Deviations from normal food and fluid intake are recorded and reported to the charge nurse and the attending physician.				

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NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	G. **Administration of Drugs**				
F183	SNF (405.1124(g)) (Standard) ☐ MET ☐ NOT MET				
F184	ICF (442.337) (Standard) ☐ MET ☐ NOT MET				
F185	1. The resident is identified prior to administration of a drug.				
F186	2. Drugs and biologicals are administered as soon as possible after doses are prepared.				
F187	3. Administered by same person who prepared the doses for administration except under single unit dose package distribution systems.				
F188	**Exception: ICF residents may self administer medication only with their physician's permission.**				
	H. **Conformance with Physician Drug Orders**				
F189	SNF (405.1124(h)) (Standard) ☐ MET ☐ NOT MET				
F190	ICF (442.334) (Standard) ☐ MET ☐ NOT MET				
F191	Drugs are administered in accordance with written orders of the attending physician.				
F192	Drug Error Rate _____% (See Form HCFA-522)				

Form HCFA-519 (2-86) Page 17

NAME OF FACILITY

CODE	DIETETIC SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	DIETETIC SERVICES *(CONDITION OF PARTICIPATION)*				
F193	SNF (405.1125) ☐ MET ☐ NOT MET				
F194	ICF (442.332) (Standard) ☐ MET ☐ NOT MET Indicators A and B apply to this standard for ICFS.				
	A. Menus and Nutritional Adequacy				
F195	SNF (405.1125(b)) (Standard) ☐ MET ☐ NOT MET				
F196	Menus are planned and followed to meet the nutritional needs of each resident in accordance with physicians' orders and, to the extent medically possible, based on the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences.				
	B. Therapeutic Diets				
F197	SNF (405.1125(c)) (Standard) ☐ MET ☐ NOT MET				
F198	1. Therapeutic diets are prescribed by the attending physician.				
F199	2. Therapeutic menus are planned in writing, prepared, and served as ordered with supervision from the dietitian and advice from the physician whenever necessary.				
F200	Number of Regular Diets_____				
F201	Number of Therapeutic Diets_____				
F202	Number of Mechanically Altered Diets _____				
F203	Number of Tube Feedings_____				

Form HCFA-519 (2-86)

Page 18

NAME OF FACILITY

CODE	DIETETIC SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	C. **Preparation**				
F204	SNF (405.1125(e)) (Standard) ☐ MET ☐ NOT MET				
F205	1. Food is prepared by methods that conserve its nutritive value and flavor.				
F206	2. Meals are palatable, served at proper temperatures. They are cut, ground, chopped, pureed or in a form which meets individual resident needs.				
F207	3. If a resident refuses food served, appropriate substitutes of similar nutritive value are offered.				
	D. **Frequency**				
F208	SNF (405.1125(d)) (Standard) ☐ MET ☐ NOT MET				
F209	ICF (442.331) (Standard) ☐ MET ☐ NOT MET				
F210	1. At least three meals are served daily at regular hours with not more than a 14-hour span between a substantial evening meal and breakfast.				
F211	2. To the extent medically possible, bedtime nourishments are offered to all residents. **Exception: Not required for ICF Residents.**				
	E. **Staffing**				
F212	SNF (405.1125.(a)) (Standard) ☐ MET ☐ NOT MET				
F213	1. Food service personnel are on duty daily over a period of 12 or more hours.				

Form HCFA-519 (2-86)

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NAME OF FACILITY

CODE	SPECIALIZED REHABILITATIVE SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	SPECIALIZED REHABILITATIVE SERVICES *(CONDITION OF PARTICIPATION)*				
F214	SNF (405.1126) ☐ MET ☐ NOT MET				
F215	SNF (405.1128(b)) (Standard) ☐ MET ☐ NOT MET				
F216	ICF (442.343) (Standard) ☐ MET ☐ NOT MET				
	A. Plan of Care				
F217	Rehabilitative services are provided under a written plan of care, initiated by the attending physician and developed in consultation with appropriate therapists(s) and the nursing service.				
	B. Therapy				
F218	Therapy is provided according to orders of the attending physician in accordance with accepted professional practices by qualified therapists or qualified assistants.				
	C. Progress				
F219	1. A report of the resident's progress is communicated to the attending physician within 2 weeks of the initiation of specialized rehabilitative services. **Exception: ICF resident's progress must be reviewed regularly.**				

Form HCFA-519 (2-86) Page 20

NAME OF FACILITY

CODE	SPECIALIZED REHABILITATIVE SERVICES/PHARMACEUTICAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F220	2. The resident's progress is thereafter reviewed regularly, and the plan of rehabilitative care is reevaluated as necessary, but at least every 30 days, by the physician and the therapist. **Exceptions: ICF residents' plans must be revised as necessary.**				
	PHARMACEUTICAL SERVICES *(CONDITION OF PARTICIPATION)*				
F221	SNF (405.1127) ☐ MET ☐ NOT MET				
	A. **Supervision**				
F222	SNF (405.1127(a)) (Standard) ☐ MET ☐ NOT MET				
F223	ICF (442.336) (Standard) ☐ MET ☐ NOT MET				
F224	The pharmacist reviews the drug regimen of each resident at least monthly and reports any irregularities to the medical director and administrator.				

NAME OF FACILITY

CODE	PHARMACEUTICAL SERVICES LABORATORY AND RADIOLOGIC SERVICES/SOCIAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	B. Labeling of Drugs and Biologicals				
F225	SNF (405.1127(c)) (Standard) ☐ MET ☐ NOT MET				
F226	ICF (442.333) (Standard) ☐ MET ☐ NOT MET				
F227	The labeling of drugs and biologicals is based on currently accepted professional principles and includes the appropriate accessary and cautionary instructions as well as an expiration date when applicable.				
	LABORATORY AND RADIOLOGIC SERVICES *(CONDITION OF PARTICIPATION)*				
F228	SNF (405.1128) ☐ MET ☐ NOT MET				
F229	SNF (405.1128(a)) (Standard) ☐ MET ☐ NOT MET				
	Provision of Services				
F230	1. All services are provided only on the orders of a physician.				
F231	2. The attending physician is notified promptly of diagnostic findings.				
F232	3. Signed and dated reports of a clinical laboratory, X-ray and other diagnostic services are filed with the resident's medical record.				

Form HCFA-519 (2-86)

Page 22

NAME OF FACILITY

CODE	SOCIAL SERVICES/ACTIVITIES	YES	NO	N/A	EXPLANATORY STATEMENT
	SOCIAL SERVICES *(CONDITION OF PARTICIPATION)*				
F233	SNF (405.1130) ☐ MET ☐ NOT MET				
F234	SNF (405.1130(a)) (Standard) ☐ MET ☐ NOT MET				
F235	ICF (442.344) (Standard) ☐ MET ☐ NOT MET				
	A. Plan				
F236	The medically related social and emotional needs of the resident are identified.				
	B. Provision of Services				
F237	1. Services are provided to meet the social and emotional needs by the facility or by referral to an appropriate social agency.				
F238	2. If financial assistance is indicated, arrangements are made promptly for referral to an appropriate agency.				
	ACTIVITIES *(CONDITION OF PARTICIPATION)*				
F239	SNF(405.1131) ☐ MET ☐ NOT MET				
	Provision of Services				
F240	SNF (405.1131(b)) (Standard) ☐ MET ☐ NOT MET				

Form HCFA-519 (2-86) Page 23

NAME OF FACILITY

CODE	ACTIVITIES	YES	NO	N/A	EXPLANATORY STATEMENT
F241	ICF (442.345) (Standard) ☐ MET ☐ NOT MET				
F242	1. An ongoing program of meaningful activities is provided based on identified needs and interests of each resident. It is designed to promote opportunities for engaging in normal pursuits, including religious activities of their choice, if any.				
F243	2. Unless contraindicated by the attending physicians each resident is encouraged to participate in the activities program.				
F244	3. The activities promote the physical, social and mental well-being of the resident.				
F245	4. Equipment is maintained in good working order.				
F246	5. Supplies and equipment are available.				

Form HCFA-519 (2-86)

NAME OF FACILITY

CODE	MEDICAL RECORDS	YES	NO	N/A	EXPLANATORY STATEMENT
	MEDICAL RECORDS *(CONDITION OF PARTICIPATION)*				
F247	SNF (405.1132) ☐ MET ☐ NOT MET				
	Content				
F248	SNF (405.1132(c)) (Standard) ☐ MET ☐ NOT MET				
F249	ICF (442.318) (Standard) ☐ MET ☐ NOT MET				
F250	1. The medical record contains sufficient information to identify the resident clearly, to justify diagnoses and treatment, and to document results accurately.				

Form HCFA-519 (2-98) Page 25

NAME OF FACILITY

CODE	MEDICAL RECORDS	YES	NO	N/A	EXPLANATORY STATEMENT
	2. The medical record contains the following information:				
F251	a. Identification information				
F252	b. Admission data including past medical and social history				
F253	c. Transfer form, discharge summary from any transferring facility				
F254	d. Report of resident's attending physician				
F255	e. Report of physical examinations				
F256	f. Reports of physicians' periodic evaluations and progress notes				
F257	g. Diagnostic reports and therapeutic orders				
F258	h. Reports of treatments				
F259	i. Medications administered				
F260	j. An overall plan of care setting forth goals to be accomplished through each service's designed activities, therapies and treatments.				
F261	k. Assessments and goals of each service's plan of care				
F262	l. Treatments and services rendered				
F263	m. Progress notes				
F264	n. All symptoms and other indications of illness or injury including date, time and action taken regarding each problem.				

Form HCFA-519 (2-86) Page 26

NAME OF FACILITY

CODE		YES	NO	N/A	EXPLANATORY STATEMENT
	TRANSFER AGREEMENT *(CONDITION OF PARTICIPATION)*				
F265	SNF (405.1133) ☐ MET ☐ NOT MET				
F266	SNF (405.1133(a)) (Standard) ☐ MET ☐ NOT MET				
F267	ICF (442.316) (Standard) ☐ MET ☐ NOT MET				
F268	A. Whenever the attending physician determines that a transfer is medically appropriate between a hospital or a facility providing more specialized care and the nursing facility, admission to the new facility shall be effected in a timely manner.				
F269	B. Information necessary for providing care and treatment to transferred individuals is provided.				

Form HCFA-519 (2-86)

Page 27

NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	PHYSICAL ENVIRONMENT *(CONDITION OF PARTICIPATION)*				
F270	SNF (405.1134) ☐ MET ☐ NOT MET				
	A. Nursing Unit				
F271	SNF (405.1134(d)) (Standard) ☐ MET ☐ NOT MET				
F272	1. The unit is properly equipped for preparation and storage of drugs and biologicals.				
F273	2. Utility and storage rooms are adequate in size.				
F274	3. The unit is equipped to register resident calls with a functioning communication system from resident areas including resident rooms and toilet and bathing facilities.				
	B. Dining and Activities Area				
F275	SNF (405.1134(g) (Standard) ☐ MET ☐ NOT MET				
F276	ICF (442.329) (Standard) ☐ MET ☐ NOT MET				
F277	1. The facility provides one or more clean, orderly and appropriately furnished rooms of adequate size, designated for resident dining and resident activities.				
F278	2. Dining and activity rooms are well lighted and ventilated.				
F279	3. Any multipurpose room used for dining and resident activities has sufficient space to accommodate all activities and prevent their interference with each other.				

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NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F280	SNF (405.1134(e)) (Standard) ☐ MET ☐ NOT MET				
	INDICATORS C AND D APPLY TO THIS STANDARD FOR SNF				
	C. Resident Rooms				
F281	ICF (442.325) (Standard) ☐ MET ☐ NOT MET				
F282	1. Single resident rooms have at least 100 square feet.				
F283	2. Multiple resident rooms have no more than four residents and at least 80 square feet per resident.				
F284	3. Each room is equipped with or conveniently located near toilet and bathing facilities.				
F285	4. There is capability of maintaining privacy in each.				
F286	5. There is adequate storage space for each resident.				
F287	6. There is a comfortable and functioning bed and chair plus a functional cabinet and light.				
F288	7. The resident call system functions in resident rooms.				
F289	8. Each room is designed and equipped for adequate nursing care and the comfort and privacy of the residents.				
F290	9. Each room is at or above grade level.				
F291	10. Each room has direct access to a corridor and outside exposure. **Exception: Not required for ICF residents.**				

NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	D. Toilet and Bath Facilities				
F292	ICF (442.326) (Standard) ☐ MET ☐ NOT MET				
F293	1. Facilities are clean, sanitary and free of odors.				
F294	2. Facilities have safe and comfortable hot water temperatures.				
F295	3. Facilities maintain privacy.				
F296	4. Facilities have grab bars and other safeguards against slipping.				
F297	5. Facilities have fixtures in good condition.				
F298	6. The resident call system functions in toilet and bath facilities.				
	E. Social Service Area				
F299	SNF (405.1130(b)) (Standard) ☐ MET ☐ NOT MET				
F300	1. Ensures privacy for social service interviewing.				
F301	2. Adequate space for clerical and interviewing functions is provided.				
F302	3. Facilities are easily acessible to residents and staff.				

Form HCFA-519 (2-86)

Page 30

NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	F. **Therapy Areas**				
F303	SNF (405.1126(a)) (Standard) ☐ MET ☐ NOT MET				
F304	ICF (442.328(a)) ☐ MET ☐ NOT MET				
F305	1. Space is adequate for proper use of equipment by all residents receiving treatments.				
F306	2. Equipment is safe and in proper working condition.				
	G. **Facilities for Special Care**				
F307	SNF (405.1134(f)) (Standard) ☐ MET ☐ NOT MET				
F308	ICF (442.328(b)) ☐ MET ☐ NOT MET				
F309	1. Single rooms with private toilet and handwashing facilities are available for isolating residents.				
F310	2. Precautionary signs are used to identify these rooms when in use.				
	H. **Common Resident Areas**				
F311	SNF (405.1134(j)) (Standard) ☐ MET ☐ NOT MET				
F312	ICF (442.324) (Standard) ☐ MET ☐ NOT MET				
F313	1. All common resident areas are clean, sanitary and free of odors.				
F314	2. Provision is made for adequate and comfortable lighting levels in all areas.				
F315	3. There is limitation of sounds at comfort levels.				

Form HCFA-519 (2-86)

Page 31

NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F316	4. A comfortable room temperature is maintained.				
F317	5. There is adequate ventilation through windows or mechanical means or a combination of both.				
F318	6. Corridors are equipped with firmly secured handrails on each side.				
F319	7. Staff are aware of procedures to ensure water to all essential areas in the event of loss of normal supply.				
	I. **Maintenance of Building and Equipment**				
F320	SNF (405.1134(i)) (Standard) ☐ MET ☐ NOT MET				
F321	1. The interior and exterior of the building are clean and orderly.				
F322	2. All essential mechanical and electrical equipment is maintained in safe operating condition.				
F323	3. Sufficient storage space is available and used for equipment to ensure that the facility is orderly and safe.				
F324	4. Resident care equipment is clean and maintained in safe operating condition.				
F325	ICF (442.331(b)) ☐ MET ☐ NOT MET Indicators J thru L apply to ICFs.				
	J. **Dietetic Service Area**				
F326	SNF (405.1134(h)) (Standard) ☐ MET ☐ NOT MET				
F327	1. Kitchen and dietetic service areas are adequate to insure proper, timely food services for all residents				
F328	2. Kitchen areas are properly ventilated, arranged, and equipped for storage and preparation of food as well as for dish and utensil cleaning, and refuse storage and removal.				

Form HCFA-519 (2-86) Page 32

NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT/INFECTION CONTROL	YES	NO	N/A	EXPLANATORY STATEMENT
	K. HYGIENE OF DIETARY STAFF				
F329	SNF (405.1125(f)) (Standard) ☐ Met ☐ Not Met				
F330	Dietetic service personnel practice hygienic food handling techniques.				
	L. DIETARY SANITARY CONDITIONS				
F331	SNF (405.1125(g)) (Standard) ☐ Met ☐ Not Met				
F332	1. Food is stored, refrigerated, prepared, distributed, and served under sanitary conditions.				
F333	2. Waste is disposed of properly.				
	M. **Emergency Power**				
F334	SNF (405.1134(b)) (Standard) ☐ MET ☐ NOT MET				
F335	1. An emergency source of electrical power necessary to protect the health and safety of residents is available in the event the normal electrical supply is interrupted.				
F336	2. Emergency power is adequate at least for lighting in all means of egress; equipment to maintain fire detection, alarm, and extinguishing systems; and life safety support systems.				
F337	3. Emergency power is provided by an emergency electrical generator located on the premises where life support systems are used.				
	INFECTION CONTROL *(CONDITION OF PARTICIPATION)*				
F338	SNF (405.1135) ☐ MET ☐ NOT MET				
	A. Infection Control				
F339	SNF (405.1135(b)) (Standard) ☐ MET ☐ NOT MET				
F340	Aseptic and isolation techniques are followed by all personnel.				

Form HCFA-519 (2-86)

Page 33

NAME OF FACILITY

CODE	INFECTION CONTROL/DISASTER PREPAREDNESS	YES	NO	N/A	EXPLANATORY STATEMENT
	B. Sanitation				
F341	SNF (405.1135(c)) (Standard) ☐ MET ☐ NOT MET				
F342	The facility maintains a safe, clean, and orderly interior.				
	C. Linen				
F343	SNF (405.1135(d) (Standard) ☐ MET ☐ NOT MET				
F344	ICF (442.327) (Standard) ☐ MET ☐ NOT MET				
F345	1. The facility has available at all times a quantity of linen essential for proper care and comfort of residents.				
F346	2. Linens are handled; stored, processed, and transported in such a manner as to prevent the spread of infection.				
	D. PEST CONTROL				
F347	SNF (405.1135(e)) (Standard) ☐ Met ☐ Not Met				
F348	ICF (442.315(c)) (Standard) ☐ Met ☐ Not Met				
F349	The facility is maintained free from insects and rodents.				
	DISASTER PREPAREDNESS *(CONDITION OF PARTICIPATION)*				
F350	SNF (405.1136) ☐ MET ☐ NOT MET				
F351	SNF (405.1136(a)) (Standard) ☐ MET ☐ NOT MET				
F352	ICF (442.313) (Standard) ☐ MET ☐ NOT MET Indicators A and B apply to this standard for ICFS.				
	A. Disaster Plan				
F353	1. Facility staff are aware of plans, procedures to be followed for fire, explosion or other disaster.				

Form HCFA-519 (2-86) Page 34

NAME OF FACILITY

CODE	DISASTER PREPAREDNESS	YES	NO	N/A	EXPLANATORY STATEMENT
F354	2. Facility staff are knowledgeable about evacuation routes.				
F355	3. Facility staff are aware of their specific responsibilities in regard to evaluation and protection of residents.				
F356	4. Facility staff are aware of methods of containing fire.				
	B. Drills				
F357	**SNF (405.1136(b))** (Standard) ☐ MET ☐ NOT MET				
F358	1. All employees are trained, as part of their employment orientation in all aspects of preparedness for any disaster.				
F359	2. Facility staff participate in ongoing training and drills in all procedures so that each employee promptly and correctly carries out a specific role in case of a disaster.				

Form HCFA-619 (2-86) Page 35

SKILLED NURSING FACILITY & INTERMEDIATE CARE FACILITY

SURVEY REPORT — PART B
CRUCIAL DATA EXTRACT
(To be used with 2-86 Revision of Form HCFA-519)

PROVIDER NO.	FACILITY NAME	SURVEY DATE

SURVEY TEAM COMPOSITION

*F1: INDICATE THE NUMBER OF SURVEYORS ACCORDING TO DISCIPLINE:

A.	_____	ADMINISTRATOR	H.	_____	LIFE SAFETY CODE SPECIALIST
B.	_____	NURSE	I.	_____	LABORATORIAN
C.	_____	DIETITIAN	J.	_____	SANITARIAN
D.	_____	PHARMACIST	K.	_____	THERAPIST
E.	_____	RECORDS ADMINISTRATOR	L.	_____	PHYSICIAN
F.	_____	SOCIAL WORKER	M.	_____	NATIONAL INSTITUTE OF MENTAL HEALTH
G.	_____	QUALIFIED MENTAL RETARDATION PROFESSIONAL	N.	_____	OTHER

NOTE: MORE THAN ONE DISCIPLINE MAY BE MARKED FOR SURVEYORS QUALIFIED IN MULTIPLE DISCIPLINES.

*F2: INDICATE THE TOTAL NUMBER OF SURVEYORS ONSITE: ____

*F193 DRUG ERROR RATE: _____% (Round % to nearest whole number.)

*SF5 Survey Form Indicator (Check one)

Traditional Survey (1) ☐ New LTC Survey (2) ☐

NOTE: PLEASE ATTACH COPY OF PAGES 2, 14 AND 15.

*Mandatory

Form HCFA-519E (2-86)

☆U.S. GOVERNMENT PRINTING OFFICE : 1986 O - 153-203 : QL 3

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

RESIDENTS SELECTED FOR INDEPTH REVIEW

PROVIDER NUMBER | SURVEY DATE

	RESIDENT NAME (TARGETED)*	ROOM NUMBER	REASON FOR SELECTION
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			
16.			
17.			
18.			
19.			
20.			

FORM HCFA-520 (2-86) * NOTE IF ICF OR SNF RESIDENT

* U.S.GPO:1986-0-181-264/53839

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

TOUR NOTES WORKSHEET

PROVIDER NUMBER	SURVEY DATE

INSTRUCTIONS

1. *Note care and problems in care on all units.*
2. *Report deficiencies directly to survey report form or evaluate further during indepth sample review.*
3. *Select residents for indepth review.*
4. *Select a proportionate number from each section.*

INDEPTH SAMPLE

Facility Census	0-60	61-120	121-200	200+
Sample Size	25% (Min10)	20% (Min15)	15% (Min24)	10% (Min30) (Max50)

OBSERVE RESIDENTS FOR THE FOLLOWING CARE PROBLEMS

GROOMING/PERSONAL HYGIENE

POSITIONING

ASSISTIVE DEVICES

AMBULATION

RESTRAINTS

HYDRATION

INFECTION CONTROL

PATIENT RIGHTS

OTHER

FORM HCFA-521 (2-86)

* U S GPO 1986 O-181-284/53827

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

OBSERVATION / INTERVIEW RECORD REVIEW WORKSHEET

PROVIDER NUMBER	SURVEY DATE	OBSERVATION/INTERVIEW OF: (RESIDENT IDENTIFIER)

INSTRUCTIONS

1. **Observe each resident in sample to identify ADL needs and potential problems. Check appropriate blocks.**
2. **Interview only residents in sample who are capable and willing.**
3. **Review each resident's record to ensure assessments, plans, interventions and evaluations are appropriate and current.**
4. **Note deficiencies on survey report form after reviewing all residents in sample.**

RESIDENT NEEDS

ADL's
- ☐ Bathing
- ☐ Dressing
- ☐ Toileting
- ☐ Transferring
- ☐ Continence
- ☐ Feeding

SKIN
- ☐ Tears/Wounds
- ☐ Ulcers
- ☐ Rashes
- ☐ Flaking
- ☐ Scaling
- ☐ Red Area

DECUBITUS
- ☐ Grade
- ☐ Foul Odor
- ☐ Draining
- ☐ Dressing
- ☐ Unclean
- ☐ Not Dry
- ☐ Not Intact
- ☐ Poor Technique

GROOMING/HYGIENE
- ☐ Eyes/Ears/Mouth
- ☐ Oral/Dental Hygiene
- ☐ Foot Care
- ☐ Facial Hair
- ☐ Hair/Scalp
- ☐ Nails
- ☐ Clothing
- ☐ Shoes/Slippers
- ☐ Odors

POSITIONING
- ☐ Need Present
- ☐ Contracted Extremities
- ☐ Improper Position
- ☐ No Protective Device
- ☐ ROM Improper
- ☐ Lack of Turning as Needed
- ☐ Schedule Not Present
- ☐ Improper Techniques
- ☐ Aseptic/Other

DRESSINGS
- ☐ Present
- ☐ Unclean
- ☐ Not Dry
- ☐ Not Intact
- ☐ Foul Odor
- ☐ Poor Technique

RESTRAINTS
- ☐ Type
- ☐ Inappropriate Application
- ☐ Improper Body Alignment/Support
- ☐ Not Released/Exercised Every 2 Hours
- ☐ Chemically Restrained

BOWEL/BLADDER
- ☐ Incontinent
- ☐ Not Routinely Toileted
- ☐ Commode Not Available
- ☐ Schedule Not Available

CATHETER
- ☐ Present
- ☐ Inappropriate
- ☐ Poor Drainage
- ☐ Drainage System Open
- ☐ No Urine in Bag
- ☐ Urine Leaking
- ☐ Abdomen Distended
- ☐ Tubing Not Clean
- ☐ No I/O Recording
- ☐ Supply Storage Unclean

INJECTIONS
- ☐ Receives Injections
- ☐ Site Red/Swollen
- ☐ Improper Technique
- ☐ Resident Reacts

COLOSTOMY/ILEOSTOMY
- ☐ Present
- ☐ Not Well Regulated
- ☐ Odors
- ☐ Diarrhea/Constipation
- ☐ Site Red/Irritated

PARENTERAL FLUID/IV'S
- ☐ Present
- ☐ Rate Incorrect/Stopped
- ☐ Site Red/Swollen
- ☐ Dressing Unclean
- ☐ Unsafe Splint
- ☐ Improper Label
- ☐ Outdated Solution
- ☐ No I/O Recording

TRACHEOSOTOMY
- ☐ Present
- ☐ Site Red/Swollen
- ☐ Obstructed
- ☐ Unclean
- ☐ Improper Suctioning
- ☐ Equipment Not Available

SUCTIONING
- ☐ Need Present
- ☐ Audible Rales
- ☐ Labored Breathing
- ☐ Drainage
- ☐ Equipment Not Available

RESPIRATORY
- ☐ Congested/Short Breath
- ☐ IPPB Not Available
- ☐ Oxygen Not Available
- ☐ Improper Equipment Use

DIETARY NEEDS
- ☐ Over/Underweight
- ☐ Dehydrated
- ☐ Edema
- ☐ Emaciated
- ☐ Dull/Dry Hair
- ☐ Swollen/Red Tongue
- ☐ Bleeding Gums
- ☐ Cracked Lips
- ☐ Inability to Chew
- ☐ Swallowing Prob.
- ☐ Pallor

TUBE FEEDING
- ☐ Present
- ☐ Nutrition Inadequate
- ☐ Poorly Tolerated
- ☐ Vomits
- ☐ Dehydrated
- ☐ Over/Underweight
- ☐ Diarrhea/Constipation
- ☐ Poor Skin Condition
- ☐ Poor Mouth Condition
- ☐ Improper Technique

REHABILITATION NEEDS
- ☐ Cannot Communicate
- ☐ Ineffective Use of Assistive Device
- ☐ Improper Equipment Use
- ☐ Improper Technique
- ☐ Equipment Inadequate

SOCIAL SERVICE NEEDS
- ☐ Not Oriented
- ☐ Not Able to Converse
- ☐ Uncooperative/Disrupts
- ☐ Withdrawn
- ☐ Anxious
- ☐ Confused
- ☐ Lonely
- ☐ Vision/Hearing Needs
- ☐ Mentally Retarded

OTHER
- ☐
- ☐
- ☐
- ☐
- ☐

ACTIVITY NEEDS
- ☐ Not Participating
- ☐ Vision/Hearing
- ☐ Chair/Bedfast
- ☐ Dependence ≥ 4 ADL's

PATIENT RIGHTS
- ☐ Privacy Not Maintained
- ☐ Staff Not Courteous
- ☐ Not Informed of Rights
- ☐ Mental/Physical Abuse
- ☐ Cannot Exercise Rights
- ☐ Cannot Manage Affairs

NOTES:

Form HCFA 524 (2-86)

SEE REVERSE

RECORD REVIEW

☐ Drug Regimen Review (See SOM Appendix N Part 1): ☐ Satisfactory ☐ Unsatisfactory

ROUTINE REPORTS: ☐ Weights ☐ Lab ☐ X-ray ☐ Other

ASSESSMENT	PLAN	INTERVENTION	EVALUATION

PHYSICIAN SERVICES

☐ Admission Information
☐ Rehabilitation Information
☐ Physical Exam
☐ Written Care Plan
☐ Signs Orders/Notes
☐ Required Visits
☐ Emergency Availability
☐ Review of Care

★ U.S. GPO: 1986-0-181-264/53835

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

DRUG PASS WORKSHEET

PROVIDER NUMBER	SURVEY DATE	ERROR RATE

INSTRUCTIONS	DEFICIENCY FORMULA
1. Perform Drug Pass Observations on 20 Residents. *2. Record Observation of each Opportunity.* *3. Compare Observation Notes with Physician Orders.* *4. Calculate and Note Error Rate.* *5. Note Deficiencies on Survey Report Form.*	*1. One or more Significant Errors = Deficiency* *Significant + Non-significant* *2. Doses Given + Doses Ordered But Not Given X 100 ≥ 5% = Deficiency*

IDENTIFIER	POUR	PASS	RECORD
RESIDENT'S FULL NAME, ROOM NUMBER, TIME	DRUG PRESCRIPTION NAME, DOSE AND FORM	OBSERVATION OF ADMINISTRATION	DRUG ORDER WRITTEN AS *(IF DIFFERS FROM ADMINS ONLY)*

FORM HCFA-522 (2-86)

SEE REVERSE

DRUG ERROR CALCULATION
(SEE SOM Appendix N Part 2)

How to Calculate a Medication Error Rate—In calculating the percentage of errors, the numerator in the ratio is the total number of errors that you observe, both significant and non-significant. The denominator is all the doses observed being administered **plus** the doses ordered but not administered. The equation for calculating a medication error rate is as follows:

$$\text{Medication Error Rate} = \frac{\text{Number of errors observed}}{\text{Opportunities for errors}} \times 100$$

Where: Opportunities for errors equals the number of doses administered **plus** the number of doses ordered but not administered.

