CMS Manual System

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Pub. 100-07 State Operations Provider Certification

Transmittal 213 | **Date: February 10, 2023**

SUBJECT: Revisions to State Operations Manual (SOM), Chapter 7

I. SUMMARY OF CHANGES: Technical Changes – Changed "regional office" to "CMS Location" and "Central Office" to "CMS Headquarters".

NEW/REVISED MATERIAL - EFFECTIVE DATE: **February 10, 2023**
IMPLEMENTATION DATE: February 10, 2023

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Table of Contents
R	7000 – Introduction
R	7002 - Change in Certification Status for Medicaid Nursing Facilities
R	7014.1.1 - Waiver of 7-Day Registered Nurse (RN) Requirement for Skilled Nursing Facilities
R	7014.1.3 - Waivers of Nurse Staffing Requirements for Dually Participating Facilities
R	7014.3 - Variations of Patient Room Size and/or Beds Per Room
R	7201.1 - Survey Team Size
R	7201.2 - Team Composition
R	7202.1 – Introduction
R	7202.3 - Report and Investigation of Improper Acts
R	7203.6 - Extended Survey/Partial Extended Survey
R	7203.7 -State Monitoring Visits
R	7205.3 - Determining Standard Survey Interval for Each Facility
R	7205.4 - Assessing Compliance with Survey Frequency Requirements
R	7205.5 - Actions to Ensure Compliance with Standard Survey Interval
R	7207.2 - All Surveys Must Be Unannounced
R	7207.2.2 - Variance in Timing (Time of Day, Day of Week, Time of Month)
R	7207.3 - CMS Review of State Scheduling Procedures

R	7210.2 - Expansion of the Survey
R	7212.1 – Introduction
R	7213.2 – Purpose
R	7213.3 - Independent Informal Dispute Resolution Requirements
R	7213.5- Key Elements of Independent Informal Dispute Resolution
R	7213.7 - Approval of an Independent Informal Dispute Resolution Process
R	7213.9 - Independent Informal Dispute Resolution Recommendation and Final Decision
R	7213.10 - Additional Elements for Federal Independent Informal Dispute Resolution Process
R	7300.1 – Introduction
R	7300.2 - Survey and Certification Responsibility
R	7300.3 - Initial Survey and Certification Responsibility
R	7300.4 - Effect of CMS' Validation Authority
R	7301.1 - Immediate Jeopardy Exists
R	7301.2 - Immediate Jeopardy Does Not Exist
R	7303 - Appeal of Certification of Noncompliance
R	7304 - Mandatory Immediate Imposition of Federal Remedies
R	7304.1 - Criteria for Mandatory Immediate Imposition of Federal Remedies Prior to the Facility's Correction of Deficiencies
R	7304.2 - Effective Dates for Immediate Imposition of Federal Remedies
R	7304.3 - Responsibilities of the State Survey Agency and the CMS Location when there is an Immediate Imposition of Federal Remedies
R	7305.1.1 – When No Immediate Jeopardy Exists and an Opportunity to Correct Will be Provided Before Remedies Are Imposed
R	7305.1.2 – When No Immediate Jeopardy Exists and No Opportunity to Correct Will be Provided Before Remedies Are Imposed
R	7305.1.3 – When Immediate Jeopardy Exists
R	7305.2 - CMS Location, State Medicaid Agency, and State Formal Notices When Remedies are Imposed
R	7305.2.1 - Who Sends the Formal Notice of Remedies
R	7305.3 - Overlap of Notice of Remedies
R	7308 - Enforcement Action When Immediate Jeopardy Exists
R	7309 - Key Dates When Immediate Jeopardy (IJ) Exists
R	7309.1 - 2nd Calendar Day
R	7309.2 - 5th -21st Calendar Day
R	7310 - Immediate Jeopardy (IJ) Does Not Exist
R	7314 - Special Procedures for Recommending and Providing Notice of Imposition and Rescission of Category 1 Remedies and Denial of Payment for New Admissions Remedy
R	7315 - Disagreements About Remedies When Immediate Jeopardy Does Not Exist
R	7316.1 - Required Actions When There Is an Opportunity to Correct
R	7316.2 - Required Actions When There Is No Opportunity to Correct
R	7317.2 – Revisits

