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State Operations Manual
Chapter 7 - Survey and Enforcement Process for Skilled Nursing Facilities and Nursing Facilities

(Rev. 185, 11-16-18)

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7000 - Introduction

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Chapter 7 implements the nursing home survey, certification, and enforcement regulations at 42 CFR Part 488. No provisions contained in this chapter are intended to create any rights or remedies not otherwise provided in law or regulation.

The nursing home reform regulation establishes several expectations. The first is that providers remain in substantial compliance with Medicare/Medicaid program requirements as well as State law. The regulation emphasizes the need for continued, rather than cyclical compliance. The enforcement process mandates that policies and procedures be established to remedy deficient practices and to ensure that correction is lasting; specifically, that facilities take the initiative and responsibility for continuously monitoring their own performance to sustain compliance. Measures such as the requirements for an acceptable plan of correction emphasize the ability to achieve and maintain compliance leading to improved quality of care. (See §7304.4 for plan of correction requirements.)

The second expectation is that all deficiencies will be addressed promptly. The standard for program participation mandated by the regulation is substantial compliance. The State and the regional office will take steps to bring about compliance quickly. In accordance with §7304, remedies such as civil money penalties, temporary managers, directed plans of correction, in-service training, denial of payment for new admissions, and State monitoring can be imposed before a facility has an opportunity to correct its deficiencies.

The third expectation is that residents will receive the care and services they need to meet their highest practicable level of functioning. The process detailed in these sections provides incentives for the continued compliance needed to enable residents to reach these goals.

It should be noted that references to the State would be applicable, as appropriate, to the regional office throughout this chapter when the regional office is the surveying entity. It should also be noted that in cases where the State is authorized by CMS and/or the State Medicaid Agency, the State may provide notice of imposition of certain remedies on their behalf, within applicable notice requirements.

It should be noted that failure of CMS or the State to act timely does not invalidate otherwise legitimate survey and enforcement determinations.

The ASPEN Enforcement Manager (AEM) is the data system used by CMS and all States for data entry and reporting on nursing home survey and enforcement activities.

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7001 - Definitions and Acronyms

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

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 in ownership, management, or director of nursing; or other indicators of specific concern. (42 CFR 488.301)

Abuse - means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain, or mental anguish. (42 CFR 488.301)

ACO - Automated Survey Processing Environment (ASPEN) Central Office.

Act - the Social Security Act

AEM - Automated Survey Processing Environment (ASPEN) Enforcement Manager.

ASPEN - Automated Survey Processing Environment.

CASPER - Certification and Survey Provider Enhanced Reporting.

Certification of Compliance means that the facility is in at least substantial compliance and is eligible to participate in Medicaid as a nursing facility, or in Medicare as a skilled nursing facility, or in both programs as a dually participating facility.

Certification of Noncompliance means that the facility is not in substantial compliance and is not eligible to participate in Medicaid as a nursing facility, or in Medicare as a skilled nursing facility, or in both programs as a dually participating facility.

CFR - Code of Federal Regulations.

CMP - civil money penalty.

CMPTS - Civil Money Penalty Tracking System.

CMS - Centers for Medicare & Medicaid Services (formerly HCFA).

Deficiency means a skilled nursing facility's or nursing facility's failure to meet a participation requirement specified in the Act or in 42 CFR Part 483 Subpart B. (42 CFR 488.301)

DoPNA or **DPNA -** denial of payment for new admissions.

DPoC - directed plan of correction.

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

Educational programs means programs that include any subject pertaining to the long-term care participation requirements, the survey process, or the enforcement process.

Enforcement action means the process of imposing one or more of the following remedies: termination of a provider agreement; denial of participation; denial of payment for new admissions; denial of payment for all residents; temporary manager; civil money penalty; State monitoring; directed plan of correction; directed in-service training; transfer of residents; closure of the facility and transfer of residents; or other CMS-approved alternative State remedies.

Expanded survey means an increase beyond the core tasks of a standard survey. A standard survey may be expanded at the surveying entity's discretion. When surveyors suspect substandard quality of care they should expand the survey to determine if substandard quality of care does exist.

Extended survey means a survey that evaluates additional participation requirements subsequent to finding substandard quality of care during a standard survey. (42 CFR 488.301)

Facility means a skilled nursing facility or nursing facility, or a distinct part of a skilled nursing facility or nursing facility, in accordance with 42 CFR 483.5. (42 CFR 488.301) (See §7008 for entities that qualify as skilled nursing facilities and nursing facilities.)

FSES – Fire Safety Evaluation System.

IDR – informal dispute resolution.

IJ – immediate jeopardy.

Immediate family means a 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. (42 CFR 488.301.)

Immediate jeopardy means a situation in which the facility'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. (42 CFR 488.301)

Independent IDR – Independent informal dispute resolution

LSC – Life Safety Code.

MAC means Medicare Area Contractor.

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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. (42 CFR 488.301)

NATCEP – Nurse Aide Training and Competency Evaluation Program.

Neglect means failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness. (42 CFR 488.301)

New admission, for purposes of a denial of payment remedy, 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. (See §7506 for examples of what does and does not constitute a new admission for purposes of the remedy.) (42 CFR 488.401)
NF – nursing facility.

Noncompliance means any deficiency that causes a facility not to be in substantial compliance. (42 CFR 488.301)

No Opportunity to Correct means the facility will have remedies imposed immediately after a determination of noncompliance has been made.

NOTC – no opportunity to correct.

Nurse aide means any individual providing nursing or nursing-related services to residents in accordance with 42 CFR 483.75(e)(1). (CFR 42 488.301)

Nursing facility means a Medicaid nursing facility. (42 CFR 488.301)

OBRA '87 - the Omnibus Budget Reconciliation Act of 1987.

Opportunity to Correct means the facility is allowed an opportunity to correct identified deficiencies before remedies are imposed.

OTC – opportunity to correct.

Partial extended survey means a survey that evaluates additional participation requirements and verifies the existence of substandard quality of care during an abbreviated standard survey. (42 CFR 488.301.)

Past Noncompliance means a deficiency citation at a specific survey data tag (F-tag or K-tag), that meets all of the following three criteria:

1) The facility was not in compliance with the specific regulatory requirement(s) (as referenced by the specific F-tag or K-tag) at the time the situation occurred;

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2) The noncompliance occurred after the exit date of the last standard (recertification) survey and before the survey (standard, complaint, or revisit) currently being conducted, and

3) There is sufficient evidence that the facility corrected the noncompliance and is in substantial compliance at the time of the current survey for the specific regulatory requirement(s), as referenced by the specific F-tag or K-tag.

Per day civil money penalty means a civil money penalty imposed for the number of days a facility is not in substantial compliance.

Per instance civil money penalty means a civil money penalty imposed for each instance of facility noncompliance.

PNC – past noncompliance.

PoC - plan of correction. (42 CFR 488.401)

QIES - Quality Improvement and Evaluation System.

Representative-for purposes of educational programs, means family members, legal guardians, friends, and ombudsmen assigned to the facility; for purposes of Independent IDR, means either the resident's legal representative or the individual filing a complaint involving or on behalf of a resident.

Self-Reported Noncompliance- Noncompliance that is reported by a facility to the State Survey Agency before it is identified by the State, CMS, or reported to the State or CMS by an entity other than the facility itself.

SFF – Special Focus Facility.

Skilled nursing facility means a Medicare-certified nursing facility that has a Medicare provider agreement. (42 CFR 488.301)

SMA – State Medicaid Agency.

SNF – skilled nursing facility.

SQC – substandard quality of care.

Standard survey means a periodic, resident-centered inspection that gathers information about the quality of service furnished in a facility to determine compliance with the requirements of participation. (42 CFR 488.301)

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State survey agency (SA) means the entity responsible for conducting most surveys to certify compliance with the Centers for Medicare and Medicaid Services' participation requirements.

State Medicaid Agency means the entity in the State responsible for administering the Medicaid program.

Substandard quality of care means one or more deficiencies related to participation requirements under 42 CFR 483.13, resident behavior and facility practices, 42 CFR 483.15, quality of life, or 42 CFR 483.25, quality of care, that constitute either immediate jeopardy to resident health or safety (level J, K, or L); a pattern of or widespread actual harm that is not immediate jeopardy (level H or I); or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm (level F). (42 CFR 488.301)

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. Substantial compliance constitutes compliance with participation requirements. (42 CFR 488.301)

7002 - Change in Certification Status for Medicaid Nursing Facilities
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

When Medicaid nursing facilities wish to participate as Medicare skilled nursing facilities, the State does not necessarily need to conduct a new survey. The State submits the information obtained during the most recent Medicaid survey and other documentation required for an initial certification of a skilled nursing facility to the regional office. The regional office will consider guidance in §2777D and §2778 of this manual in making a determination about whether a new survey should be conducted. (Also see §1819(g) and §1919(g) of the Act, and 42 CFR 488.308 for authority to conduct surveys anytime there is a question about compliance.)

7004 - Skilled Nursing Facility - Citations and Description
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7004.1 - Citations
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A skilled nursing facility is defined in §1819(a) of the Act and 42 CFR 488.301.

7004.2 - Description of Skilled Nursing Facility
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A skilled nursing facility is a facility which:

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- Is primarily engaged in providing to residents skilled nursing care and related services for residents who require medical or nursing care; or

- Is primarily engaged in providing to residents skilled rehabilitation services for the rehabilitation of injured, disabled, or sick persons **and is not primarily for the care and treatment of mental diseases**;

- Has in effect a transfer agreement (meeting the requirements of §1861(1) of the Act with one or more hospitals having agreements in effect under §1866 of the Act); and

- Meets the requirements for a skilled nursing facility described in subsections (b), (c), and (d) of §1819 of the Act.

A skilled nursing facility provides a level of care distinguishable both from the level of intensive care furnished by a general hospital and from the level of custodial or supportive care furnished by nursing homes primarily designed to provide daily services above room and board. This level of care is reflected in the participation requirements for skilled nursing facilities. While the requirements call for a wide range of specialized medical services and the employment by the facility of a variety of paramedical and skilled nursing personnel, the emphasis on restorative services is oriented toward providing services for residents who require and can benefit from skilled nursing and one or more types of skilled restorative services, e.g., physical or speech therapy.

7006 - Nursing Facility - Citations and Description

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7006.1 - Citations

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A nursing facility is defined in §1919(a) of the Act and 42 CFR 488.301.

7006.2 - Description of Nursing Facility

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A nursing facility is a facility that:

- Is primarily engaged in providing residents with skilled nursing care and related services for residents who require medical or nursing care; rehabilitation services for the rehabilitation of injured, disabled, or sick persons; or on a regular basis, health-related care and services to individuals who because of their mental or physical condition require care and services (above the level of room and board) which is available to them only through these facilities, **and is not primarily for the care and treatment of mental diseases;**

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- Has in effect a transfer agreement (meeting the requirements of §1861(l) of the Act) with one or more hospitals having agreements in effect under §1866 of the Act; and

- Meets the above requirements and subsections (b), (c), and (d) of §1919 of the Act.

7008 - Types of Facilities That May Qualify as Skilled Nursing Facilities and Nursing Facilities

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A Skilled Nursing Facility or Nursing Facility may be:

- An entire facility for skilled nursing facility or nursing facility care;

- A distinct part of a rehabilitation center;

- A distinct part of a hospital, such as a wing or a section;

- A distinct part of a skilled nursing facility or nursing facility (see §2762.B of this manual); or

- A religious nonmedical health care institution operated or listed and certified by the First Church of Christ, Scientist, Boston, Massachusetts.

An institution that is primarily for the care and treatment of mental diseases cannot be a skilled nursing facility or nursing facility.

7010 - Skilled Nursing Facilities Providing Outpatient Physical Therapy, Speech Pathology, or Occupational Services

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A skilled nursing facility may provide Part B outpatient physical therapy, speech therapy, or occupational therapy services either directly or under arrangement.

7012 - Reserved

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7014 - Special Waivers Applicable to Skilled Nursing Facilities and Nursing Facilities

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7014.1 - Waiver of Nurse Staffing Requirements

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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7014.1.1 - Waiver of 7-Day Registered Nurse (RN) Requirement for Skilled Nursing Facilities

(Rev. 97, Issued, 12-13-13, Effective: 12-13-13, Implementation: 12-13-13)

The requirements for long-term care facilities require that a skilled nursing facility provide 24-hour licensed nursing services, an RN for 8 consecutive hours a day, 7 days a week (more than 40 hours a week), and that there be an RN designated as Director of Nursing on a full time basis. The regional office, acting on behalf of the Secretary, may waive the requirement in the following circumstances:

- The facility is located in a rural area and the supply of skilled nursing facility services is not sufficient to meet area needs;

- The facility has one full-time registered nurse regularly on duty 40 hours a week. This may be the same individual or part-time individuals. This nurse may or may not be the Director of Nursing and may perform some Director of Nursing and some clinical duties if the facility so desires; and either;

- The facility has residents whose physicians have indicated, through admission notes or physicians' orders, that the residents do not need RN or physician care for a 48 hour period; or

- A physician or RN will spend the necessary time at the facility to provide the care that residents need during the days that an RN is not on duty. This requirement refers to clinical care of the residents who need skilled nursing services.

If a waiver is granted, the regional office, acting on behalf of the Secretary, must provide notice of the waiver to the State long-term care ombudsman and to the State protection and advocacy system for the mentally ill and intellectually disabled. The facility granted such a waiver must notify residents of the facility (or responsible guardians) and members of their immediate families of the waiver.

A waiver of the RN requirement is subject to annual renewal by the Secretary.

7014.1.2 - Waivers of Nurse Staffing Requirements in Nursing Facilities

(Rev. 97, Issued, 12-13-13, Effective: 12-13-13, Implementation: 12-13-13)

The requirements for long-term care facilities also require that nursing facilities provide 24-hour licensed nursing, provide an RN for 8 consecutive hours a day, 7 days a week, and that there be an RN designated as Director of Nursing on a full-time basis. The State may waive these requirements if the following conditions are met:

- The facility demonstrates to the satisfaction of the State that it has made diligent efforts to recruit the appropriate personnel and is unable to do so;

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- The State determines that a waiver will not endanger the health or safety of the residents in the facility; and

- The State finds that an RN or physician is obligated to respond immediately to phone calls from the facility for periods when licensed nursing services are not available.

The State may grant a waiver from the 24-hour licensed nursing requirement; the 8 consecutive hours a day, 7 days a week requirement, or both. A facility may be waived from the requirement to designate a Director of Nursing if it has been waived from either the requirement to provide 24-hour licensed nursing services or the 8 consecutive hours a day, 7 days a week requirement.

If a waiver is granted, the State must provide notice of the waiver to the State long-term care ombudsman and to the State protection and advocacy system for the mentally ill and intellectually disabled. The facility granted the waiver must notify residents of the facility (or responsible guardians) and members of their immediate families of the waiver.

7014.1.3 - Waivers of Nurse Staffing Requirements for Dually Participating Facilities

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

If a facility dually participates in both the Medicare and Medicaid programs, it is subject to the waiver criteria for skilled nursing facilities. Therefore, a skilled nursing facility/nursing facility may only have the 8 consecutive hours a day, 7 days a week requirement waived. In this case, the waiver is granted by the regional office.

7014.1.4 - Initial Requests for Nurse Waiver

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The first time that a nursing facility applies for a waiver, the State conducts an onsite survey before it may grant a waiver. The purpose of the survey is to establish that the waiver will not endanger the health and safety of residents. A full survey is not required. However, the survey must be of sufficient scope to ensure that the granting of the waiver will not endanger the health and safety of the residents.

While the acuity of illness of skilled nursing facility level residents makes an onsite visit desirable to confirm that the facility actually meets the requirements for a nurse staffing waiver, it is not required. The waiver determination may be made based on documentation of these requirements submitted by the skilled nursing facility.

7014.2 - Waiver of Life Safety Code

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

(See §2472 and §7410.)

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7014.3 - Variations of Patient Room Size and/or Beds Per Room
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Resident rooms may have no more than four beds per room and must afford a minimum of 80 square feet per bed in multi-patient rooms. Single rooms must measure at least 100 square feet. 42 CFR 483.70(d)(3) states that variations may be permitted in individual cases where the facility demonstrates in writing that the variations are in accordance with the special needs of the residents and will not adversely affect their health and safety. A variation is construed to mean a waiver. The regional office has jurisdiction to approve such waivers or variances. The State has jurisdiction to approve them in Medicaid-only cases.

7014.4 - Documentation to Support Waivers or Variations
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The State should place an asterisk to the left of the data tag item on the "Statement of Deficiencies and Plan of Correction," Form CMS-2567, and include the required documentation to support the recommendation with the certification packet. The State enters a "W" in the plan of correction field in the certification tab in ASPEN for the waived requirement.

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Survey Process

7200 -Emphasis, Components, and Applicability
(Rev. 97, Issued, 12-13-13, Effective: 12-13-13, Implementation: 12-13-13)

Skilled nursing facilities and nursing facilities must be in compliance with the requirements in 42 CFR Part 483, Subpart B to receive payment under Medicare or Medicaid. To certify a skilled nursing facility or nursing facility, complete at least:

- A life safety code survey; and
- A standard survey (Forms CMS-670, 671, 672, 677, 801 through 807, and Exhibits 85, 86, 88 to 95).

Follow the procedures in Appendix P of this manual for conducting all surveys of skilled nursing facilities and nursing facilities, whether freestanding, distinct parts, or dually participating. Do not use these procedures for surveys of intermediate care facilities for individuals with intellectual disabilities (ICFs/IID), swing-bed hospitals, or skilled nursing sections of hospitals that are not separately certified as skilled nursing facility distinct parts.

7201 - Survey Team Size and Composition - Length of Survey
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7201.1 - Survey Team Size
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Survey team size will vary, depending primarily on the size of the facility being surveyed. The State (or, for Federal teams, the regional office) determines how many members will be on the team. Survey team size is normally based upon the following factors:

- The bed size of the facility to be surveyed;
- Whether the facility has a historical pattern of serious deficiencies or complaints;
- Whether the facility has special care units; and
- Whether new surveyors are to accompany a team as part of their training.

7201.2 - Team Composition
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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The State (or, for Federal teams, the regional office) decides what the composition of the survey team will be, as long as certain statutory and regulatory requirements are met. Sections 1819(g)(2)(E) and 1919(g)(2)(E) of the Act and 42 CFR 488.314 require that:

- Skilled nursing facility and nursing facility standard surveys be conducted by a multidisciplinary team of professionals, at least one of whom must be a registered nurse;

- Surveyors be free of conflicts of interest (see §7202); and

- Surveyors successfully complete a training and testing program in survey and certification techniques that has been approved by the Secretary. In other words, surveyors must successfully complete the CMS-approved training and pass the Surveyor Minimum Qualifications Test. (See §4009.1 of this manual for additional information concerning Surveyor Minimum Qualifications Test requirements.)

Within these parameters, the States (or, for Federal teams, the regional offices) are free to choose the composition of each team, and it is the State that determines what constitutes a professional. However, CMS offers the following guidance:

- The State or regional office should consider using more than one registered nurse on teams that will be surveying a facility known to have a large proportion of residents with complex nursing or restorative needs.

- Because of the strong emphasis on resident rights, the psychosocial model of care, and rehabilitative aspects of care in the regulations and the survey process, the team should include social workers, registered dietitians, pharmacists, activity professionals, or rehabilitation specialists, when possible.

- It is important, to the extent practical, to utilize team members with clinical expertise and knowledge of current best practices that correspond to the resident population's assessed needs, the services rendered in the facility to be surveyed, and the type of facility to be surveyed. For example, if the facility has a known problem in dietary areas, there should be an effort to include a dietitian on the team; if a known problem in quality of life, a social worker. If the facility specializes in the care of residents with post trauma head injuries and strokes, a physical therapist may be included on the team.

- In addition to members of individual disciplines routinely included as members of the survey team, consideration should be given to the use of individuals in specialized disciplines who may not routinely participate as team members. These individuals would be available to assist the survey team when specific problems or questions arise. Consultants in these suggested disciplines include, but are not limited to, physicians, physician assistants, nurse practitioners,

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physical, speech, and occupational therapists, dieticians, sanitarians, engineers, licensed practical nurses, social workers, pharmacists, and gerontologists.

- In order to comply with the requirement that "No individual shall serve as a member of a … team (surveying a SNF or NF) unless the individual has successfully completed (the CMS-approved) training and testing program," surveyors in training, i.e., those who have not successfully completed the required training, must be accompanied on-site by a surveyor who has successfully completed the required training and testing. While it is desirable that all survey team members be fully qualified, CMS recognizes that trainees must be given opportunities to perform survey functions so that they can achieve "fully qualified" status. Participation in actual surveys is a valuable and integral part of a training program. In fact, in the orientation program designed for newly employed surveyors, CMS recommends that 3 weeks be spent in the field as part of the training.

7201.3 - Length of Survey
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The length of a standard survey in terms of person hours is expected to vary, based on the size and layout of the facility and the number and complexity of concerns that need to be investigated onsite.

7202 - Conflicts of Interest for Federal and State Employees
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7202.1 - Introduction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Conflicts of interest may arise within the Medicare/Medicaid certification when public employees' duties give them the potential for private gain (monetary or otherwise) or the opportunity to secure unfair advantages for outside associates. The same should be required of State employees whose positions may produce possible conflicts of interest. This includes all State surveyors and their supervisors. There are a number of Federal and State laws setting forth criminal penalties for abuses of privileged information, abuses of influence, and other abuses of public trust.

Federal employees are required to make a declaration of any outside interests and to update it whenever such interests are acquired. The same should be required of State employees whose positions may produce possible conflicts of interest. Both CMS and the State are responsible for evaluating the need for preventive measures to protect the integrity of the certification program. When certification work is performed by agencies other than CMS or the State, the State administrators and the subagency administrators have a shared responsibility for this surveillance.

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In the case of States, it is not necessary to inform CMS of all potential conflict situations. However, if an overt abuse requires corrective action, the regional office must be informed as described in §7202.

7202.2 - Conflicts of Interest
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7202.2.1 - Prima Facie Conflicts of Interest
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Under 42 CFR 488.314(a)(4), any of the following circumstances disqualifies a surveyor for surveying a particular skilled nursing facility or nursing facility:

a. The surveyor currently works, or, within the past 2 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;

b. The surveyor has any financial interest or any ownership interest in the facility. (Indirect ownership, such as through a broad based mutual fund, does not constitute financial or ownership interest for purposes of this restriction.);

c. The surveyor has an immediate family member who has a relationship with a facility described in §7202. An immediate family member is defined in 42 CFR 488.301; or

d. The surveyor has an immediate family member who is a resident in the facility.

7202.2.2 - Examples of Potential Conflicts of Interest
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

CMS and the States must consider all relevant circumstances that may exist beyond the benchmarks given in §7202 to ensure that the integrity of the survey process is preserved. For example, a surveyor may not have worked for the facility to be surveyed for more than 2 years, but may have left the facility under unpleasant circumstances, or, may not currently have an immediate family member who resides there, but may have recently had one residing there who the surveyor considers to have received inadequate care.

The following are typical of situations that may raise a question of possible conflicts of interest for Federal or State employees of an agency representing the Medicare/Medicaid survey and certification program. However, they do not necessarily constitute conflicts of interest.

a. Participation in ownership of a health facility located within the employing State;

b. Service as a director or trustee of a health facility;

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c. Service on a utilization review committee;

d. Private acceptance of fees or payments from a health facility or group of health facilities or association of health facility officers for personal appearances, personal services, consultant services, contract services, referral services, or for furnishing supplies to a health facility;

e. Participation in a news service disseminating trade information to a segment of the health industry; and

f. Having members of one's immediate family engaged in any of the above activities.

7202.3 - Report and Investigation of Improper Acts

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Any acts of employees in violation of Federal or State laws or regulations regarding conflicts of interest should be handled in accordance with applicable Federal or State procedures. In the case of State employees, conflicts of interest violations must be reported to the regional office, and the regional office must be kept advised of the corrective actions. States should ask for assistance or advice in the case of any impropriety involving a conflict of interest that cannot be handled immediately under an applicable State procedure. The regional office of the Inspector General, along with the CMS regional office, will then work in close cooperation with the responsible State officials until the matter is resolved.

7203 - Survey Protocol

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7203.1 - Introduction

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

This protocol is established pursuant to §1819(g)(2)(C) and §1919(g)(2)(C) of the Act to provide guidance to surveyors conducting surveys of long-term care facilities participating in the Medicare and Medicaid programs. The protocol consists of survey procedures, worksheets, and interpretive guidelines. It serves to explain and clarify the requirements for long-term care facilities and all surveyors measuring facility compliance with Federal requirements are required to use it. The purpose of this protocol is to provide suggestions, interpretations, check lists, and other tools for use both in preparation for the survey and when performing the survey onsite.

The interpretive guidelines merely define or explain the relevant statutes and regulations and do not impose any additional costs or place other burdens on any health care facility. (See §2712 of this manual.)

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7203.2 - Initial Certification Surveys
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

(See also §2005 and §7300 of this manual.)

All initial surveys must verify substantial compliance with the regulatory requirements contained in 42 CFR 483.5 through 42 CFR 483.75. Follow Appendix P, Survey Protocol for Long Term Care Facilities.

If distinct part status is at issue, determine whether the facility meets the criteria for certification as a distinct part. (See §2762.B of this manual.)

7203.3 - Resurvey of Participating Facilities
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Follow the procedures specified in Appendix P of this manual for standard and extended surveys.

7203.4 - Post Survey Revisit (Follow-Up)
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

When the State has cited deficiencies during the course of a survey, the survey agency may, as necessary, conduct a post survey revisit to determine if the facility now meets the requirements for participation. (See also §7317.)

7203.5 - Abbreviated Standard Survey
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

(See also Appendix P, VII of this manual.)

This survey focuses on particular tasks that relate, for example, to complaints received, or a change of ownership, management, or Director of Nursing. It does not cover all the aspects covered in the standard survey, but rather concentrates on a particular area of concern(s). The survey team (or surveyor) may investigate any area of concern and make a compliance decision regarding any regulatory requirement, whether or not it is related to the original purpose of the survey complaint.

1 - Complaint Investigations

If the State's review of a complaint allegation(s) concludes that one or more violations of requirements may have occurred, and only a survey can determine whether a deficiency(ies) exist, conduct a standard or abbreviated standard survey. (See Chapter 5 and Appendix P of this manual.)

2 - Substantial Changes in a Facility's Organization and Management

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If a facility notifies you of a change in organization or management, review the change to ensure compliance with the regulations. Request copies of the appropriate documents, e.g., written policies and procedures, personnel qualifications and agreements, etc., if they were not submitted. If changes in a facility's organization and management are significant and raise questions of its continued substantial compliance, determine, through a survey, whether deficiencies have resulted. Collect information about changes in the facility's organization and management on the "Medicare and other Federal Care Program General Enrollment," Form CMS-855.

7203.6 - Extended Survey/Partial Extended Survey

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

If, as a result of its findings during the standard survey or abbreviated standard survey, the team suspects substandard quality of care as defined in 42 CFR 488.301, it expands the survey. If the expanded survey verifies substandard quality of care, the State or regional office conducts an extended survey or a partial extended survey in accordance with procedures in Appendix P of this manual. (See §7210.2 and Appendix P of this manual.)

7203.7 -State Monitoring Visits

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

"State monitoring visits" are visits by the State to oversee a provider's compliance status and are not done as part of the State monitoring remedy. Some regional offices and States call these State monitoring visits "monitoring visits". For example, these visits may occur:

- During bankruptcy, in those cases in which CMS has authorized such visits.
- After a change of ownership, as authorized by the CMS regional office;
- During or shortly after removal of immediate jeopardy when the purpose of the visit is to ensure the welfare of the residents by providing an oversight presence, rather than to perform a structured follow-up visit; and
- In other circumstances, as authorized by the CMS regional office.

When a State monitoring visit results in a Federal deficiency, the State will identify the survey in ASPEN as "complaint" and create an intake and survey record in ACTS. (See Chapter 5 of this manual for additional instructions.)

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7205 - Survey Frequency: 15-Month Survey Interval and 12-Month State-wide Average

(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

This section does not apply to the date of survey for remedy imposition and termination timeframes. *The survey and certification provisions set forth in §§1819(g)(2)(A)(iii) and 1919(g)(2)(A)(iii) of the Act and in 42 CFR §488.308 require that each skilled nursing facility and nursing facility be subject to a standard survey no later than 15 months after the last day of the previous standard survey and that the statewide average interval between standard surveys of skilled nursing facilities and nursing facilities not exceed 12 months. This date is entered in L34 on the form CMS-1539.*

7205.1 - *Last Day of Survey*

(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

The last day of survey is the last day of onsite observations during a survey, regardless of whether the exit conference was performed on that same day.

For purposes of computing three months or six months from a finding of noncompliance when the health and life safety code portions of the survey are on the same enforcement track, use the last day of onsite observations of the standard health survey on which the noncompliance was identified, regardless of which survey preceded the other. Even when the life safety code was the second of the two surveys to be performed on the same enforcement track, and it was the survey that found the noncompliance, the clock still starts on the last day of the standard health survey and will always be used to begin counting the number of noncompliance days. For purposes of the first notice of noncompliance, use the last day of the survey that found the cited noncompliance.

When two separate enforcement tracks are being used (one track for the health portion and one track for the life safety code portion of the standard survey), the mandatory denial of payment for new admissions and termination time frames would be three months and six months, respectively, for each separate portion.

7205.1.1- Setting the Mandatory 3-Month and 6-Month Sanction Time Frames

(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

These dates should be set based on full months rather than on a number of days. With few exceptions, these dates should be set by simply going to the same numerical date in the 3rd or 6th month following the survey date. For example, if a survey ended on January 15, the 3-month effective date for the mandatory denial of payment for new admissions remedy is April 15, and the 6-month mandatory termination date is July 15.

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Exceptions to this rule involve those cases for which a 3-month or 6-month numerical date is not on the calendar. In these cases, move ahead a day or two to the beginning of the next month. For example, if a survey ended on January 31, the 3-month effective date for the mandatory denial of payment for new admissions remedy would be April 31. However, since there is no April 31, the 3-month effective date is May 1 and the 6-month mandatory termination date is July 31.

7205.2 - Scheduling and Conducting Surveys
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The State must complete a standard survey of each skilled nursing facility and nursing facility not later than 15 months after the previous standard survey.

Facilities with excellent histories of compliance may be surveyed less frequently to determine compliance, but no less frequently than every 15 months and the State-wide standard survey average must not exceed 12 months.

1 - Changes That May Prompt Survey

If the State is concerned that a change of ownership, management firm, administrator, or Director of Nursing may have caused a decline in the quality of care or services furnished by a skilled nursing facility or nursing facility, it may conduct a standard or abbreviated standard survey within 60 days of the change.

Facilities with poor histories of compliance may be surveyed more frequently to ensure that residents are receiving quality care in a safe environment.

2 - Frequency

The State may conduct surveys as frequently as necessary to determine if a facility complies with the participation requirements as well as to determine if the facility has corrected any previously cited deficiencies. There is no required minimum time which must elapse between surveys.

3 - Conducting Complaint Surveys

Refer to complaint investigation procedures in Chapter 5 and Appendix P of this manual.

7205.3 - Determining Standard Survey Interval for Each Facility
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The standard survey interval for each facility (which may not exceed 15 months) is calculated as follows:

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- The number of days between the completion of the current and last standard survey is divided by 31 to determine the number of months between standard surveys for each provider;

- The last day of the entire health and life safety code survey is the date used to calculate the interval.

- If an extended survey is conducted as a result of the health portion of a standard survey, the last day of the health portion of the standard survey is used to calculate the survey frequency requirements, if the health portion occurs after the life safety code portion. The date of the extended survey is **not** used in calculating the survey interval or state-wide average requirements;

- Abbreviated standard surveys are not counted in the calculation. An abbreviated standard survey is a survey other than a standard survey to gather information on facility compliance with the requirements for participation primarily through resident-centered techniques. 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. (See 42 CFR 488.301.);

- When an abbreviated standard survey is changed to a standard survey, the standard survey is counted in the calculation of the standard survey interval using the last date of the entire health and life safety code survey as the survey date; and

- Revisits are not counted in the calculation of the standard survey interval.

The Certification and Survey Provider Enhanced Reporting system (CASPER) is used to identify facilities that have not received a standard survey within 15 months.

Survey information for the fiscal year must be entered by November 15 of each year in order for CMS-Central Office to calculate the state-wide average.

7205.4 - Assessing Compliance with Survey Frequency Requirements
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The state-wide average interval for each State is available through the Certification and Survey Provider Enhanced Reporting system (CASPER).

The regional office has ongoing responsibility to monitor a State's compliance with the survey frequency requirements.

