DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality

Ref: QSO-26-03-NH REVISED

DATE: **April 3,** 2026

TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: **REVISED:** Revisions to the State Operations Manual (SOM) Chapters 5 and 7

Memo Information:
Memo revision date: **2026-04-03**
Original release date: **2026-01-30**

Memorandum Summary

CMS is releasing the following guidance in Chapter 5 of the SOM:

- Revisions to Immediate Jeopardy Priority Definition examples for Nursing Homes; and
- Clarification of Off-site investigations.

CMS has updated and revised guidance in Chapter 7 of the SOM that includes:

- Survey Team Composition, Survey Procedures, Plans of Correction, Verifying Corrections, Survey Revisit and Offsite Revisit Paper Review, Off-hours Survey, Enforcement, Nurse Staffing Waivers, Disposition of Civil Money Penalties (CMP), Federal Civil Penalties Inflation Reduction Act, Informal Dispute Resolution (IDR), and Independent Informal Dispute Resolution (IIDR);
- Additionally, guidance previously found in Appendix P of the State Operations Manual has been added to Chapter 7; and
- Technical changes that include updates for accurate references.

Background:

To protect the health and safety of nursing home residents, CMS continues to enhance oversight and enforcement when non-compliance with federal statutes and regulations is identified. The instructions and interpretive guidance in the State Operations Manual (SOM) explain specific federal requirements and clarify how surveyors should cite non-compliance.

Discussion:

CMS has updated Chapters 5 and 7of the SOM to align instructions and guidance with current policies in QSO memos and established practices.

Chapter 5 Updates:

The revisions to Chapter 5 ensure that the oversight and investigations of alleged non-compliance are thorough and consistent across the country. They also clarify that off-site investigations must be approved by CMS in advance to ensure uniform application. The revisions also expand examples of intakes that warrant immediate jeopardy prioritization, such as discharging a resident to an unsafe setting.

Chapter 7 Updates:

The revisions to Chapter 7 standardize oversight, investigation procedures, enforcement actions, and the Civil Money Penalty Reinvestment Program (CMPRP). The revisions update a wide variety of survey guidance, such as survey team composition, resident privacy and confidentiality, photography during survey, off-hours survey, past non-compliance, severity and scope of deficient practices, and conducting exit conferences. We also incorporated instructions previously outlined in Appendix P of the SOM, which was removed when the Long Term Care Survey Process (LTCSP) launched in 2017.

Key Revisions include:

- **Nurse Staffing Waivers and Resident Room Variances**: This section of guidance simply provides a process for nursing homes to obtain a waiver and is not related to the survey process. Therefore, CMS is moving this guidance from Appendix PP to Chapter 7.
- **Onsite vs. Off-site revisits:** Clarifies procedures for conducting revisits after surveyors identify non-compliance.
- **Immediate Jeopardy (IJ):** Updated guidance on identifying immediate jeopardy, determining when it has been removed, and outlining conditions for lowering the severity level once IJ has been removed.
- **Acceptable Plan of Correction:** Addresses an OIG recommendation to clarify areas related to the acceptable plans of correction after a facility was found to be non-compliant with the requirements for participation.
- **Enforcement Guidance**: Revises policies for Civil Money Penalties (CMP) to align with current practices, including use of the CMP Analytic Tool and the annual adjustment of CMP amounts according to the Annual CMP Inflation Adjustment Act of 2015. Updates also reflect changes to the CMP policy that align with the Fiscal Year 2025 Skilled Nursing Facilities Prospective Payment System (SNF PPS) final rule (89 FR 64048, Aug. 6, 2024), which expands CMS' ability to impose per instance and per day CMPs to promote sustained correction of health and safety deficiencies. *These revisions will be reflected in the CMP Analytic Tool for all enforcement cycles starting on and/or after March 31, 2026. Per-Instance CMPs will be displayed on Nursing Home Care Compare beginning June 24, 2026.*
- **Civil Money Penalty Reinvestment Program:** The updated guidance clarifies the allowable and non-allowable uses of CMP funds, the current application review process, and reporting requirements for project results. Additionally, the updates clarify that State CMP Fund Balances from the State Plan will be publicly posted. The updates were made to align with the release of QSO-25-26-NH.

- **Informal Dispute Resolution (IDR):** Aligns IDR procedures with the Independent IDR (IIDR) process and adds guidance on uploading deficiencies pending IDR or IIDR to the CMS record-keeping system to improve transparency.

- ***Survey Expectations:*** *The updated guidance clarifies the minimum amount of time the survey team should be onsite on the first day of a survey, and the minimum amount of consecutive days that the survey team should be onsite for standard and abbreviated surveys.*

Contact:

For questions or concerns relating to this memorandum, please contact DNH_TriageTeam@cms.hhs.gov

Effective Date:
April 30, 2026. Please communicate to all appropriate staff within 30 days.

/s/

Karen L. Tritz
Director, Survey & Operations Group

Melissa C. Daly
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Attachment(s)-
Table: Summary of changes
Attachment A - Advanced copy of Chapter 5, Complaint Procedures
Attachment B - Advanced copy of Chapter 7, Survey and Enforcement Process for Skilled Nursing Facilities and Nursing Facilities

Resources to Improve Quality of Care:
Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid. Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus

Get guidance memos issued by going to CMS.gov page and entering your email to sign up. Check the box next to "CCSQ Policy, Administrative, and Safety Special Alert Memorandums" to be notified when we release a memo.

Summary of Revisions to the State Operations Manual (SOM) Chapters 5 and 7

Guidance	Status	Description	Reason for the update
Long-Term Care Survey	Revised	Eliminated references to Appendix P, Regional Offices, and added references to the LTCSP Procedure Guide. CMS provided guidance for team composition, including the role of the new surveyor who is not SMQT.	Since the larger nursing home regulatory reform in 2016, CMS took this opportunity to bring updated guidance into Chapter 7.
Nurse Staffing Waivers and Resident Room Variances	Revised	Regulatory requirements and guidance for nursing waivers and structural variances have been relocated from Appendix PP to Chapter 7 and are further detailed.	This section of guidance simply provides a process for nursing homes to obtain a waiver and is not related to the survey process. Therefore, CMS is moving this guidance from Appendix PP to Chapter 7.
Onsite vs. Off-site revisits	Revised	Clarified the procedures for conducting revisits after noncompliance has been identified during surveys.	CMS made updates to provide guidance and parameters for post-survey revisits to assist state agencies in being more efficient.
Immediate Jeopardy (IJ)	Revised	Revised guidance on identifying immediate jeopardy, determining when it has been removed, and outlining conditions for lowering the severity level once IJ has been removed has been incorporated.	Updates were made to align with Appendix Q, clarify guidance, and improve consistency.
Acceptable Plan of Correction	Revised	Clarifying areas related to acceptable plans of correction after a facility was found to be non-compliant with the requirements for participation.	CMS revised the guidance to align with and address an OIG recommendation.
Enforcement Guidance	Revised	Revised policies for Civil Money Penalties (CMP) to align with current practices. This includes references to	The updates are being made to align with current practices and to incorporate revisions in alignment with

Guidance	Status	Description	Reason for the update
		the CMP analytic tool and the adjustment of CMP amounts according to the Annual CMP Inflation Adjustment Act of 2015. Additionally, we incorporated revisions to the CMP policy that align with the Fiscal Year 2025 Skilled Nursing Facilities Prospective Payment System (SNF PPS) final rule. These policies expanded CMS' ability to impose financial penalties to drive sustained correction of health and safety deficiencies by allowing for more per instance and per day CMPs to be imposed, as appropriate.	the Fiscal Year 2025 Skilled Nursing Facilities Prospective Payment System (SNF PPS) final rule.
Civil Money Penalty Reinvestment Program:	New	The updated guidance clarifies the allowable and non-allowable uses of CMP funds, the current application review process, and reporting requirements for project results. Additionally, the updates clarify that State CMP Fund Balances from the State Plan will be publicly posted.	Updates were made to strengthen the program's capacity to support high-quality, resident-centered nursing home projects by encouraging more applications, ensuring accountability, and expanding access to funding. CMS has also included the language released in QSO-25-26-NH.
Informal Dispute Resolution (IDR)	Revised	The IDR process was revised to align with the Independent IDR (IIDR) process. Guidance was also included for uploading deficiencies pending IDR or IIDR to the CMS record-keeping	Updates were made to increase transparency and align similar processes.

Guidance	Status	Description	Reason for the update
		system to increase transparency.	
Complaint procedures	Revised	The complaint procedures in Ch. 5 were updated to ensure national consistency. Immediate jeopardy prioritization examples were updated. Complaint procedures for fires resulting in serious injury or death were updated to align with current processes. Examples of complaint intakes that can be reviewed off-site were clarified. The terms substantiated and unsubstantiated were removed from LTC providers to align with current practices.	Updates were made to align with current practices and ensure uniform application of complaint policies.

State Operations Manual
Chapter 5 - Complaint Procedures

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5000 - Management of Complaints and Incidents

5000.1 – Purpose of the Complaint/Incident Process

(Rev. 212; Issued; 02-10-23; Effective: 10-21-22; Implementation: 10-24-22)

Mission: To protect Medicare/Medicaid beneficiaries from abuse, neglect, exploitation, inadequate care or supervision.

The goal of the Federal complaint/incident process is to establish a system that will assist in promoting and protecting the health, safety, and welfare of residents, patients, and clients receiving health care services. The complaint/incident management system has three objectives.

1. The first objective and priority for the complaint/incident management system is protective oversight. This is accomplished by analyzing the complaint allegations and reported incidents received to identify and respond to those that appear to pose the greatest potential for harming beneficiaries (has caused or is likely to cause, serious injury, harm, impairment or death). Complaints/incidents of this type that allege an immediate threat to the health, safety or welfare of individuals are investigated immediately.

2. The second objective is prevention. Complaints/incidents that do not allege a threat of serious harm are investigated to determine if a problem exists that could have a negative impact on the healthcare services provided. The investigation of these complaints/incidents is designed to identify and correct less serious complaints/incident to prevent the escalation of these problems into more serious situations that would threaten the health, safety and welfare of the individuals receiving the service. These complaints/incidents are also prioritized and investigated based on the seriousness of the allegations.

   Numerous or more frequent complaints/incidents may indicate systemic problems and therefore may be assigned a higher priority for investigation.

3. The third objective is to promote efficiency and quality within the health care delivery system. Complaints/incidents that are not directly related to Federal requirements are forwarded to the appropriate agency(ies) for follow-up and investigation. Complaints/incidents in this category may include but are not limited to Medicare/Medicaid fraud, complaints against individual licensed practitioners, and billing issues.

5000.2 – Overview

All the procedures in this chapter are followed when complaints and reported incidents, including referrals from public entities, involve Medicare-certified providers/suppliers, Medicaid-certified providers/suppliers, or CLIA-certified laboratories. The investigation and resolution of complaints are critical certification activities. The CMS, the State Medicaid Agency (SMA), and the State survey agency (SA) are responsible for ensuring that participating providers/suppliers of health care services continually meet Federal requirements. This requires that the SA promptly reviews complaints/incidents, conducts **unannounced** onsite investigations of reports alleging noncompliance, and informs the CMS *location* and/or the SMA any time certification requirements are found to be out of compliance.

Since there are multiple activities associated with the management of complaints and incidents, responsibilities often cut across organizational lines. Thus, the SA must demonstrate clear-cut accountability for each step of the process and a focal coordinating/controlling responsibility to assure timely and appropriate action. The SA's responsibilities cannot be delegated.

5010 - General Intake Process

A complaint is an allegation of noncompliance with Federal and/or State requirements. If the SA determines that the allegation(s) falls within the authority of the SA, the SA determines the severity and urgency of the allegations, so that appropriate and timely action can be pursued. Each SA is expected to have written policies and procedures to ensure that the appropriate response is taken for all allegations and is consistent with Federal requirements as well as with procedures in the State Operations Manual. This structure needs to include response timelines and a process to document actions taken by the SA in response to allegations. If a State's time frames for the investigation of a complaint/incident are more stringent than the Federal time frames, the intake is prioritized using the State's timeframes. The SA is expected to be able to share the logic and rationale that was utilized in prioritizing the complaint/incident for investigation. The SA response must be designed to protect the health and safety of all residents, patients, and clients.

Besides the SA, other public entities receive information and/or perform investigations. These entities include the office of the coroner or medical examiner, end-stage renal disease (ESRD) networks, quality improvement networks (QINs), law enforcement, the ombudsman's office, and protection and advocacy systems. At times, these public entities will forward information to the SA if there are concerns about the health and safety of residents, patients, and clients. The SAs are required to manage and investigate these referrals as complaints.

An allegation is an assertion of noncompliance with Federal health and safety regulations. The point of receipt of the allegation is a critical fact-finding and decision-making point. The SA ensures that its complaint telephone number is listed in local directories. Information regarding the care, treatment and services provided to beneficiaries can come from a variety of sources, including beneficiaries themselves,

beneficiaries' family members, health care providers, concerned citizens, public agencies, or media reports. Report sources may be verbal or written. In some instances, the complainant may request anonymity.

The SA and *CMS location* ensure the privacy and anonymity of every complainant. Generally, the SA follows the disclosure procedures under chapter 3, §3308. The SA discloses the complainant's identity only to those individuals with a need to know who are acting in an official capacity to investigate the complaint.

In addition to these Federal requirements, the SA abides by any State procedures not in direct conflict with CMS instructions. The SA notifies the *CMS location* if State regulations conflict directly with any part of these complaint procedures.

See also Section 5310.1 for information related to facility-reported incidents.

5010.1 - Information to Collect From Complainant

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

The SA collects information necessary to make important decisions about the allegations. In instances where written or verbal allegations are received, subsequent communication may be necessary to obtain additional information.

Comprehensive information should be collected during the intake process to allow for proper prioritization, including the following:

- Information about the complainant (e.g., name, address, telephone, etc.);
- Individuals involved and affected;
- Narrative/specifics of the complainant's concerns including the date, and time of the allegation;
- The complainant's views about the frequency and pervasiveness of the allegation;
- Name of the provider/supplier including location (e.g., unit, room, floor) of the allegation, if applicable;
- How/why the complainant believes the alleged event occurred;
- Whether the complainant initiated other courses of action, such as reporting to other agencies, discussing issues with the provider, and obtaining a response/resolution; and
- The complainant's expectation/desire for resolution/remedy, if appropriate.

5010.2 - Information to Provide to Complainant

The complaint intake process assists the complainant in resolving his/her conflicts. As part of the intake process the SA provides the following:

- Policies and procedures for handling intakes including the scope of the SA's regulatory authority and any considerations pertaining to confidentiality;
- The course of action that the SA or *CMS location* will take and the anticipated time frames;
- Information about other appropriate agencies that could provide assistance including the name and telephone number of a contact person, if available; and
- A SA contact name and number for follow-up by the complainant.

NOTE FOR DEEMED PROVIDERS/SUPPLIERS: If a complaint does not allege condition-level noncompliance, the SA may: 1) advise the complainant to file the complaint to the accrediting organization (AO), or 2) ask for the complainant's permission to release the information to the AO.

5010.3 – Notification to the *CMS Location*

1 – Notification to the *CMS location*

The SA immediately forwards allegations involving the following to the *CMS location*:

- Deemed providers/suppliers;
- Hospital and psychiatric residential treatment facility (PRTF) restraint/seclusion-related deaths;
- EMTALA complaints;
- Fires resulting in serious injury or death in a Medicare/Medicaid-certified facility;
- Federal facilities;
- Religious Non-medical Health Care Institutions (RNHCIs)(evaluation performed by Region I, Boston, only);
- CLIA-certified laboratories holding a certificate of accreditation. (See Chapter 6).
- CLIA-exempt laboratory. (See Chapter 6);
- Blood transfusion-related fatalities (See Chapter 6 and Appendix C);

- Over-utilization or inappropriate utilization of services within the QIO's jurisdiction;
- Civil rights violations; or
- Medicare or Medicaid fraud

2 – Special Cases

The SA considers whether notification to the *CMS location* is appropriate. If a complaint is especially significant, sensitive, or attracting broad public or media attention, the SA informs the *CMS location* immediately. Additionally, the SA needs to consider any other early notice requirements prescribed by other State or Federal policies or interagency agreements.

5050 - CMS Regional Office Responsibility for Monitoring SA Management of Complaints and Incidents

CMS *locations* are responsible for monitoring the SAs' management of complaints and incidents to assure that the SAs are complying with the provisions set forth in Federal regulations, the SOM, and CMS policy memoranda. As part of the monitoring process, the SAs will be evaluated in accordance with the criteria set forth by the State Performance Standard Review. Many States have State laws and regulations that specify how to manage complaints and incidents. Whenever possible, State and Federal requirements should be integrated to avoid unnecessary duplication. CMS *locations* should accept State requirements that meet or exceed the intent of the Federal requirements. At a minimum, it is expected that noncompliance with Federal requirements resulting from a complaint or reported incident will receive follow-up and be documented in the Aspen Complaints Tracking System (ACTS).

5060 – ASPEN Complaints/Incidents Tracking System (ACTS)

The SA collects information related to complaints and facility-reported incidents and uses a system to track and monitor the receipt and disposition of complaint and incident intakes.

The ASPEN Complaints/Incidents Tracking System (ACTS) is designed to track, process, and report on complaints and incidents reported against health care providers and suppliers regulated by CMS. It is designed to manage all operations associated with complaint/incident processing, from initial intake and investigation through the final disposition.

The ACTS must be used for the intake of all allegations against Medicare/Medicaid-certified providers/suppliers and CLIA. The ACTS is a Federal system and data entered

into ACTS is subject to Federal laws governing disclosure and the protection of an individual's right to privacy.

A complaint/incident record is created in ACTS based on how the allegation is received by the SA or *CMS location*. For example, if one person calls with ten allegations about one provider/supplier, this is counted as one complaint record. If six people call with the same allegation, this is counted as six telephone calls and is counted as six complaint records. If one letter is received with one or many allegations and is signed by 20 people, this is counted as one complaint record.

5060.1 - Data Entry

The SAs and *CMS location*s are required to enter into ACTS:

- All complaints gathered as part of Federal survey and certification responsibilities, regardless if an onsite survey is conducted [i.e., complaints related to noncompliance with the Federal condition(s) of participation (COPs), condition(s) for coverage (CFCs), condition(s) for certification, requirement(s) for participation (RFPs), or EMTALA requirement(s)]; **and**

- For nursing homes, all self-reported incidents that are reported under Federal law and the requirements for participation [i.e., reporting to law enforcement of crimes occurring in LTC facilities – §1150B of the Social Security Act and §483.12(b)(5); alleged violations of abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property – §483.12(c)(1) and (4)]. For non-long term care providers/suppliers, all self-reported incidents that require a Federal onsite survey.

The information recorded in ACTS reflects the allegation furnished by the complainant/provider/supplier at the time of the intake. At a minimum, if the intake information requires an onsite survey and the allegation may involve both Federal and State licensure requirements, a Federal onsite survey is completed and entered into ACTS.

If an investigation finds one or more violations of Federal requirements, the findings must be cited under the appropriate tags and entered into the Federal system even if the information is entered into a State licensure data system. Since this information is essential to the effective management of the survey and certification program, it is important that SAs complete the required fields in ACTS in a timely manner.

Exhibit 23 defines the required fields in ACTS.

Tracking of Referrals in ACTS

The SAs are required to enter into ACTS all referrals from public entities that allege noncompliance with the Federal requirements. For reporting purposes, the SAs should

enter these cases as complaints (i.e., Intake Type=Complaint, Intake Subtype=Federal COPs, CFCs, RFPs, EMTALA). In order to more quickly identify which of these cases stem from a referral, the SAs are expected to check the appropriate category under the "Source" field. For example, for referrals from the coroner's office, states would check "Coroner" under the "Source" field for the intake.

Tracking of State Monitoring Visits (See Section 5077) in ACTS

When a State Monitoring Visit results in a Federal deficiency, the SA will identify the survey in ASPEN as "complaint" and create an intake and survey record in ACTS. The data should be entered into ACTS as follows:

- Intake Type = Complaint;
- Intake Subtype = Federal COPs, CFCs, RFPs, EMTALA;
- Source = State SA;
- Priority = can vary; and
- Allegation Type = State Monitoring.

5060.2 - Reports

(Rev. 212; Issued; 02-10-23; Effective: 10-21-22; Implementation: 10-24-22)

The ACTS produces a variety of reports that may be used for analysis and evaluation of provider/supplier performance. Complaint/incident reports are generated and displayed through menus that can be accessed in ACTS. Reports may be produced for one provider/supplier, or reports may be combined and present information for multiple providers/suppliers. Report filtering criteria is available through the Report Customization window, which allows the user to select criteria for the report to meet the user's specifications. Refer to the ACTS Procedures Guide for a list and description of the reports available in ACTS.

NOTE:

FOR ADDITIONAL INFORMATION ON SPECIFIC POLICIES RELATED TO:

- **DEEMED PROVIDERS AND SUPPLIERS, EXCLUDING CLIA, SEE SECTION 5100**
- **NON-DEEMED PROVIDERS AND SUPPLIERS, SEE SECTION 5200**
- **NURSING HOMES, SEE SECTION 5300**
- **EMTALA, SEE SECTION 5400**
- **CLIA LABORATORIES, SEE SECTION 5500**

- **ESRD, SEE SECTION 5160 AND SECTION 5170**

5070 - Priority Assignment for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA

This section does not apply to clinical laboratories subject to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). See Sections 5500 – 5590 for CLIA information.

An assessment of each complaint or incident intake must be made by an individual who is professionally qualified to evaluate the nature of the problem based upon his/her knowledge of Federal requirements and his/her knowledge of current clinical standards of practice.

From a complainant's allegation(s) or an allegation from a facility-reported incident, the SA/CMS Location identifies potential concerns where the provider/supplier may not be in compliance with Federal requirements. The SA/CMS Location must review the allegation(s) for all requirements that apply and should be investigated. These requirements will be specific to each health care entity. The surveyor then investigates each of those areas of concern and health care entity type.

The role of the surveyor is not to validate whether the events contained in the allegation had occurred, but it is to determine whether the facility is in compliance with the Federal requirements for Medicare/Medicaid-certified providers/suppliers. If CMS or the SA believes that the complaint or facility-reported incident should also be investigated under the jurisdiction of another entity, referrals should be made as appropriate (e.g., law enforcement for criminal activity, State licensing boards for health care practitioners, the Medicare Administrative Contractor (MAC) for billing issues).

In the case of nursing homes, in situations where a determination is made that immediate jeopardy may be present and ongoing, the SA must start the on-site investigation within three business days of receipt of the initial complaint or incident report. Receipt of the initial complaint or incident report means when the report is received by the SA, whether it is received by the SA directly, or another State agency under arrangement or contractor that is receiving the report on behalf of the SA from the complainant or facility. Also, if a complaint or facility-reported incident is received after business hours, then it is considered to be received on the next business day, for purposes of calculating the investigation timeframe. For example, if a complaint is received on Saturday and the SA office is closed during the weekend, then the following Monday will be used to calculate the investigation timeframe.

For non-long term care providers/suppliers, in situations where a determination is made that immediate jeopardy may be present and ongoing, the SA is required to start the on-site investigation within two business days of receipt of the complaint or incident report, or, in the case of a deemed provider or supplier, within two business days of *CMS*

location authorization for investigation. The same process applies to EMTALA complaints or a survey related to a report of a hospital or CAH Distinct Part Unit patient death associated with the use of restraint or seclusion. The SA's investigation must be initiated within two business days of *CMS location* authorization for investigation.

Generally, an alleged event occurring more than 12 months prior to the intake date would not require a complaint investigation. However, the SA is not precluded from conducting a Federal investigation (with appropriate *CMS location* authorization, where required) to determine current compliance status based on the concerns identified in the complaint.

For nursing homes, an onsite survey may not be required if there is sufficient evidence that the facility does not have continuing noncompliance and the alleged event occurred before the last standard survey.

For all intakes concerning deemed status providers or suppliers where the intake involves allegations of substantial noncompliance (in other words, the allegation would result in a condition-level deficiency citation if found to be true and uncorrected), the SA must submit a request for *CMS location* approval of a complaint validation survey (i.e., substantial allegation validation survey). The SA must obtain *CMS location* approval before conducting a substantial allegation validation survey. The *CMS location* will authorize the SA to conduct the survey by issuing electronically via *iQIES* a Form CMS-2802, which will indicate the specific conditions for which the SA must assess compliance. The *CMS location* must authorize assessment of compliance for a whole condition and not just for particular standards within a condition, unless the Form CMS-2802 for the applicable provider/supplier type permits selection of a specific standard, e.g., Life Safety Code.

All allegations of EMTALA violations related to a hospital (which also includes cancer, children's, long term care, psychiatric and rehabilitation hospitals) or CAH, regardless of whether the hospital or CAH is deemed, must be referred to the *CMS location*. The *CMS location* will determine whether the SA will conduct an EMTALA investigation.

In cases where the SA or *CMS location* has noted a pattern of similar complaints about a specific provider or supplier, each of which on its own merits would be triaged at a medium or low level, the SA or *CMS location* has the discretion to assign a higher triage level to a current intake based on the noted pattern, in order to ensure timely investigation of the provider's/supplier's compliance with the applicable requirements or Conditions.

CMS expects SAs to prioritize complaints at the appropriate level that is warranted. The timeframes in Section 5075 below represent maximum timeframes for investigation ; the SA is not precluded from investigating complaints and facility-reported incidents within a shorter timeframe. In addition, the SA is not precluded from taking other factors into consideration in its triage decision. For example, the SA may identify a trend in allegations that indicates an increased risk of harm to residents or the SA may receive corroborating information from other complainants regarding the allegation.

See also Section 5310.2 for requirements for nursing home facility-reported incidents.

5075 - Priority Definitions for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA
(Rev. 212; Issued; 02-10-23; Effective: 10-21-22; Implementation: 10-24-22)

5075.1 - Immediate Jeopardy (for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)

General Provisions

The regulations at 42 CFR 489.3 define immediate jeopardy as, "A situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." Appendix Q contains the Guidelines for Determining Immediate Jeopardy. Intakes are assigned this priority if the alleged noncompliance indicates there was serious injury, harm, impairment or death of a patient or resident, or the likelihood for such, and there continues to be an immediate risk of serious injury, harm, impairment or death of a patient or resident unless immediate corrective action is taken. In addition, for nursing homes, facility-reported incidents are assigned this priority if immediate jeopardy may have occurred, regardless of whether an immediate risk may continue to exist. Examples of intakes that are assigned this priority include, but are not limited to, the following:

- All intakes alleging abuse of a resident/patient/client *that involve serious injury, harm, impairment, or death of a resident/patient/client or likelihood for such,* and it is uncertain that they are adequately protected.
- *For nursing homes, all intakes where a resident was discharged to an unsafe setting, or in a manner that place the resident at risk for serious harm (e.g. the resident still has medical needs but they cannot be supported in the setting they were discharged to).*
- Intakes alleging EMTALA noncompliance may also be assigned this priority.
- Any hospital self-reported incident of patient death associated with use of restraint or seclusion which the *CMS location* determines requires an on-site investigation is also assigned this priority.

When the SA or *CMS location* makes the determination that a complaint or incident report suggests an immediate jeopardy may be present, the investigation is to be initiated in accordance with Section 5075.9.

See also Section 5310.2A for additional guidance related to nursing home facility-reported incidents. (Note: Please see Section 5075.9 for maximum time frames related to Federal onsite investigation of complaints/incidents.)

Fires Resulting in Serious Injury or Death

Fires resulting in serious injury or death are prioritized as "immediate jeopardy". The following actions are taken when a report of a fire resulting in serious injury or death in a Medicare/Medicaid certified facility is received from any source:

The SA

- Enters the complaint or self-reported incident into *the CMS system* (Priority = IJ, Allegation Category = Life Safety Code);
- Informs the appropriate *CMS location* of fire resulting in serious injury or death no later than one working day after receipt of the intake;
- Compiles information as needed to present a comprehensive picture of the situation surrounding the fire;
- Takes appropriate action necessary to assist the Medicare/Medicaid-certified provider/supplier to protect and/or relocate residents or patients from further harm; and
- Performs the Life Safety Code investigation.

The *CMS location*

- Informs CMS Central Office (CO) *Division of Emergency Preparedness and Life Safety Code (DEPL)* of the fire and planned actions, sending a copy of the alert to the Life Safety Code specialist;
- Consults with the CO *DEPL* to determine whether there is an indication for CO *DEPL* participation in the survey for program evaluation purposes;
- Reports any findings and actions taken by the SA to the CO *DEPL* at the end of the on-site survey; and
- At its discretion, may accompany the SA during the on-site survey.

The CO

- Consults with the *CMS location* to determine whether or not issues are present that indicate further investigation to determine the adequacy of current standards and their application; and
- In certain cases, CO *DEPL* staff may accompany *CMS location* and/or state personnel on the on-site survey.

5075.2 - Non-Immediate Jeopardy - High Priority (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)

Nursing Homes:

Intakes are assigned a "high" priority if the alleged noncompliance with one or more requirements may have caused harm that negatively impacts the individual's mental, physical and/or psychosocial status and are of such consequence to the person's well-being that a rapid response by the SA is indicated. Usually, specific rather than general information (such as: descriptive identifiers, individual names, date/time/location of occurrence, description of harm, etc.) factors into the assignment of this level of priority.

Note: Please see Section 5075.9 for maximum time frames related to Federal onsite investigation of complaints/incidents.

NOTE: Exhibit 22 provides additional guidance to distinguish between the priorities of "immediate jeopardy" and "non-immediate jeopardy - high" for nursing home complaints/incidents.

NOTE: Please refer to Tag F610 in Appendix PP of the State Operations Manual for information related to facility responses to alleged violations, including facility investigation, resident protection, and corrective actions.

Non-Long Term Care Providers/Suppliers

Intakes are assigned this priority if the alleged noncompliance with the applicable Conditions of Participation, Coverage or Certification, or EMTALA requirements, if found to be true and uncorrected, would not represent an IJ, but would result in a determination of substantial noncompliance, i.e., at least one condition-level deficiency.

Intakes assigned this priority require an onsite survey to be initiated within 45 calendar days after intake prioritization for non-deemed providers/suppliers, and within 45 calendar days after authorization of the investigation by the *CMS location* for deemed status providers/suppliers. The *CMS location* has the discretion to request the onsite survey be initiated in less than 45 calendar days.

5075.3 - Non-Immediate Jeopardy - Medium Priority (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers)

Nursing Homes:

Complaints are assigned a "medium" priority if the alleged noncompliance with one or more requirements caused no actual physical and/or psychosocial harm but there is the

potential for more than minimal harm to the resident(s) (Severity Level 2). Facility-reported incidents are assigned a "medium" priority if the alleged noncompliance with one or more requirements caused no actual physical and/or psychosocial harm but there is the potential for more than minimal harm to the resident(s) (Severity Level 2) and the facility has not provided an adequate response to the allegation or it is not known whether the facility provided an adequate response. *Please see Section 5075.9 for maximum time frames related to Federal onsite investigation of complaints/incidents.*

NOTE: Please refer to Tag F610 in Appendix PP of the State Operations Manual for surveyor guidance related to facility responses to alleged violations, including facility investigation, resident protection, and corrective actions.

Non-Long Term Care Providers/Suppliers

Intakes are assigned this priority if the alleged noncompliance with one or more standards within a Condition of Participation, Condition for Coverage or Condition for Certification is limited in manner and degree and/or caused, or may cause, harm that is of limited consequence and does not impair the individual's mental, physical and/or psychosocial status or function. In other words, the incident or complaint, if found to be true and uncorrected, would not result in a determination of substantial non-compliance, i.e., there would not be any condition-level deficiency.

For non-deemed providers/suppliers, intakes assigned this priority are scheduled in accordance with section 5075.9 for investigation no later than when the next on-site survey occurs.

For deemed providers/suppliers, the SA (or *CMS location*, if the *CMS location* handled the intake) advises the complainant that the allegation does not meet the criteria for a Federal investigation and refers the complainant to the applicable accrediting organization(s)(AOs) in accordance with the provisions of section 5100.2.

5075.4 - Non-Immediate Jeopardy – Low Priority (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers)

Nursing Homes

Intakes are assigned a "low" priority if the alleged noncompliance with one or more requirements may have caused no actual harm with a potential for minimal harm (Severity Level 1). *Please see Section 5075.9 for maximum time frames related to Federal onsite investigation of complaints/incidents.*

In addition, facility-reported incidents are assigned a "low" priority if the alleged noncompliance with one or more requirements may have caused no actual physical and/or psychosocial harm but there is the potential for more than minimal harm to the resident(s)(Severity Level 2) and the facility has provided a potentially adequate response to the allegation.

NOTE: Please refer to Tag F610 in Appendix PP of the State Operations Manual for information related to facility responses to alleged violations, including facility investigation, resident protection, and corrective actions.

The SA reviews these intakes for tracking of possible trends in order to determine if there are common themes that suggest areas for focused attention when the next on-site survey occurs. If the SA identifies a trend that suggests similar concerns, the SA either investigates the concerns during the next standard or complaint survey or initiates a complaint survey.

Non-Long Term Care Providers/Suppliers

Intakes are assigned this priority if the alleged noncompliance with one or more standards within a Condition of Participation, Coverage or Certification may have caused physical, mental and/or psychosocial discomfort that does not constitute injury or damage.

For non-deemed providers/suppliers, the SA reviews these intakes for tracking of possible trends in the nature of complaints in order to determine if there are common themes that suggest areas for focused attention when the next on-site survey occurs. Individual investigations of each intake are not required, although the SA has the discretion to conduct a complaint survey if trending suggests a number of similar problems that might warrant an on-site investigation.

For deemed providers/suppliers, the SA (or *CMS location*, if the *CMS location* handled the intake) advises the complainant that the allegation does not meet the criteria for a Federal investigation and refers the complainant to the applicable accreditation organization(s)(AOs) in accordance with the provisions of section 5100.2.

5075.5 - Administrative Review/Offsite Investigation (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers)

Nursing Homes

The SA conducts the review/offsite investigation and may confirm the findings at the next on-site survey.

Offsite investigations are rare and are not permitted unless approved in advance by CMS. For example, if a complaint is received related to arbitration agreements, prohibition on third party guarantee of payment, or prohibition on charges for services covered under Medicaid, CMS may approve an offsite review of these or other documents to assess compliance and cite noncompliance and require corrections, as necessary.

Non-long Term Care Providers/Suppliers

For non-long term care providers/suppliers, both deemed and non-deemed, administrative review or offsite investigation is generally not permitted. Exceptions are usually limited to the following types of cases:

- *CMS location* review of alleged noncompliance with provider agreement requirements found in 42 CFR Part 489, such as:
    - Alleged discrimination against Medicare beneficiaries, or
    - Failure of a hospital to accept Medicare-like payment rates for treatment provided to a patient referred by an Indian Health Service or tribal facility.
- *CMS location* review in the case of a CAH:
    - Of a notice by the MAC of failure of a CAH to maintain an average annual per patient length of stay not exceeding 96 hours, or
    - Whether a relocating CAH or an existing hospital seeking to convert to CAH status satisfies the CAH location requirements.

The *CMS location* documents in the provider/supplier file the results of such administrative review or offsite investigation. Note: depending on *CMS location* practice, such administrative review cases may or may not be entered into *iQIES*.

5075.6 - Referral – Immediate (for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)

Intakes are assigned a "Referral – Immediate" priority if the nature and seriousness of a complaint/incident or State procedures requires the referral or reporting of this information for investigation to another agency, board, or ESRD network **without delay**.

For example, if a complaint has criminal implications and the complainant has not reported the incident to law enforcement, the SA must report the suspected crime to law enforcement immediately (NOTE: In such cases, the referral is recorded in the Contact/Refer tab under the *iQIES* intake). This priority may be assigned **in addition to** one of the priorities in sections 5075.1 through 5075.5.

When the SA refers the complaint/incident to another agency or entity (e.g., law enforcement, Ombudsman, licensure agency, etc.) for action, the SA must request a written report on the results of the investigation by the outside entity. Referral to an outside entity does not relieve the SA of the responsibility to assess compliance with Federal conditions or requirements, when applicable. The timeframes for investigation are not altered by the referral. (Expressed requests by law enforcement that the SA defer an onsite investigation should be discussed with the CMS *location*, as appropriate.)

5075.7 - Referral – Other (for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)

Intakes are assigned a "Referral – Other" priority when they are referred to another agency, board, or ESRD network for investigation or for informational purposes. This priority may be assigned **in addition to** one of the priorities in sections 5075.1 through 5075.5.

When the SA refers the complaint/incident to another agency or entity (e.g., law enforcement, Ombudsman, licensure agency, etc.) for action, the SA must request a written report on the results of the investigation by the outside entity. Referral to an outside entity does not relieve the SA of the responsibility to assess compliance with Federal conditions or requirements, when applicable. The time frames for investigation are not altered by the referral. (Expressed requests by law enforcement that the SA defer an onsite investigation should be discussed with the CMS *location*, as appropriate.)

5075.8 - No Action Necessary (for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)

Intakes are assigned a "No Action Necessary" priority if the SA or *CMS location* determines with certainty that no further investigation, analysis, or action is necessary.

For example, no action is necessary if the allegation is not related to any Federal COPs, CFCs, conditions for certification, RFPs, or EMTALA requirement(s); or situations in which a previous survey investigated the exact same event(s) and either did not find noncompliance, or noncompliance was previously identified and subsequently corrected by the provider/supplier.