R	7319.2 - State-Operated Facilities
R	7321.2 - Reasonable Assurance Concept
R	7321.3 - Reasonable Assurance Surveys
R	7321.3.1 - First Visit
R	7321.3.2 - Second Visit
R	7321.4 - Effective Date of Provider Agreement
R	7400.2 - Enforcement Remedies for the State Medicaid Agency
R	7400.3 - Selection of Remedies
R	7400.6.2 - Category 2
R	7400.6.3 - Selection from Category 3
R	7500.1 – Introduction
R	7500.2 – Purpose
R	7500.4 – Causes
R	7502.1 – Introduction
R	7502.3 - Appropriate Resources for Directed In-Service Training Programs
R	7502.4 - Further Responsibilities
R	7506.1 – Introduction
R	7506.2 - Optional Denial of Payment for All New Admissions Remedy
R	7506.4 - Duration and Resumption of Payments
R	7510 - Basis for Imposing Civil Money Penalties
R	7510.1 – Determining Citations of Past Noncompliance at the Time of the Current Survey
R	7512 - Compliance With Section 1128A of the Social Security Act
R	7516.2 - Factors Affecting Amount of Penalty
R	7520 - Notice of Imposition of Civil Money Penalty
R	7522.1 - Revisit Identifies New Noncompliance and Same Data Tag is Selected
R	7522.3 - Noncompliance - Immediate Jeopardy Does Not Exist
R	7524 - Settlement of Civil Money Penalty
R	7526.1 - Facility Requests Hearing on Noncompliance That Led to Imposition of Civil Money Penalty
R	7526.2 - Facility Waiver of Right to Hearing
R	7528.1 – When a Civil Money Penalty Subject to Being Collected and Placed in an Escrow Account is Imposed
R	7528.2 - After Final Administrative Decision
R	7530.1 - Contents of Notice
R	7530.2 - Method of Payment
R	7534.1 - Collected From Medicare or Dually-Participating Facility
R	7550.4 - Selection of Temporary Manager
R	7550.9 - Alternatives to Temporary Management
R	7556.3 - When There Is No Immediate Jeopardy
R	7600.2 – Purpose
R	7600.3 - Criteria for Continued Payment During Correction Period
R	7600.4 - Approval of Plan and Timetable for Corrective Action

R	7600.6 - Facility Does Not Take Corrective Action According to Its Approved Plan of Correction and Has Not Achieved Substantial Compliance
R	7600.7 - Facility Takes Corrective Action According to its Plan of Correction But Fails to Achieve Substantial Compliance
R	7701 - Reporting Abuse to Law Enforcement and the Medicaid Fraud Control Unit
R	7800.1 – Introduction
R	7800.2 - Measuring Consistency
R	7805.1 – Introduction
R	7805.3 - Alternative Remedies
R	7807.1 – Introduction
R	7807.2 - Disagreement About Whether Facility Has Met Requirements
R	7807.3 - Disagreement About Decision to Terminate
R	7807.4 - Disagreement About Timing of Facility Termination
R	7807.5 - Disagreement About Remedies
R	7807.6 - One Enforcement Decision
R	7903.1 - Information That Must Be Disclosed Within 14 Days of Request
R	7903.2 - Disclosure Time Frames
R	7905.3 - Federal Surveys

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

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

Table of Contents
(Rev.213, 02-10-23)

Transmittals for Chapter 7

7304.3 - Responsibilities of the State Survey Agency and the CMS ***Location*** when there is an Immediate Imposition of Federal Remedies

7305.2 - ***CMS Location***, State Medicaid Agency, and State Formal Notices When Remedies are Imposed

7000 - Introduction

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *Centers for Medicare and Medicaid Services (CMS) Location* 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 *CMS Location* throughout this chapter when the *CMS Location* 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.