7205.5 - Actions to Ensure Compliance with Standard Survey Interval
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

No action is necessary if the standard survey interval for a provider is not greater than 15 months and the state-wide average is not greater than 12 months.

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If the standard survey interval for a provider is greater than 15 months and/or the state-wide average interval is greater than 12 months, the regional office will notify the State, determine if a problem exists, and take appropriate action. This action is specified in Chapter 8 of this manual.

7207 - Unannounced Surveys

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

(Also see §2700 and Chapter 5 of this manual.)

7207.1 - Introduction

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

This instruction implements §§1819(g)(2)(A) and 1919(g)(2)(A) of the Act, and 42 CFR 488.307. It also reiterates CMS policy that all nursing home surveys are to be unannounced, including standard surveys, complaint surveys and onsite revisit surveys.

7207.2 - All Surveys Must Be Unannounced

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The State has the responsibility for keeping surveys unannounced and their timing unpredictable. This gives the State agency doing the surveying greater ability to obtain valid information because it increases the probability that the surveys will observe conditions and care practices that are typically present. While the Act and implementing regulations referenced in §7207.1 require that standard surveys be unannounced, it is CMS' intention and expectation to not announce **any** type of nursing home survey such as abbreviated, onsite revisit, or complaint surveys. Therefore, if CMS conducts standard surveys or validation surveys, the regional office must follow the same procedures as required of the States to not announce surveys. The only exceptions to this policy would be if, for instance, some additional documentation was required and the most efficient way to obtain it would be through making an appointment and revisiting the facility or asking that it be provided via electronic means. The State should notify the State ombudsman's office according to the protocol developed between the State and the State ombudsman's office. This protocol must ensure strict confidentiality concerning the survey dates. (See Appendix P of this manual.)

To increase the opportunity for unpredictability in standard surveys, the State survey agencies and Federal surveyors should incorporate the following procedures when planning facility surveying:

7207.2.1 - Nonsequential Order

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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Facilities, within a given geographical area, should not be surveyed in the same order as was conducted in the previous standard survey;

7207.2.2 - Variance in Timing (Time of Day, Day of Week, Time of Month)

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

(See also Appendix P and Appendix PP of this manual)

When facilities are surveyed, the time of day, day of the week, and time of month should be varied from the time of the previous standard survey. The time of day that surveyors begin should extend beyond the business hours of 8:00 a.m. to 6:00 p.m. In addition, the day of the week should vary to include weekend days, Saturday, and Sunday. **At least 10 percent** of standard health surveys must begin either on the weekend or in the evening/early morning hours before 8:00 a.m. or after 6:00 p.m. Likewise, the month in which a survey begins should not, if possible, coincide with the month in which the previous standard survey was conducted. For example, unannounced standard health surveys could begin at:

- 7:30 p.m. on a Monday evening in early July (previous standard survey occurred early June);
- 6:00 a.m. on a Wednesday morning and survey continues through the weekend until it is completed; or
- 11:00 a.m. on a Saturday morning.

In addition, standard health surveys that are conducted to satisfy the 10 percent requirement must be conducted on **consecutive days**. Consecutive days mean calendar days and are to include Saturdays, Sundays, and Holidays. For example, beginning a survey at 8:00 a.m. on a Saturday morning must be continued until its completion through the weekend and into the following week. Since survey time on holidays is reported as weekend time, surveys initiated on holidays can be counted toward the 10 percent off-hour survey requirement. "Holidays" are defined as those days that are recognized by the State as a State or Federal holiday.

Since the off-hour survey requirement is to reduce the predictability of when a survey will occur, States must begin some off-hour surveys in each of these targeted time frames, i.e., early morning, evening, and holidays/weekend.

NOTE: If there are situations that arise and the State determines that a standard survey cannot be conducted on consecutive days, the State must contact the regional office and obtain approval prior to the commencement of the standard survey or within reasonable time after the initial start day.

7207.3 - CMS Review of State Scheduling Procedures

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(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The regional office reviews annually each of its State's procedures for assuring that nursing home surveys are not announced through the methods by which they are scheduled or conducted.

7207.4 - Imposition of Civil Money Penalties

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

If any individual has, in any way, given prior notification to a facility of the date of a standard survey, the State or CMS is to contact the regional Office of the Inspector General and report the name of the individual and what has occurred. The Office of the Inspector General will further investigate and make a determination as to whether or not a Federal civil money penalty will be imposed. A civil money penalty of up to $2,000 may be imposed under §§1819(g)(2)(A)(I) and 1919(g)(2)(A)(I) of the Act. The provisions of §1128A of the Act apply to civil money penalties. The imposition of a civil money penalty applies only when a **standard** survey is announced. See 42 CFR Part 1005 for policy developed by the Office of the Inspector General regarding administrative appeals of Federal civil money penalties.

7207.5 - Withdrawal of Nurse Aide Training and Competency Evaluation Program or Competency Evaluation Program When Entity Providing the Program Refuses to Permit Unannounced State Visit

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Regulations at 42 CFR 483.151(e)(3) require the State to withdraw approval of a nurse aide training and competency evaluation program or a nurse aide competency evaluation program when the entity providing the program refuses to permit an unannounced visit by the State.

7210 - Substandard Quality of Care and Extended and Partial Extended Surveys

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

(See also Appendix P, III of this manual.)

7210.1 - Introduction

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

This section is established pursuant to §§1819(g)(2)(B) and 1919(g)(2)(B) of the Act and 42 CFR 488.310 to provide guidance to surveyors in conducting an extended or partial extended survey. The only time an extended or partial extended survey is conducted is when substandard quality of care is identified. This section also explains notice requirements as required in §1819(g)(5)(C) and §1919(g)(5)(C) of the Act and 42 CFR 488.325, disclosure of results of surveys and activities, when substandard

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quality of care is found. This section discusses the consequences to a nurse aide training and competency evaluation program and competency evaluation program when an extended or partial extended survey is conducted. (See §7001 for the definition of substandard quality of care.)

7210.2 - Expansion of the Survey

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

When the State or regional office conducts a standard survey or abbreviated standard survey and suspects substandard quality of care but does not have sufficient information to confirm or refute the substandard quality of care, the survey may be expanded. (See Appendix P and §7210 of this manual.) This expansion of the standard or abbreviated standard survey does not necessarily constitute an extended or partial extended survey.

If the expanded survey does not verify substandard quality of care but finds noncompliance, the State or regional office prepares Form CMS-2567 and follows the procedures required in §7305.

If the expanded survey verifies substandard quality of care, the State or regional office conducts an extended survey or a partial extended survey in accordance with procedures in Appendix P of this manual.

7210.5 - Time frames

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

An extended or partial extended survey should be conducted immediately after the standard or abbreviated standard survey, but, if delayed, not later than 14 calendar days after completion of a standard survey or abbreviated standard survey which found that the facility had furnished substandard quality of care.

7210.6 - Notices

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

When substandard quality of care is identified as a result of a standard or abbreviated standard survey, an extended or partial extended survey is conducted. In addition to the notices required of all surveys in §7300, the State must issue notices to the following:

- The State board responsible for the licensing of the nursing home administrator; and

- The attending physician of each resident who was identified as having been subject to substandard quality of care. (See §7320.)

According to 42 CFR 488.325, disclosure of results of surveys and activities, the facility is responsible for submitting to the State the names of the attending physician for each

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resident who was identified as having been subject to substandard quality of care, regardless of whether payment is made through Medicare, Medicaid, or private pay. (See §7905.)

7210.7 - Nurse Aide Training and Competency Evaluation Program and Competency Evaluation Program

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

As required in §1819(f)(2)(B)(iii)(I)(b) and §1919(f)(2)(B)(iii)(I)(b) of the Act, the nurse aide training and competency evaluation program and competency evaluation program must be denied or withdrawn when an extended or partial extended survey is conducted. (Also see §7809.)

7212 - Informal Dispute Resolution

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

7212.1 - Introduction

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Regulations at 42 CFR 488.331 require that CMS and the States, as appropriate, offer skilled nursing facilities, nursing facilities, and dually participating facilities an informal opportunity to dispute cited deficiencies upon the facility's receipt of the official Form CMS-2567. A State does not need to create any new or additional processes if its existing process meets the requirements described in §7212.3. The informal dispute resolution process, as established by the State or CMS regional office, must be in writing so that it is available for review upon request.

7212.2 - Purpose – To Provide Facilities an Opportunity To Informally Dispute Cited Deficiencies After a Survey

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

7212.3 - Mandatory Elements of Informal Dispute Resolution

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

The following elements must be included in each informal dispute resolution process offered:

1. Upon their receipt of the official Form CMS-2567, facilities must be offered an informal opportunity, to dispute deficiencies with the entity that conducted the survey.

2. Facilities may not use the informal dispute resolution process to delay the formal imposition of remedies or to challenge any other aspect of the survey process, including the:

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- Scope and severity assessments of deficiencies with the exception of scope and severity assessments that constitute substandard quality of care or immediate jeopardy;

- Remedy(ies) imposed by the enforcing agency;

- Alleged failure of the survey team to comply with a requirement of the survey process;

- Alleged inconsistency of the survey team in citing deficiencies among facilities;

- Alleged inadequacy or inaccuracy of the informal dispute resolution process.

3. Facilities must be notified of the availability of informal dispute resolution in the letter transmitting the official Form CMS-2567. (See Exhibit 139 in this manual for transmission of Form CMS-2567.) Notification of this process should inform the facility:

    - That it may request the opportunity for informal dispute resolution, and that if it requests the opportunity, the request must be submitted in writing along with an explanation of the specific deficiencies that are being disputed. The request must be made within the same 10 calendar day period the facility has for submitting an acceptable plan of correction to the surveying entity;

    - Of the name, address, and telephone number of the person the facility must contact to request informal dispute resolution;

    - How informal dispute resolution may be accomplished in that State, e.g., by telephone, in writing, or in a face-to-face meeting.

    - Of the name and/or the position title of the person who will be conducting the informal dispute resolution, if known.

States should be aware that CMS holds them accountable for the legitimacy of the informal dispute resolution process including the accuracy and reliability of conclusions that are drawn with respect to survey findings. This means that while States may have the option to involve outside persons or entities they believe to be qualified to participate in this process, it is the States, not outside individuals or entities that are responsible for informal dispute resolution decisions. So, when an outside entity conducts the informal dispute resolution process, the results may serve only as a recommendation of noncompliance or compliance to the State. The State will then make the final informal dispute resolution decision and notify the facility of that decision. CMS will look to the

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States to assure the viability of these decision- making processes, and holds States accountable for them.

Since CMS has ultimate oversight responsibility relative to a State's performance, it may be appropriate for CMS to examine specific informal dispute resolution decisions or the overall informal dispute resolution process to determine whether a State is arriving at a correct result. For dually participating or Medicare-only facilities, informal dispute findings are in the manner of recommendations to CMS and, if CMS has reason to disagree with those findings, it may reject the conclusions from informal dispute resolution and make its own binding determinations of noncompliance.

4. Failure to complete informal dispute resolution timely will not delay the effective date of any enforcement action against the facility.

5. When a facility is unsuccessful during the process at demonstrating that a deficiency should not have been cited, the surveying entity must notify the facility in writing that it was unsuccessful.

6. When a facility is successful during the informal dispute resolution process at demonstrating that a deficiency should not have been cited:

    - On the CMS Form-2567, annotate deficiency (ies) citations as "deleted" and/or change deficiency (ies) citation findings, as recommended. A State survey agency manager or supervisor will sign and date the revised CMS Form-2567.

    - Adjust the scope and severity assessment for deficiencies, if warranted and in accordance with CMS policy.

    - The State survey agency will promptly recommend to CMS that any enforcement action(s) imposed solely because of deleted or altered deficiency citations be reviewed, changed or rescinded.

The facility has the option to request a clean (new) copy of the Form CMS-2567. However, the clean copy will be the releasable copy only when a clean (new) plan of correction is both provided and signed by the facility. The original Form CMS-2567 is disclosable when a clean plan of correction is not submitted and signed by the facility. Any Form CMS-2567 and/or plan of correction that is revised or changed as a result of informal dispute resolution must be disclosed to the ombudsman in accordance with §7904.

Deficiencies pending informal dispute resolution should be entered into the Automated Survey Processing Environment system (ASPEN) and the ASPEN Informal Dispute Resolution (IDR) Manager within ten (10) calendar days of receiving the request for an informal dispute resolution. This information however will not be uploaded to the Certification and Survey Provider Enhanced Reporting system (CASPER) for posting to

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the Nursing Home Compare website until informal dispute resolution has been completed.

7. A facility may request informal dispute resolution for each survey that cites deficiencies. However, if informal dispute resolution is requested for deficiencies cited at a subsequent survey, a facility may not challenge the survey findings of a previous survey for which the facility either received informal dispute resolution or had an opportunity for it. The following table indicates when informal dispute resolution may be requested based on the results of a revisit or as a result of the previous informal dispute resolution outcome.

Situation	Eligibility for Informal Dispute Resolution
Continuation of same deficiency at revisit	Yes
New deficiency (i.e., new or changed facts, new tag) at revisit or as a result of an informal dispute resolution	Yes
New instance of deficiency (i.e., new facts, same tag) at revisit or as a result of an informal dispute resolution.	Yes
Different tag but same facts at revisit or as a result of an informal dispute resolution	No, unless the new tag constitutes substandard quality of care

8. Written description of the surveying entity's informal dispute resolution process must be made available to a facility upon the facility's request.

9. States are encouraged to include in the informal dispute resolution process at least one person as part of the decision making process who was not directly involved in the survey. This may include, but is not limited to, another surveyor, ombudsman, a member of another survey team, etc.

7212.4 - Additional Elements for Federal Informal Dispute Resolution

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

In addition to those elements cited in §7212.3, CMS has adopted the following elements to be incorporated in all cases involving deficiencies cited as a result of Federal surveys. They are designed to clarify and expedite the resolution process. States are free to incorporate these elements into their procedures.

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1. Notice to the facility will indicate that the informal dispute resolution, including any face-to-face meetings, constitutes an informal administrative process that in no way is to be construed as a formal evidentiary hearing.

2. Notice to the facility will indicate that counsel may accompany the facility. If the facility chooses to be accompanied by counsel, then it must indicate that in its request for informal dispute resolution, so that CMS may also have counsel present.

3. CMS will verbally advise the facility of CMS's decision relative to the informal dispute, with written confirmation to follow.

7213 - Independent Informal Dispute Resolution (Independent IDR)
(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

All regulatory references are in 42 CFR unless otherwise stated.

7213.1 - Introduction
(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

Under sections 1819(h)(2)(B)(ii)(IV) and 1919(h)(2)(B)(ii)(IV) of the Act and regulations at 42 CFR 488.331 and 488.431 SNFs, NFs and SNF/NFs are provided the opportunity to request and participate in an Independent IDR if CMS imposes civil money penalties against the facility and these penalties are subject to being collected and placed in an escrow account pending a final administrative decision.

NOTE: All CMP funds are subject to escrow. If the nursing home elects not to request an Independent IDR or to appeal, then after any IDR (if requested), CMP amount becomes due and payable in accordance with the process in §7528.3.

A State survey agency does not need to create any new or additional processes for Independent IDR if its existing process meets the requirements at 42 CFR 488.331 and 488.431 and described throughout §7213.

7213.2 – Purpose
(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

To provide facilities, under certain circumstances, an additional opportunity to informally dispute cited deficiencies through a process that is independent from the State survey agency or, in the case of Federal surveys, the CMS Regional Office.

7213.3 - Independent Informal Dispute Resolution Requirements
(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

The requirements and specific core elements that must be included in an acceptable Independent IDR process are specified in the regulations at 42 CFR 488.331 and 488.431.

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CMS retains ultimate authority for the survey findings and imposition of civil money penalties. However, an opportunity for an Independent IDR is provided within 30 calendar days of the notice of imposition of a civil money penalty that is subject to being collected and placed in escrow. An Independent IDR will –

1. Be completed within 60 calendar days of a facility's request, if an Independent IDR is requested timely by the facility;

   NOTE: Independent IDR is completed when a final decision from the Independent IDR process has been made, a written record has been generated and the State survey agency has sent written notice of this decision to the facility. The Independent IDR process is also considered to be completed if a facility does not timely request or chooses not to participate in the Independent IDR process.

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;

   NOTE: "Involved resident" is a resident who was the subject of a complaint or who filed a complaint that led to a deficiency finding that is the subject of Independent IDR. "Representative" means either the resident's legal representative or an individual filing a complaint involving or on behalf of a resident.

4. Be approved by CMS and conducted by the State, 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 IDR process is not used, and which has no conflict of interest, such as:

   a. A component of an umbrella State agency provided that the component is organizationally separate from the State survey agency, or

   b. An independent entity with a specific understanding of Medicare and Medicaid program requirements selected by the State and approved by CMS, and,

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.

The Independent IDR process, as established by the State survey agency, must be approved by CMS. If an Independent IDR entity or person provides services in multiple

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States and/or CMS Regions, each State and its CMS Regional Office (RO) must approve the Independent IDR entity's or person's process and procedures for the State's or RO's jurisdiction. In order to ensure compliance of the Independent IDR process with Federal statute and regulations, each State survey agency will submit its written process and procedures, including any subsequent changes, to the applicable CMS RO for review and prior approval. The Independent IDR process must be in writing and available for review upon request.

7213.4 - Applicability of the Independent Informal Dispute Resolution Process

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

The Independent IDR process must be offered to a facility when a civil money penalty is imposed and that penalty is subject to being collected and placed in escrow under 42 CFR 488.431(b). Beginning on January 1, 2012, CMS may collect and place imposed civil money penalties in an escrow account on whichever of the following occurs first:

- The date on which the Independent IDR process is completed, or
- The date which is 90 calendar days after the date of the notice of imposition of the civil money penalty.

The Independent IDR is conducted only upon the facility's timely request. The facility must request an Independent IDR within 10 calendar days of receipt of the offer. The facility's request will be considered timely if the request is dated within 10 calendar days of the receipt of the offer, and, in the case of the request being mailed, the postmark verifies that it was mailed within that same 10 day time period.

1. A facility may request an Independent IDR for each survey that cites deficiencies for which a civil money penalty has been imposed that is subject to collection and placement in an escrow account. However, when a facility requests an Independent IDR for a survey, the facility cannot raise questions or issues regarding a previous survey, and consideration of such previous survey results is beyond the scope of the independent IDR. The following table indicates when independent informal dispute resolution may be requested based on the results of a revisit or as a result of the previous independent informal dispute resolution outcome.

Situation	Eligibility for Independent Informal Dispute Resolution
Continuation of same deficiency at revisit which results in the continuation of the imposed civil money penalty	Yes
New deficiency resulting in the imposition of a civil money penalty(i.e., new or	Yes

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Situation	Eligibility for Independent Informal Dispute Resolution
changed facts, new tag) at revisit or as a result of an independent informal dispute resolution	
New instance of deficiency resulting in the imposition of a civil money penalty (i.e., new facts, same tag) at revisit or as a result of an informal dispute resolution.	Yes
Different tag but same facts at revisit or as a result of an informal dispute resolution	No, unless the new tag constitutes substandard quality of care and results in the imposition of a civil money penalty

The Independent IDR process does not delay the imposition of any remedies, including a civil money penalty. During the Independent IDR process a facility may dispute the factual basis of the cited deficiencies for which it requested Independent IDR. During the Independent IDR process, a facility may not challenge other aspects of the survey process, such as:

- Scope or severity classifications, with the exception of assessments that constitute substandard quality of care or immediate jeopardy;
- Remedy(ies) imposed;
- Alleged failure of the survey team to comply with a requirement of the survey process;
- Alleged inconsistency of the survey team in citing deficiencies among other facilities;
- Alleged inadequacy or inaccuracy of the IDR or Independent IDR process.

The focus of the Independent IDR process is the deficiency or deficiencies from a survey that led to the imposition of a civil money penalty that is subject to being collected and placed in escrow under §488.431(b). However, while such factors as the scope and severity classification, and the amount of the penalty, are not the subjects of the Independent IDR, State survey agencies and CMS, will take into consideration any changes in deficiency findings that result pursuant to State or CMS review of the completed Independent IDR process. Based on such review, States and CMS will assess whether any changes to scope and severity or civil money penalty amount are warranted.

While States have discretion to limit participation in the Independent IDR process by attorneys or other parties, notice to the facility should indicate that the Independent IDR,

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including face-to-face meetings, constitutes an informal administrative process that is not to be construed as a formal evidentiary hearing.

Independent IDR is not intended to be a formal or evidentiary hearing nor are the results of the Independent IDR process an initial determination that gives rise to appeal rights pursuant to 42 CFR 498.3(b). The Independent IDR results are recommendations to the State and CMS and are not subject to a formal appeal.

7213.5- Key Elements of Independent Informal Dispute Resolution

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

At a minimum, the Independent IDR process must provide for the following:

1. **Offer of Independent IDR:** The opportunity for Independent IDR must be provided within 30 calendar days of CMS's notice of imposition of a civil money penalty that is subject to being collected and placed in an escrow account. The CMS RO will communicate the offer for an Independent IDR in its initial Notice of Imposition of a Penalty letter to a facility. In addition, the CMS notice will provide the State survey agency contact information, including the name, address, and telephone number of the person and/or agency or office that the facility must contact to request an Independent IDR. The Notice of Imposition of a Penalty may be sent by e-mail and/or fax. The Statement of Deficiencies (Form CMS-2567) may be included with the Notice of Imposition of a Penalty letter. The CMS RO must confirm receipt by the facility of such notice letter. A copy of this letter will also be sent to the State survey agency.

Upon a facility's timely request for an Independent IDR, the State survey agency, or the Independent IDR entity or person (as appropriate) will provide the following information to the facility:

- Information on the Independent IDR process including where, when and how the process may be accomplished, e.g., by telephone, in writing, or in a face-to-face meeting, and

- Contact information, i.e. the name, address, phone number and e-mail of the person(s) who will be conducting the Independent IDR, if appropriate.

As with the current IDR process, the Independent IDR process will be available to a facility at no charge. Collected civil money penalty funds may not be used to cover State expenses for IDR or Independent IDR. IDR and Independent IDR are part of the survey and certification process.

2. **Timing:** The Independent IDR is conducted only upon the facility's timely request. The facility must request an Independent IDR within 10 calendar days of receipt of the offer. The facility's request will be considered timely if the request is dated within 10 calendar days of the receipt of the CMS offer, and, in the case

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of the request being mailed, the postmark verifies that it was mailed within that same 10 day time period. The facility must submit its request in writing to the State survey agency, or the approved Independent IDR entity or person, as appropriate. The facility's request should also include copies of any documents, such as facility policies and procedures, resident medical record information that are redacted to protect confidentiality and all patient identifiable information, or other information on which it relies in refuting the survey findings.

§488.431(a)(1) require that the Independent IDR be completed within 60 days of the facility's request. Every effort must be made to comply with this time frame, however, failure to comply with the Independent IDR process does not invalidate any cited deficiencies or any remedies imposed.

The Independent IDR process should be completed as soon as practicable but no later than 60 calendar days of receipt of the facility's request. The Independent IDR process is considered completed if a facility does not timely request or chooses not to participate in the Independent IDR process or when a final decision has been made, a written record has been generated, AND the State survey agency has sent written notice of this final decision to the facility.

3. **Opportunity to Comment:** Once a facility requests an Independent IDR, the State must notify the involved resident or resident representative, as well as the State's long term care ombudsman, that they have an opportunity to submit written comment. The State should request information from the long-term care ombudsman program, asking for specific information based on the ombudsman program's direct involvement or knowledge and directly related to the deficiency (ies) being disputed by the facility. Information about the facility or provider in general, but not related to the deficiency (ies) at issue, is not relevant to the Independent IDR process. This notification must be done before the Independent IDR review begins and with sufficient time for the resident or their representative to provide comment. At a minimum, this notification must include:

   - A brief description of the findings of noncompliance for which the facility is requesting Independent ID, a statement about the CMP imposed based on these findings, and reference to the relevant survey date;

   - Contact information for the State survey agency, or the approved Independent IDR entity or person as appropriate regarding when, where and how potential commenters must submit their comments;

   - A designated contact person to answer questions/concerns;

   - For residents and/or resident representatives, contact information for the State's long term care ombudsman.

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4. **Written Record:** The Independent IDR entity or person must generate a written record as soon as practicable but no later than within 10 calendar days of completing its review. The Independent IDR entity or person will forward the written record to the State survey agency, for retention by the surveying entity. The State survey agency will provide the final decision to the facility as soon as practicable but no later than 10 calendar days of its receipt of the written record. The final Independent IDR decision to the facility shall contain the result for each deficiency challenged and a brief summary of the rationale for that result. The written record from the Independent IDR entity or person shall include:

   - List of each deficiency or survey finding that was disputed;
   - A summary of the Independent IDR recommendation for each deficiency or finding at issue and the justification for that result;
   - Documents submitted by the facility to dispute a deficiency, to demonstrate that a deficiency should not have been cited, or to demonstrate a deficient practice should not have been cited as immediate jeopardy or substandard quality of care; and,
   - Any comments submitted by the State's long term care ombudsman and/or residents or resident representatives, as appropriate, taking care to protect confidentiality and protected health information.

7213.6 - Qualifications of an Independent Informal Dispute Resolution Entity or Person(s)

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

In order to be approved as an Independent IDR entity or person, whether it is a State agency or an outside organization contracted by the State agency, the entity or person must meet the following requirements:

Expertise and Training: The entity or person has an understanding of:

- Medicare and Medicaid program requirements including, but not limited to:

  a) 42 CFR Part 483, Subpart B, and Part 488, Subparts A, E and F;
  b) The State Operations Manual (SOM), including;
  1) Chapter 7, Definitions and §§ 7212, 7213 and 7900;
  2) Appendix P, Appendix PP, Appendix Q; and

- Applicable health care standards of practice, health care management, and/ or life safety code knowledge and experience, relevant to the disputed issues.

Independence: The entity or person –

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- Has no financial or other conflict of interest;
- May be a component of an umbrella State agency provided that the component is organizationally separate from the State survey agency;
- May be an independent entity or person with an understanding of specific Medicare and Medicaid program requirements selected by the State and approved by CMS.

Examples of possible conflict of interest include, but are not limited to, individuals who:

a) Were employed by the State survey agency or the State ombudsman program within the past year;

b) Have a family member who is either a resident or an employee of the facility involved in the Independent IDR;

c) Is currently employed by the facility or organization involved in the Independent IDR;

d) Have worked within the past year as an employee, consultant or volunteer for the facility or a related corporation, involved in the Independent IDR;

e) Have ownership interest or currently serves or within the past year has served on the Board of Directors or Governing Body of a facility or organization involved in the Independent IDR; or

f) Have acted within the past year as legal counsel for or against the facility involved in the Independent IDR.

7213.7 - Approval of an Independent Informal Dispute Resolution Process

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

A State's Independent IDR process must be approved by CMS. The State must submit all proposed processes, including any process that may have been used by or already existed in the State prior to January 1, 2012, to the CMS RO for approval.

The CMS RO will review and approve all written policies and procedures of the State's Independent IDR process. Any subsequent changes to an approved Independent IDR process must be submitted as soon as possible to the applicable CMS RO for review and approval prior to these changes taking effect.

The State survey agency and the Independent IDR entity or person must enter into a written contract or Memorandum of Understanding (MOU) which ensures that the Independent entity or person meets all of the qualifications and responsibilities set forth

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in regulations and guidelines specified in Chapter 7, §7213.7 of the SOM and will comply with all applicable Federal record laws and regulations concerning protected health information and the survey process or the Independent IDR process. An Independent IDR entity or person must not disclose to the public any information related to the facility that requested the Independent IDR, including the results of the Independent IDR review.

7213.8 - State Budget and Payment for Expenses

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

Costs incurred by the State survey agency for conducting Independent IDRs are eligible for federal funding using standard cost allocation principles. If the State has a State law or regulation that obliges the State to offer an Independent IDR, or specifies the manner in which an Independent IDR is to be provided, or who must provide the Independent IDR, then the State must use the existing cost allocation methodology and proportions in place for the State's surveys of Skilled Nursing Facilities (SNF)/Nursing Facilities (NF), with costs allocated between Medicare, Medicaid, and State-only sources, as appropriate. In all other cases, the costs should be allocated between Medicare and Medicaid using the existing cost allocation methodology and proportions in place for the State's surveys of Skilled Nursing Facilities (SNF)/Nursing Facilities (NF), but adjusted for the absence of a State-only share (that is, there would not need to be State-only funds beyond the requirement for State match for the Medicaid portion).

States may not charge facilities for the Independent IDR process required under 42 C.F.R. §488.431. For deficiencies that are the basis for a CMP which is not collected and placed in escrow under §488.431(b), or for deficiencies that lead to the imposition of another remedy that is not a CMP, a State is not required to provide Independent IDR. In situations where the Independent IDR process is not required but is provided by the State directly at its option, the State may choose to charge a facility a user fee for those processes.

7213.9 - Independent Informal Dispute Resolution Recommendation and Final Decision

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

1. Upon receipt of the Independent IDR written record, the State survey agency, will review the Independent IDR recommendation(s) and:

    (a) If the State survey agency, agrees with the Independent IDR recommendation(s) and no changes will be made to the disputed survey findings, the State survey agency will send written notification of the final decision to the facility within 10 calendar days of receiving the written record from the Independent IDR entity or person.

    (b) If the State survey agency disagrees with one or more of the recommendations of the Independent IDR entity or person, the complete

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written record will be sent to the applicable CMS RO for review and final decision. The State survey agency should identify the portion(s) of the Independent IDR recommendation with which it disagrees, the basis for its disagreement including any relevant survey documents that support its recommendation to the CMS RO. As soon as practicable, but no later than 10 calendar days, the CMS RO will review the Independent IDR recommendation and records along with the State's written disagreement of the Independent IDR's recommendation and will provide written notification to the State survey agency of the final decision. The CMS review will be conducted by persons familiar with LTC requirements but who have not had any input or activity with respect to the survey or deficiencies at issue. The State survey agency will then send written notification of the final decision to the facility within 10 calendar days of receiving the final decision from the CMS RO.

NOTE: Regulations at §488.431(a) (1) require that an Independent IDR will be completed within 60 days of a facility's timely request. **Completed** means that a final decision from the Independent IDR process has been made, a written record generated AND the State survey agency has sent written notice of the Independent IDR recommendation to the facility. The Independent IDR process is also considered completed if a facility does not timely request or chooses not to participate in the Independent IDR process.

2. If the State survey agency agrees with the Independent IDR recommendation(s) or has received a final decision from the CMS RO and changes will need to be made to the disputed survey findings, the State survey agency will , within 10 calendar days of receiving the written record:

    a) Change deficiency(ies) citation content findings, as recommended;

    b) Adjust the scope and severity assessment for deficiencies, if warranted by CMS policy after taking into consideration recommendations from the Independent IDR regarding the deficiency(ies);

    c) Annotate deficiency(ies) citations as "deleted or amended as recommended", where appropriate;

    d) Have a State survey agency manager or supervisor sign and date the revised CMS Form-2567;

    e) Promptly recommend to CMS that any enforcement action(s) imposed solely because of deleted or altered deficiency citations be reviewed, changed or rescinded as appropriate; and

    f) Provide written notification of the final decision to the facility.

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NOTE: Based on a final Independent IDR recommendation and final State and CMS action, if one or more deficiencies on the Form CMS-2567 have been changed, deleted or altered, the facility has the option to request a clean (new) copy of the Form CMS-2567. However, the clean copy will be the releasable copy only when a clean (new) plan of correction is both provided and signed by the facility. The original Form CMS-2567 is disclosable when a clean plan of correction is not submitted and signed by the facility. Any Form CMS-2567 and/or plan of correction that is revised or changed as a result of informal dispute resolution must be disclosed to the ombudsman in accordance with §7904.

Deficiencies pending Independent IDR should be entered into the Automated Survey Processing Environment (ASPEN) and the ASPEN Informal Dispute Resolution (IDR) Manager within ten (10) calendar days of receiving the request for an independent informal dispute resolution. This information however will not be uploaded to the Certification and Survey Provider Enhanced Reporting System (CASPER) for posting to the Nursing Home Compare website until the Independent IDR has been completed. .