Comments

For example, you observed the administration of drugs to 20 patients. There were a total of 47 drugs administered (47 opportunities for errors). At the completion of the reconciliation of your Observations with the physicians' orders, you find that three medication errors were made in administration and one medication was omitted (ordered but not administered). The omitted dose is included in both the numerator and the denominator. Therefore, following the above formula, your equation would be as follows:

$$\frac{3 + 1}{47 + 1} \times 100 = 8.3\%$$

★U.S.GPO:1986-0-181-264/53836

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

DINING AREA & EATING ASSISTANCE WORKSHEET

PROVIDER NUMBER	SURVEY DATE

INSTRUCTIONS

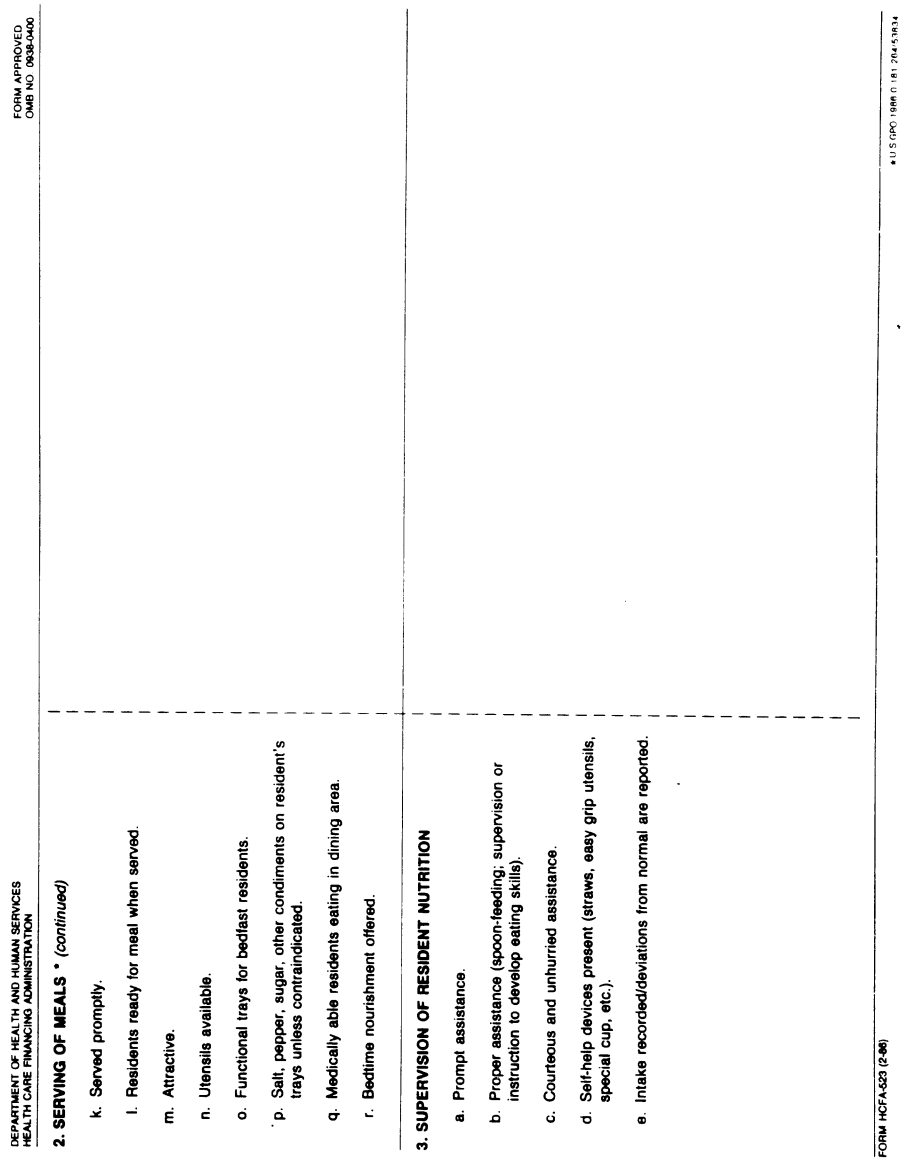
TASKS 1. Observe Dining Area.
2. Note Meals Served/Review Physicians Orders.
3. Note Assistance Provided.
4. Note Deficiencies on Survey Summary Form.

➡ *SAMPLE A MINIMUM OF FIVE (5) RESIDENTS ⬅

1. DINING AREA AND MEALS	
a. Size does not restrict movement.	
b. Accommodates all residents.	
c. Cleanliness.	
d. Adequate/comfortable lighting.	
e. Adequate/comfortable ventilation.	
2. SERVING OF MEALS *	
a. Number of meals/time span between meal.	
b. Conformance to physicians order.	
c. Nutritional adequacy.	
d. Adequacy of portions.	
e. Residents eat approximately 75% of meals.	
f. Puree dishes served individually.	
g. Food cut, chopped or ground for individual resident needs.	
h. Acceptable taste.	
i. Proper temperature.	
j. Plates covered.	

FORM HCFA-523 (2-86)

SEE REVERSE



DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

2. SERVING OF MEALS * *(continued)*

k. Served promptly.

l. Residents ready for meal when served.

m. Attractive.

n. Utensils available.

o. Functional trays for bedfast residents.

p. Salt, pepper, sugar, other condiments on resident's trays unless contraindicated.

q. Medically able residents eating in dining area.

r. Bedtime nourishment offered.

3. SUPERVISION OF RESIDENT NUTRITION

a. Prompt assistance.

b. Proper assistance (spoon-feeding; supervision or instruction to develop eating skills).

c. Courteous and unhurried assistance.

d. Self-help devices present (straws, easy grip utensils, special cup, etc.).

e. Intake recorded/deviations from normal are reported.

FORM HCFA-523 (2-86)

* U.S. GPO 1986 0-181-264/53834

§488.110 Procedural guidelines.

SNF/ICF Survey Process. The purpose for implementing a new SNF/ICF survey process is to assess whether the quality of care, as intended by the law and regulations, and as needed by the resident, is actually being provided in nursing homes. Although the onsite review procedures have been changed, facilities must continue to meet all applicable Conditions/Standards, in order to participate in Medicare/Medicaid programs. That is, the methods used to

compile information about compliance with law and regulations are changed; the law and regulations themselves are not changed. The new process differs from the traditional process, principally in terms of its emphasis on resident outcomes. In ascertaining whether residents grooming and personal hygiene needs are met, for example, surveyors will no longer routinely evaluate a facility's written policies and procedures. Instead, surveyors will observe residents in order to make that determination. In addition, surveyors will confirm, through interviews with residents and staff, that such needs are indeed met on a regular basis. In most reviews, then, surveyors will ascertain whether the facility is actually providing the required and needed care and services, rather than whether the facility is capable of providing the care and services.

THE OUTCOME-ORIENTED SURVEY PROCESS—SKILLED NURSING FACILITIES (SNFS) AND INTERMEDIATE CARE FACILITIES (ICFS)

(a) General.
(b) The Survey Tasks.
(c) Task 1—Entrance Conference.
(d) Task 2—Resident Sample—Selection Methodology.
(e) Task 3—Tour of the Facility.
(f) Task 4—Observation/Interview/Medical Record Review (including drug regimen review).
(g) Task 5—Drug Pass Observation.
(h) Task 6—Dining Area and Eating Assistance Observation.
(i) Task 7—Forming the Deficiency Statement.
(j) Task 8—Exit Conference.
(k) Plan of Correction.
(l) Followup Surveys.
(m) Role of Surveyor.
(n) Confidentiality and Respect for Resident Privacy.
(o) Team Composition.
(p) Type of Facility-Application of SNF or ICF Regulations.
(q) Use of Part A and Part B of the Survey Report.

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

- Life Safety Code requirements;
- Administrative and structural requirements (Part A of the Survey Report, Form CMS–525); and
- Direct resident care requirements (Part B of the Survey Report, Form CMS–519), along with the related worksheets (CMS–520 through 524).

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

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

- Task 1. Entrance Conference.
- Task 2. Resident Sample—Selection Methodology.
- Task 3. Tour of the Facility. Resident Needs. Physical Environment. Meeting with Resident Council Representatives. Tour Summation and Focus of Remaining Survey Activity.
- Task 4. Observation/Interview/Medical Record. Review of Each Individual in the Resident Sample (including drug regimen review).
- Task 5. Drug Pass Observation.
- Task 6. Dining Area and Eating Assistance Observation.
- Task 7. Forming the Deficiency Statement (if necessary).
- Task 8. Exit Conference.

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

- Introduce all members of the team to the facility staff, if possible, even though the whole team may not be present for the entire entrance conference. (All surveyors wear identification tags.)
- Explain the SNF/ICF survey process as resident centered in focus, and outline the basic steps.
- Ask the facility for a list showing names of residents by room number with each of the following care needs/treatments identified for each resident to whom they apply:

—Decubitus care
—Restraints
—Catheters
—Injections
—Parenteral fluids
—Rehabilitation service
—Colostomy/ileostomy care
—Respiratory care

—Tracheostomy care
—Suctioning
—Tube feeding

Use this list for selecting the resident sample.

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

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

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

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

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

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

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

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

[1] Maximum—50.

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

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

- Decubitus Care
- Restraints
- Catheters
- Injections, Parenteral Fluids, Colostomy/Ileostomy, Respiratory Care, Tracheostomy Care, Suctioning, Tube Feeding
- Rehabilitative Services (physical therapy, speech pathology and audiology services, occupational therapy)

Due to the relatively low prevalence of these care needs/treatments, appropriate residents may be either underrepresented or entirely omitted from the sample. Therefore, determine during the tour how many residents in the random selection fall into each of these care categories. Then, compare the number of such residents in the random selection with the total number of residents in the facility with each specified care need/treatment (based on either the resident census or other information provided by the facility).

Review no less than 25 percent of the residents in each of these special care needs/treatments categories. For example, if the facility has 10 residents with

decubitus ulcers, but only one of these residents is selected randomly, review two more residents with decubitis ulcers (25% of 10 equals 2.5, so review a total of 3). Or, if the facility has two residents who require tube feeding, neither of whom is in the random selection, review the care of at least one of the these residents. This can be accomplished in the following manner:

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

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

(e) *Task 3—Tour of the Facility*—(1) *Purpose.* Conduct the tour in order to:

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

• View the physical environment; and

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

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

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

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

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

—Personal hygiene, grooming, and appropriate dress
—Position
—Assistive and other restorative devices
—Rehabilitation issues
—Functional limitations in ADL
—Functional limitations in gait, balance and coordination
—Hydration and nutritional status
—Resident rights
—Activity for time of day (appropriate or inappropriate)
—Emotional status
—Level of orientation
—Awareness of surroundings
—Behaviors
—Cleanliness of immediate environment (wheelchair, bed, bedside table, etc.)
—Odors
—Adequate clothing and care supplies as well as maintenance and cleanliness of same

(4) *Review of the Physical Environment.* As you tour each resident's room and

auxiliary rooms, also examine them in connection with the physical environment requirements. You need not document physical environment on the Tour Notes Worksheet. Instead, you may note any negative findings directly on the Survey Report Form in the remarks section.

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

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

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

- ''What is best about this home?''
- ''What is worst?''
- ''What would you like to change?''

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

- ''Can you be more specific?''
- ''Can you give me an example?''
- ''What can anyone else tell me about this?''

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

- ''Tell me what you think about the food/staff/cleanliness here.''
- ''What would make it better?''
- ''What don't you like? What do you like?''

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

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

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

(1) *Observation.* Conduct observations concurrently with interviews of residents, family/significant others, and

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

Bowel and bladder training
Catheter care
Restraints
Injections
Parenteral fluids
Tube feeding/gastrostomy
Colostomy/ileostomy
Respiratory therapy
Tracheostomy care
Suctioning

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

At each interview:

- Introduce yourself.
- Address the resident by name.
- Explain in simple terms the reason for your visit (e.g., to assure that the care and services are adequate and appropriate for each resident).
- Briefly outline the process—entrance conference, tour, interviews, observations, review of medical records, resident interviews, and exit conference.
- Mention that the selection of a particular resident for an interview is not meant to imply that his/her care is substandard or that the facility provides substandard care. Also mention that most of those interviewed are selected randomly.
- Assure that you will strive for anonymity for the resident and that the interview is used in addition to medical records, observations, discussions, etc., to capture an accurate picture of the treatment and care provided by the facility. Explain that the official findings of the survey are usually available to the public about three months after completion of the survey, but resident names are not given to the public.
- When residents experience difficulty expressing themselves:

—Avoid pressuring residents to verbalize
—Accept and respond to all communication
—Ignore mistakes in word choice
—Allow time for recollection of words
—Encourage self-expression through any means available

- When interviewing residents with decreased receptive capacity:

—Speak slowly and distinctly
—Speak at conversational voice level
—Sit within the resident's line of vision

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

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

reliable than that from more alert individuals.

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

Activities of daily living
Grooming/hygiene
Nutrition/dietary
Restorative/rehabilitation care and services
Activities
Social services
Resident rights

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

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

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

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

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

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

- An assessment has been performed.
- A plan with goals has been developed.
- The interventions have been carried out.
- The resident has been evaluated to determine the effectiveness of the interventions.

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

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

- If the resident has been properly assessed for all his/her needs.
- That normal and routine nursing practices such as periodic weights, temperatures, blood pressures, etc., are performed as required by the resident's conditions.

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

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

(g) *Task 5—Drug Pass Observation.* The purpose of the drug pass observation is to observe the actual preparation and administration of medications to residents. With this approach, there is no doubt that the errors detected, if any, are errors in drug administration, not

documentation. Follow the procedure in Part Two of Appendix N, Surveyor Procedures for Pharmaceutical Service Requirements in Long-Term Care Facilities, and complete the Drug Pass Worksheet, Form CMS–522. Be as neutral and unobtrusive as possible during the drug pass observation. Whenever possible, select one surveyor, who is a Registered Nurse or a pharmacist, to observe the drug pass of approximately 20 residents. In facilities where fewer than 20 residents are receiving medications, review as many residents receiving medications as possible. Residents selected for the in-depth review need not be included in the group chosen for the drug pass; however, their whole or partial inclusion is acceptable. In order to get a balanced view of a facility's practices, observe more than one person administering a drug pass, if feasible. This might involve observing the morning pass one day in Wing A, for example, and the morning pass the next day in Wing B.

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

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

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

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

(i) *Task 7—Forming the Deficiency Statement*—(1) *General.* The Survey Report Form contains information about all of the negative findings of the survey. Be sure to transfer to the Survey Report Form data from the tour, drug pass observation, dining area and eating assistance observation, as well as in-depth review of the sample of residents. Transfer only those findings which could possibly contribute to a determination that the facility is deficient in a certain area.

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

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

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

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

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

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

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

(j) *Task 8—Exit Conference.* The purpose of the exit conference is to inform the facility of survey findings and to arrange for a plan of correction, if needed. Keep the tone of the exit conference consistent with the character of the survey process—inspection and enforcement. Tactful, business-like, professional presentation of the findings is of paramount importance. Recognize that the facility may wish to respond to various findings. Although deficiency statements continue to depend, in part, on surveyor professional judgment, support your conclusions with resident-specific examples (identifiers other than names) whenever you can do so without compromising confidentiality. Before formally citing deficiencies, discuss any allegations or findings that could not be substantiated during earlier tasks in the process. For example, if information is gathered that suggests a newly hired

R.N. is not currently licensed, ask the facility officials to present current licensure information for the nurse in question. Identify residents when the substandard care is readily observed or discerned through record review. Ensure that the facility improves the care provided to all affected residents, not only the identified residents. Make clear to the facility that during a follow-up visit the surveyors may review residents other than those with significant problems from the original sample, in order to see that the facility has corrected the problems overall. Do not disclose the source of information provided during interviews, unless the resident has specifically requested you to inform the facility of his/her comments or complaints. In accordance with your Agency's policy, present the Statement of Deficiencies, form CMS–2567, on site or after supervisory review, no later than 10 calendar days following the survey.

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

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

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

• Is compliance expected timely?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SNF/ICF SURVEY TEAM MODEL

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

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

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

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

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

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

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

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

(q) *Use of Part A and Part B of the Survey Report*—(1) *Use of Part A (CMS–525).* Use Part A for initial certification surveys only, except under the following circumstances:

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

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

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

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

(iii) *Substantial Changes in a Facility's Organization and Management.* If you receive such information, review the changes to ensure compliance with the regulations. Request copies of the appropriate documents (e.g., written policies and procedures, personnel qualifications, or agreements) if they were

not submitted. If the changes have made continued compliance seem doubtful, determine through a Part B survey whether deficiencies have resulted. Cite any deficiencies on the CMS–2567 and follow the usual procedures.

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

The worksheets are:

- CMS–520—Residents Selected for In-depth Review
- CMS–521—Tour Notes Worksheet
- CMS–522—Drug Pass Worksheet
- CMS–523—Dining Area and Eating Assistance Worksheet
- CMS–5245—Observation/Interview/Record Review Worksheet

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

§ 488.115 Care guidelines.

§ 488.115 Care guidelines.

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Resident Rights					
F53 SNF 405.1121(k)(1) ICF 442.311(a)		Ask Resident: - Did you receive a copy of the Resident's Bill of Rights? Was it explained to you?	Looked for signed acknowledgement of receipt of resident rights information. Residents unable to sign name may have their "mark" witnessed.	Because of the confusion surrounding admission to a new facility and the large amount of information given to a resident or resident's family on admission, information given at this time is often forgotten. Therefore, surveyor should verify resident's recollection with staff interviews and record checks. Written information on services and costs must be given to the resident, as well as copies of residents rights and responsibilities. Copies of residents' rights should also be available to patients and visitors, e.g., in resident lounges, lobbies, or other area where residents and visitors could easily see and read them.	Notification of Change in Status 405.1121(j) 442.307
F54 SNF 405.1121(h)(1) ICF 442.311(a)(1)			Look for written statement of charges services.		Patient Care Policies 405.1121(e)
A. Information*					
F55 SNF 405.1121(h)(1) ICF 442.311(a)(2) 1. Rights and Responsibilities	Where is information concerning resident rights and responsibilities available in the facility?	- Were you told of any responsibilities you have in living here?	Social Work records may idicate patient rights information discussed with resident.		442.308 442.309 442.310 442.305 Medical Direction 405.1122(a)
F56 SNF 405.1121(k)(1) ICF 442.311(a)(3) 2. Rules of Resident Conduct		- Were you given a chance to ask questions?			Medical Records 405.1132(b)(d) 442.310
F57 SNF 405.1121(h)(2) ICF 442.311(a)(4) 3. Resident Acknowledgement		- Did he/she receive a written copy of services provided by the facility and any additional costs for these services?			

INTENT
To assure that the resident maintains, in so far as possible, those personal rights that are a part of normal, adult life, and including the right to personal dignity.

*Information concerning incompetent residents is given in L. Delegation of Rights and Responsibilities.

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F58 SNF 405.1121(k)(2) ICF 442.311(a)(4) 4. Resident informed in writing of changes in services and charges for services.		Ask Resident: - If there are changes in services or costs does someone explain these? Ask Administrative Staff: - How do residents learn what is expected of them? - How do they learn about any changes in the facility's procedures and/or costs?			
F59 SNF 405.1121(k)(2) ICF 442.311(a)(4) 5. Information to resident of services not covered by Medicare or Medicaid and not covered in the basic rate.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
B. Medical Condition & Treatment F60–64 SNF 405.1121(k)(2) ICF 442.311(b)		Ask Resident: – Has your doctor discussed your health with you, how is it, what's wrong, and what you can expect in the future? – Have you had the opportunity to help plan what you need and how you are taken care of? – Do you know that you can refuse treatment or medication? – Have you ever refused medication or treatment? – What happened when you did? Ask Staff: – Is the facility participating in any experimental research? If yes, ask what residents are involved. Interview a sample of these residents. Ask Resident (or Guardian: – Are you participating in the _____ study? – Was this explained to you well enough so that you understand what the study is about and any risks that may be involved?	If the resident has not been informed of his/her medical condition, physician notes should document that the resident was not informed because it was medically contraindicated. Do care plans or other documentation reflect resident participation in care planning? If resident states he/she has refused treatment or medication does documentation indicate adherence to/violation of resident rights. Review records of residents identified as participating in a clinical research study. Are informed consent forms signed? Do these signed forms list all known risks for the resident? All needed informed consent statements are present and properly signed.	Unless there is documentation that the residents medical condition should not be discussed with him/her resident interviews/record reviews should indicate that the resident and physician have discussed his/her medical condition.* If you cannot confirm that this has occurred, interview staff to get further clarification. Almost all residents who are able to participate to some extent in their care planning do so. You should find evidence of this for the majority of the residents (e.g., care planning interview, nurses notes, social worker progress notes). Residents do have the right to refuse medication or other treatment, but you would expect that the facility would discuss the implications of this refusal with the resident and possibly do some "gentle persuasion".*	Patient Care Management 405.1124(d) 442.319 442.341

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F60-64 (cont'd)				However, except in an emergency situation force should never be used to compel a resident to accept medication or treatment. Deceit is also a violation of resident rights, except in the case of therapeutically indicated placebos ordered by the physician. Any resident participating in research studies should fully understand the implication of the study. The facility is not in compliance with the resident rights regulation if the resident consents to participate in a clinical study without full knowledge of the study. (Record review only as other nonclinical studies may not require informed consent).	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
C. Transfer and Discharge F65-68 SNF 405.1121(k)(4) ICF 442.311(c)	Look for residents that may be inappropriately placed physically - an alert resident rooming with a confused, noisy resident; very ill resident placed far from the nurses station; residents not compatible with each other, (e.g., different life-styles, habits, etc.).	Ask Resident: - How well do you get along with your roommate? - Have you ever been moved from one room to another? If yes, why? - How were you involved in the decision to move? - How much time was there between the time they told you you were to be moved, and when you were moved? - Have you asked for your room to be changed? Ask Direct Care and Other Staff: - What are some of the reasons residents rooms are changed? - What are some of the reasons for discharge of residents or transfer to a hospital or LTC facility? - How are residents involved in the decision to move? - If a resident requests a room change, how is this handled? - When a resident requests a room change are the following areas of consideration presented and discussed:	Nursing, physician, and/or social service progress notes should indicate reason for transfer and discussion with resident and/or family/guardian. If staff interviews give you cause to feel that transfers and discharges may be in violation of these regulations, review a sample of closed records for transfer information on how it was handled. If residents are transferred between facilities with common ownership and similar levels of care, transfers must be reviewed to determine reasons for transfer. Efforts to maintain the census is not an acceptable reason for transfer. Do discharge records review: - reason for discharge, medical non-payment or need for different level of care?	To be in compliance with transfer and discharge regulations the facility must be able to confirm that all discharges/transfers were for medical or resident welfare reasons, or non-payment. Welfare reasons include physical, emotional, social issues. Transfers and discharges made solely for the convenience of the facility are unacceptable. (Relocation to accommodate contagious or other disorders requiring isolation procedures are not for the convenience of the facility).	Status Change Notification 405.1121(j) Medical Records 405.1132(c)(e) 442.318(c)(4) Transfer Agreement 405.1133(a)(2) 442.307(b)(1)(2)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F65-68 (cont'd)		+ cost factors + resident welfare + resident's reason for requesting the move + facility's assessment of whether the move would be beneficial or not for the resident.			