7002 - Change in Certification Status for Medicaid Nursing Facilities

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location*. The *CMS Location* 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.)

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

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location*, 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 *CMS Location*, 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.

7014.1.3 - Waivers of Nurse Staffing Requirements for Dually Participating Facilities

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location*.

7014.3 - Variations of Patient Room Size and/or Beds Per Room

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* has jurisdiction to approve such waivers or variances. The State has jurisdiction to approve them in Medicaid-only cases.

Survey Process

7201.1 - Survey Team Size

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

Survey team size will vary, depending primarily on the size of the facility being surveyed. The State (or, for Federal teams, the *CMS Location*) 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

The State (or, for Federal teams, the *CMS Location*) 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 *CMS Location*) 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 *CMS Location* 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,

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.

7202.1 - Introduction

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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.

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 *CMS Location* must be informed as described in §7202.

7202.3 - Report and Investigation of Improper Acts

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* , and the *CMS Location* 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 *Location*, will then work in close cooperation with the responsible State officials until the matter is resolved.

7203.6 - Extended Survey/Partial Extended Survey

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

"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 *CMS Locations* 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 *Location*;
- 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 *Location*.

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.)

7205.3 - Determining Standard Survey Interval for Each Facility

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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

- 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 *Headquarters* to calculate the state-wide average.

7205.4 - Assessing Compliance with Survey Frequency Requirements

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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

The *CMS Location* 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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.

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 *CMS Location* will notify the State, determine if a problem exists, and take appropriate action. This action is specified in Chapter 8 of this manual.

7207.2 - All Surveys Must Be Unannounced

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* 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:

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

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

(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 *CMS Location* 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

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

The *CMS Location* 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.

7210.2 - Expansion of the Survey

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

When the State or *CMS Location* 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 *CMS Location* prepares Form CMS-2567 and follows the procedures required in §7305.

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

7212.1 - Introduction

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *Location*, must be in writing so that it is available for review upon request.

7213.2 – Purpose

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *Location*.

7213.3 - Independent Informal Dispute Resolution Requirements

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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. 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 States and/or CMS *Location*, each State and its CMS *Location* must approve the Independent IDR entity's or person's process and procedures for the State's or *CMS Location'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 *Location* for review and prior approval. The Independent IDR process must be in writing and available for review upon request.

7213.5- Key Elements of Independent Informal Dispute Resolution

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *Location* 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 *Location* 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 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.

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.

7213.7 - Approval of an Independent Informal Dispute Resolution Process

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *Location* for approval.

The CMS *Location* 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 *Location* 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 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.

7213.9 - Independent Informal Dispute Resolution Recommendation and Final Decision

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 written record will be sent to the applicable CMS *Location* 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 *Location*. As soon as practicable, but no later than 10 calendar days, the CMS *Location* 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 *Location*.

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 *Location* 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.

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.

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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* will offer the facility the opportunity for an Independent IDR. The *CMS Location* will follow the applicable elements cited in §7213. The *CMS Location* should advise the facility that all requests for an Independent IDR should be directed in writing to the *CMS Location* 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 *Location* with its request.

The *CMS Location* 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 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 *CMS Location* 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 *Headquarters* . 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 *Headquarters* 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 *Headquarters* 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 *CMS Location* along with their final written record/report.

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

Upon receipt of the Independent IDR written record, the *CMS Location*, will review the Independent IDR recommendation(s) and:

1. If the *CMS Location* agrees with the Independent IDR recommendation(s) and no changes will be made to the disputed survey findings, the *CMS Location* 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 *CMS Location* disagrees with one or more of the recommendations of the Independent IDR entity or person, the complete written record will be sent to CMS *Headquarters* for review and final decision. The *CMS Location* should identify the Independent IDR recommendation with which it disagrees, the basis

for its disagreement and any relevant survey documents to CMS *Headquarters* . As soon as practicable, but no later than 10 calendar days, CMS *Headquarters* will review the Independent IDR recommendation and corresponding records along with the CMS Location's written disagreement of the Independent IDR's recommendation and will provide written notification to the CMS *Location* of the final decision. The CMS *Location* will then send written notification of the final decision to the facility within 10 calendar days of receiving the final decision from CMS *Headquarters* .