IDR or Independent IDR requests from the facility should be entered in the ASPEN system within 10 working days of the IDR or Independent IDR request and necessary changes should be entered in the ASPEN system within 10 working days of completion of the IDR or Independent IDR process.
Specific instructions are provided in the current ASPEN Users Guides

7213.10 - Additional Elements for Federal Independent Informal Dispute Resolution Process

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

In the case where a Federal survey, conducted solely by Federal surveyors, or its contractors, results in the imposition of a civil money penalty (CMP) that is subject to being collected and placed in escrow, the Regional Office will offer the facility the opportunity for an Independent IDR. The Regional Office will follow the applicable elements cited in §7213. The Regional Office should advise the facility that all requests for an Independent IDR should be directed in writing to the Regional Office and an electronic copy of the request should also be sent to the CMS mailbox at CMSQualityAssurance@cms.hhs.gov. The facility should send any and all documentation, such as facility policies and procedures, resident medical record information or other information on which it relies in disputing the survey findings directly to the entity contracted by CMS to provide the Federal Independent IDR process. The facility must also send a copy of the supporting documentation to the CMS Regional Office with its request.

The Regional Office must also inform the involved resident or resident representative as well as the State's long term care ombudsman to submit any written comments directly to the Federal Independent IDR entity. This Independent IDR will be a paper review performed by the Federal Independent IDR entity under contract with CMS, Survey & Certification Group, Division of Nursing Homes. The Independent IDR will be

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completed within 60 calendar days of the facility's timely request. Upon completion of the review the Federal Independent IDR entity will send all documents submitted by the facility and any comments submitted by the State's long term care ombudsman and/or residents or resident representatives to the respective Regional Office along with its final written record/report.

In the event that any conflict of interest exists between the facility and the contracted Federal Independent IDR entity, or in the event that the Federal Independent IDR entity is unavailable, the Independent IDR will be conducted by CMS Central Office. In this case, the facility should be instructed to send all documentation to:

Centers for Medicare & Medicaid Services
Survey and Certification Group - Division of Nursing Homes
7500 Security Blvd - Mailstop C2-21-16
Baltimore, MD 21244

This Independent IDR will be a paper review performed by a panel of CMS Central Office employees who meet the criteria for an Independent IDR entity. The Independent IDR will be completed within 60 calendar days of the facility's timely request. Upon completion of the review, CMS Central Office will send all documents submitted by the facility and any comments submitted by the State's long term care ombudsman and/or residents or resident representatives to the respective Regional Office along with their final written record/report.

Upon receipt of a facility's request for an Independent IDR the Regional Office should enter the appropriate information into the Automated Survey Processing Environment (ASPEN).

Upon receipt of the Independent IDR written record, the Regional Office, will review the Independent IDR recommendation(s) and:

1. If the Regional Office agrees with the Independent IDR recommendation(s) and no changes will be made to the disputed survey findings, the Regional Office will send written notification of the final decision to the facility within 10 calendar days of receiving the written record from the Independent IDR entity or person.

2. If the Regional Office disagrees with one or more of the recommendations of the Independent IDR entity or person, the complete written record will be sent to CMS Central Office for review and final decision. The Regional Office should identify the Independent IDR recommendation with which it disagrees, the basis for its disagreement and any relevant survey documents to the CMS Central Office. As soon as practicable, but no later than 10 calendar days, the CMS Central Office will review the Independent IDR recommendation and corresponding records along with the Regional Office's written disagreement of the Independent IDR's recommendation and will provide written notification to the CMS Regional Office of the final decision. The CMS Regional Office will

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then send written notification of the final decision to the facility within 10 calendar days of receiving the final decision from the CMS Central Office.

NOTE: The regulations at §488.431(a) (1) require that an Independent IDR will be completed within 60 days of a facility's timely request. **Completed** means that a final decision from the Independent IDR process has been made, a written record generated AND the CMS Regional Office has sent written notice of the Independent IDR recommendation to the facility.

3. If the CMS Regional Office agrees with the Independent IDR recommendation(s) or has received a final decision from the CMS Central Office and changes are to be made to the disputed survey findings, the CMS Regional Office will, within 10 calendar days of receiving the written record:

    a) Change deficiency (ies) citation content findings, as recommended;

    b) Adjust the scope and severity assessment for deficiencies, if warranted by CMS policy after taking into consideration approvable recommendations from the Independent IDR regarding the deficiency (ies);

    c) Annotate deficiency (ies) citations as "deleted or amended as recommended "where appropriate;

    d) Have a CMS Regional Office manager or supervisor sign and date the revised CMS Form-2567;

    e) Ensure that any enforcement action(s) imposed solely because of deleted or altered deficiency citations will be reviewed, changed or rescinded, as appropriate; and

    f) Provide written notification of the final decision to the facility.

NOTE: Based on a final Independent IDR recommendation and final State and CMS action, if one or more deficiencies on the Form CMS-2567 have been revised or removed, the facility has the option to request a clean (new) copy of the Form CMS-2567. However, the clean copy will be the releasable copy only when a clean (new) plan of correction is both provided and signed by the facility. The original Form CMS-2567 is disclosable when a clean plan of correction is not submitted and signed by the facility. Any Form CMS-2567 and/or plan of correction that is revised or changed as a result of IDR must be disclosed to the ombudsman in accordance with §7904.

Deficiencies pending Independent IDR should be entered into the Automated Survey Processing Environment (ASPEN) and the ASPEN Informal Dispute Resolution (IDR) Manager but will not be uploaded to the Certification and Survey Provider Enhanced Reporting System (CASPER) for posting to the Nursing Home Compare website until the Independent IDR has been completed. .

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IDR or Independent IDR requests from the facility and necessary changes should be entered in the ASPEN system within 10 working days of the IDR or Independent IDR request and necessary changes should be entered in the ASPEN system within 10 working days of completion of the IDR or Independent IDR process.

Specific instructions are provided in the current ASPEN Users Guide.

The ASPEN Enforcement Manager (AEM) will be enabled to include the Independent IDR process for enforcement actions with survey cycles that begin on or after January 1, 2012.

7300 - Certification of Compliance and Noncompliance for Skilled Nursing Facilities and Nursing Facilities

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7300.1 - Introduction

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

These procedures are established pursuant to sections 1819(g) and 1919(g) of the Act and 42 CFR 488.330 to provide guidance about when the State or the regional office has the responsibility for certifying compliance or noncompliance and what procedures to follow. This section also defines the concept of "substantial compliance" for certification purposes.

The State has the responsibility for certifying a skilled nursing facility's or nursing facility's compliance or noncompliance, except in the case of State-operated facilities. However, the State's certification for a skilled nursing facility is subject to CMS's approval. "Certification of compliance" means that a facility's compliance with Federal participation requirements is ascertained. In addition to certifying a facility's compliance or noncompliance, the State recommends appropriate enforcement actions to the State Medicaid Agency for Medicaid and to the regional office for Medicare. The State is authorized by CMS to both recommend and impose category 1 remedies. In addition, when authorized by the regional office or the State Medicaid Agency, the State may also provide notice of imposition of the denial of payment for new admissions remedy. As specified in 42 CFR 488.10, the regional office determines a facility's eligibility to participate in the Medicare program based on the State's certification of compliance and a facility's compliance with civil rights requirements.

Throughout this chapter, references are made to the State Medicaid Agency in taking enforcement actions against a Medicaid facility. However, there is nothing in Federal regulation that precludes the State Medicaid Agency from delegating the authority to act on its behalf in imposing enforcement remedies for Medicaid nursing facilities. The regional office has the responsibility for certifying a State-operated skilled nursing facility's or nursing facility's compliance or noncompliance. In accordance with §1919(h)(3), the regional office may take independent and binding enforcement

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action against any nursing facility based on its findings of noncompliance. However, the regional office's certification is usually based on the State's survey and findings.

7300.2 - Survey and Certification Responsibility
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Except as specified in §7300, the following entities are responsible for surveying and certifying a skilled nursing facility's or nursing facility's compliance or noncompliance with Federal requirements:

- **State-Operated Skilled Nursing Facilities or Nursing Facilities or State-Operated Dually Participating Facilities** - The State conducts the survey, but the regional office certifies compliance or noncompliance and determines whether a facility will participate in the Medicare or Medicaid programs.

- **Non-State Operated Skilled Nursing Facilities** - The State conducts the survey and certifies compliance or noncompliance, and the regional office determines whether a facility is eligible to participate in the Medicare program.

- **Non-State Operated Nursing Facilities** - The State conducts the survey and certifies compliance or noncompliance. The State's certification is final. The State Medicaid Agency determines whether a facility is eligible to participate in the Medicaid program.

- **Non-State Operated Dually Participating Facilities (Skilled Nursing Facilities/Nursing Facilities)** - The State conducts the survey and certifies compliance or noncompliance. The State's certification of compliance or noncompliance is communicated to the State Medicaid Agency for the nursing facility and to the regional office for the skilled nursing facility. In the case where the State and the regional office disagree with the certification of compliance or noncompliance, see §7807 for rules to resolve such disagreements.

7300.3 - Initial Survey and Certification Responsibility
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The State determines whether a prospective provider is in substantial compliance with the nursing home participation requirements. If the facility is in substantial compliance, the State certifies and recommends that the regional office and/or State Medicaid Agency enter into an agreement with the facility. Using the guidance below about the methods by which substantial compliance may be determined, if the facility is determined not to be in substantial compliance, the State recommends that the regional office and/or State Medicaid Agency deny participation. The regional office and/or State Medicaid Agency sends the letter notifying the facility of its denial of participation in the Medicare and/or Medicaid programs, and includes the appeal rights available under 42 CFR 431.153 and 42 CFR 498.3(b). (See also §2005 and §7203 of this manual.)

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With the exception of an initial survey for reasonable assurance, if the initial survey of the prospective provider finds that the noncompliance is such that the deficiencies fall at levels D, E, or F (without a finding of substandard quality of care) on the scope and severity scale, the State survey agency may opt to accept evidence of correction to confirm substantial compliance in lieu of an onsite revisit; however, the State survey agency always has the discretion to conduct an onsite revisit to determine if corrections have been made. If the noncompliance falls at level F (with a finding of substandard quality of care), or any level higher than level F, the option to accept evidence of correction in lieu of an onsite revisit does not apply. In this case, an onsite revisit is necessary to determine substantial compliance after the facility submits an acceptable plan of correction. For reasonable assurance, deficiencies at level D or above on the first survey will result in denial for purposes of starting Medicare reasonable assurance. (See §7321.3.1.)

The plan of correction does not assure the execution of a provider agreement. The effective date of the provider agreement would be the date the survey agency verifies substantial compliance as determined by the appropriate evidence of correction as discussed above.

With the exception of an initial survey for reasonable assurance, the option to accept evidence of correction in lieu of an onsite revisit is also applicable when an existing Medicaid nursing facility with deficiencies at levels D, E, or F (without substandard quality of care) wishes to participate as a Medicare skilled nursing facility. The survey agency does not conduct a new survey. The survey agency submits the information obtained during the most recent Medicaid survey and other documentation as required, e.g., compliance with 42 CFR 483.30(c) and (d) and 42 CFR 483.40(e) and (f), for the initial certification of the Medicare nursing home to the regional office. The Medicare provider agreement would be effective when the survey agency determines the facility is in substantial compliance either through evidence of correction submitted or by an onsite revisit. For reasonable assurance, deficiencies at level D or above on the first survey will result in denial for purposes of starting Medicare reasonable assurance. (See §7321.3.1.)

When the State recommends that the regional office and/or State Medicaid Agency deny participation, the regional office and/or State Medicaid agency sends the letter notifying the facility of its denial of participation in the Medicare and/or Medicaid programs, and includes the appeal rights available under 42 CFR 431.153 and 42 CFR 498.3(b).

7300.4 - Effect of CMS' Validation Authority

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The regional office may make independent findings of compliance or noncompliance based on its own validation survey. The regional office's finding of noncompliance is binding and takes precedence over the State's certification of compliance based on the State's survey.

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The regional office may also make independent findings of compliance or noncompliance based on its review of the State's certification of compliance or noncompliance. The regional office need not conduct an onsite visit in order to exercise its validation authority. However, the regional office's determination of compliance based on the State's findings that resulted in the State's certification of noncompliance does not take precedence. (See §7807 for resolving disagreements between the regional office and the State.)

7301 - Action When Facility Is Not in Substantial Compliance

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7301.1 - Immediate Jeopardy Exists

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

(See also §7307 and Appendix Q of this manual.)

When immediate jeopardy exists:

1. The regional office or State Medicaid Agency will impose termination and/or temporary management in as few as 2 calendar days (one of which must be a working day) after the survey which determined immediate jeopardy. In all cases of immediate jeopardy, the provider agreement must be terminated by CMS or State Medicaid Agency no later than 23 calendar days from the last day of the survey if the immediate jeopardy is not removed.

2. The regional office or State Medicaid Agency should impose another remedy in addition to termination when immediate jeopardy has been determined. Immediate imposition of an alternative remedy should be considered even if the facility successfully removes the immediate jeopardy but is still not in substantial compliance.

3. The regional office or State Medicaid Agency may impose a civil money penalty between $3,050 and $10,000 per day of immediate jeopardy or a "per instance" civil money penalty from $1,000 to $10,000 for each deficiency. The specific procedures for civil money penalties can be found in §7510-§7536.

4. The regional office or State Medicaid Agency may impose other remedies as described in §7500. Except for State monitoring, which requires no notice, the regional office or State Medicaid Agency may impose remedies 2 calendar days (one of which must be a working day) from the date the facility receives notice.

5. The regional office, State Medicaid Agency, or State (as authorized by CMS) may impose State monitoring immediately without notice.

6. The State, as authorized by CMS, may also provide notice of the imposition of denial of payment for new admissions effective 2 calendar days (one of which

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must be a working day) from the date the facility receives notice. (See also §7311, §7314, and §7506.1.)

7. The State will require that the facility submit an allegation that the immediate jeopardy has been removed as well as provide sufficient detail to demonstrate how the immediate jeopardy has been addressed so that the State can verify onsite the removal of the immediate jeopardy. A plan of correction should be deferred until the facility has successfully demonstrated removal of immediate jeopardy. Facilities should be cautioned that the allegation of removal of the immediate jeopardy does not guarantee a revisit before the effective date of termination.

8. The State will require an acceptable plan of correction for all deficiencies cited after it conducts the revisit to confirm removal of the immediate jeopardy.

9. The State is authorized to recommend and impose category 1 remedies. When authorized by the regional office, the State may also provide notice of imposition and rescission of the denial of payment for new admissions remedy. (See also §7311, §7314, and §7506.1.)

7301.2 - Immediate Jeopardy Does Not Exist

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

(See also §7310)

When immediate jeopardy does not exist:

1. CMS or the State must determine whether the facility will be given an opportunity to correct its deficiencies before remedies are imposed (see §7304).

2. The regional office or State Medicaid Agency should impose another remedy in addition to termination for a facility not being given an opportunity to correct.

3. The regional office or State Medicaid Agency terminates the Medicare and/or Medicaid provider agreements that are in effect no later than 6 months from the date of the survey that determined noncompliance if noncompliance still exists (see §7600). Except for State monitoring, which requires no notice, the regional office or State Medicaid Agency may impose these remedies 15 calendar days from the date the facility receives notice.

4. When there is an opportunity to correct before remedies are imposed, the State will request an acceptable plan of correction, provide initial notice of recommended remedies (including recommendation for subsequent termination, conduct a revisit if applicable, then provide formal notice of denial of payment for new admissions (if authorized by the regional office) and other remedies if noncompliance continues at revisit. While formal notice of imposition of denial of payment for new admissions by the State (if authorized by the regional office)

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is generally provided in the revisit letter, the State may provide such notice in its initial notice to the facility. (See also §7305.1, §7311, §7313.2, §7314, §7316.2 and §7506.1.)

5. The regional office or State Medicaid Agency must impose denial of payment for new admissions no later than 3 months after the last day of the survey that identified the noncompliance if substantial compliance is not achieved.

6. The regional office or State Medicaid Agency (or State, as authorized by CMS) may impose State monitoring without notice.

7. The regional office or State Medicaid Agency may impose either a per day civil money penalty between $50 and $3,000 per day or a "per instance" civil money penalty between $1,000 and $10,000 for each deficiency. The specific procedures for civil money penalties can be found in §7510-§7536.

8. The State is authorized to recommend and impose category 1 remedies. When authorized by the regional office, the State may also provide notice of imposition and rescission of the denial of payment for new admissions remedy. (See also §7311, §7314, and §7506.1.)

7301.3 - Prospective Providers

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

See §7203.2 and §7300.3.

7303 - Appeal of Certification of Noncompliance

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

With the exception of the State monitoring remedy, facilities may appeal the finding of noncompliance that led to an enforcement remedy. Enforcement includes termination, alternative remedies provided in §7400, and any alternative or additional State remedies approved by CMS. Rather than sending an appeal to the regional office, facilities may appeal directly to the Departmental Appeals Board in the Office of the Secretary for Health and Human Services, with a copy to the State and regional office. However, in the case of an enforcement action taken by the State against a Medicaid-only facility, the appeal should be sent to the State. The appeal procedures for facilities are found at:

- 42 CFR Part 498 for State-operated skilled nursing facilities, nursing facilities or skilled nursing facilities/nursing facilities;

- 42 CFR Part 498 for non-State operated skilled nursing facilities or skilled nursing facilities/nursing facilities, and non-State nursing facilities for which the regional office disagrees with the State's finding of compliance; and

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- 42 CFR Part 431 for non-State operated nursing facilities in which the determination was made by the State Medicaid Agency or was subject to a validation review by the regional office and the regional office agrees with the State's finding. (See §7300.4 and §7311.2 for more information about CMS' validation authority.)

With the exception of civil money penalties, enforcement actions may be imposed while the facility is appealing the noncompliance that led to the enforcement action. For example, a facility could have its provider agreement terminated effective May 1, while the hearing of the facility's appeal may not occur until after that date. Except in the case of civil money penalties, a request for a hearing will not defer the effective date of the enforcement action. Further, in accordance with 42 CFR 431 153(e)(2), a nursing facility's request for a hearing on denial or termination does not delay the enforcement action and need not be completed before the effective date of the action. In the case of civil money penalties, the hearing, if requested, must be completed before the civil money penalty can be collected. However, the daily civil money penalty amount continues to accrue from the effective date until the facility is either terminated or has achieved substantial compliance.

In accordance with 42 CFR 498.40(b), the content of the request for a hearing must identify the specific issues, the findings of fact and conclusions of law with which the facility disagrees, and specify the basis for contending that the findings and conclusions are incorrect.

See §7809 for appeals of substandard quality of care that resulted in disapproval of a Nurse Aide Training and Competency Evaluation Program.

7304 - Mandatory Immediate Imposition of Federal Remedies

(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

Noncompliance may occur for a variety of reasons and can result in harm to residents or put residents at risk for harm. When facilities do not maintain substantial compliance, CMS may use various enforcement remedies to address a facility's responsibility to promptly achieve, sustain and maintain compliance with all federal requirements. To support this purpose, we are directing the immediate imposition of federal remedies in certain situations outlined in §7304.1 below, and we recommend using the type of remedy that best achieves the purpose based on the circumstances of each case.

This guidance does not apply to ***past noncompliance*** *deficiencies as described in §7510.1 of this chapter. The determination to impose a federal remedy for past noncompliance is not mandatory and is at the discretion of the CMS Regional Office (RO).*

7304.1 - Criteria for Mandatory Immediate Imposition of Federal Remedies Prior to the Facility's Correction of Deficiencies

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(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

CMS will impose federal remedies and the survey will be identified as a "No Opportunity to Correct" if the situation meets *any one or more of* the *following* criteria:

- Immediate Jeopardy (IJ) (scope and severity levels J, K, and L) is identified on the current survey; **OR**
- *Any d*eficiency *from the current survey at levels "G, H or I" that falls into any of the regulatory sections that constitute* Substandard Quality of Care (SQC); **OR**
- *Any d*eficiency *at "*G*"* or above on the current survey ***AND*** *if there were any* deficiencies *at "G" or above* on the previous standard health or LSC survey **or** *if there was any* deficiency *at "G"* or above on any type of survey between the current survey and the last standard *health or LSC* survey. *These surveys (standard health or LSC, complaint, revisit) must be separated by a certification of compliance, i.e., they must be from different noncompliance cycles. For instance, level G or above deficiencies from multiple surveys within the same noncompliance cycle must not be combined to make this a "double G or higher" determination*; **OR**
- A facility classified as a Special Focus Facility (SFF) **AND** has a deficiency citation at level "F," *(excluding any level "F" citations under tags F812, F813 or F814)* or higher for the current health survey or "G" or higher for the current Life Safety Code (LSC) survey.

*The remedies to be imposed by statute do not change, (e.g., 3-month automatic Denial of Payment for new admissions (DPNA), 23-day termination when IJ is present and 6-month termination). In addition to these statutory remedies, t*he CMS RO **must** ***also*** *immediately* impose *one or more additional* remedies *for any situation that* meets the criteria identified above. The State Survey and/or Medicaid Agencies **shall not** permit changes to this policy.

Use of Federal Remedies in Immediate Jeopardy (IJ) Citations *- When IJ is identified on the current survey that resulted in serious injury, harm, impairment or death, a CMP* ***must*** *be imposed.*

For IJ citations where there is ***no resultant*** *serious injury, harm, impairment or death but the likelihood is present, the CMS RO must impose a remedy or remedies that will best achieve the purpose of attaining and sustaining compliance. CMPs may be imposed, but they are not required.*

NOTE: "*C*urrent" survey is whatever Health and/or LSC survey is currently being performed, e.g., standard, revisit, or complaint. *"Standard" survey (which does not include complaint or revisit surveys) is a periodic, resident-centered inspection that gathers information about the quality of service furnished in a facility to determine compliance with the Requirements of Participation.*

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Process for State Enforcement Recommendations *- While States are not required to recommend the types of remedies to be imposed, they are encouraged to do so since States may be more familiar with a facility's history and the specific circumstances in the case at hand. The CMS RO will consider these recommendations but ultimately makes the enforcement determination. To ensure effective communication and exchange of information, CMS encourages that all documentation is included in the ASPEN - Enforcement Manager (AEM) system or any subsequent system*.

Regardless of a State's recommendation, the CMS RO must take the necessary actions to impose a remedy or multiple remedies, based on the seriousness of the deficiencies following the criteria set forth in *42 C.F.R.* §488.404. *Also refer to §§7400.5.1 and 7400.5.2 of this chapter. In addition to any statutorily imposed remedy, additional remedies should be selected that will bring about compliance quickly and encourage facilities to achieve and maintain compliance. When making remedy choices, the CMS RO should consider the extent to which the noncompliance is the result of a one-time mistake, larger systemic concerns, or an intentional action of disregard for resident health and safety. The surveyor investigation and corresponding CMS-2567 should provide evidence to assist with that determination.*

The State Survey Agency is authorized to both recommend and impose one or more Category 1 remedies, in accordance with §7314 of this Chapter. **CATEGORY 1** remedies include:

- Directed plan of correction,
- State monitoring, and
- Directed in-service training.

Types of Remedies *- The choice of remedy is made that best achieves the purpose of attaining and sustaining compliance based on the circumstances of each case and recommendations from the State. Federal remedies are summarized below. Refer to §§7500 - 7556 of this chapter for more detail on these remedies.*

Civil Money Penalties (CMPs) *- Federal CMPs may only be imposed by the CMS RO. If a CMP is imposed, it must be done in accordance with instructions in the CMP Analytic Tool and §§7510 through 7536 of this chapter.*

Directed In-Service Training *– Refer to §7502 of this chapter. Consider this remedy in cases where the facility has deficiencies where there are knowledge gaps in standards of practice, staff competencies or the minimum requirements of participation and where education is likely to correct the noncompliance. Depending on the topic(s) that need to be addressed and the level of training needed, facilities should consider using programs developed by well-established centers of geriatric health services such as schools of medicine or nursing, centers for the aging, and area health education centers which have established programs in geriatrics and geriatric psychiatry. If it is willing and able, a State may provide special consultative services for obtaining this type of training. The State or regional office may also compile a list of resources that can provide directed in-service training and could make this list available to facilities and*

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interested organizations. Facilities may also utilize the ombudsman program to provide training about residents' rights and quality of life issues.

Directed Plan of Correction - *Refer to §7500 of this chapter. This remedy provides for directed action(s) from either the State or CMS RO that the facility must take to address the noncompliance or a directed process for the facility to more fully address the root cause(s) of the noncompliance. Achieving compliance is ultimately the facility's responsibility, whether or not a directed plan of correction is followed.*

Temporary Management *- Refer to 42 CFR §§488.408 and 488.410. This is 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. A temporary manager may be imposed anytime a facility is not in substantial compliance but may also be imposed when a facility's deficiencies constitute IJ or widespread actual harm and a decision is made to impose an alternative remedy in lieu of termination. It is the temporary manager's responsibility to oversee correction of the deficiencies and assure the health and safety of the facility's residents while the corrections are being made. The temporary manager's term can extend beyond the time which deficiencies are corrected by agreement of the facility and the temporary manager. A temporary manager remedy may also be imposed to oversee orderly closure of a facility. The State will select the temporary manager when the State Medicaid Agency is imposing the remedy and will recommend a temporary manager to the regional office when CMS is imposing the remedy. Each State should compile a list of individuals who are eligible to serve as temporary managers. These individuals do not have to be located in the State where the facility is located.*

Denial of Payment for all New Medicare and Medicaid Admissions (DPNA) - *See §7506 of this chapter. This remedy may be imposed alone or in combination with other remedies to encourage quick compliance. Regardless of any other remedies that may be imposed, a mandatory denial of payment for new admissions* ***must*** *be imposed when the facility is not in substantial compliance three months after the last day of the survey identifying deficiencies, or when a facility has been found to have furnished substandard quality of care on the last three consecutive standard surveys (see 42 CFR 488.414).*

Denial of all Payment for all Medicare and Medicaid Residents (DPAA) (Discretionary). - *See §7508 of this chapter. Only CMS has the authority to deny all payment for Medicare and/or Medicaid residents. This is in addition to the authority to deny payment for all new admissions (discretionary) noted above. This is a severe remedy. Factors to be considered in selecting this remedy include but are not limited to:*

1. *Seriousness of current survey findings;*
2. *Noncompliance history of the facility; and*
3. *Use of other remedies that have failed to achieve or sustain compliance.*

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State Monitoring *- Refer to §7504 of this chapter. A State monitor oversees the correction of cited deficiencies in the facility as a safeguard against further harm to residents when harm or a situation with a potential for harm has occurred. Consider imposing this remedy when, for example, there are concerns that the situation in the facility has the potential to worsen or the facility seems unable or unwilling to take corrective action. A State monitor* ***must*** *be used when a facility has been cited with substandard quality of care (SQC) deficiencies on the last three consecutive* ***standard health*** *surveys.*

Termination of Provider Agreement *- See §7556 of this chapter. While this remedy may be imposed at any time the circumstances warrant regardless of whether IJ is present; regardless of any other remedies that may be imposed, termination of a facility's provider agreement* ***must*** *be imposed when the facility is not in substantial compliance six months after the last day of the survey identifying deficiencies or within no more than 23 days if IJ is identified and not removed.*

Mandatory Criteria for Immediate Imposition of Federal Remedies

Mandatory Criteria for Immediate Imposition of Federal Remedies	Immediate Jeopardy is identified on the current survey	Deficiencies of SQC that are not IJ are identified on the current survey	Any G level deficiency is identified on the current survey in 42 C.F.R. §483.13, Resident Behavior and Facility Practices, 42 C.F.R. §483.15, Quality of Life, or 42 C.F.R. §483.25, Quality of Care	Deficiencies of actual harm are identified on the current survey AND deficiencies of immediate jeopardy OR actual harm were identified on any type of survey between the current survey and the last standard survey	Facilities classified as a SFF AND has a deficiency citation of "F" level or higher for the current health survey or G or higher for the current LSC survey
Types of Remedy(ies) that, at a minimum, should be considered for immediate imposition by CMS in addition to the CMPs when immediate jeopardy is cited, mandatory 3-month DPNA for new admissions or	1. Termination 2. CMPs must be imposed immediately 3. DDPNA[1] 4. Temp. Mgmt. 5. State Monitoring 6. Directed Plan of Correction 7. Directed In-service 8. Denial of Payment for ALL Individuals[2]	1. Termination 2. CMPs 3. DDPNA 4. Directed Plan of Correction 5. Directed In-service Training 6. Denial of Payment for All Individuals	1. Termination 2. CMPs 3. DDPNA 4. Directed Plan of Correction 5. Directed In-service Training 6. Denial of Payment for All Individuals	1. Termination 2. CMPs 3. DDPNA 4. Temp. Mgmt. 5. State Monitoring 6. Directed Plan of Correction 7. Directed In-service 8. Denial of Payment for All Individuals	1. Termination 2. CMPs 3. DDPNA 4. Temp. Mgmt. 5. State Monitoring 6. Directed Plan of Correction 7. Directed In-service 8. Denial of Payment for All Individuals

[1] *DDPNA = Discretionary Denial of Payment for New Admissions*

[2] *This remedy shall ONLY be imposed by CMS and may not be imposed by a State Medicaid Agency. A state survey agency may only impose Category 1 remedies if authorized by the CMS RO.*

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mandatory 6-month termination, as required. NOTE: Multiple remedies may be imposed for any situation as appropriate.					
Decisions, Responsibilities & Actions (refer to §7304.3)	Within 5 business days from when the initial notice was sent to the facility the survey agency must assure that all cases that meet the criteria outlined in 7304.1 above are entered into ASPEN/AEM and that all of these cases are referred to the CMS RO for their imposition of remedies. The CMS RO must take the necessary action to impose remedies as appropriate, regardless of a State's recommendation for imposition of remedies, based on the seriousness of the deficiencies following the criteria set forth in 42 C.F.R. §488.404 - Factors to be considered in selecting remedies. Civil Money Penalties (CMPs) must be imposed in accordance with instructions in the CMP Tool.				

NOTE: Denial of Payment for New Admissions - Whenever a State's remedy is unique to its State plan and has been approved by CMS, then that remedy may also be imposed by the CMS RO against a dually-participating facility in that State. Therefore, if a State's ban on admissions remedy is determined to be an acceptable State alternative, it must be understood that in dually participating facilities, CMS can impose a State's ban on admissions remedy only with regard to all Medicare/Medicaid residents. Only the State can ban admissions of private pay residents.

7304.2 - Effective Dates for Immediate Imposition of Federal Remedies

(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

Once a remedy is imposed, it *becomes* effect*ive* as of the date *specified* in the notice letter *for the remedy being imposed.* All remedies remain in effect and continue until the facility *has demonstrated and is determined to be* in substantial compliance. Substantial compliance must be verified in accordance with §7317 of this chapter. Substantial c*ompliance may be determined to occur anytime between the latest correction date on the approved Plan of Correction (PoC) up until the date of the revisit. The date of substantial compliance is determined by the date on which the evidence provided by the facility supports correction of deficiencies as determined by the Survey Agency.*

For Immediate Jeopardy *(IJ)* Situations: *A facility's* removal of the conditions that *caused the* IJ may, at CMS's discretion, result in the rescission of the 23-day termination. *A per day CMP must be lowered when the survey agency has verified that the IJ has been removed but deficiencies at a lower level continue. Refer to the CMP Analytic Tool instructions for determining the dates of a per day CMP. H*owever, CMS **shall not** rescind any *other* remedies imposed *until the facility achieves substantial compliance or is terminated.* Remedies imposed must remain in effect, irrespective of when the IJ is removed, unless otherwise rescinded *or revised* as a result of legal

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proceedings. Remedies will be immediately imposed and effectuated whether the *IJ* was:

- removed during the survey, or,
- removed in a subsequent IJ removal revisit before the 23rd day.

7304.3 - Responsibilities of the State Survey Agency and the CMS Regional Office *(RO)* when there is an Immediate Imposition of Federal Remedies

(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

When *federal remedies are to be immediately imposed as outlined in §7304:*

- *Within five (5) business days after the last day of the current survey when any of the criteria in §7304.1 is met the survey agency* ***must*** *notify the CMS RO their review and action; and,*
- *The CMS RO will review these cases within five (5) business days of receipt from the survey agency and decide if an immediate imposition of remedies is appropriate.*

Timeliness is important to ensure that remedies are imposed, and notices are sent to the facility before the effective dates of the remedies to be imposed and meet the timelines for notices as outlined in §7305 of this chapter.

The *s*urvey *a*gency *(State or Federal)* must *enter all of these cases as a NO opportunity to correct into the Automated System Processing Environment (ASPEN)/ASPEN Enforcement Manager (AEM)* system within five (5) business days of sending the initial notice to the facility. The State Survey Agency and the CMS RO must have systems in place to routinely check and monitor the ASPEN-AEM database to identify cases that may require enforcement action or additional follow-up, as needed.