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
D. Exercising Rights F69 SNF 405.1121(k)(5) ICF 442.311(d)	Do residents appear comfortable when speaking to the surveyors as opposed to being afraid that someone may see them or overhear their conversation?	Ask Resident: - Do you belong to, or have representation on the resident council? - Are you informed of changes in the facility that will affect you? - Are you given a chance to express views on these changes prior to their implementation? - Does the facility assist in arranging for you to vote either at the polls or via absentee ballot? - Are you assisted in obtaining legal or Social Services if needed? - Do you feel comfortable in expressing yourself freely or are you concerned about retaliation? - Is staff/administration responsive to complaints? Do you know who to complain to? Ask Staff: - What arrangements are made for residents to vote? - How do you handle it if someone needs a lawyer or other service that you don't provide?	Review resident council documentation, as available, to determine level of activity. Review social work or progress notes for legal referrals. Is there documentation in progress notes or elsewhere, of resident complaints and disposition of complaints?	Compliance determinations will be made based primarily on resident/staff interviews and the correlation of interview information with documentation in the Medical record. If residents ask, they should be allowed to speak to the surveyor without facility personnel being present. However the resident has the right to have a third party of their choosing present during an interview.	Social Services 405.1130 442.344

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
E. Financial Affairs F72-78 SNF 405.1121(k)(6) 405.1121(m) ICF 442.311(e) 442.320		Ask Residents: - Are you able to take care of your own financial affairs? - Does the facility keep some money for you that you can have when you request it? - When you ask for this money, how quickly do you get it? - Do you know the amount of money you have available at this time? - If the facility pays bills for you do they periodically provide an itemized listing of the transactions they have made? - When did you receive the last itemized statement? - Are you comfortable that your funds are taken care of correctly? - If you deposit money or valuables with the facility, do you receive a receipt for this deposit? - Are you or your family able to review your financial records when you request to do so? - Have you ever had money or anything else stolen? If so, what was done about it?	A copy of the statement should be in the residents financial record and given to the resident at least quarterly. Receipts, account logs showing deposits/withdrawals, authorization/reasons for withdrawals, and interest earned should be reviewed. If resident indicates there may be a problem, an in-depth interview should be conducted. Resident records indicate separate financial records from facility records.	Residents should have reasonable access to their funds (may not be available at 2 A.M.) and should have at least a quarterly accounting of their funds. If questions arise they should be resolved. Personal possessions and funds received from the residents should be protected from theft and other loss. If losses do occur there should be: 1. a procedure which is implemented to investigate the loss, and 2. a plan to prevent recurrence. Resident funds must not be appropriated for facility furnishings; linen direct care supplies, etc	Social Services 405.1130(a)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F72–78 (cont'd)		- Does the home provide safe-keeping for valuables? - Have they ever lost anything of yours? Ask Staff: - What is the procedure when residents lose personal belongings? Valuables? - How are resident personal funds handled? - What is your procedure when a resident asks to get an accounting of their funds? * The special needs of residents with Alzheimer's disease who "lose" personal possessions should be noted. Individuals in stages 2 and 3 of Alzheimer's disease sometimes believe their personal possessions were stolen.			

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F. Freedom From Abuse and Restraints F79-83 SNF 405.1121(k)(7) ICF 442.311(f)	- How many residents are physically restrained? - What type or restraints are used? - Are they applied correctly? - What is the apparent physical/mental condition of those residents restrained? - Do you observe the release of restraints every 2 hours and the provision of at least 10 minutes exercise for the resident? - Do staff respond to request for water, assistance to bathroom, etc.; from a resident who is restrained? What is the interval between request and response?	Ask Resident: - Why are you wearing this? - How often is this worn? - Do you know what would happen if it were removed? - How often is it removed? - What is done for you when the restraint is removed? - For nonrestrained resident-- + Have you ever been restrained? + For what reason? + What explanation was given for the restraint? - Do you ever feel that you receive medication when you don't need it?	Look for a physician's order for the restraint. Review nurses', physicians' progress notes re: reason for restraints and resident reaction to them. Also any alternative methods tried. What time of day are restraints most often applied? Review schedule of releasing restraints. Care plans: - When restraint is to be used. - for how long. - What are plans for alternative measures. - Is the resident periodically re-evaluated? If appropriate are the Social Service or activities departments involved in providing different directions for resident attention?	There must be a physician's order for all restraints, including "safety devices" which are defined in some State laws. Progress notes should show evidence that methods other than restraints were initially used to protect the resident from injury, and that restraints were used only when other methods were not adequate If used in an "emergency" the reason for use must be documented and show that: a. Its use was necessary to protect the resident from injury. b. Its use was necessary to protect others from injury. The resident must be observed by a staff member at least every 30 mins. while restrained. The restraints must be released and the resident exercised, toileted, etc. at least every 2 hours.	Nursing Services 405.1124(c)(5) Rehab Nursing 405.1124(e) Patient Care Management 405.1124(d)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F79–83 (cont'd)	- How often are restrained residents observed by staff? - Observe effect on residents. Do you see what may be signs of over-medication? - How often is this observed? - Residents should be free from mental and physical abuse. -Observe interaction of staff and residents for any sign of harassment, humiliation or threats. - Do residents appear comfortable with staff? - Look for numbers of residents with bruises or other injuries (skin of the elderly bruises easily, so do not automatically assume abuse or injury). - Observe resident to resident interactions and staff response to any physical or mental abuse of one resident to another.	Ask Staff: - What is the facility policy regarding re: restraints? - What is considered an "emergency" need for restraints? - What is the most common reason for use of restraints? - Do you try any alternative measures before using restraints? - What information do you give the physician to help him make the decision to order restraints? - What do you routinely do for the resident when you periodically release the restraints? - Does use of restraints increase on evenings or nights when there are fewer staff members? - Have you had any accidents or incidents in the last year while residents were restrained? - How do you define the difference between a "safety device" and a "restraint"? - How do your policies differ in regard to "safety devices" and restraints?	Who authorizes the use of restraints in an emergency? Do progress notes indicate that a professional staff member authorized the use of "emergency" restraints? There should be documentation that the use of "emergency" restraint has been promptly reported to the residents physician. Review incident and accident reports to identify any problematic trends. Does the drug regimen review indicate appropriate use of psychoactive drugs? Are there resident complaints documented? What is the resolution of these complaints?	The restraint must be applied correctly. If the use of restraints increased during evening and night hours review progress notes, nurses notes and staffing to make a determination as to whether the restraints are justified or if they are for staff convenience. Care plans should plan not only for care while the resident is restrained but should show effort to find alternative treatments to restraints, or there should be documentation in the medical record that no alternative is appropriate. An appropriate drug regimen reviews should be conducted on the resident. Your observations should show interaction between residents and staff to be, except in unusual situations, free from tension and hostility. Staff should step into situation where one resident may be abusing another.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCI
F79-83 (cont'd)	- Observe for evidence of resident neglect, residents left in urine/feces without cleaning.	Ask Resident: - Do you feel safe in the facility? - Do you ever feel intimidated, harassed, or otherwise abused? - How are confused residents treated? - Is anyone ever hit or treated roughly? - Do you feel as if you are treated with respect /dignity? - Is the staff/administration responsive to complaints? - Do you know who to complain to?		Resident should feel free to voice complaints. If no complaints are noted in records or on record review, why not? Residents should seem comfortable in relating how they are treated?	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
G. Privacy F84–89 SNF 405.1121(k)(8)(9)(14) ICF 442.311(g)	– Observe interactions between staff and residents for indications of respect, consideration, dignity and individuality. – How do staff members enter a residents room or go behind a privacy curtain? – Are privacy curtains used or doors shut when personal care needs and/or treatments are rendered? – Are there areas for residents to be alone or meet in private with visitors?	Ask Resident: – Do you feel that you are treated as a worthwhile, adult individual? – – When you are being cared for, are you comfortable? – What is the degree of privacy and respect you receive? – Do you feel comforatable that if the door to your room is closed staff will knock or otherwise make their presence known before entry? – Do you have a private place to make telephone calls? – – Can you see your record if/when you ask? – Has any information about your condition been given to someone outside of the facility without your permission?	Review progress notes for indications that staff see resident as an individual– i.e., resident eats breakfast in bed because he/she enjoys it. Signed consent for release of information. Do maintenance of and content of medical records indicate that confidentiality is practiced?	Observations and interviews will give you information to determine if residents are respected and treated as individuals. Is privacy available– e.g., access to a private place to meet or make phone calls, ability to shut door when having visitors, etc. Medical records should not be left where unauthorized personnel can read them and there should be identification codes needed to access computerized records. Married residents should be sharing rooms if they desire to do so unless there are appropriate contradictions.	Medical Records 405.1132(b) 442.318(d)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F84-89 (cont'd)	- Are medical records kept in their assigned spots not carelessly left for nonauthorized persons to view? - Are married residents sharing rooms? - Observe for negative attitudes toward aging-infantilization and patronizing of residents. - If residents undress in public area, how does staff handle this? - Listen to staff conversation in public places (elevator, lobby). Are resident issues being discussed?	For Married Residents: - When your husband/wife visits can you shut your door and be assured of privacy? - Can you ask that you not be disturbed and have that request respected? Ask Staff: - What is done to assure that each resident maintains his/her dignity and individuality? - How are medical records kept secure? Who has access? - Do you have married couples here? - Do they share rooms? - If not, why? - What arrangements do you make for spouses or significant others to visit? - Do you allow their door to be closed? - Can you adhere to a request that they not be disturbed? - How are residents' medical records and conditions kept confidential?			

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
H. Work F90 SNF 405.1121(k)(10) ICF 442.331(h)	- Are residents doing any type of work such as picking up dirty trays, pushing laundry hampers, etc.? - What about clerical work?	Ask Resident: - Are you ever asked to help out in the facility such as pick up dirty trays or stamp mail? - If yes, do you do this? - Do you want to, or do you feel it is expected of you? - Do you feel you can say "no"? Ask Staff: - Are residents asked to help with facility staff if you are shorthanded? - What is their reaction? - What useful work is available for residents who want/need to be usefully "employed"?	If residents are performing services for the facility, is that included in their care plan with specific therapeutic goals defined? If appropriate does the family concur? Are results documented in progress notes? What service (activities, nursing, etc.) is responsible for planning reevaluating and adjusting work activity? Look for physician's orders for approval or disapproval of work activity or restrictions on this activity. Look for evidence that the resident is given opportunities to refuse to do the work. The resident, however, is not restricted from doing the amount and type of work they desire unless it is in conflict with the plan of care.	Services performed by a resident should be part of the resident's plan of care and should be done only if the resident is in full agreement. Service rewards are specifically identified and not obtained using the residents own funds.	405.1124(d) 442.341

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
I. Freedom of Association and Correspondence F91-92 SNF 405.1121(k)(11)(12) ICF 442.311(i)	- Are there areas in the facility-e.g., small lounges, etc., where residents can and do meet privately? - Is mail delivered unopened or unopened? - Are facility personnel assisting residents, if needed, in opening and/or reading mail?	Ask Residents: - Can you have visits from anyone? - Can you find a private place to visit? - Do you receive your mail unopened unless you request otherwise? - Are there telephones you have access to? - Does the staff or volunteers assist you in reading or sending mail, if needed? - How timely is your mail delivered? - How do you receive incoming calls? Ask Staff: - Where do residents go when they want privacy? - What telephones are available to residents? - What is the facility visiting policy?	Physician orders and care plans for indications of restrictions on visitors and/or receiving and sending mail.	All residents may have access to and maintain contact with the community and members of that community have access to them. Subject to reasonable scheduling restrictions, residents may receive visits from anyone they wish. A particular visitor may be restricted by the facility for one of the following reasons: - The resident refuses to see the visitor. - The resident's physician documents specific reasons why such a visit would be harmful to the resident's health. - The visitor's behavior is unreasonably disruptive of the functioning of the facility (reasons are documented and kept on file). Decisions to restrict a visitor are reviewed and reevaluated each time the resident's plan of care and medical orders are reviewed by the physician and nursing staff or at the resident's request.	Resident Rights 405.1121(k)(8) 442.311(g)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F91–92 (cont'd)	Do the available telephones accomodate the physically handicapped (e.g., wheelchair bound, hearing impaired, etc.).			Space is provided for residents to receive visitors in reasonable comfort and privacy. Telephones, consistent with ANSI standards (45.1134(c)), are made available and accessible for residents to make and receive calls with privacy. Residents who need help are assisted in using the phone. The fact that telephone communication is possible, as well as any restrictions, is made known to residents. Arrangements are made to provide assistance to residents who require help in reading or sending mail.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
J. Activities F93 SNF 405.1121(k)(12) ICF 442.311(j)	- What planned activities are occurring? - What unplanned activities are occurring—individual, 2 or 3 persons or a larger group. - If there is a facility chapel, is it open? - Are activities posted at wheelchair level and kept up to date? - Are residents lined up in front of a T.V. in a common room for hours? - Are activities offered during the evening and on weekends.	Ask Residents: - What do you like to do? - What did you do yesterday? (compare answers) - Is participation in activities optional? - Are you encouraged to participate? - Is pressure exerted on you to attend specific activities? - Which ones? (Surveyors should be aware of special encouragement—"gentle persuasion", which might be important for the depressed or withdrawn resident.) - Are residents notified of community activities? - Are arrangements made for transportation, etc. so that residents can participate? - Can residents go to religious services if they wish? - What opportunities are you given to make choices in your life within the facility? (eg. are all residents "put to bed" at the same time?). Ask Staff: - Are arrangements ever made to take residents to community activities? - Do friends and relatives ever take them to community activities? - Do your residents attend religious service of their choice? - How are residents kept informed/notified of activities?	Care plans or other documentation should indicate resident preferences for both facility and non-facility planned activities. Progress notes of responses to activities.	Compliance with this element is determined by evidence that residents are given the opportunity to participate in available activities they choose unless medically contraindicated. Residents must not be forced to participate against their wishes.	Patient Activities 405.1133(b) 442.345(a)(c)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
K. Personal Possessions F94 SNF 405.1121(k)(13) ICF 442.311(k)	- Are residents wearing their own clothing or facility nightgowns, robes, etc.? - In resident rooms observe for personal belongings. - Ask residents if you can look in the closet is personal clothing in there? - Ask residents if belongings such as clothing are identified with name tags or other identifying methods? - Is there enough space to store clothing?	Ask Residents: - What clothing and personal belongings can you have? - Is there a place that you can secure any valuables that you may not want to keep in your room? Ask Staff: - What personal belongings may residents have? - What do you do to secure valuables and other personal property? - What provisions are made for the care of personal clothing?	Admission notes on personal property inventory (e.g., the record should indicate a list of any personal property secured by the facility). The record should indicate how personal clothing will be laundered.	Residents are permitted to keep reasonable amounts of personal clothing and possessions for their use while in the facility and such personal property is kept in a safe location which is convenient to the resident. The amount that is reasonable will be dependent on space available in the facility. Patients are advised, prior to or at admission, of the kinds and amounts of clothing and possessions permitted for personal use, and whether the facility will accept responsibility for maintaining these items (e.g., cleaning and laundry). Any personal clothing or possessions retained by the facility for the patient during his stay is identified. The facility is responsible for secure storage of such items, and they are returned to the patient promptly upon request or upon discharge from the facility.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
L. Delegation of Rights and Responsibilities F95-97 SNF 405.1121(k) ICF 442.312		Ask Administrative Staff: - When do you have relatives make decisions for residents-i.e., how do you decide when the resident isn't capable of making decisions himself? - Have any legal steps been taken? Ask Resident and/or Guardian: - Do you feel that you are given all pertinent information? - What opportunities do you have to make decisions regarding clothing, meals, bathing schedules, etc.? - For guardian: are you notified/informed in a timely manner as appropriate?	Review physician progress notes--incapability must be documented. Is there clear documentation as to whom rights and responsibilities have been assigned? Are pertinent consents/documents signed by appointed guardian?	The fact that a resident has been judged incompetent, is medically incapable of understanding, or exhibits a communication barrier, does not absolve the facility from advising the resident of their rights to the extent the patient is able to understand them. If the resident is incapable of understanding their rights, the facility advises the guardian or sponsor and acquires a statement indicating an understanding of resident's rights. The surveyor reviews records of residents selected for indepth review who are classified either incompetent, medically incapable of understanding their rights, or have a communication barrier to verify documented evidence (signed acknowledgment) that the guardian or other sponsor has been advised of these resident rights and understand their role in acting on behalf of the resident.	Resident Rights 405.1121(k)(1) 442.311(a)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
STAFF DEVELOPMENT F98 SNF 405.1121 F99 ICF 442.314		Ask Residents - Does staff know how to take care of you? - What things do they do to help you accommodate your (poor vision, unsteady walking, arthritis, etc.)?	Care plans reflect staff's knowledge of the problems and needs of the residents and special adaptations that are needed. Progress notes indicate that the special needs are considered in implementing planned care.	Facility staff adjusts care to needs/problems of resident. Staff is knowledgeable concerning facility policies and procedures.	Residents Rights SNF 405.1121(k) ICF 442.311 Infection Control 405.1135(a)(b)(c) (d)(e) 442.327(b)
F100 1. Facility staff are knowledgeable about the problems and needs of the aged, ill, and disabled.	How do staff relate to residents? Does the facility reflect adaptations for the elderly, i.e., information given in large print, floors covered with materials that allow for ease of movement with walkers, wheel chairs, etc.?	Ask Staff - What, if any, training have you had here to learn about unique problems and needs of the aged? - What training have you had during the last 12 months? - How have you learned about facility policies and procedures?		Staff practices correct techniques, i.e., infection control rehabilitation nursing techniques, etc. Staff interacts and treats residents in a kind, caring way.	Physical Environment 405.1134(a) 442.315(b)(c) 442.326(a)(c) Nursing Services 405.1124(a)(c)(e) 442.338(a)(2)
F101 2. Facility staff practices proper techniques in providing care to the aged, ill and diseased.	Is resident care given using accepted professional standards? Is privacy maintained during bathing treatment, toileting?	- Does the facility ask your needs when they develop a training program? - In what areas would you like to have training?			Social Services 405.1130(a)
F102 3. Facility staff practice proper technique for prevention and control of infection, fire prevention	Are housekeeping staff courteous and responsive to resident needs?				

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F102 (cont'd) and safety, accident prevention, confidentiality of resident information, and preservation of resident dignity including protection of privacy and personal and property rights. INTENT To assure that facility provides ongoing training to staff so that they will be knowledgeable in current practices, use proper techniques, and interact with residents in a kind, caring way.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Status Change Notifications F103-104 SNF 405.1121(j) ICF 442.307 F105 1. The facility notifies the resident's attending physician and other responsible persons in the event of an accident involving the resident, or other significant change in the resident's physical, mental, or emotional status, or patient charges, billings, and related administrative matters.	Note residents condition: - Clean - Well groomed - Well adjusted - Casts - Bruises - Decubitus Ulcer - Multiple sites of edema - Aberrant behavior, e.g., abusive, disruptive, not reasonable, etc.	Ask Resident: - Have you been injured since you have been in the facility? - If you are injured or become ill, is your physician called? - Are your relatives notified? - Do you know who is notified if administrative changes such as changes in charges, billings, etc. occur? Ask Staff: - Who do you notify if a resident is injured or has a change in condition? - When would they be notified? Does the facility have a policy regarding how soon a relative or responsible party would be notified? - Do you notify them of actual changes in resident condition and also if resident's condition is getting progressively worse?	- Progress note should document injury/change in condition plus notification of physician and appropriate family member/guardian. - Changes in charges should be documented. Ask facility where this is located. - Review accident and incident reports for indepth sample.	- All injuries and changes in condition must be documented. The resident's physician and family must be notified of significant changes. This should be documented, but this notification should be confirmed by the resident if possible.	Resident Supervision by Physician 405.1123(b)(3) Emergency Services 405.1123(c)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F106 2. Except in a medical emergency, a resident is not transferred or discharged, nor is treatment altered radically, without consultation with the resident or, if the resident is incompetent, without prior notification of next of kin or sponsor. INTENT To assure that: - the resident receives proper treatment in the event of an accident or change of condition. - resident and/or next of kin or responsible party is aware in advance of any changes. - resident is not discharged to gain a higher source payment for that bed or facility convenience.		Ask Resident: - Have you ever been or do you know if others have been transferred or discharged without discussing it with you first?	- Nursing, physician and social work progress notes should be reviewed for evidence of discussion of transfer/discharge with resident or other designated person.	- Except in an emergency, all transfers or discharges are first discussed with the resident or next of kin as evidenced by documentation in the medical record or confirmed by asking resident.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Physician's Services F107 SNF 405.1123 A. Medical findings and Orders at Time of Admission F108 SNF 405.1123(a) F109 1. There is made available to the facility prior to or at the time of admission, resident information which includes current medical findings diagnoses, and orders from a physician for immediate care of the resident. F110 2. Information about the rehabilitation potential of		Ask Staff: - Interview nursing staff to determine if they receive transfer information and admission orders on day of admission. - Ask Administrator and Director of Nursing to explain procedure if a resident arrives without sufficient medical information and/or orders.	Review records of residents selected for indepth review to ascertain that: - There is a referral form from the transferring facility that was received in advance of admission or on date of admission that includes current medical findings, diagnosis and orders from a physician for the immediate care of the residents. - If the medical orders were not obtained from the residents attending physician, there are temporary orders from the emergency care physician. - Information on the rehabilitation potential (prognosis) of the resident and a summary of the course of treatment followed in the transferring facility were transmitted within 48 hours of admission. - The summary of treatment should include discharge summaries from therapies or special services when appropriate. - For residents admitted directly from the	Examine medical records of the residents selected for indepth review to determine if date of orders, medical data and other required information is the date of admission or within 48 hours of admission. The facility should receive sufficient information and orders to provide continuity of care of all residents.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F110 (cont'd) the resident and a summary of prior treatments are made available to the facility at the time of admission, or within 48 hours thereafter.			community, the attending physician provided current medical findings, diagnosis, prognosis, and orders. - The order should cover: + Medications and treatments + Diet + Therapies (P.T., O.T., Speech) + Activities (bedrest, ambulatory, able to participate with any specific limitations on activity).		