This category would also be used for intakes concerning an event that occurred more than 12 months in the past, unless the SA (or the *CMS location*, in the case of a deemed status provider/supplier) determines that a complaint investigation is nevertheless warranted.

Nursing Homes

The following are examples of reports that require no further action or investigation by the SA/*CMS location*:

1) Facility-reported incidents that are not reportable events under Federal law or regulations;

2) Facility-reported incidents involving lost items, which are found and no theft is suspected; and

3) The alleged event occurred before the last standard survey and there is sufficient evidence that the facility does not have continuing noncompliance since the last standard survey.

NOTE: Sufficient evidence that the facility does not have continuing noncompliance may be indicated by a recent survey that reviewed the concern, no additional complaints or facility reported incidents have been received regarding the same issue, and interview with the Long-term Care Ombudsman which reveal no concerns.

5075.9 - Maximum Time Frames Related to the Federal Onsite Investigation of Complaints/Incidents

	Intake Prioritization		
Provider Type	Immediate Jeopardy (IJ)	Non-IJ High	Non-IJ Medium
Nursing home complaints	SA must initiate an onsite survey within 3 business days of receipt of the initial report.	SA must initiate an onsite survey within an annual average of 15 business days of receipt of the initial report, not to exceed 18 business days.	SA must initiate an onsite survey within 45 calendar days of receipt of the initial report.
Nursing home incidents	With inadequate resident protection, SA must initiate an onsite survey within 3 business days of receipt of the initial report. With potentially adequate resident protection, SA must initiate an onsite survey within 7 business days of receipt of the initial report. See Section 5310.2A.	SA must initiate an onsite survey within an annual average of 15 business days of receipt of the initial report, not to exceed 18 business days.	With an inadequate facility response, SA must initiate an onsite survey within 45 calendar days of receipt of the initial report.
Non-deemed non-long term care providers/suppliers	SA must initiate an onsite survey within 2 business days of receipt.	SA must initiate an onsite survey within 45 calendar days of prioritization	SA must investigate no later than when the next onsite survey occurs
Deemed providers/suppliers	SA must initiate an onsite survey within 2 business days of receipt of *CMS location* authorization	SA must initiate an onsite survey within 45 calendar days of receipt of *CMS location* authorization.	Complainant is referred to the applicable accrediting organization(s)
EMTALA	SA must initiate an onsite survey within 2 business days of receipt of *CMS location* authorization.	SA must initiate an onsite survey within 45 calendar days of receipt of *CMS location* authorization	N/A
Death associated with restraint/seclusion-Hospitals	SA must initiate an onsite survey within 2 business days of receipt of *CMS location* authorization.	N/A	N/A
Fires resulting in serious injury or death	SA must initiate an onsite survey within 2 business days of receipt.	N/A	N/A

5077 - State Monitoring Visits

"State monitoring visits" refers to visits by the SA to oversee a provider's/supplier's compliance status:

- 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/clients/patients by providing an oversight presence, rather than to perform a structured follow-up visit.

- In other circumstances, as authorized by the CMS *location*.

See Section 5060 for data entry requirements for this type of visit.

5078 – Pre-Survey Activities
(Rev. 120, Issued: 09-19-14, Effective: 09-19-14, Implementation: 09-19-14)

To assist in planning the complaint investigation, prior to going on-site the SA should review the provider's or supplier's prior compliance record and, as applicable, quality indicators, ESRD Outcome List and Data or supporting information received from other programs, such as the Ombudsman program or Protection and Advocacy program. This process may require additional contact with the complainant. More information on pre-survey activities may be found in Section 5170 for ESRD facilities, Section 5300.1 for long term care facilities, in the provider/supplier-specific SOM appendices and in Appendix V concerning EMTALA of the SOM.)

5079 – Entrance Conference - Non-Long Term Care Providers/Suppliers
(Rev. 120, Issued: 09-19-14, Effective: 09-19-14, Implementation: 09-19-14)

Onsite complaint investigations must always be unannounced. Upon entrance, advise the provider/supplier CEO or other senior official on duty of the general purpose of the visit. The SA explains the reason for the survey and avoids any impression that a predetermination has been made as to the validity of the allegation. It is important to let the facility know why you are there, but to also protect the confidentiality of those involved in the complaint. Do not release information that will cause opportunities to be lost for pertinent observations, interviews, and record reviews required for a thorough investigation. For example, in the case of a hospital, critical access hospital or ambulatory surgical center, if the complaint is that a patient developed a life-threatening infection in a post-surgical wound, do not tell the facility the exact complaint. Rather, tell them it is a situation related to infection control for surgical patients. Another example, in the case of a long term care facility, would be when a complaint that food that is intended to be served hot is always served cold. In this case, do not tell the provider the exact complaint. Rather, tell them it is a situation related to dietary requirements.

(See Section 5300.2 for guidance on the entrance conference for long term care facilities as well as the provider/supplier-specific appendices of the SOM, and Appendix V of the SOM concerning EMTALA.)

5080 - Investigation Findings and Reports
(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

Each SA establishes reporting policies, procedures and formats including report language targeted to specific audiences.

5080.1 - Report to the Complainant

(Rev. 212; Issued; 02-10-23; Effective: 10-21-22; Implementation: 10-24-22)

The SA/CMS *location* provides the complainant a written report of the investigation findings as a summary record of the investigation.

The following principles guide preparation of the report to the complainant:

- Acknowledge the complainant's concern(s);
- Identify the SA's regulatory authority to investigate the complaint/incident and any statutory or regulatory limits that may bear on the authority to conduct an investigation;
- Provide a summary of investigation methods (e.g., on-site visit, written correspondence, telephone inquiries, etc.);
- Provide date(s) of investigation;
- Provide an explanation of your SA's decision-making process (NOTE: CMS and the SA should avoid using terms such as "substantiated" and "unsubstantiated");
- Provide the complainant with information regarding whether or not noncompliance was identified during the complaint investigation. (**NOTE**: To the extent possible, the summary should not compromise the anonymity of individuals, or include specific situations that may be used to identify individuals, when anonymity has been requested or is appropriate in the judgment of the SA);
- Identify where the complainant may find the Statement of Deficiencies and Plan of Correction (e.g., posted at the nursing home, Nursing Home Care Compare, request the CMS-2567 from the SA);
- Describe how the complainant may request a copy of the investigation report, subject to Federal and State disclosure requirements (e.g., see 42 CFR §488.325 and FOIA requirements at 45 CFR Part 5); and
- Identify appropriate referral information (i.e., other agencies that may be involved).

5080.2 - Survey Exit Conference and Report to the Provider/Supplier

Generally, the SA conducts an exit conference with the provider/supplier at the completion of the on-site portion of the complaint investigation survey. The SA informs the provider/supplier of the survey findings, including a general description of any deficiencies found. The description should be detailed enough to inform the provider/supplier of the types of activities that require the provider's/supplier's corrective action. However, the SA must not comment on the scope and severity of the deficiencies

identified for long term care facilities. For non-long term care providers/suppliers, the SA must not comment on manner and degree, that is, whether the deficiencies identified were condition- or standard-level. Surveyors must also not make reference to any "Tags" related to deficiencies identified in non-long term care as this identifies condition- or standard-level. Instead identify the regulatory grouping where concerns exist. See Section 2724 for additional information about presenting findings during the Exit Conference.

For non-long term care providers/suppliers, the SA must not provide a list of patients interviewed, observed, or whose medical records were reviewed, and does not identify specific patients whose cases are associated with specific deficiencies. (The provider/supplier has the right to request a copy of any documentation the surveyors copy to support deficiency findings; therefore the provider/supplier should have enough information after the exit conference to begin corrective actions.)

The SA informs the provider/supplier that survey findings will be documented on Form CMS 2567, which will be sent to the provider/supplier and subsequently will be made available to the public under the disclosure of survey information provisions. For deemed providers/suppliers, the SA informs the provider/supplier that the *CMS location* will be consulted and (depending on *CMS location* practice), either the *CMS location* or the SA will inform the facility of the results of the survey investigation via the Form CMS 2567.

The SA/*CMS location* sends to the provider/supplier a written report of the investigation findings as a summary record of the investigation. At a minimum, this would include the Form CMS 2567 and applicable notices. For surveys of deemed providers/suppliers (not including EMTALA surveys), the *CMS location* sends a copy of the written report to the applicable accrediting organization(s), following the procedures specified in Section 5110. At the *CMS location*'s or SA's discretion, the materials may be sent to the accrediting organization via e-mail.

(See Section 5300.5 for guidance on the exit conference for long term care facilities, Section 5440.5 for EMTALA investigations, as well as the provider/supplier-specific appendices of the SOM, and Appendix V of the SOM concerning EMTALA.)

NOTE: Sections 5300 to 5390 relate to nursing homes.

5100 - Investigation of Complaints for Deemed Providers/Suppliers

(Rev. 120, Issued: 09-19-14, Effective: 09-19-14, Implementation: 09-19-14)

Sections 5100 - 5130 apply to all deemed providers and suppliers, with the exception of clinical laboratories subject to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). See Sections 5500 – 5590 for CLIA information, including investigation of complaints related to accredited laboratories.

5100.1 - Basis for Investigation

Sections 1864(c) and 1865 of the Social Security Act (the Act) provide the basis for conducting substantial allegation validation – i.e., complaint investigation - surveys of deemed providers/suppliers. Before the SA may conduct a complaint investigation survey at a deemed provider/supplier, it must receive authorization to do so from the *CMS location*. In accordance with 42 CFR 488.7, the *CMS location* may authorize a complaint investigation only in response to a "substantial allegation" of noncompliance. A "substantial allegation of noncompliance" is defined at 42 CFR 488.1 as a complaint from any of a variety of sources, including complaints submitted in person, by telephone, through written correspondence, or in news media articles, that, if substantiated, would have an impact on the health and safety of patients, and that raises doubts as to a provider's or supplier's compliance with any Medicare condition. In other words, the complaint, if verified and uncorrected at the time of the survey, would result in a condition-level deficiency citation. The SA survey conducted in response to a substantial allegation is one type of validation survey.

NOTE: Deemed status is irrelevant for EMTALA complaints. Hospitals and CAHs may not be deemed to be in compliance with EMTALA requirements at 42 CFR 489.24 and the related requirements at 42 CFR 489.20, since these requirements are not part of an approved Medicare hospital or CAH Medicare accreditation program. SAs must refer all EMTALA-related allegations concerning a hospital or CAH to the *CMS location*, regardless of whether the hospital or CAH is deemed or not. The provisions of Section 5100 do not apply to EMTALA investigations.

The SA must notify the *CMS location* of all complaints/incidents it receives which, if substantiated, would by their manner and degree suggest condition-level noncompliance. The *CMS location* authorizes the SA to conduct a complaint investigation if it concurs that the nature of the allegation, if it were true and uncorrected, suggests condition-level noncompliance. If the *CMS location* does not concur that the allegation rises to this level, either the *CMS location* will change the prioritization of the intake in ACTS to the appropriate level or it will instruct the SA to do so. Regardless of who makes the change in ACTS, the *CMS location* instructs the SA to refer the complainant to the applicable accrediting organization, following the procedures in section 5100.2

The *CMS location* communicates its authorization to conduct a complaint investigation of the deemed provider/supplier by completing the applicable Form CMS 2802 (See Exhibit 33) in ACTS, indicating which Conditions of Participation or Conditions for Coverage or Certification are to be investigated by the SA. Absent *CMS location* authorization, the SA may not conduct a Federal complaint investigation of the deemed provider/supplier. The SA may have authority under State law to conduct its own non-Federal investigation.

The *CMS location* completes the Form CMS 2802 in ACTS even if the SA received an initial verbal authorization from the *CMS location* to initiate the complaint survey of a deemed provider/supplier. Since ACTS allows the *CMS location* to authorize a complaint survey electronically it is not necessary for the *CMS location* to send a signed

hard copy of the Form CMS 2802 to the SA via fax or U.S. Postal Service. Once the SA receives the authorization, it may begin its complaint investigation of a deemed provider/supplier. Whether the survey is of one or all Medicare conditions, it will be treated as a complaint survey under ACTS rather than a re-certification survey, since the complaint/incident is the basis for the survey.

If the *CMS location* learns directly of a complaint/incident concerning a deemed provider/supplier, it will review the complaint/incident to assign a priority consistent with Section 5075. If the complaint/incident is found to be a substantial allegation of noncompliance, prioritized for investigation as either immediate jeopardy or non-IJ high, the *CMS location* authorizes the SA to conduct a complaint investigation or, in a limited number of cases, the *CMS location* conducts the complaint investigation.

There may be occasions during the course of a State-only activity in a deemed provider/supplier when State surveyors observe a situation they believe may constitute IJ or other substantial noncompliance with a Medicare condition. In such circumstances, the State must contact the *CMS location* by telephone or e-mail, explain the situation, and request authorization to conduct a Federal complaint survey. CMS authorizes the investigation as a complaint validation (i.e., substantial allegation validation) survey if it concurs that there may be condition-level noncompliance. The complaint is entered into ACTS at the earliest possible opportunity.

5100.2 – Initial Response to Complainant

- If the SA concludes that a complaint represents a substantial allegation of noncompliance (i.e., it is appropriately triaged as an IJ or non-IJ high), it requests authorization in ACTS from the *CMS location* to conduct a survey. If the *CMS location* authorizes a survey, the SA acknowledges receipt of the complaint by a letter to the complainant, and advises that a SA investigation will be initiated. The acknowledgment letter also advises that the complainant may also wish to file a complaint with the applicable accrediting organization (AO), naming the AO and attaching a current list of AOs and their contact information. This list may be found at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Accrediting-Organization-Complaint-Contacts.pdf

- If the SA concludes that a complaint does not represent a substantial allegation of noncompliance (i.e., it is appropriately triaged as non-IJ medium or low) the SA sends the complainant a letter indicating that the complaint does not meet the criteria for a Federal on-site investigation of an accredited health care facility. The letter also advises the complainant which AO(s) accredit the provider/supplier for Medicare participation purposes and provides the above AO contact information, should the individual wish to pursue a complaint with the AO.

If the *CMS location* directly receives a complaint, it is responsible for sending the complainant a letter which acknowledges the receipt of the complaint and advises the complainant in the same manner as indicated above for complaints received by the SA**.**

5110 - Post-Survey Procedures

(Rev. 88, Issued: 08-27-13, Effective: 07-19-13, Implementation: 7-19-13)

5110.1 - Substantial Compliance

If a condition-level deficiency is not cited at a survey, the provider/supplier is in substantial compliance with the Federal requirements. The SA certifies its survey findings in ACTS within 30 calendar days after the completion of the survey. A Form CMS 2567 is prepared in all cases. Even if no deficiencies were cited, the Form CMS 2567 is issued with a statement that a survey was conducted to evaluate compliance with the listed requirements identified on the CMS-2802 and that no deficiencies were identified in these areas.

The *CMS location* randomly selects several Form CMS 2567s with standard-level deficiencies for review to determine if the *CMS location* concurs with the SA's finding of substantial compliance.

- For all cases not selected for review of the Form CMS 2567, the *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS, and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System.

- For cases selected for review of the Form CMS 2567:

    - If the *CMS location* concurs with the finding, the *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS, and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System.

    - If the *CMS location* does not concur with the SA's findings of substantial compliance, the *CMS location* discusses with the SA any revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for a survey finding substantial noncompliance. (See Section 5110.2 or 5110.3, as applicable.)

The *CMS location* either issues a notice, or authorizes the SA in ACTS to issue the provider/supplier a notice of its compliance status. The *CMS location* or SA, as applicable, issues this notice to the provider/supplier, along with a copy of the Form CMS 2567containing the survey findings. The notice indicates that the provider/supplier was found to be in substantial compliance even though there may, or may not, also be

standard-level deficiencies cited. In such circumstances, the provider/supplier is not required to submit a plan of correction for any cited standard-level deficiencies, but may choose to do so because the Form CMS 2567 is available to the public. The SA and *CMS location* do not review any plan of correction the provider/supplier submits; no revisit survey is conducted. **The *CMS location* promptly sends a copy of the notice letter and Form CMS 2567 to the applicable AO(s).** At the *CMS location*'s or SA's discretion, the materials may be sent to the AO via e-mail.

5110.2 - Condition-Level, IJ

1. IJ Removed while the SA is On-site

If deficiencies pose an IJ and the IJ is removed while the SA is on-site, deficiency citations are made at the condition-level. Follow the procedure for condition-level noncompliance, non-IJ, in Section 5110.3 below.

Note: The Form CMS 2567 must state at the beginning that an IJ was cited, regardless of the fact that it was removed while the SA was on-site. An entry in ASPEN/ACTS must also be made by the *CMS location* indicating that there was an IJ citation before the survey can be uploaded to the national database, the CMS National Reporting System (CASPER). The ASPEN/ACTS systems will prompt the *CMS location* whenever a survey includes condition-level deficiencies to indicate whether there was also an IJ.

Details of the IJ situation and the actions taken by the provider/supplier to remove the IJ must also be documented on the Form CMS 2567. Even though the IJ was removed while the SA was on-site, the provider or supplier must still be cited for condition-level noncompliance for the applicable Condition of Participation, Condition for Coverage, or Condition for Certification that is cited for non-compliance related to the IJ. The documentation must also include the date the surveyors verified that the IJ was removed prior to completion of the survey.

2. IJ not Removed while the SA is On-site

If condition-level deficiencies pose an IJ and the IJ is not removed while the SA is on-site, the SA certifies its findings in ACTS within 2 working days after the completion of the survey.

If the *CMS location* concurs with the SA's findings, the deemed provider/supplier is placed on a 23 calendar-day termination track. The *CMS location* sends the provider/supplier the Form CMS 2567, notifies the provider/supplier of the proposed termination action and effective date, which is 23 calendar days after the date of the *CMS location*'s notice, and requests submission of an acceptable plan of correction to the *CMS location* within 5 calendar days of the notice. The provider/supplier is advised it will be surveyed after receipt of an acceptable plan of correction and prior to the termination

date. The notice also contains a statement that "removes" the "deemed status" of the provider/supplier and places it under SA jurisdiction.

The *CMS location* sends a copy of the notice to the SA and a copy of the notice and Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

Note: Although deemed status technically has been removed and the provider/supplier is placed under SA jurisdiction, because it is expected that deemed status will be restored once corrections are made and verified, no change is made in ASPEN to the provider's/supplier's deemed status. However, periods during which the provider/supplier is under SA jurisdiction are entered and tracked in ASPEN. Further, the AO may also conduct a survey of the facility, so long as it continues to accredit the provider/supplier under its approved Medicare accreditation program.

When the *CMS location* receives a timely and acceptable plan of correction from the provider/supplier, it directs the SA to conduct either a full survey or an IJ follow-up survey, which is a focused, revisit-type survey, before the scheduled termination date in order to confirm that the IJ has been removed and that the provider/supplier is in substantial compliance. See Section 5110.3 for a discussion of factors the *CMS location* should consider when deciding whether a full survey is needed. If the *CMS location* authorizes a full survey, see Section 5110.4 for procedures to follow, except that the full survey must be conducted prior to the 23-day termination date.

i. No Acceptable Plan of Correction Submitted

No revisit is necessary if the provider/supplier fails to submit a timely and acceptable plan of correction. CMS will proceed to terminate a provider/supplier if it does not submit a timely and acceptable POC. See SOM Section 3254F. The public notice must be published 15 calendar days prior to the termination date. The *CMS location* notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System.

The *CMS location* sends a copy of the termination letter to the applicable AO(s). At the *CMS location*'s discretion, the copy may be sent to the AO via e-mail.

ii. Post-IJ First Revisit: IJ Not Removed

At least 5 calendar days in advance of the scheduled termination date, the SA certifies to the *CMS location* in ACTs its findings, based on on-site verification,

that the IJ has not been removed, and recommends that the termination action proceed.

The *CMS location* reviews the SA's findings, and if it concurs with the SA's recommendation, the *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into the CMS National Reporting System (CASPER). The termination of the provider's/supplier's Medicare agreement is processed in ASPEN.

The *CMS location* sends the provider/supplier a final termination letter and publishes a public notice, in accordance with the termination process in Section 3010B. The provider/supplier is terminated from the Medicare program. The *CMS location* notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The *CMS location* sends a copy of the termination notice and the Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

iii. Post-IJ First Revisit: IJ Removed, Substantial Compliance

The termination action is rescinded if the IJ has been removed and substantial compliance has been achieved prior to the effective date of the termination, i.e., there are no condition-level deficiencies identified during the follow-up survey by the SA. The SA certifies its findings to the *CMS location* via ACTS at least 5 calendar days in advance of the scheduled termination date, and recommends that the termination action be rescinded.

The *CMS location* randomly selects several Form CMS 2567s with standard-level deficiencies for review, to determine if the *CMS location* concurs with the SA's finding of substantial compliance. If the *CMS location* concurs, and in all other cases where the Form CMS 2567 is not reviewed by the *CMS location*, the *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS, and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System. If the *CMS location* does not concur with the SA's finding, the *CMS location* discusses with the SA any revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for substantial noncompliance.

When substantial compliance is achieved, the *CMS location* either issues a notice, or authorizes the SA in ACTS to issue the provider/supplier a notice of its compliance status, restoring its deemed status. The *CMS location* or SA, as

applicable, issues this notice to the provider/supplier, along with a copy of the Form CMS 2567 containing the survey findings.

In addition, the *CMS location* sends a copy of the notice letter to the applicable AO(s). At the *CMS location*'s discretion, the copy may be sent to the AO via e-mail.

Although the follow-up survey found the provider/supplier to be in substantial compliance, it may have resulted in citation(s) of standard-level deficiencies of the Form CMS 2567. Because deemed status has been restored, the provider/supplier is not obligated to submit a plan of correction to the SA, nor are any further revisits conducted. The provider/supplier may voluntarily choose to submit a plan of correction because the Form CMS 2567 will be made available to the public. The SA and *CMS location* do not review any plan of correction the provider/supplier submits; no further revisit survey is conducted.

iv. Post-IJ First Revisit: IJ Removed, Substantial Noncompliance Remains

If the IJ has been removed but substantial noncompliance (i.e., condition-level deficiencies), remain, the SA certifies its findings to the *CMS location* in ACTS within 10 working days after the survey completion date. The SA certifies that the IJ has been removed and recommends rescission of the 23 calendar-day IJ termination action, but continuation of the termination action on a 90 calendar-day termination track.

The *CMS location* reviews the SA's findings, and if it concurs with the SA's recommendation, the *CMS location* gives the provider/supplier up to 67 additional calendar days, or a total of 90 calendar days (23 plus 67) to achieve substantial compliance. The resulting revised termination date is 90 calendar days after the date of the *CMS location*'s original 23-day notice. The *CMS location* sends the CMS Form 2567 from the follow-up survey to the provider/supplier with notice of the new termination date, and requests that an acceptable POC be provided to the SA within 10 calendar days of the notice.

Post-IJ Second Revisit: The SA conducts the second revisit survey by the 60th calendar day after the date of the *CMS location*'s original 23-day termination notice. Unlike the post-IJ first revisit survey, advance authorization from the *CMS location* is not required.

(i) Post-IJ Second Revisit Survey Findings: Substantial Compliance

The termination action is rescinded if substantial compliance (i.e., no condition-level deficiencies) is achieved and documented through the onsite verification at the revisit survey. There may or may not be standard-level deficiencies cited. Within 10 working days after the completion of the revisit

survey, the SA certifies to the *CMS location* its findings via ACTS and recommends that the termination action be rescinded.

The *CMS location* randomly selects some Form CMS 2567s with only standard-level deficiencies for review, to determine if the *CMS location* concurs with the SA's finding of substantial compliance. If the *CMS location* concurs, and in all other cases where the Form CMS 2567 is not reviewed by the *CMS location*, the *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on *CMS location* practice, either the SA or the *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System. If the *CMS location* does not concur, the *CMS location* discusses with the SA revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for substantial noncompliance.

The *CMS location* either issues a notice, or authorizes the SA in ACTS to issue a notice to the provider/supplier of its compliance status and that its deemed status is restored. The *CMS location* or SA, as applicable, issues this notice to the provider/supplier, along with a copy of the Form CMS 2567 with the survey findings.

The *CMS location* sends a copy of the notice and Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

i. **Post-IJ Second Revisit Survey Findings: Substantial Noncompliance**

If the second revisit shows that the provider/supplier fails to demonstrate substantial compliance (i.e., condition-level deficiencies are identified through on-site verification by the SA), the SA certifies to the *CMS location* its findings within 10 calendar days after the survey completion date, and recommends that the termination action proceed.

The *CMS location* reviews the SA's findings, and if it concurs with the SA's recommendation, the *CMS location* sends the provider/supplier a final termination letter and publishes a public notice 15 calendar days prior to the termination date. The provider/supplier is terminated from the Medicare program. The *CMS location* notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on *CMS location* practice, either the SA or *CMS location* uploads

the complaint survey package into CASPER. The provider's or supplier's Medicare agreement is terminated in ASPEN.

The *CMS location* sends a copy of the final termination notice and Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

5110.3 - Condition-Level, Non-IJ

If the provider/supplier fails to demonstrate substantial compliance, i.e., condition-level deficiencies are identified by the SA, but they do not pose an IJ, the SA certifies its findings to the *CMS location* via ACTS within 10 working days after the survey completion date.

The *CMS location* reviews the SA's findings, and if it concurs with the SA's recommendation, the *CMS location* **either** places the deemed provider/supplier on a 90 calendar-day termination track **or** it requires a full survey after a complaint survey.

In determining whether to exercise its discretion to require a full survey for deemed providers and suppliers, the *CMS location* may consider factors including, but not limited to, the following:

- The manner and degree of noncompliance identified as a result of the complaint investigation;
- The provider's/supplier's compliance history;
- Recent changes in the provider's/supplier's ownership or management;
- The length of time since the provider's/supplier's last accreditation survey;
- The availability of SA resources at the time required to conduct a full survey; and/or
- The advantages associated with conducting a more extensive survey compared to the advantages associated with the faster enforcement (and thus a faster potential corrective action) that result when proceeding directly to enforcement action after the complaint survey.

Paragraph a) below discusses the procedures when the *CMS location* does not require a full survey after the complaint survey; paragraph b) discusses the procedures to follow when the *CMS location* directs the SA to conduct a full survey.

a) No full survey – proceed directly to termination track based on the complaint survey

If the *CMS location* places the deemed provider/supplier on a 90 calendar-day termination track as a result of the complaint investigation, it sends the provider/supplier the Form CMS 2567, notifies the provider/supplier of the proposed termination action and effective date, which will be 90 calendar days after the date of the *CMS location*'s notice. The *CMS location* requests submission of an acceptable plan of correction to the SA within 10 calendar days. The notice also contains a statement that "removes" the "deemed status" of the provider/supplier and places it under SA jurisdiction.

The *CMS location* sends a copy of the notice to the SA and a copy of the notice and Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

NOTE: Although deemed status has technically been "removed" and the provider/supplier is placed under SA jurisdiction, because it is expected that deemed status will be restored once corrections are made and verified, no change is made in ASPEN to the provider's/supplier's deemed status. However, periods during which the provider/supplier is under SA jurisdiction are entered and tracked in ASPEN. Further, the AO may also conduct a survey of the facility so long as it continues to accredit the provider/supplier.

The SA conducts a complaint survey revisit after the SA has received a timely and acceptable plan of correction, but no later than the 45th calendar day after the notice to the provider/supplier.

1) No Timely, Acceptable Plan of Correction Submitted

If the provider/supplier fails to submit a timely and acceptable plan of correction to the SA and as a result the SA is unable to conduct a timely revisit before the termination date, the SA notifies the *CMS location* and the *CMS location* may proceed with termination. See SOM Section 3254F. The *CMS location* publishes a public notice 15 days prior to the termination date. The *CMS location* notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The *CMS location* approves the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into the CMS National Reporting System (CASPER). The provider's or supplier's Medicare agreement is terminated in ASPEN.

Additionally, the *CMS location* sends a copy of the notice of termination letter to the applicable AO(s).

2) First Revisit Survey Findings: Substantial Compliance

The termination action is rescinded if substantial compliance (i.e., no condition-level deficiencies) is achieved and documented through the onsite verification at the first revisit survey. There may or may not be standard-level deficiencies cited. Within 10 working days after the completion of the revisit survey, the SA certifies to the *CMS location* in ACTS its findings and recommends that the termination action be rescinded.

The *CMS location* randomly selects several Form CMS 2567s with standard-level deficiencies for review to determine if the *CMS location* concurs with the SA's finding of substantial compliance.

- For all cases not selected for review of the Form CMS 2567, the *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS, and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System.

- For cases selected for review of the Form CMS 2567:

    - If the *CMS location* concurs with the finding, the *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS, and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System.

    - If the *CMS location* does not concur with the SA's findings of substantial compliance, the *CMS location* discusses with the SA any revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for a survey finding substantial noncompliance. (See Section 5110.2 or 5110.3, as applicable.)

The *CMS location* either issues a notice, or authorizes the SA in ACTS to issue a notice to the provider/supplier of its compliance status and that its deemed status is restored. The *CMS location* or SA, as applicable, issues this notice to the provider/supplier, along with a copy of the Form CMS 2567 with the survey findings.

The *CMS location* sends a copy of the notice and Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

3) First Revisit Survey Findings: Substantial Noncompliance

If the SA finds during the first revisit survey that the provider/supplier is not in substantial compliance with one or more Medicare conditions, the SA consults with the *CMS location* on its findings and whether to conduct a second revisit. If the *CMS location* agrees that condition-level deficiencies remain, the *CMS location* considers whether the survey findings warrant a second revisit or proceeding immediately to termination. Generally the *CMS location* authorizes a second revisit, but the *CMS location* has discretion to make an exception, based on the facts of the situation. For example, if the SA and *CMS location* determine that an immediate jeopardy was present during the first revisit, the *CMS location* might find it prudent to proceed to termination without a second revisit.

If the *CMS location* agrees that condition-level deficiencies remain and does not authorize a second revisit, the *CMS location* and SA follow the procedures outlined in paragraph 3ii. below.

If a second revisit is authorized by the *CMS location*, the SA sends the provider/supplier the Form CMS 2567 for the first revisit with notice that substantial noncompliance remains, the 90-day termination date remains in effect, a new acceptable plan of correction is required, and that an additional revisit will be conducted prior to the termination date. The SA conducts the second revisit no later than 60 calendar days after the date of the termination notice.

i. Second Revisit Survey Findings: Substantial Compliance

If substantial compliance is achieved by the provider/supplier (i.e., no condition-level deficiencies are identified through the on-site verification by the SA), the SA certifies its findings to the *CMS location* via ACTS within 10 working days after the survey completion date, and recommends that the termination action be rescinded.

The *CMS location* randomly selects some Form CMS 2567s with only standard-level deficiencies for review, to determine if the *CMS location* concurs with the SA's finding of substantial compliance. If the *CMS location* concurs, and in all other cases where the Form CMS 2567 is not reviewed by the *CMS location*, *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System. If the *CMS location* does not concur, the *CMS location* discusses with the SA revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for substantial noncompliance.

The *CMS location* either issues a notice, or authorizes the SA in ACTS to issue the provider/supplier a notice letter of its compliance status and that its deemed status is restored. The *CMS location* or SA, as applicable, forwards

this notice to the provider/supplier, along with a copy of the Form CMS 2567 with the survey findings.

Additionally, the *CMS location* sends a copy of the notice and the Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

ii. Second Revisit Survey Findings – Substantial Noncompliance

If the second revisit survey shows that the provider/supplier fails to demonstrate substantial compliance (i.e., condition-level deficiencies are identified through on-site verification by the SA), the SA certifies its findings to the *CMS location* via ACTS within 10 calendar days after the survey completion date, and recommends that the termination action proceed.

The *CMS location* reviews the SA's findings, and if it concurs with the SA's recommendation, the *CMS location* sends the provider/supplier a final termination letter and publishes a public notice at least 15 calendar days prior to the termination date, consistent with the requirements of Section 3012. The provider/supplier is terminated from the Medicare program. The *CMS location* notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System. The provider's or supplier's Medicare agreement is terminated in ASPEN.

Additionally, the *CMS location* sends a copy of the termination notice and the Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

b) Full Survey After the Complaint Survey

If the *CMS location* directs the SA to conduct a full survey following the complaint survey, it sends the Form CMS 2567 for the complaint survey to the provider/supplier in addition to a notice letter indicating that it is "removing" the provider's/supplier's deemed status and that a full survey will be conducted on an unannounced basis. The provider/supplier is not required to submit a plan of correction in response to the complaint survey findings, but may choose to do so.

The *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on *CMS*

location practice, either the SA or *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System.

Additionally, the *CMS location* sends a copy of the notice letter and Form CMS 2567 for the complaint survey to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

NOTE: Although deemed status technically has been removed and the provider/supplier is placed under SA jurisdiction, because it is expected that deemed status will be restored once corrections are made and verified, no change is made in ASPEN to the provider's/supplier's deemed status. However, periods during which the provider/supplier is under SA jurisdiction are entered and tracked in ASPEN. Further, the AO may also conduct a survey of the facility so long as, since it continues to accredit the provider/supplier.

The full survey must be conducted within 60 calendar days after the *CMS location*'s notice to the provider/supplier of the complaint survey results and removal of deemed status. The *CMS location* and SA follow the procedures in Section 5110.4.

5110.4 - Full Survey after Complaint Survey with Condition-level Deficiencies, When Authorized by the *CMS location*

If the *CMS location* authorizes the SA to conduct a full survey after the complaint survey, the timeframes and procedures described in this section apply.

Timeframe

The full survey must be conducted within:

- 23 days after the *CMS location*'s notice to the provider/supplier, if the complaint survey involved an IJ that was not removed while the survey team was on-site; or

- 60 calendar days after the *CMS location*'s notice to the provider/supplier in all other cases.

Procedures following the full survey with findings of:

a) Full Survey Findings: Substantial Compliance

If the SA full survey finds the deemed provider or supplier to be in substantial compliance, the SA and *CMS location* follow the same procedures and timeline as at Section 5110.1. In addition, since the *CMS location* had removed deemed status, the *CMS location* either issues a notice, or authorizes the SA to issue a notice to the provider or supplier of its compliance status and that its deemed status is restored, along with a copy of the Form CMS 2567 with the survey findings.

The *CMS location* sends a copy of the notice and Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

b) Full Survey Findings: Condition-Level, IJ

1. **IJ Removed while the SA is On-site**

If deficiencies pose an IJ and the IJ is removed while the SA is on-site, deficiency citations are made at the condition-level. Follow the procedure for condition-level noncompliance, non-IJ, in Section 5110.4c below.

Note: The Form CMS 2567 must state at the beginning that an IJ was cited, regardless of the fact that it was removed while the SA was on-site. An entry in ASPEN must also be made by the *CMS location* indicating that there was an IJ citation before the survey can be uploaded to the national database, the CMS National Reporting System (CASPER). The ASPEN systems will prompt the *CMS location* whenever a survey includes condition-level deficiencies to indicate whether there was also an IJ.

Details of the IJ situation and the actions taken by the provider/supplier to remove the IJ must also be documented on the Form CMS 2567. Even though the IJ was removed while the SA was on-site, the provider or supplier must still be cited for condition-level noncompliance for the applicable Condition of Participation or Condition for Coverage that is cited for non-compliance related to the IJ. The documentation must also include the date the surveyors verified that the IJ was removed prior to completion of the survey.

2. **IJ not Removed while the SA is On-site**

If condition-level deficiencies pose an IJ and the IJ is not removed while the SA is on-site, the SA certifies its findings to the *CMS location* within 2 working days after the completion of the survey.

If the *CMS location* concurs with the SA's findings, the deemed provider/supplier is placed on a 23 calendar-day termination track. The *CMS location* sends the provider/supplier the Form CMS 2567, notifies the provider/supplier of the proposed termination action and effective date, which is 23 calendar days after the date of the *CMS location*'s notice, and requests submission of an acceptable plan of correction to the *CMS location* within 5 calendar days of the notice.

The *CMS location* sends a copy of the notice to the SA and a copy of the notice and Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

When the *CMS location* receives a timely and acceptable plan of correction from the provider/supplier, it directs the SA to conduct an IJ follow-up survey before the rescheduled termination date in order to confirm that the IJ has been removed and that the provider/supplier complies with the conditions previously cited for noncompliance.

2.1 First Revisit after Full Survey with IJ

i. No Acceptable Plan of Correction Submitted

No revisit is necessary if the provider/supplier fails to submit a timely and acceptable plan of correction. CMS will proceed to terminate a provider/supplier if it does not submit a timely and acceptable POC. See SOM Section 3254F. The public notice must be published 15 calendar days prior to the termination date. The *CMS location* notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The SA and *CMS location* complete the processing in ASPEN of the survey kit and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System.

The *CMS location* sends a copy of the termination letter to the applicable AO(s). At the *CMS location*'s discretion, the copy may be sent to the AO via e-mail.

ii. First Revisit Survey Findings: IJ Not Removed

At least 5 calendar days in advance of the scheduled termination date, the SA certifies to the *CMS location* its findings, based on on-site verification, that the IJ has not been removed, and recommends that the termination action proceed.

The *CMS location* reviews the SA's findings, and if it concurs with the SA's recommendation, the SA and *CMS location* complete the processing of the survey kit in ASPEN and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the survey package into the CMS National Reporting System (CASPER). The termination of the provider's/supplier's Medicare agreement is processed in ASPEN.