7305 - Notice Requirements

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7305.1 - Initial Notices by Surveying Entity

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7305.1.1 – When No Immediate Jeopardy Exists and an Opportunity to Correct Will be Provided Before Remedies Are Imposed

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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When no immediate jeopardy exists and an opportunity to correct will be provided before remedies are imposed, the surveying entity sends out an initial notice notifying the facility of the following (and the State sends a copy of this notice to the State Medicaid Agency and the CMS regional office):

a. Transmits deficiencies cited (those listed on the Form CMS-2567, as well as those isolated deficiencies which cause no harm and potential for only minimal harm);

b. Provides notice of the mandatory remedy which must be imposed if the facility fails to achieve substantial compliance at 6 months, (i.e., termination of provider agreement and consequent cessation of payments);

c. Provides that the approved plan of correction will establish the outside date by which correction must be made.

d. May serve as the formal notice of the imposition of any category 1 remedy, as authorized by CMS or the State Medicaid Agency, to be effective on (date the State expects correction based on the outside correction date on the facility's approved plan of correction, but no earlier than 15 calendar days from date of receipt of notice by the facility). Also, if authorized by the regional office, the State may provide formal notice to the facility of imposition of denial of payment for new admissions in the initial notice rather than in the first revisit letter, to be effective on (date the State expects correction based on the outside correction date on the facility's approved plan of correction) but in no case later than 3 months from the date of the survey if the facility fails to achieve substantial compliance; (See also §7301, §7311, §7313.2, §7314, §7316.2, and §7506.1.)

e. Provides that the State's proposed remedies will be forwarded to CMS and/or the State Medicaid Agency if correction is not achieved at the first revisit. Civil money penalties will be effective as of the date that substantial compliance began, usually the date of the survey (see also §7518). All other remedies can be imposed as soon as the 15 day notice requirement is met. The remedies for which the State has provided notice, as authorized by CMS and the State Medicaid Agency, will take effect without further notice from the regional office or State Medicaid Agency;

f. Provides that an acceptable plan of correction is required in response to deficiencies listed on the Form CMS-2567 and must be received within 10 calendar days of the facility's receipt of the CMS-2567 (see §7304.4). The plan of correction will serve as the facility's allegation of compliance;

g. Informs the facility of the opportunity for informal dispute resolution;

h. Specifies that if an acceptable plan of correction is not received within 10 calendar days of the facility's receipt of the CMS-2567, the State will notify the

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facility that it is recommending to the regional office and/or the State Medicaid Agency that remedies other than category 1, and/or denial of payment for new admissions, be imposed effective as soon as notice requirements are met. As authorized by CMS and/or the State Medicaid Agency, formal notice of imposition of category 1 remedies may be officially provided in this initial notice, and notice of imposition of denial of payment for new admissions may be officially provided in this notice or in the first revisit letter; (See also §7301, §7311, §7313.2, §7314,§7316.2, and §7506.1.)

i. Provides elements of an acceptable plan of correction (See §7304.4.);

j. Informs the facility of the disapproval of its nurse aide training and competency evaluation program and competency evaluation program, as well as its appeal rights if the program loss is based on a finding of substandard quality of care (see §7809); and

k. Provides that when substandard quality of care is determined, the facility must provide a list of physicians for residents identified with substandard quality of care on the survey. The State must notify each physician and refer the administrator to the State's licensing board.

l. When no formal notification of remedies is being provided in this initial notice, the following language will be inserted in **bold type** in the letter to make it clear that the initial notice is not the notice that triggers the imposition of remedies and that any such determination will be provided in a separate notice: **"Please note that this notice does not constitute formal notice of imposition of alternative remedies or termination of your provider agreement. If it is determined that termination or any other remedy is warranted, you will be provided with a separate formal notification of that determination."**

7305.1.2 – When No Immediate Jeopardy Exists and No Opportunity to Correct Will be Provided Before Remedies Are Imposed

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

When no immediate jeopardy exists, and no opportunity to correct will be provided before remedies are imposed, the surveying entity sends an initial notice which:

a. Transmits deficiencies cited (those listed on the Form CMS-2567, as well as those isolated deficiencies which cause no harm and potential for only minimal harm);

b. Provides notice of the provider agreement termination that must be imposed if the facility has not achieved substantial compliance 6 months from the last day of the survey that found the noncompliance;

c. May provide that this notice serves as a formal notice of the imposition of denial of payment for new admissions and/or any category 1 remedy, as authorized by

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CMS and/or the State Medicaid Agency, to be effective no sooner than 15 calendar days from date of receipt of this notice by the facility, but in no case later than 3 months from the date of the survey; (See also §7311, §7314, and §7506.1.)

d. Provides than an acceptable plan of correction is required in response to deficiencies listed on the Form CMS-2567 and must be received within 10 calendar days of the facility's receipt of the CMS-2567 (see §7304.4). The plan of correction will serve as the facility's allegation of compliance;

e. Informs the facility of the opportunity for informal dispute resolution;

f. Specifies that when an acceptable plan of correction is not submitted within 10 calendar days, the State may propose to the regional office and/or State Medicaid Agency that remedies be imposed immediately within applicable notice requirements;

g. Informs the facility of the disapproval of its nurse aide training and competency evaluation program and competency evaluation program, as well as its appeal rights if the program loss is based on a finding of substandard quality of care;

h. Provides that when substandard quality of care is determined, the facility must provide a list of physicians for residents identified with substandard quality of care on the survey. The State must notify each physician and refer the administrator to the State's licensing board;

i. Provides elements of an acceptable plan of correction. (See §7304.4.) and,

j. When no formal notification of remedies is being provided in this initial notice, the following language will be inserted in **bold type** in the letter to make it clear that the initial notice is not the notice that triggers the imposition of remedies and that any such determination will be provided in a separate notice: **"Please note that this notice does not constitute formal notice of imposition of alternative remedies or termination of your provider agreement. If it is determined that termination or any other remedy is warranted, you will be provided with a separate formal notification of that determination."**

7305.1.3 – When Immediate Jeopardy Exists

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

The surveying entity sends the initial notice to the facility of the following:

a. The nature of the immediate jeopardy, including regulatory cites or initial assessment of immediate jeopardy findings;

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b. Requests an allegation of removal of immediate jeopardy, including evidence of steps taken to remove the immediate jeopardy. The plan of correction will usually be deferred until immediate jeopardy has been determined to be removed;

c. Consequences of failure to submit an allegation of removal, e.g., provider agreement termination;

d. Remedies recommended with effective dates;

e. Opportunity for informal dispute resolution;

f. Opportunity for independent informal dispute resolution if a civil money penalty subject to being collected and placed in an escrow account is imposed;

g. Disapproval of nurse aide training and competency evaluation program and competency evaluation program and appeal rights if the program loss is based on a finding of substandard quality of care;

h. When substandard quality of care is determined, the facility must provide the State with a list of the physicians of those residents who were found to be subject to the substandard quality of care. The State must notify each attending physician and refer the administrator to the State's licensing board; and,

i. When no formal notification of remedies is being provided in this initial notice, the following language will be inserted in **bold type** in the letter to make it clear that the initial notice is not the notice that triggers the imposition of remedies and that any such determination will be provided in a separate notice: **"Please note that this notice does not constitute formal notice of imposition of alternative remedies or termination of your provider agreement. If it is determined that termination or any other remedy is warranted, you will be provided with a separate formal notification of that determination."**

j. May serve as the formal notice of the imposition of any category 1 remedy, as authorized by CMS or the State Medicaid Agency, to be effective on (date the State expects correction based on the outside correction date on the facility's approved plan of correction, but no earlier than 2 calendar days from the date of receipt of notice by the facility). Also, if authorized by the regional office, the State may provide formal notice to the facility of imposition of denial of payment for new admissions in the initial notice rather than in the first revisit letter, to be effective on (date the State expects correction based on the outside correction date on the facility's approved plan of correction but no earlier than 2 calendar days from the date of receipt of notice by the facility). (See also §7301, §7313.2, §7314, §7316.2, and §7506.1.)

7305.2 - Regional Office, State Medicaid Agency, and State Formal Notices When Remedies are Imposed

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(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7305.2.1 - Who Sends the Formal Notice of Remedies

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A formal notice of remedies is sent by:

a. The State, in either its initial notice or in its first revisit notice for category 1 remedies and denial of payment for new admissions, when and as authorized by CMS and/or the State Medicaid Agency;

b. The regional office for remedies other than those provided in accordance with 1a. above; for skilled nursing facilities, skilled nursing facilities/nursing facilities, and nursing facilities where the regional office is taking the enforcement action; and/or,

c. The State Medicaid Agency for remedies other than those provided in accordance with a. above for nursing facilities.

7305.2.2 - Contents of the Formal Notice of Remedies

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The formal notice of remedies is notification to the facility of the following:

a. Facts regarding when the survey occurred, which requirements were found out of compliance, and, where applicable, subsequent actions on the part of the State or facility;

b. Basis for the enforcement remedy, including termination (i.e., the facility has failed to achieve substantial compliance);

c. Enforcement remedy(ies) being imposed and the effective date; e.g., except for State monitoring and civil money penalties, no sooner than 2 calendar days or 15 calendar days from the facility's receipt of notice, depending on whether or not immediate jeopardy exists;

d. Appeal rights and how to request a formal appeal; and

e. The mandatory enforcement remedies not yet imposed that must occur at a later date if the facility continues to be out of compliance (i.e., mandatory denial of payment for new admissions and/or termination of the provider agreement).

7305.2.3 - Required Time Periods for Formal Notice

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The notice period begins once the facility receives its notice as indicated below.

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a. **Immediate Jeopardy – 2 calendar day notice**

   Except for civil money penalties and State monitoring, notice must be given at least 2 calendar days before the effective date of the enforcement action.

b. **No Immediate Jeopardy – 15 calendar 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.

7305.2.4 - Nurse Aide Training and Competency Evaluation Program/Competency Evaluation Program

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Instructions and notification requirements for the disapproval of a nurse aide training and competency evaluation program or competency evaluation program can be found in §4132 of this manual. See §7303 for appeal rights for loss of the program.

7305.3 - Overlap of Notice of Remedies

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

1. When the State recommends a category 1 remedy and/or a denial of payment for new admissions, and/or the regional office or State Medicaid Agency imposes any other category of remedies at the same time, the regional office or State Medicaid Agency will send the notice that includes both category 1 and/or denial of payment for new admissions, and other category remedies.

2. When the State recommends and provides notice, as authorized by the regional office or State Medicaid Agency, of a category 1 remedy and/or of imposition of denial of payment for new admissions, and the regional office or State Medicaid Agency imposes other category remedies at a later date, both the State and the regional office or the State and the State Medicaid Agency, send separate notices.

7305.4 - Means of Sending Notice

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The notice shall be in writing and shall be addressed directly to the provider/facility; or to an individual, an officer, managing or general agent, or other agent authorized by appointment or law to receive the notice.

The notice shall be dispatched through first-class mail, or other reliable means. Other reliable means refers to the use of alternatives to the United States mail in sending notices. Electronic communication, such as facsimile transmission, is equally reliable and on occasion more convenient than the United States mail. If electronic means such as

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facsimile transmission are employed to send notice, the sender should maintain a record of the transmission to assure proof of transmission if receipt is denied.

7307 - Immediate Jeopardy Exists
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7307.1 - Statutory and Regulatory Basis
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Sections 1819(h)(2)(A)(I), 1919(h)(1)(A), and 1919(h)(3)(B)(1) of the Act, as well as 42 CFR 488.410, provide how cases involving immediate jeopardy will be processed. In addition, Appendix Q of this manual discusses immediate jeopardy.

7307.2 - Purpose
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Immediate action is required to remove the immediate jeopardy to resident health or safety (as defined in 42 CFR 488.301) and to subsequently correct the deficiencies. The application of the remedies of temporary management or termination, or both, is required to address immediate jeopardy situations. While the use of other remedies in addition to temporary management or termination is allowed, the Act makes it clear that the enforcement action for noncompliant facilities with immediate jeopardy deficiencies is intended to be swift.

7308 - Enforcement Action When Immediate Jeopardy Exists
(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

If at any time during the survey one or more team members identify a possible IJ, the team must meet immediately to confer. If the team agrees that deficiencies pose an IJ, the team leader must contact, while on-site, its management to discuss the findings. If it is determined that IJ exits the team must notify the facility administration, while on-site, of the IJ findings.

When the State Survey Agency identifies IJ, it must notify the CMS Regional Office (RO), or the State Medicaid Agency, or both, as appropriate, so that either agency terminates the provider agreement within 23 calendar days of the last date of the survey, and/or appoints a temporary manager who must remove the IJ within 23 calendar days of the last date of the survey which identified the IJ. When the CMS RO imposes termination of a Medicaid provider agreement, it notifies the State Medicaid Agency to terminate the agreement. However, action can be taken more quickly than 23 days as long as the required notice is given. In either case, the IJ must be removed no later than 23 days from the last day of the survey or the provider agreement will be terminated.

In addition, when IJ is identified on the current survey, (whatever Health and/or LSC survey is currently being performed, e.g., standard, revisit, or complaint), that resulted in serious injury, harm, impairment or death a CMP ***must*** *be imposed.*

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For IJ citations where there is no resultant serious injury, harm, impairment or death but the likelihood is present, a remedy must be imposed; however, the CMS RO may select any remedy that best achieves the purpose of achieving and sustaining compliance and address various levels of noncompliance. See Section 7400 which describes available remedies.

When IJ is identified, the facility must submit an allegation that the IJ has been removed. This allegation must include a plan of sufficient detail to demonstrate how and when the IJ has been removed.

A plan of correction for the deficiencies should be deferred until a revisit is conducted to verify the removal of the IJ. Documentation resulting from the revisit must be completed indicating whether the IJ was removed and deficiencies corrected (Form CMS-2567B), or that the IJ was removed but compliance had not been achieved (Form CMS-2567). When a new Form CMS-2567 is necessary, it should be written with evidence that supports the remaining noncompliance.

NOTE: In order for a 23-day termination to be stopped, the *IJ* **must be removed, even if the underlying deficiencies have not been fully corrected.** Waiting for acceptable plans of correction can result in undue delay in determining removal of *IJ*. Therefore, plan of corrections should be deferred until the *IJ* is removed.

If the facility alleges that the *IJ* is removed and a revisit verifies that it has been removed but the facility is still not in substantial compliance, use the non-*IJ* process, which requires a plan of correction for all citations. *Waiting for the complete statement of deficiencies (Form CMS-2567) and the facility's plan of correction for the non-IJ deficiencies can result in undue delay in determining removal of IJ. Therefore, a Statement of Deficiencies (Form CMS-2567) and a facility's plan of correction for the non-IJ deficiencies may be deferred until the survey agency verifies the IJ is removed.*

In addition, whenever a facility has deficiencies that constitute both IJ ***and*** *substandard quality of care (SQC) (as defined in 42 CFR §488.301), the survey agency must notify the attending physician of each resident found to have received SQC as well as the State board responsible for licensing the facility's administrator. Notify physicians and the administrator licensing board in accordance with §7320.*

7309 - Key Dates When Immediate Jeopardy *(IJ)* Exists

(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

NOTE*: These timelines apply whether the survey was conducted by a State Survey Agency, CMS Regional Office (RO) or a CMS contractor.*

7309.1 - 2nd Calendar Day

(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

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No later than two (2) calendar days (one of which must be a working day) following the last date of the survey which identified *the IJ* the *survey entity must notify* in writing;

- *The CMS RO and the State Medicaid Agency of its findings by e-mail or facsimile (FAX): and,*
- *The facility of the IJ findings and that the survey entity is recommending to the CMS RO and the State Medicaid Agency that the provider agreement be terminated and that a Civil Money Penalty (CMP) or other remedies may be imposed.* A temporary manager may be imposed in lieu of or in addition to termination *(see §488.410)*

This *notice may also* serve as *the* formal notice *from the State Survey Agency* for imposition of any category 1 remedy or denial of payment for new admissions remedy when authorized by *the* CMS *RO* and/or the State Medicaid Agency. *This notice must also* include the facility's right to informal dispute resolution *(IDR) or an independent informal dispute resolution (IIDR)* and to a formal appeal of the noncompliance.

NOTE: *this written notice is separate from the survey entity's responsibility to inform the facility onsite during the survey of the IJ findings and their responsibility to provide a written allegation of removal of the IJ with sufficient detailed information to demonstrate how and when the IJ was removed.*

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7309.2 - 5th -*21st* Calendar Day

(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

Except when formal notice of remedies is provided by the State *Survey Agency*, as authorized by CMS and/or the State Medicaid Agency, the *CMS RO* and/or the State Medicaid Agency issues a formal notification of remedies to the facility. In addition, the notice should include the facility's right to a formal appeal of the noncompliance which led to the temporary management remedy, termination, or any other enforcement actions (except State monitoring). For the temporary management remedy, the notice will advise the facility of the conditions of temporary management and that failure to relinquish control to the temporary manager will result in termination. The general public is also given notice of the impending termination.

7309.3 - *No Later Than 10th Business* Day

(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

If the survey entity verifies that the IJ has been removed, then it must *send the Statement of Deficiencies (Form CMS-2567)* to the facility.

NOTE: *T*he facility must submit *a written* allegation of removal of the *IJ* with sufficient *detailed* information to *demonstrate* how *and when* the *IJ w*as removed. If a *PoC* is to be submitted, it must be received no later than 10 calendar days after the facility receives their *Statement of Deficiencies (Form* CMS-2567).

7309.*4* - By 23rd Calendar Day

(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

Termination takes effect unless the *IJ* has been removed.

7310 - Immediate Jeopardy *(IJ)* Does Not Exist

(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

These procedures incorporate §§1819(h)(2)(A)(ii), 1919(h)(1)(B), and 1919(h)(3)(B)(ii) of the Act, as well as implementing regulations in 42 CFR 488.412.

The broad array of remedies varies in form and severity in recognition of the fact that there can be variations in impact posed by each violation of participation requirements. Therefore, while provider agreement terminations are authorized in non-immediate jeopardy cases, it is not generally necessary or desirable to choose that remedy when substantial compliance may be achieved rapidly through imposition of one or more alternative remedies.

When the surveying entity finds that a facility's deficiencies do not pose IJ to resident health or safety, but the facility is not in substantial compliance, the surveying entity may recommend that the enforcing entity either terminate the facility's provider agreement, or impose alternative remedies, or do both. The State may also provide formal notice of

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imposition and rescission of category 1 remedies and/or denial of payment for new admissions, as authorized by CMS and/or the State Medicaid Agency. The action may be taken immediately, or the facility may be given an opportunity to correct, as described in §7304.

*When the CMS R*egional *O*ffice finds through a validation survey or review of the State's findings that any of the facility's deficiencies do not pose *IJ* to resident health or safety but the facility is not in substantial compliance, the *CMS R*egional *O*ffice must, as appropriate, take action itself to terminate the facility's provider agreement (or stop Federal financial participation), or impose alternative remedies instead of terminating the provider agreement, or both; or direct the State Medicaid Agency to terminate the facility's Medicaid provider agreement. The authority for CMS to take enforcement action for any nursing facility, when CMS finds the nursing facility to be out of compliance, is at §1919(h)(3)(A) and (B).

7312 - Considerations Affecting Enforcement Recommendation to Impose Remedies When Immediate Jeopardy Does Not Exist

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

If the State's recommendation is that alternative remedies be imposed **instead** of terminating the provider agreement, the criteria that permits a Medicare facility (for Medicare) and the State (for Medicaid) to receive continued Federal payment must be met. However, the provision requiring the State's agreement to repay for Medicaid was deleted by the Balanced Budget Act of 1997. The criteria are codified in 42 CFR 488.450 and are included in §7600. If any one of the criteria is not met, the recommendation to impose alternative remedies **instead** of termination cannot be made. When alternative remedies are not preferable as the sole enforcement response, the enforcing entity can either impose remedies in addition to terminating the provider agreement, or only terminate the provider agreement. However, at a minimum, the mandatory denial of payment for all new admissions remedy must be imposed and effective within 3 months from the last date of the survey if the facility has not achieved substantial compliance. (See 42 CFR 488.417 and §7506 for guidance about when and how to impose this mandatory remedy.)

The State recommends, (and/or as appropriate, imposes or gives notice about certain remedies as authorized by CMS or the State Medicaid Agency), termination, or termination plus alternative remedies, or alternative remedies **instead of** termination. (See §7600 for considering alternative remedies instead of termination.)

7313 - Procedures for Recommending Enforcement Remedies When Immediate Jeopardy*(IJ)* Does Not Exist

(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

Once noncompliance is identified, the surveying entity *must first* determine whether to *immediately* impose remedies *in accordance with the criteria in §7304.1* or give the facility an opportunity to correct its deficiencies before *remedies* are imposed.

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7313.*1* - Facilities Given an Opportunity to Correct Deficiencies prior to the Immediate Imposition of Federal Remedies

(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

A facility may be permitted to correct its deficiencies and *delay* the imposition of remedies only when the criteria outlined in §7304.1 of this chapter are not met. *Facilities must submit an acceptable plan of correction for its deficiencies (other than Scope/Severity level A).*

7314 - Special Procedures for Recommending and Providing Notice of Imposition and Rescission of Category 1 Remedies and Denial of Payment for New Admissions Remedy

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Before the State provides formal notice of the imposition of a category 1 remedy and/or denial of payment for new admissions, as authorized by CMS and/or the State Medicaid Agency, the State notifies the regional office and the State Medicaid Agency of its proposed action.

The notice to the regional office or State Medicaid Agency can be electronic or written. If the regional office or State Medicaid Agency has not indicated its disapproval of the category 1 remedies and/or denial of payment for new admissions within 2 calendar days (at least one of which is a work day) of the date of notice, the State sends a letter to the facility providing notice "as authorized by CMS and/or the State Medicaid Agency," (as appropriate) that a category 1 remedy and/or denial of payment for new admissions is being imposed. (See §7311 for CMS's authority to take enforcement action against any nursing facility). A State official signs the letter on behalf of the regional office and/or State Medicaid Agency. A copy of the letter is sent to the regional office and State Medicaid Agency. The regional office notifies the Medicare Area Contractor and the State Medicaid Agency of the denial of payment for new Medicare and/or Medicaid admissions. Formal notice of the rescission of these remedies may also be provided by the State, as authorized by the regional office and/or the State Medicaid Agency. (See also §7311 and §7506.1.)

7315 - Disagreements About Remedies When Immediate Jeopardy Does Not Exist

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Disagreements between the regional office and the State Medicaid Agency about the application of remedies, including the remedy of termination and its timing, should be resolved in accordance with 42 CFR 488.452 and §7807. If the regional office disagrees with the State's recommendation, the regional office will contact the State Medicaid Agency and the State to resolve the differences.

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7316 - Key Dates When Immediate Jeopardy Does Not Exist
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7316.1 - Required Actions When There Is an Opportunity to Correct
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

1. By no later than the 10th working day after the last day of the survey, the State must forward to the facility Form CMS-2567, and an initial letter and other documents and information in accordance with §7305.1.1.

2. By the 10th calendar day after the facility receives Form CMS-2567, it submits its plan of correction to the State addressing all of the required elements as described in §7304.

3. If the facility does not submit an acceptable plan of correction by the 10th calendar day after it receives the Form CMS-2567, the State notifies the facility that it is recommending to the regional office and/or the State Medicaid Agency that remedies be imposed effective as soon as notice requirements are met and/or to effectuate category 1 remedies and/or denial of payment for new admissions. (Civil money penalties may be imposed retroactively, predating the initial notice.)

4. If the State finds the plan of correction acceptable, it notifies the facility by phone, e-mail, etc. The State sends written notice to the facility if the plan of correction is unacceptable. The letter also states recommended remedies if substantial compliance is not verified in accordance with the instructions for verifying compliance in §7317. (See §7305 for notice requirements.)

5. The regional office and/or State Medicaid Agency may provide formal notice of imposition of category 1 remedies and/or denial of payment for new admissions.

6. The State may provide formal notice as authorized by the regional office and/or State Medicaid Agency, of imposition of category 1 remedies and/or denial of payment for new admissions, if applicable. However, such formal notice of imposition of denial of payment for new admissions will most often be provided in the revisit letter rather than in the initial letter. (See also §7301, §7305.1, §7311, §7313.2,§7314, and §7506.1)

7. Except in the case of category 1 remedies and denial of payment for new admissions, if applicable, the regional office and State Medicaid Agency **must** provide notice before enforcement actions are imposed and effective in accordance with §7305.

8. If the State provides formal notice of imposition of a category 1 remedy and/or denial of payment for new admissions, if applicable, it notifies the regional office and/or the State Medicaid Agency 2 calendar days (at least one of which is a working day) before notice is sent to the facility.

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9. If denial of payment for new admissions has not already been imposed and the facility is still out of compliance at the 3rd month after the last day of the survey, the regional office and/or State Medicaid Agency must impose a mandatory denial of payment for all new admissions to be effective 3 months after the last day of the survey. (See §7506.) Formal notice of this remedy may have already been provided in the State's initial letter to the facility (see §7305).

10. No later than the 6th month after the last day of the survey, termination is effective, **or** if an agreement to repay is signed for Medicare, Federal funding is stopped. (See §7600.)

11. The facility may request informal dispute resolution during the same 10 calendar days it has for submitting its plan of correction to the surveying entity; and

7316.2 - Required Actions When There Is No Opportunity to Correct

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

1. By no later than 10 working days after the last day of the survey, the State must forward to the facility Form CMS-2567, an initial letter, and other documents and information in accordance with §7305.1.2. This letter may also provide official notice for imposition of category 1 remedies and/or denial of payment for new admissions by the State, as authorized by CMS and/or the State Medicaid Agency. (See §7305.)

2. If the State provides formal notice of imposition of a category 1 remedy and/or denial of payment for new admissions, if applicable, it notifies the regional office and/or the State Medicaid Agency 2 calendar days (at least one of which is a working day) before notice is sent to the facility. (See also §7311, §7314, and §7506.1)

3. Within the same 10 working days and when the State is not imposing any remedies, as authorized by CMS and/or the State Medicaid Agency, the State forwards notice to the regional office and/or State Medicaid Agency of its recommendation(s) for immediate remedies.

4. The regional office or State Medicaid Agency must provide formal notice of the remedies imposed unless official notice has already been provided by the State, as authorized by CMS and/or the State Medicaid Agency.

5. By the 10th calendar day after the facility receives Form CMS-2567, it submits its plan of correction to the State addressing all of the core elements as described in §7304.

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6. The State may provide notice, as authorized by the regional office or State Medicaid Agency, of imposition of category 1 remedies and/or denial of payment for new admissions.

7. If denial of payment for new admissions has not already been imposed and the facility is still out of compliance at the 3rd month after the last day of the survey, the regional office and/or State Medicaid Agency must impose a mandatory denial of payment for new admissions to be effective 3 months after the last day of the survey. (See §7306.)

8. If the facility has still failed to substantially comply no later than the 6th month after the last day of the survey, termination is effective and Federal funding is stopped.

9. Substantial compliance must be verified in accordance with §7317 in order to stop any remedy(ies) imposed.

10. The facility may request informal dispute resolution during the same 10 calendar day period it has for submitting a plan of correction to the surveying entity.

7317 - *Acceptable* Plan of Correction

(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

Except in cases of past noncompliance, facilities having deficiencies (other than those at scope and severity level A) must submit an acceptable plan of correction. An acceptable plan of correction must:

- *Address how corrective action will be accomplished for those residents found to have been affected by the deficient practice;*
- *Address how the facility will identify other residents having the potential to be affected by the same deficient practice;*
- *Address what measures will be put into place or systemic changes made to ensure that the deficient practice will not recur;*
- *Indicate how the facility plans to monitor its performance to make sure that solutions are sustained; and*
- *Include dates when corrective action will be completed. The corrective action completion dates must be acceptable to the State. If the plan of correction is unacceptable for any reason, the State will notify the facility in writing. If the plan of correction is acceptable, the State will notify the facility by phone, e-mail, etc. Facilities should be cautioned that they are ultimately accountable for their own compliance, and that responsibility is not alleviated in cases where notification about the acceptability of their plan of correction is not made timely.*

The plan of correction serves as the facility's allegation of compliance and, without it, CMS and/or the State have no basis on which to verify compliance. A plan of correction must be submitted within 10 calendar days from the date the facility receives its Form

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CMS-2567. If an acceptable plan of correction is not received within this timeframe, the State notifies the facility that it is recommending to the RO and/or the State Medicaid Agency that remedies be imposed effective when notice requirements are met. The requirement for a plan of correction is in 42 CFR 488.402(d). Further, 42 CFR 488.456(b)(ii) requires CMS or the State to terminate the provider agreement of a facility that does not submit an acceptable plan of correction.

A facility is not required to provide a plan of correction for a deficiency cited as past noncompliance because that deficiency is corrected at the time it is cited; however, the survey team must document the facility's corrective actions on Form CMS-2567.

7317.1 - Verifying Facility Compliance

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

While the plan of correction serves as the facility's allegation of compliance in non-immediate jeopardy cases, substantial compliance cannot be certified and any remedies imposed cannot be lifted until facility compliance has been verified. The chart that follows in this section provides a course of action for certifying compliance based on the seriousness of the noncompliance and the number of revisits that have already occurred. It represents a continuum, ranging from accepting the latest correction date on the facility's approved plan of correction as the date of compliance without an onsite revisit, to conducting an onsite revisit to establish that date. The chart also indicates the circumstances under which revisits must occur and remedies must be imposed, as well as provides policy for conducting revisits, lifting remedies, and certifying compliance. It is important to remember that: revisits may be conducted anytime for any level of noncompliance subject to the allowed number of revisits (see §7317.2, below); remedies may be imposed anytime for any level of noncompliance; and revisits are not assured before termination can occur. Also, it should be noted that this guidance applies to prospective, as well as currently participating, facilities.

7317.2 - Revisits

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

While both paper reviews and onsite reviews are considered to be revisits, only onsite revisits are considered in the revisit count for purposes of the revisit policy.

1. **Mandatory onsite revisits.** An onsite revisit is required when a facility's:

    - beginning survey finds deficiencies that constitute substandard quality of care, harm, or immediate jeopardy. Onsite revisits must continue for these deficiencies even if they lessen to lower levels of noncompliance. However, if the first onsite revisit finds substantial compliance with these tags, no continued onsite revisits are necessary for any other tags that are cited at or below level F (no substandard quality of care).

    - first onsite revisit finds deficiencies that constitute substandard quality of

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care, harm, or immediate jeopardy. Onsite revisits must continue for these deficiencies even if they lessen to lower levels of noncompliance.

- second onsite revisit finds any noncompliance.

The State will seek CMS regional office approval for a third onsite revisit or recommend to the regional office that the facility be terminated.

2. No guarantee of revisit. A facility is not entitled to any revisits; revisits are performed in accordance with guidelines provided in this section and at the discretion of CMS or the State. When conducted, however, one revisit will normally be conducted after a survey which found noncompliance and another before the expiration of the 6-month period by which a facility must be in substantial compliance to avoid termination of its provider agreement. Authorization must be obtained from the regional office for more than two onsite revisits for Medicare-only and dually participating facilities.

The following chart provides the course of action for certifying substantial compliance and for conducting onsite revisits:

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Revisit/Date of Compliance Policy

Revisit #	Substantial Compliance	Old deficiencies corrected but continuing noncompliance at F(no SQC) or below	Old deficiencies corrected but continuing noncompliance at F(SQC), harm or IJ	Noncompliance continues	Any noncompliance
1st revisit	Compliance is certified as of the latest correction date on the approved PoC, unless it is determined that either correction actually occurred between the latest correction date on the PoC and the date of the 1st onsite revisit, or correction occurred sooner than the latest correction date on the PoC.	1. A 2nd onsite revisit is discretionary if acceptable evidence is provided. When evidence is accepted with no 2nd onsite revisit, compliance is certified as of the date confirmed by the evidence. 2. When a 2nd onsite revisit is conducted, acceptable evidence is required if the facility wants a date earlier than that of the 2nd onsite revisit to be considered for the compliance date.	1. A 2nd onsite revisit is required. 2. Acceptable evidence is required if the facility wants a date earlier than that of the 2nd onsite revisit to be considered for the compliance date.	1. A 2nd onsite revisit is required. 2. Acceptable evidence is required if the facility wants a date earlier than that of the 2nd onsite revisit to be considered as the compliance date.	
2nd revisit	Compliance is certified as of the date of the 2nd onsite revisit or the date confirmed by the acceptable evidence, whichever is sooner.				1. A remedy must be imposed if not already imposed. 2. Either conduct a 3rd onsite revisit or proceed to termination.
A 3rd REVISIT IS NOT ASSURED AND MUST BE APPROVED BY THE RO					
3rd revisit	Compliance is certified as of the date of the 3rd onsite revisit.				Proceed to termination.

Examples of acceptable evidence may include, but are not limited to:

- An invoice or receipt verifying purchases, repairs, etc.
- Sign-in sheets verifying attendance of staff at in-services training.
- Interviews with more than 1 training participant about training.
- Contact with resident council, e.g., when dignity issues are involved.