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Resident Supervision by Physician F111 SNF 405.1123(b) F112 ICF 442.346 B. Resident Supervision by Physician F113 1. Every resident must be under the supervision of a physician F114 2. A physician prescribes a planned regimen of care based on a medical evaluation of each resident's immediate and long-term care needs.	Observe resident for any problem/conditions that should be addressed by physician, e.g., edema, loss of appetite, weight loss, etc.	Ask Resident: - How often physician visits. - If physician has discussed plan of care and medical treatment. - If resident feels treatment and/or plan of care meets his/her needs. - What kinds of questions do you ask the physician about your health problems? (Cite examples). Ask Licensed Nursing Staff - How often physician visits and is it often enough to meet resident's need? - Does physician participate in evaluation and reevaluation of resident's plan of care? - Does plan of care meet resident's needs? - Is physician available in an emergency? - Is physician available to discuss residents treatment and care? Ask Administrator - Facility's policy regarding a physician to provide care in the absence of the resident's own physician. - Facility's policy on physician visits.	Review medical records of selected for indepth review for: - A current plan of care that is based upon physician's orders and resident needs. - Evidence that the plan is reviewed and revised as needed. - Evidence through physician's progress notes, nurses notes, physician's orders, that the physician participates in the resident's overall plan of care. - Evidence that rehabilitation potential is addressed. - Long range plans include an estimate of the length of time for skilled nursing care and a discharge plan. - Physician's orders for medications and treatments on admission and during stay. - A medical evaluation completed within 48 hours of admission unless done within 5 days prior to admission that includes attention to needs such as diet, vision, hearing, speech	Medical records should provide evidence that the residents are under the supervision of a physician by the coordination of physician's orders and progress notes with the resident's plan of care and observations of residents needs. There is evidence that the physician reviews and revises the plan of care as needed. There is evidence that physician services are available to the residents when the residents need such services. An alternate schedule for physician visits may be established if the attending physician determines that the resident need not be seen every 30 days. Justification for the decision is placed in the resident's medical record and is reviewed by the U.R. Committee and State medical review team. Where there is a change in the resident's condition and the physician has failed to document his findings or evaluation of the condition, the physician has failed to provide	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F114 (cont'd)			level of activity, emotional adjustment. - Evidence in care plans and treatment records that physician's orders are being implemented. - Discrepancies in medication record, diet order, intake and output records. - Evidence that an alternate physician provided care if applicable. - Progress notes by physician at least every 30 days for first 90 days (ICF-at least every 60 days). - Review of medications and treatments every 30 days or 60 days if an alternate schedule of visits has been approved. - Documentation of physician observations, actions and plans for treatment. - Justification for alternate schedule of visits. A few closed records should be reviewed to determine if residents were appropriately discharged by an order written by the attending physician. Also review	evidence of his evaluation of resident needs and supervised care. A physician is available to respond within a reasonable time when a resident needs medical attention. Although medical evaluation can be noted as a revision of the previous H&P A statement such as "no change" when in conflict with the status of the	
F115 3. A physician is available to provide care in the absence of any resident's attending physician.					
F116 4. Medical evaluation is done within 48 hours of admission unless done within 5 days prior to admissions. NOT ICFs.					
F117 5. Each SNF resident is seen by their attending physician at least once every 30 days for the first 90 days after admission.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F117 (cont'd) Exception: ICF residents must be seen every 60 days unless otherwise justified and documented by the attending physician. F118 6. Each resident's total program of care including medications and treatments is reviewed during a visit by the attending physician at least once every 30 days for the first 90 days and revised as necessary.			discharge plans to assure that they were adequate and implemented. Verbal medication orders are countersigned by a physician. Physician is reviewing all medication orders every quarter.	resident on this admission to the facility, does not constitute a medical evaluation. Verbal medication orders must be countersigned with 48 hours.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Exception: Only medications must be reviewed quarterly for ICF residents.					
F119 7. Progress notes are written and signed by the physician at the time of each visit, and all orders are signed by the physician.					
F120 8. Alternate physician visit schedules that exceed a 30-day schedule adopted after the 90th day following admission are justified by the attending physician in					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F120 (cont'd) the medical record. These visits cannot exceed 60 days or apply to patients who require specialized rehabilitation schedules. Exception ICF residents must be seen every 60 days unless justified otherwise documented by the attending physician.					
C. Emergency Services F121 SNF 405.1123(c) F122 Emergency services from a physician are available and provided to each resident who requires emergency care		Ask Staff: - Are you aware of physician reporting procedures and medical protocols to be followed during a fire emergency? - Do you know where names and telephone numbers are of physicians to be called in case of emergency?	- If records document an accident or a medical emergency, was the patient seen by a physician or was the physician notified promptly of the emergency? - Review physician's orders to see if specific medications or treatments were ordered to treat emergency situation if applicable.	- Surveyor verifies that there are readily available written procedures for securing a physician in case of emergency. - Names and telephone numbers are posted or on rolodex. - An alternate physician is designated.	Status Change Notification 405.1121(j)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F122 (cont'd) INTENT: To assure that a physician has overall responsibility for the managment and supervision of the residents care.			- Review physicians progress notes to see if emergency situation was addressed.	- There is provision for: + Notification of attending physician/ emergency and other responsible person. + Arrangements for transportation. + Preparation of reports. + There is evidence in the medical records that proper procedures have been carried out. + Residents with sudden changes in condition have been evaluated by the physician.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Nursing Services F123 SNF 405.1124					
F124 SNF 405.1124(c) F125 F126 ICF 442.1124(c) A facility provides nursing services sufficient to meet nursing needs of all residents all hours of each day.	Basic care provided to residents: Surveyors should observe the basic care provided by staff to the residents. Listed below are suggested areas of attention which may provide evidence of the quality of personal care: - Eyes/Ears/Mouth Presence/absence of: + Secretions forming around eyelids, redness or irritation of eyes. + Eyeglasses worn when appropriate are clean, in good repair and fit properly. + Backs of ears scaly, obvious wax build-up, discharge, odor. + Hearing aid worn when appropriate, is in good repair and working. + Dried food particles or drool, etc. around mouth.	Ask Resident: - If the resident's clothing is inappropriate, ask: + Did you choose your clothing today? + Is this what you want to wear? + Do you have other clothing available? - If the resident is not clean, poorly groomed, or inappropriately groomed, ask the resident: + Have you had any help in caring for yourself today (e.g., washing your face, brushing your teeth, etc.)? + How often do you have a bath/shower? + How often is your hair washed? + How often do you brush your teeth/clean your dentures? + Were there extenuating circumstances (e.g.,	Nursing notes, flow sheets or bathing records should indicate that the care plan for grooming and personal hygiene is being followed. For example: - Bathing schedules are being followed (including the use of any soaps or special lotions). - Assistance instruction and/or supervision is being provided as identified for each activity. Nursing documentation should also indicate resident response or any changes in the resident's behavior, reaction to an activity, or the ability to carry out grooming and personal hygiene activities. Look for indications of progress toward a goal or further deterioration of resident functioning.	Refer to information on observation. A pattern of evidence of poor personal care indicates noncompliance unless the care plan specifically deals with this and appropriate planning and implementation is occurring. The regulations require that individual preferences are taken into account when providing for grooming and personal hygiene and that residents are encouraged in self-care activity. Do your patient interviews substantiate compliance with the regulations?	Resident Rights 405.1121(k)(8)(13) 442.311 (g)(k) Social Services 405.1130(a) 442.344 Activities 405.1131 442.345(a)(c) Patient Care Management 405.1124(d) 442.341 Training 405.1121(h) 442.314
F127 Grooming and Personal Hygiene SNF 405.1124(c)					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F127 (cont'd)	+ Dentures worn when appropriate and in good repair. + Oral hygiene. - Odors presence/absence of: + Body odors - Hair/Scalp + Clean and free of rashes + Hair combed - Nails are clean and appropriate length - Clothing is appropriate, clean, and in good repair. + Extremities elevated as necessary while in chair or wheelchair. + Appropriate techniques to prevent infection. + Use of whirlpool as a treatment modality as available and appropriate. - With resident's permission check: + heels, feet and toes + lateral hip + scapular area + sacrum + buttocks + bony prominences in contact with braces + condition of stump (especially diabetic	resident is participating in dressing retraining program)? - Special consideration might be given to the demented patient who frequently "borrows" clothes and for whom removal may elicit catastrophic reaction- whether clothing "matches" may not be the most important issue in the care of these patients. Ask Direct Care Staff: - How do you choose what clothing each of your residents wear each day? - Do you have a specific schedule for washing residents' hair? - How did you learn to bathe resident? - How did you learn to wash residents hair? - How did you learn to shave residents? - How do you handle situations when residents want to wear dirty clothes, or mismatched clothes? - How much care do you let the residents do on their own?			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F127 (cont'd)	amputees with elastic bandage or sock removed).				
Skin Condition F128–129 SNF 405.1124(c)	Observe with residents' permission: - General condition of skin + Redness + Blanching + Soft/dry/rough etc. + Rashes/irritation + Bruises + Scabs + Free of above - Measures taken to prevent skin breakdown. - Pressure sores - Pressure sores Rx - Factors contributing to prevention of pressure sores + Overall cleanliness and maintenance of dry and aerated skin (uncompromised by urine/feces/perspiration) + Padding for pressure points and bony prominences including padding on bed/chair + Proper gentle massage to bony areas several times a day.	Ask Resident: - Are your feet usually swollen? - Do you know what causes the swelling? - What do you do to alleviate it? - Is this discoloration normal for you? - How did this wound/bruise develop? - Are the treatments done about the same time every day? - What staff person has looked at your skin recently?	Look at nursing notes and P.O.C. for evidence of: - Planned preventive measures - Treatments/intervention including nutrition - Routine assessment/evaluation of skin condition - Documentation of specific skin problems with location number, severity, measurements as appropriate, and cause - Progress or lack of progress in healing - Assessment/Reevaluation of interventions with alterations in plan - Appropriate nutritional plan - Methods to control edema of lower extremities	Preventable pressure sores are not occurring. Ulcers present are treated on a routine basis according to P.O.C. Is skin clean? Is resident dry? Is turning schedule adhered to? Are linens clean and smooth? Do personnel know preventive measures and practice these? Has a nutritional assessment been done, and if appropriate, recommendations implemented?	Dietetic Services 405.1125(i)(c)(e) 442.332(a)(1)(b)(1) Activities 405.1131(b) 442.345(a) Patient Care Management 405.1124(d) 442.341 Training 405.1121(h) 442.314 Rehabilitative Nursing 405.1124(e) 442.342 Supervision of Patient Nutrition 405.1124(f) 442.332(b)(2)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F128-129 (cont'd)	+ Regular assistance for resident to turn or shift weight (bed-rails, footboards, trapeze). + Bed linens, clothing, underpads smooth and free from wrinkles. + Elastic bandages or hose are smooth and wrinkle free. + Elastic bandages wrapped smooth with appropriate overlap. + Dietary/nutritional support for skin integrity. (See Guidelines for Dietary/Nutrition Prevention of shearing force when resident's position altered by staff. + Turning and repositioning as needed. - Care and Treatment: + Turning and repositioning every two hours or as needed (e.g., alternative approach that is justified by the facility.) + Positioning of the ulcer site or protection of affected areas. + Use of effective pressure relief devices.	Ask Direct Care Staff: - What can you tell me about Mr./Mrs. _____ swollen feet/wounds/ bruisses/etc.? - What do you do for them? Ask Charge Nurse: - How did _____ get cuts, bruises, etc.? - What is being done to prevent further occurance? - What treatment is he/she receiving?			Resident Supervision by Physician 405.1123(b)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Wounds/Wound Dressings F126 SNF 405.1124(c)	- Condition of dressing - i.e., clean, firmly secured unless contraindicated. - Observe, if possible, and with resident's permission, a dressing change + Pre-dressing Removal Equipment and supplies organized Hands washed Residents provided with privacy - Dressing Is: + Old dressing observed for drainage? + Wound examined + Appropriate technique used + Proper disposal of old dressing? + Post dressing + Does staff member wash hands? + Return resident to comfortable position or previous activity?	Ask Resident: - How often is the dressing changed? - By whom is the dressing changed? - Does it seem dressing changes are frequent enough? - Are there any odors from the dressing? - Is the dressing change always done in a similar way? - If not, what are the differences? - Do you feel confident that the wound is being well cared for? - Is the area/wound healing? - What caused the ulcer, wound, etc.? Is it healing? Does the staff keep you informed of its status? Ask Staff: - Specific treatment and schedule for each resident?	- Physician orders for wound care - Progress notes detailing condition of wound - i.e., size, drainage, surrounding tissue, odor - Treatment provided - Progress/change - Plan of Care (POC) + The plan of care should address: - Area in need of treatment, treatment to be performed, frequency, and responsible staff. - All necessary solutions, ointments, irrigations, types of dressings, and materials. - Any necessary precautions, drains, if present, sutures and tubing. - Specific goals of treatment as well as any problems or limitations imposed as a result of treatment.	Physician orders, your observations, progress notes and POC should reflect the same information. Treatment provided over a period of time with no improvement and no re-evaluation also would represent non-compliance, unless nursing/physician progress notes address the "no improvement" problem. Compliance is evidenced by: - treatment given according to doctor's orders and POC. - use of appropriate technique when caring for wound/changing dressing (e.g., follows facility's written procedures). - periodic evaluation of healing process and revision of care plan as needed.	Physician Services 405.1123 442.346 Infection Control 405.1135(b) Pt. Care Management 405.1124 442.341 Dietetic Services 405.1125(b)(c)(e) 442.332(a)(1)(b)(1) Medical Records 405.1132 442.318

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Restraints F130 When residents require restraints the application is ordered by the physician, applied properly, and released at least every two hours. (See also information under Resident rights-Freedom from abuse & restraints)	Direct to evidence of: - Proper application - Proper use - Maintenance of good body alignment - Resident observation, release and exercise Observe frequently throughout your visit to validate care. Specific observations should include the following items: - Type of restraint: belts, wrist or ankle cuffs, blanket restraints, vests, bed nets, locked, etc., (When locked restraints are used can you readily find the key and/or scissors?) as well as geriatric chair or geri-table/tray in place for prolonged periods. - Protective devices and/or safety devices that are used as restraints must be evaluated as restraints. - Appropriate application: skin protected from injury (restraint neither too loose nor too tight to prevent	Use of restraints may be precipitated by an "emergency" situation in which there is a threat to the resident's health or safety, or a threat to the health and safety of others due to the resident's behavior. Restrained residents may not be coherent or rational enough to respond to questions and caution in interviewing therefore, must be exercised. However, observation of a resident in a geri-chair with table in place or a resident in a wheelchair (with vest restraint) for several hours would warrant appropriate questions as to when the staff last assisted him or her to move about or whether the resident would like to get out of the chair. Staff interviews focus on the reason why the resident is restrained. <u>Ask Direct Care Staff and Charge Nurse:</u> - When, why, and how to release and apply restraints? - Why is the resident	- Physician orders for restraint: reason, length of time, type - Progress notes - Describe the resident's status/behavior which prompted the use of the restraint. - If a chemical restraint, the order should indicate a specific time period for its use as well as a stop date. - Plan of Care should + Identify other methods or therapies that are being used in conjunction with restraints. + What alternatives to restraints have been considered. + Identify staff responsible for observing the resident (every 30 minutes), and releasing and exercising the resident (every 2 hours for at least 10 minutes). Time intervals should be identified. + Indicate involvement and input of other disciplines necessary to overcome the problem. + Indicate a specific period of time for	- Is there a physician's order, including the circumstances in which they will be used, the length of use, and the type of restraint? - Is the restraint applied properly? - Is it released at least every two hours and the resident provided with exercise and toilet facilities if needed? - Does the staff observe the resident frequently while he/she is restrained? - Are chemical restraints administered in accordance with physician's orders? - Is the order for restraints renewed only after a reassessment of the patient?	<u>Patient Rights</u> 405.1121(k)(1)(7) 442.311(f)(2)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F130 (cont'd)	rubbing and blistering or impeded circulation). - Body alignment and support: use of pillows, footboards, and wheelchair footrests to maintain appropriate posture, circulation, and to prevent skin injury or breakdown. - Periodic release and exercise: exercise may include ambulation, range of motion, massage, or other opportunities for motion (at least 10 minutes every 2 hours during day and evening hours). - Chemical restraints: residents appear drowsy throughout the day (may indicate tranquilizers or other drgus are being used to limit or control behavior for staff convenience).	restrained? - Was the resident given an option of restraint? - When were you taught the use of restraints? By whom? - If chemically restrained (excessively sedated) + Why is this done? + Whether alternate means of restraint have been attempted; for how long this will continue, etc. This should elucidate from staff whether the chemical restraint is necessary, or whether it is done for staff convience by controlling resident behavior - Do you ask the resident for permission before using restraints? - How does the restrained resident summon assistance? - What is the usual timeframe for assistance to reach the restrained resident? Ask Resident: + Why are you restrained? + What would happen if the restraint were removed? + When do you use bad rails? + What purpose do they serve? + How do you gain assistance?	using the restraint. - Indication of assessment of factors which precipitate residents behavior which has warrented restraints and plans to intervene early enough to prevent occurence. - Type, duration and frequency of exercise should be documented. - An assessment of why restraints are continued should be documented.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Bowel and Bladder F131 SNF 405.1124(c) Each resident with incontinence is provided with care necessary to encourage continence including frequent toileting and opportunities for rehabilitative training.	- There should be a chart/record in the resident's room on which the program is documented accurately. - If the room is located a distance from the toileting room or for residents with problems ambulating, a commode may be present in the room. - Verify that a call light is available to the resident if non-ambulatory or restrained. - Are fluids available at bedside? - Is there roughage on meal tray? - Diet is appropriate to enhance elimination?	Both the resident and direct care staff should be interviewed and should exhibit a good understanding of the importance of maintaining a regular schedule of elimination. If neither are aware of the intake and toileting schedule, then determine whether they are appropriately panning the resident or carrying out a retraining program. - Verify that the resident is aware that he/she is on a retraining program and knows the content of the program. Ask Resident: Suggested questions are: - How do you deal with constipation/diarrhea? - Are you involved in a special bowel/bladder training program? - If so, how does your program work? - Any problems with it? - Any successes to date? - What does the staff do for you in this matter? - Are they consistent and timely? - How long do you have to wait to be taken to the toilet?	- Physician orders if required by facility policy - Nursing notes for + Assessment + Documentation of techniques and progress, reevaluation - Plan of care The plan of care should clearly address: + Goals that resident will aim for. + Methods to accomplish the goals. + Schedule for fluid intake. + Schedule for toileting. + Responsible staff + Any limitations the resident may encounter as a result of either incontinence or the training program. - Progress notes/physician orders for cause of incontinence. - Laboratory tests of kidney function when available - Treatment for diarrhea/constipation - Residents preference for treatment of constipation. - Recently admitted and newly incontinent residents should be thoroughly assessed for at	- Are all incontinent patients assessed for cause of incontinence and ability to be helped by a bowel/bladder rehabilitative training program or an incontinence management program? - Are all appropriate residents involved in bladder/bowel training programs or, incontinence management and there is a schedule that shows when the program will be started? - Is there evidence of follow through on all shifts? - For residents not on bowel/bladder retraining programs, the plan of care should address specific measures for managing incontinence with a view to prevention of skin and other problems and maintenance of resident dignity.	Nursing Services 405.1124(e) Dietetic Services 405.1125(c)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F131 (cont'd)	- When a resident puts on his/her call bell for toileting assistance, how long is it before assistance is given/ - Observe pre-meal toileting. - Privacy provided. - Schedule for toileting should allow for resident's normal sleep pattern, to avoid disrupted sleep.	Ask Nurses Aides and Charge Nurse: + Will you describe this resident's bowel/bladder (B/B) training program? + How long has it been in effect? + When will you evaluate the results? + If this program is not successful - What assessment was done to determine B/B status - For residents not on B/B retraining programs what is the facility program for managing incontinence?	at least 7 days for the cause of incontinence and when appropriate an intensive bowel and bladder B/B training program should be instituted. - A trial B/B training program is suggested for all residents with incontinance problems. - I & O		
Catheter Care F132 SNF 405.1124(c) Each resident with a urinary catheter receives proper routine care including periodic evaluation	The indwelling catheter should promote a continuous flow of urine unless ordered otherwise. The surveyor should also observe for the following: - Ample supplies for catheter insertion and care. - Proper positioning of the tubing and drainage bag. - Cleaniness of the	Ask Resident: - What is the tubing/catheter for? - Why do you have one? - Does it cause any discomfort? - If it does, what is done about it? - How do you feel about having the catheter? - Is any special care given in relation to the catheter?	The surveyor should verify that there is a physicians order for an indwelling catheter, including the type and frequency of catheter care. If irrigation is ordered, the order should include type of solution and frequency of irrigation. The record should also indicate the color, consistency, and amount of urinary drainage.	*The facility should follow accepted professional standards in their catheter care. There should be medical reasons for catheter insertion - staff convenience cannot be justification. Direct care staff should know signs and symtoms of urinary tract	Infection Control 405.1135(b)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F132 (cont'd)	tubing and drainage bag. - Color and consistency of urine in bag. - Availability and accuracy of documentation on the I&O sheet if ordered or policy. - Proper equipment for ambulation - leg bag if resident is ambulating. (if ordered) - Availability of fluids. - When indicated monitor intake to ensure adequate intake and output or conformance with physician orders. - How many observed residents are on catheter care?	Ask Nursing Aide and Charge Nurse: - How do you routinely position and secure catheters and drainage bags? - How often is each part of the system changed? - What are the indications for insertion of the catheter? - What is the facility's procedure for routine catheter care? - How do you observe for U.T.I.'s in residents with indwelling catheters? - What is the facility's procedure for the cleansing and storage of reusable catheter equipment and drainage receptacles? - How do you care for catheter tubing?	- Assessment should address: + Need for an indwelling catheter. + Resultant problems or limitations. - Plan of Care should address: + Type of catheter and type and frequency of care. + For irrigation, the rationale, the type of solution, amount, and frequency of irrigation. + Frequency of symptoms which would precipitate catheter change. + Time frames of catheter change and responsible staff. + Appropriate increase in oral fluid intake. - Intervention The record must reflect: + When and by whom the catheter was inserted and for what reason. + Any special care provided + New problems or changes + Only appropriately trained staff should deliver catheter care. + Only licensed staff should insert	infections (U.T.I.s) and these should be reported and treated promptly. "The Center for Disease Control has developed standards for catheter care which may be used but it is not a requirement.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F132 (cont'd)			indwelling catheter. + The specific type and size of equipment used should be noted. + Signs and symptoms of urinary tract infections (UTI) should be acted upon and documented as to follow-up. - Evaluation/Reevaluation The record should reflect that the resident: + Is assessed for UTI. + Has no abdominal distention. - Notes should also include: + The color and odor of urine and the development of any problems after insertion of indwelling catheter. + Verify that catheter is patent.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCES
Injections F133 SNF 1124(c)	- Observe for preparation of injection - i.e maintenence of sterility; correct dilution, handwashing, before preparation, etc. - Observe injection site for: + Redness + Discoloration + Swelling + Lesions - Observe for proper technique when injection is given + correct site + correct needle size + correct volume of drug + sterility maintained - Resident is observed for any adverse reaction - What is the disposal method for used needles or syringes?	Ask Nurse: - What is your plan for alternating injection sites? Show me. - What is the medication for and what are potential adverse reactions? - Is there nonspecific pain at the injection site or shooting pains down a limb? - Is there skin irritations or lumps under the skin? - If adverse reaction occur, how soon are they reported? - Could this be given by any other route? Ask Resident: Suggested questions are: 1. What kind of medicine do you receive by injection/shot? Why do you need that medicine? 2. Do you have pain or numbness at or around your injection site? 3. Who gives the injection? 4. Do you receive your injection according to a schedule?	- Physician order sheet - Nursing notes for: + Resident response to medication if appropriate + Any problems noted at injection site + Any other adverse reactions + Site of injection - Plan of care + Rotation of injection site + Care for any special problems related to the injection. - Infection Control: reports for any infections connected with injections.	- Is the medication administered according to the physicians order? - Is proper technique used in preparation and administration including site rotation? - Does the nurse administering the medication know the expected action of the drug? - If infection control reports show infections at injection sites. - Is the resident's response to the medication noted in the progress notes?	Staff Development 405.1121(h) 442.314 Infection Control 405.1135(b)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCES
Parenteral Fluids F133 SNF 405.1124(c)	The surveyor should observe that parenteral fluids are administered with safe, aseptic technique providing fluids as ordered by the physician. Safety and comfort measures are to be taken insuring maximum protection and optimum hydration of the resident. The surveyor should note the following items: - Labeling of the solution bottle/bag. - Rate of infusion/cc/ml per hour. - Date and time started —additives, if any. - Any signs of swelling or redness at site; - Site dressing is clean, dry and dated. - Accurate I&O of parental and P.O. fluids - If splint (armboard) is used, it is applied to prevent movement but not impede circulation. - Positioning of I.V. tubing. - Comfort of restraint used to allow for maximum resident freedom while preventing movement of I.V. site.	<u>Ask Resident</u>: - Why do you have this tube in your (arm)(leg)? - Is it comfortable? - Is there a way it would be more comfortable? - How long has it been in? - How much longer will it stay in? <u>Ask Appropriate Staff</u>: - Why the resident is receiving I.V. therapy? - What the drip rate is (the amount of fluid to be received per hour). - How often the dressing is changed. - How often the tubing is changed. - What are possible side effects? - How often is the site checked? - How often is the infusion checked for drip rate and the remaining volume to be administered? <u>Ask Nursing Aide</u> - What are your responsibilities when caring for a resident receiving IV fluids? - What training have you had?	- Physician's order for parental therapy specifying type of fluid, rate of infusion/hour, and additives, if any, is available and current. - Twenty-four hour I&O record. - Nursing documentation indicates physician's orders are being followed. - Any adverse reactions are noted in the medical record. - Record indicates: + Infusion started by whom; cite time, rate of flow + Note is made of observation of pain or swelling at infusion site. + The need or reason for parenteral fluids. + Response to the therapy. + Problems and limitations encountered by the resident as a result of receiving parenteral fluids. - Plan of Care* The plan of care should include + Type, rate of infusion /hour, and additives (if ordered).	- Is the parenteral fluid administered according to the physician's order and in accordance with accepted nursing practice? - Are infiltrations noted in a timely manner before a large amount of fluid infiltrates? - Is the facility procedure for care of the IV site and tubing changes followed for all patients unless contraindicated? - Does documentation reflect what the patient received, any problems, and his/her response to the parenteral fluid? - Have any adverse effects been caused by administration of IV fluid? - If yes, were these preventable?	<u>Resident Care Policies</u> 405.1121(1) <u>Infection Control</u> 405.1135(b) <u>Patient Care Management</u> 405.1124(d) 442.341

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F133 (cont'd)			specified goals for correction, time frames, and responsible staff. - Documentation must include time administered and by whom, the amount of fluid infused, and any other special care administered as a result of IV therapy (i.e., mouth care, assistance with ADLs, etc.). - The record must reflect: + Conditions of site and any infiltrations, phlebitis, necrosis, etc. noted, along with measures taken to correct these. + The resident's response to therapy + Changes in laboratory studies *Plan of care would not be modified for a one-time IV infusion.		
Colostomy/Ileostomy F133 SNF 405.1124(c)	The surveyor should ascertain that the facility is providing appropriate nursing care to those residents who have had bowel surgery resulting in a colostomy or ileostomy. It is recommended that the surveyor, with the resi-	Ask Resident: - Why was the ostomy performed? - How do you feel about the ostomy? - Does it ever cause you problems (e.i., pain, skin problems, odors accidents)? If so, what	The surveyor should determine that: - Colostomy irrigations, if ordered, are documented as performed by the resident or appropriately trained staff. - In the case of sigmoid colostomy regular patterns of bowel elimination are	Compliance would be indicated if residents are physically and emotionally comfortable with the ostomy with minimal or no skin problems. If residents are not comfortable with the ostomy, are having skin or other problems, the facility	Patient Care Management 405.1124(d)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Colostomy/Ileostomy F133 (cont'd)	dents permission, observe care being given to determine that proper techniques are being used. The following steps should be taken to assure that proper ostomy care is being provided. - The ostomy dressing should be changed or the bag emptied and thoroughly cleaned promptly after each bowel evacuation or more frequently, if drainage continues. - The peristomal skin should be cleansed and dried, and appropriate measures taken to prevent excoriation and infection. - The resident's privacy should be considered while providing care. - The resident should be provided with information and instruction in self-care at the appropriate level of understanding. - The resident should be observed for signs of withdrawal, disgust anxiety, or other emotional responses which may be related to his/	does staff do about it? - What does the staff generally do with or for the ostomy? Are they consistent and timely? - Has staff talked to you about doing some of the care for this? If so, what was the outcome? If not, is this something you'd be interested in learning more about? Ask Staff: - If nurses aid: + How did you learn to take care of colostomies? + What do you do if the skin around the colostomy becomes red or sore? + Do you ever teach the residents to care for their own colostomies? - If nurse (RN or LPN) + What is the procedure if the resident becomes constipated? Ask Other Nursing Staff: - Is there a facility procedure for ostomy care? - Do you have skin problems with your	documented as established through management of diet, fluid intake, exercise, and the use of prescribed laxatives, suppositories, and/or irrigations. - Ostomy care is documented in the resident's record along with a description of the excreta. - Problems in irregularity, skin breakdown, or other observable concerns are documented and reported to the physician. - Documentation indicates that nursing measures are taken to assist the resident who is experiencing problems in understanding and/or accepting the presence of the ostomy. - Documentation of nursing measures to maintain skin integrity. - Assessment The assessment should indicate: + Needs, problems, and limitations as a result of an ostomy. + Specific degree of	should be responding to these and correcting them as reasonable. Care plans should indicate specific goals in relation to problems and specific interventions for reaching these goals. When available an enterostomal therapy nurse should be involved in developing the care plan for residents with urinary and intestinal stomas.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Colostomy/Ileostomy F133 (cont'd)	her acceptance of the colostomy/ileostomy. - The surveyor should observe the staff giving ostomy care to verify that proper technique is used.	ostomy residents? - What do you do when skin becomes excoreated? - What teaching do you do with the residents? - What in general is the response to this teaching?	self-care performed or assistance needed. + Special skin care needs. + Special dietary needs. + Emotional support. + Medications and treatments if needed. - Plan of Care The plan of care should clearly address: + Specific goals to overcome or improve the problems(s) identified. + Methods to accomplish the goal (training, assistance, supervision, treatments, emotional support). + Services necessary and who will perform the services. + Time frame for accomplishing goals.		Social Services 405.1130(a) 442.334(a)(b)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Respiratory Therapy F133 SNF 405.1124(c)	- Aerosol Compressor or IPPB (Intermittent Positive Pressure Breathing Machine) The surveyor must determine that the facility is providing respiratory therapy as ordered by the physician. Observation for this indicator should focus on the necessary equipment as well as on the resident. In order to determine that the necessary equipment is available, the surveyor must look for the following: + Aerosol compressor or IPPB Machine. Check that the machine is clean and operable. + Tubing – If tubing is not attached to the machine, ask to see it. Check that it is stored dry and with consideration for cleanliness. + Nebulizer Cup – should be attached to tubing. It is filled with either the prescribed medicine or distilled water only if about to be used. It should not be	While interviewing the resident, observe for sounds of congestion. Note color of lips and nail beds. Ask Resident: - Do you ever feel short of breath? - If yes, what is done when this occurs? - Is the therapy helping you to feel better? - Are there any problems with it? - If so, how does the staff respond? - Is the therapy consistently performed – both concerning time and method of providing it. Ask Staff: - What is the reason the resident is getting this therapy? - What are the expected results? - Can you demonstrate how you use the equipment? - How often is the equipment cleaned? - What are the infection control procedures in regard to use of res-	The surveyor should determine that: - Respiratory/oxygen therapy is performed or administered by appropriately trained staff. - There is a physician's order for therapy, and it is specific as to rate of delivery, etc. - If the physician's order is for prn therapy, it should specify for what symptoms. - Any information gained from resident or staff is verified in the record. - Assessment + The assessment should address both the need or reason for therapy and any problems or limitations which result from the need for therapy. - Plan of Care The surveyor should note: + The kind, amount, frequency, and/or duration of therapy based on the physician's order. + Specific goals to overcome to improve any identified	Only qualified (trained) personnel should administer/assist with respiratory therapy. Therapy must be provided as ordered. The effectiveness of the therapy must be periodically evaluated and therapy revised as appropriate. Effective infection control measures must be practiced. Needed safety precaution for the use of oxygen must be practiced. Equipment should be available and in working order.	Staff Development 405.1121 (h) 442.314 Infection Control 405.1135(b) Patient Care Management 405.1124(d) 442.341