The *CMS location* sends the provider/supplier a final termination letter and publishes a public notice, in accordance with the termination process in Section 3010B. The provider or supplier is terminated from the Medicare program. The *CMS location* notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The *CMS location* sends a copy of the termination notice and the Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

iii. First Revisit Survey Findings: IJ Removed, Substantial Compliance

The termination action is rescinded if the IJ has been removed and substantial compliance has been achieved prior to the effective date of the termination, i.e., there are no condition-level deficiencies identified during the first revisit survey by the SA. The SA certifies its findings to the *CMS location* at least 5 calendar days in advance of the scheduled termination date, and recommends that the termination action be rescinded.

The *CMS location* randomly selects several Form CMS 2567s with standard-level deficiencies for review, to determine if the *CMS location* concurs with the SA's finding of substantial compliance. If the *CMS location* concurs, and in all other cases where the Form CMS 2567 is not reviewed by the *CMS location*, depending on *CMS location* practice, either the SA or *CMS location* uploads the survey package into CASPER, the CMS National Reporting System. If the *CMS location* does not concur with the SA's finding, the *CMS location* discusses with the SA any revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for substantial noncompliance.

When substantial compliance is achieved, the *CMS location* either issues a notice, or authorizes the SA to issue the provider/supplier a notice of its compliance status, restoring its deemed status, along with a copy of the Form CMS 2567containing the survey findings.

In addition, the *CMS location* sends a copy of the notice letter to the applicable AO(s). At the *CMS location*'s discretion, the copy may be sent to the AO via e-mail.

Although the revisit survey found the provider/supplier to be in substantial compliance, it may have resulted in citation(s) of standard-level deficiencies of the Form CMS 2567. Because deemed status has been restored, the provider or supplier is not obligated to submit a plan of correction to the SA, nor are any further revisits conducted. The provider or supplier may voluntarily choose to submit a plan of correction because the Form CMS 2567 will be made available to the public. The SA and *CMS location* do not review any plan of correction the provider/supplier submits; no further revisit survey is conducted.

iv. First Revisit Survey Findings: IJ Removed, Substantial Noncompliance Remains

If the IJ has been removed but substantial noncompliance (i.e., condition-level deficiencies), remains, the SA certifies its findings to the *CMS location* within 10

working days after the survey completion date. If the *CMS location* concurs that the IJ has been removed but that condition-level deficiencies remain, the *CMS location* considers whether the survey findings warrant a second revisit or proceeding immediately to termination. At this point the provider/supplier will have been surveyed three times, including the preceding complaint survey, with continued substantial noncompliance found in each survey and at least one IJ. Generally the *CMS location* authorizes a second revisit, but the *CMS location* has discretion to make an exception, based on the facts of the case, including the risks to patients associated with the remaining deficiencies versus providing the provider/supplier further opportunity to correct its problems in a timely manner.

If the *CMS location* does not authorize a second revisit, it follows the procedures in paragraph ii above.

If the authorizes a second revisit, the *CMS location* gives the provider/supplier up to 67 additional calendar days, or a total of 90 calendar days (23 plus 67) from the date of the notice of the IJ, to achieve substantial compliance. The resulting revised termination date is 90 calendar days after the date of the *CMS location*'s original 23-day termination notice. The *CMS location* provides the provider/supplier the Form CMS 2567 for the revisit with notice of the new termination date, and requests that an acceptable POC be provided to the SA within 10 calendar days of the notice.

2.2 Second Revisit after Full Survey with IJ

The SA conducts the second revisit survey no later than 60 calendar days after the date of the *CMS location*'s 23-day termination notice to the provider or supplier.

i. Second Revisit Survey Findings: Substantial Compliance

If substantial compliance is achieved by the provider/supplier (i.e., no condition-level deficiencies are identified through the on-site verification by the SA) during the second revisit survey, the SA certifies its findings to the *CMS location* within 10 working days after the survey completion date, and recommends that the termination action be rescinded.

The *CMS location* randomly selects some Form CMS 2567s with standard-level deficiencies for review, to determine if the *CMS location* concurs with the SA's finding of substantial compliance. If the *CMS location* concurs, and in all other cases where the Form CMS 2567 is not reviewed by the *CMS location*, depending on *CMS location* practice, either the SA or *CMS location* uploads the survey kit into CASPER, the CMS National Reporting System. If the *CMS location* does not concur, the *CMS location* discusses with the SA revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for substantial noncompliance.

The *CMS location* also either issues a notice, or authorizes the SA to issue the provider/supplier a notice, of its compliance status and that its deemed status is restored, along with a copy of the Form CMS 2567 with the survey findings.

Additionally, the *CMS location* sends a copy of the notice and the Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

ii. Second Revisit Survey Findings: Substantial Noncompliance

If the second revisit shows that substantial noncompliance (i.e., condition-level deficiencies) remain, the SA certifies to the *CMS location* its findings within 10 calendar days after the survey completion date, and recommends that the termination action proceed.

The *CMS location* reviews the SA's findings, and if it concurs with the SA's recommendation, the *CMS location* sends the provider or supplier a final termination letter and publishes a public notice 15 calendar days prior to the termination date. The provider or supplier is terminated from the Medicare program. The *CMS location* notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The SA and *CMS location* complete the processing in ASPEN of the survey kit and, depending on *CMS location* practice, either the SA or *CMS location* uploads the survey package into CASPER. The provider's or supplier's Medicare agreement is terminated in ASPEN.

The *CMS location* sends a copy of the final termination notice and Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

c) Full Survey Findings: Condition-Level, Non-IJ

If the results of the full survey indicate there is substantial noncompliance (i.e., condition-level deficiencies), but the deficiencies do not constitute an IJ, the SA certifies its findings to the *CMS location* within 10 working days after the survey completion date.

The *CMS location* reviews the SA's findings, and if it concurs with the SA's recommendation, the *CMS location* places the provider or supplier on a 90 calendar-day termination track as a result of the full survey. The *CMS location* sends the provider or supplier the Form CMS 2567 and notifies it of the proposed termination action and effective date, which will be 90 calendar days after the date of the *CMS location*'s notice. The *CMS location* requests submission of an acceptable plan of correction to the SA within 10 calendar days of the notice.

Additionally, the *CMS location* sends a copy of the notice of termination letter to the applicable AO(s).

1. **First Revisit:** The SA conducts the first revisit survey no later than the 45th calendar day after the date of the *CMS location*'s termination notice to the provider or supplier.

   i. First Revisit Survey Findings: Substantial Compliance

   The termination action is rescinded if substantial compliance (i.e., no condition-level deficiencies) is achieved and documented through the onsite verification at the revisit survey. There may or may not be standard-level deficiencies cited. Within 10 working days after the completion of the revisit survey, the SA certifies to the *CMS location* its findings and recommends that the termination action be rescinded.

   The *CMS location* randomly selects some Form CMS 2567s with only standard-level deficiencies for review, to determine if the *CMS location* concurs with the SA's finding of substantial compliance. If the *CMS location* concurs, and in all other cases where the Form CMS 2567 is not reviewed by the *CMS location*, the *CMS location* completes the processing of the survey kit in ASPEN and then, depending on *CMS location* practice, either the SA or the *CMS location* uploads the survey package into CASPER, the CMS National Reporting System. If the *CMS location* does not concur, the *CMS location* discusses with the SA revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for substantial noncompliance.

   The *CMS location* either issues a notice, or authorizes the SA to issue a notice to the provider or supplier of its compliance status and that its deemed status is restored, along with a copy of the Form CMS 2567 with the survey findings.

   The *CMS location* sends a copy of the notice and Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

   ii. **First Revisit Survey Findings: Substantial Noncompliance**

   If the SA confirms during the first revisit survey that the provider/supplier is not in substantial compliance with one or more Medicare conditions, the SA consults with the *CMS location* on its findings and whether to conduct a second revisit. If the *CMS location* concurs that condition-level deficiencies remain, the *CMS location* considers whether the survey findings warrant a second revisit or proceeding immediately to termination. At this point the provider/supplier will have been surveyed three times, including the complaint survey, the full survey and the first revisit, with substantial noncompliance found on each survey. Generally the *CMS location* authorizes a second revisit, but the *CMS location* has

discretion to make an exception, based on the facts of the case, including the risks to patients associated with the remaining deficiencies versus providing the provider/supplier further opportunity to correct its problems in a timely manner.

If the *CMS location* does not authorize a second revisit, the *CMS location* and SA will follow the procedures outlined in paragraph 2(ii). below.

If the *CMS location* authorizes a second revisit, the SA sends the provider/supplier the Form CMS 2567 for the first revisit with notice that substantial noncompliance remains, the 90-day termination date remains in effect, a new acceptable plan of correction is required, and that an additional revisit will be conducted prior to the termination date.

2. **Second Revisit:** The SA conducts the second revisit survey no later than 60 calendar days after the date of the termination notice to the provider or supplier.

(i) Second Revisit Survey Findings: Substantial Compliance

If substantial compliance is achieved by the provider/supplier (i.e., no condition-level deficiencies are identified through the on-site verification by the SA) during the second revisit survey, the SA certifies its findings to the *CMS location* within 10 working days after the survey completion date, and recommends that the termination action be rescinded.

The *CMS location* randomly selects some Form CMS 2567s with standard-level deficiencies for review, to determine if the *CMS location* concurs with the SA's finding of substantial compliance. If the *CMS location* concurs, and in all other cases where the Form CMS 2567 is not reviewed by the *CMS location*, the *CMS location* completes the processing in ASPEN of the survey kit and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint and revisit surveys into CASPER, the CMS National Reporting System. If the *CMS location* does not concur, the *CMS location* discusses with the SA revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for substantial noncompliance.

The *CMS location* also either issues a notice, or authorizes the SA in ACTS to issue the provider or supplier a notice, of its compliance status and that its deemed status is restored, along with a copy of the Form CMS 2567 with the survey findings.

Additionally, the *CMS location* sends a copy of the notice and the Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

(ii) Second Revisit Survey Findings: Substantial Noncompliance

If the second revisit shows that the provider or supplier has substantial noncompliance (i.e., condition-level deficiencies are identified through on-site verification by the SA), the SA certifies to the *CMS location* its findings within 10 calendar days after the survey completion date, and recommends that the termination action proceed.

The *CMS location* reviews the SA's findings, and if it concurs with the SA's recommendation, the *CMS location* sends the provider/supplier a final termination letter and publishes a public notice 15 calendar days prior to the termination date. The provider or supplier is terminated from the Medicare program. The *CMS location* notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The *CMS location* completes the processing in ASPEN of the survey kit and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the survey package into CASPER. The provider's or supplier's Medicare agreement is terminated in ASPEN.

The *CMS location* sends a copy of the final termination notice and Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

5120 - Life Safety Code Guidance for Deemed Providers/Suppliers

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

In most States, an engineer or other fire safety specialist surveys for compliance with the Life Safety Code (LSC) standard and others survey the remaining standards in the Physical Environment Condition. If the allegation pertains only to LSC requirements, it is not necessary to survey the remainder of the Physical Environment Medicare condition.

5130 – Deemed Provider/ Supplier Refusal of Complaint Investigation Surveys

The SA informs the provider/supplier that refusal to allow a complaint investigation survey is a basis for termination and exclusion from the Medicare program, in accordance with Section 1128(b)(12) of the Social Security Act. The SA notifies the *CMS location* immediately of a refusal to allow a complaint investigation survey.

5140 - Complaints Involving HIV-Infected Individuals

As direct recipients of Federal funds, providers and suppliers are subject to provisions of Section 504 of the Federal Rehabilitation Act of 1973. Symptomatic and asymptomatic

individuals who are infected with the human immunodeficiency virus (HIV), or "AIDS virus," are protected by the Rehabilitation Act as "individuals with handicaps." Therefore, HIV-infected individuals who are provided services, are employed, or are to be employed by providers and suppliers in Federally-conducted or financed programs or activities would be treated like anyone else in the workforce, so long as these individuals do not, on a case-by-case basis, pose a substantial health and safety risk to others, or pose a performance problem, and are "otherwise qualified."

A provider participating in the Medicare or Medicaid programs cannot discriminate against individuals who are HIV-infected so long as these individuals do not, on a case-by-case basis, pose a substantial health and safety risk to others and so long as the provider provides comparable services and care to non HIV-infected individuals.

The SA or the *CMS location* refers discrimination complaints to the Office of Civil Rights (OCR), which is the authority to determine whether Medicare or Medicaid providers and suppliers comply with this non-discrimination statute.

5150 - Investigating Complaints Involving ESRD Services Provided by Deemed Hospitals or CAHs

(Rev. 88, Issued: 08-27-13, Effective: 07-19-13, Implementation: 7-19-13)

Many of the hospitals or CAHs participating in the ESRD program are deemed to meet the Medicare Conditions of Participation on the basis of their accreditation by a CMS-approved Medicare accreditation program. "Deemed status" applies only to the hospital's or CAH's approval as a provider, not to its status as a supplier of ESRD transplantation or dialysis services. The SA investigates all complaints and allegations related solely to ESRD services since ESRD services fall outside the purview of accreditation.

5160 - Investigating Complaints Against ESRD Suppliers

(Rev. 88, Issued: 08-27-13, Effective: 07-19-13, Implementation: 7-19-13)

1. General

Refer to the guidance for investigation of complaints against non-deemed providers and suppliers. See SOM §5200.

The ESRD Networks are required to have a complaint /grievance resolution system. Networks (NW) and the SA are frequently contacted by the same complainant with the same or similar allegations. If the allegations require an onsite investigation or allege potential risk to patient health or safety, the SA is responsible for the investigation. If the allegations are primarily focused on relationship or communication issues, the NW may assume primary responsibility for the investigation. If the focus of the allegations is a medical practice issue, the SA and NW may need to collaborate on the investigation. The NWs and SA are encouraged to communicate and collaborate to reduce or prevent redundant investigations.

2. Conducting the ESRD Investigation

The SA surveyors must use the ESRD survey protocol in Appendix H to investigate complaints. The allegations of the complaint will determine the tasks needed. For example, an allegation of inadequate patient care staffing would require use of the following tasks, at a minimum:

- Pre survey activities;
- Entrance Conference: Provide an overview of the complaint allegations and the planned agenda for your survey time;
- Tour and observations;
- Patient interviews;
- Staff interviews;
- Record reviews;
- Review of quality management materials; and
- Exit conference.

Conduct each of the identified survey tasks in Appendix H, "Guidance to Surveyors: End-Stage Renal Disease Facilities."

3. Pre-survey Task for ESRD Complaint Investigations

Review the allegations of the complaint to identify needed survey tasks. Review the State Outcomes List and the Dialysis Facility Report to determine if there are data outliers related to the allegations. For example, if the complaint alleges staff members do not wash their hands, the surveyor should review the facility's rate of hospitalization and hospitalizations related to septicemia, and consider this information in the survey process.

To facilitate meeting the requirement of surveying each ESRD facility every 3 years, the SA evaluates all available information (outcome list rank, Dialysis Facility Report, time since last survey, complaint history, NW information, etc.) to determine whether a recertification survey should be conducted at the time of the complaint investigation.

5170 – Hospital Restraints/Seclusion Death Reporting and Investigation

(Rev. 88, Issued: 08-27-13, Effective: 07-19-13, Implementation: 7-19-13)

This section applies to both deemed and non-deemed hospitals, as well as to deemed and non-deemed CAH distinct part psychiatric and rehabilitation units.

5170.1 - Background
(Rev. 88, Issued: 08-27-13, Effective: 07-19-13, Implementation: 7-19-13)

The Medicare hospital restraint and seclusion requirements are found under the Patients' Rights provisions at 42 CFR 482.13(e),(f) and (g).

Hospitals are required to report a death associated with the use of restraint/seclusion to their CMS *location* in accordance with 42 CFR 482.13(g)(1).

The interpretive guidelines found in the Hospital Appendix A at 42 CFR 482.13(e) – (g) discuss in detail what is considered a restraint or seclusion, the requirements governing hospital use of restraint or seclusion, and these reporting requirements.

5170.2 - Responsibilities

*CMS Location*s

The *CMS location* receives Hospital Restraint/Seclusion Death Reports which hospitals are required to submit in accordance with 42 CFR 482.13(g)(1). The *CMS location* is responsible for communicating with hospitals in its region whether the required reports are to be submitted electronically by facsimile and/or e-mail, providing appropriate addresses or fax numbers, or whether it will also accept mail submissions.

The *CMS location* is also responsible for data entry of reports received into the Automated Survey Processing Environment (ASPEN) Complaint Tracking System (ACTS) Hospital Restraint/Seclusion Death Module and for maintenance in ACTS of information related to disclosures to Protection and Advocacy Agencies. (See Process discussion below.)

Each *CMS location* designates one contact person and a backup person who serves as the hospital point of contact regarding reporting, and who is responsible for coordinating the review of reports received, and authorization of complaint surveys when appropriate.

State Agencies (SAs)

Hospitals report patient deaths associated with restraint or seclusion to their CMS *location*, not to the SA. Any hospital patient restraint or seclusion death report received by a SA directly from a hospital (or other source) must be forwarded immediately by the SA to its *CMS location*.

The SA conducts a complaint investigation related to a patient death associated with a hospital's use of restraints or seclusion only when the *CMS location* authorizes the investigation. The investigation must be completed no later than five working days after *CMS location* authorization.

SAs assist *CMS location*s in educating the hospitals in their State about their obligation to report to their *CMS location* any death that meets the reporting requirements found at 42 CFR 482.13(g)(1). Upon request, SAs are to provide hospitals with the applicable *CMS location* contact information, as well as the hospital reporting procedures contained in this policy.

The SAs respond to requests from Protection and Advocacy (P&A) organizations, or any other parties, for information on survey findings related to specific cases identified by the requestor. The SAs handle these requests in accordance with standard CMS policy on disclosure of Federal survey information.

5170.3 - Process

The *CMS location* evaluates the information required to be reported by the hospital or CAH DPU under 42 CFR 482.13(g)(1) to determine whether the situation might involve a violation of 42 CFR 482.13(e) through 42 CFR 482.13(g) and authorizes an on-site investigation if there appears to be a possible violation.

Using the information provided by the hospital or CAH DPU in the worksheet, the *CMS location* evaluates whether the case warrants an on-site investigation. If the *CMS location* determines that the restraint/seclusion death report requires on-site investigation, within two business days of receiving the report, the *CMS location* enters the reported information into the ACTS restraint/seclusion module and immediately notifies the SA to authorize a complaint survey to investigate the hospital's or CAH DPU's compliance with the Patient's Rights requirement at 42 CFR 482.13(e), (f), and (g), including the reported case. The SA accesses the ACTS restraint/seclusion module to see the information reported by the hospital or CAH DPU prior to conducting the on-site investigation. The SA is expected to be onsite to initiate the investigation within two business days of receipt of survey authorization from the *CMS location*.

Notice to Protection and Advocacy Organizations

At the same time that the *CMS location* notifies the SA that it authorizes the on-site survey, consistent with the ACTS Notice of a Modified or Altered System of Records (SOR) (71 FR 29643, May 23, 2006, SOR 09-70-0565), the *CMS location* also provides written notification, by mail or email, to the appropriate Protection and Advocacy Organization (P&A) within the State where the hospital is located, only if the P&A has a current Data Use Agreement (DUA) with CMS. The *CMS location* may contact CMS Central Office for a list of P&A's with current DUAs. The names and addresses for each State's P&A can be located at the following website, at the drop down menu entitled "Get Help in Your State:" www.ndrn.org . **Notification is provided only in those cases for which an on-site survey is authorized.**

The *CMS location* provides the following information to the P&A: hospital or CAH DPU name, hospital or CAH DPU address, name of the deceased, and a copy of the restraint/seclusion death report submitted by the hospital or CAH DPU. **An entry must be made on the intake in ACTS indicating the name of the P&A to which the restraint/seclusion death report data was sent and the date it was sent.**

The P&A must have an approved CMS Data Use Agreement (DUA), Form CMS-R-0235, (Exhibit 292) in place before restraint/seclusion death report data may be disclosed to it. In order to get an approved DUA, the P&A must complete and submit a signed CMS DUA, Form CMS-R-0235, including an initialed DUA ACTS SOR- P&A Attachment (Exhibit 293) to the Director, Division of Information Security and Privacy Management (DISPM), Centers for Medicare and Medicaid Services, Mailstop N2-04-27, 7500 Security Boulevard, Baltimore, MD 21244-1850. DISPM will review the DUA, assign a unique DUA identifier and expiration date to it, and return a signed copy to the P&A, including an expiration date. CMS Central Office Survey and Certification will maintain and make available to *CMS location*s a list of P&As with DUAs.
When completing the Form, P&As must note the following in particular:

- Line 5 of the DUA must state "Restraint/Seclusion Hospital Death Reports." The "Years" and "System of Record" columns should be left blank;

- Line 12 must state "CMS DUA: ACTS SOR Attachment – P&A;"

- The DUA must be signed by the P&A official whom the P&A designates as "Custodian," i.e., the individual who will have actual possession of and responsibility for the data released under the DUA; and

- A P&A may designate more than one Custodian, but if it does so, each individual must complete and sign a Multi-Signature Addendum Form (Exhibit 294).

When approved, the DUA will have an expiration date. DISPM will alert an organization with a DUA of its upcoming expiration date and will give the organization the option of requesting a one-year DUA extension via e-mail, or to close the DUA with a DUA destruction certificate. DISPM has set up a DUA resource email box which accepts all expired DUA resolution requests at DataUseAgreement@cms.hhs.gov.

Custodians may be added or deleted over the life of the primary DUA. To add a new Custodian under an existing DUA, the P&A must submit the following to CMS/DISPM: a letter from the P&A describing the activities planned for the new Custodian and the length of time over which the Custodian will serve, and a Multi-Signature Addendum signed by the appropriate official from the P&A. The Multi-Signature Addendum must show the DUA number of the existing primary P&A DUA. The P&A must assign a case number to all Multi-Signature Addendums beginning with "1" and adding consecutively thereafter. CMS/DISMP will use this number to track the number of Custodians in each P&A. When a P&A seeks to delete an existing Custodian, it must send the CMS/DISPM a letter to this effect. CMS/DISPM will strike out the name of the deleted Custodian

from the DUA or Multi-Signature Addendum that added that Custodian, dating and initialing the deletion.

The DUA process described in this section applies to disclosure of hospital and CAH DPU restraint/seclusion death reports by CMS to P&As in those cases where the P&A did not first make a request specific to an identified patient; a DUA is not required for other disclosures of information in ACTS to a P&A when permitted in accordance with the ACTS System of Records Notice.

- A P&A may request information about an on-site survey by submitting its request to the SA. The SA will process this request and release information to the P&A in accordance with standard CMS policy for disclosure of Form CMS 2567, Statement of Deficiencies and Plan of Correction.

If the P&A identifies a particular patient, hospital, and approximate date or dates when the patient was in that hospital or CAH DPU, and if the P&A makes a request for additional information, beyond the Form CMS 2567, related to use of restraint or seclusion on that patient, the request is forwarded to the *CMS location*. The *CMS location* may, in accordance with the ACTS System of Records Notice, release additional information to the P&A.

NOTE: Sections 5200 to 5240 relate to all non-deemed provider/supplier types, excluding nursing homes (SNFs/NFs).

5200 - Investigating Complaints for Non-Deemed Providers/Suppliers, Excluding Nursing Homes (SNFs/NFs)

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

5200.1 - General Procedures

For complaint surveys on non-deemed providers/suppliers, the SA uses the appropriate survey protocol and interpretive guidelines. A focus survey is conducted on the specific regulatory requirements related to the allegation. Based on an initial assessment or other observations, if significant problems are identified, the SA expands the scope of review as necessary to determine compliance or noncompliance. The SA does not refer complaints regarding non-deemed providers/suppliers to the *CMS location*.

If deficiencies are cited, the SA documents the deficiencies on Form CMS-2567 and obtains an acceptable POC. If non-compliance with the Medicare conditions is identified, the SA will follow the appropriate termination procedures and document and report as required. (See SOM Chapter 3, §§3010-3028 for termination procedures.)

5200.2 - Special Procedures for Psychiatric Hospitals

The special conditions for psychiatric hospitals cannot be deemed to meet the Medicare requirements. The remaining conditions for hospitals apply to psychiatric hospitals, and a hospital may be deemed to meet those conditions.

When the SA receives a complaint allegation against a psychiatric hospital under the general conditions of participation, it must determine whether or not the hospital is deemed. If the hospital is deemed, the SA follows the appropriate survey protocol for deemed facilities. If the hospital is not deemed, the SA investigates the complaint if appropriate under these procedures listed above in §5200.1.

If the complaint allegation concerns the special conditions for psychiatric hospitals, the SA may conduct an investigation if it has appropriate qualified personnel or refer it to the *CMS location*. If the complaint is referred to the *CMS location*, the *CMS location* will evaluate and refer it to the CO as required.

5210- Processing of Complaints Originating with or Investigated by the *CMS location*

The *CMS location* establishes procedures and clear organizational accountability to ensure that complaints are properly evaluated, documented, acknowledged, and handled timely and appropriately. The *CMS location* uses ACTS to ensure timely and appropriate action on all allegations originating with or investigated by the *CMS location*. The extent and nature of the *CMS location* involvement with a given complaint varies depending on the nature of the allegation and the receiving organization.

Most complaints originate through the SA and are recorded and controlled by the SA. When a complaint is filed directly with the *CMS location*, the *CMS location* assumes those initial SA responsibilities.

5220- Investigation Conducted Directly by the *CMS location*

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

This less frequent class of complaints includes allegations retained by the *CMS location* or forwarded to the *CMS location* by the SA for investigation. The *CMS location*'s responsibilities vary based on the type of complaint.

The *CMS location* uses the appropriate survey protocol and interpretive guidelines for the provider/supplier. These procedures apply when a direct *CMS location* investigation is conducted, such as for Federal facilities, Religious Non-Medical Health Care Institutions (RNHCIs), or special situations. When directly investigating, the *CMS location* begins by ensuring that it or the SA has met all initial data collection and acknowledgement requirements.

If the allegation involves an IJ, the *CMS location* investigates within two working days. Otherwise, the *CMS location* schedules the investigation based on the severity of the allegation. (See §5075.9 for time frames related to Federal onsite investigations.)

5230 - Special *CMS location* Processing

The following types of allegations are subject to special *CMS location* handling:

1. Over-Utilization or Inappropriate Utilization of Services- The *CMS location* refers to the local QIO for investigation, and documents the provider's files as for other allegations. The *CMS location* acts, as necessary, on any findings returned by the QIO;

2. Civil Rights Violations- The *CMS location* refers to the regional OCR for investigation. The *CMS location* documents the provider's files as for other allegations. The *CMS location* acts as necessary on any findings returned by OCR; and

3. Medicare/Medicaid/CLIA fraud- The *CMS location* refers to the *CMS location* of the Inspector General/DHHS for investigation. The *CMS location* documents the provider's files as for other allegations.

In each of the above instances, the *CMS location* ensures that the complainant and SA are notified of any findings.

5240 - Complaints - HHA Hotline

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

Each State has a Medicare home health hotline that can be called by patients who are dissatisfied with the home health services they are receiving or by other individuals with a complaint about a specific HHA. Under the Medicare COPs for Patient Rights at 42 CFR 484.10, HHAs are required to provide their patients with the hotline number for their state. Concerns about an HHA not complying with the COPs, or reports that an HHA is misinforming beneficiaries or inappropriately terminating care for patients, can be referred to the SA for investigation via the home health hotline. Concerned consumers may also call the SA directly. A violation of the COPs or the provider agreement could lead to termination of the HHA from the Medicare program.

As part of the patient rights COPs, the HHA is required to investigate complaints made by a patient or the patient's family or guardian regarding treatment or care that is, or fails to be, furnished, and to document both the existence of the complaint and resolution of the complaint.

Surveyors, as part of their investigation of the HHA's compliance of the COPs, may ask to review complaints received by the HHA and the resolution of these complaints. The HHA must permit examination of these records by or on behalf of CMS, or risk termination from the Medicare program.

NOTE: Sections 5300 to 5390 relate to nursing homes.

5300 - Investigation of Complaints for Nursing Homes
(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

Section 42 CFR 488.332 provides the Federal regulatory basis for the investigation of complaints about nursing homes.

The survey agency must review all complaint allegations and conduct a standard or an abbreviated standard survey to investigate complaints of violations of requirements if its review of the allegation concludes that:

- A deficiency in one or more of the requirements may have occurred; and
- Only a survey can determine whether a deficiency or deficiencies exist.

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

Complaint investigations follow, as appropriate, the pertinent survey tasks, and information gathered is recorded on the appropriate survey worksheets. However, if the documentation required is minimal, use Form CMS-807 to record information during the complaint investigation. Record deficiencies on Form CMS-2567 and/or, the "Statement of Isolated Deficiencies Which Cause No Harm with Only a Potential for Minimal Harm for SNFs and NFs" . The completed Form CMS-2567 must be made a part of the complaint record.

If necessary, a specialized team may be used to investigate complaints. Team members may include, but are not limited to, an attorney, auditor, and appropriate health professionals. The specialized team is not necessarily composed of qualified surveyors. However, specialized team members provide unique talents and expertise that assist at least one qualified surveyor in identifying, gathering, and preserving documented evidence. Further information regarding the composition of the survey team is provided in Chapter 7.

The timing, scope, duration and conduct of a complaint investigation are at the discretion of the SA, except when a determination is made that immediate jeopardy may be present and ongoing or a higher level of actual harm may be present. If the complaint concerns conditions on a certain day (e.g., on weekends), or on a certain shift (e.g., 11 p.m. - 7 a.m.), the SA should make an attempt to investigate it at the relevant time. In most cases, the following tasks, or portion of tasks, should be performed during a complaint investigation.

Abbreviated surveys must be conducted on two consecutive calendar days from the day of entrance. Exceptions to this guidance would be an emergency situation as deemed by the state agency or a competing IJ at another location requiring the survey team's immediate attention. Additionally, the surveyor or survey team should plan to be onsite for a

minimum of five hours after entrance, unless the investigation can be completed in less than five hours.

5300.1 - Task 1: Offsite Survey Preparation

Review any information about the facility that would be helpful to know in planning the investigation. Contact the ombudsman to discuss the nature of the complaint and whether there have been any similar complaints reported to the ombudsman.

Review the related regulatory requirements or standards that pertain to the complaint. For example, if it is a complaint about abuse, review the requirements at 42 CFR 483.13.

Plan the investigation. Before going to the nursing home, plan what information to obtain during the complaint investigation based on the information already acquired. Consider practical methods to obtain that information.

5300.2 - Task 2: Entrance Conference/Onsite Preparatory Activities
(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

Onsite complaint investigations should always be unannounced. Upon entrance, advise the facility's Administrator of the general purpose of the visit. The SA explains the reason for the survey and avoids any impression that a predetermination has been made as to the validity of the allegation. It is important to let the facility know why you are there, but protect the confidentiality of those involved in the complaint. Do not release information that will cause opportunities to be lost for pertinent observations, interviews, and record reviews required for a thorough investigation. For example, if the complaint is that food that is intended to be served hot is always served cold, do not tell the facility the exact complaint. Rather, tell them it is a situation related to dietary requirements.

5300.3 - Task 5: Information Gathering
(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

The order and manner in which information is gathered depends on the type of complaint that is being investigated. Conduct comprehensive, focused, and/or closed record reviews as appropriate for the type of complaint. Generally, it is not necessary to review records and information from more than one year ago. However, the SA is not precluded from doing so if concerns identified during the investigation indicate it is necessary in order to determine current compliance. It is very important to remember that the determination of whether the complaint happened is not enough. The surveyor needs to determine noncompliant facility practices related to the complaint situation and which, if any, requirements are not met by the facility.

Perform information gathering in order of priorities, i.e., obtain the most critical information first. Based on this critical information about the incident, determine what other information to obtain in the investigation.

Observations, record review and interviews can be done in any order necessary. As information is obtained, use what has been learned to determine what needs to be clarified or verified as the investigation continues.

Observe the physical environment, situations, procedures, patterns of care, delivery of services to residents, and interactions related to the complaint. Also, if necessary, observe other residents with the same care need. After determining what occurred, i.e., what happened to the resident and the outcome, investigate what facility practice(s) or procedures affected the occurrence of the incident.

EXAMPLE

It was verified through the investigation that a resident developed a pressure sore/ulcer which progressed to a Stage IV, became infected and resulted in the resident requiring hospitalization for aggressive antibiotic therapy. Observe as appropriate: dressing changes, especially to any other residents with Stage III or IV pressure sores; infection control techniques such as hand washing, linen handling, and care of residents with infections; care given to prevent development of pressure sores (e.g., turning and repositioning, use of specialized bedding when appropriate, treatments done when ordered, keeping residents dry, and provision of adequate nutritional support for wound healing).

Record Review: If a specific resident is involved, focus on the condition of the resident before and after the incident. If there are care issues, determine whether the appropriate assessments, care planning, implementation of care, and evaluations of the outcome of care have been done as specified by the regulatory requirements.

EXAMPLE

For a complaint of verbal and physical abuse, review the record to determine the resident's mood and demeanor before and after the alleged abuse. Determine if there are any other reasons for the change in the resident's demeanor and behavior. Determine whether an assessment has been done to determine the reason for the change in mood and behavior. Does the record document any unexplained bruises and/or complaints of pain, and whether they occurred in relation to the alleged incident?

Interviews: Interview the person who made the complaint. If the complainant is not at the facility at the time of the survey, he/she should be interviewed by telephone, if possible. Also, interview the person the complaint is about. Then, interview any other witnesses or staff involved. In order to maintain the confidentiality of witnesses, change the order of interviews if necessary. It may not always be desirable to interview the person who made the complaint first, as that may identify the person as the complainant to the facility. Interview residents with similar care needs at their convenience.

As interviews proceed, prepare outlines needed for other identified witnesses and revise outlines as new information is obtained.

During information gathering to investigate a complaint about the care and services provided to residents in a nursing home, findings of past noncompliance may be identified. Before considering a citation of past noncompliance with a specific regulatory tag, surveyors must determine if current compliance with the specific regulatory tag exists. Similar to verifying correction of current noncompliance on a revisit, surveyors should use a variety of methods to determine whether correction of the past noncompliance occurred and continues. This may include, but is not limited to, the following:

- Interviews with facility staff, such as the administrator, nursing staff, social services staff, medical director, quality assessment and assurance committee members, and/or other facility staff, as indicated, to determine what procedures, systems, structures, and processes have been changed.

- Reviewing through observation, interview and record review, how the facility identified and implemented interventions to address the noncompliance. Examples of interventions may include, but are not limited to:

    - The facility's review, revision, or development of policies and/or procedures to address the areas of concerns;

    - The provision and use of new equipment, as necessary;

    - The provision of staff training required to assure ongoing compliance for the implementation and use of new and/or revised policies, procedures, and/or equipment, especially with new and/or temporary staff;

    - The provision of additional staffing, changes in assignments or deployment of staff, as needed; and

    - The provision of a monitoring mechanism to assure that the changes made are being supervised, evaluated, and reinforced by responsible facility staff.

- Evaluating whether the facility has a functioning quality assessment and assurance committee whose responsibilities include the identification of quality issues; providing timely response to ascertain the cause; implementing corrective action; implementing monitoring mechanisms in place to assure continued correction and revision of approaches, as necessary, to eliminate the potential risk of occurrence to other residents and to assure continued compliance.

A citation of past noncompliance must meet all of the criteria described in Task 6 below.

5300.4 - Task 6: Information Analysis

Review all information collected. If there are inconsistencies, do additional data collection as needed, to resolve the inconsistencies. Determine if there is any other information still needed.

Determine whether:

- The facility failed to meet any of the regulatory requirements; and
- The facility practice or procedure that contributed to the complaint has been changed to achieve and/or maintain compliance.

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 as the deficiency is already corrected; however, the survey team documents the facility's corrective actions on Form CMS-2567.

5300.5 - Task 7: Exit Conference

Conduct an Exit Conference related to a complaint survey in accordance with the process described in the Exit Conference section located in the Long-Term Care Survey Process (LTCSP) Procedure Guide (https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Nursing-Homes.html). Do not inform the nursing facility of confidential information unless the individual who provided the information specifically authorizes you to do so.

If a deficiency is not present now, but was present and has been corrected, notify the facility orally and in writing that there *was noncompliance related to the* complaint because deficiencies existed at the time that the complaint situation occurred. (See SOM Chapter 7, Survey and Enforcement Process for Skilled Nursing Facilities and Nursing Facilities, for specific information about citing past noncompliance.)

If *there was no noncompliance related to the* complaint, notify the facility of this decision.

5310 - Action on Allegations of Resident Neglect and Abuse, and Misappropriation of Resident Property for Nursing Homes

(Rev. 212; Issued; 02-10-23; Effective: 10-21-22; Implementation: 10-24-22)

5310.1 - Written Procedures

(Rev. 212; Issued; 02-10-23; Effective: 10-21-22; Implementation: 10-24-22)

The State must develop and implement written procedures for the timely review and investigation of allegations of resident abuse and neglect, and misappropriation of resident property, including both complaints and facility-reported incidents. The State's policies and procedures must be consistent with Federal requirements as well as with procedures in the State Operations Manual.

Nursing homes send the following types of incidents to the State Survey Agency:

- All alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property;

- The results of all facility investigations involving alleged violations of abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property; and

- Reasonable suspicions of crimes against nursing home residents.