Givens:

- An approved PoC is required whenever there is noncompliance;
- Remedies can be imposed anytime for any level of noncompliance;
- Onsite revisits can be conducted anytime for any level of noncompliance;

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Revisit #	Substantial Compliance	Old deficiencies corrected but continuing noncompliance at F(no SQC) or below	Old deficiencies corrected but continuing noncompliance at F(SQC), harm or IJ	Noncompliance continues	Any noncompliance

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3. Purpose of revisit. The purpose of a revisit is to determine whether substantial compliance has been achieved.

4. Number of onsite revisits. Two onsite revisits are permitted, at the State's discretion, without prior approval from the regional office; a third onsite revisit may be approved only at the discretion of the regional office. Regional offices are limited to approving only this one additional onsite revisit. This policy applies to Medicare-only, dually participating, and State-operated facilities. For Medicaid-only facilities, CMS can neither limit the number of revisits nor require States to obtain approval from the regional office or the State Medicaid Agency for a third onsite revisit; however, States should follow this policy so that the Medicare and Medicaid programs are run consistently.

The effect of specific survey activities on the onsite revisit count follows:

- **Complaint surveys**. Initial complaint investigation visits, whether substantiated or not, are not included in the onsite revisit count. However, when the complaint survey is conducted at the same time as the onsite revisit, the revisit is included in the onsite revisit count. And, although the complaint survey itself is not considered a revisit, any revisits associated with it count toward the onsite revisit count. This also applies to Federal complaint guidelines.

  When a complaint is received and the complaint survey is conducted **after** the third onsite revisit but **before** the 6-month termination date, any deficiencies identified by the complaint survey should be cited and would provide additional evidence in support of the termination action. Since three onsite revisits have already been conducted, another onsite revisit cannot be conducted without consultation with the regional office and central office. Situations such as this should be discussed with the regional office since it may have already sent a termination letter. In addition, States should not use this complaint survey as an opportunity to determine if deficiencies from the third onsite revisit have been corrected.

- **Life safety code surveys**. When the onsite revisit is for the sole purpose of **either** the health survey or the life safety code survey, **but not both**, there are separate revisit counts toward each survey, regardless of the timing of the two surveys and regardless of whether the same entity is performing the surveys and onsite revisits. When the onsite revisit is for both the health survey and the life safety code survey, both surveys are covered by the same onsite revisit count.

- **Visits to determine removal of immediate jeopardy**. An onsite visit to determine if immediate jeopardy has been removed will be included in the onsite revisit count. (See §7308 for documentation requirements.)

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- **Visits to special focus facilities**. The onsite revisit policy applies to Special Focus Facilities as it does to all other facilities, but the extra drop-by visits to these facilities do not count against the onsite revisit count.

- **State monitoring**. Monitoring visits are not included in the onsite revisit count because no survey is being performed. State monitoring is a remedy to oversee the correction of cited deficiencies and ensure that residents are protected from harm; onsite revisits are onsite visits specifically intended to verify correction of deficiencies cited in a previous survey.

5. Timing of revisit. When conducted, onsite revisits occur any time between the last correction date on the plan of correction and the 60th day from the survey date to confirm that the facility is in substantial compliance and, in certain cases, has the ability to remain in substantial compliance. Conducting a revisit before the 60th day allows time for a notice of a mandatory denial of payment for new admissions at the 3rd month, if necessary. If the facility is found to be in substantial compliance, the State will certify compliance.

6. Correction of level A, B, and C deficiencies. While facilities are expected to correct deficiencies at levels A, B, and C, deficiencies at these levels are within the substantial compliance range and, therefore, need not be reviewed for correction during subsequent revisits within the same noncompliance cycle.

7. Revisits to surveys for which substandard quality of care, harm, and immediate jeopardy are cited. When substandard quality of care, actual harm, or immediate jeopardy is cited. onsite revisits must continue for these deficiencies even if they lessen to lower levels of noncompliance. However, if the first onsite revisit determines that the facility has achieved substantial compliance with those affected tags, no continued onsite revisits are necessary for any **other** tags that are cited at or below level F (no substandard quality of care).

8. New Owner. If a new operator assumes the existing provider agreement, he or she is responsible for assuring that corrections are made within the revisit policy.

7317.3 - Noncompliance Cycles

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A noncompliance cycle begins with a recertification, complaint or temporary waiver revisit survey that finds noncompliance and ends when substantial compliance is achieved or the facility is terminated (or voluntarily terminates) from the Medicare or Medicaid program. (See also §7001.) The noncompliance cycle cannot exceed 6 months. Once a remedy is imposed, it continues until the facility is in substantial compliance (and in some cases, until it can demonstrate that it can remain in substantial compliance), or is terminated from the programs.

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7319 - Procedures for Certifying Compliance
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7319.1 - Non-State Operated Skilled Nursing Facilities and Nursing Facilities or Dually Participating Facilities
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

1. The State conducts the survey and certifies compliance.

2. The State sends the facility Form CMS-2567 and if applicable, the "Notice of Isolated Deficiencies Which Cause No Actual Harm With the Potential for Minimal Harm" (Form A), within 10 working days of the last day of survey.

3. If the facility is in substantial compliance, but deficiencies constitute a pattern or widespread findings causing no actual harm and potential for only minimal harm, the State instructs the facility to submit a plan of correction to the State's office. (This must be submitted within 10 calendar days after the facility has received its Statement of Deficiencies.) There is no requirement for the State to conduct a revisit to verify correction, but the facility is expected to comply with its plan of correction.

4. If the facility is in substantial compliance, but has deficiencies that are isolated with no actual harm and potential for only minimal harm, the State records the deficiencies on the Notice of Isolated Deficiencies Which Cause No Actual Harm With the Potential for Minimal Harm (Form A). A plan of correction is not required for these deficiencies, but facilities are expected to correct them.

5. The State enters the certification information into the Certification and Transmittal screen of the certification tab in the Automated Survey Processing Environment system (ASPEN). This can occur as soon as substantial compliance is achieved.

7319.2 - State-Operated Facilities
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

1. The State conducts the survey and documents its findings on Form CMS-2567 and if applicable, on the Notice of Isolated Deficiencies Which Cause No Actual Harm With the Potential for Minimal Harm (Form A).

2. The State forwards its survey findings to the regional office within 10 working days of the last day of the survey.

3. If the facility has deficiencies that are widespread or constitute a pattern and which cause no actual harm and potential for only minimal harm, the regional office instructs the facility to submit its plan of correction to the regional office. The plan of

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correction must be submitted within 10 calendar days after the facility has received its Statement of Deficiencies.

4. The regional office enters the certification information into the Certification and Transmittal screen of the certification tab in the Automated Survey Processing Environment system (ASPEN).

7320 - Action When There is Substandard Quality of Care
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Sections 1819(g)(5)(C) and 1919(g)(5)(C) of the Act and 42 CFR 488.325 require that when a facility is found to have provided substandard quality of care, notification of that finding must be provided to the attending physician of each resident found to have received such care as well as to the State board responsible for licensing the facility's administrator. The facility's ability to provide a nurse aide training and competency evaluation program must also be prohibited for 2 years from the date of the finding of substandard quality of care. (See §7303 for related appeal rights.)

7320.1 - Repeated Substandard Quality of Care
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7320.1.1 - Action to Be Taken When a Facility Is Found to Have Provided Substandard Quality of Care on Last Three Standard Surveys
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Sections 1819(h)(2)(E) and 1919(h)(2)(D) **o**f the Act and 42 CFR 488.414 require that when a facility has been found to have provided substandard quality of care (as defined in 42 CFR 488.301) on the last three consecutive standard surveys, CMS or the State Medicaid Agency, as appropriate, must, regardless of other remedies:

- Deny payment for all new admissions no later than 3 months from the last day of the third consecutive survey in accordance with §7506;
- Impose State monitoring in accordance with §7504; and
- Provide notification of the finding of substandard quality of care to the attending physician of each resident found to have received such care, as well as to the State board responsible for licensing the facility's administrator. These notifications occur **whenever** there is a finding of substandard quality of care.

7320.1.2 - Factors Which May or May Not Affect a Determination of Repeated Substandard Quality of Care
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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The fact that a facility has had any change in its program participation will not affect this determination. In other words, any standard survey completed for Medicare, Medicaid, or both, will be considered in this determination. Termination of a facility would allow the count of repeated substandard quality of care surveys to start over. A change of facility ownership would not allow the count to start over unless the new owner can demonstrate to the State's satisfaction that the poor past performance is no longer a factor due to the change of ownership.

7320.1.3 - Notification Requirements

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Notification to the facility by CMS, or the State Medicaid Agency, or the State, as appropriate, would be in accordance with 42 CFR 488.402. The notice will inform the facility that the remedies will continue until the facility has demonstrated that it is in substantial compliance with requirements and that it will remain in substantial compliance with the requirements. The facility will also be notified that it cannot avoid the imposition of remedies or the obligation to demonstrate that it will remain in compliance when it either alleges correction of the deficiencies cited in the most recent standard survey, or when it achieves compliance before the effective date of the remedies. The finding of repeated substandard quality of care results in the imposition of the remedies specified in §7320.1.1 above, regardless of subsequent correction.

7321 - Skilled Nursing Facility or Dually Participating Facility Readmission to Medicare or Medicaid Program After Termination (Excludes Medicaid-only Nursing Facilities)

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7321.1 - Readmission Criteria

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The general guidelines for readmission can be found in §2016 of this manual.

7321.2 - Reasonable Assurance Concept

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A Medicare provider terminated under 42 CFR 489.53 may not be reinstated into the Medicare program until it has been verified through the "reasonable assurance" process that the provider is capable of achieving **and** maintaining substantial compliance with all applicable participation requirements. There is no statutory or regulatory requirement that States must establish a reasonable assurance period for facilities seeking readmission as a Medicaid-only facility. However, if a terminated facility is readmitted as a nursing facility without undergoing a reasonable assurance period, before it can reenter the Medicare program as a skilled nursing facility or dually participating facility, it must successfully undergo the Medicare reasonable assurance process. With the exception of cases described in 3.2.d of this section, this means that the facility must be found in

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substantial compliance during one survey at the beginning, and another survey at the end, of the reasonable assurance period before it will be readmitted into the Medicare program. The regional office has discretion to accept the Medicaid re-entry survey as the initial reasonable assurance survey. If the facility is found not to be in substantial compliance during **either** reasonable assurance survey, then the facility's application for readmission to the Medicare program following termination is denied and the facility's Medicaid provider agreement is subject to termination.

The reasonable assurance decision is an administrative action, not an initial determination, and is not subject to the appeals process at 42 CFR 498.3(d)(5).

7321.3 - Reasonable Assurance Surveys

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Two surveys are required to verify that the reason for termination no longer exists and that the facility has maintained continued compliance. While both visits need not be full standard surveys, the regional office may require, at its discretion, two full surveys be done in any particular case. Typically, if both visits are not full standard surveys, the first one is partial and the second a full standard. The first survey is conducted at the beginning of the reasonable assurance period to document compliance with the requirements for which there were previous deficiencies. The second is a full standard survey at the end of the reasonable assurance period to document compliance with participation requirements.

7321.3.1 - First Visit

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The first visit only needs to determine whether the deficiencies that led to the termination have been corrected (i.e., are they now completely removed or at the level of substantial compliance). If, upon looking into compliance in these previously problematic areas, the State's first visit finds:

a. there are deficiencies at only levels A, B, or C, then the facility is determined to be in substantial compliance. Therefore, the first visit is acceptable as the first of two mandatory surveys. Any deficiencies found at levels B and C during this visit continue to require the submission of a plan of correction. This visit may be the survey conducted for initial Medicaid certification following termination. If a second survey, conducted at the end of the reasonable assurance period, finds that the facility has maintained substantial compliance throughout that period, the facility may qualify for readmission to the Medicare program.

   The regional office then sets the reasonable assurance period, after which a second (full) survey will be completed. Sometimes, the regional office will already have set the reasonable assurance period in the termination notice. The reasonable assurance period can vary from 1 month to 6 months based upon the

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regional office's judgment of the period necessary to ensure that the facility demonstrates its ability to maintain compliance.

b. deficiencies that fall at level D or higher on the first visit, then these findings will result in denial for purposes of starting Medicare reasonable assurance even if the deficiencies are not in the same regulatory grouping of requirements as those deficiencies that led to termination. The facility does not need to submit a plan of correction.

Any subsequent visit that finds substantial compliance may start the reasonable assurance period.

Following certification for Medicaid and prior to certification for Medicare, any visit that determines noncompliance (either based on a complaint or incident) will result in a finding that reasonable assurance has not been demonstrated. The regional office will issue a denial notice and start the period of reasonable assurance again when the State determines that substantial compliance has been achieved.

7321.3.2 - Second Visit

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The second visit will typically be a full standard survey.

EXCEPTION: The regional office may instruct the State to conduct the full survey during the first visit and the partial survey at the second.

a. If the survey finds no deficiencies or only deficiencies at levels A, B, or C, the facility is determined to be in substantial compliance, and the survey is acceptable for program participation purposes. The facility must submit a plan of correction for any level B and/or C deficiencies found during the second visit/full standard survey.

b. If the survey finds deficiencies at levels D, E, or F, **AND** any of those deficiencies are in the same regulatory grouping of requirements as the deficiencies that caused the facility's termination, the regional office will issue a notice of denial of participation.

c. If the survey finds deficiencies that fall at levels D, E, or F, and the survey finds substandard quality of care, the regional office will issue a notice of denial of participation.

d. If the survey finds deficiencies that fall at levels D, E, or F that do not constitute substandard quality of care and are not in the same regulatory grouping as the deficiencies that caused termination, the regional office **may** accept the second visit/full standard survey for participation based upon receipt of an acceptable plan of correction for all deficiencies above level A, and verification of

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substantial compliance through an onsite visit. While the plan of correction submittal date does not determine the effective date of the agreement, the facility must meet this requirement before an agreement can be issued per 42 CFR 488.402(d).

e. If the survey finds deficiencies above level F (i.e., those that would constitute actual harm or immediate jeopardy), the regional office will issue a notice of denial of participation.

7321.4 - Effective Date of Provider Agreement

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The controlling regulation for setting the effective date of the provider agreement is 42 CFR 489.13(b)(3), which provides that the agreement is effective on the date the skilled nursing facility is in substantial compliance as defined in 42 CFR 488.301 and, if applicable, submits an approvable waiver request. Regulations at 42 CFR 488.301 define substantial compliance as having no deficiencies above level C. This is paralleled at 42 CFR 488.330(f). The effective date is the date the second visit/full standard survey (or its follow-up visit, where required as indicated below) finds substantial compliance.

1. If the second visit finds substantial compliance, the effective date is the survey completion date, regardless of whether the visit is a full standard or a partial survey.

2. If, on the second visit, CMS accepts a plan of correction for deficiencies at levels D, E, or F (without substandard quality of care), the effective date is the date of the facility's attainment of substantial compliance, as verified by a single onsite follow-up visit conducted by the State. This can be a date during the follow-up visit or an earlier date that the State can verify.

NOTE: While the plan of correction submittal date does not determine the effective date of the agreement, the facility must meet this requirement before an agreement can be issued per 42 CFR 488.402(d).

REASONABLE ASSURANCE EXAMPLES

The following examples are illustrative only and do not purport to control any specific case. Terminations occur for a variety of reasons, and the regional office and State will need to exercise discretion in each case.

EXAMPLE 1: NURSING HOME A

Prior History - Nursing Home A is a 150-bed dually participating facility located in a rural area. The facility serves residents with a high acuity level. It is part of a large national, for-profit chain. The facility had been in the program since 05/01/1978. Surveys had revealed condition-level noncompliance in 1987, 1988, 1989, and five level

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A deficiencies in 1994. The facility avoided termination each time by correcting its deficiencies prior to termination. The facility underwent a change of ownership on 06/01/1996. Since 07/01/1995, the facility had been out of compliance in 1996, 1997, and 1998 surveys, but avoided enforcement remedies by attaining compliance before remedies were imposed. The highest level of noncompliance had been at level G during this time with no substandard quality of care. Thus, between the change of ownership in 1996 and the current cycle of surveys leading to termination, the facility's compliance history had been fair.

The termination - The facility was terminated from both programs on 08/08/1999, for failure to attain substantial compliance with program requirements as demonstrated on five State visits within a 6-month period. The survey cycle started with a 02/08/1999 complaint investigation that revealed 22 deficiencies, with no actual harm, and the highest scope and severity of one level F (substandard quality of care due to poor record-keeping of criminal background checks). After an opportunity to correct, a revisit and another complaint investigation conducted on 04/12/1999 revealed continued noncompliance, again with 22 deficiencies, many of which were the same deficiencies (again, no harm). A second revisit on 06/16/1999 revealed continued noncompliance with 10 deficiencies, two of which were at level G. The third revisit on 07/26/1999 was also a standard survey, which revealed 28 deficiencies, with no harm and no substandard quality of care. At this point the organization infused the facility with many additional resources and a decision was made to revisit a final time. The final revisit was conducted on 08/10/1999 and found only three deficiencies at the noncompliance level (two level D's and one level E). Termination was effective 08/08/1999 since the facility was not in substantial compliance within 6 months.

Reasonable Assurance Decision - The facility first applied for Medicaid-only recertification. Medicare certification was not initially sought due to the delay in Form CMS-855 review by the fiscal intermediary, the prohibition on the conduct of a Medicare survey pending Form CMS-855 clearance, and the absence of a reasonable assurance requirement for re-entry into the Medicaid program. Since this would be the initial certification survey for Medicaid, the tasks of both the standard and extended surveys are required, as well as confirming compliance with all regulatory requirements. The Medicaid re-entry survey was conducted on 09/11/1999, with only two level B deficiencies. The facility was certified for Medicaid effective 09/11/1999, the date of receipt of an acceptable plan of correction. On 09/12/1999, the facility applied for re-entry into the Medicare program. After Form CMS-855 clearance by the fiscal intermediary on 11/15/1999, the regional office determined that, based on the initial Medicaid survey, the cause for termination had been removed. The regional office established a reasonable assurance period of 90 days from the date of the Medicaid survey on 09/11/1999. Thus, the second reasonable assurance survey, a standard survey, would be conducted after 12/11/1999.

Rationale - A 90-day reasonable assurance period was chosen due to the fact that the facility remained out of compliance, having many of the same deficiencies over a 6-month period. A longer period was not deemed necessary in consideration of the

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following:

1. The “clean” Medicaid re-entry survey, even though residents continued with a high acuity level;

2. A fair history of compliance since the change of ownership;

3. The State was late in conducting the “annual survey” until 2 weeks before the termination date, yet the facility removed all but three deficiencies by the termination date;

4. The lack of actual harm on three of five visits, with only three deficiencies at a level G over the entire 6-month period despite the fact that the facility provided services to residents with a very high acuity level; and

5. The lack of additional, satisfactory Medicare beds in the area, with the closest facility with vacancies determined to be a problem chain facility in bankruptcy

EXAMPLE 2: NURSING HOME B.

Prior History - Nursing Home B is a 100-bed dually participating facility located in a major metropolitan area. It has been in both programs since 1968. It was previously owned and operated by a large national chain until 1992, when a local corporation that operates no other nursing homes leased the facility. In 1989, the facility had two Conditions of Participation not met. In 1990, one level A deficiency (refers to participation requirement level designation prior to 07/01/1995) was cited. From 1991-1994, several level B deficiencies (refers to participation requirement level designation prior to 07/01/1995 were cited on each survey, but no level A findings. From 07/01/1995 through 03/20/1998, the facility had no findings of substandard quality of care, with one level G, actual harm cited 03/20/1998. In 1995, the remedy of denial of payment for new admissions was initiated, but rescinded because the facility attained compliance prior to the effective date of the remedy. Prior to the 1999 survey cycle, no enforcement actions had ever been taken since the facility consistently corrected its deficiencies after an opportunity to correct.

The termination - The facility was terminated from both programs effective 07/19/1999 due to continued noncompliance cited on five surveys/follow-ups over a 6-month period. The cycle started with a 01/19/1999 complaint survey that revealed 13 deficiencies, three of which were actual harm in Quality of Care. After an opportunity to correct, the State returned on 03/19/1999 and conducted a follow-up and a standard/extended survey that revealed 23 deficiencies, with two deficiencies reflecting substandard quality of care. Another revisit on 05/19/1999 revealed 19 deficiencies, with an immediate jeopardy. A 05/21/1999 monitoring revisit documented removal of the immediate jeopardy, but the prior deficiencies remained. The facility alleged compliance again and the State conducted the final revisit on 07/09/1999, with eight cited deficiencies including actual

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harm and one substandard quality of care. Upon receipt of the regional office's termination notice, a chain organization (with no other facilities in the State) alleged to have purchased the facility on 03/01/1999 and asked the regional office to stop all remedies based on the change of ownership. The regional office did not authorize an additional revisit beyond the 07/09/1999 follow-up since, despite of the facility's repeated allegations of compliance, subsequent revisits found worsening noncompliance. In addition, no change of ownership application had been submitted. Termination was effective on 07/19/1999.

Reasonable Assurance Decision - The facility applied for recertification as a Medicaid-only facility in order to facilitate re-entry and avoid the delays of the fiscal intermediary's Form CMS-855 review. The Medicaid survey was conducted on 08/20/1999 and revealed noncompliance with actual harm with a requirement that was the basis for termination. The facility alleged compliance, and a revisit was conducted on 09/10/1999, which revealed compliance. Medicaid certification was effective 09/10/1999. Since re-entry into the Medicaid program on 09/10/1999, the State returned to the facility on 12/01/1999 to investigate complaints and found noncompliance in one of the regulations that led to the previous termination. The State gave the facility an opportunity to correct before imposing remedies. The facility alleged compliance, and a revisit was conducted on 01/19/2000 which found substantial compliance.

The facility applied for Medicare recertification on 03/01/2000. Upon clearance from the fiscal intermediaries of Form CMS-855 on 05/05/2000, the regional office established a reasonable assurance period of 150 days, with two Medicare re-entry surveys required. The regional office did not accept the Medicaid surveys as a part of its reasonable assurance determination. As a result, the 150-day reasonable assurance period begins with a State survey to determine if the cause for termination still exists. The first reasonable assurance survey was conducted on 05/29/2000. Two level D deficiencies were cited, with neither being the cause for termination. The regional office accepted that survey for establishing the 150-day reasonable assurance period on 05/29/2000. Thus, the State will return after 10/29/2000 to conduct the second reasonable assurance survey (standard and extended survey tasks, as well as confirm compliance with all regulatory requirements).

Rationale - A 150-day reasonable assurance period was sought because:

1. The facility had a worsening compliance record during the 6 months leading to termination;

2. Upon re-entry into Medicaid following termination, the facility could not maintain compliance; and

3. The change of ownership was considered in determining the length of the reasonable assurance process, but was overshadowed by the facility's failure to maintain compliance following termination.

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Enforcement Process

7400 - Enforcement Remedies for Skilled Nursing Facilities *(SNFs)*, Nursing Facilities *(NFs) and Dually Participating* Facilities *(SNFs/NFs)*

(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

Sections 1819(h) and 1919(h) of the Act, as well as 42 CFR §§488.404, 488.406, and 488.408, provide that CMS or the State may impose one or more remedies in addition to, or instead of, termination of the provider agreement when the State or CMS finds that a facility is out of compliance with federal requirements. *Enforcement protocols/procedures are based on the premise that all requirements must be met and take on greater or lesser significance depending on the specific circumstances and resident outcomes in each facility.*

7400.1 - *Available Federal Enforcement Remedies*

(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

In accordance with 42 CFR §488.406, the following remedies are available:

- *Termination of the provider agreement;*
- *Temporary management;*
- *Denial of payment for all Medicare and/or Medicaid residents by CMS;*
- *Denial of payment for all new Medicare and/or Medicaid admissions;*
- *Civil money penalties;*
- *State monitoring;*
- *Transfer of residents;*
- *Transfer of residents with closure of facility;*
- *Directed plan of correction;*
- *Directed in-service training; and*
- *Alternative or additional State remedies approved by CMS.*

7400.2 - *Enforcement Remedies for the State Medicaid Agency*

(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

Regardless of what other remedies the State Medicaid Agency may want to establish in addition to the remedy of termination of the provider agreement, it must establish, at a minimum, the following statutorily-specified remedies or an approved alternative to these specified remedies:

- *Temporary management;*
- *Denial of payment for all new admissions;*
- *Civil money penalties;*
- *Transfer of residents;*
- *Transfer of residents with closure of facility; and*
- *State monitoring.*

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The State Medicaid Agency may establish additional or alternative remedies if the State has been authorized by CMS to do so under its State plan. Guidance on the review and approval (or disapproval) of State Plan amendment requests for alternative or additional remedies can be found in §7805.

Whenever a State Medicaid Agency's remedy is unique to its State plan and has been approved by CMS, then that remedy may also be imposed by the Regional Office against the Medicare provider agreement of a dually participating facility in that State. For example, where CMS has approved a State's ban on admissions remedy as an alternative remedy under the State plan, CMS may impose this remedy but only against Medicare and Medicaid residents; only the State can ban the admission of private pay residents.

7400.3 - *Selection of* Remedies

(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

*T*o select the appropriate remedy(ies) for a facility's noncompliance, the seriousness, *scope and severity* of the deficiencies must first be assessed. *The purpose of federal remedies is to address a facility responsibility to promptly achieve, sustain and maintain compliance with all federal requirements. In addition to the required enforcement action(s), remedies should be selected that will bring about compliance quickly. While a facility is always responsible for all violations of the Medicare and Medicaid requirements, when making remedy choices, the CMS RO should consider the extent to which the noncompliance is the result of a one-time mistake, larger systemic concerns, or an intentional action of disregard for resident health and safety.*

7400.3.1 - *Matrix for Scope & Severity*

(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

Immediate jeopardy to resident health or safety	***J*** ▒	***K*** ▒	***L*** ▒
Actual harm that is not immediate	***G***	***H*** ▒	***I*** ▒
No actual harm with potential for more than minimal harm that is not immediate jeopardy	***D***	***E***	***F*** ▒
No actual harm with potential for minimal harm	***A*** ▇ *No PoC* ▇	***B*** ▇	***C*** ▇
	Isolated	***Pattern***	***Widespread***

▒ *Substandard Q*uality of *C*are *(SQC)* is *defined in* 42 C.F.R. §48*8.301 as one or more deficiencies 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*, related to certain participation requirements.*

▇ 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. Substantial compliance constitutes compliance with participation requirements (42 C.F.R. §488.301).

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residents.

7400.4 - *Other Factors That May Be Considered in Selecting Enforcement Remedy Within a Remedy Category*
(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

Additional factors that may be considered to assist in determining which and/or how many remedies to impose within the available remedy categories for levels of noncompliance, include but are not limited to:

- *The relationship of one deficiency to other deficiencies;*
- *The facility's prior history of noncompliance in general, and specifically with reference to the cited deficiencies; and*
- *The likelihood that the selected remedy(ies) will achieve correction and continued compliance.*

EXAMPLE: *If failure to spend money is the root cause of the facility's noncompliance, then any civil money penalty that is imposed should at least exceed the amount saved by the facility by not maintaining compliance.*

7400.6 - When To Select Remedy From Specific Remedy Category
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7400.6.1 - Category 1
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Select at least one remedy from category 1 when there:

- are isolated deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

- is a pattern of deficiencies that constitutes no actual harm with a potential for more than minimal harm but not immediate jeopardy.

EXCEPT when the facility is in substantial compliance, one or more of the remedies in category 1 may be applied to any deficiency.

CATEGORY 1 remedies include:

- Directed plan of correction (see §7500);

- State monitoring (see §7504); and

- Directed in-service training (see §7502).

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NOTE: As an agent of CMS or the State Medicaid Agency, the State may impose one or more category 1 remedies, as authorized by CMS or the State Medicaid Agency, in accordance with §7314.

7400.6.2 - Category 2

(Rev. 161, Issued: 09-28-16, Effective: 09-23-16, Implementation: 09-23-16)

Select at least one remedy from category 2 when there are:

- Widespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

- One or more deficiencies (regardless of scope) that constitute actual harm that is not immediate jeopardy.

EXCEPT when the facility is in substantial compliance, one or more of the remedies in category 2 may be applied to any deficiency.

NOTE: The State Medicaid Agency does not have the statutory authority to impose the remedy of denial of payment for all Medicare and/or Medicaid residents.

CATEGORY 2 remedies include:

- Denial of payment for all new Medicare and/or Medicaid admissions;
- Denial of payment for all Medicare and/or Medicaid residents, imposed only by the regional office;
- Lower range per day civil money penalties
- Per instance civil money penalties.

7400.6.3 - Selection from Category 3

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Termination or temporary management, or both, must be selected when there are one or more deficiencies that constitute immediate jeopardy to resident health or safety. A civil monetary penalty of $3,050 - $10,000 per day or a civil money penalty of $1,000 - $10,000 per instance may be imposed in addition to the remedies of termination and/or temporary management. Temporary management is also an option when there are widespread deficiencies constituting actual harm that is not immediate jeopardy.

CATEGORY 3 remedies include:

- Temporary management (see §7550);

- Termination (see §7556);

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- Civil money penalties of $3,050 - $10,000 per day of noncompliance optional, in addition to the remedies of termination and/or temporary management (See §7510); or

- Civil money penalties of $1,000 - $10,000 per instance of noncompliance optional (see §7510).

NOTE: Termination may be imposed by the State Medicaid Agency or the regional office at any time. Transfer of residents or transfer of residents with closure of the facility will be imposed by the State, as appropriate. Although temporary management must be imposed when there is a finding of immediate jeopardy (and termination is not sought), temporary management may be imposed for lesser levels of noncompliance.

7410 - Life Safety Code Enforcement Guidelines for Skilled Nursing Facilities and Nursing Facilities

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7410.1 - Application of the Enforcement Regulations to Life Safety Code Surveys Conducted in Skilled Nursing Facilities and Nursing Facilities

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Skilled nursing facilities and nursing facilities must meet the requirements at 42 CFR Part 483, Subpart B, in order to receive payment under Medicare or Medicaid. To certify a skilled nursing facility or nursing facility, complete at least a standard health survey and a life safety code survey. Nursing home enforcement regulations at 42 CFR Part 488, Subpart F, are also applicable to life safety code surveys.

The specific requirement for life safety code is found at 42 CFR 483.70(a), "Life Safety From Fire." A facility may meet this requirement by complying with the prescriptive requirements of the 2000 edition of the life safety code by either waivers of the prescriptive requirements or by the Fire Safety Evaluation System. The Fire Safety Evaluation System is an equivalent system acceptable to CMS as the authority having jurisdiction. These instructions do not require the completion of a Fire Safety Evaluation System (State regulations may restrict its use).

This instruction is applicable when completing Form CMS-2786 - Fire Safety Survey Report forms in long-term care facilities.

7410.2 - Life Safety Code Scope and Severity Determination

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

After a life safety code survey is completed, the life safety code surveyor will use the following guidance to determine the scope and severity level of the resulting deficiencies and the appropriate enforcement action. The definitions below are similar to those used

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for health surveys but have been modified, where appropriate, to be applicable to life safety code surveys.

7410.2.1 - Scope Levels

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The scope of the deficiency reflects the pervasiveness of the deficiency throughout the facility.

Scope is **isolated** when one or a very limited number of residents or employees is/are affected and/or a very limited area or number of locations within the facility are affected.

Scope is a **pattern** when more than a very limited number of residents or employees are affected, and/or the situation has occurred in more than a limited number of locations but the locations are not dispersed throughout the facility.

Scope is **widespread** when the problems causing the deficiency are pervasive (affect many locations) throughout the facility and/or represent a systemic failure that affected, or has the potential to affect, a large portion or all of the residents or employees.

7410.2.2 - Severity Levels

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The severity of the deficiency reflects the impact the deficiency has on the fire safety of the individual. The four severity levels are defined as follows:

- **Level 1 - No actual harm with potential for minimal harm:** A deficiency that has the potential for causing no more than a minor negative impact on the resident(s) or employees.

- **Level 2 - No actual harm with a potential for more than minimal harm that is not immediate jeopardy:** Noncompliance with the requirements of the life safety code that results in the potential for no more than minimal physical, mental, and/or psychosocial harm to the resident or employee and/or that result in minimal discomfort to the residents or employees of the facility, but has the potential to result in more than minimal harm that is not immediate jeopardy.

- **Level 3 - Actual harm that is not immediate jeopardy:** Noncompliance with the requirements of the life safety code that results in actual harm to residents or employees that is not immediate jeopardy.