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Respiratory Therapy F133 (cont'd)	stored wet. If it is not attached to the tubing, ask to see it. The mouthpiece is connected to the nebulizer cup. The surveyor should also check that all involved equipment is clean. - Oxygen Therapy The surveyor must establish that the facility is meeting the oxygen needs of the resident. When the facility does not have wall units, check that: + There are enough cylinders for oxygen delivery. + There should be flow meters and regulators for tanks in use. + A wrench should be attached or stored close by. + If using large cylinders (size G or H), look for a carrier since these tanks cannot be transported without it. + The cylinder at the resident's bedside should either be on	piratory equipment? - What training was given you in the use of this equipment? - Where is the emergency oxygen supply?	problems and/or limitations. + Specific methods to accomplish the goals (observation, supervision, training, etc.). + Who is responsible to perform therapy or assist in accomplishment of goal. - Intervention - The record should display evidence that: + The plan of care is functional + The therapy was administered in accordance with physician's order for the specified reason(s) by an appropriately trained staff member + Change in condition is documented and acted upon promptly. - Evaluation/Reevaluation The record should reflect: + The resident's response to therapy. + If response was undesirable, evidence of further intervention. + Any progress, deterioration, or development of new problems.		Physical Environment 405.1134 (1) Medical Records 405.1132 442.318

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Respiratory Therapy F133 (cont'd)	the carrier, sitting on a metal skirt, or otherwise secured. + There should be other necessary equipment available such as humidifiers, nebulizers, masks, nasal cannulas, T-pieces, etc., all should be dry and clean when stored. + Check to see that non bed-bound residents are not limited to their own chair/room when using oxygen (portable units will prevent social isolation. + Water reservoir is appropriately filled per manufacturers instructions. + Check to make certain the tank is not empty and that any tank is labeled as such. + Check for good oral hygiene of resident. + The room should be posted with a "No Smoking" sign. - Residents on respirators: + Are alarm systems turned on?	Residents on Respirators Ask Staff (all levels): - What training have you had in caring for	+ Based on the above information, possible modification of goals.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Respiratory Therapy F133 (cont'd)	+ Is sufficient Oxygen supply available? + Is the ventilator accessible to an emergency outlet? + Is the resident in a location that allows for frequent observation by staff? + How does the resident communicate with staff? + What level of staff (aide, LPN, RN) caring for the resident? + Is such equipment at bedside? + Is there reserve back-up equipment? + What is the condition of the residents skin around intubation tube/tracheostomy. + Does the care given use appropriate technique in caring of the patient?	residents on respirators? - Can you show me how the alarm system works? - What is your procedure for pulmonary care? - What is your procedure for changing tubing and the water reservoir? - What happens if the power goes off?			

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Tracheostomy Care F133 SNF 405.1124(c)	Satisfactory tracheostomy care is a procedure which promotes a clean, unobstructed air passageway and maintains the skin integrity surrounding the tracheostomy site. The surveyor should determine whether: - Adequate supplies are available for the care of the tracheostomy such as tracheostomy kits, hydrogen peroxide, normal saline or sterile water, suction machine, catheter, sterile gloves, and clean dressings. - The resident is breathing without difficulty and is comfortable. - The dressing is clean, dry, and intact; the cannula is clean, in the proper position, and secured. - The skin surrounding trach is clean and dry with no redness or inflammation. - The resident has adequate oral hygiene. - An extra tube, the same size as the one in [- May I observe your tracheostomy care?]	Resident interviews must be guided by the resident's communication ability. Ask Resident: - How long will you have it? - What care can you do for yourself? - What do you need help with? - Who helps you? - Is someone always available to suction him/her when needed? - Is the suction equipment always available in working order? - Is the dressing kept clean and comfortable? - Is the tube kept clean and changed as needed? - How often are the tubes and dressings changed? - Does he/she feel confident in the personnel caring for his trach- - What is communicating with staff and other residents like? - Are staff patient and do they allow you enough time to express your needs/thoughts/ feelings? Ask Staff: - Why does resident have	- The surveyor should determine that tracheostomy care is done as scheduled and as needed following the proper procedure. - Any special solutions that are needed should be addressed in the physician's orders. - Assessment – The record should reflect that the need for tracheostomy care was assessed in terms of: + Frequency + Skin integrity surrounding the tracheostomy, noting redness, inflammation, and/or excoriations. - Plan of Care should include: + Specific times of trach care and the responsible, appropriate trained person performing this task. + Specific problems relating to skin and breathing as well as the goals set to overcome these problems listing the appropriate personnel responsible; + Time frames for resolving problems	Stoma and surrounding skin should be in good condition and if not, there should be treatment directed to resolving this problem. All staff caring for the tracheostomy must be trained and emergency procedures must be known. All needed equipment must be available and in working order. Resident must at all times have readily available a means of communicating with the staff in an emergency.	Infection Control 405.1135 (b) Training 405.1121(h) 442.314 Patient Care Management 405.1124(d) Physicians Services 405.1123(b) Social Services 405.1130(a)

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Tracheostomy Care F133 (cont'd)	place, is available at bedside. - Does resident have an adequate method of communicating with the staff? - Does staff allow enough time for residents to communicate?	tracheostomy? - What training were you given to enable you to care for tracheostomies? - What is the procedure for tracheostomy care? - How often is the tube changed? - What do you do if the tube comes out? - May I watch you do a dressing change? - If not convenient, describe what you do. [- How do you communicate with a tracheostomized resident?]	listed in goals. + Plan for periodic assessment of appropriateness of residents own self care re: teaching or nursing assuming more responsibility as appropriate. - Intervention - The surveyor should look for documentation of: + Trach care and oral hygiene administration, including responsible personnel, time and date, and effects. + Any problems or changes noted in resident condition (e.g., redness, swelling, tracheal obstruction). + Emotional response to tracheostomy. - Evaluation/Reevaluation + Resident is or is not benefiting from trach care and skin care. + If problems are noted, the progress notes and plans for care should indicate changes in treatment. + Resident's emotional response to care of the tracheostomy should be evaluated,		

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Tracheostomy Care F133 (cont'd)			since this may require additional care planning.		
Suctioning F133 SNF 405.1124(c)	Suctioning is necessary for any resident who is unable to cough up secretions that are obstructing his airway. Suctioning may occur via the oral or nasal route, or stoma route with sterile technique. Attempts should be made to observe a resident being suctioned should such an opportunity arise. If so, observe that a clean/aseptic technique is observed throughout and that the resident tolerated the procedure. There should not be bloody aspirant, cyanosis, or broncho-spasm. Check that equipment is in good working order, frequency of procedure, etc. Resident observations which indicate need for intervention include: - Secretions are draining from a resident's mouth or trach and the resident is unable to	<u>Ask Resident:</u> - How are you feeling now after the suctioning? Does the suctioning seem to help? - Has staff explained to you the need for suctioning? Why do you need to be suctioned? How often? - Who performs the suctioning (i.e., nurses or nurses aides)? Do you feel safe with the staff performing the suctioning? - Does everyone do it about the same way? <u>Ask Staff:</u> - When and where did you learn to suction? - Tell me what procedure you use when you suction a resident. - Do you always have enough suction machines and catheters? - How frequently is suction tubing changed? - What provisions do you have for suctioning if the electricity is lost?	- Assessment – The record should reflect that: + The resident is frequently observed for suctioning needs. + Any limitations a resident has as a result of his suctioniong needs should be specifically noted. + Any problems resulting must be specified. - Plan of Care should include: + Awareness of the resident's suctioning needs, goals, approaches, and responsible staff needed to improve the problem or at least to maintain the resident at his present status without further deterioration. The plan must clearly indicate specific approaches towards: - Prevention of skin problems around the trach if one exists. - Correction of any existing skin pro-	- All equipment must be available and in working order. - All staff caring for the resident must know what to do in an emergency. - Current professionally accepted standards of care must be maintained.	<u>Infection Control</u> 405.1135(b) <u>Patient Care Management</u> 405.1124(d)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Suctioning F133 (cont'd)	cough or clear himself. - There are audible crackles or wheezes and/or diminished breath sounds. - The resident is dyspneic. - Restlessness or agitation may also be an indication that suctioning is needed. Upon completion of suctioning above symptoms should, in most cases, be relieved. The surveyor should observe that the resident is positioned to facilitate breathing (usually at a 45 degree angle). Check to see that the facility has an ample supply of suction machines and suction catheters to meet the needs of residents requiring them and that they are clean and properly stored.	- Where are your emergency electrical outlets? - What is your procedure for disposing of the secretions from suctioning? - How often does Mrs./Mr. need to be suctioned? - May I observe you when you suction Mrs./Mr.?	blems. - Provision of good oral hygiene including a rigid schedule for mouth care, schedules, or procedures for maintaining clean equipment at bedside, as well as disposal of used (dirty) equipment. - Route of suctioning (i.e., oral/nasal/trach). - Intervention - The record should indicate clearly that: + The plan of care is being implemented. Documentation should reflect: + The number of times the resident required suctioning, for what specific reason, and by whom the resident was suctioned. + Any special treatment the resident received in conjunction with suctioning		

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Suctioning F133 (cont'd)			(i.e., oral hygiene, skin care, etc.). - Evaluation/Reevaluation The record should reflect: + How well the resident tolerates suctioning procedures. + Any bloody aspirant, cardiac arrhythmia, cyanosis, or bronchospasm. + Further interventions utilized to overcome or improve these. + The amount of sputum as well as its color and consistency. + Any progress or lack of progress, deterioration, and/or the development of new problems. + The evaluation should determine whether goals are being reached or if new goals must be addressed.		
Tube Feedings F133 SNF 405.1124(c)	- Staff use proper technique in administering feedings and medications. Check to see that staff checks for location of tube before feeding and that tubing	If the resident is able to be interviewed, suggested questions may be: Do you feel comfortable/safe with all the staff who perform the feeding?	Tube Feeding Review: - Plan of care - Must document tube placement and formula potency prior to each feeding.	- Has the feeding been ordered by a physician? - Is tube feeding nutritionally adequate? - Have attempts been made to discontinue tube feeding if indicated?	Nursing Services 405.1124(d)(f) 442.338(a)(2) Meal Service 442.331(c)

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Tube Feedings F133 (cont'd)	is irrigated before and after addition of medication. - The tube is clean and formula flows freely. - The equipment is clean and protected. If dressings are ordered, they are in place, clean, and dry. - The nasal tube is securely but comfortably secured on the face with skin maintained intact and without irritation. - The skin around the gastrostomy is kept clean and free from irritation or infection. It should be checked carefully for leakage of gastric contents. - A resident who has a N/G tube for a prolonged period of time should be observed for possible complications, such as nasal erosion, sinusitis, esophagitis, gastric ulceration, and pulmonary infection. - Resident is fed slowly with head elevated to 45° during feeding and at least 1 hour post-feeding.	If not, what happens? Are you losing or gaining weight? What is your goal? Ask Staff: - Please describe how you would carry out a resident's tube feeding.	- In the case of continuous feeding, tube placement must be documented at least every 4 hours. - Naso gastric tube must be secured in a manner that avoids creating pressure on the nose and nasopharynx. - Identify frequency, amt. of feeding based on the physician's order and time span over which each feeding is accomplished. - Medication and treatment records. - Fluid intake records. - Number of calories as well as amount of additional water. - Documentation present regarding removal and reinsertion of tubes. - Record should indicate measures taken to prevent diarrhea and constipation and to treat if they have developed.	- Is skin free from irritation; mouth care is given several times daily? (More frequent mouth care in the case of continuous feeding.) - Have changes in resident condition been noted and addressed (weight loss, constipation, diarrhea, skin condition)? - Have observed problems been coordinated with other departments and resolved? - Is feeding being monitored to ensure that feeding is occurring at the ordered/appropriate rate? - Varied supplements as preferences allow?	Dietetic Services 405.1125(c)

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Tube Feedings F133 (cont'd)	- Supplies for mouth care are in evidence, observe if possible for technique; mouth shows evidence of good care (i.e., moist, clean.)				
Nursing Services F137 SNF (405.1124) ICF (442.338) B. Twenty-four hour nursing. F137 1. Assigned duties consistent with their education and experience/ based on the characteristics of the resident load. F138 2. Weekly time schedules are maintained. F139 3. There is a sufficient number of nursing staff	Are personnel performing duties that are allowed under the State Nurse Practice Act? Do you observe care being rendered in an appropriate, competent manner? Does the time schedule posted indicate that at least the minimum required personnel are scheduled and actually on duty? What is the usual response time before a call bell is answered? In SNF's is an RN on duty during the day? Are licensed staff and aide staff functioning in appropriate roles? Where are staff spending their time?	Ask Resident: - Do residents generally feel that people taking care of them know what they are doing? - If no, explain. - Are your treatments done in a consistent manner? - If no, explain. - Do you feel that there are enough people here to take care of you? - If no, explain. - How long do you usually wait for help when you put your call light on? - Is there anything that doesn't get done as often as it should? Ask Staff: - Do you feel qualified to do all the work you are assigned to do? - If no, explain. - Do you feel you have enough training to keep up with the care the residents require?	- Review progress notes to determine who is giving care. - Review care plan to determine who the facility has assigned to care responsibility to. - Check staffing sheets for minimal requirements and time and attendance for actual staffing. - Review charts maintained for ADL medications, I & O, restraints, etc., to assure that sufficient staff are available for carrying out responsibilities as specified in patient care plans.	All nursing personnel must function within their State Nursing Practice Act. Levels of staffing meet at least minimum requirements. Nursing care needs must be identified by the facility & documentation, resident and staff interviews should determine if these needs are met. All nursing staff should have education or training to prepare them for the care they perform.	Patient Rights 405.1121(k)(g) Patient Care Policies 405.1121(1) Medical Records 405.1132(c) 442.318(a)(c) Patient Care Management 405.1124(d) 442.341 Staff Development 405.1121(h) 442.314

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F139 (cont'd) available to meet the total needs of all residents.	Check for staff who are actually on duty.	- If no, what else do you need?			
F140 4. There is a registered nurse on the day tour of duty 7 days a week (for SNF only). Intent That all residents are cared for by personnel qualified to provide the care & that sufficient numbers & classifications of personnel are available.					

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Patient Care Management F167 SNF 405.1124(d)	Observe resident level of physical, mental, emotional and social functioning. Note problems, potential problems, needs, using observation/interview/record review work sheet.	Ask Resident: - Are you aware that you have a plan of care? - Did you participate in developing a plan of care? - Do you/your family know what the plan is and details? (e.g., diet, ambulation, dressing, etc.) - Do you attend and participate in plan of care meetings? - Who else attends the plan of care meetings? - When did you last attend the meeting for your plan of care? - Does the staff assist you in achieving the goals on the plan of care? If not, who does or why not? - Do you have all necessary assistive devices and equipment? - Is there anything that is not part of your plan of care that you think should be included? - What happens if you question any treatment or procedure? Can you give an example?	Review: - Plan of care The content of the plan of care is of primary importance rather than the format. Separate care plans are not required for each discipline, but may be accepted if there is evidence that the various disciplines coordinate their planning. - Nursing assessment/reassessments and notes. - Physician orders. - Physician notes. - Assessments/evaluations and progress notes from all professional disciplines as appropriate. - Medication and treatment records as applicable. - Lab reports, as applicable.	- Are all resident's needs/problems identified? - Is the plan developed to meet these needs? - Does the plan demonstrate an interdisciplinary approach, and include: + Goals stated in measurable/observable terms? + Approaches (staff action) to meet the resident action goals? + Responsible disciplines/staff responsible for approaches to assist resident in achieving goal/goals? + Is plan being reassessed and changed as needed to reflect current status? + Does plan of care accurately reflect information gained from observation, interview and record review?	Physician Services 405.1123 442.346 Medical Records 405.1132 442.318 Resident Rights 405.1121(k) 442.311 24 Hour Nursing Service 405.1124 442.338 Specialized Rehabilitation Services 405.1126 442.343 Training 405.1121(h) 442.314 Resident Rooms 405.1134(e) 442.325 442.326 Infection Control 405.1135 442.328 442.324
F168 ICF 442.341					
F169 A. Each resident's needs are addressed in a written plan of care which demonstrates that the plans of all services are integrated, consonant with the physician's plan of medical care, and is implemented shortly after admission.					
F170 B. Each professional service identifies needs,					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F 170 (cont'd) goals, plans, and evaluates the effectiveness of interventions plus institutes changes in the plan of care in a timely manner. INTENT The intent is to assure that the facility identifies the resident's (with residents/family input if applicable) needs through the coordinated efforts of all disciplines.		Ask Staff: - What is your input into resident's plan of care? - What aspect of the resident plan of care are you carrying out? - What is this particular resident's plan of care? - How do you assist the resident in carrying out the plan of care? - Who attends the care planning meeting? - Is the plan of care useful to you in caring for the resident? - Is there anything the resident needs that is not addressed in the plan of care? - How often is it reassessed?			Social Services 405.1130 405.1130(a) 442.344(d) Activities 405.1131 442.345 Dietetic Services 442.1135 442.332

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Restorative Nursing Activities of Daily Living F17_176 SNF 405.1124(e) ICF 442.342 442.343(a)(c) INTENT To assist the resident to attain or maintain his/her maximum level of independence and function?	A. Observe residents in need of assistance. 1. Is needed assistance provided? 2. Is resident provided assistance and instruction, as appropriate, in all ADL's to increase his/her level of independence? 3. Does staff minimize pain/discomfort while assisting resident? 4. Is resident taught transfer techniques? 5. Is resident assisted to toilet in timely manner? 6. Resident personal equipment available & within reach? Glasses Hearing aids Dentures [Artificial larynx]	Ask Resident: - What assistance do you need with bathing and/or dressing? Who helps you? - Does the staff plan with you your dressing/bathing schedule? - Do the nursing and activities staff coordinate your schedule so that you have the opportunity to participate in favorite activities? - Are you able to dress/bathe at times convenient for you? - Are you bathed consistently? (i.e., on the day(s) scheduled does the bath get performed?) - Where are you bathed? (bed, shower, tub?) - Are there adequate clothes available for you to wear? - Do they come back from laundry in appropriate condition? - How do you get in and out of bed? - If staff assists you, do they seem to be able to do their job appropriately? Do you always feel safe when	Review: - Plan of care + Reflects assessment, goals, methods to reach goals, service providers, evaluation, and achievement. + Addresses restorative nursing assessment, program initiation, implementation and evaluation of the progress over a reasonable time period. Professional judgement determines the assessment of appropriate time frames. + Identifies planning for potential discharge for all residents to determine a disposition on home care or an alternate level of care. - Nursing Notes + Demonstrate evidence of assessment, intervention, response to treatments/teaching and their progress toward independence, a maintenance level or a deterioration. + Provide evidence of interdisciplinary conferences.	Are patient needs identified? Verify that the plan of care addresses resident needs and is implemented as scheduled and that all appropriate information is documented. If goals are not reached, has a reevaluation been performed and goals revised? Does restorative nursing assist the resident to acquire a higher level of independence? Is sufficient time allowed to resident for learning to increase his/her level of independence? Are assistive devices used regularly as per plan and are they in good repair? Is there an assessment, and if appropriate, a plan for each ADL that the resident needs to gain independece in? Maintenance goals should be noted as appropriate.	Physicians Services 405.1124(a)(b) Nursing Services 405.1124(a)(b)(c) 442.342 Dietetic Services 405.1125(a) 442.331(c) Activities 405.1133(a)(b) 442.345(a)(b) Specialized Rehab. Services 405.1126 442.343(e)(1)(2)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F171-176 (cont'd) ADL's (cont'd)	Prosthetic devices (eg. braces, artificial extremities). Adaptive equipment (e.g., built-up spoon, reachers). Orthotic devices (eg. splints, AFO's). Restraints (eg. vest, waist, wrist, ankle, mitts, nets, geri-chairs). Grooming items (eg. comb, brush, shaver). Oral hygiene (eg. toothbrush, tooth-paste, mouthwash, denture cup). Self-feeding devices. Assistive devices for special sensory loss needs (eg. communication boards, large print books, magnifiers, writing tablets, picture cards, talking books). Training/re-training Prosthetic management Stroke adapted ADL's Self-injections of medications Bowel/Bladder Self-feeding Self grooming Ambulation	being helped? - Are staff members encouraging you to do things for yourself? - Do you have any problems getting to the bathroom on time? - Do you have any problems with leakage when you sneeze, laugh or at any other particular time? - How does the staff help you with these problems? - Are they aware of the problems? - Do you bowels move regularly? - If not, what do you/staff do about this? Are you able to feed yourself? - Are you able to get to the dining room by yourself? If not, why? In that case, what does staff do about this? - How long have you been up today? - Do you usually lie down for a rest? - If you need help getting into or out of bed, is staff available to help you when you need it? - Where do you spend most of your time - in your chair, wheelchair or in bed?			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F171-176 (cont'd)	Colostomy/Ileostomy Care Respiratory Care (oxygen inhalation) Speech Mobility Upper extremity dressing Lower extremity dressing Observe at mealtime whether staff encourages/guides residents in self-feeding or feeds the residents.	Does anyone move your arms or legs or help you with exercises? - Have your sleeping habits changed since you came to the nursing home? If yes, in what way? - Are you able to get help during the night if needed? + What kind of help is needed? + Is staff response timely? - Do you feel there are adequate care supplies at this facility? - If not, can you give me an example of why you feel this way? - Is your family involved in assisting you or if learning to help you? - Do you feel there is adequate staff at this facility? - If not, can you give me an example of why you feel this way? - Does staff assist and/or encourage activities (e.g., R.O.M., ambulation ADL, communication programs, feeding)? - How often does staff assist in activities? - Is there anything resident would like to do			

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F171-176 (cont'd)		for himself/herself that staff is doing? - Is resident comfortable (e.g. free from pain)? - Is your cane/walker/crutches comfortable for you to use? - Did anyone measure you so you have the right size cane/walker/crutches? - Did anyone show you the correct way to use your cane/walker/crutches? - If the facility arranged so that you can get around easily? Ask Activities Staff Do you provide information to nursing staff about time and place of activities, plus names of residents who are to attend or those who might be interested in attending? Chair-bound Resident Ask Resident: - Does he/she know why he/she is in a chair? - Is resident assisted to use bathroom? - Is resident comfortable? - Does he/she see therapist? (O.T., Speech, P.T.) and how often? - Does resident go to a			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F171–176 (cont'd)		therapy area or does therapist come to resident? - Is able to reach items needed? Ask Nurses Aide –Who give you information about the time and place of activities and which residents are to attend? How are you given this information? –How do you encourage a resident to do the most for themself? Wheelchair Resident Ask Resident: - Does he/she know why he/she needs a wheelchair? - Is resident trained and/or encouraged in independent W/C ambulation and activity? - Does resident know how to lock and unlock wheelchair? Ask Staff: - How is a resident set up for independent W/C ambulation? - Nurse Aide - has resident received instruction in transfer techniques? For Bed Bound Resident In addition to appropriate interview questions above:			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F171-176 (cont'd)		Ask Resident: - How do you spend your day? - Can you do some things for yourself? - Does the staff give you a chance to learn self-care skills? Ask Nurse: - If the resident had access to a recliner chair, would he/she be able to be out of bed? - Is the time out of bed coordinated with the activity schedule and necessary care? Ask Nurses Aide: - Does this resident do any self-care? Why not? - If no, has anyone tried to teach him/her to do some care?			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Positioning F175 SNF 405.1124(e) Intent To assure that the resident is positioned at all times to promote maximum therapeutic benefit and comfort, as well as safety.	Observe residents in bed, chairs, restrained, or in "protective devices" for - body alignment - positioning - contractures (when did they occur and what is being done)? - ROM program (observe extent & technique of provider) - Assistive devices (overhead pulleys, slings, splints, etc.) - Turning/repositioning schedule and adherence to the schedule. - Devices to maintain positioning, i.e., sandbags, extra pillows, etc. Specific Observations for the Bed Resident (as appropriate to condition). Positioning/body alignment Resting splints & correct application Foot positioning boards Trapeze Hand rolls Elbow/leg splints & correct application Restraints Siderails (padded) Special mattresses	Ask Resident: - How often are you turned/repositioned by the staff? - Is that often enough? - Are you comfortable now? Do you have any pain or discomfort? Where? - How long have you had joint stiffness (contractures)? - What kinds of exercise do you do every day, including range of motion (ROM)? How long does the exercise last and how frequently do you exercise each week? - Do you wear special devices? How often? Consistently? - Are they always applied and removed appropriately and promptly? How Often? - By whom? Bed Rest Resident Ask Resident: - Why do you have to stay in bed? - How often does staff get you OOB? - Do they know how to get you up? - Who sets you up and/or assists you in bedside ADL's? - Does staff, therapist check positioning, supportive devices?	- MD orders for non-nsq interventions/treatments. - Plan of care should include at a minimum: + Restorative goals + specific joints to be exercised + devices to be used in positioning + frequency of treatment or repositioning + resident teaching information + resident teaching information + services responsible for carrying out the procedures + time frames for reaching goals - Nursing progress notes indicate: + Plan has been implemented + Progress toward goals + Response to information from reevaluation - Look for actual turning/repositioning schedule	Plan of care should be complete (addressing resident positioning needs) and plan is implemented on a daily basis. Care givers are knowledgeable re plan content Residents are turned as scheduled. In good body alignment with proper assistive devices & equipment. Contractures are prevented and/or treated. Plan is reviewed, reevaluated and revised at least quarterly, but must be done as often as patient condition dictates: Ask aide assigned to demonstrate the hand holds he/she uses for ROM. If aide doesn't know, ROM is probably not being done. Do it "at bath time" is not sufficient.	Rehabilitative Services 405.1126(h) 442.343(c)(2) MD Orders Activities Resident Rights Nursing-Staffing Inservice Social Service Dietary