NOTE: If the SA receives information that a suspected crime may have occurred in a facility and there is indication that it has not been reported or the SA cannot verify that a report was made to law enforcement, then the SA forwards the information from the initial report immediately to law enforcement. The SA must follow applicable laws and regulations related to information disclosures, privacy and confidentiality, as it makes referrals. The SA may also contact the CMS Location office for more information.

A. Initial Reporting of Facility-Reported Incidents

The information collected during intake is critical in determining what may be occurring in a facility and the effect(s) that it may have on residents. While States have discretion in how they collect information from facilities (e.g., through electronic submission), at a minimum, the State Survey Agency must provide instructions to the facility and collect sufficient information to determine how the incident should be prioritized. See also Exhibit XX for sample instructions with examples of information and Appendix PP, Tag F609. If the facility has not provided sufficient information, the SA should take this into consideration as it triages the incident.

1. Facility Reported Incidents – Initial Report

The facility must provide in its report sufficient information to describe the alleged violation and indicate how residents are being protected [See §483.12(c)(3)]. It is important that the facility provide as much information as possible, to the best of its knowledge at the time of submission of the report, so that state agencies can initiate action necessary to oversee the protection of nursing home residents. See Exhibit XX for a sample form for initial reporting with examples of information and see also Appendix PP, Tag F609.

B. Reporting of Investigation Findings for Facility-Reported Incidents

For alleged violations of abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property, the facility is required to submit a report of the results of the investigation within 5 working days to the State Survey Agency (See 42 C.F.R. §483.12(c)(4), Tag F609 of Appendix PP of the State Operations Manual). While States have discretion in how they collect information from facilities (e.g., through electronic submission), at a minimum, the State Survey Agency must provide instructions to the facility and collect sufficient information to determine how the incident should be prioritized.

5-Day Final Report of Suspected Allegation

Within 5 working days of the incident, the facility must provide in its report sufficient information to describe the results of the investigation, and indicate any corrective actions taken, if the allegation was verified. It is important that the facility provide as much information as possible, to the best of its knowledge at the time of submission of the report, so that State agencies can initiate action necessary to oversee the protection of nursing home residents [see §483.12(c)(4)]. See Exhibit XX for a sample form for the investigation report with examples of information, and see also Appendix PP, Tag F609.

5310.2 - Review and Triage of Allegations
(Rev. 212; Issued; 02-10-23; Effective: 10-21-22; Implementation: 10-24-22)

The State reviews all allegations of resident neglect and abuse and misappropriation of resident property regardless of the source.

5310.2A-Immediate Jeopardy Priority
(Rev. 212; Issued; 02-10-23; Effective: 10-21-22; Implementation: 10-24-22)

In cases where the initial report indicates the following, the SA must initiate an onsite survey within three business days of receipt of the initial report:

1) The alleged noncompliance may have caused, or may likely cause, serious injury, harm, impairment, or death to a resident, and
2) The facility has not implemented adequate protection for all residents or the SA has not received sufficient evidence to conclude that residents are adequately protected.

For these cases, the SA will enter into *iQIES*: Intake Type=Incident; Priority = IJ; and Investigate Within X Days = 3 Working Days.

In cases where the initial report indicates the following, the SA must initiate an onsite survey within seven business days of receipt of the initial report:

1) The alleged noncompliance may have caused, or may likely cause, serious injury, harm, impairment, or death to a resident, and

2) The facility has potentially implemented adequate protection for all residents.

For these cases, the SA will enter into *iQIES*: Intake Type=Incident; Priority = IJ; and Investigate Within X Days = 7 Working Days.

NOTE: See Appendix Q of the State Operations Manual for guidance related to immediate jeopardy situations.

Depending on the nature of the allegation, the facility would be expected to take immediate action(s) to ensure the protection of residents. Information provided by the facility may assist the SAs in determining whether there are potentially adequate protections provided to the resident. Examples of such information include, but are not limited to:

- Monitoring of the alleged victim and other identified residents who are at risk, such as conducting unannounced management visits at different times and shifts;
- Evaluation of whether the alleged victim feels safe and if he/she does not feel safe, taking immediate steps to alleviate the fear, such as a room relocation, increased supervision, etc.;

- Providing social services (e.g., emotional support and counseling) to the resident, as needed;

- Immediate assessment of the alleged victim and provision of medical treatment as necessary;

- Provision of goods and/or services that are necessary to avoid serious injury, harm, impairment, or death to a resident;

- Immediate notification of the alleged victim's physician and the resident representative, when there is injury or a change in condition or status;

- If the alleged perpetrator is staff- Removal of access by the alleged perpetrator to the alleged victim and other residents and assurance that ongoing safety and protection is provided for the alleged victim and other residents

- If the alleged perpetrator is a resident or visitor- Removal of access by the alleged perpetrator to the alleged victim and, as appropriate, other residents and assurance that ongoing safety and protection is provided for the alleged victim and other residents

- Notification of the alleged violation to other agencies or law enforcement authorities, within timeframes as specified under Federal or State law or regulations; and

- Whether administrative staff, including the administrator, were informed and involved as necessary in the investigation.

Below are examples that indicate that a resident(s) may not be protected in the facility:

- The alleged perpetrator continues to have access to the alleged victim and/or other residents;

- Retaliation occurs against a resident who reports an alleged violation;

- A resident who repeatedly fondles other residents is moved to another unit, where he/she continues to exhibit the same behaviors to other residents; and

- A resident with a history of striking a resident is left unsupervised with a resident who has been targeted in the past.

The SA may contact the resident/representative to determine whether adequate protections are provided to the resident

5310.3 - Investigating Allegations

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

If there is reason to believe, either through oral or written evidence, that an individual used by a facility to provide services to residents could have abused or neglected a resident or misappropriated a resident's property, the State must investigate the allegation. During the investigation, the SA should evaluate how the facility developed policies and procedures to prevent the abuse, and after the abuse occurred, how the facility took action to report and investigate the allegations while ensuring the safety of the residents.

5310.4 - Factors Beyond the Control of the Individual
(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

The State must not make a finding that an individual neglected a resident if the individual demonstrates that such neglect was caused by factors beyond the control of the individual.

EXAMPLE: A nurse aide could not be found negligent for not providing clean bed and bath linens to a resident if the facility had no clean bed and bath linens available. However, the facility is responsible for providing clean bed and bath linens to residents.

5320 – Reporting Findings of Abuse, Neglect, or Misappropriation of Property to the Nurse Aide Registry
(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

5320.1 - Notification Procedures - Preliminary Determinations

If the State makes a preliminary determination, based on oral or written evidence and its investigation, that resident neglect, abuse, or misappropriation of property has occurred, the State completes the following notification procedures:

1. **Individuals Notified - The State notifies the following individuals in writing within 10 working days of the investigation:**

   a. Individual(s) implicated in the investigation; and

   b. The current administrator of the facility in which the incident occurred.

2. **Notice Information - The following information is included in the notice:**

   a. Nature of the allegation (specific facts);

   b. Date and time of the occurrence;

   c. A statement that the individual implicated in the investigation has a right to a hearing and must request the hearing within 30 days from the date of the notice. Provide the individual with the specific information needed to request a hearing, such as the name and address of a contact in the State to request a hearing;

   d. Statement that if the individual fails to request a hearing, in writing, within 30 days from the date of the notice, the findings are reported to the nurse aide registry or the appropriate licensure authority;

e. The intent to report findings *upheld* by a hearing in writing to the nurse aide registry and/or to the appropriate licensure authority;

f. Consequences of waiving the right to a hearing;

g. Consequences of a finding through the hearing process that the resident abuse or neglect, or misappropriation of property did occur; and

h. Right of the accused individual to be represented by an attorney at the individual's own expense.

5320.2 - Conduct of Hearing for Nurse Aides

1- Time frame to Complete the Hearing

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

2 - Hearing Location

The State must hold the hearing in a manner consistent with State practice at a reasonable place and time convenient for the individual.

5320.3 - Reporting Findings

1 - Reporting to Entities

If the individual waives the right to a hearing or the time to request a hearing has expired, or if the hearing finding is that the individual neglected or abused a resident or misappropriated a resident's property, the findings must be reported in writing within 10 working days to:

a. The individual;

b. Current administrator of the facility in which the incident occurred;

c. The administrator of the facility that currently employs the individual, if it is not the same facility in which the incident occurred;

d. Applicable licensing authorities; and

The nurse aide registry for nurse aides as specified in 42 CFR 483.156(c) and discussed in §4141. Section 4141 discusses the function of the registry, the information contained in the registry, and responsibility for the registry.

2 - Information Submitted to the Nurse Aide Registry

The following information must be included and remain in the registry permanently, unless the finding was made in error, the individual was found not guilty in a court of law, or the State is notified of the individual's death. See §4141.B.

a. Documentation of the investigation, including the nature of the allegation and the evidence that led to the conclusion that the allegation was valid;

b. The date of the hearing, if the individual chose to have one, and its outcome; and

c. A statement by the individual disputing the allegation if the individual chose to make one.

3 - Information Retained in the Nurse Aide Registry Permanently

The registry must remove entries for individuals who have performed no nursing or nursing-related services for 24 consecutive months, unless the individual's registry entry includes documented findings of abuse, neglect, or misappropriation of property.

5330 - Reporting Abuse to Law Enforcement and the Medicaid Fraud Control Unit for Nursing Homes

If the SA receives information that a suspected crime may have occurred in a facility and there is indication that it has not been reported or the SA cannot verify that a report was made to law enforcement, the SA must report the suspected crime to law enforcement immediately.

Verifying that a complainant, facility, and/or covered individual(s) has made a report to law enforcement would include review and confirmation of the following information:

- Who submitted the report to law enforcement, including name and contact information;
- Who did the reporter contact, including law enforcement entity, name, and contact information;
- Date/Time that the report was filed;
- Any copies of the report made to law enforcement, if available;
- What information was conveyed to law enforcement; and
- The police report number provided by law enforcement.

When the SA or *CMS location confirms noncompliance related to abuse*, the SA or *CMS location* must report the *cited* finding *of noncompliance* to local law enforcement and, if appropriate, the Medicaid Fraud Control Unit.

NOTE: "Covered individual" is defined in section 1150B(a)(3) of the Act as anyone who is an owner, operator, employee, manager, agent or contractor of the facility (§483.12(b)(5)(i)).

5340 - Post-Survey Certification Actions for Nursing Homes

(Rev. 155, Issued: 06-10-16, Effective: 06-10-16, Implementation: 06-10-16)

Following the investigation, the survey team records any findings on Form CMS-2567, the SA conducts a supervisory review of the CMS-2567 form and sends the provider a copy. The SA requests a POC for any uncorrected deficiencies. See §2728.

When Federal deficiencies are identified, the SA initiates certification actions as follows:

1. **Noncompliance that Constitutes Immediate Jeopardy to Resident Health and Safety -** The SA initiates procedures in accordance with §§7307 to 7309.

2. **Noncompliance that Does Not Constitute Immediate Jeopardy to Resident Health and Safety -** The SA initiates procedures in accordance with §§7311 to 7316.

3. **In Substantial Compliance** - The SA initiates procedures in accordance with §7319.

5350 – Data Entry

The SA enters survey information into the *CMS* system, including Forms CMS-670 and CMS-2567.

5360 - Processing of Complaints Originating with or Investigated by the CMS *location*

The *CMS location* establishes procedures and clear organizational accountability to ensure that any complaint is properly evaluated, documented, acknowledged, and handled timely and appropriately. The *CMS location* uses ACTS to ensure timely and appropriated action on all allegations originating with or investigated by the *CMS location*.

The extent and nature of *CMS location* involvement with a given complaint varies depending on the nature of the allegation and the receiving organization. The following procedures address the major variants of *CMS location* involvement.

5370 - Pre-Investigation Actions on Allegations Originating Through the *CMS location*

Most complaints originate through the SA and are recorded and controlled by the SA. When a complaint is filed directly with the *CMS location*, however, the *CMS location* assumes those initial SA responsibilities.

5380 - *CMS location* Processing of *CMS location* Investigated Complaints

This less frequent class of complaints includes allegations retained by the *CMS location* or forwarded to the *CMS location* by the SA for investigation or special processing. The *CMS location* responsibilities vary based on the type of complaint.

1 - Direct *CMS location* Investigation

These procedures apply when a direct *CMS location* investigation is conducted. When directly investigating, the *CMS location* begins by ensuring that it or the SA has met all intake, acknowledgment, and priority assignment requirements in §5010 to §5020.

2 - Conducting the Investigation

The *CMS location* follows the procedures for investigation in §5300.

3 – *CMS location* Certification Actions

When Federal deficiencies are identified, the *CMS location* initiates certification actions as follows:

a. Noncompliance that Constitutes Immediate Jeopardy to Resident Health and Safety - The *CMS location* initiates procedures in accordance with §§7307 to 7309. The *CMS location* performs the SA responsibilities described in these sections.

b. Noncompliance that Does Not Constitute Immediate Jeopardy to Resident Health and Safety - The *CMS location* initiates procedures in accordance with §§7311 to 7316.

c. In Substantial Compliance - The *CMS location* initiates procedures in accordance with §7319.

4 - Reporting

The *CMS location* should report survey information into the *iQIES* system , including Forms CMS-670 and CMS-2567.

5390 – *CMS location* Oversight of Complaint-Related Processes

1. The *CMS location* considers any complaint data in targeting look-behind surveys or reviews.

2. The *CMS location* monitors data in summary form - either through a log or data system. See §5060.

These records should include:

- Identification of region or State-wide patterns;
- Pinpointing of problem providers or States;
- Evaluation of SA processing times, workloads, performance, etc.; and
- Identification of overall SA workloads, including *review of complaints where noncompliance was not found* and Medicaid-only complaint volumes.

3. Based on needs identified from oversight activities, the *CMS location* provides SA training and technical assistance.

NOTE: Sections 5400 to 5480.2 relate to alleged EMTALA violations.

5400 - Investigations Involving Alleged Emergency Medical Treatment and Labor Act (EMTALA) Violations

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

Section 1866 of the Act, Agreements with Providers of Services, specifies that for a hospital, or any provider of services, to qualify for participation in the Medicare program, it must enter into an agreement with the Secretary of HHS. Effective August 1, 1986, participating hospitals with emergency departments must comply with the requirements of §1867 of the Act as a condition of their provider agreement.

The following Medicare provider agreement requirements, which closely parallel provisions contained in §1866of the Act, must be met by Medicare participating hospitals with emergency departments:

- 42 CFR 489.20(l) requires a hospital to comply with the requirements of 42 CFR 489.24**.** Section **1866(a)(1)(I)** of the Act requires a hospital to have and enforce policies to ensure compliance with the requirements of §1867;
- 42 CFR 489.20(m) requires a hospital to report to CMS or the SA any time it has reason to believe it may have received an individual who has been transferred in an unstable emergency medical condition (EMC) from another hospital in violation of the requirements of 42 CFR 489.24(e)**;**

- 42 CFR 489.20(q) requires a hospital to post conspicuously a sign(s) specifying the rights of individuals, under **§1867** of the Act, with respect to examination and treatment for emergency medical conditions and women in labor and to indicate whether or not the hospital participates in the Medicaid program. The letters within the signs must be clearly readable at a distance of at least 20 feet or the expected vantage point of the emergency department clients. The wording of the sign(s) must be clear and in simple terms and language(s) that are understandable by the population served by the hospital;

- 42 CFR 489.20(r)(1) requires a hospital to maintain medical and other records related to individuals transferred, including discharges, to or from the hospital for a period of five years from the date of transfer;

- 42 CFR 489.20(r)(2) requires a hospital to maintain a list of physicians who are on call to provide treatment necessary to stabilize an individual with an emergency medical condition;

- 42 CFR 489.20(r)(3) requires a hospital to maintain a central log on each individual who comes seeking assistance and whether he or she refused treatment, was refused treatment, or whether the individual was transferred, admitted and treated, stabilized and transferred, or discharged.

When hospitals do not conform to the requirements of §1867 of the Act, the practice is commonly called "dumping." A hospital with a dedicated emergency department is defined in 42 CFR 489.24(b) as a hospital that offers services for emergency medical conditions within its capacity to do so. The regulations at 42 CFR 489.24 parallel the provisions of §1867 of the Act and contain the following requirements that a hospital with a dedicated emergency department must meet:

- 42 CFR §489.24(a) General. Applicability of provisions of this section.

- 42 CFR §489.24(b) Definitions. As used in this section.

- 42 CFR §489.24(c) Use of dedicated emergency department for non-emergency services.

- 42 CFR §489.24(d) Necessary stabilizing treatment for emergency medical conditions.

- 42 CFR §489.24(d)(1) General. Subject to the provisions of paragraph (d)(2).

- 42 CFR §489.24(d)(2) Exception: Application to inpatients.

- 42 CFR §489.24(d)(3) Refusal to consent to treatment.

- 42 CFR §489.24(d)(4) Delay in examination or treatment.
- 42 CFR §489.24(d)(5) Refusal to consent to transfer.
- 42 CFR §489.24(e) Restricting transfer until the individual is stabilized.
- 42 CFR §489.24(e)(1) General.
- 42 CFR §489.24(e)(2) Appropriate transfer to another medical facility.
- 42 CFR §489.24(e)(3) Provides whistleblower protection to physicians and qualified medical personnel.
- 42 CFR §489.24(f) Recipient hospital responsibilities.
- 42 CFR §489.24(g) Termination of provider agreement.
- 42 CFR §489.24(h) Consultation with Quality Improvement Organization (QIO).
- 42 CFR §489.24(i) Release of QIO Assessment.
- 42 CFR §489.24(j) Availability of on-call physicians.
- 42 CFR §489.24 (j)(1) On-call list.
- 42 CFR §489.24 (j)(2) Hospital on-call policy and procedures.

If a hospital fails to meet these requirements, CMS may terminate the provider agreement in accordance with 42 CFR 489.53. The Office of the Inspector General (OIG) has the responsibility and authority to assess civil monetary penalties (CMPs) or to exclude physicians from the Medicare program when a hospital or physician violates these requirements. Additionally, individuals suffering personal harm and medical facilities suffering financial loss as a result of a violation of these provisions can bring civil action against the offending hospital and physicians. Filing for such civil action is limited to a period of 2 years after the date of the alleged violation. This legislation does not preempt any State or local laws, except to the extent that State or local requirements directly conflict with a requirement of this legislation.

5410 – EMTALA and Born-Alive Infants Protection Act of 2002

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

5410.1 - Interaction of the Born-Alive Infant Protection Act and EMTALA

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

With the definition of the terms “person” and “individual” codified at 1 U.S.C. §8, it is clear that there are circumstances where EMTALA protections are applicable to an infant who is born alive, as that term is defined in 1 U.S.C. §8(b).

For example, assume that a hospital’s labor and delivery department meets the definition of a “dedicated emergency department.” If an infant was born alive in that dedicated emergency department, and a request was made on that infant’s behalf for screening for a medical condition, (or if a prudent layperson would conclude, based on the infant’s appearance or behavior, that the infant needed examination or treatment for an emergency medical condition and that a request would have been made for screening) the hospital and physician could be liable for violating EMTALA for failure to provide such a screening examination. The born-alive infant is a “person” and an “individual” under 1 U.S.C. § 8(a) and the screening requirement of EMTALA applies to “any individual” who comes to the emergency department.

Another example is a case of an infant born alive elsewhere on the hospital’s campus (i.e., not in the hospital’s dedicated emergency department) and a prudent layperson observer concluded, based on the born-alive infant’s appearance or behavior, that the infant was suffering from an emergency medical condition. In such a circumstance, the hospital and its medical staff are required to perform a medical screening examination on that infant to determine whether or not an emergency medical condition existed. If the hospital or its medical staff determined that the infant was suffering from an emergency medical condition, the hospital has an obligation to admit the infant, or to comply with either the stabilization requirement or the transfer requirement of EMTALA. The born-alive infant is a “person” and an “individual,” as described above, and the stabilization and transfer requirements of EMTALA apply to “any individual” who comes to the hospital.

Finally, a third example is when the hospital admits a born-alive infant. EMTALA does not apply to inpatients. If a born–alive infant is admitted to the hospital, EMTALA would not apply to protect the infant in most circumstances. However, the Medicare COPs would apply to the infant once he or she was admitted to the hospital as an inpatient.

5410.2 - Conduct of Investigations

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

If a complaint indicates that a born-alive infant has been denied a screening examination, stabilizing treatment, or an appropriate transfer, the complaint is prioritized as an alleged EMTALA violation. It is not necessary to determine that the hospital acted with an improper motive in any failure to provide a screening examination, stabilizing treatment, or an appropriate transfer in order to conclude that an EMTALA violation has occurred. The Supreme Court of the United States has held that a finding of improper motive is not required to conclude that an EMTALA violation has occurred.

5420 - Basis for Investigation

The SA enters alleged EMTALA violations into ACTS. The *CMS location* approves or disapproves requests for EMTALA investigations in ACTS.

5430 - *CMS location* Direction of Investigation

5430.1 - Evaluation of Allegation

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

The *CMS location* evaluates all complaints and refers to the SA those that warrant SA investigation. The SA or the *CMS location* sends a letter to the complainant acknowledging the complaint and informing the complainant of whether an investigation is warranted. The SA's responsibility is to verify whether a violation of 42 CFR 489.24 and/or the related requirements at 42 CFR 489.20 occurred, and if there were other violations.

5430.2 - Request for Investigation of Allegations

The *CMS location* gives an initial verbal authorization to the SA to investigate the EMTALA allegation, and then completes Form CMS-1541A in ACTS. If the *CMS location* identifies Medicare conditions or standards it wants the SA to survey, related to the EMTALA allegation at a deemed hospital, the *CMS location* completes Form CMS-2802 in ACTS. If the *CMS location* identifies conditions or standards it wants the SA to survey related to the EMTALA allegation at a non-deemed hospital, it directs the SA to conduct a survey by completing Form CMS-1541A in ACTS.

5440 - Conducting an Investigation

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

5440.1 - Selecting the Team

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

The SA selects surveyors with a background in the profession or area to be investigated. Preferably, the surveyors should have acute care training and experience. All surveyors must be adequately trained in the evaluation of 42 CFR 489.24 cases. Physicians should have experience in peer review.

5440.2 - Scheduling the Investigation

Allegations of EMTALA violation against a non-deemed or deemed hospital or CAH may represent a probable immediate jeopardy to the next individual who comes to the hospital requesting examination and treatment for an emergency medical condition. Therefore, when triaged as IJ by the *CMS location*, initiate the investigation within two business days after receipt of the authorization from the *CMS location*. The onsite investigation must be conducted on consecutive business days. The survey must be

completed promptly and is not to be interrupted by other activities. DO NOT ANNOUNCE ANY INVESTIGATIONS.

Based on review of the complaint allegations by the *CMS location*, the EMTALA complaint may also be prioritized as Non-IJ High. In these situations, the investigation must be initiated within 45 business days of *CMS location* authorization. The onsite investigation must be conducted on consecutive business days. The survey must be completed promptly, should not be interrupted by other activities, and must be unannounced.

5440.3 - Guidelines for Surveyors Conducting Investigations

Attention to Procedures

The purpose of conducting the investigation is to ascertain whether or not the hospital violated the EMTALA requirements. The survey must be in accordance with applicable survey procedures and policies. Review instructions in Appendix V, before beginning the investigation. The guidelines provide a detailed interpretation of the regulations.

Involvement of Complainants

Complainants, if known, receive a letter of acknowledgment from the SA or *CMS location*. Do not disclose the identity of complainants. When information obtained during the investigation appears to be in conflict with the information supplied by the complainant, consult with the complainant, if this can be done without disclosing the person's identity.

5440.4 - Conducting the Investigation

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

A complete investigation consists of assessment of the following components:

- Completeness, adequacy and enforcement of policies and procedures which address the provisions of 42 CFR 489.24;
- Prompt reports to the SA or CMS of receipt of an improperly transferred individual by the receiving hospital;
- Presence and completeness of signs posted in emergency departments specifying the rights of individuals under 42 CFR 489.24, and information indicating whether the hospital participates in the Medicaid program;
- Maintenance of medical and other records related to individuals transferred to or from the hospital for a period of five years from the date of transfer, including discharged patients;

- Maintenance of a list of physicians who are on call to provide necessary stabilizing treatment;

- Maintenance of a central log on each individual who comes to the hospital seeking emergency services;

- Provision of an appropriate medical screening examination sufficient to determine the presence of an emergency medical condition;

- Provision of necessary stabilizing treatment;

- Provision of no delay in examination or treatment in order to inquire about insurance status or capability for payment;

- Provision of an appropriate transfer to another medical facility/provider;

- Provision of whistleblower protections; and

- Adequacy of responsibilities of the recipient hospital with specialized capabilities (nondiscrimination).

The survey tasks are listed below for easy reference. See Appendix V for detailed guidance.

- Task 1: Entrance Conference;

- Task 2: Case Selection Methodology;

- Task 3: Record review;

- Task 4: Interviews;

- Task 5: Exit Conference;

- Task 6: Professional Medical Review; and

- Task 7: Assessment of Compliance and Completion of the Deficiency Report.

After the investigation is concluded, complete a Form CMS-1541B (Exhibit 137). If one or more of the provisions of EMTALA are not met, complete Form CMS-2567, using "Principles of Documentation." Describe in detail the facts of each individual case. In addition, specify whether the hospital was aware of the problem and took steps to remedy it prior to the survey. If a SA physician was a member of the investigation team, include the medical review of the case. Use the "Physician Review Outline for Emergency Care Obligations of Medicare Hospitals," (Exhibit 138) for this purpose. In addition, complete

Form CMS-562. All the forms must be signed, showing the professional titles of all participating surveyors, and dated.

A hospital may have multiple sites listed under its Medicare provider number. These sites may not be in close proximity of each other and each site may have its own dedicated emergency department (DED). In cases where the alleged EMTALA violation is against a specific site of the hospital, the surveyors should focus their survey investigation at the hospital site mentioned in the complaint intake. However, the surveyors should review all EMTALA related Policies and Procedures of all sites of the hospital. The surveyors need to survey the other sites of the hospital if the survey findings indicate that the potential EMTALA violation maybe widespread.

5440.5 - Exit Conference

It is usually desirable and appropriate to conduct an exit conference. The surveyor(s) may outline the basic facts uncovered during the onsite investigation. However, the surveyor(s) must inform the hospital that the *CMS location* makes the final compliance determination, and the determination is often made with information obtained after the onsite investigation. Do not reveal the complainant and do not venture an opinion on what determination the *CMS location* might make. The exit conference should include a description of the process that is followed if the *CMS location* determines that a violation has occurred.

5450 - Forwarding Report of Investigation to the *CMS location*

Transmit the results of the investigation and your recommendations to the *CMS location* through ACTS within 10 working days following completion of the onsite survey, if it appears there may be an EMTALA violation. If there appears to be no violation, this time frame may be extended to 15 working days, in order to allow the SA additional processing time.

Transmit the following materials to the *CMS location* through ACTS:

- Form CMS-562,"Medicare/Medicaid/CLIA Complaint Form;"

- Form CMS-1541B, "Responsibilities of Medicare Participating Hospitals in Emergency Cases Investigation Report." Recommend one or more of the actions below on the form:

    - **None -** This means the complaint was not substantiated;

    - **In Compliance, but Previously Out of Compliance -** This means that the hospital identified the problem on its own and took effective corrective action prior to the investigation. In addition to this recommendation, document on the Form CMS-2567 when the hospital identified the violation or a similar problem, the corrective action taken, and the date of

such action. Also, document that the hospital has had no violations or similar problems for at least the past 6 months;

- **Recommend Termination (23 calendar day track) -** This means that the hospital is out of compliance with 42 CFR 489.24 or the related requirements at 42 CFR 489.20(l), (m), (q) or (r) and the violation presents an immediate jeopardy to patient health and safety;

- **Recommend Termination (90 calendar day track) -** This means that the hospital is out of compliance with 42 CFR 489.24 or the related requirements at 42 CFR 489.20(l), (m), (q) or (r), but the violation does not present an immediate jeopardy to patient health and safety;

- **Request Physician Review.** This means that it is recommended that the *CMS location* obtain a medical review of the case;

- **Possible Discrimination.** This means that it is believed that discrimination occurred based on financial status, race, color, nationality, handicap, or diagnosis.

- Form CMS-670, "Survey Team Composition and Workload Report;"

- Form CMS-2567, "Statement of Deficiencies and POC;"

  NOTE: If the hospital had identified the deficiency and took corrective action prior to the investigation, indicate on the Form CMS-2567 that the requirement was not met. However, indicate on the Form CMS-2567 and the narrative report that the hospital took corrective action prior to the investigation, what action was taken, and for how long the hospital has been in compliance.

- Physician Review Outline for Emergency Care Obligations of Medicare Hospital (if physician review was done by SA);

- Complaint investigation narrative;

- Copies of pertinent hospital policies and procedures that relate to the identified deficiencies;

- Summary listing of all patients comprising the sample, including an explanation of how and why the cases were selected for review;

- Summary of interviews.

Transmit the following to the *CMS location* by overnight mail:

- Copies of medical records for substantiated cases, medical records of individuals named in the complaints, and other medical records for which a QIO review is requested;

- Certification of benefits versus risks of the transfer, if this is a transfer case.

5460 - *CMS location* Review of Investigation

Upon receiving the case from the SA, the *CMS location* has 10 working days to review the investigation findings. The *CMS location* requests a 5-day advisory medical review of the case by the QIO to determine if there is an EMTALA violation. The *CMS location* has 5 working days to review the case upon return from the QIO. With this information, and any other additional information, the *CMS location* determines whether the hospital complied with the EMTALA requirements and determines whether the violation constitutes an immediate jeopardy to patient health and safety.

Prior to determining compliance or noncompliance, the *CMS location* is encouraged to confer with the State Agency, and **may** confer with the hospital's representatives. The *CMS location* shares as much data as possible in accordance with current Privacy Act requirements.

5460.1 - Hospital Is In Compliance - No Past Violation

If the *CMS location* determines that the allegation is not substantiated and that the hospital is in compliance with 42 CFR 489.24 and/or the related requirements at 42 CFR 489.20, the *CMS location* notifies the hospital and forwards a copy of the letter to the SA. If the SA received the complaint, it notifies the complainant that the complaint was not substantiated. If the *CMS location* received the complaint, the *CMS location* notifies the complainant.

5460.2 - Hospital Is In Compliance - Past Violation, No Termination

If the *CMS location* determines that the allegation was substantiated, but the hospital had identified the violation on its own, took effective corrective action prior to the investigation, and has had no EMTALA violations for at least the past 6 months, termination action is not initiated. The *CMS location* notifies the hospital via a "Past Violation - No Termination Letter." The SA receives a copy of the letter through ACTS. The *CMS location* or SA sends a letter to the complainant regarding the outcome of the investigation. Although no termination action is taken, the *CMS location* refers past violations of 42 CFR 489.24 to the OIG for assessment of civil monetary penalties (CMPs) if warranted.

5460.3 - Hospital Is Not in Compliance - Immediate Jeopardy to Patient Health and Safety

If the *CMS location* determines that the hospital is not in compliance and the violation represents an immediate jeopardy to patient health and safety, the *CMS location* follows a 23 calendar-day termination process. The termination procedures in §3010 are followed. Uncorrected deficiencies that resulted in a violation of 42 CFR 489.24 may pose an immediate jeopardy to people seeking emergency care. The *CMS location* notifies the complainant that the complaint was substantiated. It also informs the hospital in writing of the specific violations via a preliminary determination letter, and sends the hospital a copy of Form CMS-2567. The SA receives a copy of the letter through ACTS.

5460.4 - Hospital Is Not in Compliance - Situation Does Not Pose an Immediate Jeopardy to Patient Health and Safety

If the *CMS location* determines that the hospital is not in compliance with the EMTALA requirements, but the violation does not pose an immediate jeopardy to patient's health and safety, or the hospital took corrective action after the investigation to remove the immediate jeopardy, the *CMS location* follows a 90 calendar-day termination process. The termination procedures in §3012 are followed. The *CMS location* notifies the complainant that the complaint was substantiated. The *CMS location* informs the hospital, in writing, of the specific violations via a preliminary determination letter and sends the hospital a copy of Form CMS-2567. The SA receives a copy of the letter through ACTS.

Examples of noncompliance that usually do not pose an immediate jeopardy:

1. A transfer which was appropriate, but not signed or dated by the physicians;

2. An appropriate, functioning, central log that on one particular day is not fully completed; and

3. A written hospital policy that is missing, but is nonetheless being implemented.

The fact that the hospital has completed a POC should not be interpreted to mean that the hospital admits violating the EMTALA requirements. However, the hospital is included on the log of facilities with EMTALA violations, with the notation that an acceptable POC was received by CMS, and termination action was stopped.

5465 - Procedures for the 5-day QIO Review of Alleged Violations of 42 CFR 489.24

Prior to terminating a hospital from the Medicare program because of possible violation(s) of EMTALA, the *CMS location* requests the QIO to assess whether the individual involved was provided an appropriate medical screening examination, stabilizing treatment, or an appropriate transfer as required by EMTALA.

The QIO 5-day review is mandatory if the *CMS location* determines that a case involves a possible violation of 42 CFR 489.24 to support possible termination action against a

hospital if in fact it violated EMTALA. The *CMS location* is responsible for providing the QIO with all information relevant to the case that is within its possession and control. The *CMS location* sends the "Physician Review Outline for Emergency Care Obligations of Medicare Hospitals," (Exhibit 138) to capture this information. The QIO completes the review within 5 working days upon the receipt of *CMS location*'s request. The QIO sends the case file back to the *CMS location* including a copy of the review report. It is not required that the physician reviewer give the hospital and/or the physician an opportunity to respond to the allegations at this time. If the affected physician and/or hospitals have questions concerning the case, they are to consult with the *CMS location*.

The QIO Review is not required in cases where a delay in effecting a sanction would jeopardize the health and safety of individuals or in situations where medical review is inappropriate (e.g., cases where the individual was denied a medical screening examination). The QIO 5-day review is required to seek medical expertise on whether the individual was adequately screened, examined and treated.

The *CMS location* shall release upon request the 5 day QIO review to the affected physician and/or hospital, after the *CMS location* has made a determination as to whether the hospital violated or is in compliance with EMTALA. In addition, the *CMS location* may release the QIO review to the complainant or his/her representative upon request. The physician reviewer's identity is confidential, therefore, when releasing the QIO report the physician's identity is not to be disclosed unless he or she consents to the release of their identity in accordance with the disclosure regulations at 42 CFR 480.132 and 480.133.

The cases in which the *CMS location* determined that the hospital was in compliance with 42 CFR 489.24 but in violation of 42 CFR 489.20 of the EMTALA regulation do not need to be forwarded to the QIO for review. The *CMS location* takes action as warranted.

5470 - Termination Procedures for EMTALA Violations

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

5470.1 - Procedures for Termination when the EMTALA Violation is an Immediate Jeopardy to Patient Health and Safety

In cases where the *CMS location* determined that an immediate jeopardy existed, after a 5-day QIO advisory review has been completed, the *CMS location* follows the termination procedures in §3010. The processing timeframes are the maximum allowed. The termination procedures are not postponed or stopped unless evidence of correction of the deficiencies or proof that the violation did not exist is provided by the hospital to the *CMS location*. The *CMS location* forwards the supporting documents to the QIO (for a 60 day QIO review) in order to provide a medical opinion on the case. The *CMS location* refers the case to the OIG that has the responsibility for assessment of CMPs against the hospital and/or physician and physician exclusion provisions for violations of 42 CFR 489.24. The case is also referred to the Office for Civil Rights (OCR) because OCR may

take action under the Hill-Burton Subpart G Community Services regulations at 42 CFR 124.603(b) (1).

The termination track starts on the date that the *CMS location* makes the determination of noncompliance with 42 CFR 489.24. It is the date of the preliminary determination letter. The letter is forwarded to the hospital by the fastest method available (fax, e-mail or telephone). In addition, a written letter follows up by mail. The preliminary determination letter informs the hospital of:

- The *CMS location*'s findings based on the investigation and the results of medical review;

- The projected termination date (the 23rd calendar day from the date of the preliminary determination letter);

- The date on which the *CMS location* issues a Notice of Termination Letter and notifies the public (at least two calendar days, but no more than four calendar days prior to the termination date); and

- That the hospital may avoid the termination action and notice to the public by either providing acceptable POCs for the deficiencies or by successfully showing that the deficiencies did not exist. In either case, the necessary information must be furnished to the CMS *location* in time for the SA to verify the corrections before the projected termination date.

If, during the resurvey, the SA finds that the provider had implemented systems and processes to ensure that the likelihood of further violation is remote and there is adequate evidence that the provider is in compliance with the requirements, the termination action is rescinded and the provider is put back in compliance.

If, during the resurvey, the SA finds that the provider has not adequately implemented systems and processes to ensure compliance, the *CMS location* gives the hospital an additional 67 days or a total of 90 days (23 plus 67) to achieve compliance.

This allows the hospital time to prove that the corrective action is good for the long-term (i.e., the corrective action is adequate to ensure that no further violations will occur). The *CMS location* directs the SA to conduct a second survey by the 60th calendar day. On the resurvey, the surveyor(s) reviews patients' emergency department (ED) records and other relevant documents for the period since the last survey to assess continued compliance. If the hospital fails to achieve compliance, it is terminated from the Medicare program. The *CMS location* sends the complainant a letter reporting the final results of the investigation.

If the termination takes place and the hospital desires to become re-certified as a Medicare provider, the hospital must provide reasonable assurance that compliance will be maintained. The procedures at §2016 are followed.