- **Level 4 - Immediate jeopardy to resident health or safety:** Noncompliance with the requirements of the life safety code that results in immediate jeopardy to resident or employee health or safety in which immediate corrective action is necessary because the provider's noncompliance with one or more of those life safety code requirements has caused, or is likely to cause, serious injury, harm,

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impairment or death to a resident receiving care in a facility or an employee of the facility.

The determination of the scope and severity level when a facility has life safety code deficiencies should be based on the impact the life safety code deficiencies have on the overall level of life safety in the facility. This is because nearly all life safety code requirements deal with safety from harm due to fire. Each instance of threat in a facility can compound attempts at containment, extinguishment, evacuation and/or overall safety. Like health deficiencies, for which a scope and severity determination is made for each deficiency, the survey agency should make a scope and severity assessment for each life safety code deficiency.

This determination should include the likelihood of harm from a fire incident and/or the likelihood of the spread of fire in the facility from any one incident. Consideration in this determination may include, but is not limited to, whether the facility is sprinklered or unsprinklered, the facility's construction type and any special fire protection features the facility may have.

7410.3 - Survey Coordination and Data Entry
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

States vary in the coordination of their life safety code and health surveys (see §2700.C of this manual). While the two surveys occur simultaneously in some States, they do not occur simultaneously in other States. In order to complete data submissions in a timely manner, yet give operational flexibility, input of the life safety code survey data of long-term care facilities should occur no later than 60 days after the conclusion of the long-term care survey. There is no prescribed order of the life safety code survey and health surveys; either may precede the other. Sometimes the same team conducts both the health survey and the life safety code survey but it is more typical that different teams are responsible for each.

7410.4 - Guidance on Enforcement Remedies
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

If a facility does not meet the life safety code requirements at 42 CFR 483.70(a), or the Fire Safety Evaluation System does not show an equivalent level of fire safety, or no Fire safety evaluation system is completed, then the State would determine the scope and severity level for the life safety code deficiencies found on the life safety code survey to determine the enforcement response. The pertinent procedures are found at §§7301 - 7400. If a facility does not meet the requirements at 42 CFR 483.70(a), but shows an equivalent level of fire safety after completion of the Fire Safety Evaluation System, then the facility is found in substantial compliance.

If, after 3 months from the health survey, the facility has not achieved substantial compliance, the denial of payment for new admissions sanction takes effect (see 42 CFR 488.417).

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All deficiencies cited at 42 CFR 483.70(a) that do not constitute immediate jeopardy must be corrected within 6 months. A facility's failure to achieve substantial compliance within 6 months will result in termination. (Immediate jeopardy deficiencies will result in termination within 23 days if the facility does not remove the threat to resident and employee safety by then.).

CMS's revisit policy can be found in §7317. The scope and severity grid can be found in §7400.

The policies and procedures related to citations of past noncompliance are applicable to health (F-tags) and life safety code (K-tags) deficiency citations. For specific guidance, see §7510.

7410.5 - Imposition of Remedies

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

For standard surveys that begin a noncompliance cycle, the survey agency will follow one of two enforcement processes. Instructions follow about how to determine which process to follow. The first process is one in which one enforcement track and set of time frames is followed for all deficiencies, regardless of whether they are life safety code deficiencies or health deficiencies. This process is used when the life safety code portion and health portion of a standard survey occur together or when the beginning of the second (of the two surveys) occurs no more than 7 days from the exit of the first (of the two surveys). Time frames are combined and notices can be combined at the discretion of the survey agency. The second process is one in which two enforcement tracks and two sets of time frames are used for deficiencies, i.e., one track for the life safety code survey and another track for the health survey. This process is used when the standard survey is the beginning survey, and the life safety code portion and health portion of a standard survey occur more than 7 days apart, i.e., the beginning of the second (of the two surveys) occurs more than 7 days after the exit of the first (of the two surveys). Time frames and notices are separate for each survey. Both processes are predicated on the assumption that one or more life safety code requirements have not been waived.

7410.6 - Life Safety Code Survey Waiver Guidance

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The authority to grant waivers of life safety code provisions is found at §1819(d)(2)(B)(I) of the Act and states, "The Secretary may waive, for such periods as he deems appropriate, specific provisions of such Code which if rigidly applied would result in unreasonable hardship upon a facility, but only if such waiver would not adversely affect the health and safety of the residents or personnel, …" The facility must document to the survey agency that there will be no adverse effect on the health and safety of the residents and employees of the facility and that compliance would result in an unreasonable hardship on the facility for each specific code provision recommended for a waiver.

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The above authority to grant life safety code waivers does not include other Physical Environment requirements at 42 CFR 483.70 unless specifically provided for. Refer to §7014 for further guidance of non-life safety code requests for waivers or variations.

Waivers are classified into two groups: temporary waivers for a defined time period; and continuing waivers that are of indeterminate duration.

7410.6.1 - Temporary Waiver

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A temporary waiver for a defined time period may be considered for a finding for which corrective action will take more than 90 days to complete. If a waiver is granted during that time, sanctions will not be imposed under the long-term care enforcement regulations. Examples of the type of corrective action that could warrant a temporary waiver could include installation of a sprinkler system or a smoke barrier. Examples of deficiencies that could warrant such waivers include the obstruction of exiting, penetrations of smoke barriers, and increased travel distances to exits due to new construction or remodeling of a wing of a facility. In these cases, the waiver would be for a reasonable period of time for construction activities, including planning and design. The waiver documentation submitted by the facility for approval would include a timetable with milestone dates of major activities to correct the deficiency that the surveyor could monitor on any subsequent follow-up visits. Extensions and modifications of this timetable are not envisioned except under extreme circumstances. Failure of the facility to follow the timetable and the milestones established in the approved temporary waiver would subject the facility to the remedies prescribed in the enforcement regulations. If the construction activities are completed within the agreed upon timetable and the deficiency is corrected, the existence of the waiver is no longer cited on the Form CMS-2567.

When the temporary waiver of life safety code requirements is in effect, the facility should have increased fire safety awareness. This increased fire safety awareness may include the establishment of interim safety measures such as a fire watch during construction, an increased number of fire drills and training of staff at the facility, or other measures that would provide an increased measure of fire protection.

7410.6.2 - Continuing Waivers

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Continuing waivers of a specific life safety code requirement are granted when the noncompliance cannot be corrected without an unreasonable financial hardship on the facility and it does not pose a threat to residents' health and safety. The State cites the deficiency on each annual survey although they do not expect it to be corrected by the facility due to the existence of the waiver. Examples of this type of finding may include improper corridor width either before or after remodeling, a dead-end corridor longer than the specified life safety code length, a specific construction type not met, a

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noncompliant interior finish type, excessive exit travel distance, or waiting areas open to the corridor in a non-sprinklered facility. CMS grants waivers after an evaluation of the specific life safety code deficiency cited and its impact on the life safety of the facility.

A waiver of a life safety code requirement that cannot be corrected and which is likely to be cited on each future life safety code survey may be granted for more than 1 year or survey interval. For example, CMS could grant a waiver for a 3-year period after which the State reviews it during the life safety code survey; if the waiver is still appropriate, it can be extended for another 3-year period. The survey agency cites the deficiency on the annual survey and on the Form CMS-2567 but reviews the waiver only after the expiration of the 3-year period. The plan of correction, submitted by the facility for that deficiency, would cite the existence of a waiver.

7410.6.3 - Enforcement and Waived Life Safety Code Requirements

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

For those life safety code requirements that CMS has temporarily waived, the following enforcement timetable should be used:

ENFORCEMENT TIMETABLES

Day 1:	**The date of the follow-up survey to determine if they have met the plan of correction.** This date can be no sooner than the provider's projected correction date, indicated on an approved plan of correction. Even if substantial compliance is not achieved, CMS lifts the waiver on this date and the "enforcement clock" starts.*
3rd Month:	**Denial of payment for new admissions** is imposed based on life safety code noncompliance cited when CMS lifts the waiver, and noncompliance continues for a 3-month period after that date.
6th Month	**Termination occurs**, based on life safety code noncompliance cited when CMS lifts the waiver, and noncompliance continues up to a 6-month period after that date.

*Day 1 can occur a substantial amount of time after the life safety code survey that originally triggered the waiver.

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Remedies

7500 - Directed Plan of Correction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7500.1 - Introduction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

These procedures implement the regulatory requirements in 42 CFR 488.424 for imposing a directed plan of correction. A directed plan of correction is one of the category 1 remedies the State or regional office can select when it finds a facility out of compliance with Federal requirements.

7500.2 - Purpose
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The purpose of the directed plan of correction is to achieve correction and continued compliance with Federal requirements. A directed plan of correction is a plan that the State or the regional office, or the temporary manager (with State or regional office approval), develops to require a facility to take action within specified time frames.

Achieving compliance is ultimately the facility's responsibility, whether or not a directed plan of correction is followed. If the facility fails to achieve substantial compliance after complying with the directed plan of correction, the State or regional office may impose another remedy until the facility achieves substantial compliance or is terminated from the Medicare or Medicaid programs.

7500.3 - Elements of a Directed Plan of Correction
A directed plan of correction should address all of the elements required for a facility-developed plan of correction. (See §7304)

7500.4 - Causes
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Use of a directed plan of correction should be dependent upon causes identified by the State, regional office, or temporary manager. For example, a directed plan of correction may be appropriate when a facility's heating system fails. The directed plan of correction would specify that the heating system must be repaired or replaced within a specific time frame. If the cause of the noncompliance was a specific structural problem, the facility could be directed to implement identified structural repairs such as a new roof, or renovations such as replacement of rusted sinks in common bathrooms.

7500.5 - Notice of Imposition of Directed Plan of Correction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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A directed plan of correction may be imposed 15 calendar days after the facility receives notice in non-immediate jeopardy situations and 2 calendar days after the facility receives notice in immediate jeopardy situations. The date the directed plan of correction is imposed does not mean that all corrections must be completed by that date.

7502 - Directed In-Service Training

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7502.1 - Introduction

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

These instructions implement 42 CFR 488.425. Directed in-service training is one of the remedies the State or regional office can select when it finds a facility out of compliance with Federal requirements.

7502.2 - Purpose

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Directed in-service training is a remedy that may be used when the State, CMS, or the temporary manager believe that education is likely to correct the deficiencies and help the facility achieve substantial compliance. This remedy requires the staff of the facility to attend an in-service training program. The purpose of directed in-service training is to provide basic knowledge to achieve and remain in compliance with Federal requirements.

7502.3 - Appropriate Resources for Directed In-Service Training Programs

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Facilities should use programs developed by well-established centers of geriatric health services education such as schools of medicine or nursing, centers for the aging, and area health education centers which have established programs in geriatrics and geriatric psychiatry. If it is willing and able, a State may provide special consultative services for obtaining this type of training. The State or regional office may also compile a list of resources that can provide directed in-service training and could make this list available to facilities and interested organizations. Facilities may also utilize the ombudsman program to provide training about residents' rights and quality of life issues.

7502.4 - Further Responsibilities

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The facility bears the expense of the directed in-service training. After the training has been completed, the State will assess whether compliance has been achieved. If the facility still has not achieved substantial compliance, the State Medicaid Agency or the regional office may impose one or more additional remedies as specified in 42 CFR 488.206.

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7502.5 - Notice of Imposition of Directed In-Service Training
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Directed in-service training may be imposed 15 calendar days after the facility receives notice in non- immediate jeopardy situations and 2 calendar days after the facility receives notice in immediate jeopardy situations.

7504 - State Monitoring
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7504.1 - Introduction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

This section is established pursuant to §1819(h)(2)(E)(ii) and §1919(h)(2)(D)(ii) of the Act (which cross-refers to §1819(g)(4)(B) and §1919(g)(4)(B) of the Act) and 42 CFR 488.422 to provide guidance in applying the remedy of State monitoring. This section also explains when State monitoring is imposed and the qualifications for a State monitor.

7504.2 - Purpose
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A State monitor oversees the correction of cited deficiencies in the facility as a safeguard against further harm to residents when harm or a situation with a potential for harm has occurred.

7504.3 - Qualifications
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Monitors are identified by the State as appropriate professionals to monitor cited deficiencies. A monitor meets the guidelines regarding conflicts of interest in §7202 and:

- Is an employee or contractor of the State;
- Is not an employee or contractor of the monitored facility; and
- Does not have an immediate family member who is a resident of the facility.

7504.4 - When to Impose the State Monitoring Remedy
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The Act requires State monitoring if a facility has been found on three consecutive standard surveys to have provided substandard quality of care. Otherwise, State monitoring may be considered an optional remedy. For example, some situations in

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which State monitoring may be appropriate include, but are not limited to, the following:

- Poor facility compliance history, e.g., a pattern of poor quality of care, many complaints, etc.;
- State concern that the situation in the facility has the potential to worsen;
- Immediate jeopardy exists and no temporary manager can be appointed;
- If the facility refuses to relinquish control to a temporary manager, a monitor may be imposed to oversee termination procedures and transfer of residents; or
- The facility seems unable or unwilling to take corrective action for cited substandard quality of care.

7504.5 - Frequency

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

When State monitoring is imposed, the State appoints a monitor or monitors. Monitoring may occur anytime in a facility, e.g., the State may determine that ongoing monitoring is needed 24 hours a day, 7 days a week, or it may determine that monitoring is only needed periodically. In all instances, monitors have complete access to all areas of the facility, as necessary, for performance of the monitoring. Factors used to determine how often a facility is monitored may include, but are not limited to, the following:

- The nature and seriousness of the deficiencies as specified by the State; and
- The timing and frequency of when the problems occurred, e.g., mealtimes, evening shifts, daily, etc.

Monitors may be assigned to the facility at these specific times for a specified number of days, as determined by CMS or the State, to ensure corrective action.

7504.6 - Duration

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The remedy is discontinued when:

- The facility's provider agreement is terminated; or
- The facility has demonstrated to the satisfaction of CMS or the State that it is in substantial compliance with the requirements and, if imposed for repeated substandard quality of care, that it will remain in substantial compliance.

Continued compliance can be demonstrated by adherence to a plan of correction which delineates what systemic changes will be made to ensure that the deficient practice will

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not recur and how the facility will monitor its corrective actions to ensure it does not recur.

7506 - Denial of Payment for all New Medicare and Medicaid Admissions for Skilled Nursing Facilities and Nursing Facilities

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7506.1 - Introduction

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Sections 1819(h) and 1919(h) of the Act and 42 CFR 488.417 provide for the denial of payment for all new Medicare and Medicaid admissions when a facility is not in substantial compliance. Substantial compliance is defined in 42 CFR 488.301 and in §7001 and guidance on situations likely to be encountered can be found in Appendix P of this manual. This remedy may, and in certain instances, must, be imposed by CMS or the State Medicaid Agency. Denial of payment for new admissions may be imposed alone or in combination with other remedies to encourage quick compliance. Formal notice of the imposition and rescission of this remedy may also be provided by the State, as authorized by the regional office and/or the State Medicaid Agency (See §7311 and §7314.)

7506.2 - Optional Denial of Payment for All New Admissions Remedy

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Sections 1819(h)(2)(B)(i) and 1919(h)(2)(A)(i) of the Act and 42 CFR 488.417(a) cover the optional denial of payment for new admissions. This remedy may be imposed anytime a facility is found to be out of substantial compliance, as long as the facility is given written notice at least 2 calendar days before the effective date in immediate jeopardy situations and at least 15 calendar days before the effective date in non-immediate jeopardy situations. CMS will accomplish the denial of payment remedy through instructions to the appropriate Medicare Area Contractor and/or the regional office. States must have written procedures approved by CMS through their State plans on how to apply the denial of payment remedy. These procedures must be approved by the regional office.

- Medicare Facilities. CMS must deny payment to the facility for all new Medicare admissions.

- Medicaid Facilities. The State Medicaid Agency must deny payment to the facility, and CMS must deny Federal financial participation to the State Medicaid Agency for all new Medicaid admissions.

7506.3 - Mandatory Denial of Payment for All New Admissions Remedy

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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Sections 1819(h)(2)(D) and (E) and 1919(h)(2)(C) and (D) of the Act and 42 CFR 488.417(b) require that, regardless of any other remedies that may be imposed, denial of payment for new admissions must be imposed when the facility is not in substantial compliance 3 months after the last day of the survey identifying deficiencies, or when a facility has been found to have furnished substandard quality of care on the last three consecutive standard surveys (see 42 CFR 488.414).

- Medicare Facilities. CMS must deny payment to the facility for all new Medicare admissions.

- Medicaid Facilities. The State Medicaid Agency must deny payment to the facility, and CMS must deny Federal financial participation to the State Medicaid Agency for all new Medicaid admissions to the facility.

7506.4 - Duration and Resumption of Payments
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Generally, if the facility achieves substantial compliance and it is verified in accordance with §7317, CMS or the State Medicaid Agency must resume payments to the facility **prospectively** from the date it determines that substantial compliance was achieved. However, when payment is denied for repeated instances of substandard quality of care, the remedy may not be lifted until the facility is in substantial compliance **and** the State or CMS believes that the facility will remain in substantial compliance. No payments are made to reimburse the facility for the period of time between the date the remedy was imposed and the date that substantial compliance was achieved. CMS accomplishes the denial of payment remedy through written instructions to the appropriate Medicare Area Contractor in Medicare cases, and in Medicaid cases, through written instructions from the regional office.

7506.5 - Effect of Remedy on Status of Residents Admitted, Discharged, or on Temporary Leave and Readmitted Before, On, or After the Effective Date of the Denial of Payment for New Admissions Remedy
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

(See also instructions for Fiscal Intermediaries, Pub. 60AB, Program Memorandum AB-01-131.) The resident's status on the effective date of the denial of payment for new admissions remedy is the controlling factor in determining whether readmitted residents are subject to the sanction. Guidelines follow:

- Medicare and Medicaid residents admitted and discharged before the effective date of the denial of payment for new admissions remedy are considered new admissions if they are readmitted on or after the effective date. Therefore, they are subject to the sanction.

- Medicare and Medicaid residents admitted on or after the effective date of the denial of payment for new admissions remedy are considered new admissions. If

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readmitted after being discharged, they continue to be considered new admissions and are subject to the sanction.

- Medicare and Medicaid residents admitted before and discharged on or after the effective date of the denial of payment for new admissions remedy are considered new admissions if subsequently readmitted. Therefore, they are subject to the sanction.

- Medicare and Medicaid residents admitted on or after the effective date of the denial of payment for new admissions remedy who take temporary leave are not considered new admissions when they return, but continue to be subject to the sanction.

- Private pay residents admitted after the effective date of the denial of payment for new admissions remedy and then become eligible for Medicare or Medicaid, are subject to the sanction.

- Medicare and Medicaid residents admitted before the effective date of the denial of payment for new admissions remedy who take temporary leave before, on, or after the effective date of the denial of payment remedy are not considered new admissions upon return and, therefore, are not subject to the sanction.

- Private pay residents in a facility prior to the effective date of the denial of payment for new admissions remedy who become eligible for Medicare or Medicaid on or after the effective date of the denial of payment for new admissions remedy are not subject to the sanction.

NOTE:

1. The term “temporary leave” refers to residents who leave temporarily for any reason. If residents were not subject to a denial of payment when they went on temporary leave, the term indicates that upon return they are not considered new admissions for purposes of the sanction. Therefore, since there is an expectation that this resident will return to the facility, the term “temporary leave” is used to justify a resumption of any interrupted payment upon re-entry into the facility.

2. The term “discharge” refers to individuals who have left the facility and there is no expectation that they will return.

3. Only Part A providers are subject to the denial of payment for new admissions remedy.

A resident who is not subject to the denial of payment sanction and goes on temporary leave, whether or not there is a leave of absence, is not considered to be a new admission for the purposes of the denial of payment remedy, upon his/her return to the facility. Any

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interrupted payment will be resumed. In either situation, it is expected that the resident will return to the facility following leave.

7508 - Secretarial Authority to Deny All Payment for All Medicare and Medicaid Residents

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7508.1 - Introduction

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Sections 1819(h)(2)(B)(i) and 1919(h)(3)(C)(i) of the Act and 42 CFR 488.418 provide that if a facility has not met a requirement, the Secretary may deny any further payment to the facility for all Medicare residents, and to a State Medicaid Agency for all Medicaid residents in the facility. This is in addition to the authority to deny payment for all new admissions discussed in §7506. Although either CMS or the State Medicaid Agency may deny payment for all new Medicare and/or Medicaid admissions as described in §7506, only CMS has the authority to deny all payment for Medicare and/or Medicaid residents. (The State, however, may recommend that CMS impose this remedy.) The denial of all payment remedy may be imposed anytime the facility is found to be out of substantial compliance (as defined in 42 CFR 488.301), as long as the facility is given written notice at least 2 calendar days before the effective date in immediate jeopardy situations and at least 15 calendar days before the effective date in non-immediate jeopardy situations. CMS will provide the State with timely notification whenever it decides to impose this remedy.

Although §1819(h)(2)(B)(i) and §1919(h)(3)(C)(i) of the Act and 42 CFR 488.418(a) provide that the Secretary may impose this remedy whenever a facility has not met a requirement, it is a severe sanction. Factors to be considered in selecting this remedy could include:

1. Seriousness of current survey findings;

2. Noncompliance history of facility; and

3. Use of other remedies that have failed to achieve or sustain compliance.

7508.2 - Duration and Resumption of Payments

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Generally, if a facility achieves substantial compliance, CMS resumes payments to the facility **prospectively** from the date that it verifies (in accordance with §7317) as the date that the facility achieved substantial compliance. No payments are made to reimburse the facility for the period of time between the date the remedy was imposed and the date that CMS verifies as the date that the facility achieved substantial compliance. When CMS denies payment for all Medicare residents for three consecutive findings of substandard quality of care, the denial of payment cannot be lifted until the facility achieves

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substantial compliance and CMS believes that the facility will remain in substantial compliance.

Civil Money Penalties

7510 - Basis for Imposing Civil Money Penalties
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The following procedures incorporate §1819(h)(1) and (2)(B) and §1919(h)(1) of the Act and 42 CFR 488.430 through 488.444. CMS or the State may impose a civil money penalty for the number of days that a facility is not in substantial compliance with one or more participation requirements, or for each instance that a facility is not in substantial compliance, regardless of whether the deficiencies constitute immediate jeopardy. Additionally, the per day or per instance civil money penalty maybe imposed for past noncompliance. An "instance" is a single deficiency identified by the tag number used as a reference on the CMS-2567 and in Appendix PP of this manual. There can be more than one instance of noncompliance identified during a survey. (See §7510.2 for guidance on past noncompliance.)

> **NOTE:** The per day and the per instance civil money penalty cannot be used simultaneously during a specific survey (i.e., standard, revisit, complaint), but both types of civil money penalties may be used during a noncompliance cycle if more than one survey takes place **and** the per day civil money penalty was not the civil money penalty initially imposed. However, when a per day civil money penalty is the civil monetary penalty sanction initially imposed, a per instance civil money penalty cannot be imposed on a subsequent survey within the same noncompliance cycle.

The regional office or State Medicaid Agency may impose a civil money penalty between $3,050 and $10,000 per day of immediate jeopardy, or between $50 and $3,000 per day of non-immediate jeopardy, or a "per instance" civil money penalty from $1,000 to $10,000 for each deficiency.

A civil money penalty is a valuable enforcement tool because it can be imposed, under certain circumstances, for each day that a facility is out of compliance with participation requirements or for each instance of noncompliance. If imposed, a facility cannot avoid the remedy. The civil money penalty may be imposed immediately or after a facility is given an opportunity to correct and a revisit finds that the facility remains out of compliance. However, a menu of remedies from which to choose exists, and a civil money penalty may not be the most appropriate choice of remedy in every situation of noncompliance. The imposition of a civil money penalty may be most appropriate when a facility is not given an opportunity to correct, when immediate jeopardy exists, when noncompliance is at levels G, H, I, or when there is a finding of substandard quality of care. States and regional offices are encouraged to develop methods to ensure that civil money penalty amounts are applied consistently within the broad ranges identified at 42 CFR 488.408.

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7510.1 – Determining Citations of Past Noncompliance at the Time of the Current Survey

(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

Past noncompliance may be identified during any survey. For the purpose of making determinations of current noncompliance or past noncompliance, the survey team is expected to follow the investigative protocols and surveyor guidance. To cite past noncompliance with a specific survey data tag (F-tag or K-tag), all of the following three criteria must be met:

1. The facility was not in compliance with the specific regulatory requirement(s) (as referenced by the specific F-tag or K-tag) at the time the situation occurred;
2. The noncompliance occurred after the exit date of the last standard (recertification) survey and before the survey (standard, complaint, or revisit) currently being conducted; and
3. There is sufficient evidence that the facility corrected the noncompliance and is in substantial compliance at the time of the current survey for the specific regulatory requirement(s), as referenced by the specific F-tag or K-tag.

A nursing home does not provide a plan of correction for a deficiency cited as past noncompliance because the deficiency is already corrected; however, the survey team documents the facility's corrective actions on the CMS-2567.

Regulations at 42 CFR 488.430(b) provide that a Civil Money Penalty *(CMP)* may be imposed for past noncompliance since the last standard survey. CMS strongly urges States to recommend the imposition of a *CMP* for past noncompliance cited at the level of immediate jeopardy.

When a *CMP* is recommended, the State *Survey Agency* notifies the *CMS* Regional Office *(RO)* and/or State Medicaid Agency within 20 days from the last day of the survey that determined past noncompliance of its recommendation to impose a *CMP*. The *CMS RO* and/or State Medicaid Agency responds to the recommendation within 10 days, and if accepted, sends out the formal notice in accordance with the notice requirements in §7305 and §7520.

7510.2 – Documentation of Past Noncompliance Citations on the CMS-2567

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Past noncompliance may be cited on health and/or life safety code surveys of nursing homes. Past noncompliance may be cited on any type of survey (standard, recertification, abbreviated standard, e.g., complaint and revisit). Data about past noncompliance tags are not carried forward to subsequent revisit surveys.

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Past noncompliance is documented at the actual deficiency tag (F-tags for health deficiencies or K-tags for life safety code deficiencies) where past noncompliance is identified. A scope and severity determination is assigned to a past noncompliance citation. Surveyors document on the CMS-2567 the nursing home's actions to correct the past noncompliance.

CMS or the State indicates in the appropriate data field in the Automated Survey Processing Environment system (ASPEN) whether a citation is past noncompliance. Tags cited as past noncompliance will appear in tag number order on the CMS-2567. The provider's plan of correction column on the CMS-2567 will print "Past noncompliance-no plan of correction required" for tags identified as past noncompliance.

The ASPEN Certification Procedures Guide includes technical information about past noncompliance citations. This guide is located at the following Web site address: https://www.qtso.com/aspenmanguide.html.

7510.3 – Applicability to Disapproval of Nurse Aide Training and Competency Evaluation Program

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The provisions of §7809 (NATCEP Disapprovals) apply to findings of past noncompliance. (See also §7809.2.)

7512 - Compliance With Section 1128A of the Social Security Act

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The regional office consults with the regional attorney's office to ensure compliance with §1128A of the Act and Department of Justice requirements. Section 1128A of the Act requires CMS to offer a hearing before collecting, **but not before imposing**, a civil money penalty.

For nursing facilities, §1919(h)(2) of the Act require States to implement remedies by either State statute or regulation. State law may include additional specific requirements that must be met. Section 1919(h)(8) of the Act requires States to offer a hearing before collecting a civil money penalty.

7514 - Special Procedures Regarding Compliance Decision and Overlap of Remedies

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

If CMS and the State Medicaid Agency both want to impose civil money penalties on any given facility, only CMS's civil money penalty is imposed. Special procedures specified in §7807 implement the provisions of §1919(g)(6) and §1919(g) (7) of the Act as well as 42 CFR 488.452 regarding whether the State or Federal remedy decision takes

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precedence in non-immediate jeopardy situations involving non-State operated nursing facilities and dually participating facilities.

7516 - Determining Amount of Civil Money Penalty
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7516.1 - Range of Penalty Amounts
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Civil money penalties are imposed in increments of $50.00.

1. Lower Range of Penalty Amounts for Per Day Civil Money Penalty

Penalties in the range of $50 to $3,000 per day may be imposed when immediate jeopardy does not exist, but the deficiencies either caused actual harm, or caused no actual harm, but have the potential for more than minimal harm. A civil money penalty may not be less than $50.00 per day.

2 Upper Range of Penalty Amounts for Per Day Civil Money Penalty

Penalties in the range of $3,050 to $10,000 per day may be imposed for deficiencies constituting immediate jeopardy. Penalties may also be in the upper range of penalty amounts for deficiencies when immediate jeopardy does not exist if a penalty in the lower range of penalty amounts was previously imposed and the deficiencies in the same regulatory grouping are repeated. Repeated deficiencies are defined in §7516.3.

2. Range of Per Instance Penalty Amounts

Penalties in the range of $1,000 to $10,000 per instance(s) may be imposed for noncompliance that constitutes actual harm, or for noncompliance that has the potential for more than minimal harm. The terminology “per instance” is not used to suggest that only one instance of noncompliance may be assigned a civil money penalty. There can be more than one instance of noncompliance identified during a survey where the State utilizes the per instance civil money penalty as an enforcement remedy. The total dollar amount of the civil money penalty for the instance or multiple instances of noncompliance may not exceed $10,000 for that specific survey, and may not be less than $1,000 per instance.

NOTE: In situations of past noncompliance, see §7510.1 and §7510.2.

7516.2 - Factors Affecting Amount of Penalty
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

(Also see §7400.) Once the decision is made to impose a civil money penalty for facility noncompliance, regardless of whether the noncompliance is current or past, the following

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factors are considered in determining the specific amount of the civil money penalty to impose within the appropriate range:

1. The facility's history of noncompliance, including repeated deficiencies. This information may be obtained from:

    a. Provider files maintained in the State or the regional office from the current survey and the past three surveys, and,

    b. Facility-specific reports maintained in the Automated Survey Processing Environment system (ASPEN) and the Certification and Survey Provider Enhanced Reporting system (CASPER), from the current survey and the past three surveys;

2. The facility's financial condition. The following is only a suggested list of sources for this information and is not intended to represent exclusive or mandatory sources of information:

    a. Resources available to the facility;

    b. Information furnished by the facility (e.g., in the letter notifying the facility that civil money penalties are being imposed, ask the facility to provide any information that could have an impact on the amount of the civil money penalty);

    c. Consultation with the Medicare Area Contractor (e.g., ask for pertinent facility financial information before CMS sends the notice to the facility to impose civil money penalties); or

    d. Consultation with the State Medicaid Agency (e.g., ask for pertinent facility financial information before CMS sends the notice to impose civil money penalties);

3. Seriousness and scope of the deficiencies. Appendix P of this manual provides guidance about the seriousness and scope of the identified deficiencies. Appendix Q of this manual provides guidance about determining the existence of immediate jeopardy.

4. The relationship of one deficiency to other deficiencies.

5. The facility's degree of culpability. A facility is always responsible for the health and safety of its residents. A facility is culpable if noncompliance causing harm or placing a resident at risk of harm is intentional or is a product of neglect, indifference, or disregard.

6. Any other remedies being imposed in addition to the civil money penalty.

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7516.3 - Changing Amount of Civil Money Penalty
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

When the per instance civil money penalty has been selected as an enforcement remedy, the provision for changing the amount of the civil money penalty does not apply and no opportunity to correct is provided.

The amount of a per day civil money penalty can be adjusted within a given civil money penalty range.

The range of a per day civil money penalty amount may be decreased or increased in accordance with the guidance that follows:

1. Decreasing Per Day Civil Money Penalty Range

If a civil money penalty is imposed for a situation of immediate jeopardy and the immediate jeopardy is removed but the noncompliance continues, CMS or the State will shift the penalty amount to the lower range of penalty amounts.

2. Increasing Per Day Civil Money Penalty Range

Before the hearing, and following a revisit showing continued noncompliance, CMS or the State may propose to increase the penalty amount for facility noncompliance, which after imposition of a lower level penalty amount, becomes sufficiently serious to pose immediate jeopardy.

If a civil money penalty is imposed, CMS and the State must increase the 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 deficiencies when immediate jeopardy does not exist.

3. Repeated Deficiencies

(See 42 CFR 488.438(d)(3).) These are deficiencies found at the last standard or abbreviated standard survey for which a civil money penalty was imposed and sustained, and which are subsequently corrected and the facility is certified in compliance, but deficiencies in the same regulatory grouping of requirements are found again at the next standard or abbreviated standard survey. For example, a civil money penalty is imposed and sustained in some amount for deficiencies under Quality of Care related to hydration (see 42 CFR 483.25(j)) during a standard survey. These deficiencies are corrected at the time of the revisit. However, at the next survey, the facility has deficiencies in Quality of Care related to nutrition. (See 42 CFR 483.25(i).) In this situation, if a civil money penalty is imposed for the repeated noncompliance, it should be higher than the civil money penalty that was previously imposed for the Quality of Care deficiencies pertaining to hydration.