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F175 (cont'd)	Blankets/pillows Clean, smooth linen Clean, appropriate bed wear Turning schedules ROM schedule O.O.B. (as tolerated) Water available All adaptive devices are clean and in good repair. All assistive supportive devices are clean and in good repair. Specific Observation for the OOB Resident in Chair (geri-chair, lounge chair in room, as appropriate to condition) Arrangement of room facilitates residents optimal independence (e.g., independent eating, grooming, T.V., radio, water). Positioning/body alignment. Blankets/lap robe, pillows, foot stool. Hand rolls, splints. Clean, dry attire. Pressure relief device. Restraints, with release & activity schedule. Call bell available.	- When? - Does staff answer call bells propmtly? How soon? - Is resident able to reach items (e.g., water call bell, urinal, emesis basin, tissues)? - How much confidence do you have when the nurses are helping you transfer, or turn and so on? - Does resident go to therapy area or does therapist come to resident? Bed Rest Resident Ask Staff: - How often is position changed? - What activity is done at the time (e.g., R.O.M., toileting, OOB, grooming? - What can resident do independently? - Is equipment available? - Who maintains and cleans the equipment? - What is the schedule for this? - What training have you had to learn to position patients correctly?			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F175 (cont'd)	Specific Observation for the Wheel Chair Resident (as appropriate to condition, including deliberate alterations made to equipment for specific reasons.) - Proper fit - Good working condition - Appropriate arm rest, footrest, leg support, lap tray, - Proper positioning - Pressure relief aids, (e.g., gel flotation pads, egg crate mattress, sheepskin) - Set up for independent W/C ambulation - Functional adapted toilet area - Transfer techniques Observe how staff wheel the resident (e.g., do they inform before, starting movement)? Are patients moved wheeling forward and facing elevator doors? Observe staff for: - verbal cues - physical support - body mechanics Specific Observation for the Ambulatory Resident (as appropriate to condition) - Gait (steady/unsteady) - Appropriate devices for	- Was there any part of your orientation when you first came to work here that addressed positioning? - Do you have any periodic reviews/updates on positioning? Chair Bound Resident Ask Staff: - How often is resident repositioned/taken out of chair? - What is the activity at time of repositioning and/or release of the restraint? - What can resident do independently? Ambulatory Resident Ask Staff: Is resident encouraged to independently ambulate to and from activities and dining room (with or without personal assistance)? - Does resident do as much as he/she can independently? - What does resident do? - How do you know that resident is maximally independent? - If it is not working independently, how do			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F175 (cont'd)	ambulation (e.g., cane, crutches, hemi-sling - Posture - Appropriate staff assistance in ambulation - Grab bars (halls, bath/shower area) - Functionally adapted toilet area	you deal with it? - Is there something resident would like to do that he/she is not allowed to do (e.g., shave self, apply make-up, style own hair)? - What training have you had in learning to position residents and do range of motion? - What opportunity do you have for ongoing training? - Who does the actual training? Check question placement under Interviewing. May be more appropriate for resident's rights section. Observe wheeling technique used by staff.			
Nursing Services G. Administration of Drugs F183-184 SNF 405.1124(g) ICF 442.337 F186 1. The patient is identified prior to administration of a drug.	Observe a drug pass with at least 20 residents receiving medication. See SOM Appendix N. Transmittal No. 174 for details of the Surveyor Methodology for Detecting Medication Errors. - Observe medication administration techniques (e.g., hand-	Ask Resident - Do you always receive your medication on time? - If not, what is the problem? - Do you receive the correct medication? - What does it look like? - Who explained your medications to you? - What reactions do you have? - What happens if you have a question or refuse to take your medication? - Who gives you your medication? - Do your medications change in appearance?	Review the medication administration record. (as appropriate) See S.O.M. Appendix N, Transmittal No. 174 for details of the record review.	If the combined total of significant & non-significant errors is 5% or above, a deficiency is present. Any significant error is cause for a deficiency. See Appendix N for details.	Physician Services 405.1124(b)(7) Pharmaceutical Services Supervision 405.1127(a) 442.336(a)(b)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F187 2. Drugs and biologicals are administered as soon after doses are prepared. F188 b. Administered by same person who prepared the doses for administration except under single unit dose packet distribution system. Exception: ICF residents may self administer medications with their physician's permission.	washing, pouring of dosage, position of resident).	- Do the nurses stay with you when you take your medication? - Do any of the medications bother you? Ask Staff: - Do you generally have available the medications you need? - Are there any problems in administering medications? Note drug doses refused by resident and how handled by staff.			

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
H. Conformance with Physician Drug Orders F189 F190 F191 SNF 405.1124(h) ICF 442.334(a) Drugs are administered in accordance with written orders of the attending physician. Intent All residents receive medications as ordered by the physician.	Combine with observation of drug pass.		- Review the latest recap of the physicians orders - Review the medication administration record (as appropriate) - See S.O.M. Appendix N, Transmittal No. 174 for details of the record review.	See Appendix N for details	Physician Services 405.1123(b)(7)

LONG TERM CARE SURVEY

SURVEY AREA CROSS REFERENCE	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	
DIETETIC SERVICES (Condition of Participation) F193 SNF (405.1125) A. Menus and Nutritional Adequacy F194 SNF (405.1125(b)) F194 ICF 442.332(a)(1) F196 Menus are planned and followed to meet the nutritional needs of each resident in accordance with physicians' orders and, to the extent medically possible, based on the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences.	o Specific Observations which might be indicative of possible nutrition problems: Clinical – underweight/ overweight – dehydration – edema – cracked lips – pallor – dull or dry hair – swollen or red tongue – bleeding gums – decubitus ulcers – infections o Physiologic factors which may affect intake: – Swallowing difficulties – Vomiting – Food intolerance – Poor dentition – Sore mouth – Constipation – Diarrhea – Inability to feed self – Decreased visual and olfactory acuity – Unable to communicate – Loss of appetite o Psychological/Social – Confusion	Ask dietary manager to explain the procedure for making substitutions and recording the changes. – Is menu usually followed? Ask Resident: 1. How are your meals? 2. Are there foods you are not allowed to have? 3. Are you on a special diet? 4. Do you receive foods that are not appropriate for your diet? If so, what do you and the staff do about that? 5. What time do you receive breakfast, lunch and supper? Do you always receive a meal at mealtime? If not, why? What happens then? 6. Do you like the taste of the food? 7. Is the temperature appropriate (i.e., milk chilled, coffee hot, etc.)? 8. Do you get enough to eat? What do you do if you're still hungry after a meal?	Review Nutrition assessment for the following documentation: o Usual/ideal body weight/ height o Dietary allergies/ sensitivities, ability to chew and swallow regular foods without difficulty. o Full or partial dentures o Mental and emotional condition o Physical appearance, skin condition o Appetite and food preference. o Vitamin and mineral supplements. o Food and fluid intake in measurable terms and frequency of meals. o Degree of assistance needed in eating, related mobility, vision, or other identified problems. o Medications (e.g., diuretics, insulin, antibiotics, etc.) o Related laboratory findings (e.g., fasting blood sugar, cholesterol, sodium, potassium, hemoglobin, BUN, serum albumin, transferrin or creatinine-height index if available).	o Were physician diet orders followed? o Did nursing plan for feeding and assistance at mealtime? o Is there rehabilitative use of assistive devices, if appropriate? o Is modification of consistency of meals made if resident has a problem or change in condition? o Are between meal and bedtime snacks provided as needed? o Is socialization at meals provided? o Has dietitian provided counseling of resident and family as needed (related to diet)? o Usual body weight is maintained/supported? o Is there evidence that the plan is being carried out (e.g., documentation in the resident's chart, observation by the surveyor, and resident/staff interviews)? If the resident refuses meals or does not respond to intervention, the notes in the chart should indicate efforts to intervene or provide counseling.	Physician Services 405.1123 442.346 Medical Records 405.1132 442.318 Nursing Services 405.1124(e)(f) Specialized Rehabilitative Services 405.1126 Patient Care Management 405.1124(d)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196(cont'd) Intent Ensures that each resident receives food in the amount, kind, and consistency to support optimal nutritional status.	- Excessive food likes and dislikes - Refusal to eat o Selected biochemical changes which might indicate changes in nutritional status: - Visceral protein status o serum albumin o transferrin o BUN o Serum electrolytes During mealtime observe the resident for: - adherence to food preferences - adequate space for eating - self-feeding skills - proper position for eating - ability to eat foods served - use of adaptive feeding devices - amount of food actually eaten - protection of resident's clothes - amount of time resident is allowed to chew and swallow - Assistance provided as needed to and from dining area - All beverages are covered]	9. Do you receive nourishment in the evening? Do you have a choice about what you want to eat? 10. Do you receive medicines during meals? If yes, do you know what it is or what it is for? 11. Do you get food from outside of facility that you buy or family brings? How often? What kind of food? 12. How often does anyone from the kitchen come to ascertain your feelings and opinions on the food service, your portion size, etc.? 13. Where do you eat (e.g., dining room, your room, etc.)? Is this your choice? Do you have a choice of where you eat? 14. How often have you seen a therapist for your swallowing difficulties?" "How has the therapist instructed you/staff/family on methods to improve your swallowing? Ask Dietician - Describe the meal planning input you receive from residents.	o Food/drug interactions o Mental/emotional assessment as it relates to resident's food habits. Review: o Plan of Care o Nursing Notes Review: o Physicians orders o Progress notes o Notes from other professional disciplines as appropriate. Nutritional status depends not only on adequacy of menu planning but also whether the resident eats the food and how the body uses it. While the surveyor is not responsible for individual nutritional assessments of residents, when specific information is needed during the survey to make a compliance decision, the surveyor will utilize the following minimum assessment guideline: Menu Evaluation o Adequate in energy and nutrients - Protein - Calories	Is there evidence that the resident's progress is regularly observed (e.g., awareness of food and fluid intake such as acceptance of foods, food consumed, and resident's appetite)? o Is fluid intake for resident encouraged, Foley catheter, problem feeders monitored? o Is there general evidence as to whether poor resident conditions are due to poor care or whether the facility has taken appropriate measures to prevent or resolve problems. o Is there indication of progress toward desired outcomes? If not, is the evidence of re-evaluation available within specified time frames? o When the antropometric and clinical data do not correlate with dietary data, (food intake, dietary supplements) the surveyor should take note that the problem may not be nutritional.	Nursing Services -405.1124(f)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196(cont'd)	Assistance being provided in case of choking, incontinence, falling, or other emergencies. Nursing Staff supervision of dining areas including residents' rooms during meal times.		- Vitamin C - Calcium Selected evaluation of residents for in depth review: A check list can be used to evaluate daily menus for basic foods: (use standard serving protions) Daily food plan should include: MILK GROUP 1 pt milk MEAT GROUP 5 equivalents:* 1 equivalent equals 1 oz. of meat (edible portion) weighed after cooking (this includes eggs, dried peas, beans, nuts, and all meat, fish and poultry). VEGETABLE AND FRUIT GROUP 5 services or more, including a dark green or deep yellow vegetable for vitamin A value every other day and a citrus fruit or other fruit rich in Vitamin C daily.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196 (cont'd)	Observe serving portions sizes on all menu items: MILK GROUP - 1 pint daily Source of: Protein Calcium Phosphorus B Complex MEAT GROUP - 5 lean meat equivalents (1 meat equivalent = 1 oz meat, poultry, fish, cheese & eggs; also dried peas, beans, and nuts). Source of: Protein Iron Vitamin B12 VEGETABLE AND FRUIT GROUP - 5 servings or more (1/2 cup = 1 serving) Source of: Vitamin A,C, B6, Folacin, Fiber BREAD-CEREAL-POTATO-LEGUME-PASTA GROUP - 7 servings (1 serving = 1 slice bread; 1/2 cup other; 3/4 cup flake-type cereal).		BREAD-CEREAL-POTATO-LEGUME-PASTA GROUP 7 servings FATS AND SWEETS (Without this group the diet contains 1,415 Kcal) Diets should be adapted from facility's currently approved diet manual. Menus are dated and contain minimum portion sizes. Are substitutions noted on the file copy? Are substitutions made within the same food group i.e., meat for another source of protein in the meat group, or vegetable of similar nutritional value?		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196 (cont'd)	FATS AND SWEETS (to increase caloric intake) IODIZED SALT (unless contraindicated) Adequate fiber in diet		o Documentation of decision to withdraw or begin artificial feeding and hydration. Check menus for variety Are they specific (i.e., states kinds of fruit, juice, vegetable)? DIETARY SERVICES SELECTED NUTRITIONAL REQUIREMENT RECORD REVIEW N.B. The basal energy expenditure (BEE) and calorie requirement using Harris-Benedic formula recognizes the variation in energy needs for individuals. 1. Anthropometry- Weight /Height NOTE: The following sample formulas and guidelines are not the only acceptable guides available. The surveyor should ask to use the assessment guidelines used by the facility before using the ones provided here. o Important indicator of nutritional outcomes. o Disease state can have adverse effect on desired body weight.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196 (cont'd)			2. Weight for Height Calculation Females: Allow 100 lbs. for first 5 ft. of height plus 5 lbs. for each additional inch Males: Allow 106 lbs. for first 5 ft. of height plus 6 lbs. for each additional inch Estimating Caloric Needs 1. FORMULA: Harris-Benedict Equation Men: 66 + (13.7 x Wt. in Kg) + (5 x Ht. in cm) - (6.8 x Age)=BEE Women; 65.5 + 9.6 X Wt. in Kg.) + (1.7 x Ht. in cm) - (4.7 x Age)=BEE Parenteral Anabolic: 1.75 x BEE Oral Anabolic: 1.5 x BEE (Kcals)		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196 (cont'd)			Oral Maintenance: 1.20 x BEE (Kcals) Metric Conversions (Approx) pounds (lb.) x 0.45 = kilograms (Kg) inches (in.) x 2.5 = centimeters (cm) Estimating Protein Needs 1. Allow 0.8 gram protein per kilogram of ideal body weight. 2. Increase to 1.2 – 1.5 gm/kg for patients with depleted protein stores (decubitus, draining wounds, fractures, etc.). Fluid Requirement Based on actual body weight: Over 55 years with no major cardiac or renal diseases: (NOTE: 2.2 lbs. equals 1 kg of body weight)		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196 (cont'd)			Example: 120 lbs/2.2 lbs. = 54.5 kg (55 kgs) 55 kg x 30 cc = 1,650 cc/day Note: Isotonic Standard Tube Feeding = Approximately 80% water. Amputation % of Body Weight Leg 20% Below Knees 10% Arm 6% At Elbow 3.6% Suggested Standards for Evaluating Significance of Weight Loss % of body weight loss Inter- val / Significant Loss / Severe Loss 1 week 1-2% 2% 1 month 5% 5% 3 months 7 1/2% 7 1/2% 6 months 10% 10% From Blackburn, et al: "Nutritional and Metabolic Assessment of the Hospitalized Patient: JPEN vol. 1, 1977.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS			CROSS REFERENCE
				Mild Deficiency	Moderate Deficiency	Severe Deficiency	
F196 (cont'd)			Lab Indices for Visceral Proteins				
			Albumin g/dl	3.5–3.2	3.2–2.8	2.8	
			Total Lymphocyte Count (cu/mm)	1800–1500	1500–900	900	
			Transferrin (If Available)	200–180	180–160	160	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
B. Therapeutic Diets F197 SNF 405.1125(c)	System for the provision of diets: o Dietetic service Kardex or file o Therapeutic menus o Nourishment preparation and service o Adequacy of nourishment o Individual menus or diet cards	Ask Staff: o Number, type of therapeutic diets? o Time of nourishment activity, who's responsible? o Nourishment provided for day of survey?	Review: - Physician diet orders in medical record - Nurses' Kardex - Dietary Kardex - Therapeutic diet menu - Diet cards		Nursing Services 405.1124 405.1124(c) (d.) Patient care plan (f.) Supervision of patient nutrition
F198 ICF 442.332(b)(1)(2)			Note: - Consider appropriateness of special diet-updated and reviewed since admission. - Progress notes reflect reevaluation of resident's progress on diet.		
F199 1. Therapeutic diets are prescribed by the attending physician.	SPECIAL FEEDINGS: The surveyor should also attempt to observe that: o Staff use proper technique in administering feedings and medications. Check to see that staff checks for location of tube before feeding and that tubing is irrigated before and after addition of medication. o Unused milk-based tube feeding should be discarded in a timely manner	The surveyor should interview staff regarding their knowledge of the feeding schedule and training in administering tube feedings. Some residents having difficulty in speaking or swallowing with the tube in place (i.e., poor toleration). The surveyor should inquire if mouth feeding was attempted. Ask Resident: If the resident is able to be interviewed, suggested questions may be: 1. How long have you been fed by this tube? 2. When was the last time you tried to eat by mouth? What happened? 3. How often do you receive the feeding? Is this consistent?	Selected number of residents on therapeutic diets should be considered for indepth reviews. Tube Feeding Review: - Plan of Care - Identify frequency, amt. of feeding based on the physician's order and the time span over which each feeding is accomplished. - Medication and treatment records - Fluid intake records - Number of calories as	On Pureed diets: o Ordered by physician o Prepared fresh daily o Same calories and/or food groups as if served whole. Pureed foods are coordinated with general/regular menu. On Tube Feeding: o Has the feeding been ordered by physician? o Is tube feeding nutritionally adequate? o Have attempts been made to progress tube feeding if indicated? o Have changes in resident condition been noted and addressed.	
F182 2. Therapeutic menus are planned in writing, prepared, and served as ordered with supervision from the dietician and advice from the attending physician whenever necessary.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F197–199 (cont'd)		4. Does the staff help you in feeding? Do you feel comfortable/safe with all the staff who perform the feeding? If not, what happens? 5. Are you losing or gaining weight? What is your goal? 6. How often is the tube changed? Who does this? Do you feel comfortable/safe with all staff who perform this procedure? Interview staff regarding knowledge of diabetic diets. o What nourishment does the diabetic patient receive? o If diabetic patient refuses the meal, what is done to supplement the meal? If resident is able to be interviewed, suggested questions: 1. How long have you been on your diabetic diet? 2. Do your know some of foods you must avoid? What are they?	well as amount of additional water – Periodic reassessment of ability to swallow – Record should indicate measures taken to prevent diarrhea and constipation and to treat if they have developed. Diabetic Diets Review: o Pertinent Laboratory data: – urinary glucose – serum glucose o Wt. gain/losses	weight loss, constipation, diarrhea, skin condition)? o Have observed problems been coordinated with other departments and resolved? o Is feeding being monitored to ensure that feeding is occurring at the ordered/appropriate rate? o Varied nourishments as preferences allow? On Diabetic Diets and Other Therapeutic Diets o Ordered by Physician o Varied, nutritionally adequate o Individualized to suit resident o Re-evaluation indicates diet meets objectives. If not appropriate, documentation is provided o Laboratory results support diagnosis o Between meals nourishment provided as needed and recorded in measurable amounts.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F197-199 (cont'd) F198 Therapeutic diets prescribed by the attending physician	Observe tray/meal service: o Low sodium diets are palatable (taste) o Sugar sources on diabetic diet trays o Salt sources on sodium restricted diet trays.	3. Do you receive a nourishment between meals or before going to bed?			
		FOR THE RESIDENT WITH DECUBITUS ULCERS			
F199 Therapeutic menus are planned in writing, prepared and served as ordered with supervision from the dietician and advice from the physician whenever necessary.	Functioning system to provide the needed nutrients: - Resident's general appearance - Meal service + Food acceptance + Adherence to food preferences - Food supplement + Type to support + Method of service + Assistance provided + Timely provision as ordered - Portion sizes - Conforms to physicians orders	Ask Staff: 1. Regarding knowledge of dietary needs. 2. What do you do when this resident refuses milk, meats, bread, etc.? 3. What nourishments are provided to this resident? How often? 4. What happens when a weight loss is noticed with this resident? Ask Resident: 1. Has anyone talked with you about the importance of eating your meals? 2. Do you get foods that you don't eat on your tray? 3. When do you feel hungry? 4. Do you get between meal nourishments?	1. Identify residents with conditions that immobilize or prevent voluntary body movement. 2. Identify location, number, size and depth of decubitus ulcers. 3. Calculations of kilocaloric and protein levels as needed. 4. Micronutrient need assessment and recommendation. 5. Progress notes. + monitor weight + monitor healing of decubitus ulcers. 6. Pertinent Laboratory Data + Hemoglobin/Hematocrit + Serum Albumin + Total Lymphocyte Count 7. Fluid Intake + sufficient to maintain hydration	A system is in place to provide the type and amount of nutritional support needed by the residents who have developed decubitus ulcers. Food and supplementation are provided in a method to ensure intake of nutrients needed by residents with decubitus ulcers. Nutritional intervention is assessed and reassessed to ensure appropriate intervention for acceptable health care outcome.	Nursing Service 405.1124 (d) Patient Care Plan (f) Supervision of Patient Nutrition

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F197-199 (cont'd) F198 Therapeutic diets prescribed by the attending physician F199 Therapeutic menus are planned in writing, prepared and served as ordered with supervision from the dietician and advice from the physician whenever necessary.	RENAL REVIEW System in place for the the correct provision of renal diets. – Individualized menu – Dietary Staff Utilize menu when serving diets.	Interview Staff regarding knowledge of renal diets: 1. What foods should be restricted when a patient has kidney problems? 2. What nourishments are given to these patients? 3. Are fluids restricted? Ask Resident: 1. Are you on a special diet? 2. What foods must you avoid? 3. Do you feel hungry? 4. Do you eat everything at mealtimes? 5. Are the foods the kitchen sends you the correct ones for your diet? 6. Has the dietitian explained your diet to you?	Renal Patient Diet Review – Pertinent Laboratory Data + Serum Sodium + BUN + Serum Potassium + Albumin + Hematocrit + Creatinine – Pertinent Medications + Vitamin/Mineral + Supplements – Weight gains/losses	On Renal Diets – Ordered by physician – Written menu nutritionally complete in so far as medically possible, including calories – Individualized to suit resident – Laboratory testing as needed – Coordination with dialysis unit to determine effectiveness of diet	Nursing Service 405.1124 (d) Patient Care Plan (f) Supervision of Patient Nutrition