5470.2 - Procedures for Termination When the EMTALA Violation is Not Immediate Jeopardy to Patient Health and Safety

In cases where the *CMS location* determined that a violation existed but not an immediate jeopardy, after a 5-day QIO advisory review has been completed when it was warranted, the *CMS location* follows the termination procedures in §3012 The processing timeframes are the maximum allowed. The termination procedures are not postponed or stopped unless evidence of correction of the deficiencies or proof that the violation did not exist is provided to the *CMS location* by the hospital. If warranted, the *CMS location* forwards supporting documents to the QIO (for a 60 day QIO review) in order to provide a medical opinion on the case. The *CMS location* refers the case to the OIG, if warranted, that has the responsibility for assessment of CMPs against the hospital and/or physician and physician exclusion provisions for violations of 42 CFR 489.24 The case is also referred to the Office for Civil Rights (OCR) because OCR may take action under the Hill-Burton Subpart G Community Services regulations at 42 CFR 124.603(b)(1)

The termination track starts on the date that the *CMS location* makes the determination of noncompliance with 42 CFR 489.24 and/or the related requirements at 42 CFR 489.20. It is the date of the preliminary determination letter.

5480 - Procedures for QIO Review of Confirmed EMTALA Violation

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

Before imposing sanctions under **§1867** of the Act for violations of 42 CFR 489.24, 42 CFR 489.24(h) requires that CMS obtain consultation from the QIO. The OIG holds the authority to assess CMPs against the hospital or physicians or to exclude physicians from the Medicare program for violations of 42 CFR 489.24.

5480.1 - Procedures for Coordinating 60 day QIO Review

The *CMS location* requests the QIO to provide a medical opinion on EMTALA violation cases within 60 calendar days. The cases referred for 60-day QIO review are outlined in §5480B. The *CMS location* uses the "Model Letter Requesting QIO Review of a Confirmed Violation of 42 CFR 489.24 for Purposes of Assessing Civil Monetary Penalties or Excluding Physicians," (Exhibit 212). The QIO provides the physician and the hospital reasonable notice of its review a reasonable opportunity for discussion, and an opportunity for the physician and hospital to submit additional information before issuing its report. (Instructions on notice of review and opportunity for discussion, and additional information that follow the regulatory requirements in 42 CFR 489.24(h) are found in §§9100-9150 of the QIO Manual.)

The *CMS location* is responsible for providing the QIO with all information relevant to the case that is within its possession and control. The *CMS location* sends the "Physician Review Outline for Emergency Care Obligations of Medicare Hospitals," (Exhibit 138) to capture this information. This outline is helpful for organizing the review of the

medical record. The specialty of the reviewing physician should be matched to the specialty of the physician who attended the patient and/or the individual's medical condition. If the patient was not seen by a physician, the QIO uses the diagnosis of the patient or the usual physician assignment practice of the hospital to determine the specialty of the physician reviewer.

Within 60 calendar days of receiving the case, the QIO must submit to the *CMS location* a report on its findings. The report provides an expert medical opinion regarding whether the individual involved had an emergency medical condition, whether the individual's emergency medical condition was stabilized, whether the individual was transferred appropriately, and whether there are any medical utilization or quality of care issues involved in the case. Upon request, the *CMS location* provides copies of the QIO report to the affected physician and/or hospital after all investigative activity has been completed.

When there was no screening examination or when a delay would jeopardize the health or safety of individuals, QIO Review is not required before the OIG may impose CMPs or exclude a physician from the Medicare program. In addition, if the QIO determines, after a preliminary review, that there was an appropriate medical screening examination and the individual did not have an emergency medical condition, the QIO returns the case to the *CMS location* with its documented opinion. The *CMS location* will close the case and no referral to OIG is necessary.

When the *CMS location* determines that a hospital was non-compliant with the requirements of 42 CFR 489.24, one of its notice requirements is to notify the OIG that the violation was confirmed and that termination action was initiated. (See Exhibit 208.) The *CMS location* completes the notification after receipt of the QIO 60-day review report. If the QIO report does not support an EMTALA violation, the *CMS location* closes the case without referring it to the OIG.

The *CMS location* forwards the following documents to the OIG:

- Form CMS-1541B;
- Form CMS-2567;
- Medical record;
- Summary of interviews;
- Explanation of sample selection;
- Copies of pertinent hospital policies and procedures related to the identified deficiencies;
- Complaint investigation narrative;

- Certification of benefits versus risks of the transfer (if this is a transfer case);
- Copy of the 5 working-day advisory QIO Review, and
- Copy of the 60 calendar-day advisory QIO Review.

The *CMS location* sends the above information and any other pertinent documentation in its possession to the OIG at the following address:

Office of Inspector General
Office of Counsel to the Inspector General
Department of Health and Human Services
Room 5527, Cohen Building
330 Independence Avenue SW
Washington, D.C. 20201

5480.2 - EMTALA Case Referral to OIG

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

CMS refers appropriate cases to the OIG for investigation. Periodically, OIG will advise us of the criteria they would prefer CMS to use in referring cases. Examples of the types of cases that may be referred include:

1. **Financial Screening -** The hospital and/or responsible physician refused to examine or treat a person based on the person's insurance status or inability to pay a fee. The financial basis for the decision must be clearly supported by evidence in the file, e.g., documented policy, interview reports.

2. **Patient with Trauma or Acute Emergency Condition -** The hospital and/or responsible physician (including an on-call physician who failed to come to the hospital) failed to screen, stabilize, or appropriately transfer (or, in the case of a hospital with specialized capabilities or facilities, refused to accept an appropriate transfer of) a person with trauma, e.g., a severe head injury, or other acute emergency condition, e.g., heart attack or stroke, requiring immediate and substantial medical intervention.

3. **High Risk Event (such as Birth) Occurs Prior to Arrival at Another Hospital -** The hospital and/or responsible physician discharged or refused to screen/treat a person who gave birth (or is subject to another high risk medical event) prior to arriving at another hospital (especially if transport is by private vehicle).

4. **Death or Serious Harm Results from Dump -** The evidence in the file (including the QIO Review) demonstrates that the dumping violation caused serious medical harm or death to the victim of the violation.

5. **Egregious Violation Prioritized by CMS -** CMS concludes that a CMP is appropriate because of the seriousness of the violation (the person must have had an emergency medical condition) and other relevant factors, e.g., long history of noncompliance, hospital policy resulting in violations, pattern of serious violations, knowing and willful violation. This category is for those cases that CMS determines are very serious and merit a CMP but do not fit within other categories identified by OIG.

5480.3 - Releasing QIO Assessment

Upon request, the *CMS location* may release QIO assessment(s) to the physician and/or hospital or the affected individual, or his/her representative. The QIO physician's identity is confidential unless he/she consents to its release. The QIO Review may be released pursuant to the requirements of 42 CFR 480.132 and 480.133.

Sections 5500 to 5590 relate CLIA.

5500 - Complaints Involving Unaccredited Laboratories

NOTE: This section applies to complaints against laboratories that hold a CLIA certificate of compliance, certificate of waiver (COW), and certificate of PPM (See §§5540-5590 for complaints regarding accredited laboratories).

A complaint is an allegation that could result in citing noncompliance with CLIA requirements. A complaint may be substantiated or unsubstantiated as a result of an investigation or survey. A substantiated complaint is one resulting in a finding of noncompliance at the time of the investigation, or a finding that noncompliance was proven to exist, but was corrected prior to the investigation. An unsubstantiated complaint is an allegation where sufficient evidence could not be found to conclude that noncompliance with CLIA requirements existed during the investigation or at the time of the alleged violation. A complaint may be received in either the SA or the *CMS location*. The receiving organization should follow the procedures outlined below.

The SA obtains the following information for every complaint:

- Complainant's name, address, and telephone number, unless the complainant requests anonymity;
- Laboratory's name and address; and
- Description of problem, (e.g., personnel, places, and dates of occurrence).

5500.1 - Control

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

The SA establishes a file for the complaint and logs the action in a control system. The system may be manual or automated, but must facilitate tracking and control of the complaint.

5500.2 - Acknowledgment

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

If the complainant is known, the SA promptly issues written acknowledgment that the complaint is being investigated. The SA should not delay acknowledgment pending an investigation unless the investigation takes place within three working days. The SA must take appropriate precautions to protect the complainant's anonymity and privacy. The SA maintains a copy or record of the notification with the complaint documentation.

5500.3 - Evaluation

The SA evaluates any complaint to determine whether it should be investigated by the SA, or whether it should be forwarded to the *CMS location* for investigation or referral to the appropriate authority (e.g., OCR, OSHA, *CMS location*). The SA assesses the complaint to determine if an immediate survey is necessary. While the SA will perform most complaint surveys, complaints involving State-operated facilities are the responsibility of the *CMS location*. When the SA does not have jurisdiction, it should forward the complaint to the *CMS location* within three working days. If referral is not necessary, the SA considers whether or not any special notification is appropriate.

If a complaint is especially significant, sensitive, or attracting broad public or media attention, the SA informs the *CMS location* immediately.

5500.4 - Scheduling Investigations

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

The SA investigates within two working days of receiving the complaint and focuses on the specific problem area if the complaint involves possible immediate jeopardy to patient health and safety. Otherwise, the SA follows procedures for prioritizing and investigating certification-related complaints. Laboratories with complaints pending are identified and given priority in scheduling of regular certification surveys.

5500.5 - Conducting Investigations

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

The SA investigates complaints by means of an onsite survey, by telephone, by electronic communication, by letter, or by a documentary review. Complaint investigations are unannounced.

For onsite complaint investigations, the SA performs a full or partial survey based on the allegations. If a complaint alleges generalized inappropriate laboratory practices, the SA evaluates compliance with applicable requirements or conducts a full survey, as needed.

If the complaint is of a specific nature, the SA performs a survey focused on areas relevant to the complaint.

5500.6 - Conducting Investigations in a Laboratory with a Certificate of Waiver

The *CMS location* authorizes an unannounced complaint survey of a laboratory holding a certificate of waiver only if it is based on a substantial allegation of noncompliance. The fact that a deficiency is not at the Condition-level does not preclude taking adverse action based on provisions contained in 42 CFR 493.1840. As with other laboratories, the SA investigates complaints made against laboratories with a certificate of waiver by means of an onsite survey, by telephone, letter, or by a review of documents.

The SA performs the onsite investigation based on the allegation and determines whether a laboratory is performing only waived tests and if the laboratory is following the manufacturer's instructions for performing the tests (See Appendix C).

5500.7 - Conducting Investigations in a Laboratory with a Certificate for PPM Procedures

The *CMS location* authorizes an unannounced complaint survey of a laboratory holding a certificate for PPM procedures only if based on a substantial allegation of noncompliance. This survey should not differ from a complaint survey done in any other laboratory performing non-waived testing, as all requirements for moderate complexity apply except routine survey.

Substantial indication that a laboratory is performing tests that do not appear on the PPM procedures test list; e.g., through billing procedures, should prompt a complaint survey of a certificate for PPM procedures laboratory followed by either proper registration or appropriate sanctions.

5500.8 - Post Investigation Actions

Following the investigation, the SA records any deficiencies on a Form CMS-2567 and provides it to the facility using regular procedures. Subsequent actions depend on the severity and nature of the deficiencies cited and the facility's willingness or ability to correct them.

When deficiencies are identified, the SA initiates actions as follows:

1. **Condition-Level Deficiencies - Immediate Jeopardy** - Certifies noncompliance and initiates procedures to recommend imposing alternative and principal sanctions.

2. **Condition-Level Deficiencies - No Immediate Jeopardy; Facility Provides an Acceptable POC** - Certifies noncompliance and initiates procedures to

recommend imposing alternative sanctions based on the severity and nature of the deficiencies found.

3. **Lower Level Deficiencies - Facility Provides an Acceptable POC** - Certifies compliance based upon an acceptable POC and assembles documentation for *CMS location* review.

4. **Lower Level Deficiencies - Facility Unable or Unwilling to Provide Acceptable POC** - A facility with deficiencies may not participate without an acceptable POC. The SA recommends sanction action to the *CMS location*.

When no deficiencies are identified, no certification action is required.

5500.9 - Resolution/Closeout

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

1 - Unsubstantiated

The SA enters the unsubstantiated complaint into ACTS and documents the facility's certification file.

2 - Substantiated

The SA reports substantiated complaints using the Form CMS-2567 and any appropriate supporting documentation. The SA logs summary information in the control system and files a copy of the complaint documents in the facility's certification file. The SA enters complaints into ACTS. The laboratory will be charged a fee to cover the cost of the survey if noncompliance is documented.

The SA closes out all complaints with a follow-up notice to the complainant with the findings and disposition of the complaint. The SA should send this notice soon after the investigation and retains a copy with the complaint record.

The SA provides follow-up reports, as necessary, to any other appropriate parties such as the State Medicaid agency and/or initial referring agencies. The SA must be sure to protect the anonymity and privacy of the complainant.

The SA inputs the investigation information into ACTS within 45 days of the completion of the complaint survey.

5510 - CLIA-Exempt Laboratory Complaint Investigations - General

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

Complaints may be from any source, including verbal, written, electronic or in the media.

Complaints are investigated if they meet the following criteria:

- If substantiated, would have an impact on the health and safety of the general public or individuals served by the laboratory, and

- Would raise doubt as to the laboratory's compliance with one or more CLIA Conditions and/or requirements.

An attempt to maintain the anonymity of the complainant should always be made.

There are a number of entities that must address laboratory complaints including: CMS Central and Regional Offices, the state agencies (including those with state licensure programs), approved states, and accreditation organizations. Each of these entities shares a strong interest in ensuring the quality of patient care and the services provided by laboratories. When the complaint involves more than one of these entities, there should be coordination and communication to ensure an effective and timely resolution of the issue.

5520 - Review of CLIA-Exempt Laboratory Complaints

If the *CMS location* receives a complaint against a CLIA-exempt laboratory, the *CMS location* determines what action is appropriate. The *CMS location* may do any of the following:

- Determine the severity of the complaint;

- Send the information to the approved State for their action;

- Conduct a survey (full or partial);

- Investigate the complaint during the course of a validation survey (full survey), if it is conducted within 45 days of the laboratory's licensure survey and the complaint does not present immediate jeopardy concerns.

- If the seriousness of the complaint or the circumstances warrant, the *CMS location* should invoke the Rapid Response Alert Protocol.

NOTE: Transfusion-related fatality investigations must be conducted by the *CMS location*. They may not be delegated to the approved State; however, the approved State may accompany the *CMS location* on the investigation. In either case, there must be coordination and communication between the *CMS location* and the State. Where State laws apply to transfusion-related incidents, the approved State program should follow its established procedures and coordinate with the *CMS location*.

The *CMS location* Reviews the approved State program's complaint activities as part of the overall annual review. The *CMS location* has the discretion to maintain its own

complaint tracking system for those that have been forwarded to the approved State program. However, this information should be an integral part of the State's annual review.

If the approved State program receives a complaint against a CLIA-exempt laboratory, the approved State program determines what action is appropriate. If the approved State sanctions a CLIA-exempt laboratory in any way (e.g., licensure is withdrawn), it must notify the *CMS location* within 30 days.

If the laboratory against which the complaint is alleged is accredited, the State must also notify the accreditation organization.

5530 - Conducting Complaint Investigations and Surveys for CLIA-Exempt Laboratories

The *CMS location* will complete the "Medicare/Medicaid/CLIA Complaint Form," Form CMS-562, for every complaint investigation it performs in a CLIA-exempt laboratory. When an investigation can be conducted via telephone (e.g., personnel credentials), the *CMS location* should do so. The *CMS location* obtains the following information for every allegation:

- Complainant's name and address, unless complainant requests anonymity. Do not disclose the identity of the complainant to the laboratory;
- Laboratory's name and address; and
- Description of problem, involving names, places, and dates.

The *CMS location* follows the same procedures for control and acknowledgement indicated in §5500. Complaints involving potential immediate jeopardy will be investigated by the *CMS location* within 2 working days of receipt. Complaints not involving potential immediate jeopardy are investigated within 45 days. All complaint surveys are unannounced.

If a laboratory representative refuses to permit a complaint survey, the *CMS location* contacts the State and requests that it contact the laboratory to explain the protocol and, if necessary, suggest that the State take enforcement action against the CLIA-exempt laboratory. The *CMS location* conducts the complaint survey in accordance with the survey protocol and uses the appropriate survey forms specified in Exhibit 63 and the outcome-oriented protocol found in Appendix C.

Initially, the *CMS location* focuses the survey only on the Condition(s) or requirement(s) related to the complaint area(s). If the complaint is substantiated or if additional deficiencies are found during the course of the investigation, the *CMS location* expands the scope of the survey to include additional standards, conditions, and other CLIA requirements. If the complaint is not substantiated, the *CMS location* notifies the

laboratory that it is in compliance with the CLIA Condition(s) (Exhibit 243). The *CMS location* also notifies the approved State program of the Condition-level compliance (Exhibit 244).

At the exit conference, the *CMS location* informs the laboratory of the deficiencies found. If the deficiencies pose immediate jeopardy to the health and safety of individuals served by a laboratory or that of the general public, the *CMS location* notifies the approved State program and the laboratory within two working days by overnight mail and includes a copy of the Form CMS-2567. The *CMS location* directs the State program to take the appropriate enforcement action. (See Exhibits 231 and 228). The *CMS location* follows-up with the State program within 15 working days of its notification to the laboratory to verify that the enforcement action has either been taken against the laboratory or that the laboratory has achieved compliance with CLIA requirements.

If the State program fails to take appropriate enforcement action for an immediate jeopardy case within 23 days of the *CMS location*'s notification, and the laboratory has not achieved Condition-level compliance, the *CMS location* may request CO to either contact the State or attempt other resolution to eliminate the jeopardy.

If the deficiencies do not pose immediate jeopardy to the health and safety of individuals served by a laboratory or that of the general public, the *CMS location* prepares a Form CMS-2567 and forwards a letter along with the Form CMS-2567 to the laboratory and to the State program within 10 working days of completing the survey. The State program is responsible for taking any enforcement action, if necessary, monitoring the correction of the deficiencies, and providing a report to the *CMS location*. (See Exhibit 231.)

The *CMS location* completes a Survey Team Composition and Workload Report, Form CMS-670, for all complaint surveys and related activity.

If the approved State program fails to take appropriate enforcement action in non-immediate jeopardy situations, the *CMS location* documents its files accordingly and notifies CO. Failure to take and document the necessary enforcement action may subsequently jeopardize current or future approval of the State's laboratory licensure program.

5540 - Complaint Investigations and Surveys of Accredited Laboratories Under CLIA

There are a number of entities that must address laboratory complaints including: CMS Central and Regional Offices, the state agencies (including those with state licensure programs), approved states, and accreditation organizations. Each of these entities shares a strong interest in ensuring the quality of patient care and the services provided by laboratories. When the complaint involves more than one of these entities, there should be coordination and communication to ensure an effective and timely resolution of the issue.

The statutory basis for conducting surveys of accredited laboratories based on allegations of noncompliance is found in §353(e)(2)(D) of the Public Health Service Act (PHSA). Since accreditation organization (AO) requirements are equivalent to CLIA requirements, a complaint may affect the laboratory's accreditation status as well.

Complaints are investigated if they meet the following criteria:

- If substantiated, would have an impact on the health and safety of the general public or individuals served by the laboratory, and

- Would raise doubt as to the laboratory's compliance with one or more CLIA Conditions and/or requirements.

The *CMS location* should evaluate the complaint and take appropriate investigatory action. If the seriousness of the complaint or the circumstances warrant, the *CMS location* should invoke the Rapid Response Alert Protocol. Every effort should be made to secure a written form of the complaint, while maintaining anonymity, if requested.

All complaint surveys are unannounced and conducted according to outcome-oriented survey principles (See Appendix C). If an investigation can be conducted by letter or telephone, in lieu of an onsite survey, those means should be utilized.

Upon receipt, all complaints are logged and tracked and the same information as for CMS certified laboratories is collected, monitored and maintained (see Section 5500).

5550 - *CMS location* Direction of Complaint Investigation of an Accredited Laboratory

The *CMS location* has primary responsibility for the coordination of all activities involving complaints relating to an accredited laboratory.

This includes:

- Ensuring that all pertinent information concerning the complaint is obtained;

- Assessing the level of severity of the complaint;

- Determining actions required for investigation;

- Determining whether multiple AOs may be involved; and

- When warranted (e.g., in cases potentially involving media coverage, Federal/State Congressional or political interest, legal intervention, etc.), informing and coordination with all affected parties, including AO's, State Agencies and Central Office.

Although the *CMS location* has the lead role in directing the investigation of complaints involving accredited laboratories, all affected entities (i.e., State Agencies, AO's, Central Office) share responsibility in ensuring timely and effective action is taken.

Complaints received by the SA:

If the SA receives a substantial allegation of noncompliance directly from a complainant about an accredited laboratory, it promptly acknowledges receipt of the complaint and advises the complainant that it is being forwarded to the *CMS location* for action. The SA forwards a copy of the acknowledgment letter and the complaint to the *CMS location*. This includes SAs with a State laboratory licensure program.

Complaints received by the *CMS location*:

If the complaint is received directly by the *CMS location*, the *CMS location* will promptly send a letter to the complainant acknowledging the complaint and advising the complainant of the intended course of action, and subsequently the results of any investigation, if appropriate, and of the corrective action taken.

In either case (complaint received by SA or *CMS location*), the *CMS location* evaluates the complaint and has the lead in determining the course of action. The *CMS location* determines whether the *CMS location*, the SA, or the AO, including multiple AOs if circumstances so warrant, will investigate the complaint. The *CMS location* will also determine whether one or multiple AOs may be impacted by the complaint and, if so, alert them of the pending action. In certain instances the *CMS location* may enlist CO support to help determine the most effective course of action.

If the *CMS location* determines that the SA should investigate the complaint, the *CMS location* prepares a "Request for Complaint Investigation or Validation Survey of Accredited Laboratory, Form CMS-2802A," (See **Exhibit 107**) and a "Medicare/Medicaid/CLIA Complaint," Form CMS-562, and forwards them to the SA along with a copy of the complaint and notifies the AO. If the *CMS location* authorizes the SA to perform a full survey (all specialties and subspecialties covered by the certificate), and the survey can be performed within 90 days of the AO's inspection, the survey can be counted in the SA's validation workload.

If the *CMS location* determines that the complaint involves a potential immediate jeopardy to the individuals served by the laboratory, or to the general public, the SA investigates the complaint within two working days of receiving it from the *CMS location*. Otherwise, the *CMS location* will direct the SA to investigate non-Immediate Jeopardy complaints within 45 days and report their findings to the *CMS location* and AO at the conclusion of the survey.

Complaints investigated by AOs:

If the *CMS location* determines that the accreditation organization should carry out its own investigation, it promptly forwards the complaint to the accreditation organization for immediate attention. The *CMS location* will request to be notified of the results of any investigative action taken. The *CMS location* will then notify the SA and, if warranted, CO.

NOTE: Transfusion-related fatality investigations must be conducted by the *CMS location* or SA. Transfusion-related fatality investigations must not be referred to an accreditation organization for action. However, the AO or multiple AOs, as appropriate, should be notified when such an investigation is taking place.

Complaints received by AOs:

Complaints received directly by AOs will be investigated under each AOs own standards and procedures. If multiple AOs are potentially impacted, the AO receiving the complaint will promptly inform the other AOs and a determination should be reached regarding the need for coordinated action. In cases potentially involving media coverage, Federal/State Congressional or political interest, legal intervention, etc., the SA, *CMS location* and CO should be promptly alerted by the AO receiving the complaint and consulted concerning appropriate action.

5560 - Conducting Complaint Survey of an Accredited Laboratory

If an onsite survey is warranted, the SA will conduct an unannounced survey of an accredited laboratory based on the substantial allegation of noncompliance. The SA conducts the complaint survey in accordance with outcome-oriented principles (see Appendix C). The SA conducts a focused complaint survey, as instructed by the *CMS location* on Form CMS-2802A. If the SA finds additional deficiencies during the course of the complaint investigation, it may expand the scope of the survey with *CMS location* approval.

At the exit conference, the SA informs the laboratory director of the deficiencies found and the procedures to respond to them. If the deficiencies do not pose an immediate jeopardy to the health and safety of individuals served by a laboratory, or to the general public, the SA prepares a Form CMS-2567 and requests that the laboratory submit a POC for all Condition-level deficiencies. Condition level deficiencies **must** be corrected; those at the standard level are optional. The SA informs the laboratory that the Form CMS-2567 will be made available to the public under the disclosure of survey information provisions. The SA indicates to the laboratory that the "Statement of Deficiencies" (Form CMS-2567) will be forwarded to the laboratory within 10 working days and that the POC must be returned to the SA within 10 calendar days. Upon receipt of the survey information and POC, the *CMS location* makes a determination of whether or not sanctions will be imposed against the laboratory and notifies the AO.

5570 – Forwarding Investigation Report to *CMS location*

If non-immediate jeopardy is found, the SA will submit the appropriate information as specified in the List of Documents in the Certification Packet (see Exhibit 63) to the *CMS location*, or through an update to ACTS within 45 days of completing the survey and notifies the *CMS location* of the entry. If the laboratory chooses not to submit a POC when deficiencies are found, the SA reports any known information about the laboratory's efforts to correct deficiencies to the *CMS location* and AO.

5580 - Accredited Laboratory Found in Compliance Following a Complaint Survey

If after review of the documentation the *CMS location* determines that the accredited laboratory is in compliance with all CLIA Condition-level requirements, it officially notifies the laboratory and forwards a copy of this letter to the SA and the AO. This letter advises that the accreditation organization may contact the laboratory about correcting any deficiencies below Condition-level.

5590 - Accredited Laboratory Found Not in Condition-level Compliance Following a Complaint Survey

If the deficiencies found pose an immediate jeopardy to the health and safety of individuals, the SA prepares the Form CMS-2567, (which is included as part of the List of Documents in the Certification Package, See Exhibit 63) and notifies the *CMS location* and sends Form CMS-2576 to the laboratory within 2 working days. *CMS location* will notify the AO. Based on the information forwarded, and the laboratory's POC, the *CMS location* determines if sanctions are to be imposed against the laboratory. The *CMS location* will then notify the AO.

Should the immediate jeopardy situation be corrected before the adverse action is taken or completed, the SA will advise the laboratory that it will revisit it to inspect all remaining Conditions not in compliance. The *CMS location* will notify the AO.

If non-immediate jeopardy is found, the SA will submit the appropriate information as specified in the List of Documents in the Certification Packet (See Exhibit 63) to the *CMS location*, or through an update to ACTS within 45 days of completing the survey and notifies the *CMS location* of the entry. The POC should also be forwarded to the *CMS location*. If the laboratory chooses not to submit a POC when deficiencies are found, the SA reports any known information about the laboratory's efforts to correct deficiencies to the *CMS location* and the *CMS location* will notify the AO and the laboratory that the laboratory is out of compliance and has been placed under SA monitoring jurisdiction (see Exhibit 241). The laboratory is monitored by the SA, *CMS location*, and/or AO until it reaches Condition-level compliance or its certificate of accreditation is revoked. A copy of all correspondence is provided to the accreditation organization by the *CMS location*.

For standard only deficiencies, responsibility rests with the AO to follow-up and pursue corrective action. The laboratory continues to be accredited by its accreditation organization and retains its CLIA certificate of accreditation during this monitoring period; however, it becomes subject to the same CLIA requirements, survey and enforcement procedures as applied to non-accredited laboratories found out of compliance.

CROSSWALK TO THE OLD CHAPTER 5

A crosswalk from sections of the State Operations Manual Chapter Five published 5-21-2004 to the revised chapter five is as follows:

Name of Old Section	Old Section Number	New Section Number	Name of New Section
Management of Complaints and Incidents	5000	5000	Management of Complaints and Incidents
Intake Process	5010	5010	Intake Process
Triage and Priority Assignment	5020	5070	Priority Assessment for Nursing Homes, Deemed and Non-Deemed Providers/Suppliers, and EMTALA
Priority Definitions	5030	5075	Priority Definitions for Nursing Homes, Deemed and Non-Deemed Providers/Suppliers, and EMTALA
Investigation Findings and Reports	5040	5080	Investigation Findings and Reports
CMS Regional Office Responsibility for Monitoring SA Management of Complaints and Incidents	5050	5050	CMS *Location* Responsibility for Monitoring SA Management of Complaints and Incidents
Aspen Complaints/Incidents Tracking System (ACTS)	5060	5060	ASPEN Complaints/Incidents Tracking System (ACTS)
Investigation of Complaints Against Accredited/Deemed Providers and Suppliers	5100	5100	Investigation of Complaints for Deemed Providers/Suppliers
Basis for Investigation of Complaints Against Accredited/Deemed Providers and Suppliers	5110	5100.1	Basis for Investigation
RO Direction of Accredited Hospital Complaint Investigation	5120	5210	Processing of Complaints Originating with or Investigated by *CMS Location*
Conducting an Accredited Hospital Complaint Validation Survey	5130	5050	CMS *Location* Responsibility for Monitoring SA Management of Complaints and Incidents
Forwarding Investigation Report to RO	5140	5050	CMS *ocation* Responsibility for Monitoring SA Management of Complaints and Incidents
Accredited Hospital Found in Compliance Following Complaint Validation Survey	5150	5100	Investigation of Complaints for Deemed Providers/Suppliers
Accredited Hospital Found Not in Compliance Following Complaint Validation Survey	5160	5100	Investigation of Complaints for Deemed Providers/Suppliers
Reinstatement to Accreditation Organization Jurisdiction	5170	5100.2	Post-Survey Procedures
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Complaints Involving Unaccredited Laboratories	5500-5590	5500-5590	Complaints Involving Unaccredited Laboratories

Chapter Five State Operations Manual

Acronyms

(Rev. 18, 03-17-06)

ACTS	ASPEN Complaint Tracking System
AIDS	Auto-immune deficiency syndrome
AO	Accreditation Organization
the ACT	Social Security Act
CFC	Conditions for Coverage
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments
CMP	Civil Monetary Penalties
CMS	Center for Medicare and Medicaid Services
CO	Central Office
CoP	Conditions of Participation
COW	Certificate of Waiver
DED	Dedicated Emergency Department
DHHS	Department of Health and Human Services
EMS	Emergency Medical System
EMTALA	Emergency Medical Treatment and Labor Act
ESRD	End-Stage Renal Disease
FDA	Food and Drug Administration
HHA	Home Health Agency
HIV	Human Immunodeficiency Virus

IJ	Immediate Jeopardy
iQIES	*Internet Quality Improvement & Evaluation System*
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
LSC	Life Safety Code
NF	Nursing Facility
NW	Networks
OCR	Office of Civil Rights
OIG	Office of Inspector General
OSHA	Occupational Safety and Health Administration
P & A	Protection and Advocacy Group
PHSA	Public Health Service Act
POC	Plan of Correction
PPM	Provider Perform Microscopy (PPM) Procedures
PRTF	Psychiatric Residential Treatment Facility
QIO	Quality Improvement Organization
RFP	Requirements for Participation
RNHCI	Religious Non-Medical Health Care Institutions
RO	Regional Office
SA	State Agency
SMA	State Medicaid Agency
SNF	Skilled Nursing Facility
SOM	State Operations Manual
USC	United States Code

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R212SOM	02/10/2023	Revisions to State Operations Manual (SOM) Chapter 5	10/24/2022	N/A
R208SOM	10/21/2022	Revisions to State Operation Manual (SOM), Appendix PP Guidance to Surveyors for Long Term Care Facilities	10/24/2022	N/A
R191SOM	07/19/2019	Revisions to the State Operations Manual (SOM) Chapter 5 and Appendix V	07/19/2019	N/A
R155SOM	06/10/2016	Revisions to State Operations Manual (SOM) Chapter 5	06/10/2016	N/A
R120SOM	09/19/2014	Revisions to State Operations Manual (SOM) Chapter 5	09/19/2014	N/A
R88SOM	08/27/2013	Revisions to State Operations Manual (SOM) Chapter 5	07/19/2013	N/A
R86SOM	07/19/2013	Revisions to State Operations Manual (SOM) Chapter 5 – Rescinded and replaced by Transmittal 88	07/19/2013	N/A
R50SOMA	07/10/2009	Revisions to Chapter 5, "Complaint Procedures"	07/10/2009	N/A
R18SOMA	03/17/2006	Revisions to Chapter 5, "Complaint Procedures"	03/17/2006	N/A
R01SOM	05/21/2004	Initial Issuance of Pub 100-07	N/A	N/A

State Operations Manual

Chapter 7 - Survey and Enforcement Process for Skilled Nursing Facilities and Nursing Facilities

(Rev. 213, 02-10-23)

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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 *§7317* 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.

iQIES is the Internet Quality Improvement and Evaluation System used by CMS and all States for data entry and reporting on nursing home survey and enforcement activities.

7001 - Definitions and Acronyms

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

Abbreviated Standard Survey means a survey other than a standard survey that gathers information primarily through resident-centered techniques on facility compliance with the requirements for participation. An abbreviated standard survey may be premised on complaints received; a change in ownership, management, or director of nursing; or other indicators of specific concern. *(42 CFR 488.301)NOTE: Abbreviated standard surveys may also be referred to as complaint investigations.*

Abuse - *The willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. Abuse also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. Instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through the use of technology. Willful, as used in this definition of abuse, means the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm. (42 CFR 483.5)*

Act - the Social Security Act

CASPER - Certification and Survey Provider Enhanced Reporting.

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

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

CFR - Code of Federal Regulations.

CMP - *C*ivil *M*oney *P*enalty.

CMPTS - Civil Money Penalty Tracking System.

CMS - Centers for Medicare & Medicaid Services.

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

DoPNA or **DPNA** - *D*enial of *P*ayment for *N*ew *A*dmissions.

DPoC - Directed *P*lan of *C*orrection.

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

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

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

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

Extended survey means a survey that evaluates additional participation requirements subsequent to finding *SQC* during a standard survey. *(42 CFR 488.301)*

Facility means a skilled nursing facility *(SNF) that meets the requirements of sections 1819(a), (b), (c), and (d) of the Act, or a* nursing facility *(NF) that meets the requirements of sections 1919(a), (b), (c), and (d) of the Act. "Facility" may include a* distinct part of a*n institution (as defined in §483.5 and specified in §440.40 and §440.155) but does not include an institution for individuals with intellectual disabilities or persons with related conditions described in §440.150 of this chapter. For Medicare and Medicaid purposes (including eligibility, coverage, certification, and payment), the "facility" is always the entity that participates in the program, whether that entity is comprised of all, or a distinct part of, a larger institution. For Medicare, a SNF, and for Medicaid, a NF may not be an institution for mental diseases as defined in §435.1010 of this chapter. (42 CFR 483.5)*

FSES – Fire Safety Evaluation System.

IDR – *I*nformal *Dispute R*esolution.

Immediate family *as defined in 42 CFR 488.301 means a husband or wife; natural or adoptive parent, child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild. NOTE: see guidance at tag F563 in Appendix PP under Resident Rights §483.10(f)(4)(ii)-(v) – "For purposes of this regulation, immediate family is not restricted to individuals united by blood, adoptive, or marital ties, or a State's*

common law equivalent. It is important to understand that there are many types of families, each of which being equally viable as a supportive, caring unit. For example, it might also include a foster family where one or more adult serves as a temporary guardian for one or more children to whom they may or may not be biologically related. Residents have the right to define their family."

Immediate *J*eopardy *(IJ)* means a situation in which the facility's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident. *(42 CFR 488.301)*

IIDR – Independent *I*nformal *D*ispute *R*esolution

Instance or instances of noncompliance *means a factual and temporal occurrence(s) when a facility is not in substantial compliance with the requirements for participation. Each instance of noncompliance is sufficient to constitute a deficiency and a deficiency may comprise of multiple instances of noncompliance. (42 CFR 488.401)*

IQIES *- Internet Quality Improvement and Evaluation System*

LSC – Life Safety Code.

MAC means - Medicare Area Contractor.

Misappropriation of resident property means the deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a resident's belongings or money without the resident's consent. *(42 CFR 488.301)*

NATCEP – Nurse Aide Training and Competency Evaluation Program.

Neglect means failure *of the facility, its employees or service providers* to provide goods and services *to a resident that are* necessary to avoid physical harm, *pain,* mental anguish, *or emotional distress*. *(42 CFR 483.5)*

New admission, for purposes of a denial of payment remed*y*, *new admission* means a resident who is admitted to the facility on or after the effective date of a denial of payment remedy and, if previously admitted, has been discharged before that effective date. *Residents admitted before the effective date of the denial of payment, and taking temporary leave, are not considered new admissions, nor subject to the denial of payment. (42 CFR 488.401)* (See §7506 for examples of what does and does not constitute a new admission for purposes of the remedy.)

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

Noncompliance cycle - *See 7317.3 for definition.*

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

Nurse aide means any individual providing nursing or nursing-related services to residents *in a facility. This term may also include an individual who provides these services through an agency or under a contract with the facility, but is not a licensed health professional, a registered dietitian, or someone who volunteers to provide such services without pay. Nurse aides do not include those individuals who furnish services to residents only as paid feeding assistants as defined in 42 CFR §488.301. (42 CFR 483.5)*

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

Partial extended survey means a survey that evaluates additional participation requirements *subsequent to finding SQC* during an abbreviated standard survey. *(42 CFR 488.301.)*

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

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

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

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

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

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

Plan of Correction (*PoC*) *means a plan developed by the facility and approved by CMS or the State agency that describes the actions the facility will take to correct deficiencies and specifies the date by which those deficiencies will be corrected. (42 CFR 488.401)*

QIES - Quality Improvement and Evaluation System.