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If the amount of the civil monetary penalty is modified, a notice is sent to the facility as quickly as possible notifying it of the revised penalty amount, the date that the revised amount is effective, and an explanation for the changed amount. The revised amount is effective on the date that is verified as the date of the change in the facility's noncompliance.

The following example illustrates how the accrual is calculated when a civil money penalty is altered.

EXAMPLE: A civil money penalty is imposed for 4 days of immediate jeopardy at $3,500 per day; the amount is shifted to $1,000 per day when the immediate jeopardy is removed; and the facility is in substantial compliance with the requirements on the 11th day. A civil money penalty is imposed for 10 days of noncompliance. The total amount of the penalty is $20,000. [($3,500x4) + ($1,000 x6) = $20,000.] The revised amount is also recorded in the Automated Survey Processing Environment (ASPEN) Civil Money Penalty Tracking System.

7516.4 – Reduction of a Civil Money Penalty by 50 Percent for Self-Reporting and Prompt Correction of Noncompliance

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

CMS will reduce a civil money penalty by 50 percent when a facility self-reports and promptly corrects a deficiency for which a civil money penalty is imposed by CMS provided all of the following conditions are met:

a) The facility must have 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;

b) Correction of the noncompliance must have occurred on the earlier of either 15 calendar days from the date of the self-reported circumstance or incident that later resulted in a finding of noncompliance or 10 calendar days from the date a civil money penalty was imposed;

c) The facility waives its right to a hearing;

d) 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;

e) The civil money penalty was not imposed for a repeated deficiency that was the basis of a civil money penalty that previously received a 50 percent reduction; and

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f) 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.

Correction will be determined by CMS or the State with an on-site visit or based upon an examination of credible written evidence that CMS or the State can verify without an on-site visit.

NOTE: Under no circumstances will a facility receive both the 50 percent reduction for self-reporting and correcting and the 35 percent reduction for waiving its right to a hearing.

7518 - Effective Date of Civil Money Penalty

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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. The per instance civil money penalty is for a deficiency or deficiencies within a specific survey (i.e., standard, revisit, complaint) up to a maximum of $10,000 for that specific survey. The effective date of the per day civil money penalty will often be the date of the survey because it may be difficult to document precisely when noncompliance begins if before the date of survey. For purposes of recording the imposition of the per instance civil money penalty, the date of occurrence of the noncompliance may be used. However, for purposes of recording the deficiency on the Form CMS-2567, the effective date of the per instance civil money penalty must be the last day of the survey that identified the noncompliance against which it is being imposed. This will permit the input of deficiencies into the Automated Survey Processing Environment system (ASPEN).

A civil money penalty cannot be collected until a facility has an opportunity for a hearing if it properly requests one. Allowing an effective date for the accrual of a per day civil money penalty to be as early as the date of the noncompliance permits the noncompliance to be sanctioned promptly and requires that the facility be notified promptly of the imposition of the civil money penalty. However, if there is undue delay in notifying the facility of the civil money penalty, it is possible that the effective date of the penalty could be moved to a date later than the date of the noncompliance. (See §7306 regarding timing of civil money penalties.)

7520 - Notice of Imposition of Civil Money Penalty

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The State notifies the facility of the possibility of a civil money penalty being imposed for noncompliance in its initial letter to the facility after the survey. The State may:

- Recommend that the regional office and/or the State Medicaid Agency impose the civil money penalty promptly as a result of noncompliance found during a standard, complaint, or revisit survey;

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- Recommend that a civil money penalty accrue from the date of the noncompliance as a result of a revisit substantiating the facility's failure to correct the noncompliance;

- Recommend that the regional office and/or the State Medicaid Agency impose a civil money penalty for each instance that results in a deficiency during a survey; and

- Recommend a civil money penalty upon identification of past noncompliance. The specific procedures specified in §7306, "Timing of civil money penalties," are followed.

NOTE: Both the per day and the per instance civil money penalties cannot be recommended for the same survey.

However, upon the regional office's and/or the State Medicaid Agency's acceptance of the State's recommendation, the regional office or the State Medicaid Agency issues a formal notice, as specified in §7305. The formal notice also incorporates the specific civil money penalty information below. Since the civil money penalty may start accruing as early as the date of the finding of noncompliance found during the standard survey or a complaint survey, it is important that the regional office or the State Medicaid Agency send the formal notification of the imposition of the civil money penalty to the facility as quickly as possible.

7520.1 - Responsibility for Issuing Notice

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

CMS sends a written notice of the imposition of the civil money penalty when CMS is imposing the civil money penalty on a skilled nursing facility, nursing facility, or dually participating facility. The State Medicaid Agency sends a written notice of the imposition of the civil money penalty when the State Medicaid Agency is imposing a civil money penalty on a non-State operated nursing facility.

7520.2 - Content of Notice

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

In addition to the notice requirements in §7305, the following civil money penalty information is included:

1. The nature of the noncompliance (regulatory requirements not met);

2. The statutory basis for the civil money penalty;

3. The amount of the penalty per day of noncompliance or the amount of the penalty per instance of noncompliance during a survey;

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4. The factors that were considered in determining the amount of the civil money penalty;

5. The date on which the per day civil money penalty begins to accrue;

6. A statement that the per day civil money penalty will stop accruing on the date on which the facility comes into substantial compliance or is terminated from participation in the program;

7. When the civil money penalty is collected;

8. Statement of the facility's right to a hearing and information about how to request a hearing; and

9. Implications of waiving the right to a hearing and information about how to waive the right to a hearing. (See §7526.2.)

7522 - Duration of Civil Money Penalty

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The per day civil money penalty accrues for the number of days of noncompliance from the date that the deficiency starts until the date that the facility achieves substantial compliance or, if applicable, the date of termination. For example, if a facility is found in substantial compliance or its provider agreement is terminated on May 18, the accrual of the civil money penalty stops on May 17.

The per instance civil money penalty is imposed for each instance of noncompliance based on a deficiency during a specific survey. It is applied to as many instances as is deemed appropriate during a specific survey up to a total of $10,000.

EXAMPLE: When the per instance civil money penalty is used on the original survey, the revisit is considered another survey to determine compliance. If noncompliance is identified and a civil money penalty is selected as the enforcement response, either the per instance or per day remedy may be selected.

7522.1 - Revisit Identifies New Noncompliance and Same Data Tag is Selected

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

If the same data tag is selected to identify noncompliance, the State (or regional office) could choose to utilize either the per instance or per day civil money penalty as an enforcement remedy. It would not matter whether the same data tag was selected to identify the new noncompliance. The issue is whether noncompliance is present and whether the deficient practice rises to a level that will support selecting a civil money penalty as an enforcement remedy. For instance, noncompliance was identified at Tag 323 during the original survey. During the revisit survey, a different problem dealing

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with the elopement of three residents was cited at Tag 323. The per instance or per day civil money penalty would be selected for the noncompliance identified at Tag 323. If the per instance civil money penalty was used, the amount of the civil money penalty might be influenced by factors leading to the elopement. However, only one per instance civil money penalty would be appropriate. It would not be appropriate to assign a separate civil money penalty for each of the elopements (findings) identified at Tag 323.

7522.2 - Revisit Identifies New Noncompliance and a Different Data Tag is Selected

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

If a revisit identifies new deficiencies at a different data tag, either a per instance or per day civil money penalty could be selected as an enforcement remedy.

7522.3 - Noncompliance - Immediate Jeopardy Does Not Exist

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

For noncompliance that does not pose immediate jeopardy, the per day civil money penalty is imposed for the days of noncompliance, i.e., from the day the penalty starts (and this may be prior to the notice), until the facility achieves substantial compliance or the provider agreement is terminated. However, if the facility has not achieved substantial compliance at the end of 6 months from the last day of the original survey, the regional office terminates and the State may terminate the provider agreement. The accrual of the civil money penalty stops on the date that the provider agreement is terminated.

For noncompliance that does not pose immediate jeopardy, the per instance civil money penalty is imposed for the number of deficiencies during a survey for which the civil money penalty is determined to be an appropriate remedy. For example, Tag 314 and Tag 312 were cited on a survey. A civil money penalty of $2,000 is imposed for Tag 312 and a civil money penalty of $8,000 is imposed for Tag 314. Or, a civil money penalty of $10,000 is imposed for Tag 314. No civil money penalty could then be imposed for additional deficiencies because the total “per instance civil money penalty” may not exceed $10,000 for each survey.

7522.4 - Noncompliance - Immediate Jeopardy Exists

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

For noncompliance that poses immediate jeopardy, CMS or the State must terminate the provider agreement within 23 calendar days after the last day of the survey that identified the immediate jeopardy if the immediate jeopardy is not removed. If the life safety code survey found the immediate jeopardy, CMS or the State must terminate the provider agreement within 23 calendar days after the last day of the life safety code survey. The accrual of the per day civil money penalty stops on the date that the provider agreement is terminated. The per instance civil money penalty is limited to $10,000 per survey.

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NOTE: The per day and the per instance civil money penalty cannot be used simultaneously during a specific survey (i.e., standard, revisit, complaint) within a noncompliance cycle, but both may be used during a noncompliance cycle when more than one survey takes place **and** the per day civil money penalty was not the civil money penalty initially imposed. However, if a per day civil money penalty is imposed initially, a per instance civil money penalty cannot be imposed on a subsequent survey within the same noncompliance cycle.

7524 - Settlement of Civil Money Penalty

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The regional office has the authority to settle cases at any time prior to a final administrative decision when it imposed the civil money penalty. The State has the authority to settle cases at any time, prior to the evidentiary hearing decision when the State Medicaid Agency imposed the civil money penalty. If a decision is made to settle, the settlement should not be for a better term than had the facility opted for a 35 percent reduction.

7526 - Appeal of Noncompliance That Led to Imposition of Civil Money Penalty

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7526.1 - Facility Requests Hearing on Noncompliance That Led to Imposition of Civil Money Penalty

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Before collecting a civil money penalty, §1128A of the Act requires the Secretary (CMS) to conduct a hearing for a facility that properly requests one. Section 1919(h)(8) of the Act requires the State to offer a hearing before collecting a civil money penalty.

1. CMS Imposes Civil Money Penalty

The procedures to request a hearing specified in 42 CFR 498.40 are followed when CMS imposes a civil money penalty on a State-operated facility, a skilled nursing facility, a dually participating facility, or any other facility that has undergone a CMS validation survey or CMS review of the State's findings. (CMS's review could include a paper review of the State's survey material.) The facility should send its request for a hearing to the Departmental Appeals Board with copies to the State and regional office.

2. State Imposes Civil Money Penalty.

The procedures to request a hearing specified in 42 CFR Part 431 are followed when the State imposes a civil money penalty on a non-State operated nursing facility that has undergone neither a CMS validation survey nor a CMS review of the State's findings resulting in a CMS/State disagreement.

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3. Review of Civil Money Penalty

When the basis for imposing the civil money penalty exists, the Administrative Law Judge or State hearing officer (or higher administrative review authority) may not:

a. Set a civil money penalty of zero or reduce a civil money penalty to zero;

b. Review the exercise of discretion by CMS or the State to impose a civil money penalty;

For civil money penalties, an appeal of the level of noncompliance found by CMS in a skilled nursing facility or nursing facility is limited to situations in which a successful challenge of the issue would affect the range of civil money penalty amounts that CMS could collect; that is, a civil money penalty imposed in the upper range of penalty amounts for a situation of immediate jeopardy. The State's conclusion about a nursing facility's level of noncompliance must be upheld unless clearly erroneous.

7526.2 - Facility Waiver of Right to Hearing

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A facility may waive the right to a hearing in writing within 60 calendar days from the date of the notice of imposition of the civil money penalty.

If a facility waives its right to a hearing in writing within 60 calendar days from the date of the notice of imposition of the penalty, the regional office or the State Medicaid Agency reduces the civil money penalty amount by 35 percent. After receipt of the waiver, the regional office or the State Medicaid Agency notifies the facility of receipt of the waiver request.

If a facility does not waive its right to a hearing in accordance with specified procedures, the civil money penalty is not reduced 35 percent.

NOTE: Each time a survey is conducted within an already running noncompliance cycle and a civil money penalty is imposed, the facility is given appeal rights and may exercise its waiver of right to a hearing.

When a per day civil money penalty is imposed and then increased or decreased at subsequent surveys during an already running noncompliance cycle, a facility may elect to either appeal each separate imposition of civil money penalty or waive the right to appeal each imposition. Each civil money penalty imposition is computed separately for a set number of days. The final civil money penalty amount is established after the final administrative decision.

EXAMPLE: A civil money penalty is imposed for 10 days at $1,000 per day. The amount is increased to $3,500 per day for 4 days after a revisit finds immediate jeopardy.

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The civil money penalty is reduced, after the immediate jeopardy has been removed, to $100 per day for 20 days of noncompliance after which the facility is found to be in substantial compliance. The total amount of the penalty is $26,000 [($1,000 x 10 days) + ($3,500 x 4 days) + ($100 x 20 days) = $26,000.] The facility chooses to appeal the first and third civil money penalty amounts imposed, $10,000 + $2,000, and to waive the right to appeal the second civil money penalty imposed, $14,000. The $14,000 amount is reduced by 35 percent and the amount due is $9,100. The final amount of the first and third civil money penalty amounts imposed ($10,000 and $2,000) is established after a final administrative decision on the appeal.

When several per instance civil money penalties are imposed during a noncompliance cycle, a facility may choose to appeal or waive the right to appeal one or more of the civil money penalties, in the same manner as illustrated above for the per day civil money penalties.

After the facility achieves substantial compliance or its provider agreement is terminated, it is notified of the revised civil money penalty amount due.

7528 - When Penalty Is Due and Payable

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

7528.1 – When a Civil Money Penalty Subject to Being Collected and Placed in an Escrow Account is Imposed

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

When the Regional Office imposes a civil money penalty that is subject to being collected and placed in an escrow account as specified at 42CFR 488.431, payment is due on whichever of the following occurs first if the facility files an appeal of the enforcement action:

1. The date on which the independent informal dispute resolution process is completed; or

2. The date which is 90 calendar days after the date of the notice of imposition of the penalty.

NOTE: Payment is not due until after the facility's opportunity to waive its right to appeal has passed. If there is no appeal, CMS's determination becomes final and the CMP amount becomes due and payable in accordance with the process in §7213.

3. **NOTE:** The collection of a per day civil money penalty may be a two-step process. Under§488.431(b)(2), in instances when a facility has not achieved substantial compliance at the time a per day civil money penalty can be collected and placed in an escrow account, the penalty amount that has accrued from the effective date of the penalty through the date of collection would be collected. Another collection would occur later in the process for any final balance

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determined to be due and payable once the facility achieves substantial compliance or is terminated from the program. This two-step process may also occur if a revisit results in a per day civil money penalty being reduced to a scope and severity level below a G and thus not collected and held on an escrow account. In this case, the amount accrued from the effective date of the penalty through the date of the revisit survey would be collected and placed in escrow.

7528.2 - After Final Administrative Decision

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

When the regional office imposes a civil money penalty, a final administrative decision includes an Administrative Law Judge decision and review by the Departmental Appeals Board, if the facility requests a review of the Administrative Law Judge decision. Payment of a civil money penalty is due 15 calendar days **after** a final administrative decision, upholding the imposition of the civil money penalty, when:

1. The facility achieved substantial compliance before the final administrative decision; or

2. The effective date of termination occurred before the final administrative decision.

7528.3 - No Hearing Requested

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

Payment of a civil money penalty is due 15 calendar days after the time period for requesting a hearing has expired and a hearing request was not received when:

1. The facility achieved substantial compliance before the hearing request was due; or

2. The effective date of termination occurred before the hearing request was due.

7528.4 - After Request to Waive Hearing

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

Payment of a civil money penalty is due 15 calendar days after receipt of the facility's written waiver of a right to a hearing when:

1. The facility achieved substantial compliance before receipt of the facility's written waiver of its right to a hearing;

2. A per instance civil money penalty has been imposed. Since no opportunity to correct is available for the noncompliance against which a per instance civil money penalty is imposed, allowing time for the facility to achieve substantial compliance is not a factor in determining when the civil money penalty is due; or

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3. The effective date of termination occurred before receipt of the facility's written waiver of its right to a hearing.

7528.5 - After Substantial Compliance is Achieved
(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

Payment of a per day civil money penalty is due 15 calendar days **after** substantial compliance is achieved when:

1. A final administrative decision, upholding the imposition of the civil money penalty, is made before the facility achieved substantial compliance;

2. The facility did not file a timely hearing request before it achieved substantial compliance; or

3. The facility waived its right to a hearing before it achieved substantial compliance.

However, the period of noncompliance covered by the civil money penalty may not extend beyond 6 months from the last day of the standard health survey.

7528.6 – After Effective Date of Termination
(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

Payment of a civil money penalty is due 15 calendar days after the effective date of termination, if before the effective date of termination:

1. The final administrative decision was made upholding the imposition of the civil money penalty;
2. The time for requesting a hearing has expired and the facility did not request a hearing; or

The facility waived its right to a hearing.

7530 - Notice of Amount Due and Collectible
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7530.1 - Contents of Notice
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The following information is included in a notice of the amount due which is sent to the facility by the entity imposing the civil money penalty after the final amount due and collectible is determined:

1. The amount of the penalty per day or the amount of the penalty per instance;

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2. For the per day civil money penalty, the number of days involved;

3. The total amount due;

4. The due date of the penalty; and

5. The rate of interest to be assessed on the unpaid balance on the due date as follows:

    a. **Medicare Facility.** For Medicare, the rate of interest is the higher of either 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 and this rate is published quarterly in the "Federal Register" by the Department of Health and Human Services under 45 CFR 30.13(a); or the current value of funds rate which is published annually in the "Federal Register" by the Secretary of the Treasury, subject to quarterly revisions. (The regional office contacts CMS Central Office for the rate of interest information.)

    b. **Medicaid Facility.** If the State Medicaid Agency imposed the civil money penalty on a Medicaid facility, the State specifies the rate of interest used.

    c. **Dually Participating Facility.** Interest for these facilities is assessed at the Federal rate (see a. above).

7530.2 - Method of Payment
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

1. The civil money penalty is payable by check to CMS if the check is rendered by the due date.

2. After the due date of the penalty, the regional office or the State Medicaid Agency deducts the civil money penalty plus any accrued interest from money owed to the facility.

7534 - Disposition of Collected Civil Money Penalty
(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

7534.1 - Collected From Medicare or Dually-Participating Facility
(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

The specific use of CMP funds collected from Long Term Care Facilities as a result of federally imposed CMPs must be approved by CMS on behalf of the Secretary. Sections 1819(h)(2)(B)(ii)(IV)(ff) and 1919(h)(3)(C)(ii)(IV)(ff) of the Act provide that

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collected CMP funds may be used to support activities that benefit residents, including assistance to support and protect residents of a facility that closes (voluntarily or involuntarily) or is decertified (including offsetting costs of relocating residents to home and community-based settings or another facility), projects that support resident and family councils and other consumer involvement in assuring quality care in facilities, and facility improvement initiatives approved by the Secretary (including joint training of facility staff and surveyors, technical assistance for facilities implementing quality assurance programs, the appointment of temporary management firms, and other activities approved by the Secretary).

1. Requests for approval must be sent to the appropriate CMS Regional Office (RO) for review and final approval. No later than 45 calendar days after receiving a request for approval, CMS will respond with either:

    a) An approval;

    b) A denial, with explanation; or

    c) A request for more information. If CMS requests more information within the 45-day period, then the period needed for project approval will be extended. CMS will undertake further review and a final decision will be provided to the State by the CMS Regional Office within 30 calendar days of the date CMS receives the additional information.

NOTE: If none of the above three actions occurs within 45 days of confirmed CMS receipt of a complete project description and request for approval package, the State should contact both the Regional Office and QualityAssurance@cms.hhs.gov for priority processing.

2. Requests for approval should contain a description of the proposed use/project that includes:

    a) **Purpose and Summary:** Project title, purpose, and project summary;

    b) **Expected Outcomes:** Short description of the intended outcomes, deliverables, and sustainability;

    c) **Results Measurement:** A description of the methods by which the project results will be assessed (including specific measures);

    d) **Benefits to NH Residents:** A brief description of the manner in which the project will benefit nursing home residents;

    e) **Non-Supplanting:** A description of the manner in which the project will not supplant existing responsibilities of the nursing home to meet existing

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Medicare/Medicaid requirements or other statutory and regulatory requirements;

f) **Consumer and other Stakeholder Involvement:** A brief description of how the nursing home community (including resident and/or family councils and direct care staff) will be involved in the development and implementation of the project;

g) **Funding:** The specific amount of CMP funds to be used for this project, the time period of such use, and an estimate of any non-CMP funds that the State or other entity expects to be contributed to the project;

h) **Involved Organizations:** List all organizations that will receive funds through this project (to the extent known), and organizations that the State expects to carry out and be responsible for the project;

i) **Contacts:** Name of the State contact person responsible for the project and contact information.

NOTE: States must provide information and obtain prior approval from its CMS regional office for any project for which the State wishes to use CMP funds, and CMS reserves the right to disapprove such projects (with prior notice and reconsideration opportunity for the State should CMS disapprove the requested project or use).

3. States may contract with, or grant funds to, any entity permitted under State law and approved by CMS provided that the funds are used for CMS approved projects to protect or improve nursing home services for nursing home residents, and provided that the responsible receiving entity is:

   a) Qualified and capable of carrying out the intended project(s) or use(s);

   b) Not in any conflict of interest relationship with the entity(ies) who will benefit from the intended project(s) or use(s);

   c) Not a recipient of a contract or grant or other payment from Federal or State sources for the same project(s) or use(s);

   d) Not paid by a State or Federal source to perform the same function as the CMP project(s) or use(s). CMP funds may not be used to enlarge or enhance an existing appropriation or statutory purpose that is substantially the same as the intended project(s) or use(s).

NOTE: States may target CMP resources for projects or programs available through various organizations that are knowledgeable, skilled, and capable of meeting the project's purpose in its area of expertise as long as the above criteria are met and the use is consistent with Federal law and policy. Examples of organizations that could qualify

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include, but are not limited to, consumer advocacy organizations, resident or family councils, professional or State nursing home associations, State Long-term Care Ombudsman programs, quality improvement organizations, private contractors, etc.

7534.2 - Collected From Medicaid Facility

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A civil money penalty collected by a State from a Medicaid facility that the State or CMS finds deficient must be applied to the protection of the health or property of residents of nursing facilities that the State or CMS finds deficient (see §1919(h)(2)(A)(ii) of the Act). Statutory examples of appropriate uses by the State of the collected civil money penalty include:

1. State costs related to the operation of a facility pending correction of the deficiencies or closure;

2. 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. Established procedures for the reimbursement of residents are followed; and/or,

3. Payment for the cost of relocating residents to other facilities.

CMS does not have the authority to endorse, approve, disapprove, or otherwise make determinations about suggested uses for civil money penalties. Instead, States have the authority to determine which activities constitute acceptable and beneficial uses of the funds. In addition to the three statutorily specified examples, States have shared creative and innovative projects and activities that they have funded to stimulate quality using the civil money penalty funds. Examples of such projects are provided in S&C-09-44, dated June 19, 2009.

7534.2.1 - Entities Other Than Nursing Homes May Receive Collected Civil Money Penalty Funds from the State

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

When civil money penalties are collected and returned to the State, the statutory expectation is that these funds are to be used for purposes that will benefit nursing home residents. Aside from this usage condition and any restrictive State-specific laws, States may target these resources for projects or programs available through various interested nursing home stakeholders, e.g., facilities, consumer groups, professional nursing home associations, ombudsmen, quality improvement organizations, etc..

7534.3 - Collected From Dually Participating Facility

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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A civil money penalty collected from a dually participating facility is apportioned 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, per resident census data in the Automated Survey Processing Environment system (ASPEN) at the time of the survey.

1. The Medicare portion of the collected civil money penalty is deposited as miscellaneous receipts of the United States Treasury in the Fines, Penalties, and Forfeitures Account.

2. The Medicaid portion of the collected civil money penalty is returned to the State.

EXAMPLE: In a dually participating facility that has the capacity to provide care for 100 residents, 70 residents are in the facility on the date that the civil money penalty begins to accrue. Of the 70 residents, Medicare pays for the care of 15 residents, Medicaid pays for the care of 45 residents, and 10 residents pay for their own care. Thirty of the total 100 beds are empty. There are 60 Medicare and Medicaid residents. The amount of the civil money penalty is apportioned as follows: 25 percent (15/60) of the civil money penalty would be apportioned to the miscellaneous receipts of the United States Treasury for Medicare and 75 percent (45/60) is returned to the State to be applied to the protection of the health and property of residents of nursing facilities that the State or CMS finds deficient.

7534.4 – Collected Amounts from a Dually Participating Facility or Medicare Facility and Held in Escrow

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

A civil money penalty collected from a dually participating facility is apportioned between Medicare and Medicaid 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, per resident census data in the Automated Survey Processing Environment system (ASPEN) at the time of the survey.

After this apportionment is made, ten percent of the Medicare portion of collected civil money penalty funds that are subject to be held in escrow and that remain after a final administrative decision will be deposited with the Department of the Treasury. The remaining ninety percent of the collected civil money penalty funds that are subject to be held in escrow and that remain after a final administrative decision may not be used for survey and certification operations but must be used entirely for activities that protect or improve the quality of care for residents. These activities must be approved by CMS as provided in Sections 1819(h)(2)(B)(ii)(IV)(ff) and 1919(h)(3)(C)(ii)(IV)(ff) of the Act.

7535 - Use of Civil Money Penalty Funds

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

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Sections 1819(h)(2)(B)(ii)(IV)(ff) and 1919(h)(3)(C)(ii)(IV)(ff) of the Act incorporate specific provisions of the Patient Protection and Affordable Care Act, (the Affordable Care Act pertaining to the collection and uses of CMPs imposed by CMS when nursing homes do not meet requirements for Long Term Care Facilities.

1. The Act provides that collected CMP funds may be used to support activities that benefit residents. These include, but are not limited to:

a) Assistance to support and protect residents of a facility that closes (voluntarily or involuntarily) or is decertified (including offsetting costs of relocating residents to home and community-based settings or another facility);

b) Projects that support resident and family councils and other consumer involvement in assuring quality care in facilities; and

c) Facility improvement initiatives approved by the Secretary (including joint training of facility staff and surveyors, technical assistance for facilities implementing quality assurance programs, the appointment of temporary management firms, and other activities approved by the Secretary).

2. CMS, States and others are in general agreement about the types of expenditures that should be considered inappropriate for civil money penalty funds. These include, but are not limited to:

a) Making capital improvements to a facility;

b) Paying for items or services that are already the responsibility of the nursing home;

c) Funding projects, items or services that are not related to improving the quality of life and care of nursing home residents;

d) Projects for which a conflict of interest or the appearance of a conflict of interest exists;

e) Long term projects (greater than 3 years);

f) Temporary manager salaries; and

g) Supplementary funding of federally required services.

7536 - Loss of Nurse Aide Training and Competency Evaluation Program or Competency Evaluation Program as a Result of Civil Money Penalty

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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Sections 1819(f)(2)(B) and 1919(f)(2)(B) of the Act and 42 CFR 483.151(b) use the term "assessed" to state that the approval of a nurse aide training and competency evaluation program or competency evaluation program is prohibited in a facility which, within the previous 2 years, has been assessed a civil money penalty of not less than $5,000. Section 7809 provides additional information regarding nurse aide training and competency evaluation program and competency evaluation program disapprovals.

7536.1 - Definition of "Assessed"

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The term "assessed" is defined to reflect the fact that the civil money penalty may be revised on administrative appeal. The assessed amount of the civil money penalty is the final amount determined to be owed after a hearing, waiver of right to a hearing, or settlement.

7536.2 - Effective Date for Prohibition of Nurse Aide Training and Competency Evaluation Program or Competency Evaluation Program When Civil Money Penalty of $5,000 or More Is Assessed

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

If a civil money penalty of $5,000 or more is assessed on a facility as a result of current or past noncompliance found during a survey, the effective date of the prohibition of the nurse aide training and competency evaluation program or competency evaluation program specified in the notice cannot be before the time frame for requesting a hearing has expired, or after receipt of the written waiver, or later than the date on which a civil money penalty of $5,000 or more is upheld on administrative appeal. In accordance with 42 CFR 483.151, the State notifies the program in writing, indicating the reason(s) for withdrawal of approval of the program. However, students who have started a training and competency evaluation program for which approval has been withdrawn must be allowed to complete the course.

It is possible for a facility to experience two or more separate disapprovals of its nurse aide training and competency evaluation program or competency evaluation program that could run concurrently for at least part of the same period of time. When two periods of program disapproval overlap, the program will not be restored until the second 2-year disapproval period has been completed. (See §7809.7)

7550 - Temporary Management

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7550.1 - Introduction

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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This remedy is established pursuant to §1819(h)(2)(A)(I), §1819(h)(B)(iii), §1919(h)(1)(A), §1919(h)(2)(A)(iii), §1919(h)(3)(B)(I), and §1919(h)(3)(C)(iii) of the Act and 42 CFR 488.415.

7550.2 - Purpose

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A temporary manager may be imposed anytime a facility is not in substantial compliance. However, when a facility's deficiencies constitute immediate jeopardy or widespread actual harm and a decision is made to impose an alternative remedy to termination, the imposition of temporary management is required. It is the temporary manager's responsibility to oversee correction of the deficiencies and assure the health and safety of the facility's residents while the corrections are being made. A temporary manager may also be imposed to oversee orderly closure of a facility.

7550.3 - Authority of Temporary Manager

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A temporary manager has the authority to hire, terminate, or reassign staff; obligate facility funds; alter facility procedures; and otherwise manage a facility to correct deficiencies identified in the facility's operation.

7550.4 - Selection of Temporary Manager

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The State will select the temporary manager when the State Medicaid Agency is imposing the remedy and will recommend a temporary manager to the regional office when CMS is imposing the remedy. Each State should compile a list of individuals who are eligible to serve as temporary managers.

The following individuals are not eligible to serve as temporary managers:

- Any individual who has been found guilty of misconduct by any licensing board or professional society in any State;
- Any individual who has, or whose immediate family members have, any financial interest in the facility to be managed. Indirect ownership, such as through a mutual fund, does not constitute financial interest for the purpose of this restriction; or
- Any individual who currently serves or, within the past 2 years, has served as a member of the staff of the facility.

The State should investigate eligible candidates' past performance by reviewing any compliance histories in the Automated Survey Processing Environment system (ASPEN) of facilities managed by the candidates, and by consulting with the long-term care

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ombudsman, and State Medicaid Agency, if appropriate. The State should reject a candidate who has demonstrated difficulty maintaining compliance in the past.

The State should select or recommend a temporary manager whose work experience and education qualifies the individual to correct the deficiencies in the facility to be managed.

7550.5 - Conditions of Temporary Management

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The facility's management must agree to relinquish control to the temporary manager and to pay his/her salary before the temporary manager can be installed in the facility.

The facility cannot retain final authority to approve changes of personnel or expenditures of facility funds and be considered to have relinquished control to the temporary manager. The temporary manager must be given access to facility bank accounts that include Medicare and Medicaid receipts.

The temporary manager's salary must be at least equivalent to the prevailing annual salary of nursing home administrators in the facility's geographic area, plus the additional costs that would have reasonably been incurred by the facility if the temporary manager had been in an employment relationship, e.g., the cost of a benefits package, prorated for the amount of time that the temporary manager spends in the facility. The State is responsible for determining what constitutes a facility's geographic area.

If the facility refuses to relinquish control to the temporary manager, the facility will be terminated within 23 calendar days of the last day of the survey if the immediate jeopardy is not removed.

7550.6 - Orienting and Supervising Temporary Manager

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The State should provide the temporary manager with an appropriate orientation that includes a review of the facility's deficiencies. The State may request that the temporary manager periodically report on the actions taken to achieve compliance and on the expenditures associated with these actions.

7550.7 - Notice of Imposition of Temporary Management

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A temporary manager may be imposed 15 calendar days after the facility receives notice in non-immediate jeopardy situations and 2 calendar days after the facility receives notice in immediate jeopardy situations.

7550.8 - Duration

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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Temporary management continues until a facility is terminated, achieves substantial compliance and is capable of remaining in substantial compliance, or decides to discontinue the remedy and reassume management control before it has achieved substantial compliance. In the latter case, the facility faces termination.