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
C. Preparation F204 SNF 405.1125(e)	Observe: o Feeding assistance is provided or not provided by staff o Length of time residents sit and wait for meal service		Review: o Plan of Care o Progress notes o Notes from other professional disciplines to determine rehabilitation potential to self feed, use of assistance devices; o Record of food substitution to determine alternate choice provided o Standardized recipes	The facility has kitchen and dietetic service areas adequate to meet the food service needs. These areas are properly ventilated, arranged, and equipped for sanitary refrigeration, storage, and preparation of food. Equipment and storage areas are clean, well maintained, within proper temperatures ranges, and safe	
F205 1. Food is prepared by methods that conserve its nutritive value and flavor.	o Food is served soon after cooking or refrigerated o Trays are free of spillage of foods or liquids o Foods are appropriately covered and kept at a proper temperature			Proper temperatures: (Fahrenheit) Frozen food storage -- 0 or below Cold food storage -- 40-45 degrees	
F206 2. Meals are palatable, served at proper temperatures. They are cut, ground, chopped, pureed or in a form which meets individual resident needs.	o Cooking and service utensils are clean, sanitary and greaseless o Refrigerated foods must be covered o Leftover and pre-cooked foods must be dated and labeled o All cooked food stored above raw meats in refrigerator			Hot food holding equipment -- 140 degress minimum	
F207 3. If a resident refuses food served, appropriate substitutes of similar nutritive value are offered.	o Temperature gauge on or in refrigerator to record temperature o Shelving to allow air circulation o Food not stored in refrigerator must be stored off the floor (This is applicable to food stored in walk-in refrigerator and freezer.)			Dishwasher wash cycle -- 150 - 160 degrees Dishwasher rinse cycle -- 160-180 degrees or a color change in thermopaper; or adherence to manufacturers recommendations	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F207 (Cont'd) INTENT To provide foods that are safe and nutritious SNF 495.1125(e)	- No rust on shelves - No dripping or spillage on shelves and floors - Degree to which diet modification is communicated with residents ensurate with residents tolerance and capability - Residents for meal satisfaction - Observe appearance of food color, texture, aroma, and flavor - Less than 75% of meal is consumed - Type of substitutions provided		- Progress notes - Diet card - Day's menu substitute record	Dietary personnel are clean and free of infectious disease. They practice acceptable techniques and procedures to keep foods at proper temperatures and protected against contamination. Is dietary information pertinent to dietary modification? Has resident been assessed for eating program to maintain independence? The food substitute is of similar nutritive value as the refused item (e.g., milk refused, alternate of calcium rich food should be provided.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
D. Frequency F208 SNF 405.1124(d)	o Menus as under A on page 63 o Who serves nourishments o Nourishment list and schedule	Interview various residents about the nourishment service: o Are nourishments offered routinely? o At what time are they offered? o By whom? o What kind of nourishments are offered?	Review o Menu as under A o Nourishment List	Three meals or their equivalent are served daily with not more than a 14-hour span between the evening meal and breakfast. The nourishment service is more difficult to evaluate: must find evidence that patients are offered nourishments on a planned basis and documented.	
F209 ICF 442.331(a)					
F210 1. At least three meals are served daily at regular hours with not more than a 14-hour span between a substantial evening meal and breakfast.					
F211 2. To the extent medically possible, bedtime nourishments are offered to all residents					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
E. Staffing F212 SNF 405.1125 (a)	- Food service personnel are on duty for all defined dietary responsibilities: - Supervision - Food Preparation - Dishwashing - Cleaning	- Interview personnel to verify that they are aware of their responsibilities and job descriptions.		- From an assessment of the total dietetic service operation: + The dietetic supervisor is capable of the overall management and supervision of the dietetic service. + There are dietetic personnel on duty over a 12-hour period who demonstrate ability to perform tasks adequately. + Dietetic personnel receive appropriate orientation and training consistent with their duties and responsibilities. There is evidence that the dietetic staff are knowledgeable about food service policies and procedures and apply these accepted professionals practices in their daily work. + Services provided are consistent with the size, scope and facilities available.	
F213 1. Food service personnel are on duty daily over a period of 12 or more hours. Intent Persons are providing services commensurate with their level of training; and at the level of sophistication needed by the residents.	- Duty Schedules				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
SPECIALIZED REHABILITATIVE SERVICES F214 SNF 405.1126 F215 SNF 405.1126(b) F216 ICF 442.343 A. PLAN OF CARE ICF442.343(e)(1)(2) F217 Rehabilitative services are provided under a written plan of care, initiated by the attending physician and developed in consultation with appropriate therapist(s) and the nursing service. B. THERAPY F218 ICF442.343(a)(c)(d) Therapy is provided according to orders of the attending physician in accordance with accepted	OBSERVE RESIDENTS As per "Restorative Nursing Activities of Daily Living" SNF 405.1124(e)2(b) ALSO: OBSERVE RESIDENTS IN THERAPY AREAS: - Is privacy provided during treatment, as applicable (e.g., cubicle curtains, room dividers, one to one area)? - Is there appropriate, courteous resident/staff interaction? - Are therapy areas appropriate to treatment given (e.g., small, quiet area for speech/ language/ hearing test and sessions, large for P.T., exercise and therapy groups, O.T: perceptual testing/splinting, A.D.L. adaptations area, as applicable)? - Is equipment clean and in good working condition? Is it operating as per manufacturer instructions (e.g., hydrocollator temp., parafin, whirlpool, etc.)?	ASK RESIDENT: (or ask staff, if resident has severe communication problem): - Are you receiving any kind of therapy? P.T.? O.P.? Speech? - What kinds of therapist(s) are working with you on your swallowing problem? - What kinds of therapists have instructed you on how to improve your swallowing? - How do the methods to improve swallowing help you? - How often do you see the therapist? - What happens if the therapist is absent for scheduled treatments? - Where do you receive your therapy? - How long have you been receiving therapy? - Do other staff members assist with therapy? Who and in what way? - Are you in a comfortable environment (room temperature, privacy, etc.)? - Do you have input into developing or revising your therapy treatments? -What things did you do immediately before entering this facility, that you are unable to do now? ASK THERAPY STAFF: - How many days/hours per week do you provide therapy? - Do you participate in the development of the resident's overall plan of care? In what way? - Do you utilize P.T.	REVIEW: - Plan of care - Doctors' orders - Nursing assessment and progress notes - Aide assignment sheets - Therapy assessments/ evaluations (includes a minimum of): + name, age, date, diagnoses + referring physician and reason for referral + history, precautions, limitations + objective documentation (e.g., tests, measurements) + rehabilitation potential - Treatment plan (includes a minimum of): + specific rehabilitation needs and objectives + treatment to meet specific measureable rehabilitative goals + Type, amount, frequency, duration, modalities + name of therapist(s) who will provide treatment + restorative nursing follow-thru (recommendations for plan of care)	- Are rehabilitation services integrated with restorative nursing? - Do therapists participate in development of resident plan of care? - Do observations and interview indicate that services are provided in conjunction with 24 hour nursing, and in accordance with the overall plan of care regarding restorative nursing and specialized rehabilitation services?	Nursing Services 405.1124 442.338 442.319 442.341 Physician Services 405.1123 442.346 Medical Records 405.1132 442.318 Activities Program 405.1131 442.345 Resident Rights 405.1121(k) 442.311 Training 405.1121(h) 442.311 Infection Control 405.1135 442.315 442.327 442.328

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F218 (cont'd) professional practices by qualified therapists or qualified assistants. C. PROGRESS ICF 442.343(f)	- Are assistive devices being provided as needed? - Do assistive devices fit well, function and are used properly (e.g., wheelchairs, crutches, braces, glasses, hearing aids, canes, artificial limbs assistive eating devices)? - Is staff responsive to resident expressions of discomfort? - How are the prescribed treatments and training meeting the needs of the resident? - Are parallel bars sturdy and well secured to floor? Are systems designed for weight lifting sturdy and well secured; if attached to wall with rigging and hand grips in good conditions?	"aides" In what way (if interviewing the registered physical therapist)? - How do you assure carryover of therapeutics in your absence? - How often do you provide inservice to staff? What topics are covered? - Do you have opportunities to attend inservices? - How do you communicate patient progress/regression, etc. with physician, nursing personnel, family, other disciplines? - How many residents currently are receiving P.T., O.T., Speech-language pathology and audiology therapy (SLP/AT). - Do you utilize the services of a certified occupational/therapy assistant (if interviewing the registered occupational therapist)? - Is space available for the conduction of your therapy? - Is equipment readily available to meet resident needs? - Is there a coordinated interdisciplinary	+ identifies modalities that will be delegated to non-skill staff - Progress notes indicate that plan of rehabilitation care has been re-evaluated by the physician and therapist as necessary but at least every 30 days. - Communication with physician: + 2 week progress after initiation + monthly progress + discharge summary - Treatment documentation: + frequency + summary	Physical Environment 405.1134 442.324 442.325 442.326 442.328 442.329 442.330 Dietetic Services 405.1125(e) 442.329 442.331(c)
F219 1. A report of the resident's progress is communicated to the attending physician within 2 weeks of the initiation of specialized rehabilitative services. EXCEPTION: ICF resident's progress must be reviewed regularly.	- Are nonverbal residents provided with means of communication (e.g., writing tablets and utensils, picture cards)? - Are visually impaired residents provided with				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
	magnifiers and large print books? - Is equipment such as whirlpool cleaned between patients?	approach toward rehabilitation of the geriatric resident evident in your facility? In what way do you see this?			
F220 2. The resident's progress is thereafter reviewed regularly and the plan of rehabilitative care is reevaluated as necessary. But at least every 30 days by the physician and therapist. EXCEPTION ICF resident's plan must be revised as necessary INTENT Therapy services are provided that will assist the resident to attain his/her optimal level of function.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Pharmaceutical Services F221 SNF 405.1127	- Observe residents for excess sedation or adverse effects: + drooling + shuffling gait + involuntary movements of limbs, tongue, facial muscles + loss of affect + drowsiness + postural abnormalities + pill rolling movement - Observe for depression aggitation	Ask Resident: - Are you aware of the medications you are taking—use, frequency, contraindications? - Has your physician discussed the medications you are taking with you? - How many medications are you taking? - How do you feel the medication helps you? - How do medications bother you? (e.g., make you feel nauseated or dizzy) - Have you told anyone about this? Ask Staff: - How often does the pharmacist review the resident's medications? - To whom does he report any irregularities? - When the pharmacist reports irregularities, what is done about it? - To whom do you report any problems about medication? - Do you feel the residents are receiving the proper medications, amount and kind? - Is the pharmacist available to you for consultation?	Review medical record: - to see if pharmacist or nurse has reviewed a drug regimen on a monthly basis. - for evidence that the reviewer has reported irregularities to the physician or other who has authority to correct the irregularities for evidence that the irregularities have been evaluated. - review nurses notes, progress notes, care plan, etc. for any adverse reaction to medication and indication that corrective action was taken. - screen the drug therapy of the residents included in the sample using the indicators (forms if prepared) outlined in SOM Appendix N Transmittal #174. - review pharmacists drug regimen monthly reports to determine if pharmacist has commented on potential irregularities, screened out through this process (need full year).	Reviews were performed in the facility. There was evidence of a review performed on every resident whose record was reviewed indepth. In records reviewed, the average prescription utilization was not substantially over 6.1 If it is, review for appropriateness. Apparent irregularities were identified and reported. * Refer to SOM Appendix N in 174 for further information on drug regimen review.	Physicians Services 405.1123(b) 442.346 Nursing Services 405.1124 442.338
F222 A. Supervision F223 ICF 442.336(a)(b) F224 SNF 405.1127(a) The pharmacist reviews the drug regimen of each resident at least monthly & reports any irregularities to the medical director and administrator. A registered nurse may be utilized to perform this monthly review for ICF residents. Also the attending or staff physician must review medication quarterly.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F224 (cont'd)		- Where does the pharmacist perform his drug regimen review?			
B. Labeling of Drugs and Biologicals F225 SNF 405.1127(c) F226 ICF 442.333 F227 The labeling of drugs and biologicals is based on currently accepted professional principles and includes the appropriate accessory and cautionary instructions as well as an expiration date when applicable. INTENT To assure that residents receive medications as ordered and that they are monitored for possible side effects.	Observe labels of medications for residents observed on drug pass tour for: - name of drug - dosage form - strength of drug - quantity of drug - expiration date - presence of a control number - appropriate accessory or cautionary statement				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Laboratory and Radiological Services F228 SNF 405.1128	Observe symptoms of targeted residents, e.g., drainage, odors, jaundice, fevers, edema, etc.	Ask Nursing/Rehabilitative Staff: - What do you do when you think a resident needs laboratory work done – blood work, cultures, etc.? - How long does it take to get lab results back? - What do you do with the results when they do come back? - Do you have any problems with your laboratory services? - How are lab specimens stored? - Do you have any instruction from the lab regarding collection and storage of specimens?	Review the physician's order sheet to see if: - orders for lab services are signed - that there are orders for tests that have been done. Nursing progress notes are reviewed for documentation of physician notification of lab results. Physician progress notes or other documentation indicating that the physician is aware of lab results. There are lab reports on the medical record for all tests ordered (except if just performed).	There must be signed physician orders for all lab/radiology services performed. Record results of all testing in the medical record. There is documentation in nursing or physician notes to indicate the results of lab tests were promptly communicated to the physician. When lab tests are performed the resident should be informed of significant findings and the possible therapeutic alternatives.	Nursing Services 405.1124(a)(b)(c) 442.343 Physician Services 405.1123(b)
F229 SNF 405.1128 (a) A. Provision of Services F230 1. All services are provided only on the orders of a physician.					
F231 2. The attending physician is notified promptly of findings.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F232 3. Signed and dated reports of a clinical laboratory, x-ray and other diagnostic services are filled with the patient's medical record. INTENT To assure that lab tests are performed as ordered and findings are reported to physicians are made aware of symptoms that may require lab tests.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Social Services F233 SNF 405.1130	Observe resident for: - level of alertness - behavior exhibited (disoriented, confused, uncooperative, disruptive, aggressive, anxious, withdrawn, isolated, lonely). - personal appearance - apparent disabilities - apparent vision and/or hearing problems they exhibit as you talk to them - interaction to staff, other residents, family, visitors - participation in group activities - independence in activities, decision making - Therapeutic staff intervention: constructive reaction to resident's behavior - resident's participation on policy making bodies and committees of facility, e.g., resident councils.	- How long have you been in the facility? - Can you explain to me why you are here? - Have you had any problem adjusting to the facility i.e., loss of independence? - Have you had any other problems? - Has staff been helpful, e.g., financial? - Do you have any family or any other visitors? - Do they have any problems with which this facility has not been helpful? - If exhibiting disruptive depressed, agitated, anxious, etc. behavior- I noticed that you are upset (quiet, nervous, unhappy) today, Can you tell me what has bothered you? - Does staff respond to your suggestions about your own care? - Did you participate in planning what care you will get and who will give it to you? - Do you make use of the dining, activity, community room, and/or outdoor area?	Review medical records of residents selected for in-depth review to determine that: - Assessment and plan of care identifies residents medically related social and emotional needs and/or problems. - Resident's family and home situation, information related to medical and nursing requirements, and community resources are considered in making decisions regarding the residents care. - Medical records contain current specific information signed and dated which highlights the social and emotional needs of the ressident and significant findings and actions are entered promptly in the medical record. - Social service notes address the following, if applicable: + losses due to aging + relationship with staff and other residents + mental status + behavior problems + adjustment to the facility + illness	The residents social and emotional needs are identified. The plan of care addresses those needs. The plan of care is being followed, reviewed and revised as necessary. The family's needs and concerns are addressed if applicable. There is referral to appropriate agencies if necessary. Sufficient space is provided for private meetings and discussions. While it is not a program requirement a social worker or other staff may contribute to the resident's care plans by indicating personal strengths that can be used to build upon.	Nursing Services SNF 405.1124 ICF 442.338 Activities SNF 405.1131 ICF 442.345(a)(c)(d) Physicians Services SNF 405.1123(b) ICF 442.346 Patient Care Management SNF 1124(d) ICF 442.346 Physical Environment SNF 405.1130(b) ICF 442.344(c)
F234 SNF 405.1130(a) F235 ICF 442.344(d) A. Plan F236 The medically related social and emotional needs of the residents are identified. B. Provision of Services F237 1. Services are provided to meet the social and emotional needs by the facility or by referral to an appropriate social agency.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F233-238 (cont'd)					
F238 2. If financial assistance is indicated, arrangements are made promptly for referral to an appropriate agency.		- Can you tell me about your life here? What do you do in a usual day? - Are things like getting up, bathing, dressing, eating, done at the same time for everyone? - If you could change some things about living here, what would you change? Ask Social Worker/Nurse -When the social worker is readily available, delete "ask the nurse". -How often is the resident seen by a social worker?" - Who is responsible for identifying the resident's: + social and emotional needs + family and home situation + problems and needs + financial needs - How are needs identified and reported? - Does resident participate in the development of his/her care plan? - Ask nursing how often the social worker sees resident. - Does the social worker discuss residents needs/problems with nursing staff if there is a need for nursing to be involved?	- Plan of care, social service notes, reflect the current status of the resident. - There is evidence that the residents mental status has been considered when plan of care was developed. - Vision and hearing problems have been addressed. - Plan of care addresses residents needs as observed by the surveyor and stated by the resident. - Notes and plan indicate that needs have been re-evaluated and care plan changed as necessary. - There is evidence that the problems and needs of the family have been addressed. - There are indications that a referral has been made to the appropriate agency and a statement describing why. - There is documentation from the outside agency indicating what actions were taken and any plan for follow-up.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F233-238 (cont'd)		- How is physician notified and involved in plan of care? - Ask social service staff their role, function, and what services they provide. - Ask staff what referral services are available. - If services are being provided by outside resource, are resources documented work service? - Ask social service staff about their background and education. - If there is a consultant ask staff: + How often does the person come? + How long do they stay? + What does the person do while in the facility? + What assistance, consultation is being provided? + Ask social service staff if adequate space is provided for them by the facility to conduct private interviews and meetings.	- The time period between date of referral and date of services is reasonable and if not, there is evidence of follow-thru by staff. - The outside agency has documented their involvement and activities. - Plan of care demonstrates awareness of behavior, articulates the reasons for it, and indicates in the plan of care an approach to the behavior. - Assessment should contain: + a flexible approach to each resident (should be individualized). + awareness of a mental status evaluation. + resident history. + family availability for planning, resident support, etc. + identification of problems resulting from placement. + recent social adjustment. + discharge planning. - The record reflects	- There is documentation of collaboration between nursing and social work for meeting emotional needs.	Patient Care Management 405.1124(d)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F233-238 (cont'd)			Social Service intervention with family and resident, i.e., grief and bereavement counseling. - Review integrated plan of care for: + Plan for concerted social services. + Plan for supportive services for adjustment. - Adjustment goals. - Interventions for specific conditions.		
Activities F239 SNF 405.1131 F240 SNF 405.1131(b) F241 ICF 442.345 F242 1. An ongoing program of meaningful activities is provided based on identified needs and	General level of activities throughout the facility, as well as in specifically designated areas. How many residents are lying on their beds or sitting in chairs staring at the walls during waking hours? What is the level of residents interest in activities they are doing? Are residents positioned correctly for activity?	- How does he/she spend the day? - Of the activities resident has during the week, what does he/she enjoy most/least? - If has none, why? - Has staff asked about his/her interests? Suggested specific activities or people to get acquainted with in response to interests? - What organized activities has he/she participated in this past week? - How does resident find out about upcoming programs or happenings?	Activities Assessment Interests of the resident (past and present) are identified as to resident's current capabilities and necessary adaptations to pursue their interests. Documentation that information about social history, medical problems and limitations impacting residents' activities have been communicated to activities personnel and used in assessment and development of activities portion of care plan.	Are each resident's personal interests known? If not, what actions are being taken to identify them? Residents in facility 60 days should not be without some identified interests. Are each resident's needs identified? If not, what actions are being taken to identify them? Have medical contraindications been identified in the care plans? Needs and contraindications of residents in the facility more than 30 days should be known and/or have a plan of action.	Nursing Services 405.1124 442.319 Social Services 405.1130 442.344 Special Rehabilitative Services 405.1126 442.363 Physician Services 405.1123 442.329

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F242-(cont'd) interests of each resident. It is designed to promote opportunities for engaging in normal pursuits, including religious activities of their choice, if any.	Are needed personal equipment (e.g., splints, glasses) and adaptations for limitations and safety (e.g., cardholder, goggles, footrests) used in activities?	- Does resident get out of facility to activities? - Does resident have problems getting to activities? If so, does the staff assist? - Does the staff encourage residents to go to activities? - Does resident participate in Resident Council? - Does resident have free choice of activities? - What kind of activities do bedfast residents engage in? Ask Resident: - Have you ever had difficulty in having private visits? Give examples.	- Needs of the resident in the following areas are identified: + social interaction + creative expression + work and service opportunities + intellectual stimulation or activities adaptation + physical exercise + spiritual or religious expression - Plan of care Used all available information about: + interests + needs + indications and contraindications for activities from other assessments + physician orders and progress notes	Does each resident's activities promote his physical, social and mental well-being?	Physical Environment 405.1134 442.329 Infection Control 405.1135 442.328 Resident Rights 405.1121(k) 405.311 Medical Records 405.1132 405.318 Patient Care Management 405.1124(d) 442.341
F243 2. Unless contraindicated by the attending physician, all residents are encouraged to participate in activities.					
F244 3. The activities promote the physical, social and mental well being of the residents.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F245 4. Equipment is maintained in good working order. F246 5. Supplies and equipment for activities of interest are available. INTENT Each resident has individual and/or group activities to meet activities needs through his interests daily.	Is lighting adequate throughout the facility for activities in which residents are engaged? Do men and women have activities of interest to them? Do residents communicate with each other in activities? Are methods of communicating upcoming activities appropriate to the resident populations? Specific observation for physically impaired/alert residents: Activities adapted to meet specific needs of the resident. Alert residents have activities of interest and at their cognitive functional level. Specific observations for confused/disoriented, emotionally disturbed and mentally retarded residents: There are current calendars, clocks and patients	Ask Nursing/Activity Staff - Do they know the interests of residents under their care? TV programs they like? Activities they want to participate in today/this week? - Do they know the personal equipment needed (e.g., glasses, hearing aids, reacher)? - Do they know the adaptive equipment used by residents for specific activities (e.g., talking books, built up tools)? - Do they talk to residents to identify new interests and report these and "dislikes" to activities personnel? How? - What is staff's involvement with individual and group activities of residents in their care? - How do they determine interests of residents who have difficulty communicating? - What activities does resident participate in regularly? Which activities does he/she enjoy most/least?	Activities notes spell out implementation of plan, resident's reactions to specific activities, approaches, and people. Residents' participation in individual and group self-started and organized structured and unstructured activities timespent. Evaluation of plan of care for: changes in interests; changes in precautions, changes in needs, new problems, approaches, etc. Plans are revised as needed.	Are equipment and supplies to meet residents interests available and maintained in good working order? Are residents evaluated periodically with emphasis on participation levels and desire for new activities? Are plans readjusted if they do not reach desired outcomes? Residents in the facility more than 60 days should have at least two activities per week of interest to them personally.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F246 (cont'd)	and patients names or symbols visible to all the residents. Staff consistently use techniques such as reality orientation, empathy, and/or validation therapy as per each individual's needs. Resident has familiar items if available in room (e.g., family pictures, artwork, afghan, chair from home). Residents in restraints have activities of interest geared to their abilities when restrained (e.g., table-top activity, music, radio, reading and writing material; when out of restraints (e.g., walks, exercise, group, toileting). Small group and one-on-one involvement with staff reinforcing appropriate responses. Staff reaction to resident behavior during activities (e.g., crying, whining, demanding, non-verbal, agression,	- If he/she does not participate, why? - Which activities appear to relax/calm the resident? Excite him/her? - How does staff manage maladaptive behavior (e.g., abusive, disruptive, combative)? - Is direct care staff involved in resident activities? How? When (weekends, evenings)? - Does resident have one-to-one assistance in activities? - How many residents have few activities a day of interest to them as individuals? - Why do these residents have so little interest? - What is your plan to find more activities of interest to them that will meet their needs? - What types of residents seem not to be interested in activities? - How many (who) residents have only passive activities?			

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F 246 (cont'd.)	loudness). Specific observation for comatose or terminally ill resident: - Appropriate items for sensory enrichment in room (e.g., TV, radio, adequate lighting) - Resident placed in supportive living environment (e.g., around people, in hall, activities room, sunshine, fresh air), when appropriate to the resident needs and consistent with the resident's choice. Specific observation of environment for conducting activity program: - Adequate lighting. - Functional area is appropriate for activities of interest (e.g., religious services, arts and crafts, cooking, reading, TV watching, card playing, parties, discussion groups, gardening).	- How do you adapt activities for needs of residents who are: - confused/disoriented - emotionally disturbed - mentally retarded - physically impaired but alert - terminally ill? - Are community volunteers utilized in the activities program? In what way? - Are the residents encouraged to offer suggestions for new activities? If so, what activities have been instituted as a result? - How they manage maladaptive behavior (e.g., abusive, disruptive, combative)? - How do they help depressed residents (e.g., tearful, emotionally labile)?		Resident may refuse to participate in activity. However if the activities are part of a diagnostic or therapeutic program, the resident is responsible for assisting in the selection of mutually acceptable alternative activities.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F246 (cont'd)	- Multi-purpose room use and timing of activities does not conflict. - Outdoor activity area. - Functional furniture, indoors and outdoors. - Evidence of free choice activities: - newspapers - magazines - record player - radios - games - TV's - reading - sewing - personal visits - church services - Activities, equipment and supplies are appropriate and sufficient to meet interest of residents. - Activities equipment and supplies sufficient for conducting activities. - Activities equipment clean, safe, and in working order. - Residents rooms contain independent project materials, as appropriate. - Residents have access to the total activity environment (e.g., lobby, sunroom, day-room, porch, dining room).				

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
MEDICAL RECORDS					
F247 SNF 405.1132				All information required is present in the record. Does the record document all observable resident needs/problems?	
Content					
F248 SNF 405.1132(c)					
F249 ICF 442.318(a)(c)					
F250 1. The medical record contains sufficient information to identify the resident clearly to justify diagnoses and treatment and to document results accurately.					
F251 2. The medical record contains the following information.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F251 (cont'd) a. Identification information.					
F252 b. Admission data including past medical social history.					
F253 c. Transfer form, discharge summary from any transferring facility.					
F254 d. Report of resident's attending physician.					
F255 e. Report of physical examinations.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F256 f. Reports of physicians' periodic evaluations and progress notes.					
F257 g. Diagnostic reports and therapeutic orders.					
F258 h. Reports of treatments.					
F259 i. Medications administered.					
F260 j. An overall plan of care setting forth goals to be accomplished through each service's designed activities, therapies and treatments.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F261 k. Assessments and goals of each service's plan of care.					
F262 l. Treatments and services rendered.					
F263 m. Progress notes.					
F264 n. All symptoms and other indications of illness or injury including date, time and action taken regarding each problem.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F264 (cont'd) INTENT Brings together all resident information. Reflects the care being given to the residents and helps all care givers to make decisions on care needed.					
TRANSFER AGREEMENT F265 SNF 405.1133		Ask Staff: - What is the routine information you provide to a new facility when you transfer a resident? - Who provides this?	Review information on medical record of resident who was temporarily transferred and is again back in the facility.	All pertinent resident information must be documented on the medical record at the time of transfer.	Patient Rights 404.1121(k) 442.311
F266 SNF 405.1133(a)			Look at physician and nursing progress notes of above residents to determine if the timeliness of transfer was consistent with accepted standards of care.	The resident was not injured in any way by a delay in the transfer process.	
F267 ICF 442.316			Does facility have an agreement with a hospital? Not required if hospital under same ownership, direction and in same campus.		
F268 A. Whenever the physician determines that a transfer is medically appropriate between a					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F 268 (cont'd) hospital or a facility providing more specialized care and the nursing facility, admission to the new facility shall be effected in a timely manner.			Is transfer form complete with all data, with appropriate signatures? Does the medical record indicate that adequate and pertinent aspects of the discharge planning portion of the patient care plan accompany the patient on transfer?		
F269 B. Information necessary for providing care and treatment to transferred individuals is provided.					
PHYSICAL ENVIRONMENT F270 SNF 405.1134					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F271 A. Nursing Unit SNF 405.1134(d)				Medication preparation and storage areas provide adequate space and light to prepare medication and to store medication and needed supplies.	Nursing Service 405.1124(g) 442.337 Infection Control 405.1135
F272 1. Unit properly equipped for preparation and storage of drugs and biologicals.	There is adequate light to prepare medications. There is sufficient space to prepare medications for administration in a safe and effective manner.	Ask Nursing Staff: - What do you use the medication room (area) for? - Where is the handwashing sink? - Do you have enough, convenient storage area for I.V. fluids and medications needing refrigeration. - Where are the keys for the medication room and unit dose carts? - Do you feel you have adequate storage space for supplies and equipment? - If no, what problems does that cause? - Does the resident call system function properly? Ask Residents: - Do the call bells in your room and in the toilets and bathing areas always work?		Light is available when and where the medication cart is in use. A medication refrigerator is available and does not contain patient or employee snacks. Juice, etc., used in administering medication is allowed. Clean and dirty areas must be separated, preferably in separate rooms. Storage space must be available for bulky items and supplies so that they can be stored without blocking corridors and exits. Medications are protected from unauthorized use. Call bells must be in working order and must be present in all resident bedrooms, toilets and	Governing Body 442.325 Resident Rooms 405.1134(e) 442.325
F273 2. Utility and storage rooms are adequate size.	There is sufficient space for storage of medications. Unit dose carts are protected from tampering and theft.				
F274 3. The unit is equipped to register resident calls with a functioning communications system from resident areas including rooms and toilets and bathing facility.	Medications are stored in a locked area. Refrigeration facilities are available for medications. There is sufficient storage space for I.V. fluids. Handwashing facilities are readily accessible either in the medication preparation area or adjacent to it.				