Resident **Representative** ***or Representative*** - *means any of the following:*

(1) An individual chosen by the resident to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other

personal information of the resident; manage financial matters; or receive notifications;

(2) A person authorized by State or Federal law (including but not limited to agents under power of attorney, representative payees, and other fiduciaries) to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications; or

(3) Legal representative, as used in section 712 of the Older Americans Act; or

(4) The court-appointed guardian or conservator of a resident.

(5) Nothing in this rule is intended to expand the scope of authority of any resident representative beyond that authority specifically authorized by the resident, State or Federal law, or a court of competent jurisdiction. (42 CFR 483.5)

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

SFF – Special Focus Facility.

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

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

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

State Medicaid Agency *(SMA)* means the entity in the State responsible for administering the Medicaid program.

Substandard *Q*uality of *C*are *(SQC)* means one or more deficiencies related to participation requirements under *42 CFR 483.10 "Resident rights", paragraphs (a)(1) through (a)(2), (b)(1) through (b)(2), (e) (except for (e)(2), (e)(7), and (e)(8)), (f)(1) through (f)(3), (f)(5) through (f)(8), and (i); § 483.12 "Freedom from abuse, neglect, and exploitation"; § 483.24 "Quality of life"; § 483.25 "Quality of care"; § 483.40 "Behavioral health services", paragraphs (b) and (d); § 483.45 "Pharmacy services", paragraphs (d), (e), and (f); § 483.70 "Administration", paragraph (p), and § 483.80 "Infection control", paragraph (d), which constitute either immediate jeopardy to resident health or safety; a pattern of or widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm. (42 CFR 488.301)*

Substantial compliance means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm. *(42 CFR 488.301)* Substantial compliance constitutes compliance with participation requirements.

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 *the* authority to conduct surveys anytime there is a question about compliance.)

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

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

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

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

A skilled nursing facility is a facility which:

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

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

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

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

A skilled nursing facility provides a level of care distinguishable both from the level of intensive care furnished by a general hospital and from the level of custodial or supportive care furnished by nursing homes primarily designed to provide daily services above room and board. This level of care is reflected in the participation requirements

for skilled nursing facilities. While the requirements call for a wide range of specialized medical services and the employment by the facility of a variety of paramedical and skilled nursing personnel, the emphasis on restorative services is oriented toward providing services for residents who require and can benefit from skilled nursing and one or more types of skilled restorative services, e.g., physical or speech therapy.

7006 - Nursing Facility - Citations and Description
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7006.1 - Citations
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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

7006.2 - Description of Nursing Facility
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A nursing facility is a facility that:

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

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

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

7008 - Types of Facilities That May Qualify as Skilled Nursing Facilities and Nursing Facilities
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A Skilled Nursing Facility or Nursing Facility may be:

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

- A distinct part of a rehabilitation center;

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

- A distinct part of a skilled nursing facility or nursing facility (see *Chapter 2* of this manual); or

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

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

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

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

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

7012 - Reserved

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

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

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

7014.1 - Waiver of Nurse Staffing Requirements

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

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Under 42 CFR 483.35(e) and (f) of the Act, Medicaid-certified Nursing Facilities (NFs), Medicare-certified Skilled Nursing Facilities (SNFs), and dually-certified SNF/NFs may obtain a waiver of the requirements to have licensed nurses 24 hours a day and/or the requirement to have a registered nurse (RN) for 8 consecutive hours a day, 7 days a week, and provide the services of a RN more than 40 hours a week if the facility meets certain criteria.

To obtain a waiver, a facility must send a request to the state agency. A request may be submitted at any time, but prior to obtaining a waiver, a facility must be surveyed to determine if they meet the requirements to qualify for a waiver. During the survey:

- *If a facility has never been granted a waiver, or was granted a waiver in the past, but did not have a waiver after the last survey: the facility is cited for noncompliance with the applicable requirements, and the state agency will then determine if the facility meets the requirements to qualify for a waiver.*
    - *For NFs/SNFs, the applicable citation should **only** be reflective of the failure of the facility to meet the numerical requirements for having 24 hours of licensed nurses or eight consecutive hours per day of an RN and*

the deficiency must not be higher than a level 1 (no actual harm with a potential for minimal harm) as the waiver cannot endanger the health or safety of individuals staying in the facility, per483.35(e)(2)). For example, if the survey team finds the facility fails to provide sufficient staff to meet each resident's needs, resulting in a level 2 deficiency (no actual harm with potential for more than minimal harm), the waiver shall not be granted as the team has identified that the level of staffing has endangered the health and safety of residents.

- *For SNF-only facilities, only the requirement to have an RN onsite eight consecutive hours a day may be waived, and the survey team must verify the facility meets the criteria specified in 483.35(f)(1)(ii)*

- *If a facility was granted a waiver on the last survey: the surveyors will determine if the facility continues to meet the requirements to qualify for a waiver.*
  - *If the facility continues to meet the waiver requirements, the facility is not cited for the applicable deficiency and a renewal of the waiver may be granted.*
  - *If the facility no longer meets the requirements for a waiver, the facility is cited, and a waiver is not granted.*

The waiver(s) available to a facility is(are) based on the type of facility, as follows:

- *If a facility is a SNF-only, the facility may obtain a waiver of the requirement for an RN for 8 consecutive hours a day, 7 days a week, as long as the requirements in §483.35(g) are met.*
- *If a facility is a NF-only, the facility may obtain waivers of the requirement for an RN for at least 8 consecutive hours a day, 7 days a week, and/or the requirement to have licensed nurses 24 hours a day, as long as the requirements in §483.35(f) are met.*
- *If a facility is a dually-certified SNF/NF, both sets of waiver requirements in §483.35(f) and (g) apply, and the only waiver available is the waiver of the requirement for an RN for at least 8 consecutive hours a day, 7 days a week. This is because as a SNF, a waiver of the requirement to have licensed nurses 24 hours a day is not available. Additionally, both sets of requirements in §483.35(f) and (g) for a waiver must be met to be granted a waiver, and therefore, the limited requirements prevail. For example, a dually-certified SNF/NF must be located in a rural area with an inadequate supply of SNF services to qualify for a waiver of the RN for 8 consecutive hours a day, 7 days a week.*

More details on these waivers are described in the sections below.

Each state agency and CMS Location must accurately document any waiver granted under483.35(e) or (f). The information must be documented on the form CMS-671 and entered in the CMS survey and certification system, such as the Internet Quality Improvement and Evaluation System (iQIES), or subsequent system.

The state agency and CMS Locations must accurately document the following on the CMS-671 that is completed with the survey when a facility's qualifications for such waivers are assessed:

***When granting a waiver**:*

1. *Date the survey was completed to verify resident safety if the waiver was granted;*
2. *Date the waiver was granted;*
3. *Specific waiver granted; and*
4. *Number of hours waived each week.*

When a waiver request is denied or terminated , the state agency or the CMS Location must include the reason for the denial or termination in the Statement of Deficiencies, Form CMS-2567.

7014.1.1 – *Skilled Nursing Facility (SNF)*-Waiver of Requirement for *a Registered Nurse (RN) More than 40 Hours a Week*

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

§483.35(f)
Waiver of the requirement to provide services of a registered nurse for more than 40 hours a week.

(1) The Secretary may waive the requirement that a SNF provide the services of a registered nurse for more than 40 hours a week, including a director of nursing specified in paragraph (b) of this section, if the Secretary finds that—

> ***(i) The facility is located in a rural area and the supply of skilled nursing facility services in the area is not sufficient to meet the needs of individuals residing in the area;***
> ***(ii) The facility has one full-time registered nurse who is regularly on duty at the facility 40 hours a week; and***
> ***(iii) The facility either—***
>
> > ***(A) Has only patients whose physicians have indicated (through physicians' orders or admission notes) that they do not require the services of a registered nurse or a physician for a 48-hours period or;***
> >
> > ***(B) Has made arrangements for a registered nurse or a physician to spend time at the facility, as determined necessary by the physician, to provide necessary skilled nursing services on days when the regular full-time registered nurse is not on duty;***

(iv) The Secretary provides notice of the waiver to the Office of the State Long-Term Care Ombudsman (established under section 712 of the Older Americans Act of 1965) and the protection and advocacy system in the State for individuals with developmental disabilities or mental disorders; and
(v) The facility that is granted such a waiver notifies residents of the facility and their resident representatives of the waiver.

(2) A waiver of the registered nurse requirement under paragraph (f)(1) of this section is subject to annual renewal by the Secretary.

The CMS Location, acting on behalf of the Secretary, may waive the requirement *for services of an RN 8 consecutive hours a day, 7 days a week. However, the facility must still have an RN 40 hours a week (i.e., the waiver only permits the facility to not have an RN for a period of two days (48 hours). Also, CMS may waive the other requirement that the facility must designate an RN to serve as the director of nursing on a full-time basis. To grant a waiver on these requirements, the state agency obtains the following information below, which is then forwarded to the CMS Location*:

a) The facility is located in a rural area and the supply of skilled nursing facility services is not sufficient to meet area needs. *Rural means all areas not delineated as "urban" by the Bureau of Census, based on the most recent census.*

b) 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. *The facility must provide evidence of this, which may be in the form of a time-sheet/card or salary information showing an RN onsite for 40 hours a week (schedule of when an RN is supposed to work is not acceptable).*

c) The facility meets either of the following conditions:

i. 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

ii. 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.

For facilities that were granted a waiver under section 483.35(f) the prior year: the facility must provide evidence that they notified the residents of the facility, their guardians or their resident representatives (where appropriate), and members of their immediate families of the waiver. If a facility does not have evidence of this, they may be

granted another waiver if they meet all other requirements, as long as the facility provides evidence that the residents and their representatives have been notified of the waiver (e.g., within 30 days). If the facility does not provide this evidence, the waiver is rescinded.

The state agency forwards the above information to the CMS Location for review, and the CMS Location grants the waiver after confirming all of the requirements are met. If a waiver is granted, the CMS Location, must provide notice of the waiver to the State long-term care ombudsman and to the State protection and advocacy system for the mentally ill and intellectually disabled. The facility granted such a waiver must notify residents of the facility (or responsible guardians) and members of their immediate families of the waiver.
A waiver of the RN requirement is subject to annual renewal by the Secretary.

7014.1.2 - - *Nursing Facility (NF)-Only* Waivers of Nurse Staffing Requirements in Nursing Facilities

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

§483.35(e) Nursing facilities

Waiver of requirement to provide licensed nurses on a 24-hour basis.
To the extent that a facility is unable to meet the requirements of paragraphs (a)(2) and (b)(1) of this section, a State may waive such requirements with respect to the facility if—

> ***(1) The facility demonstrates to the satisfaction of the State that the facility has been unable, despite diligent efforts (including offering wages at the community prevailing rate for nursing facilities), to recruit appropriate personnel;***
>
> ***(2) The State determines that a waiver of the requirement will not endanger the health or safety of individuals staying in the facility;***
>
> ***(3) The State finds that, for any periods in which licensed nursing services are not available, a registered nurse or a physician is obligated to respond immediately to telephone calls from the facility;***
>
> ***(4) A waiver granted under the conditions listed in paragraph (e) of this section is subject to annual State review;***
>
> ***(5) In granting or renewing a waiver, a facility may be required by the State to use other qualified, licensed personnel;***
>
> ***(6) The State agency granting a waiver of such requirements provides notice of the waiver to the Office of the State Long-Term Care Ombudsman (established under section 712 of the Older Americans Act of 1965) and the protection and***

advocacy system in the State for individuals with a mental disorder who are eligible for such services as provided by the protection and advocacy agency; and

(7) The nursing facility that is granted such a waiver by a State notifies residents of the facility and their resident representatives of the waiver.

The requirements for long-term care facilities also require that nursing facilities provide 24-hour licensed nursing, *and* provide an RN for 8 consecutive hours a day, 7 days a week, . The State may waive these requirements *(either one, or both)* if the following conditions are met:

a. The facility demonstrates to the satisfaction of the State that it has made diligent efforts to recruit the appropriate personnel and is unable to do so. *To determine this, the facility must provide evidence of attempting to recruit RNs and/or licensed nurses, which may include advertisements or postings on online job boards. The facility also must show evidence that the compensation they are offering is similar to the compensation offered by the other providers in the same general area (e.g., county).*

b. The State determines that a waiver will not endanger the health or safety of the residents in the facility. *This is determined by the state agency completing a standard survey before granting the waiver. Based on their assessment, the survey team will determine if the time that a licensed nurse or RN would normally be onsite, but now will not, endanger the health or safety of the residents in the facility. For example, if residents need to receive narcotic pain medication or insulin which must be administered by a licensed nurse during the time that licensed nurses will not be available, the state should not grant a waiver.*

c. The State finds that an RN or physician is obligated to respond immediately to phone calls from the facility for periods when licensed nursing services are not available. *This can be determined by interviewing the RN or physician and verifying that they will be available by phone during the time that an RN and/or licensed nurses will not be onsite.*

While considering granting a waiver, the state may require the facility to use other qualified, licensed personnel (per §483.35(e)(5)). This may include licensed respiratory therapist, licensed social workers, therapists, or other personnel the state deems necessary based on the needs of the residents.

For facilities that were granted a waiver(s) the prior year: the facility must provide evidence that they notified the residents of the facility, or their guardians or their legal resident representatives (as appropriate), and members of their immediate families of the waiver. If a facility does not have evidence of this notice from the prior year, they may be granted a waiver(s) if they meet all other requirements, and as long as the facility provides evidence that the residents, their guardians/representatives, and immediate

family members have been notified of the current waiver (e.g., within 30 days). If the facility does not provide this evidence, the waiver(s) is(are) rescinded.

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

Any waivers granted are subject to annual review.

7014.1.3 - Waivers of Nurse Staffing Requirements for Dually Participating Facilities *(SNF/NFs)*

(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 *SNFs and NFs*. *Because having a licensed nurse 24 hours each day cannot be waived for SNFs,* a *SNF/NF* may only have the 8 consecutive hours a day, 7 days a week requirement waived. *However, the facility must still have an RN 40 hours a week (i.e., the waiver only permits the facility to not have an RN for a period of two days (48 hours). For SNF/NFs*, the waiver is granted by the CMS Location. *To grant a waiver, the state obtains the following information, which is then forwarded to the CMS Location:*

a) *The facility is located in a rural area and the supply of skilled nursing facility services is not sufficient to meet area needs. Rural is defined as all areas not delineated as "urban`" by the Bureau of Census, based on the most recent census.*

b) *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. The facility must provide evidence of this to a surveyor, which may be in the form of providing timesheet/card or salary information showing an RN onsite for 40 hours a week (a schedule of when an RN is supposed to work, is not acceptable).*

c) *The facility meets either of the following conditions:*
    i) *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. This is determined by reviewing the records of the residents sampled during the survey, and each resident's record reviewed must include this information.*

ii) *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 can be determined by interviewing the RN or physician and asking them when they will be in the facility during the days when an RN is not there 8 hours.*

d) *The facility demonstrates to the satisfaction of the State that it has made diligent efforts to recruit the appropriate personnel and is unable to do so. To determine this, the facility must provide evidence of attempting to recruit RN(s), which may include advertisements or postings on online job boards. The facility also must show evidence that the compensation they are offering is similar to the compensation offered by other providers in the same general area (e.g., county).*

e) *The State determines that a waiver will not endanger the health or safety of the residents in the facility. This is determined by the state completing a survey before a waiver is granted. Based on their assessment, the survey team will determine if the time that an RN would normally be onsite, but now will not, endanger the health or safety of the residents in the facility. For example, if residents will need the services of an RN during the time that an RN will not be available, the state should not forward this facility's information to the CMS Location for a waiver. Those services that must be performed by an RN include components of the nursing process (assessment, diagnosis, outcomes identification, planning, implementation, and evaluation). Examples include the assessment of a resident after a fall with injury, the subsequent development of a baseline care plan for the newly admitted resident, or the assessment and maintenance of an intravenous access that does not terminate in the arm (e.g., PICC or Central Venous lines).*

While considering forwarding a facility to the CMS Location for a waiver, the state may require the facility to use other qualified, licensed personnel (per §483.35(e)(5)). This may include licensed social workers, therapists, or other personnel the state deems necessary based on the needs of the residents.

For facilities that were granted a waiver(s) the prior year: the facility must provide evidence that they notified the residents of the facility, or guardians and their resident legal representatives (as appropriate), and members of their immediate families of the waiver. If a facility does not have evidence of this, they may be granted a waiver(s) if they meet the other requirements, and as long as the facility provides evidence that the residents, their guardians/representatives, and immediate family members have been notified of the current waiver (e.g., within 30 days). If the facility does not provide this evidence, the waiver is rescinded.

The state forwards the above information to the CMS Location for review, and the CMS Location grants the waiver after confirming all of the requirements are met. If a waiver is granted, the CMS Location 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.

7014.2 - Waiver of Life Safety Code

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

(See *Chapter 2* and §7410.)

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. *However, for facilities that receive approval of construction or reconstruction plans by State and local authorities or are newly certified after November 28, 2016, bedrooms must accommodate no more than two residents. All resident rooms* must afford a minimum of 80 square feet per bed in multi-patient rooms. Single rooms must measure at least 100 square feet. *In 42 CFR 483.90(e)(3)* 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.

- *If a facility has never been granted a waiver under this section, or was granted a waiver in the past, but did not have a waiver after the last standard survey: the facility is cited for noncompliance with the applicable requirements, and the state agency will then determine if the facility meets the requirements to qualify for a waiver.*
- *If a facility was granted a waiver on the last standard survey: the surveyor will determine if the facility continues to meet the requirements to qualify for a waiver.*
    - *If the facility continues to meet the requirements, the facility is not cited, and another waiver may be granted.*
    - *If the facility no longer meets the requirements for a waiver, the facility is cited, and a waiver is not granted. The facility must correct the noncompliance to meet the requirements at §483.90 (e)(1)(i) or (ii).*

The *CMS Location has jurisdiction to approve such waivers or variances and are subject to annual review by CMS. The State has jurisdiction to approve them in Medicaid-only NF cases. In either case, the approved waiver for the requirements at §483.90(e)(1)(i) and (ii) must be accurately documented in the CMS survey and certification system, such as ACO/ARO, or subsequent approved CMS system. When CMS or the state agency denies the request or terminates a variation / waiver under §483.90(e)(1)(i) or (ii), the state agency or the CMS Location must include the reason for the denial or termination in the Statement of Deficiencies form CMS-2567.*

The state agency determines that a variation/waiver will not endanger the health or safety of the residents in the facility by completing a standard survey. Based on their assessment, the survey team will determine if the variations of the patient room size or beds per room endanger the health or safety of the residents in the facility. The State Agency and CMS Location must accurately document any variation / waiver granted under §483.90(e)(1)(i) or (ii).

Survey Process

7200 -*Long-Term Care Survey Process (LTCSP)*

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

Skilled nursing facilities *(SNFs)* and nursing facilities *(NFs), and dually-participating facilities (SNF/NFs)* must be in compliance with the requirements in 42 CFR Part 483, Subpart B to receive payment under Medicare or Medicaid. *In order to* certify *compliance, State Survey Agencies must conduct both the Life Safety Code (LSC) and the Standard Health Surveys. Compliance with the Emergency Preparedness requirements (described in Appendix Z) will be determined in conjunction with the existing survey process for Standard Health surveys or LSC surveys for each facility.*

Follow the procedures in *the Long-Term Care Survey Process (LTCSP) Procedure Guide* for conducting all *standard health* surveys of *SNFs* and *NFs*, whether freestanding, distinct parts, or dually-participating. *Surveyors should refer to Appendix I for guidance when conducting a LSC survey.*

7201 - Survey Team Size and Composition - Length of Survey

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

7201.1 - Survey Team Size

(Rev. 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 *based on guidance provided in the LTCSP Procedure Guide, Attachment A – Sample Size, Recommended Team Size, and Initial Pool Size (located in the Survey Resources zip file located at https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/nursing-homes).* 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, *provided that* 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:

- 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 *Chapter 4*).1 of this manual for additional information concerning Surveyor Minimum Qualifications Test requirements). *If a surveyor has not passed the SMQT or if the complexity of a resident's care requires expertise of more than one discipline, surveyors should work jointly to complete the review. A surveyor must successfully complete the SMQT to survey independently, however they can serve as a team member and complete survey tasks for which they have successfully demonstrated understanding as long as they are supervised by a qualified SMQT surveyor. The supervision of the newly trained surveyor should be as hands on or direct as needed to ensure all survey tasks are completed according to appropriate survey policy and procedures.*
- *Regulations at§488.314 require that SNF* and *NF initial and recertification surveys be conducted by a multidisciplinary team of professionals, at least one of whom must be a registered nurse. Complaint investigations and on-site monitoring of compliance, including through revisits, are subject to the requirements of sections 1819(g)(4) and 1919(g)(4) of the Act and section 488.332, which allow the use a specialized investigative team that may include appropriate healthcare professionals as required to investigate the allegation or concern, but need not include a registered nurse.*

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.

- *The State is responsible for determining which members of the survey team have the appropriate skills, clinical expertise, and licenses to make observations that include a resident's genital, rectal, or the breast area. This would likely be limited to surveyors with professional licenses, such as registered nurse, licensed physical or occupational therapists, physician assistants, physicians, etc. When making these observations, surveyors must attempt to obtain consent from the resident or their representative- See Resident Privacy Section below. Additionally, surveyors must be aware of any history of trauma, and honor the resident's preferences, including cultural and religious beliefs.*

- 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.

  NOTE: *Specialty Surveyors - All members of the survey team should enter the facility at the same time, if possible. Specialty surveyors participating in surveys (e.g., a pharmacist, physician, or registered dietitian) must be onsite during that portion of the survey dealing with their area of expertise. However, they must conduct that portion while the rest of the team is present. Before leaving the facility, at the completion of his/her portion of the survey, the specialty surveyor must meet with the team or team coordinator to discuss his/her findings and to provide supporting documentation. The specialty surveyor should also share any information he/she obtained that may be useful to other team members. If he/she is not present at the information analysis for deficiency determination, the specialty surveyor should be available by telephone at that time and during the exit conference.*

- In order to comply with the requirement that "No individual shall serve as a member of a … team (surveying a SNF or NF) unless the individual has successfully completed (the CMS-approved) training and testing program," surveyors in training, i.e., those who have not successfully completed the required training, must be accompanied on-site by a surveyor who has successfully

completed the required training and testing. While it is desirable that all survey team members be fully qualified, CMS recognizes that trainees must be given opportunities to perform survey functions so that they can achieve "fully qualified" status. Participation in actual surveys is a valuable and integral part of a training program. In fact, in the orientation program designed for newly employed surveyors, CMS recommends that 3 weeks be spent in the field as part of the training.

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

The length of a standard survey in terms of person hours is expected to vary, based on the size and layout of the facility and the number and complexity of concerns that need to be investigated onsite. *See guidance provided in the LTCSP Procedure Guide, Attachment A – Sample Size, Recommended Team Size, and Initial Pool Size.*

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

7202.1 - Introduction
(Rev. 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 *sub agency* 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.

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

7202.2.1 - Prima Facie Conflicts of Interest

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

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

a. The surveyor currently works, or, within the past 2 years, has worked as an employee, as employment agency staff at the facility, or as an officer, consultant, or agent for the facility to be surveyed;

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

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

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

7202.2.2 - Examples of Potential Conflicts of Interest

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

CMS and the States must consider all relevant circumstances that may exist beyond the benchmarks given in §7202 HYPERLINK "bookmark://_7202_-_Conflicts" to ensure that the integrity of the survey process is preserved. For example, a surveyor may not have worked for the facility to be surveyed for more than 2 years, but may have left the facility under unpleasant circumstances, or, may not currently have an immediate family member who resides there, but may have recently had one residing there who the surveyor considers to have received inadequate care.

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

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

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

c. Service on a utilization review committee;

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

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

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

7202.3 - Report and Investigation of Improper Acts
(Rev. 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 - Survey Protocol
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7203.1 - Introduction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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

The interpretive guidelines merely define or explain the relevant statutes and regulations and do not impose any additional costs or place other burdens on any health care facility. (See *Chapter 2*, of this manual.)

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

(See also *Chapter 2* and §7300 of this manual.)

All initial surveys must verify substantial compliance with the regulatory requirements contained in 42 CFR 483.5 through 42 CFR 483.95. *See LTCSP instructions for conducting the Initial Certification Survey. (See also Chapter 2)*

.During the initial survey, focus both on residents and the requirements that relate to qualification standards and resident rights notification, whether or not problems are identified during the information gathering tasks. Gather additional information to verify compliance with requirements. For example, during an initial survey, verify the qualifications of the social worker, dietitian, and activities professional. Also, review the rights notification statements on admissions contracts. Complete the Statement of Deficiencies and Plan of Correction (Form CMS-2567.)

If distinct part status is at issue, determine whether the facility meets the criteria for certification as a distinct part. (See *Chapter 2* .)

7203.3 - *Survey for Recertification*

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

Follow the procedures specified in *the LTCSP Procedure Guide* for standard and extended surveys.

The Standard Survey is a periodic, resident-centered inspection which gathers information about the quality of service furnished in a facility to determine compliance with requirements for participation. The survey is outcome-oriented and relies on a case-mix stratified sample of residents. Outcomes include both actual and potential negative outcomes, as well as failure of a facility to help each resident achieve and maintain their highest practicable level of well-being.

General Survey Policy: *Follow procedures detailed in the LTCSP procedure guide to conduct the recertification survey. Key components of the survey process include conducting observations, interviews, and record reviews including reviewing for the accuracy of the residents' comprehensive assessment. This section contains CMS guidance and policy related to conducting the standard survey.*

Resident Privacy: *The survey team must conduct the survey in a manner that allows for the greatest degree of confidentiality for residents, particularly regarding the information gathered during the interviews. Use the resident identifier (e.g., a code number assigned to each resident in the resident sample) on the Form CMS-2567 in place of the resident's name, which should never be used on the Form CMS-2567.*

When observing residents, respect their right to privacy, including the privacy of their bodies. If the resident's genital, rectal area, or breast area must be observed in order to document and confirm suspicions of a care problem, a member of the nursing staff must be present at this observation, and the resident must give clear consent.

If the resident is unable to give consent, e.g., is unresponsive, incompetent, and a health care proxy who can act on the resident's behalf or legal representative (as provided by State law) is available, ask this individual for consent.
An observation of a resident's rectal, genital or breast area may be made without a resident's or legal representative's consent, under the following conditions:

- *It is determined that there is a strong possibility that the resident is receiving less than adequate care, which can only be confirmed by direct observation;*
- *The resident is unable to give clear consent; and*
- *A legal representative is not immediately accessible.*

Basic Principles of Using Photography During the Survey [1]

Although the use of photography during the survey process is not required, the State Survey Agencies (SAs) may decide to collect photographic evidence to support a finding of noncompliance. The SA will be responsible for the acquisition, accountability, and security of the photography equipment (e.g., smart phone, camera) and data/images. Additionally, the SA should develop guidance for using photography during the survey process and train staff in the proper use of the camera. States should ensure that all photos are maintained in accordance with all applicable privacy and confidentiality laws and policies.

Surveyors may use photography as a tool, supplementing written documentation, to assure accurate and effective records of observations made during surveys with the intent to produce photographs that are relevant to possible deficiencies. However, without written documentation, photographs cannot stand alone.

Photographs may enhance findings of noncompliance by providing visual evidence of injury, scene, or other relevant components of a deficient practice. Photographs should not be included as part of the Form CMS-2567. Surveyors should only reference photographs in their surveyor notes and not in the statement of deficiencies.

When taking photographs during a survey, the following basic principles should be implemented:

1. *Request the Resident's or His/her Representative's Written Permission Prior to Photographing His/her*
   - *Before beginning, ask the individual's written permission to take a photograph, to the maximum extent feasible.*
   - *The health and dignity of the individual is always a paramount concern. A surveyor should respect an individual's refusal to be photographed.*
   - *If the individual's genital, rectal, or breast area is photographed in order to document and confirm suspicions of care problems, a member of the nursing staff must be present at the time of observation, and the individual must be asked to give written consent before the photograph may be taken.*

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[1] Some material included in this guidance is from the Illinois Department of Public Health, Division of Long-Term Care Field Operations, "Guidelines for Photographic Evidence."

- *If the individual is unable to give consent (e.g., is unresponsive, incompetent), and the individual's legal representative is present, ask the representative for written consent, unless the representative is the one suspected of abusing the individual.*
- *If the individual is unable to give consent and the individual's representative is not present in the facility, then the surveyor may use discretion in determining whether a photograph of the individual's rectal, genital or breast area is necessary to support a finding of noncompliance.*
- *Surveyors should avoid taking pictures that will reveal an individual's face or other uniquely identifying information that will interfere with that person's right to privacy.*

2. Get a Complete Series of Photographs

Generally, each relevant object in the scene should appear in at least three photographs: an overview, a mid- range photograph, and a close-up.

- *Because a close-up does not indicate where the object was located, the overview photograph should cover the entire scene to bring out the relationships between the objects. Leave measuring scales and labels out of the overview photograph.*
- *The mid-range photograph shows a relevant object and its immediate surroundings.*
- *Each close-up photograph shows a key detail clearly. Have a "standard" in the close-up photograph to indicate the actual size of what is being photographed.*
  - *Measure scales and labels may be added to the close-up photograph. For example, placing a ruler with readable graduations next to a pressure ulcer will show its actual size in the photograph.*
  - *Other standards include tape measures, coins, or a pencil.*

3. Documentation and Storage of Photographs

A surveyor must handle a photograph of the individual with as much confidentiality as a medical record. Only non-personal identifiers should be used to document the photograph. A reference in the surveyor notes should be made of each photograph even if it did not portray the expected image so there will be a sequential reference to all photographs taken.

In addition to proper documentation, photographs depicting residents must be stored properly. This means that any photographs taken to support deficient practice must contain non-personal identifiers and then be attached to the survey when uploaded to the survey software. Photographs must only be shared with those having a need to know, such as survey managers, SA officials, HHS Office of the General Counsel, or others as appropriate. When sharing photographs, it is imperative that secure or encrypted email is used, and proper chain of custody must be maintained. Chain of custody as defined by the National Institute of Standards and Technology, is a process that tracks the movement of evidence through its collection, safeguarding, and analysis lifecycle by documenting each person who handled the evidence, the date/time it was collected or transferred, and the purpose for the transfer.

Immediately upon taking a photograph, document in surveyor notes the following:

- *Date;*
- *Time;*
- *The identity of the photographer;*
- *A photograph identifying number (even if just one photograph is taken);*
- *Facility name;*
- *Survey event number, as applicable; and*
- *Non-personal identifier.*

Note: Many conventional cameras and digital cameras have the capacity to imprint a date and time on the photographic image.

Do not modify an original photograph. A surveyor who wants to stress a key detail in a photograph should identify the detail by using a transparent overlay that can be removed to show the unaltered print.

Examples of Photographic Evidence:

- *Evidence of abuse, such as contusions, bruises, lacerations, or burns*
- *Evidence of improper and dangerous use of restraints or other devices*
- *Evidence of improper positioning such as leaning, or hypo- or hyper-extension of neck and/or trunk*
- *Pressure ulcers*
- *Contractures*
- *Safety hazards*
- *Evidence of extensive pest infestation*
- *Evidence of faulty or dirty equipment*

Confidentiality of Survey Materials

Surveyor notes and documentation collected during the survey process contain pre-decisional information and therefore, are not required to be disclosed to the facility at the time of the survey. If providers or other stakeholders are requesting additional information, they need to submit that request following the appropriate federal and state laws and/or processes for disclosure.

The survey team should maintain an open and ongoing dialogue with the facility throughout the survey process. This gives the facility the opportunity to provide additional information in considering any alternative explanations before making deficiency determinations. This, however, does not mean that a daily exit conference is held with the facility, or every negative observation is reported to the facility on a daily basis. Moreover, if the negative observation relates to a routine that needs to be monitored over time to determine whether a deficiency exists, the survey team should wait until a trend has been established before notifying the facility of the problem.

Identification of Past Non-Compliance Citations: *Findings cited as past noncompliance (PNC) may be identified during any survey of a nursing home. See*

additional information on PNC at 7510.1. For PNC to exist, the following criteria must be met:

- *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;*
- *The noncompliance occurred after the exit date of the last standard (recertification) survey and before the survey (standard, complaint investigation, or revisit) currently being conducted; and*
- *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.*

When a citation of PNC is written, the facility does not provide a plan of correction as the deficiency is already corrected; however, the survey team documents the facility's corrective actions on Form CMS-2567. (Additional information about citations of PNC is found at 7510.1 – Determining Citations of Past Noncompliance at the Time of the Current Survey)

7203.3.1 – Exit Conference

The general objective of the exit conference is to inform the facility of the survey team's observations and preliminary findings. The exit conference is a courtesy to the facility to provide the preliminary findings of the surveyors so that the facility can take swift corrective action to address any deficiencies. Surveyors must indicate that all findings are preliminary and are subject to supervisory review by the State and/or CMS Location. Deficiency citations are not final, and the CMS-2567 must not be given to the facility until after the State and/or CMS Location conduct a supervisory review and the report is finalized.

Conduct the exit conference with facility personnel. Ask the Administrator to invite the Medical Director to the exit conference. Invite the ombudsman and an officer of the organized resident group (e.g., resident council), if one exists, to the exit conference. Also, invite one or two residents to attend. If the ombudsman, officer of the resident group, or residents cannot attend in-person, they should be allowed to attend virtually via conference call or video conferencing. The team may provide an abbreviated exit conference specifically for residents after completion of the normal facility exit conference. If two exit conferences are held, notify the ombudsman and invite the ombudsman to attend either or both conferences.

It is important to provide clear information on the facility's noncompliance so the facility can develop an appropriate plan of correction.

If the provider asks for the regulatory basis or the specific deficiency tag, the surveyors should generally provide it (except as noted below), but always caution that such coding classifications are preliminary and are provided only to help the provider gain more insight into the compliance issues identified during the survey through the interpretive guidance at the related tag.

If the survey team is still deliberating as to which tags will be cited, the survey team should not speculate at the exit conference as to the specific tag coding that will be applied. For

example, the team may still be deliberating as to whether a finding was a care planning deficiency or staff training deficiency. Similarly, the team may believe that additional consultation should occur with other State personnel (e.g., a pharmacist) before a specific tag number is assigned to the deficiency finding. In these cases, the survey team should describe the general area of noncompliance without identifying a specific tag code. This is a judgment to be the made by the survey team onsite. So, in preparation for the exit conference the team should deliberate as to the degree of detail that will be appropriate.

Surveyors must not provide the Scope and Severity level of a given deficiency finding (unless it is an immediate jeopardy), as such levels of detail should await supervisory review. Instead, survey teams may describe the general seriousness (e.g., harm) or urgency that, in the preliminary view of the survey team, a particular deficiency may pose to the well-being of residents. This is a survey-specific decision based on the evidence gathered. As described below, states must follow the federal survey process. State licensure laws do not override the procedures outlined in the federal process. If a provider asks whether the noncompliance is isolated, a pattern, or widespread, the surveyor should respond with the facts (i.e., noncompliance was found affecting X number of residents).

Surveyors should not make general statements such as, "Overall the facility is very good." Surveyors should also not assume intent for noncompliance or assign blame to the facility or individual staff. Also, surveyors should not provide consultation, such as explaining how the facility can be compliant. Only discuss the facts. Do not rank requirements. Treat requirements as equally as possible. Cite problems that clearly violate regulatory requirements. The survey team must not discuss survey results in a manner that reveals the identity of an individual resident.

After describing the team's preliminary deficiency findings to the facility, let the facility know they will receive an official report of the survey which will contain any deficiencies that have been cited following supervisory review (Form CMS-2567, Statement of Deficiencies). If your state provides the sample list during the exit, follow instructions in the LTCSP Procedure Guide.

If an extended survey is required and the survey team cannot complete all or part of the extended survey prior to the exit conference, inform the facility Administrator that the deficiencies, as discussed in the conference, may be amended upon completion of the extended survey. (See Chapter 2 for additional information concerning exit conferences.) During the exit conference, provide the facility with the opportunity to discuss and supply additional information that they believe is pertinent to the identified findings. Because of the ongoing dialogue between surveyors and facility staff during the survey, there should be few instances where the facility is not aware of surveyor concerns or has not had an opportunity to present additional information prior to the exit conference.

7203.3.2 Determining Health Severity and Scope of Deficiencies (Rev.)

Guidance on Severity: *After the survey team decides to cite a deficiency(ies), evaluate the deficient practice's impact on the resident(s) and the prevalence of the deficient*

practice. Review deficiency statements, and results of team discussions for evidence on which to base these determinations. The team may base evidence of the impact or prevalence for residents of the deficient practices on record reviews, interviews and/or observations. Whatever the source, the evidence must be credible.