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 *Location* has sent written notice of the Independent IDR recommendation to the facility.

3. If the CMS *Location* agrees with the Independent IDR recommendation(s) or has received a final decision from CMS *Headquarters* and changes are to be made to the disputed survey findings, the CMS *Location* 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 *Location* 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.

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.

7300.1 - Introduction

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* 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 *CMS Location* for Medicare. The State is authorized by CMS to both recommend and impose category 1 remedies. In addition, when authorized by the *CMS Location* 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 *CMS Location* 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 *CMS Location* 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 *CMS Location* may take independent and binding enforcement action against any nursing

facility based on its findings of noncompliance. However, the *CMS Location's* certification is usually based on the State's survey and findings.

7300.2 - Survey and Certification Responsibility

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* 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 *CMS Location* 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 *CMS Location* for the skilled nursing facility. In the case where the State and the *CMS Location* disagree with the certification of compliance or noncompliance, see §7807 for rules to resolve such disagreements.

7300.3 - Initial Survey and Certification Responsibility

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-13-23)

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 *CMS Location* 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 *CMS Location* and/or State Medicaid Agency deny participation. The *CMS Location* 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.)

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 *CMS Location*. 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 *CMS Location* and/or State Medicaid Agency deny participation, the *CMS Location* 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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

The *CMS Location* may also make independent findings of compliance or noncompliance based on its review of the State's certification of compliance or noncompliance. The *CMS Location* need not conduct an onsite visit in order to exercise its validation authority. However, the *CMS Location'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 *CMS Location* and the State.)

7301.1 - Immediate Jeopardy Exists

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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

When immediate jeopardy exists:

1. The *CMS Location* 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 *CMS Location* 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 *CMS Location* 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 *CMS Location* or State Medicaid Agency may impose other remedies as described in §7500. Except for State monitoring, which requires no notice, the *CMS Location* 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 *CMS Location*, 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 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 *CMS Location*, 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

(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 *CMS Location* or State Medicaid Agency should impose another remedy in addition to termination for a facility not being given an opportunity to correct.

3. The *CMS Location* 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 *CMS Location* 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 *CMS Location*) 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 *CMS Location*) 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 *CMS Location* 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 *CMS Location* or State Medicaid Agency (or State, as authorized by CMS) may impose State monitoring without notice.

7. The *CMS Location* 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 *CMS Location*, 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.)

7303 - Appeal of Certification of Noncompliance

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location*, 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 *CMS Location*. 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 *CMS Location* disagrees with the State's finding of compliance; and

- 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 *CMS Location* and the *CMS Location* 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *Location.*

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

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 deficiency 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 deficiency 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, the CMS *Location* **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 *Location* 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: "Current" 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.

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 *Location* 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 *Location* 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 *Location* 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 *Location.* 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 *CMS Location* 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.

Directed Plan of Correction - Refer to §7500 of this chapter. This remedy provides for directed action(s) from either the State or CMS *Location* 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 *CMS Location* 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.

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 mandatory 6-month termination, as required. NOTE: Multiple remedies may be imposed for	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 *Location.*

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 *Location* for their imposition of remedies. The CMS *Location* 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 *Location* 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

Once a remedy is imposed, it becomes effective 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 compliance 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. However, 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

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 *Location* when there is an Immediate Imposition of Federal Remedies

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 Location their review and action; and,
- The CMS *Location* 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 survey agency (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 *Location* 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.