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE

F274 (cont'd)	Audible call system is on and working. Long cords are available for chair bound patients.	- If no:
		  - How often is it that they do not work?
		  - How long does it take to get them fixed?
				bathing areas.
				
				Audible signals, if in the system, must be in working order and turned on.	

B. Dining and activities area F275 SNF 405.1134(g) F276 ICF 442.329	Area is clean and well maintained. There is sufficient space between tables to allow for safe passage of wheelchairs and residents with walkers, canes and other assistive devices.	Ask Residents: - Is there enough room between tables to allow you to feel safe in getting to your table? - Can you sit comfortably in your wheelchair at the table? - How is the lighting and ventilation level for you? - Are sitting preferences permitted? - Do you go to the dining room for meals?		Regulations clearly set out conditions for compliance. Refer to the regulations.	Dietetic Services 405.1125 442.331 Patient Activities 405.1131 442.345
F277 1. The facility provides one or more clean, orderly, and appropriately furnished rooms of adequate size, designed for resident dining and resident activities.	Table height or design allows residents in wheelchairs to sit a normal distance from the table. Lighting and ventilation in the dining/activity areas is provided according to recommended standards. A multi-purpose room should not be used for storage of items such as beds, mattresses, boxes, etc.				

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F278 2. Dining and activity rooms are well lighted and ventilated.	Are dining areas utilized at meal service?				
F279 3. Any multi-purpose room used for dining and resident activities has sufficient space to accommodate all activities and prevent their interference with each other.					
F280 SNF 405.1134(e) Indicators C&D apply to SNFs					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
C. Resident Rooms F281 ICF 442.325	Observe rooms and furnishings for maintenance, cleanliness and safety. Look for dust/dirt on lights, high surfaces, under heating units, and in corners. Use a flashlight. Are beds, lights, plumbing all in working order?	Ask Residents: - Is your room kept clean? Who cleans it? When, and how often? - Is your bed, chair, and other furniture and fixtures kept in good repair? - Do you feel you have enough privacy? - What personal belongings are you allowed to have? - Is the lighting in your room sufficient for you? - Is your chair comfortable? - When do you permit staff to clean you room? - When do you ask staff not to clean you room?		Refer to the regulations.	Resident Rights 405.1121(k)(1)(5) (9)(13) 442.311(a)(d)(2) (g)(1)(2) (6)(k) Physical Environment 405.1134(d)(e) 442.326
F282 1. Single rooms have at least 100 sq. ft.					
F283 2. Multiple resident rooms have no more that 4 residents and at least 80 sq. feet per resident.	Observe for all regulatory requirements as noted to the left. Are privacy curtains present, and appropriate to maintain resident privacy?				
F284 3. Each room is equipped with or conveniently located near toilet and bathing facilities.	Test several call lights. Are call lights within reach, including emergency lights in toilets and bathing areas? Are toilet and bathing facilities appropriate in number, size, and design to meet resident needs? What personal belongings do residents have in their rooms? Is there				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F285 4. There is a capability of maintaining privacy in each.	sufficient storage and security for their belongings?				
F286 5. There is adequate storage space for each resident.					
F287 6. There is a comfortable and functioning bed and chair, plus a functional cabinet and light.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F288 7. The resident call system functions in resident rooms.					
F289 8. Each room is designed and equipped for adequate nursing care and the comfort and privacy of residents.					
F290 9. Each room is at or above grade level.					
F291 10. Each room has direct access to a corridor and outside exposure. Exception: Not required for ICF residents.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
D. Toilet and bath facilities F292 ICF 442.326 F293 1. Facilities are clean, sanitary and free of odors.	Are there adequate numbers of toilets, baths, and showers for the residents that are accessible to, and functional for all residents? Are these conveniently located in or near resident rooms? Check for water on floors of bath and shower rooms.	Ask Residents: - When was your last bath? The one before? - What safety precautions are used for getting in and out of the bathtub? - What equipment is needed to get in and out of the tub, and how do you feel about it? - How do you get your wheelchair into the toilet or bathroom?	Bathing schedule for patients in your indepth review.	Privacy is maintained for residents in toilet and bathing areas. Toilet and bathing areas are clean. Water is removed from floors immediately upon completion of bathing. Hot water is within the acceptable temperature range.	
F294 2. Facilities have safe and comfortable hot water temperatures.	Is privacy provided? Are facilities clean, sanitary and free of unpleasant odors?	- When, if ever, do you refuse to be bathed?		Soap, toilet paper and towels are available in the bathrooms. Grab bars are present and securely fastened to the wall.	
F295 3. Facilities maintain privacy.	Are bathrooms equipped with soap, toilet tissue, towels, etc.? Hot water is between 110-120 degrees or the acceptable State level. Hot water temperature control must be maintained. Single use, disposable towels should be available for handwashing purposes.			Ventilation and lighting systems are correctly functioning.	
F296 4. Facilities have grab bars and other safe guards against slipping.	Note also condition of grab bars, plumbing and fixtures. Bath areas are not used for storage.			Plumbing and other fixtures are in good condition.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F297 5. Facilities have fixtures in good condition.					
F298 6. The resident call system functions in toilet and bath facilities.			Facility has appropriate arrangements for providing social services, either using: – outside resources (contract or consultant services) – qualified facility personnel under a clearly defined plan.	Refer to regulations.	
E. Social Service Area F299 SNF 405.1130(b) ICF 442.344	Does the social worker have a locked file available? Where are social service interviews and clerical functions performed?	Ask Resident: – Does the social worker see you in a private room or in your own room? – If in your own room, do you feel that you have enough privacy?			
F300 1. Ensures privacy for social service interviewing.	Are rooms in areas easily accessible to residents?				
F301 2. Adequate space for clerical and interviewing functions is provided.					
F302 3. Facilities are easily accessible to residents and staff.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F. Therapy areas F303 SNF 405.1126(a)	Therapy areas are accessible to all residents needing the facilities. Space allows for safe maneuvering of residents and equipment and staff.	Ask Resident: - Do you feel that the equipment you use is safe? - Do you have enough room for your treatment? Ask Therapy Staff: - Is your equipment adequately maintained? - Do you have enough room to safely and adequately provide treatment?	Refer to regulations.		
F304 ICF 442.328(a)	All residents are able to be observed and supervised during therapy.				
F305 1. Space is adequate for proper use of equipment by all residents receiving treatment	Equipment has labels (stickers, etc.) to indicate proper maintenance. All equipment fastened to floor and walls is secure.				
G. Facilities for Special care F307 SNF 405.1134(f)	Are therapy areas properly ventilated to effectively reduce heat, moisture and odors? Are private rooms available that meet regulatory criteria.	Ask Supervisory personnel: - What room(s) do you use for isolation? - What is your procedure if the room is already occupied when you need it for isolation? - Will you show me the signs you use to identify the isolation room?		Rooms meeting the regulatory requirements are available in the facility. There is a procedure that is implemented when an isolation is needed, but it is already occupied. Isolation signs are visable and clearly convey their intended message.	Resident Rights 405.1121(k)(4) 442.311(c)(2) Infection Control 405.1135(b)
F308 ICF 442.328(b)	If a resident is infected and in isolation, are precautionary signs posted, and are they legible and understandable?				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F309 1. Single rooms with private toilet and handwashing facilities are available for isolating residents.					
F310 2. Precautionary signs are used to identify these rooms when in use.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
H. Common Resident Areas F311 SNF 405.1134(j)	Use senses - sight, hearing, olfactory when surveying common areas as lounges, lobby, corridors. Note levels of lighting for both reading and non-reading areas. Is it bright enough but without glare? Are areas clean and without offensive odors? Do background sound levels allow for ease of communication and comfort for residents/visitors? Do residents seem comfortable with the room temperature - note the use of several layers of clothing, many residents fanning themselves, etc. Are handrails on each side of the corridor and are they secure? Are smoking/no smoking areas designated?	Ask Residents: - Do you think that the lounges and corridors are usually clean? - Do they have any unpleasant odors? - Is the lighting level comfortable for you to read? Is it adequate for you to feel safe walking? - Do you have any difficulty with the noise level? - Is the temperature usually comfortable for you? - Do you feel there is adequate ventilation? - Are there handrails in all of the corridors? - Are they securely fastened to the wall? Ask Supervisory Staff: - If there is a water main break or other interruption in the water supply, how do you obtain water for essential areas and duties?		- Floors and furniture should appear clean - free of gross contamination. - Residents should have lighting bright enough to safely negotiate corridors, lounges, etc., and in reading area, be bright enough to read. But the brightness should be free of glare. Remember, the elderly need a higher level of lighting as their sight diminishes. - Except for times when a louder level of sound is necessary for communication, sounds should be unobtrusive and "comfortable". - Room temperature comfort levels vary widely, and in general the elderly will require a higher temperature for comfort than younger people. Use information from resident interviews and your observations to determine if the temperature is "comfortable" for most residents. - All corridors in	Infection Control 405.1135(c)
F312 ICF 442.324					
F313 1. All common resident areas are clean, sanitary and free of odors.					
F314 2. Provision is made for adequate and comfortable lighting levels in all areas.					
F315 3. There is limitation of sounds at comfort levels.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F316 4. A comfortable room temperature is maintained.				resident-used areas are equipped with handrails on each side. These rails securely fastened provide the residents with a firm support. - Supervisory staff are able to tell you how they will obtain water for drinking, cleaning/ bathing of residents, and other essential functions if their normal water supply is interrupted.	
F317 5. There is adequate ventilation thru windows or mechanical measures or a combination of both.					
F318 6. Corridors are equipped with firmly secured handrails on each side.					
F319 7. Staff are aware of procedures to ensure water to all essential areas in the event of loss of normal supply.					Disaster Preparedness 405.1136 442.313

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
I. Maintenance of Building and Equipment F320 SNF 405.1134(i)	- Ceiling and floor tile in good condition - Paint in good repair - No holes in walls - Look for rat and other rodent trails outside and inside - Preventive maintenance program for all equipment is followed - Wheelchairs not stored in hallways, bathrooms, etc. - Window screens are in good repair - Check overbed tables, wheelchairs, etc., for cleanliness and operation	Ask Staff: - How many housekeeping staff are available? - How late are housekeepers on duty during the week? - How is weekend coverage different? Ask Resident: - What if any problems have you had with special equipment you need to use?			Physical Environment 405.1134(d)
F321 1. The interior and exterior of the building are clean and orderly.					
F322 2. All essential mechanical and electrical equipment is maintained in safe operating condition.					
F323 3. Sufficient storage space is available and used for equipment to ensure that the facility is orderly and safe.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F324 4. Resident care equipment is clean and maintained in safe operating condition.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Indicator J applies to ICFs. J. Dietetic Service Area F326 SNF 405.1134(h)	Observe for - needed space to carry out routine operations - maintenance of working surfaces equipment, utensils, and serving dishes - operable dish washer machine. - 3-sink method of pot/dish washing properly carried out/or written procedure posted - operable and clean exhaust fan - stored dishes and pots are free of baked-on food particles and chipped/cracked surfaces - food stored off floor - protective covers for fluorescent lights - handwashing sink readily accessible	Ask Staff: - What have you been trained to do? - What type of dishwasher machine do you have? How does it operate?	The proper temperature for the Dishwasher wash cycle is 150-160 degrees Fahrenheit. The dishwasher rinse cycle is acceptable at temperature of 180 degrees Fahrenheit or when there is a change in the temperature-sensitive tape (thermolabel). The individual manufacturers' specifications may countermand these instructions, particulary in the case of chemical sanitization.		Dietetic Services 405.1125(g) 442.331(b)
F327 1. Kitchen and dietetic service areas are adequate to insure proper, timely service for all patients.					
F328 2. Kitchen areas are properly ventilated, arranged, and equipped for storage and preparation of food as well as for dish and utensil cleaning, and refuse storage and removal.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Indicator K applies to ICF K. Dieteary Staff Hygiene F329 SNF 405.1125(f)	Observe the following: - cleanliness of hands, fingernails, hair, clothing - use of hair restraint - whether employees wash hands with soap and water after using the toilet, smoking, blowing their nose, touching raw meat, poultry or eggs - employees using hands to mix food when utensils could be used - employees using the same spoon more than once for tasting food while preparing, cooking, or serving.	Ask Staff: - What happens when you report to work with a cold, a cut or sore on your hand? - Where is handwashing sink for dietary staff? - Do you use disposable plastic hand covers? If so, when? - Where are your serving utensils located? - What are temperatures for the refrigerators and freezers? Who is responsible for checking temperatures? - Do you have thermometers to check water and food temperatures? (ask them to demonstrate how they take temperatures)			Dietetic Services 405.1125(e)(f)(g)
Indicator L applies to ICF L. Dietary Sanitary Conditions F331 SNF 405.1125(g)	Verify that: - hot foods are 140 degrees or above - cold foods are 45 degrees or lower (*note: food held for more than 2–3 hours between 60 and 125 degrees may not be safe to eat) - cooked meats held longer than 72 hours are used, discarded or put in the freezer				
F332 1. Food is stored, refrigerated, prepared, distributed, and served under sanitary conditions.					
F333 2. Waste is disposed of properly.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F333 (cont'd)	- check that the refrigerators are equipped with an accurate thermometer - food does not have an "off" or bad odor - cracked eggs are discarded - foods are dated and then stored as to their preparation date. Observe that waste is in covered containers, bagged and tied for disposal, and that dumpsters are covered.				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
L. Emergency Power F334 SNF 405.1134(b)	Is an emergency generator available? Test generator under full load conditions.			As per regulations and covered by the Life Safety Code surveyor	
F335 1. An emergency source of electrical power necessary to protect the health and safety of residents is available.	Check items of emergency power: - lighting - fire detection - alarms - extinguishing systems - life support systems Transfer time from normal power to emergency power to occur within 10 seconds.				
F336 2. Emergency power is adequate at least for lighting in all means of egress; equipment to maintain fire detection, alarm, and extinguishing systems; and life support systems.	Check for gounded extension cords at nurses stations. Where are emergency outlets?				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F337 3. Emergency power is provided by an emergency generator located on the premises where life support systems are used.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Infection Control F338 SNF 405.1135	- Observation of dressing technique to identify if infection control principles are being adhered to: - sterile technique - sterile/clean field - disposal of dressing - handwashing - use of gloves	Ask Staff: - What type of dressing changes are you performing? - How often are dressings changed? - Why is resident on isolation/precautions? - Do laundry/housekeeping personnel/aides know procedures?	Review records of residents selected for indepth review for infection.	Compliance will be based mainly on your observations. Deficiencies will be cited if you see: - breaks in aseptic or isolation technique - clutter or unclean conditions that would cause unsafe conditions - inadequate supplies of linen to provide proper care and comfort for residents - inadequate techniques for handling clean and dirty linen - evidence of insect or rodent infestation - use flash light to check for roaches in closets, cabinets.	Nursing Services 405.1124 442.338
A. Infection Control F339 SNF 405.1135(b)					
F340 Aseptic and isolation techniques are followed by all personnel.	- Observation of isolation precautions: - signs - linen, double bagged - soiled linen, double bagged - gowns/masks - gloves - handwashing - disposable dishes - information for visitors	Ask Resident: - Do you know why you have dressings? - Do you know why you are on isolation/precautions? - Do you have clean linen when you need it?			
B. Sanitation F341 SNF 405.1135(c)					
F342 The facility maintains a safe, clean, and orderly interior.	- Procedures followed by: - Laundry - Housekeeping How is dirty linen transported to laundry or holding area?				
C. Linen F343 SNF 405.1135(d)	Do aides wash hands after cleaning dirty linen? How do aides handle clean/dirty linen while changing beds?				

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F344 ICF 442.327					
F345 1. The facility has available at all times a quantity of linen essential for proper care and comfort of residents.					
F346 2. Linens are handled: stored, processed, and transported in such a manner as to prevent the spread of infection.					
D. Pest Control F347 SNF 405.1135(e)	Look for evidence of insect or rodent presence (mouse or rat droppings, roaches, ants, flies	Ask Staff: - Have you seen insects (roaches, ants, flies, etc.)? - Have you seen rodents and/or droppings?			
F348 ICF 442.315(c)	- Screen doors closed - Windows that can be opened have screens that are in good repair	- What foods are residents permitted to keep in their rooms?			
F349 The facility is maintained free from insects and rodents.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
DISASTER PREPAREDNESS F350 SNF 405.1136 F351 SNF 405.1136(a) F352 ICF 442.313	- Disaster plan is located at each nursing station. - Evacuation plans posted in each smoke compartment.	Ask Residents: - Do you know what to do in case of fire? - How often do you rehearse it? Ask Staff: - What are your responsibilities at a fire drill? - What is the facilities disaster plan? (Specify types, [(e.g., fire, flood, etc.)] - How you undergone disaster training? - Have you participated in a fire disaster drill? When? - How frequently are drills held? - Have you been trained/ instructed in the use of fire equipment, fire containment methods? - Have you been trained in transfer or casualties and routes? - How would staff meet emotional needs of residents during/following a "disaster", e.g., fire		A disaster plan is available and facility staff know their roles.	Physical Environment 405.1134(a)(b) 442.321
Indicators A and B apply to ICFs.					
A. Disaster Plan					
F353 1. Facility staff are aware of plans, procedures to be followed for fire, explosion, or other disaster.					
F354 2. Facility staff are knowledgeable about evacuation routes.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F355 3. Facility staff are aware of their specific responsibilities in regard to evaluation and protection of residents.					
F356 4. Facility staff are aware of methods of containing fire.					
B. Drills F357 SNF 405.1136(b)					
F358 1. All employees are trained as part of their employment orientation in all aspects of preparedness for any disaster.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F359 2. Facility staff participate in ongoing training and drills in all procedures so that each employee promtly and correctly carries out a specific role in case of a disaster. INTENT To ensure a clean, safe environment for residents.					

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

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

§ 488.201 Reconsideration.

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

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

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

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

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

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

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

§ 488.203 Withdrawal of request for reconsideration.

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

§ 488.205 Right to informal hearing.

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

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

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

§ 488.207 Informal hearing procedures.

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

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

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

(i) Authorized representatives;

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

(iii) Legal counsel;

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

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

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

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

§ 488.209 Hearing officer's findings.

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

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

(1) Separate numbered findings of fact; and

(2) The legal conclusions of the hearing officer.

§ 488.211 Final reconsideration determination.

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

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

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

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

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

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

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

§ 488.300 Statutory basis.

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

§ 488.301 Definitions.

As used in this subpart—

Abbreviated standard survey means a survey other than a standard survey that gathers information primarily through resident-centered techniques on facility compliance with the requirements for participation. An abbreviated standard survey may be premised on complaints received; a change of ownership, management, or director of nursing; or other indicators of specific concern. 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 onsite by a surveyor who has successfully completed the required training and testing program.

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

Instance or instances of noncompliance means a factual and temporal occurrence(s) when a facility is not in substantial compliance with the requirements for participation. Each instance of noncompliance is sufficient to constitute a deficiency and a deficiency may comprise of multiple instances of noncompliance.

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, as amended at 89 FR 64162, Aug. 6, 2024]

§ 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) For each instance of noncompliance, 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, $1,000–$10,000 (as adjusted annually under 45 CFR part 102) per instance of noncompliance, or both, in addition to imposing the remedies specified in paragraph (e)(2)(i) of this section. For multiple instances of noncompliance, CMS may impose any combination of per instance or per day civil money penalties for each instance within the same survey. The aggregate civil money penalty amount may not

exceed $10,000 (as adjusted annually under 45 CFR part 102) for each day of noncompliance.

(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; 89 FR 64162, Aug. 6, 2024]

§ 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 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, or both, regardless of whether or not the deficiencies constitute immediate jeopardy. When a survey contains multiple instances of noncompliance, CMS or the State may impose any combination of per instance or per day civil money penalties for each instance of noncompliance within the same survey.

(b) CMS or the State may impose a civil money penalty for the number of days or instances of previously cited noncompliance, including the number of days of immediate jeopardy, since the last three standard surveys.

[89 FR 64163, Aug. 6, 2024]

§ 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 its right to a hearing as specified in § 488.436, the State initiates collection of civil money penalty imposed per day of noncompliance after 60 days from the date of the notice imposing the penalty and the State has not received a timely request for a hearing.

(2) If a facility waives its right to a hearing as specified in § 488.436, the State initiates collection of civil money penalty imposed per instance of noncompliance after 60 days from the date of the notice imposing the penalty and the State has not received a timely request for a hearing.

(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; 88 FR 53347, Aug. 7, 2023]

§ 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) Either the amount of penalty per day of noncompliance or the amount of the penalty per instance of noncompliance or both;

(iv) Any factors specified in §488.438(f) that were considered when determining the amount of the penalty;

(v) The date(s) of the instance(s) 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; 89 FR 64163, Aug. 6, 2024]

§ 488.436 Civil money penalties: Waiver of hearing, reduction of penalty amount.

(a) *Constructive waiver of a hearing.* A facility is considered to have waived its right to a hearing after 60 days from the date of the notice imposing the civil money penalty if CMS has not received a request for a hearing from the facility.

(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, as amended at 76 FR 15127, Mar. 18, 2011; 88 FR 53347, Aug. 7, 2023]

§ 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 per instance.

(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; 89 FR 64163, Aug. 6, 2024]

§ 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 the facility waives its right to a hearing in accordance with § 488.436(a).* Except as provided for in § 488.431, a civil money penalty is due 75 days after the notice of the penalty in accordance

with § 488.436 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; 88 FR 53347, Aug. 7, 2023]

§ 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 noncompliance 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 reapplication 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.

(g) *Change of ownership.* An accrediting organization that wishes to undergo a change of ownership is subject to the requirements set out at § 488.5(f).

[83 FR 56631, Nov. 13, 2018, as amended at 87 FR 25428, Apr. 29, 2022]

§ 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.

Hospice Special Focus Program (SFP) means a program conducted by CMS to identify hospices as poor performers, based on defined quality indicators, in which CMS selects hospices for increased oversight to ensure that they meet Medicare requirements. Selected hospices either successfully complete the SFP program or are terminated from the Medicare program.

IDR stands for informal dispute resolution.

Noncompliance means any deficiency found at the condition-level or standard-level.

SFP status means the status of a hospice provider in the SFP with respect to the provider's progress in the SFP, which is indicated by one of the following status levels:

(1) Level 1—in progress.

(2) Level 2—completed successfully.

(3) Level 3—terminated from the Medicare program.

SFP survey means a standard survey as defined in this section and is performed after a hospice is selected for the SFP and is conducted every 6 months, up to 3 occurrences.

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.

[86 FR 62425, Nov. 9, 2021, as amended at 88 FR 77879, Nov. 13, 2023]

§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.

§ 488.1130 Informal dispute resolution (IDR).

(a) *Opportunity to refute survey findings.* Upon the provider's receipt of an official statement of deficiencies, hospice programs can request an informal opportunity to dispute condition-level survey findings.

(b) *Failure to conduct IDR timely.* Failure of CMS, the State, or the AO, as appropriate, to complete IDR must 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, the State, or the AO 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.* (1) If the survey findings indicate a condition-level deficiency, the hospice program is notified in writing of its opportunity for participating in an IDR process at the time the official statement of deficiencies is issued.

(2) The request for IDR must—

(i) Be submitted in writing;

(ii) Include the specific deficiencies that are disputed; and

(iii) Be made within the same 10 calendar day period that the hospice program has for submitting an acceptable plan of correction.

[88 FR 77879, Nov. 13, 2023]

§ 488.1135 Hospice Special Focus Program (SFP).

(a) *Applicability.* (1) The provisions of this section are effective on or after January 1, 2024. ; and

(2) SFP selection begins in CY 2024.

(b) *Selection criteria.* (1) Selection of hospices for the SFP is made based on the highest aggregate scores based on the algorithm used by CMS.

(2) Hospice programs with accrediting organization deemed status placed in the SFP—

(i) Do not retain deemed status; and

(ii) Are placed under CMS or State survey agency jurisdiction until completion of the SFP or termination.

(c) *Survey and enforcement criteria.* A hospice in the SFP—

(1) Is surveyed not less than once every 6 months by CMS or the State agency; and

(2) With condition level deficiencies on any survey is subject to standard enforcement actions and may be subject to progressive enforcement remedies at the discretion of CMS.

(d) *Completion criteria.* A hospice in the SFP that has two SFP surveys within 18 months with no condition-level deficiencies, and that has no pending complaint survey triaged at an immediate jeopardy or condition level, or that has returned to substantial compliance with all requirements may complete the SFP.

(e) *Termination criteria.* (1) A hospice in the SFP that does not meet the SFP completion requirements in paragraph (d) of this section is considered for termination from the Medicare program in accordance with 42 CFR 489.53.

(2) CMS may consider termination from the Medicare program in accordance with § 488.1225 if any survey results in an immediate jeopardy citation while the hospice is in the SFP.

(f) *Public reporting.* CMS posts all of the following at least annually on a CMS public-facing website:

(1) A subset of 10 percent of hospice programs based on the highest aggregate scores as determined by the algorithm used by CMS.

(2) Hospice SFP selection from the list in paragraph (f)(1) of this section as determined by CMS.

(3) SFP status as defined in § 488.1105.

[88 FR 77879, Nov. 13, 2023]

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.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

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