***NOTE:** The survey team must always assess the level of severity of noncompliance beginning with the highest level of harm, and if the outcome doesn't reach that level of harm, to proceed to review the other levels in consecutive order until a determination of severity has been made.*

Assessment Factors Used to Determine the Seriousness of Health Deficiencies Matrix

	Isolated	***Pattern***	***Widespread***
Immediate jeopardy to resident health or safety (Level 4)	***J*** [redacted] *PoC Required* [redacted]	***K*** [redacted] *PoC Required* [redacted]	***L*** [redacted] *PoC Required* [redacted]
Actual harm that is not immediate jeopardy (Level 3)	***G*** *PoC Required*	***H*** [redacted] *PoC Required* [redacted]	***I*** [redacted] *PoC Required* [redacted]
No actual harm with potential for more than minimal harm that is not immediate jeopardy (Level 2)	***D*** *PoC Required*	***E*** *PoC Required*	***F*** [redacted] *PoC Required* [redacted]
No actual harm with potential for minimal harm (Level 1)	***A*** ***No*** *PoC Required* [redacted] *Substantial compliance No remedies Commitment to Correct Not on CMS-2567*	***B*** *PoC Required* [redacted] *Substantial compliance*	***C*** *PoC Required* [redacted] *Substantial compliance*

[redacted] ***Substandard quality of care***

[redacted] ***Substantial compliance***

There are four severity levels which are defined accordingly:

- ***Level 4 - Immediate Jeopardy to resident health or safety****: Noncompliance with the Requirements for Participation that results in Immediate Jeopardy to resident health or safety in which immediate corrective action is necessary because the provider's noncompliance with one or more of those requirements has caused, or is likely to cause, serious injury, harm, impairment or death to a resident receiving care in a facility. (See Appendix Q)*
- ***Level 3 - Actual harm that is not Immediate Jeopardy:*** *Noncompliance with the Requirements for Participation that results in actual harm to residents that is not immediate jeopardy.*
- ***Level 2 No actual harm with a potential for more than minimal harm that is not immediate jeopardy:*** *Noncompliance with the Requirements for Participation that results in the potential for no more than minimal physical, mental, and/or psychosocial harm to the resident and/or that result in minimal discomfort to the residents of the facility, but has the potential to result in more than minimal harm that is not immediate jeopardy.*
- ***Level 1 - No actual harm with potential for minimal harm:*** *A deficiency that has the potential for causing no more than a minor negative impact on the resident(s).*

Guidance on Scope: *After determining the severity level of a deficient practice, determine the scope of the noncompliance which reflects the number of residents actually or potentially affected by the provider's noncompliance*

Scope is ***isolated*** *when one or a very limited number of residents are affected and/or one or a very limited number of staff are involved, and/or the situation has occurred only occasionally or in a very limited number of locations within the facility.*

Scope is a ***pattern*** *when more than a very limited number of residents are affected, and/or more than a very limited number of staff are involved, and/or the situation has occurred in several locations of the facility, and/or the same resident(s) have been affected by repeated occurrences of the same deficient practice. The effect of the deficient practice is not found to be pervasive (affect many locations) throughout the facility.*

Scope is ***widespread*** *when the problems causing the deficiencies are pervasive in the facility and/or represent systemic failure that affected or has the potential to affect a large portion or all of the facility's residents. Widespread scope refers to the entire facility population, not a subset of residents or one unit of a facility. In addition, widespread scope may be identified if a systemic failure in the facility (e.g., failure to maintain food at safe temperatures) would be likely to affect a large number of residents and is, therefore, pervasive in the facility.*

NOTE: *If the evidence gathered during the survey for a particular requirement includes examples of various severity or scope levels, surveyors should generally classify the deficiency at the highest level of severity. For example, if there is a deficiency in which one resident suffered a severity 3 while there were widespread findings of the same deficiency at severity 2, then the deficiency would be classified as severity 3, isolated. In these situations, the survey team should expand the sample to rule out the presence of SQC.*

When Immediate Jeopardy (IJ) Exists: *Identification of IJ triggers additional survey tasks and should be determined while the team is onsite.*

IJ as defined at §488.301, means a situation in which the provider's noncompliance with one or more requirements of participation has caused or is likely to cause serious injury, harm, impairment, or death to a resident.

At any time during the survey, if one or more survey team members identify possible IJ, the survey team leader must be immediately notified so that the survey team can gather to discuss the IJ concern and, if necessary, conduct further investigation. The survey team must use its professional judgment and evidence gathered from observations, interviews, and record reviews to carefully consider each key component of IJ.

Survey teams must use the IJ Template (found in Appendix Q) to document evidence of each component of IJ and to convey information to the entity. In order to determine that IJ exists, the team must verify that all three components of IJ have been established:

1. *Noncompliance: An entity has failed to meet one or more federal health, safety, and/or quality regulations; AND*
2. *Serious Adverse Outcome or Likely Serious Adverse Outcome: As a result of the identified noncompliance, serious injury, serious harm, serious impairment or death has occurred, is occurring, or is likely to occur to one or more identified recipients at risk; AND*
3. *Need for Immediate Action: The noncompliance causes a serious adverse outcome or likely serious adverse outcome and creates a need for immediate corrective action by the entity to prevent serious injury, serious harm, serious impairment or death from occurring or recurring.*

Survey teams must use the IJ Template to determine if IJ exists and use the template to communicate the finding of IJ to the entity. When the surveyor/survey team determines the entity's noncompliance has caused a serious adverse outcome, or has made a serious adverse outcome likely, and immediate action is needed to prevent serious harm from occurring or recurring, the survey team must consult with their SA for confirmation that IJ exists and seek direction. In some cases, it may be necessary for the survey team to stop all other investigations due to the need for additional investigation into the IJ situation.

When there is agreement from the SA (and/or CMS Location) that IJ exists, the survey team must immediately:

- *Notify the administrator (or appropriate staff member who has full authority to act on behalf of the entity) that IJ has been identified and provide a copy of the completed IJ template to the entity; and*
- *Request a written IJ removal plan, which is the immediate action(s) the entity will take to address the noncompliance that resulted in or made serious injury, serious harm, serious impairment, or death likely.*

The administrator/designee should immediately begin to take action to remove the IJ. If the IJ is not removed prior to the end of the survey, an onsite revisit must be conducted for determination of removal of the IJ. The SA and/or CMS Location will invoke appropriate termination procedures. See Appendix Q for additional guidance regarding determination of IJ.

When IJ is removed: *Appendix Q states, "When IJ has been identified and removed during the current survey or the revisit, the SA must ensure the core components of IJ and the actions taken by the entity to remove the IJ are documented on the Form CMS-2567. The documentation must identify and describe the following information:*

- *The date the IJ began (the date entity's noncompliance caused a serious adverse outcome,* ***or*** *made a serious adverse outcome likely), if known;*
- *The date the entity was notified;*
- *The specific requirement that has been violated, including a description of the noncompliance and the serious adverse outcome that occurred, or was likely to occur;*
- *Identification of recipients that were affected or were identified at risk of serious injury, harm, impairment, or death within the deficient practice statement;*
- *Date when the IJ was removed, as confirmed by an onsite verification by surveyor(s); and*
- *A statement of the seriousness of the remaining noncompliance, if any (i.e. Condition/ Standard/Element-level, or scope/severity)."*

Lowering Severity when IJ is removed*: As noted above, once IJ has been removed, surveyors must identify the level of severity any remaining noncompliance poses at the tag cited for IJ. When the facility has taken action to remove IJ, such that no further serious injury, serious harm, serious impairment, or death is occurring to the resident(s) involved and is not likely to occur to any other resident(s), any remaining noncompliance for that tag should be lowered to severity level 2 (No actual harm with potential for more than minimal harm that is not immediate jeopardy). If there are multiple occurrences of noncompliance at the same tag involving different residents with one cited at IJ and the other cited at harm, once IJ is removed, the remaining noncompliance is lowered to harm.*

Example at 483.25(d), Accidents and Supervision:
During a recertification survey, IJ was determined to exist for Resident A who was seriously harmed when the facility failed to supervise this resident's smoking break, resulting in Resident A being seriously burned. During the same survey, Resident B was found to have been harmed (not serious harm at IJ) when the facility failed to ensure the

resident environment was free of accident hazards, resulting in Resident B sustaining a laceration which required sutures after slipping on spilled water near the water fountain.

The IJ was removed when the facility put a plan in place to ensure all residents are supervised on their smoke breaks, but the plan did not address correction of the accident hazards. Once that IJ removal plan was implemented, and it was determined that no further residents were being seriously harmed or had the likelihood to be seriously harmed, the next remaining level of noncompliance would be actual harm at severity level 3 until substantial compliance is achieved.

7203.4 - Post Survey Revisit (Follow-Up)

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

When deficiencies *are cited,* the state agency *must* conduct *either an onsite or offsite* post survey revisit to determine if the facility now meets the requirements for participation *and to verify correction of deficiencies.*

In accordance with the guidance at §7317 of this chapter, the SA conducts a revisit to confirm that cited deficiencies have been corrected, and the facility is in substantial compliance and has the ability to remain in compliance. The purpose of the post-survey revisit (follow-up) is to re-evaluate the specific findings of care and services that were cited as noncompliant during the original standard, abbreviated standard, extended or partial extended survey(s).

Because the long-term care survey process focuses on the care of the resident, on-site revisits are generally necessary to determine if deficient practices have been corrected. The nature of the noncompliance dictates the scope of the revisit. For example, do not perform another drug pass if no drug distribution related deficiencies were cited on the initial survey. Do interviews and closed record reviews, as appropriate. Prior to the revisit, review appropriate documents, including the plan of correction, to focus the revisit review.

Refer to the LTCSP Interim Revisit Instructions for technical directions on conducting an on-site revisit, including obtaining the sample size for the revisit. Conduct as many survey tasks as needed to determine compliance. Always conduct the QAPI/QAA review. However, the team is not prohibited from gathering information related to any requirement during a post-survey revisit.

Focus on selecting residents who are most likely to have those conditions/needs/problems cited in the original survey. If possible, include some residents identified as receiving SQC during the prior survey. If, after completing the revisit, it is determined that the cited incidence(s) of noncompliance was not corrected, inform the SA and/or CMS Location as applicable. The SA and/or CMS Location are responsible for initiating enforcement action, as appropriate.

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

The abbreviated standard survey focuses on particular tasks *used for substantial changes in a facility's organization and management.* It does not cover all the aspects covered in the standard survey, but rather concentrates on a particular area of concern.

1. **Substantial Changes in a Facility's Organization and Management -** If a facility notifies *the SA* of a change in organization or management, *including a change of ownership, administration, management or the director of nursing,* review the change to ensure compliance with the regulations. Request copies of the appropriate documents, e.g., written policies and procedures, personnel qualifications and agreements, etc., if they were not submitted. If changes in a facility's organization and management are significant and raise questions of its continued substantial compliance, determine, through a survey, whether *certain changes have caused a decline in quality of care furnished by a SNF or NF and determine whether* deficiencies have resulted. Collect information about changes in the facility's organization and management on the "Medicare and other Federal Care Program General Enrollment," Form CMS-855.

   Surveyors may investigate any area of concern *to* make a compliance decision regarding any regulatory requirement, whether it is related to the original purpose of the survey complaint. *The abbreviated standard survey may be expanded to cover additional areas, or to conduct a full standard survey if evidence is found that warrants a more extensive review.*

2. ***Complaint Investigations*** *– If the State's review of a complaint allegation(s) concludes that one or more violations may have occurred, and only an onsite investigation can determine whether a deficiency(ies) exist, conduct a complaint investigation using the procedures for either a standard or abbreviated standard survey, depending on the nature of the complaint allegation. (See also Chapter 5 of this manual and 42 CFR 488.334.)*

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 *sample*. If the expanded survey *sample* verifies substandard quality of care, the State or CMS Location conducts an extended survey or a partial extended survey in accordance with procedures in *the LTCSP Procedure Guide*. (See §7210.2 and *the LTCSP Procedure Guide*.)

Extended Survey: *An extended survey is conducted when SQC has been verified. The purpose is to explore the extent to which structure and process factors may have*

contributed to systemic problems causing SQC. This is accomplished by further evaluating the facility's compliance with all provisions. (Refer to the Extended Survey Pathway for more information). An extended survey includes all of the following:

- *Review of a larger sample of resident assessments than the samples used in a standard survey;*
- *Review of the staffing and in-service training;*
- *If appropriate, examination of the contracts with consultants;*
- *A review of the policies and procedures related to the requirements for which deficiencies exist; and*
- *Investigation of any Requirement for Participation at the discretion of the SA.*

Conduct an extended survey:

- *Prior to the exit conference, in which case the facility will be provided with findings from the standard and extended survey; or,*
- *After the standard survey, but no later than 14 calendar days after the completion of the standard survey. Advise the facility's Administrator that there will be an extended or partial extended survey conducted and that an exit conference will be held at the completion of the survey.*

Partial Extended Survey: *Must be conducted after SQC is found during an abbreviated standard survey or during a revisit, when SQC was not previously identified.*

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 *iQIES* as "complaint" and create an intake and survey record. (See Chapter 5 of this manual for additional instructions.)

7205 - Survey Frequency: 15-Month Survey Interval and 12-Month

State-wide Average

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

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

7205.1 - Last Day of Survey

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

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

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

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

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

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

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

Exceptions to this rule involve those cases for which a 3-month or 6-month numerical date is not on the calendar. In these cases, move ahead a day or two to the beginning of the next month. For example, if a survey ended on January 31, the 3-month effective date for the mandatory denial of payment for new admissions remedy would be April 31.

However, since there is no April 31, the 3-month effective date is May 1 and the 6-month mandatory termination date is July 31.

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

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

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

1 - Changes That May Prompt Survey

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

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

2 - Frequency

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

3 - Conducting Complaint Surveys

Refer to complaint investigation procedures in *Chapter 5* of this manual.

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.

7205.6 – Standard Survey Interval for Special Focus Facilities

Sections 1819(f)(8) and 1919(f)(10) of the Act require CMS to conduct a Special Focus Facility (SFF) program which focuses on enforcement of requirements on facilities that have a persistent record of noncompliance leading to poor quality of care. CMS' SFF program requires the persistently poorest performing facilities selected in each state to be surveyed no less than once every six months.

7207 - Unannounced Surveys
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

(Also see *Chapter 2* and *Chapter 5* of this manual.)

7207.1 - Introduction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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

7207.2 - All Surveys Must Be Unannounced
(Rev. 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 *the LTCSP Procedure Guide*.)

*Survey teams are expected to remain in the facility after entrance for a **minimum** of five consecutive hours. This applies to all standard health surveys and helps to ensure that the surveys remain unannounced. For example, a survey team should not enter a facility, conduct a brief entrance conference, then leave the facility only to return the next day. Additionally, a survey should not enter a facility on a Friday and not return until the following Monday. If all required first day activities (per the LTCSP procedure guide and*

entrance conference form) have been completed in under five hours, or there is an emergency, the survey team may leave sooner, but this should be a rare occurrence.

At a minimum, the first two days of a survey must be conducted on consecutive calendar days from the day of entrance. The only exception would be an emergency situation, which should be rare, or a competing IJ at another location requiring the survey team's immediate attention. To increase the opportunity for unpredictability in standard surveys, the State survey agencies and Federal surveyors *should* incorporate the following procedures when planning facility surveying:

7207.2.1 - Nonsequential Order

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

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

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

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

(Refer to the LTCSP Procedure Guide for additional off-hour guidance.)

When facilities are surveyed, the day of the week and time of month should be varied from the time of the previous standard survey. *The month in which a survey begins should not, if possible, coincide with the month in which the previous standard survey was conducted.*

At least 10 percent of standard health surveys must *be conducted as off-hour surveys. These off-hour surveys are aimed at providing better insight into how a facility is staffed and operates outside of business hours, as well as* reducing the predictability of when a survey will occur. *Off-hour surveys* begin either *on the weekend or* before *6*:00 a.m. or after *5*:00 p.m. on weekdays.

When entering a facility during residents' routine sleeping hours, surveyors are to proceed with survey activities while also respecting the residents' need for sleep. During off-hour surveys, the team coordinator (TC) is to complete the Entrance Conference with the designated person in charge and then conduct a follow-up Entrance Conference with the administrator, as needed, upon his/her arrival at the facility.

The survey team should not wait for the resident roster or matrices to begin screening residents. Additionally, the survey team that has entered the facility during off-hours should be alert to situations that might indicate concerns with the following:

- *sufficient staff;*
- *infection control;*
- *medication errors;*
- *compliance with medication storage;*

- *abuse/neglect;*
- *pain management;*
- *behavioral health;*
- *restraints;*
- *accidents/hazards/smoking; and*
- *environment.*

While concerns with compliance in these areas may exist during normal business hours, survey teams may gain a more realistic view of facility activities during the early morning or late evening time of day.

During off-hour surveys, modify the Initial Pool Process as necessary to accommodate the residents' activities occurring at the time of entry. Surveyors must respect residents' need for sleep, by taking care not to be intrusive or wake the resident. Observations of the resident and the room may be made, but interview status may have to wait until the resident is awake. If residents are found to be awake, surveyors should introduce themselves. Members of the survey team may be able to start some facility level tasks that wouldn't disturb residents (e.g., sufficient and competent staffing, medication storage, kitchen, medication administration observation, infection control).

Additionally, a minimum of 50 percent of the 10 percent of off-hour standard health surveys must begin on a weekend day (Saturday or Sunday). Facilities for weekend surveys must be selected using the list provided by CMS. State Agencies may do more than a minimum of 50 percent.

Survey time on holidays can be counted toward the 10 percent of off-hour surveys to be conducted ."Holidays" are defined as those days that are recognized by the State as a State or Federal holiday.

NOTE: If the survey is commencing during off-hours (before 6:00 a.m. or after 5:00 p.m. or on a Saturday or Sunday), once onsite, announce the survey, ascertain who is in charge, ask the person to notify the administrator that a survey has begun. Conduct Step 12 in the LTCSP Procedure Guide with the designated person in charge and complete the task and the onsite preparatory activity as appropriate within the context of the survey. Conduct a follow-up Entrance Conference with the administrator, as needed upon his/her arrival at the facility.

All standard health surveys, including those conducted to satisfy the 10 percent *off-hours* requirement, ***must*** be conducted *with the survey team onsite for a minimum of two* **consecutive *calendar* days** *after entrance*. Consecutive *calendar* days include Saturdays, Sundays, and Holidays. For example, a survey *that begins* at 8:00 a.m. on a *Friday* morning ***must*** be continued *for two* consecutive *calendar days*.

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.

7207.4 - Imposition of Civil Money Penalties
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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

7207.5 - Withdrawal of Nurse Aide Training and Competency Evaluation Program or Competency Evaluation Program When Entity Providing the Program Refuses to Permit Unannounced State Visit
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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

7210 - Substandard Quality of Care and Extended and Partial Extended Surveys
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

(See also *LTCSP Procedure Guide*.)

7210.1 - Introduction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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

competency evaluation program and competency evaluation program when an extended or partial extended survey is conducted. (See §7001 for the definition of substandard quality of care.)

7210.2 Expansion of the Survey *Sample*

(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 *sample must* be expanded. (See *LTCSP Procedure Guide and* §7210*.1* of this manual.) This expansion of the standard or abbreviated standard survey *sample* 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 *the LTCSP Procedure Guide*.

7210.5 - Time frames

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

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

7210.6 - Notices

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

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

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

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

According to 42 CFR 488.325, disclosure of results of surveys and activities, the facility is responsible for submitting to the State the names of the attending physician for each resident who was identified as having been subject to substandard quality of care,

regardless of whether payment is made through Medicare, Medicaid, or private pay. (See §7905.)

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

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

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

7212 - Informal Dispute Resolution

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

7212.1 - Introduction

(Rev. 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.

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

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

7212.3 - Mandatory Elements of Informal Dispute Resolution

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

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

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

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

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

- Remedy(ies) imposed by the enforcing agency;

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

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

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

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

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

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

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

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

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

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

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

4. *The informal dispute resolution process will be completed within 60 calendar days of a facility's request, if an informal dispute resolution is requested timely by the facility.* Failure to complete informal dispute resolution timely will not delay the effective date of any enforcement action against the facility.

5. When a facility is unsuccessful during the process at demonstrating that a deficiency should not have been cited, the surveying entity must notify the facility in writing that it was unsuccessful. *The final informal dispute resolution decision to the facility shall contain the result for each deficiency challenged and a brief summary of the rationale for that result.*

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

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

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

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

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

Deficiencies pending informal dispute resolution should be entered into *iQIES* within ten (10) calendar days of receiving the request for an informal dispute resolution. This

information however will not be *used to calculate the facility's star rating* until informal dispute resolution has been completed.

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

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

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

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

7212.4 - Additional Elements for Federal Informal Dispute Resolution

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

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

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

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

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

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

All regulatory references are in 42 CFR unless otherwise stated.

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

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

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

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

7213.2 – Purpose
(Rev. 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 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 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 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 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 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.

7213.4 - Applicability of the Independent Informal Dispute Resolution Process

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

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

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

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

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

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

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

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

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

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

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

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

Independent IDR is not intended to be a formal or evidentiary hearing nor are the results of the Independent IDR process an initial determination that gives rise to appeal rights pursuant to 42 CFR 498. The Independent IDR results are recommendations to the State and CMS and are not subject to a formal appeal.

7213.5- Key Elements of Independent Informal Dispute Resolution

(Rev. 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 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 agency.

Upon a facility's timely request for an Independent IDR, the State 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., *virtually*, 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 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 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 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 agency, for retention by the surveying entity. The State agency will provide the final decision to the facility as soon as practicable but no later than 10 calendar days of its receipt of the written record. The final Independent IDR decision to the facility shall contain the result for each deficiency challenged and a brief summary of the rationale for that result. The written record from the Independent IDR entity or person shall include:

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

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

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

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

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

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

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

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

Independence: The entity or person –

- Has no financial or other conflict of interest;

- May be a component of an umbrella State agency provided that the component is organizationally separate from the State agency;

- May be an independent entity or person with an understanding of specific Medicare and Medicaid program requirements selected by the State and approved by CMS.

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

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

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

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

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

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

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

7213.7 - Approval of an Independent Informal Dispute Resolution Process

(Rev. 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 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.

7213.8 - State Budget and Payment for Expenses

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

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

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

7213.9 - Independent Informal Dispute Resolution Recommendation and Final Decision

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

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

    (a) If the State agency, agrees with the Independent IDR recommendation(s) and no changes will be made to the disputed survey findings, the State 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 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 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 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 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 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 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 agency will *complete the following* 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 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 *iQIES* 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 *iQIES* within 10 working days of the IDR or Independent IDR request and necessary changes should be entered in *iQIE*S within 10 working days of completion of the IDR or Independent IDR process.

Specific instructions are provided in the current iQIES Survey & Certification User Manuals

7213.10 - Additional Elements for Federal Independent Informal Dispute Resolution *(Independent IDR)* 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 QualityAssurance@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 *Baltimore*. In this case, the facility should be instructed to send all documentation *with all PII redacted* to: *Qua*lityAssurance@cms.hhs.gov .

This Independent IDR will be a paper review performed by a panel of CMS *Baltimore* 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 *Baltimore* 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 Internet Quality Improvement and Evaluation System* (*IQIES).*

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 *Baltimore* 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 *Baltimore. . All documentation should be sent to QualityAssurance@cms.hhs.gov* . As soon as practicable, but no later than 10 calendar days, CMS *Baltimore* 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 Baltimore*.

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 *Baltimore* 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 *Internet Quality Improvement and Evaluation System* (*iQIES*) and the *iQIES* Informal Dispute Resolution (IDR) Manager.

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

Specific instructions are provided in the current *iQIES* Users Guide.

The *iQIE*S will be enabled to include the Independent IDR process for enforcement actions with survey cycles that begin on or after January 1, 2012.

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

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

7300.1 - Introduction

(Rev. 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: 02-10-23)

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 *Chapter 2* 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 agency may opt to accept evidence of correction to confirm substantial compliance in lieu of an onsite revisit; however, the State 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 *state* 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 state agency does not conduct a new survey. The *state* 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 483.30(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 *state* 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.

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 - Action When Facility Is Not in Substantial Compliance

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

7301.1 - Immediate Jeopardy Exists
(Rev. 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 *(CMP)* 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 *instance of noncompliance, or both per day and per instance CMPs may be imposed for the same survey (as adjusted for inflation under 45 CFR 102.3)*. The specific procedures for *CMPs* can be found in §7510-§7536. *In cases when multiple per instance civil money penalties are imposed for a survey, the total dollar amount of all civil money penalties for noncompliance on **any single day** may not exceed the statutory and regulatory maximum amount and may not be less than the applicable statutory and regulatory minimum amount for each day. When multiple per instance civil money penalties are imposed for **different days** of noncompliance, the total amount of all civil money penalties imposed for the survey may exceed the statutory and regulatory maximum (the statutory maximum only applies to the civil money penalty amount for any single day).*

   Examples:

*A) F-tags F686 & F689 were cited on a survey and the noncompliance **occurred on the same day**. A per instance civil money penalty of $5,000* is imposed for F686 and a per instance civil money penalty of $5,000* is imposed for F689. No civil money penalty could then be imposed for additional deficiencies on that day because the total civil money penalty, consisting of any per instance and/or per day civil money penalties, must not exceed the statutory and regulatory maximum for **each day**.*

*B) F-tags F684 & F687 were cited on a survey and the noncompliance **occurred on different days**. A per instance civil money penalty of $10,000* is imposed for F684 and a per instance civil money penalty of $10,000* is imposed for F687. If noncompliance **occurs on different days**, two (or more) per instance civil money penalties at the maximum amount may be imposed for the same survey if the maximum statutory and regulatory amount is not exceeded for each day.*

C) F-tag F689 was cited on a survey and the noncompliance began two months prior to the start of the survey. A per instance civil money penalty of up to $10,000 may be imposed for noncompliance related to F689 that started prior to the survey start date. A per day civil money penalty may also be imposed for noncompliance related to F689 that exists beginning on the survey start date, and it would continue to accumulate per day until substantial compliance is achieved.*

**Note: The CMP amounts referenced in the examples above are noted as the original statutory maximum amounts per day. However, the current maximum amounts are adjusted annually for inflation and published in 45 CFR 102.3 as required under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. The amounts above are being used for illustrative purposes only. Federal CMPs are imposed in accordance with the instructions in the CMP Analytic Tool.*

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 §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 §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, §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 a per day *CMP* between $50 and $3,000 per day or a "per instance" civil money penalty between $1,000 and $10,000 for each *instance of noncompliance, or both per day and per instance CMPs may be imposed for the same survey not to exceed the maximum daily*

amount when combined, as adjusted under 45 CFR 102.3. The specific procedures for civil money penalties can be found in §7510-§7536. *In cases when multiple per instance civil money penalties are imposed for a survey, the total dollar amount of all civil money penalties for noncompliance on **any single day** may not exceed the statutory and regulatory maximum amount and may not be less than the statutory and regulatory minimum amount for each day. When multiple per instance civil money penalties are imposed for **different days** of noncompliance, the total aggregate amount of all civil money penalties imposed for the survey may exceed the statutory and regulatory maximum (the statutory maximum only applies to the civil money penalty amount for any single day).*

Examples:

A) *F-tags F686 & F689 were cited on a survey and the noncompliance **occurred on the same day**. A per instance civil money penalty of $5,000* is imposed for F600 and a per instance civil money penalty of $5,000* is imposed for F607. No civil money penalty could then be imposed for additional deficiencies on that day because the total civil money penalty, consisting of any per instance and/or per day penalties, must not exceed the statutory and regulatory maximum for **each day**.*

B) *F-tags F684 & F687 were cited on a survey and the noncompliance **occurred on different days**. A per instance civil money penalty of $10,000* is imposed for F600 and a per instance civil money penalty of $10,000* is imposed for F607. If noncompliance **occurs on different days**, two (or more if each instance of noncompliance occurs on a different day) per instance civil money penalties at the maximum amount may be imposed on the same survey if the maximum statutory and regulatory amount is not exceeded for each day.*

C) *F-tag F689 was cited on a survey, and the noncompliance began two months prior to the start of the survey. A per instance civil money penalty of $10,000* could be imposed for noncompliance related to F689 that started prior to the survey. A per day civil money penalty could also be imposed for noncompliance related to F689 that exists on the survey start date, and it would continue to accumulate until substantial compliance is achieved.*

***Note:** The regulatory maximum CMP amounts referenced in the examples above are noted as the original statutory maximum amounts per day. However, the current maximum amounts have been are adjusted annually for inflation and published in 45 CFR 102.3 based as required under on the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. The amounts above are being used for illustrative*

purposes only. Federal CMPs are imposed in accordance with the instructions in the CMP Analytic Tool.

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 §7314 and §7506.1.)

7301.3 - Prospective Providers
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

See §7203.2 and §7300.3.

7303 - Appeal of Certification of Noncompliance
(Rev. 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 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 *iQIES* 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 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).

Timeliness of Mandatory DPNA Notification for Nursing Homes – The SA must adhere to enforcement processing timeframes so that mandatory DPNA is imposed when a nursing home is not in substantial compliance three months after the date of the original survey. The SA must transfer the enforcement case to CMS by the 70th day or the imposition notice is sent by the SA to the provider by the 70th day (as authorized by CMS). However, there may be other instances in which cases should be immediately transferred to the CMS Location (i.e. enhanced enforcement). Contact your CMS Location for additional information. This excludes cases involving Medicaid-only nursing homes.

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	*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*	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 <u>in addition to</u> 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	1. Termination 2. CMPs[1] <u>must</u> be imposed immediately 3. DDPNA[2] 4. Temp. Mgmt. 5. State Monitoring 6. Directed Plan of Correction 7. Directed In-service 8. Denial of Payment for ALL Individuals[3]	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] Federal CMPs are imposed in accordance with the instructions in the CMP Analytic Tool
[2] DDPNA = Discretionary Denial of Payment for New Admissions
[3] 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.

Mandatory Criteria for Immediate Imposition of Federal Remedies	Immediate Jeopardy is identified on the current survey	*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*	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
be imposed for any situation as appropriate.				

	Decisions, Responsibilities & Actions (refer to §7304.3)
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 *iQIES* 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 *State* 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 *state* 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 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 *state* 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 *state* 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 *state* agency (State or Federal) must enter all of these cases as a NO opportunity to correct into the *iQIES* within five (5) business days of sending the initial notice to the facility. The State Agency and the CMS Location must have systems in place to routinely check and monitor the *iQIES* database to identify cases that may require enforcement action or additional follow-up, as needed.

7305 - Notice Requirements

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

7305.1 - Initial Notices by Surveying Entity
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7305.1.1 – When No Immediate Jeopardy Exists and an Opportunity to Correct Will be Provided Before Remedies Are Imposed
(Rev. 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, §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 *non*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 CMS2567 (see §7317). 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, §7314, §7316.2, and §7506.1.)

i. Provides elements of an acceptable plan of correction (See §7317);

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. *(See also §7310 and §7320).*

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 §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. The plan of correction will serve as the facility's allegation of compliance;

e. Informs the facility of the opportunity for *an* 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 §7317) 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 *a* 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, §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.

7305.2.2 - Contents of the Formal Notice of Remedies

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

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

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

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

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

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

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

7305.2.3 - Required Time Periods for Formal Notice

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

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

a. Immediate Jeopardy – 2 calendar day notice

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

b. No Immediate Jeopardy – 15 calendar day notice

Except for civil money penalties and State monitoring, notice must be given at least 15 calendar days before the effective date of the enforcement action.

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

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

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

7305.3 - Overlap of Notice of Remedies

(Rev. 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.

7305.4 - Means of Sending Notice

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

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

The notice shall be dispatched through first-class mail, or other reliable means. Other reliable means refers to the use of alternatives to the United States mail in sending notices. Electronic communication, such as facsimile transmission, *secured electronic mail (email), or electronic plan of correction (ePOC) are* equally reliable and on occasion more convenient than the United States mail. If electronic means are employed to send notice, the sender should maintain a record of the transmission to assure proof of transmission if receipt is denied.

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

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

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

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

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

7308 - Enforcement Action When Immediate Jeopardy Exists
(Rev. 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 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 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 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 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.
. The general public is also given notice of the impending termination.

7309.3 - No Later Than 10th Business Day
(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

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

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

7309.4 - By 23rd Calendar Day
(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

Termination takes effect unless the IJ has been removed.

7310 - Immediate Jeopardy (IJ) Does Not Exist
(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

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

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

When the surveying entity finds that a facility's deficiencies do not pose IJ to resident health or safety, but the facility is not in substantial compliance, the surveying entity may recommend that the enforcing entity either terminate the facility's provider agreement, or

impose alternative remedies, or do both. The State may also provide formal notice of 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).

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

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

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

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

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

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

Once noncompliance is identified, the surveying entity must first determine whether to immediately impose remedies in accordance with the criteria in §7304.1 or give the

facility an opportunity to correct its deficiencies before remedies are imposed.

7313.1 - Facilities Given an Opportunity to Correct Deficiencies prior to the Immediate Imposition of Federal Remedies
(Rev. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

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

7314 - Special Procedures for Recommending and Providing Notice of Imposition and Rescission of Category 1 Remedies and Denial of Payment for New Admissions Remedy
(Rev. 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. 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 §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 - Key Dates When Immediate Jeopardy Does Not Exist
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7316.1 - Required Actions When There Is an Opportunity to Correct
(Rev. 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, ,§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). *The SA must adhere to enforcement processing timeframes so that mandatory DPNA is imposed when a nursing home is not in substantial compliance three months after the date of the original survey. The SA must transfer the enforcement case to CMS by the 70th day or the imposition notice is sent by the SA (as authorized by CMS) to the provider by the 70th day. However, there may be other instances in which cases should be immediately transferred to the CMS Location (i.e., enhanced enforcement). Contact your location for additional information. This excludes cases involving Medicaid-only nursing homes.*

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 §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. *The SA must adhere to enforcement processing timeframes so that mandatory DPNA is imposed when a nursing home is not in substantial compliance three months after the date of the original survey. The SA must transfer the enforcement case to CMS by the 70th day or the imposition notice is sent by the SA (as authorized by CMS) to the provider by the 70th day. However, there may be other instances in which cases should be immediately transferred to the CMS Location (i.e., enhanced enforcement). Contact your location for additional information. This excludes cases involving Medicaid-only nursing homes.*

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

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

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

7317 - Acceptable Plan of Correction

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

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

- Address how corrective action will be accomplished for those residents found to have been affected by the deficient practice;
- Address how the facility will identify other residents having the potential to be affected by the same deficient practice;
- Address what measures will be put into place or systemic changes made to ensure

that the deficient practice will not recur;

- Indicate how the facility plans to monitor its performance to make sure that solutions are sustained; and
- Include dates when corrective action will be completed. The corrective action completion dates must be acceptable to the State. If the plan of correction is unacceptable for any reason, the State will notify the facility in writing. If the plan of correction is acceptable, the State will notify the facility by phone, e-mail, etc. Facilities should be cautioned that they are ultimately accountable for their own compliance, and that responsibility is not alleviated in cases where notification about the acceptability of their plan of correction is not made timely.

The plan of correction serves as the facility's allegation of compliance and, without it, CMS and/or the State have no basis on which to verify compliance. A plan of correction must be submitted within 10 calendar days from the date the facility receives its Form CMS-2567. If an acceptable plan of correction is not received within this timeframe, the State notifies the facility that it is recommending to the RO and/or the State Medicaid Agency that remedies be imposed effective when notice requirements are met. The requirement for a plan of correction is in 42 CFR 488.402(d). Further, 42 CFR 488.456(b)(ii) requires CMS or the State to terminate the provider agreement of a facility that does not submit an acceptable plan of correction.

Nursing Home Official Signing the POC

When a POC is submitted, it must be signed by a facility representative, who should be the Administrator. However, other facility representatives may include the Director of Nursing, or a corporate representative. The facility representative signing the POC should have management authority and responsibility. Some SAs use the electronic POC (ePOC), which has a place for the written signature, which is generated electronically. Regardless of using a hard copy or electronic copy signature format, a nursing home official with authority and responsibility for operations of the facility should be the one who is submitting their signature on the facility's allegation of compliance.

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

7317.1 - Verifying Facility Compliance

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

While the plan of correction *(PoC)* serves as the facility's allegation of compliance in non-immediate jeopardy cases, substantial compliance cannot be certified and any remedies imposed cannot be lifted until facility compliance has been verified.

The date of substantial compliance is determined first by evaluating whether the credible written evidence provided by the facility supports the date it alleges that all deficiencies have been corrected and that it is capable of remaining in substantial compliance as determined by the survey agency. While the date of substantial compliance may not

always be the date specified by the facility in the approved POC, it also is not necessarily the date of the revisit (onsite or paper-review). In some cases, a revisit may determine that a facility was able to correct all deficiencies and return to substantial compliance with the requirements before the alleged correction date on the approved POC.

In these cases, the facilities may provide credible evidence that they achieved substantial compliance on a date prior to the alleged correction date on the POC, and/or the date of the most recent revisit, regardless of the number of revisits that have already occurred. The facility is responsible for ensuring credible evidence provided to surveyors (for either onsite revisit, or offsite review) clearly establishes the date the facility returned to substantial compliance. Any evidence presented by the facility should establish the timing or dates of actions taken by the facility and how those actions corrected the noncompliance and will prevent recurrence of such noncompliance. If the facility does not provide documentation, or evidence that supports an earlier date, surveyors will consider the alleged date of compliance in the POC, or a later date supported by evidence found during a revisit, in determining the date of substantial compliance.

If noncompliance exists at the time of a revisit, it will be considered continued noncompliance unless the facility provides evidence acceptable to CMS or the State that there was a period of substantial compliance between the time that the previous deficiencies were fully corrected and the time new deficiencies began. The new noncompliance would then begin a new enforcement cycle.