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

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *Location*):

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 *CMS Location*, 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 *CMS Location* 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 facility that it is recommending to the *CMS Location* 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 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 *CMS Location* 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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;

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 *CMS Location*, 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 - *CMS Location*, State Medicaid Agency, and State Formal Notices When Remedies are Imposed

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

7305.2.1 - Who Sends the Formal Notice of Remedies

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* 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 *CMS Location* 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.

7305.3 - Overlap of Notice of Remedies

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

1. When the State recommends a category 1 remedy and/or a denial of payment for new admissions, and/or the *CMS Location* or State Medicaid Agency imposes any other category of remedies at the same time, the *CMS Location* 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 *CMS Location* or State Medicaid Agency, of a category 1 remedy and/or of imposition of denial of payment for new admissions, and the *CMS Location* or State Medicaid Agency imposes other category remedies at a later date, both the State and the *CMS Location* or the State and the State Medicaid Agency, send separate notices.

7308 - Enforcement Action When Immediate Jeopardy Exists

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *Location*, 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 *Location* 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.

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 *Location* 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

NOTE: These timelines apply whether the survey was conducted by a State Survey Agency, CMS *Location* or a CMS contractor.

7309.1 - 2nd Calendar Day

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *Location* 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 *Location* 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 *Location* 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.

7309.2 - 5th -21st Calendar Day

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 Location* 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.

7310 - Immediate Jeopardy (IJ) Does Not Exist

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 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 *Location* 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 *Location* 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).

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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* and the State Medicaid Agency of its proposed action.

The notice to the *CMS Location* or State Medicaid Agency can be electronic or written. If the *CMS Location* 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 *CMS Location* and/or

State Medicaid Agency. A copy of the letter is sent to the *CMS Location* and State Medicaid Agency. The *CMS Location* 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 *CMS Location* and/or the State Medicaid Agency. (See also §7311 and §7506.1.)

7315 - Disagreements About Remedies When Immediate Jeopardy Does Not Exist

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

Disagreements between the *CMS Location* 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 *CMS Location* disagrees with the State's recommendation, the *CMS Location* will contact the State Medicaid Agency and the State to resolve the differences.

7316.1 - Required Actions When There Is an Opportunity to Correct

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* 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 *CMS Location* 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 *CMS Location* 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 *CMS Location* 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 *CMS Location* 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.

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 *CMS Location* 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* 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 *CMS Location* and/or State Medicaid Agency of its recommendation(s) for immediate remedies.

4. The *CMS Location* 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.

6. The State may provide notice, as authorized by the *CMS Location* 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 *CMS Location* 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.

7317.2 - Revisits

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 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 *Location* approval for a third onsite revisit or recommend to the *CMS Location* 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 *CMS Location* 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:

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 *CMS Location*					
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;

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

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 *CMS Location*; a third onsite revisit may be approved only at the discretion of the *CMS Location*. *The CMS Locations* 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 *CMS Location* 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 *CMS Location* and *CMS Headquarters* . Situations such as this should be discussed with the *CMS Location* 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.)

- **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.

7319.2 - State-Operated Facilities

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* 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 *CMS Location* instructs the facility to submit its plan of correction to the *CMS Location*. The plan of correction must be submitted within 10 calendar days after the facility has received its Statement of Deficiencies.

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

7321.2 - Reasonable Assurance Concept

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 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 *CMS Location* 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* then sets the reasonable assurance period, after which a second (full) survey will be completed. Sometimes, the *CMS Location* 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 *CMS Location'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 *CMS Location* 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

The second visit will typically be a full standard survey.

EXCEPTION: The *CMS Location* 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 *CMS Location* 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 *CMS Location* 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 *CMS Location* **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 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 *CMS Location* will issue a notice of denial of participation.

7321.4 - Effective Date of Provider Agreement

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* 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 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 *CMS Location* determined that, based on the initial Medicaid survey, the cause for termination had been removed. The *CMS Location* 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 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 harm and one substandard quality of care. Upon receipt of the *CMS Location'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 *CMS Location* to stop all remedies based on the change of ownership. The *CMS Location* 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 *CMS Location* established a reasonable assurance period of 150 days, with two Medicare re-entry surveys required. The *CMS Location* 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 *CMS Location* 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.