7550.9 - Alternatives to Temporary Management
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

In lieu of temporary management, the State Medicaid Agency may use an acceptable alternative, that it has demonstrated to CMS's satisfaction, through an approved State plan amendment, is as effective in deterring noncompliance and correcting deficiencies as temporary management. When taking enforcement action in a State with an acceptable alternative to temporary management, the regional office may also use the alternative.

7552 - Transfer of Residents and Transfer of Residents with Closure of Facility
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7552.1 - Introduction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

This section implements §1819(h)(4), §1919(h)(2)(A)(iv), and §1919(h)(5) of the Act in conjunction with §1819(c)(2) of the Act and 42 CFR 488.426.

7552.2 - Responsibility for Transferring Residents
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The State has the ultimate responsibility for transferring Medicare and Medicaid residents when a facility is terminated. In some instances, a facility may assume responsibility for the safe and orderly transfer of residents when it is closed or its provider agreement is terminated. However, this does not relieve the State of its ultimate responsibility to transfer residents. The goal must be to minimize the period of time during which residents are receiving less than adequate care. CMS is specifying that transfer requirements apply only to Medicare and Medicaid residents and **not** to private pay residents. However, when a facility is closed, regardless of whether the closure is a result of action taken by the State or by the facility, the State may have plans available to provide assistance in the relocation of private pay residents.

7552.3 - State's Prerogative to Close Facility and Transfer Residents
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A finding of immediate jeopardy will not, in and of itself, require the State to close a facility and transfer Medicare and Medicaid residents. It could, however, result in the immediate termination of a Medicare and/or Medicaid provider agreement and the subsequent transfer of Medicare and/or Medicaid residents. During an emergency, the

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State can permanently or temporarily transfer residents to another facility until the original facility is able to care for its residents.

7556 - Termination Procedures for Skilled Nursing Facilities and Nursing Facilities When Facility Is Not in Substantial Compliance With Participation Requirements

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7556.1 - Introduction

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Sections 1819(h)(4) and 1919(h)(5) of the Act and 42 CFR 488.456 and 489.53 provide for termination of skilled nursing facility and nursing facility provider agreements. Title 42 CFR Part 431, Subpart D, provides the appeals process for nursing facilities subject to enforcement actions by the State.

Under certain circumstances, Federal regulations provide for payment to a facility beyond the effective date of termination as follows:

- Under 42 CFR 489.55, Medicare payment is available for up to 30 days after the effective date of termination for inpatient hospital services (including inpatient psychiatric hospital services) and post-hospital extended care services furnished to a beneficiary who is admitted before the effective date, and home health services and hospice care furnished under a plan established before the effective date.

- Under 42 CFR 441.11, Federal financial participation may be continued for up to 30 days after the effective date of termination or expiration of a provider agreement, or after an administrative hearing decision that upholds the agency's termination or nonrenewal action, as long as the Medicaid payments are for those residents admitted to the facility before the effective date of termination or expiration, and the Medicaid agency is making reasonable efforts to transfer the residents to other facilities or to alternate care.

7556.2 - When There Is Immediate Jeopardy

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

When there is immediate jeopardy to resident health or safety, the enforcing agency must complete termination procedures within 23 days from the last day of the survey which found the immediate jeopardy if it is not removed before then. (See §7309 for time frames.) The procedure must not be postponed or stopped unless the immediate jeopardy is removed, as verified through onsite verification or review of verifiable documentation. If there is a written and timely credible allegation that the immediate jeopardy has been removed, CMS or the State will conduct a revisit prior to termination, if possible.

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7556.3 - When There Is No Immediate Jeopardy
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

When there is no immediate jeopardy, the State Medicaid Agency may and the regional office must terminate a facility, or the regional office must stop all Federal funding to a facility, if the facility does not achieve substantial compliance within 6 months of the date of the survey that found it to be of it to be out of compliance. When an agreement to repay is signed by a Medicare facility and the facility fails to achieve substantial compliance by the 6th month, the regional office stops funding. (See §7600 regarding continuation of payment.)

However, termination is always an **option** that may be imposed for any facility noncompliance regardless of whether immediate jeopardy is present. When considering whether to terminate a facility's provider agreement, the enforcing entity considers many factors, particularly the facility's noncompliance history (e.g., is it consistently in and out of compliance), the effectiveness of alternative remedies when previously used, and whether the facility has failed to follow through on an alternative remedy (e.g., directed in-service training). These considerations are not all inclusive but are factors to consider when determining whether termination is appropriate in a given case.

7600 - Continuation of Payments During Correction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7600.1 - Introduction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

These procedures are established pursuant to §1819(h)(2)(C) and §1919(h)(3)(D) of the Act and are implemented at 42 CFR 488.450. States use these procedures when they determine that a non-State operated skilled nursing facility, nursing facility, or dually participating facility is not in substantial compliance with Federal participation requirements, and that an alternative remedy is preferred **instead** of termination. If the State decides to impose alternative remedies **in addition to termination,** it does **not** follow these procedures. (See §7556 for termination procedures.)

7600.2 - Purpose
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The statute permits facilities that are not in substantial compliance to continue to participate in the Medicare and Medicaid programs for 6 months without the State Medicaid Agency or regional office initiating a termination action. To avoid termination, the specific criteria in §7600.3 must be met.

7600.3 - Criteria for Continued Payment During Correction Period
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

CMS may continue payments to a facility that is not in substantial compliance for up to 6

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months from the finding of noncompliance when immediate jeopardy does not exist and the following criteria are met:

1. The State 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 of correction which is approved by the regional office; and

3. The facility (for Medicare) agrees to repay the regional office payments received if action is not taken according to the approved plan of correction.

The State recommends to the regional office how long the facility's correction period should be based on the deficiencies and the facility's plan of correction. However, the correction period should not exceed 6 months since the statute only authorizes continued payments for 6 months. The plan and timetable for corrective action are equivalent to a plan of correction.

7600.4 - Approval of Plan and Timetable for Corrective Action
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The facility must develop a plan of correction within 10 calendar days of the receipt of the Statement of Deficiencies. The State reviews the plan of correction and notifies the facility of its acceptability in accordance with §7304. The State may recommend an alternative remedy (or remedies) in lieu of termination. The plan, timetable, recommendation and repayment agreement must be sent to the regional office by the 25th day following the last day of survey. The regional office has 5 calendar days from the date these items are received to respond to the plan of correction. If the regional office does not contact the State by the 6th calendar day, the plan of correction is deemed to be approved.

7600.5 - Facility Takes Corrective Action According to Its Approved Plan of Correction and Has Achieved Substantial Compliance
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Once the State has determined that a facility has made corrections according to its approved plan of correction and the facility has achieved substantial compliance, the facility may be certified in substantial compliance and the agreement to repay is void.

7600.6 - Facility Does Not Take Corrective Action According to Its Approved Plan of Correction and Has Not Achieved Substantial Compliance
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

If the facility does not take action according to its approved plan of correction and does

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not achieve substantial compliance by the end of the specified period, the regional office:

- Terminates a skilled nursing facility's provider agreement for Medicare; or
- Discontinues Federal funding to the skilled nursing facility for Medicare; and
- Discontinues Federal financial participation to the State for the Medicaid nursing facility.

The State Medicaid Agency may terminate the nursing facility's Medicaid provider agreement.

Termination or discontinuation of funding does not relieve the facility of the obligation to repay Federal funds received during the correction period.

EXAMPLE: The State finds a skilled nursing facility out of compliance with its health survey on May 15. The State recommends to the regional office that it impose alternative remedies in lieu of termination. The skilled nursing facility has agreed to repay all Federal funds if it does not make the needed corrections to achieve substantial compliance by August 1. The agreement to repay would begin for Federal payments made on May 15. On August 1, a revisit reveals that the skilled nursing facility did not make the corrections in accordance with its approved plan of correction. The State will notify the regional office, and the regional office will terminate the skilled nursing facility's provider agreement after providing a 15-day notice to the facility. In addition, the skilled nursing facility will be liable to repay to the regional office all the Medicare Federal funds it received for the period May 15 - August 1.

7600.7 - Facility Takes Corrective Action According to its Plan of Correction But Fails to Achieve Substantial Compliance

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The Medicare facility would not be required to repay the Federal funding received because it followed its approved plan of correction. However, because the facility failed to achieve substantial compliance, continued Federal funding beyond 6 months would stop, and, the regional office will terminate the skilled nursing facility's provider agreement.

7600.8 - Facility Does Not Take Corrective Action According to Its Plan of Correction and Has Achieved Substantial Compliance

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The facility would not be required to repay the Federal funding received because it achieved substantial compliance.

7600.9 - When State Opts for Alternative Remedies in Lieu of

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Termination and Criteria Are Not Met
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

If termination is not sought, either by itself or along with another remedy (or remedies), or if any of the applicable criteria set forth in subsection 3 are not met, the facility or State Medicaid Agency will receive no Medicare or Federal Medicaid payments, as applicable, from the last day of the survey until the date that substantial compliance is achieved.

If the State recommends an alternative remedy instead of termination and the Medicare facility refuses to sign an agreement to repay, CMS has no authority to pay for services after the last day of the survey. If funding has ceased, the State must determine if the facility is in substantial compliance before funding can resume.

7700 - Nurse Aide Registry and Findings of Abuse, Neglect, or Misappropriation of Property
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7700.1- Notification Procedures- Preliminary Determinations
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

If the State makes a preliminary determination, based on oral or written evidence and its investigation, that resident neglect, abuse, or misappropriation of property has occurred, the State completes the following notification procedures:

1. **Individuals Notified** - The State notifies the following individuals in writing within 10 working days of the investigation:

   a. Individual(s) implicated in the investigation; and

   b. The current administrator of the facility in which the incident occurred.

2. **Notice Information** - The following information is included in the notice:

   a. Nature of the allegation (specific facts);

   b. Date and time of the occurrence;

   c. A statement that the individual implicated in the investigation has a right to a hearing and must request the hearing within 30 days from the date of the notice. Provide the individual with the specific information needed to request a hearing, such as the name and address of a contact in the State to request a hearing;

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d. Statement that if the individual fails to request a hearing, in writing, within 30 days from the date of the notice, the presumed substantiated findings will be reported to the nurse aide registry or the appropriate licensure authority;

e. The intent to report findings substantiated by a hearing in writing to the nurse aide registry and/or to the appropriate licensure authority;

f. Consequences of waiving the right to a hearing;

g. Consequences of a finding through the hearing process that the resident abuse or neglect, or misappropriation of property did occur; and

h. Right of the accused individual to be represented by an attorney at the individual's own expense.

7700.2 - Conduct of Hearing for Nurse Aides

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

1- Time frame to Complete Hearing

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

2 - Hearing Location

The State must hold the hearing in a manner consistent with State practice at a reasonable place and time convenient for the individual.

7700.3- Reporting Findings

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

1 - Reporting to Entities

If the individual waives the right to a hearing or the time to request a hearing has expired, or if the hearing finding is that the individual neglected or abused a resident or misappropriated a resident's property, the substantiated findings must be reported in writing within 10 working days to:

1. The individual;

2. Current administrator of the facility in which the incident occurred;

3. The administrator of the facility that currently employs the individual, if it is not the same facility in which the incident occurred;

4. Applicable licensing authorities; and

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5. The nurse aide registry for nurse aides as specified in 42 CFR 483.156 and discussed in §4141 of this manual. Section 4141 discusses the function of the registry, the information contained in the registry, and responsibility for the registry.

2 - Information Submitted to the Nurse Aide Registry

The following information must be included and remain in the registry permanently, unless the finding was made in error, the individual was found not guilty in a court of law, or the State is notified of the individual's death. See §4141.B of this manual.

a. Documentation of the investigation, including the nature of the allegation and the evidence that led to the conclusion that the allegation was valid;

b. The date of the hearing, if the individual chose to have one, and its outcome; and

c. A statement by the individual disputing the allegation if the individual chose to make one.

3- Information Retained in the Nurse Aide Registry Permanently

The registry removes entries for individuals who have performed no nursing or nursing-related services for 24 consecutive months, **unless** the individual's registry entry includes documented findings of abuse, neglect, or misappropriation of resident property.

7701 - Reporting Abuse to Law Enforcement and the Medicaid Fraud Control Unit

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

When the regional office or SA substantiates a finding of abuse, the regional office or SA must report the substantiated findings to local law enforcement and, if appropriate, the Medicaid Fraud Control Unit.

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Program Management

7800 - Consistency of Survey Results
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7800.1 - Introduction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

This section provides guidance to the regional office and State for the development and implementation of programs to measure accuracy and improve consistency in the application of survey results and enforcement remedies, pursuant to §1819(g)(2)(D) and §1919(g)(2)(D) of the Act and 42 CFR 488.312.

7800.2 - Measuring Consistency
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

These programs should measure the uniformity of survey findings as well as remedy recommendations and enforcement actions as stipulated by the statute. Such programs may include:

1. Quality assurance or continuous quality improvement teams; and

2. Outside consultation and evaluation.

However, CMS does not want to limit the types of programs that regional offices and States use to fulfill this requirement. Additionally, CMS encourages the regional offices and States to share with each other innovative and unique methods used to measure consistency.

7801 - Sanctions for Inadequate State Survey Performance
Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

(Moved to Chapter 8 of this manual.)

7803 - Educational Programs
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7803.1 - Introduction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

This section implements §1819(g)(1) and §1919(g)(1) of the Act and 42 CFR 488.334.

7803.2 - Purpose
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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The purpose of this section is to ensure that long-term care facility staff and residents (and their representatives) are knowledgeable about current regulations, procedures, and policies relative to survey, certification, and enforcement processes.

7803.3 - Methodology

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The development of educational programs and the methods of presentation are within the purview of the agency providing the training as long as the programs cover long-term care regulations and the survey and enforcement process.

7803.4 - Suggested Training Modalities

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Suggested training modalities include the following:

- Video tapes;
- Satellite communication;
- Newsletters developed by the State;
- Formal presentations; and
- Informal sessions during or after onsite visits.

7805 - Criteria for Reviewing State Plan Amendments for Specified and Alternative Enforcement Remedies

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7805.1 - Introduction

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

This section implements §1919(h)(2)(A) and §1919(h)(2)(B)(ii) of the Act, as well as 42 CFR 488.303 and 488.406, and it provides guidance to the regional offices about reviewing, for approval or disapproval, State plan amendments for enforcement remedies as specified at 42 CFR 488.406(c).

7805.2 - Specified Remedies

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Specified remedies are those remedies defined in §1919(h) of the Act as well as 42 CFR 488.406(b). The State plan must specify the State law or regulations that establish these remedies, pursuant to §1919(h)(2)(A) of the Act.

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7805.3 - Alternative Remedies

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

If a State wants to establish a remedy in place of a remedy specified in 42 CFR 488.406(a) or (b), the State plan should describe the following:

1. **General requirements** - These requirements include:

    - Timing and notice requirements specified in 42 CFR 488.402(f);
    - How the alternative remedy satisfies the statutory intent of the specified remedy, i.e., immediate jeopardy, non-immediate jeopardy, prolonged noncompliance, and repeat noncompliance situations;
    - When the remedy will be applied;
    - How the alternative remedy is as effective as the specified remedy in deterring noncompliance;
    - Factors considered in selecting the remedy; and
    - State law or regulations which establish these alternative remedies, pursuant to §1919(h)(2)(B)(ii) of the Act.

The State's categorization of deficiencies should result in the same scope and harm assignment.

2. **Civil Money Penalties** - In addition to the general requirements above, the State plan should include the following:

    - How the fine system distinguishes between fine ranges, i.e., immediate jeopardy and non-immediate jeopardy;
    - That the fine will be increased if the noncompliance is repeated on the next survey;
    - How the fine system ensures compliance; and
    - How the fine system addresses findings of past noncompliance.

3. **Denial of Payment for New Admissions** - Whenever a State's remedy is unique to its State plan and has been approved by CMS, then that remedy may also be imposed by the regional office against the Medicare provider agreement of a dually-participating facility in that State. Therefore, if a State's ban on admissions remedy is determined to be an acceptable State alternative, it must be understood that in dually participating facilities, CMS can impose a State's ban on

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admissions remedy only with regard to all Medicare/Medicaid residents. Only the State can ban admissions of private pay residents.

4. **Temporary Management** - In addition to the general requirements above, the State plan should describe how the alternative remedy could be imposed quickly in immediate jeopardy situations.

7805.4 - Additional Remedies
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

If a State wishes to impose additional remedies to those specified in regulations, the State must describe:

- Whether the additional remedy is in category 1, 2, or 3 (see §7400 for description of remedy categories); and

- State law or regulations that established these additional remedies.

7807 - State/Federal Disagreements About Timing and Choice of Remedies
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7807.1 - Introduction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

These procedures are established pursuant to §1919(h)(6) and §1919(h)(7) of the Act and 42 CFR 488.452 to provide guidance when the regional office's findings do not agree with the State survey agency's findings.

While CMS expects that in most cases the regional office will agree with the State survey agency's findings of compliance or noncompliance and the timing of the State survey agency's enforcement action, the statute provides specific rules to apply when such disagreements occur. These rules apply to non-State operated nursing facilities and dually participating facilities. In the case of State-operated facilities, the regional office's decision always prevails because the State survey agency does not make the certification of compliance or noncompliance nor does it make any recommendations of enforcement actions. In the case of skilled nursing facilities, the regional office's decision always prevails.

7807.2 - Disagreement About Whether Facility Has Met Requirements
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

If the State survey agency finds that a facility is not in substantial compliance, but the regional office finds, either through an onsite survey or review of the State survey agency's findings, that the facility is in substantial compliance, the State survey agency's finding prevails.

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If the State survey agency finds a facility is in substantial compliance, but the regional office finds, either through an onsite survey or review of the State survey agency's findings, that the facility is not in substantial compliance, the regional office's finding prevails.

When the regional office's finding of noncompliance prevails, it may:

- Impose remedies as specified in §7400;
- Terminate the provider agreement; and/or,
- Stop Federal financial participation to the State for a nursing facility at the end of 6 months.

7807.3 - Disagreement About Decision to Terminate

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

When both the State survey agency and the regional office agree that a facility is not in substantial compliance, but disagree as to whether to terminate a facility's provider agreement, the following rules apply:

- If the regional office wants to terminate, but the State survey agency does not, the regional office and the State Medicaid Agency impose the alternative remedies (pending the regional office's termination at 6 months) and follow the procedures in §7600;
- If the State Medicaid Agency wants to terminate, but the regional office does not, the State Medicaid Agency's decision to terminate a nursing facility prevails as long as the termination date is no later than 6 months after the last day of the standard health survey; and
- If the facility is dually participating, the decision made for the Medicaid portion is applied to the Medicare portion and the regional office imposes the decision for both programs. Any applicable appeals of alternative remedies or termination would be heard under 42 CFR Part 498.

7807.4 - Disagreement About Timing of Facility Termination

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The State Medicaid Agency's timing of termination prevails as long as it does not occur later than 6 months after the last day of the standard health survey and both the State survey agency and the regional office agree that the facility has not achieved substantial compliance and agree that the facility should be terminated.

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7807.5 - Disagreement About Remedies
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The law provides that either the State or the regional office may impose additional or alternative remedies. For example, if the State decides to terminate a provider agreement and the regional office chooses to impose a civil money penalty in addition to the termination, both the termination and the civil money penalty would be imposed. If the State chooses termination and another remedy, the additional remedy would be imposed. However, if both the State and the regional office want to impose an additional remedy, only the regional office's remedy would be applied.

7807.6 - One Enforcement Decision
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Only one entity certifies noncompliance and implements enforcement remedies. The State's decision prevails for a nursing facility that is not subject to a validation survey, and the facility is entitled to an appeal under the State procedures. (See 42 CFR Part 431.) In the case of a dually participating facility, if the State's decision prevails, the regional office adopts the decision made for the Medicaid portion of the facility and applies it to the Medicare portion. The facility is entitled to a hearing under the Federal procedures. (See 42 CFR Part 498.)

7809 - Nurse Aide Training and Competency Evaluation Program and Competency Evaluation Program Disapprovals
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7809.1 - Introduction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Sections 1819(f)(2)(B)(iii) and 1919(f)(2)(B)(iii) of the Act, as well as 42 CFR 483.151(b)(2) and 483.151(e), require denial or withdrawal of approval of facility-based Nurse Aide Training and Competency Evaluation Programs and Competency Evaluation Programs offered by or in a facility which, within the previous 2 years:

- Has operated under a §1819(b)(4)(C)(ii)(II) or 1919(b)(4)(C)(ii) waiver (see §4132.1 of this manual);

- Has been subject to an extended or partial extended survey under §1819(g)(2)(B)(i) or §1919(g)(2)(B)(i) of the Act; or

- Has been assessed a civil money penalty described in the Act at §1819(h)(2)(B)(ii) or §1919(h)(2)(A)(ii) of not less than $5,000 or has been subject to a denial of payment, the appointment of a temporary manager, termination, or, in the case of an emergency, been closed and/or had its residents

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transferred to other facilities. (See §7536 for additional information regarding civil money penalties.)

The program will not be approved if it is offered by or in a facility unless the State makes the determination, upon an individual's completion of the program in the facility, that the individual is competent to provide nursing and nursing related services in skilled nursing facilities or nursing facilities.

Any reversals of Nurse Aide Training and Competency Evaluation Program or Competency Evaluation Program denials or withdrawals are limited to the informal dispute resolution process.

In accordance with 42 CFR 483.151, the State notifies the program in writing, indicating the reason(s) for withdrawal of approval of the program. However, students who have started a program for which approval has been withdrawn must be allowed to complete the course.

7809.2 - Applicability to Past Noncompliance

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The provisions of this section apply to findings of past noncompliance when a civil money penalty of $5,000 or more is assessed.

7809.3 - Waiver of Program Disapproval

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

See §4132.1.E of this manual.

7809.4 - Notice

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The State survey agency must notify the State agency responsible for Nurse Aide Training and Competency Evaluation Programs/Competency Evaluation Program when it determines that denial or withdrawal of program approval is necessary. That agency, in turn, notifies the facility. If the noncompliance which caused a sanction to be imposed, or which caused an extended or partial extended survey to be performed, is successfully refuted by the facility or otherwise determined by the State to have been improperly cited, the facility's appeal to restore the Nurse Aide Training and Competency Evaluation Program/Competency Evaluation Program approval will be granted.

7809.5 - Change of Ownership

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

If a facility undergoes a change of ownership after having had approval of its nurse aide training and competency evaluation program or competency evaluation program withdrawn for 2 years before the 2-year period has expired, the remainder of the 2-year

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period does not carry over to the new owner. If the facility meets all the other requirements for the nurse aide training and competency evaluation program or competency evaluation program, its program(s) will be approved.

7809.6 - Ability to Appeal a Finding of Substandard Quality of Care that Resulted in the Disapproval of a Nurse Aide Training and Competency Evaluation Program

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A facility may appeal the finding of substandard quality of care that resulted in the disapproval of its nurse aide training and competency evaluation program.

There are instances when a Medicare-only or dually participating facility has been found to have provided substandard quality of care but has not experienced any other adverse consequence other than the disapproval of its ability to conduct a nurse aide training and competency evaluation program. These situations provide for a hearing under 42 CFR Part 498 even though it is the State that is the responsible party for removing the approval of the facility to conduct a program at the facility. When CMS makes a determination of substandard quality of care that leads to the disapproval of a nurse aide training and competency evaluation program, this determination provides for a hearing under Part 498. For Medicaid-only nursing homes, it is left to the State to determine whether to provide a hearing to challenge the substandard quality of care determinations that have resulted in the disapproval of a nurse aide training and competency evaluation program. Accordingly, notices from States advising Medicare-only or dually participating facilities of their loss of approval to conduct a nurse aide training and competency evaluation program must provide notice of the appeal rights available under 42 CFR Part 498.

Under the regulations, it is the State, not CMS, that disapproves a facility's nurse aide training and competency evaluation program. While the hearings authorized under 42 CFR Part 498 are directed at actions initiated by CMS, they are expressly designed to confer hearing rights on Medicare-only or dually participating facilities that lose their nurse aide training and competency evaluation program authority even when no other Federal remedies have been imposed. If the appeals regulations at 42 CFR Part 498 were to be interpreted to permit challenges to a disapproval of nurse aide training and competency evaluation programs only when such disapprovals are a result of actions taken by CMS, these hearing rights would never be triggered since it is not CMS that takes these actions. This is not a result that was intended by the nurse aide training and competency evaluation program appeals regulation that was published on July 23, 1999 (64 "Federal Register" 39934).

7809.7 – Effective Date of Disapproval of Nurse Aide Training and Competency Evaluation Program or Competency Evaluation Program

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The effective date of program disapproval is based on the actual occurrence of each of the triggering events, i.e., on the date that a nurse staffing waiver was effective; on the

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last day of the extended (or partial extended) survey; or, when the specified enforcement remedy or termination was effective. The disapproval is not delayed pending the outcome of any appeal. (See §7536.2 for the effective date of disapproval of a nurse aide training and competency evaluation program or competency evaluation program resulting from a civil money penalty.)

It is possible for a facility to experience two or more separate disapprovals of its nurse aide training and competency evaluation program or competency evaluation program that could run concurrently for at least part of the same period of time. When two periods of program disapproval overlap, the program(s) will not be restored until the second 2-year disapproval period has been completed.

A facility's nurse aide training and competency evaluation program or competency evaluation program will be restored when the facility prevails at informal dispute resolution or at a formal hearing where the noncompliance is overturned that either caused the extended (or partial extended) survey to be conducted, or caused a specified remedy or termination to be imposed.

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Disclosure

7900 - Information Disclosed to Public

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

(Also see "Handling Public Inquiries", §§3300-3320 of this manual.)

As provided in §1819(g)(5) and §1919(g)(5) of the Act and 42 CFR 488.325, the State survey agency, the State Medicaid Agency, or CMS must make the following information available to the public, upon the public's request, for all surveys and certifications of skilled nursing facilities and nursing facilities:

- The fact that a facility does or does not participate in the Medicare/Medicaid program;

- The official "Statement of Deficiencies and Plan of Correction", Form CMS-2567. If it contains the name of any individual, medical information about any identifiable resident, the identity of a complainant, or the address of anyone other than an owner of the facility, that information must be blocked out before the Form CMS-2567 is released to the public;

- Approved plans of correction, Form CMS-2567. If the plan of correction contains the name of any individual, medical information about any identifiable resident, the identity of a complainant, or the address of anyone other than an owner of the facility, that information must be blocked out before the Form CMS-2567 is released to the public;

NOTE: The Statement of Deficiencies can be released before the facility has completed its plan of correction portion. However, after a plan of correction is submitted and approved, the two portions are released simultaneously since they appear on the same form.

- When applicable, a Notice of Isolated Deficiencies Which Cause No Actual Harm With the Potential for Minimal Harm (Form A) will be included with the Form CMS-2567;

- Facility comments;

- Statements that the facility did not submit an acceptable plan of correction or failed to comply with the conditions of imposed remedies, if appropriate;

- Official notices of provider terminations;

- Statistical data on facility characteristics that does not identify any specific individual. 42 CFR 401.120 states that records will not be created by compiling

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selected items from the files to give the requester data such as ratios or percentages. However, if existing documents contain such statistical data (e.g., Certification and Survey Provider Enhanced Reporting (CASPER) reports), they are subject to release;

- Final appeal results;
- Medicare and Medicaid cost reports; and
- Names of individuals with direct or indirect ownership interest in a skilled nursing facility or nursing facility, as defined in 42 CFR 420.201, who have been found guilty by a court of law of a criminal offense in violation of Medicare or Medicaid law.

7901 - Requesting Public Information

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The public may request information in accordance with disclosure procedures specified in 45 CFR Part 5.

7902 - Charges for Information

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

If the public requests copies of the records and information described in §7900 from CMS, there will generally be a charge. Charges should be in accordance with 42 CFR 401.140 for Medicare and applicable State procedures for Medicaid.

7903 - Time Periods for Disclosing Skilled Nursing Facility/Nursing Facility Information

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7903.1 - Information That Must Be Disclosed Within 14 Days of Request

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Upon the public's request, the State survey agency, regional office, or State Medicaid Agency, where appropriate, must make the following information available to the public within 14 calendar days after each item is made available to the facility:

- "Statements of Deficiencies and Plan of Correction" (Form CMS-2567);
- Separate listings of any Notice of Isolated Deficiencies Which Cause No Actual Harm With the Potential For Minimal Harm (Form A); and
- Approved plans of correction (Form CMS-2567) which contain any facility response to the Statement of Deficiencies.

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7903.2 - Disclosure Time Frames
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Although the State survey agency or regional office may choose to wait as long as 14 calendar days before disclosing the information listed in §7903.1 above in order to obtain a facility response or plan of correction prior to disclosure, the information may be disclosed at any time after it has been made available to the facility. The information could be disclosed as quickly as the day after it is made available to the facility, or as many as 14 days afterward. The State survey agency or regional office makes the determination about the appropriateness of the timing of the disclosure.

In situations generating media interest, the State survey agency should notify the regional office prior to the initial public release of the Form CMS-2567. Regional offices are expected to extend the same courtesy to State survey agencies when regional office survey findings have the potential for high publicity.

7904 - Information Furnished to State's Long Term Care Ombudsman
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7904.1 -Information Given to Long Term Care Ombudsman
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

In accordance with §1819(g)(5)(B), §1919(g)(5)(B) of the Act, and 42 CFR 488.325(f), the State survey agency must provide the State's long-term care ombudsman with the following:

- A Statement of Deficiencies reflecting facility noncompliance and, if applicable, a separate list of isolated deficiencies that constitute no actual harm with the potential for minimal harm;
- Reports of adverse actions specified in 42 CFR 488.406 imposed on a facility;
- Any written response by the facility, including plans of correction and facility requests for informal dispute resolution; and
- A facility's request for an appeal and the results of any appeal.

7904.2 - Federal Surveys
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

For Federal surveys, CMS will contact the State survey agency and provide the information needed for the State to notify the ombudsman on CMS's behalf.

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7905 - Information Furnished to State by Facility with Substandard Quality of Care

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7905.1 - Information Provided to the State Survey Agency by Facility

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

To provide for the notice to physicians required under §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 (as defined in 42 CFR 488.301), a skilled nursing facility or nursing facility must provide the State survey agency with a list of:

- Each resident in the facility with respect to whom a finding of substandard quality of care was made; and
- The name and address of his/her attending physician.

7905.2 - Failure to Provide Information Timely

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A facility's failure to disclose the information as required in §7905.1 above will result in termination of participation or imposition of alternative remedies.

7905.3 - Federal Surveys

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

In the case of a finding of substandard quality of care based on a Federal survey, the regional office will instruct the facility to provide the necessary information to the State survey agency.

7906 - Information Furnished to Attending Physician and State Board

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7906.1 - State Notification of Noncompliance

(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Not later than 20 calendar days after a skilled nursing facility or nursing facility complies with §7905.1, the State survey agency must provide written notice of the noncompliance to:

- The attending physician of each resident in the facility with respect to whom a finding of substandard quality of care was made; and
- The State board responsible for licensing the facility's administrator.

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7906.2 - Federal Surveys
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

If the finding of substandard quality of care is based on a Federal survey, the State survey agency will provide notification of noncompliance to the above parties after receiving the necessary information from the skilled nursing facility or nursing facility. (See §7905.3.)

7907 - Access to Information by State Medicaid Fraud Control Unit
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

In accordance with the procedures in 42 CFR 455.21, the State survey agency must provide access to any survey and certification information incidental to a skilled nursing facility's or nursing facility's participation in Medicare or Medicaid to a State Medicaid Fraud Control Unit as defined at 42 CFR Part 1007, consistent with current State law and the operating agreement between the State survey agency and the State Medicaid Fraud Control Unit.

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Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R161SOM	09/30/2016	Revisions to the State Operations Manual (SOM) Chapter 7	09/23/2016	N/A
R160SOM	09/23/2016	Revisions to the State Operations Manual (SOM) Chapter 7 – Rescinded and replaced by Transmittal 161	09/23/2016	N/A
R118SOM	06/12/2014	New Guidance Added to Chapter 7 – Survey and Enforcement Process for Skilled Nursing Facilities and Nursing Facilities	01/01/2012	N/A
R113SOM	04/25/2014	New Guidance Added to Chapter 7 – Survey and Enforcement Process for Skilled Nursing Facilities and Nursing Facilities – Rescinded and replaced by Transmittal 118	01/01/2012	N/A
R97SOM	12/13/2013	State Operations Manual (SOM) Chapter 7, Revisions for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)	12/13/2013	N/A
R63SOM	09/10/2010	Chapter 7-“Survey and Enforcement Process for Skilled Nursing Facilities and Nursing Facilities”	09/10/2010	N/A
R01SOM	05/21/2004	Initial Issuance of Pub 100-07	N/A	N/A