7400.2 - Enforcement Remedies for the State Medicaid Agency

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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.

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 *CMS Location* 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

To 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 *Location* 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.

7400.6.2 - Category 2

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location*;
- Lower range per day civil money penalties
- Per instance civil money penalties.

7400.6.3 - Selection from Category 3

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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);

- 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 *CMS Location* 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.

Remedies

7500.1 - Introduction

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* can select when it finds a facility out of compliance with Federal requirements.

7500.2 - Purpose

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location*, or the temporary manager (with State or *CMS Location* 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 *CMS Location* may impose another remedy until the facility achieves substantial compliance or is terminated from the Medicare or Medicaid programs.

7500.4 - Causes

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

Use of a directed plan of correction should be dependent upon causes identified by the State, *CMS Location*, 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.

7502.1 - Introduction

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

These instructions implement 42 CFR 488.425. Directed in-service training is one of the remedies the State or *CMS Location* can select when it finds a facility out of compliance with Federal requirements.

7502.3 - Appropriate Resources for Directed In-Service Training Programs

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* may impose one or more additional remedies as specified in 42 CFR 488.206.

7506.1 - Introduction

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* and/or the State Medicaid Agency (See §7311 and §7314.)

7506.2 - Optional Denial of Payment for All New Admissions Remedy

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location*. 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 *CMS Location*.

- 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.

7506.4 - Duration and Resumption of Payments

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location*.

Civil Money Penalties

7510 - Basis for Imposing Civil Money Penalties

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* 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 *CMS Locations* 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.

7510.1 – Determining Citations of Past Noncompliance at the Time of the Current Survey

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *Location* 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 *Location* 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.

7512 - Compliance With Section 1128A of the Social Security Act

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

The *CMS Location* consults with the *CMS Location* 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.

7516.2 - Factors Affecting Amount of Penalty

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

(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 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 *CMS Location* 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.

7520 - Notice of Imposition of Civil Money Penalty

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* 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;

- 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 *CMS Location* 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 *CMS Location's* and/or the State Medicaid Agency's acceptance of the State's recommendation, the *CMS Location* 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 *CMS Location* or the State Medicaid Agency send the formal notification of the imposition of the civil money penalty to the facility as quickly as possible.

7522.1 - Revisit Identifies New Noncompliance and Same Data Tag is Selected

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

If the same data tag is selected to identify noncompliance, the State (or *the CMS Location*) 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 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.

7522.3 - Noncompliance - Immediate Jeopardy Does Not Exist

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* 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.

7524 - Settlement of Civil Money Penalty

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

The *CMS Location* 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.

7526.1 - Facility Requests Hearing on Noncompliance That Led to Imposition of Civil Money Penalty

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location*.

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.

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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* or the State Medicaid Agency reduces the civil money penalty amount by 35 percent. After receipt of the waiver, the *CMS Location* 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. 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.

7528.1 – When a Civil Money Penalty Subject to Being Collected and Placed in an Escrow Account is Imposed

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

When the *CMS Location* 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 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

When the *CMS Location* 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.

7530.1 - Contents of Notice

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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;

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 *CMS Location* contacts CMS *Headquarters* 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* or the State Medicaid Agency deducts the civil money penalty plus any accrued interest from money owed to the facility.

7534.1 - Collected From Medicare or Dually-Participating Facility

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 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 *Location* 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 *Location* 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 *CMS Location* 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 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 *Location* 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 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.

7550.4 - Selection of Temporary Manager

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

The State will select the temporary manager when the State Medicaid Agency is imposing the remedy and will recommend a temporary manager to the *CMS Location* 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 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.

7550.9 - Alternatives to Temporary Management

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* may also use the alternative.

7556.3 - When There Is No Immediate Jeopardy

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

When there is no immediate jeopardy, the State Medicaid Agency may and the *CMS Location* must terminate a facility, or the *CMS Location* 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 *CMS Location* 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.

7600.2 - Purpose

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

CMS may continue payments to a facility that is not in substantial compliance for up to 6 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 *CMS Location*; and

3. The facility (for Medicare) agrees to repay the *CMS Location* payments received if action is not taken according to the approved plan of correction.

The State recommends to the *CMS Location* 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* by the 25th day following the last day of survey. The *CMS Location* has 5 calendar days from the date these items are received to respond to the plan of correction. If the *CMS Location* does not contact the State by the 6th calendar day, the plan of correction is deemed to be approved.

7600.6 - Facility Does Not Take Corrective Action According to Its Approved Plan of Correction and Has Not Achieved Substantial Compliance

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

If the facility does not take action according to its approved plan of correction and does not achieve substantial compliance by the end of the specified period, the *CMS Location*:

- 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 *CMS Location* 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 *CMS Location*, and the *CMS Location* 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 *CMS Location* 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* will terminate the skilled nursing facility's provider agreement.

7701 - Reporting Abuse to Law Enforcement and the Medicaid Fraud Control Unit

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

When the *CMS Location* or SA substantiates a finding of abuse, the *CMS Location* or SA must report the substantiated findings to local law enforcement and, if appropriate, the Medicaid Fraud Control Unit.

Program Management

7800.1 - Introduction

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

This section provides guidance to the *CMS Location* 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Locations* and States use to fulfill this requirement. Additionally, CMS encourages the *CMS Locations* and States to share with each other innovative and unique methods used to measure consistency.

7805.1 - Introduction

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Locations* about reviewing, for approval or disapproval, State plan amendments for enforcement remedies as specified at 42 CFR 488.406(c).

7805.3 - Alternative Remedies

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* 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 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.

7807.1 - Introduction

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location's* findings do not agree with the State survey agency's findings.

While CMS expects that in most cases the *CMS Location* 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 *CMS Location'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 *CMS Location's* decision always prevails.

7807.2 - Disagreement About Whether Facility Has Met Requirements

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

If the State survey agency finds that a facility is not in substantial compliance, but the *CMS Location* 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.

If the State survey agency finds a facility is in substantial compliance, but the *CMS Location* finds, either through an onsite survey or review of the State survey agency's findings, that the facility is not in substantial compliance, the *CMS Location's* finding prevails.

When the *CMS Location'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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

When both the State survey agency and the *CMS Location* 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 *CMS Location* wants to terminate, but the State survey agency does not, the *CMS Location* and the State Medicaid Agency impose the alternative remedies (pending the *CMS Location's* termination at 6 months) and follow the procedures in §7600;

- If the State Medicaid Agency wants to terminate, but the *CMS Location* 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 *CMS Location* 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. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* agree that the facility has not achieved substantial compliance and agree that the facility should be terminated.

7807.5 - Disagreement About Remedies

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

The law provides that either the State or the *CMS Location* may impose additional or alternative remedies. For example, if the State decides to terminate a provider agreement and the *CMS Location* 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 *CMS Location* want to impose an additional remedy, only the *CMS Location's* remedy would be applied.

7807.6 - One Enforcement Decision

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

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 *CMS Location* 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.)

Disclosure

7903.1 - Information That Must Be Disclosed Within 14 Days of Request

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

Upon the public's request, the State survey agency, *CMS Location*, 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.

7903.2 - Disclosure Time Frames

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

Although the State survey agency or *CMS Location* 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 *CMS Location* makes the determination about the appropriateness of the timing of the disclosure.

In situations generating media interest, the State survey agency should notify the *CMS Location* prior to the initial public release of the Form CMS-2567. *CMS Locations* are expected to extend the same courtesy to State survey agencies when *CMS Location* survey findings have the potential for high publicity.

7905.3 - Federal Surveys

(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

In the case of a finding of substandard quality of care based on a Federal survey, the *CMS Location* will instruct the facility to provide the necessary information to the State survey agency.