*R*evisits *to determine if the facility has returned to substantial compliance* may be conducted anytime for any level of noncompliance, subject to the allowed number of revisits (see §7317.2, below). *R*emedies may be imposed anytime for any level of noncompliance *in accordance with CMS enforcement regulations and policies. R*evisits are not assured *to* occur *within a certain timeframe. Facilities are ultimately accountable for their own compliance, even in situations in which notifications about the acceptability of their plan of correction or written credible evidence are not immediately provided.* Also, it should be noted that this guidance applies to prospective, as well as currently participating, facilities.

In accordance with 42 C.F.R. § 488.454(a), any enforcement remedies imposed will continue until either:

1. *The facility has achieved substantial compliance, as determined by CMS or the State based upon an on-site revisit or after an examination of credible evidence that can be verified without an on-site revisit; or*

2. *CMS or the State terminates the provider agreement.*

7317.2 - Revisits

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

*P*aper reviews and onsite reviews are considered to be revisits *however*, only onsite revisits are considered in the revisit count for purposes of the revisit policy.

1. ***Onsite versus Offsite Revisits***

    a. **Mandatory onsite revisits.** An onsite revisit is *only* required when a facility's beginning survey finds deficiencies that constitute substandard quality of care, harm, or immediate jeopardy.

    b. ***Discretionary onsite revisits:*** *States may use their discretion to conduct an onsite revisit at any time. This may be done to assess the nature of the corrections and the extent to which they address and correct the deficiencies. For deficiencies involving Quality of Care, Quality of Life, Abuse or Neglect, or repeat deficiencies, which may be indicative of systemic problems, it may be necessary to observe staff practices and interview residents before determining a facility has returned to substantial compliance.*

    c. ***Offsite revisits:*** *When onsite revisits are not required, or when CMS or States have determined an onsite revisit is not warranted, credible evidence is used to conduct an offsite revisit (see section below on credible evidence).*

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.

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.

    a. The effect of specific survey activities on the onsite revisit count *is as*

follows:

- **Complaint *investigations***. *C*omplaint investigation visits, *which occur before the alleged compliance date from the original survey Plan of Correction (PoC), regardless of* whether *deficiencies are cited* or not, are not included in the onsite revisit count. However, when the complaint *investigation* is conducted at the same time as the onsite revisit, the revisit is included in the onsite revisit count. This also applies to Federal complaint guidelines.

- When a complaint is received and the complaint *investigation* is conducted **after** the third onsite revisit but **before** the 6-month termination date, any deficiencies identified by the complaint *investigation* should be cited and *may* 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* . Situations such as this should be discussed with the CMS *Location* since it may have already sent a termination letter.

- **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 *additional standard surveys (i.e., one every six months)* 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 *alleged* 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*, then an* onsite revisit *i*s m*andatory. If the onsite revisit determines the original noncompliance remains, but at a lowered scope and severity that no longer meets the criteria for an onsite revisit, States may use their discretion to either conduct an onsite or offsite revisit (see #1 above).*

8. ***New Noncompliance identified before or during on-site revisit surveys.*** *In some cases, surveyors identify new noncompliance before facilities have been certified as having returned to substantial compliance. This can occur when complaints are investigated before the alleged date of compliance or on the revisit. New noncompliance can also be identified during the course of conducting the on-site revisit. New noncompliance may have an impact on accruing remedies such as civil money penalties, or mandatory remedies such as Denial of Payment for New Admission, and mandatory termination. In situations where it is determined that the provider clearly establishes through credible evidence that they have returned to substantial compliance, AND the newly identified noncompliance occurred on a date after the original noncompliance was corrected (i.e., alleged date of compliance), AND the noncompliance is different (regardless if it is the same F-tag) from findings on the original survey, the SA and/or the CMS Location should return the provider to substantial compliance for the original survey. This would end the enforcement cycle for the original survey and start a new enforcement cycle for the newly identified noncompliance.*

Key Points to be considered:

- *New noncompliance must always be documented on a Form CMS-2567.*
- *It is the provider's responsibility to establish the date on which it returned to substantial compliance. Surveyors should always attempt to establish the earliest date of noncompliance when conducting their investigations.*

If the survey team cannot determine a date before the alleged date of compliance on the approved POC, that is the date that will be used.

- *Determination of a period of substantial compliance can only be made after any new allegations have been appropriately investigated.*
- *For purposes of this guidance, SAs/CMS Locations would generally consider noncompliance to be different if they were cited at different Ftags or regulatory groupings. However, in some cases, citations at the same Ftag can also be different, and would require a different POC. This can occur at Ftags that cover broad areas of noncompliance, such as Quality of Care citations at F684, or Accidents/Supervision at F689, Infection Prevention and Control at F880, among others.*
- *If newly identified noncompliance which occurs on or after the alleged date of compliance is the same or similar to the noncompliance cited on the original survey, and the facility has not been returned to substantial compliance, it is reasonable to assume the provider did not correct the original deficient practice, regardless of an allegation that the provider returned to substantial compliance. In these cases, the original enforcement cycle will not end and it will continue until the state agency confirms the facility is in substantial compliance by the original or amended alleged date of compliance.*
- *If newly identified noncompliance which occurs before the alleged date of compliance is the same or similar to the noncompliance cited on the original survey, the survey team should cite the new noncompliance. The original enforcement cycle would continue until the facility submits a plan of correction for all identified noncompliance and the facility can provide evidence that the noncompliance has been corrected.*

9. 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.

Post-Survey Offsite Revisit Paper Reviews

An offsite desk paper review revisit may be conducted if the deficiencies are less serious (deficiencies with findings at a D, E, and F without substandard quality of care) and when those deficiencies do not require on-site observations to evaluate the corrective action. For more serious deficiencies (e.g. substandard quality of care or G or higher) the SA must conduct the revisit onsite. An onsite revisit is also generally required for deficiencies concerning quality of care.

For the offsite desk paper review, the State Agency (SA) follows up on deficiencies identified in the accepted Plan of Correction (PoC). The PoC serves as the facility's allegation of compliance however, facility compliance must still be verified. The SA must review evidence and verify that the nursing home corrected the identified deficiencies and is capable of remaining in compliance. The nursing home must be in substantial compliance with Federal requirements for participation in order to maintain certification.

Substantial compliance exists when deficiencies are cited at a level that represents no actual harm with potential for minimal harm. The SA completes appropriate verification before documenting that a deficiency is corrected. In some cases, the cited deficiencies may be such that a paper review will suffice in place of an onsite visit. In these cases, a paper review is performed and documentation of this review must be maintained by the SA. The SA should have a policy to ensure that Personal Health Information is protected through communications with the facility.

The nursing home is required to submit a PoC to the SA, however the PoC itself does not serve as confirmation of substantial compliance. The SA must obtain evidence of the correction of deficiencies from the nursing home. To help ensure the health and safety of nursing home residents, SAs must properly verify the correction of deficiencies and maintain sufficient documentation to support the verification of corrections and how those actions will prevent recurrence of noncompliance.

The SA should verify and maintain sufficient evidence that deficiencies identified during surveys have been corrected. The SA must ensure that deficiencies have been corrected before determining that the nursing home is in substantial compliance. The SA must maintain evidence of the review of the plan of correction and any documents that were provided by the nursing home. SAs must not accept nursing homes' PoCs as confirmation of substantial compliance with Federal requirements of participation without first obtaining from nursing homes the required evidence that each deficiency has been corrected and will prevent recurrence of such noncompliance. The correction of deficiencies must be verified through means beyond reviewing the PoC. For information on evidence that can be requested and reviewed to verity correction, see the section below, "Supporting Evidence."

Supporting Evidence

*The SA makes a request of the facility for the documentation specified in the facility's accepted POC. All five components of the accepted POC must be reviewed. (See **7317 - Acceptable Plan of Correction**) What the deficiencies were and what the facility stated in their POC will affect the specifics of what needs to be collected to support correction of the identified deficiencies. While the POC itself is not credible evidence of compliance, supporting evidence must align with the POC.*

Use of the ePOC allows the facility representative user to sign the POC electronically.

Verification of correction of deficiencies often involves reviewing in-service/training completed by the facility. It is important to review all materials addressed in the POC and ensure they are specific to the noncompliance identified during the survey. Sometimes evidence of correction includes but is not limited to specific staff. For example, in reviewing the list of in-service attendees, the reviewer must determine that the specific staff originally involved in the deficient practice were included in the list of those who attended the training, unless the staff is no longer working at the facility.

During a paper review, the surveyor is to request documentation depending on the specifics located in the accepted POC. Request additional information if the facility has not provided sufficient evidence to support substantial compliance. If the facility fails to provide credible evidence, then an onsite visit may be required.

The surveyor conducting the paper review should be a qualified surveyor (e.g. SMQT/Life Safety Code). Best practice is having a member of the original survey team conduct the paper review. The surveyor prepares by reviewing the CMS-2567 findings and the accepted POC. The POC is compared with evidence the facility submits that addresses the specific deficient practice. The documentation is reviewed against the facility's POC to ensure the facility provided evidence according to the submitted and approved plan.

If the material received is incomplete or inadequate, then communication (e.g. phone call, encrypted e-mail, secure fax, or ePOC) is required to gather all of the needed information. Some SAs use the ePOC system to document acceptance of the evidence of correction submitted by a provider. The surveyor is to review all of the documentation sent by the facility as evidence the action items in the accepted POC were completed, compliance was achieved, and that compliance can be maintained. Additionally, the SA should be sure to document all conversations with the facility.

Compliance is determined based on evidence submitted that confirms the POC was implemented and the facility was able to correct all deficiencies. Acceptable supporting documentation is required to ensure the verification process.

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

1. *Copies of In-service/Training/Education Records Documenting What Was Covered (actual training materials) and Who Attended, Including but not Limited to Specific Staff Who Were Involved in the Original Deficiency*
    - *Interviews with multiple staff who took part in a training to determine whether staff understood the topics presented and took any action, as necessary*
    - *Results from pre- and post-training tests*
2. *Staff Termination Letter*
3. *Documentation of the hiring of new staff*
4. *New or Revised Policies and Procedures*
5. *Purchase Order/Invoice/Receipt for New Equipment*
6. *Receipts Showing Repairs-contractor inspections, evidence of work completed and/or ordered on contractor letterhead*
7. *Photos-if it related to a repair or cleaning issue*
8. *Documentation/Log Showing Inspections, Monitoring and auditing results*
9. *Revised Shower or Bathing Schedule*
10. *Documentation of Grievance Resolution*
11. *Communication to Residents Encouraging Them to Bring in Personal Items*
12. *Change In/Removal of Physical or Chemical Restraint*

13. *Revised resident assessment (minimum data set (MDS))*
14. *Revised/Developed Care Plan*
15. *Health Care Professional Consultation or Outside Physician/Dental Appointment*
16. *Change in Medication*
17. *Documentation of Lab Test or X-ray.*
18. *New Physician's Order*
19. *Temperature Recordings of Refrigerators and Steam Food Table*
20. *Internal Quality Assurance Audit Results (e.g. root cause analysis/documentation of improved performance), QAPI Monitoring Tools*
21. *Revised or New Contracts Related to the Concern Identified*
22. *Revised or New Facility Forms Related to the Concern Identified*
23. *Changes in Physician Orders*
24. *Revised Menus*
25. *Medication Administration Records*
26. *Treatment Administration Records*
27. *Records Related to the Prevention, Plan, Development, Care, Size, and Treatment of Pressure Ulcers*
28. *Records Related to the Prevention, Plan, Care, and Treatment of Falls*
29. *Records Related to Supervision, Wandering, Monitoring, Plan, and Care*
30. *Revised Facility Assessment*
31. *Staff Interviews*
32. *Updated Infection Prevention and Control Plan*
33. *Revised/Developed QAPI Plan*
34. *Updated Facility Assessment*
35. *Updated Policy/Procedure for Emergency Preparedness*
36. *Communications Plan for Emergency Preparedness*
37. *Temperature Control Logs of the Air or Water*
38. *Revised Arbitration Agreement*

Documentation and Record Retention

SAs should gather and maintain documented evidence of the verification of corrected deficiencies. The documentation must explicitly indicate how the surveyor verified the facility's corrected deficiencies identified on the CMS-2567. At a minimum, the document should include:

- *Date of Revisit Survey*
- *Identify if any or all of the revisit survey was conducted on-site or off-site.*
- *2567 issued to the facility*
- *Accepted POC*
- *Alleged Date of Compliance*
    - *(Noting if different for individual requirement for participation)*
- *Obs/Int/RR (explicitly indicate how a survey agency verified correction of deficiencies)*
- *Supporting Evidence Reviewed*

The SA is responsible for documenting verified correction and the information reviewed from the POC. The SA should have a system to ensure that this review and documentation take place and that these records are maintained. All evidence should be

organized and retrievable. See S&C-10-22-ALL for guidance regarding Records Retention.

If the facility is in compliance, the correction dates are entered into iQIES. The length of time that the records are maintained should be outlined in the SA's policy and procedure and be reflective of CMS policy in Chapter 4. (See §7317.2 for Examples of Acceptable Credible Evidence)

SAs may utilize different approaches such as documenting on an 807 form and maintaining documents received from the facility. Other examples include using a SA developed Quality Assurance tool document or a POC review form to track review and then to file that document in the state's electronic records database, using the ePOC and making a copy for files.

The surveyor will need to complete the necessary steps in the CMS system to indicate dates of compliance in the system. Whether the state uses hard copy files or an electronic format, the SA is responsible for maintaining evidence that a paper review was conducted, beyond reviewing the POC. Credible evidence of compliance must be obtained, confirmed and retained. Once the documentation has been verified as acceptable for proof of compliance, completion of a paper review is entered into the iQIES and a 2567B is created to clear the deficiencies. The CMS 1539 is completed. A compliance CMS-2567 form and notice letter are created and sent to the facility.

7317.3 - Noncompliance Cycles
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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

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

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

1. The State conducts the survey and certifies compliance.

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

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

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

5. The State enters the certification information into the *iQIES* . This can occur as soon as substantial compliance is achieved.

7319.2 - State-Operated Facilities

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

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

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

3. If the facility has deficiencies that are widespread or constitute a pattern and which cause no actual harm and potential for only minimal harm, the regional office instructs the facility to submit its plan of correction to the regional office. The plan of correction must be submitted within 10 calendar days after the facility has received its Statement of Deficiencies.

4. The regional office enters the certification information into the *iQIES*.

7320 - Action When There is Substandard Quality of Care

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

Sections *1819(g)(5)(C)* and of the Act and *42 CFR 488.325* require that when a facility is found to have provided substandard quality of care, notification of that finding must be provided to the attending physician of each resident found to have received such care as well as to the State board responsible for licensing the facility's administrator. The

facility's ability to provide a nurse aide training and competency evaluation program must also be prohibited for 2 years from the date of the finding of substandard quality of care. (See §7303 for related appeal rights.)

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

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

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

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

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

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

7320.1.3 - Notification Requirements
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Notification to the facility by CMS, or the State Medicaid Agency, or the State, as appropriate, would be in accordance with *42 CFR 488.402*. The notice will inform the facility that the remedies will continue until the facility has demonstrated that it is in substantial compliance with requirements and that it will remain in substantial

compliance with the requirements. The facility will also be notified that it cannot avoid the imposition of remedies or the obligation to demonstrate that it will remain in compliance when it either alleges correction of the deficiencies cited in the most recent standard survey, or when it achieves compliance before the effective date of the remedies. The finding of repeated substandard quality of care results in the imposition of the remedies specified in §7320.1.1 above, regardless of subsequent correction.

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

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

7321.1 - Readmission Criteria

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

The general guidelines for readmission can be found in *Chapter 2* of this manual.

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.

Enforcement Process

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

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

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

7400.1 - Available Federal Enforcement Remedies

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

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

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

7400.2 - Enforcement Remedies for the State Medicaid Agency

(Rev. 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 *Chapter 7* §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. 185, Issued: 11-16-18, Effective: 11-16-18, Implementation: 11-16-18)

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 RO should consider the extent to which the noncompliance is the result of a one-time mistake, larger systemic concerns, or an intentional action of disregard for resident health and safety.

7400.4 - Other Factors That May Be Considered in Selecting Enforcement Remedy Within a Remedy Category

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

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

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

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

7400.6 - When *t*o Select Remedy *f*rom Specific Remedy Category
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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

Select at least one remedy from category 1 when there:

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

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

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

CATEGORY 1 remedies include:

- Directed plan of correction (see §7500);

- State monitoring (see §7504); and

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

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

7400.6.2 - Category 2
(Rev. 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. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Termination or temporary management, or both, must be selected when there are one or more deficiencies that constitute immediate jeopardy to resident health or safety. A *CMP* of $3,050 - $10,000 *(as adjusted under 45 CFR 102.3)* per day or a *CMP* of $1,000 - $10,000 *(as adjusted under 45 CFR 102.3)* per instance*, or both,* 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 *(as adjusted under 45 CFR 102.3)* per day of noncompliance optional, in addition to the remedies of termination and/or temporary management (See §7510); *and/*or
- Civil money penalties of $1,000 - $10,000 *(as adjusted under 45 CFR 102.3)* 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.

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

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

7410.1 - Application of the Enforcement Regulations to Life Safety Code Surveys Conducted in Skilled Nursing Facilities and Nursing Facilities
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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

The specific requirement for life safety code is found at *42 CFR 483.90(a),* "Life Safety From Fire." A facility may meet this requirement by complying with the prescriptive requirements of the *2012* edition of the life safety code by either waivers of the prescriptive requirements or by the Fire Safety Evaluation System. The Fire Safety Evaluation System is an equivalent system acceptable to CMS as the authority having jurisdiction. These instructions do not require the completion of a Fire Safety Evaluation System (State regulations may restrict its use).

This instruction is applicable when completing Form CMS-2786 - Fire Safety Survey Report forms in long-term care facilities.

7410.2 - Life Safety Code Scope and Severity Determination
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

After a life safety code survey is completed, the life safety code surveyor will use the following guidance to determine the scope and severity level of the resulting deficiencies and the appropriate enforcement action. The definitions below are similar to those used for health surveys but have been modified, where appropriate, to be applicable to life safety code surveys.

7410.2.1 - Scope Levels
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The scope of the deficiency reflects the pervasiveness of the deficiency throughout the facility.

Scope is **isolated** when one or a very limited number of residents or employees is/are affected and/or a very limited area or number of locations within the facility are affected.

Scope is a **pattern** when more than a very limited number of residents or employees are affected, and/or the situation has occurred in more than a limited number of locations but the locations are not dispersed throughout the facility.

Scope is **widespread** when the problems causing the deficiency are pervasive (affect many locations) throughout the facility and/or represent a systemic failure that affected, or has the potential to affect, a large portion or all of the residents or employees.

7410.2.2 - Severity Levels

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

The severity of the deficiency reflects the impact the deficiency has on the fire safety of the individual. The four severity levels are defined as follows:

- **Level 1 - No actual harm with potential for minimal harm:** A deficiency that has the potential for causing no more than a minor negative impact on the resident(s) or employees.

- **Level 2 - No actual harm with a potential for more than minimal harm that is not immediate jeopardy:** Noncompliance with the requirements of the life safety code that results in the potential for no more than minimal physical, mental, and/or psychosocial harm to the resident or employee and/or that result in minimal discomfort to the residents or employees of the facility, but has the potential to result in more than minimal harm that is not immediate jeopardy.

- **Level 3 - Actual harm that is not immediate jeopardy:** Noncompliance with the requirements of the life safety code that results in actual harm to residents or employees that is not immediate jeopardy.

- **Level 4 - Immediate jeopardy to resident health or safety:** Noncompliance with the requirements of the life safety code that results in immediate jeopardy to resident or employee health or safety in which immediate corrective action is necessary because the provider's noncompliance with one or more of those life safety code requirements has caused, or is likely to cause, serious injury, harm, impairment or death to a resident receiving care in a facility or an employee of the facility.

The determination of the scope and severity level when a facility has life safety code deficiencies should be based on the impact the life safety code deficiencies have on the overall level of life safety in the facility. This is because nearly all life safety code requirements deal with safety from harm due to fire. Each instance of threat in a facility can compound attempts at containment, extinguishment, evacuation and/or overall safety. Like health deficiencies, for which a scope and severity determination is made for each deficiency, the survey agency should make a scope and severity assessment for each life safety code deficiency.

This determination should include the likelihood of harm from a fire incident and/or the likelihood of the spread of fire in the facility from any one incident. Consideration in this determination may include, but is not limited to, whether the facility is sprinklered or unsprinklered, the facility's construction type and any special fire protection features the facility may have.

7410.3 - Survey Coordination and Data Entry

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

States vary in the coordination of their life safety code and health surveys (see *Chapter 2* of this manual). While the two surveys occur simultaneously in some States, they do not occur simultaneously in other States. In order to complete data submissions in a timely manner, yet give operational flexibility, input of the life safety code survey data of long-term care facilities should occur no later than 60 days after the conclusion of the long-term care survey. There is no prescribed order of the life safety code survey and health surveys; either may precede the other. Sometimes the same team conducts both the health survey and the life safety code survey but it is more typical that different teams are responsible for each.

7410.4 - Guidance on Enforcement Remedies

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

If a facility does not meet the life safety code requirements at *42 CFR 483.90(a)*, or the Fire Safety Evaluation System does not show an equivalent level of fire safety, or no Fire safety evaluation system is completed, then the State would determine the scope and severity level for the life safety code deficiencies found on the life safety code survey to determine the enforcement response. The pertinent procedures are found at §§7301 - 7400. If a facility does not meet the requirements at *42 CFR 483.90(a),* but shows an equivalent level of fire safety after completion of the Fire Safety Evaluation System, then the facility is found in substantial compliance.

If, after 3 months from the health survey, the facility has not achieved substantial compliance, the denial of payment for new admissions sanction takes effect (see *42 CFR 488.417*).

All deficiencies cited at *42 CFR 483.90(a)* that do not constitute immediate jeopardy must be corrected within 6 months. A facility's failure to achieve substantial compliance within 6 months will result in termination. (Immediate jeopardy deficiencies will result in termination within 23 days if the facility does not remove the threat to resident and employee safety by then.).

CMS's revisit policy can be found in §7317. The scope and severity grid can be found in §7400.

The policies and procedures related to citations of past noncompliance are applicable to health (F-tags) and life safety code (K-tags) deficiency citations. For specific guidance, see §7510.

7410.5 - Imposition of Remedies

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

For standard surveys that begin a noncompliance cycle, the survey agency will follow one of two enforcement processes. Instructions follow about how to determine which process to follow. The first process is one in which one enforcement track and set of time

frames is followed for all deficiencies, regardless of whether they are life safety code deficiencies or health deficiencies. This process is used when the life safety code portion and health portion of a standard survey occur together or when the beginning of the second (of the two surveys) occurs no more than 7 days from the exit of the first (of the two surveys). Time frames are combined and notices can be combined at the discretion of the survey agency. The second process is one in which two enforcement tracks and two sets of time frames are used for deficiencies, i.e., one track for the life safety code survey and another track for the health survey. This process is used when the standard survey is the beginning survey, and the life safety code portion and health portion of a standard survey occur more than 7 days apart, i.e., the beginning of the second (of the two surveys) occurs more than 7 days after the exit of the first (of the two surveys). Time frames and notices are separate for each survey. Both processes are predicated on the assumption that one or more life safety code requirements have not been waived.

7410.6 - Life Safety Code Survey Waiver Guidance

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

The authority to grant waivers of life safety code provisions is found at *§1819(d)(2)(B)(I)* of the Act and states, "The Secretary may waive, for such periods as he deems appropriate, specific provisions of such Code which if rigidly applied would result in unreasonable hardship upon a facility, but only if such waiver would not adversely affect the health and safety of the residents or personnel, …" The facility must document to the survey agency that there will be no adverse effect on the health and safety of the residents and employees of the facility and that compliance would result in an unreasonable hardship on the facility for each specific code provision recommended for a waiver.

The above authority to grant life safety code waivers does not include other Physical Environment requirements at *42 CFR 483.90* unless specifically provided for. Refer to §7014 for further guidance of non-life safety code requests for waivers or variations.

Waivers are classified into two groups: temporary waivers for a defined time period; and continuing waivers that are of indeterminate duration.

7410.6.1 - Temporary Waiver

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

A temporary waiver for a defined time period may be considered for a finding for which corrective action will take more than 90 days to complete. If a waiver is granted during that time, sanctions will not be imposed under the long-term care enforcement regulations. Examples of the type of corrective action that could warrant a temporary waiver could include installation of a sprinkler system or a smoke barrier. Examples of deficiencies that could warrant such waivers include the obstruction of exiting, penetrations of smoke barriers, and increased travel distances to exits due to new construction or remodeling of a wing of a facility. In these cases, the waiver would be for a reasonable period of time for construction activities, including planning and design. The waiver documentation submitted by the facility for approval would include a

timetable with milestone dates of major activities to correct the deficiency that the surveyor could monitor on any subsequent follow-up visits. Extensions and modifications of this timetable are not envisioned except under extreme circumstances. Failure of the facility to follow the timetable and the milestones established in the approved temporary waiver would subject the facility to the remedies prescribed in the enforcement regulations. If the construction activities are completed within the agreed upon timetable and the deficiency is corrected, the existence of the waiver is no longer cited on the Form CMS-2567.

When the temporary waiver of life safety code requirements is in effect, the facility should have increased fire safety awareness. This increased fire safety awareness may include the establishment of interim safety measures such as a fire watch during construction, an increased number of fire drills and training of staff at the facility, or other measures that would provide an increased measure of fire protection.

7410.6.2 - Continuing Waivers

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

Continuing waivers of a specific life safety code requirement are granted when the noncompliance cannot be corrected without an unreasonable financial hardship on the facility and it does not pose a threat to residents' health and safety. The State cites the deficiency on each annual survey although they do not expect it to be corrected by the facility due to the existence of the waiver. Examples of this type of finding may include improper corridor width either before or after remodeling, a dead-end corridor longer than the specified life safety code length, a specific construction type not met, a noncompliant interior finish type, excessive exit travel distance, or waiting areas open to the corridor in a non-sprinklered facility. CMS grants waivers after an evaluation of the specific life safety code deficiency cited and its impact on the life safety of the facility.

A waiver of a life safety code requirement that cannot be corrected and which is likely to be cited on each future life safety code survey may be granted for more than 1 year or survey interval. For example, CMS could grant a waiver for a 3-year period after which the State reviews it during the life safety code survey; if the waiver is still appropriate, it can be extended for another 3-year period. The survey agency cites the deficiency on the annual survey and on the Form CMS-2567 but reviews the waiver only after the expiration of the 3-year period. The plan of correction, submitted by the facility for that deficiency, would cite the existence of a waiver.

7410.6.3 - Enforcement and Waived Life Safety Code Requirements

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

For those life safety code requirements that CMS has temporarily waived, the following enforcement timetable should be used:

ENFORCEMENT TIMETABLES

Day 1:	**The date of the follow-up survey to determine if they have met the plan of correction.** This date can be no sooner than the provider's projected correction date, indicated on an approved plan of correction. Even if substantial compliance is not achieved, CMS lifts the waiver on this date and the "enforcement clock" starts.
3rd Month:	**Denial of payment for new admissions** is imposed based on life safety code noncompliance cited when CMS lifts the waiver, and noncompliance continues for a 3-month period after that date.
6th Month	**Termination occurs**, based on life safety code noncompliance cited when CMS lifts the waiver, and noncompliance continues up to a 6-month period after that date.

*Day 1 can occur a substantial amount of time after the life safety code survey that originally triggered the waiver.

Remedies

7500 - Directed Plan of Correction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

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.

7500.3 - Elements of a Directed Plan of Correction
A directed plan of correction should address all of the elements required for a facility-developed plan of correction. (See §7304)

7500.4 - Causes
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Use of a directed plan of correction should be dependent upon causes identified by the State, regional office, or temporary manager. For example, a directed plan of correction may be appropriate when a facility's heating system fails. The directed plan of correction would specify that the heating system must be repaired or replaced within a specific time frame. If the cause of the noncompliance was a specific structural problem, the facility could be directed to implement identified structural repairs such as a new roof, or renovations such as replacement of rusted sinks in common bathrooms.

7500.5 - Notice of Imposition of Directed Plan of Correction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A directed plan of correction may be imposed 15 calendar days after the facility receives notice in non-immediate jeopardy situations and 2 calendar days after the facility receives notice in immediate jeopardy situations. The date the directed plan of correction is imposed does not mean that all corrections must be completed by that date.

7502 - Directed In-Service Training

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

7502.1 - Introduction

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

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

7502.2 - Purpose

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

Directed in-service training is a remedy that may be used when the State, CMS, or the temporary manager believe that education is likely to correct the deficiencies and help the facility achieve substantial compliance. This remedy requires the staff of the facility to attend an in-service training program. The purpose of directed in-service training is to provide basic knowledge to achieve and remain in compliance with Federal requirements.

7502.3 - Appropriate Resources for Directed In-Service Training Programs

(Rev. 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 488.406*.

7502.5 - Notice of Imposition of Directed In-Service Training
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Directed in-service training may be imposed 15 calendar days after the facility receives notice in non- immediate jeopardy situations and 2 calendar days after the facility receives notice in immediate jeopardy situations.

7504 - State Monitoring
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7504.1 - Introduction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

This section is established pursuant to §1819(h)(2)(E)(ii) and §*1919(h)(2)(D)(ii)* of the Act (which cross-refers to §1819(g)(4)(B) and *§1919(g)(4)(B*) of the Act) and *42 CFR 488.422* to provide guidance in applying the remedy of State monitoring. This section also explains when State monitoring is imposed and the qualifications for a State monitor.

7504.2 - Purpose
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A State monitor oversees the correction of cited deficiencies in the facility as a safeguard against further harm to residents when harm or a situation with a potential for harm has occurred.

7504.3 - Qualifications
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Monitors are identified by the State as appropriate professionals to monitor cited deficiencies. A monitor meets the guidelines regarding conflicts of interest in §7202 and:

- Is an employee or contractor of the State;
- Is not an employee or contractor of the monitored facility; and
- Does not have an immediate family member who is a resident of the facility.

7504.4 - When to Impose the State Monitoring Remedy
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The Act requires State monitoring if a facility has been found on three consecutive standard surveys to have provided substandard quality of care. Otherwise, State monitoring may be considered an optional remedy. For example, some situations in which State monitoring may be appropriate include, but are not limited to, the following:

- Poor facility compliance history, e.g., a pattern of poor quality of care, many complaints, etc.;

- State concern that the situation in the facility has the potential to worsen;

- Immediate jeopardy exists and no temporary manager can be appointed;

- If the facility refuses to relinquish control to a temporary manager, a monitor may be imposed to oversee termination procedures and transfer of residents; or

- The facility seems unable or unwilling to take corrective action for cited substandard quality of care.

7504.5 - Frequency

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

When State monitoring is imposed, the State appoints a monitor or monitors. Monitoring may occur anytime in a facility, e.g., the State may determine that ongoing monitoring is needed 24 hours a day, 7 days a week, or it may determine that monitoring is only needed periodically. In all instances, monitors have complete access to all areas of the facility, as necessary, for performance of the monitoring. Factors used to determine how often a facility is monitored may include, but are not limited to, the following:

- The nature and seriousness of the deficiencies as specified by the State; and

- The timing and frequency of when the problems occurred, e.g., mealtimes, evening shifts, daily, etc.

Monitors may be assigned to the facility at these specific times for a specified number of days, as determined by CMS or the State, to ensure corrective action.

7504.6 - Duration

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

The remedy is discontinued when:

- The facility's provider agreement is terminated; or

- The facility has demonstrated to the satisfaction of CMS or the State that it is in substantial compliance with the requirements and, if imposed for repeated substandard quality of care, that it will remain in substantial compliance.

Continued compliance can be demonstrated by adherence to a plan of correction which delineates what systemic changes will be made to ensure that the deficient practice will not recur and how the facility will monitor its corrective actions to ensure it does not recur.

7506 - Denial of Payment for all New Medicare and Medicaid Admissions for Skilled Nursing Facilities and Nursing Facilities

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

7506.1 - Introduction

(Rev. 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. 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 §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 *Administrative* 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.

7506.3 - Mandatory Denial of Payment for All New Admissions Remedy

Sections *1819(h)(2)(D) and (E)* and *1919(h)(2)(C) and (D)* of the Act and *42 CFR 488.417(b)* require that, regardless of any other remedies that may be imposed, denial of payment for new admissions *(DPNA)* must be imposed when the facility is not in substantial compliance 3 months after the last day of the survey identifying deficiencies, or when a facility has been found to have furnished substandard quality of care on the last three consecutive standard surveys (see *42 CFR 488.414).*

- Medicare Facilities. CMS must deny payment to the facility for all new Medicare admissions.

- Medicaid Facilities. The State Medicaid Agency must deny payment to the facility, and CMS must deny Federal financial participation to the State Medicaid Agency for all new Medicaid admissions to the facility.

Timeliness of Mandatory DPNA Notification for Nursing Homes – The SA must adhere to enforcement processing timeframes so that mandatory DPNA is imposed when a nursing home is not in substantial compliance three months after the date of the original survey. The SA must transfer the enforcement case to CMS by the 70th day or the imposition notice is sent by the SA (as authorized by CMS) to the provider by the 70th day. However, there may be other instances in which cases should be immediately transferred to the CMS Location (i.e. enhanced enforcement). Contact your location for additional information. This excludes cases involving Medicaid-only nursing homes.

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 *Administrative* Contractor in Medicare cases, and in Medicaid cases, through written instructions from the CMS Location.

7506.5 - Effect of Remedy on Status of Residents Admitted, Discharged, or on Temporary Leave and Readmitted Before, On, or After the Effective Date of the Denial of Payment for New Admissions Remedy

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

(See also instructions for Fiscal Intermediaries, Pub. 60AB, Program Memorandum AB-01-131.) The resident's status on the effective date of the denial of payment for new admissions remedy is the controlling factor in determining whether readmitted residents are subject to the sanction. Guidelines follow:

- Medicare and Medicaid residents admitted and discharged before the effective date of the denial of payment for new admissions remedy are considered new

admissions if they are readmitted on or after the effective date. Therefore, they are subject to the sanction.

- Medicare and Medicaid residents admitted on or after the effective date of the denial of payment for new admissions remedy are considered new admissions. If readmitted after being discharged, they continue to be considered new admissions and are subject to the sanction.

- Medicare and Medicaid residents admitted before and discharged on or after the effective date of the denial of payment for new admissions remedy are considered new admissions if subsequently readmitted. Therefore, they are subject to the sanction.

- Medicare and Medicaid residents admitted on or after the effective date of the denial of payment for new admissions remedy who take temporary leave are not considered new admissions when they return, but continue to be subject to the sanction.

- Private pay residents admitted after the effective date of the denial of payment for new admissions remedy and then become eligible for Medicare or Medicaid, are subject to the sanction.

- Medicare and Medicaid residents admitted before the effective date of the denial of payment for new admissions remedy who take temporary leave before, on, or after the effective date of the denial of payment remedy are not considered new admissions upon return and, therefore, are not subject to the sanction.

- Private pay residents in a facility prior to the effective date of the denial of payment for new admissions remedy who become eligible for Medicare or Medicaid on or after the effective date of the denial of payment for new admissions remedy are not subject to the sanction.

NOTE:

1. The term "temporary leave" refers to residents who leave temporarily for any reason. If residents were not subject to a denial of payment when they went on temporary leave, the term indicates that upon return they are not considered new admissions for purposes of the sanction. Therefore, since there is an expectation that this resident will return to the facility, the term "temporary leave" is used to justify a resumption of any interrupted payment upon re-entry into the facility.

2. The term "discharge" refers to individuals who have left the facility and there is no expectation that they will return.

3. Only Part A providers are subject to the denial of payment for new admissions remedy.

A resident who is not subject to the denial of payment sanction and goes on temporary leave, whether or not there is a leave of absence, is not considered to be a new admission for the purposes of the denial of payment remedy, upon his/her return to the facility. Any interrupted payment will be resumed. In either situation, it is expected that the resident will return to the facility following leave.

7508 - Secretarial Authority to Deny All Payment for All Medicare and Medicaid Residents

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

7508.1 - Introduction

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

Sections *1819(h)(2)(B)(i)* and *1919(h)(3)(C)(i)* of the Act and *42 CFR 488.418* provide that if a facility has not met a requirement, the Secretary may deny any further payment to the facility for all Medicare residents, and to a State Medicaid Agency for all Medicaid residents in the facility. This is in addition to the authority to deny payment for all new admissions discussed in §7506. Although either CMS or the State Medicaid Agency may deny payment for all new Medicare and/or Medicaid admissions as described in §7506, only CMS has the authority to deny all payment for Medicare and/or Medicaid residents. (The State, however, may recommend that CMS impose this remedy.) The denial of all payment remedy may be imposed anytime the facility is found to be out of substantial compliance (as defined in *42 CFR 488.301)*, as long as the facility is given written notice at least 2 calendar days before the effective date in immediate jeopardy situations and at least 15 calendar days before the effective date in non-immediate jeopardy situations. CMS will provide the State with timely notification whenever it decides to impose this remedy.

Although *§1819(h)(2)(B)(i)* and *§1919(h)(3)(C)(i)* of the Act and *42 CFR 488.418(a)* provide that the Secretary may impose this remedy whenever a facility has not met a requirement, it is a severe sanction. Factors to be considered in selecting this remedy could include:

1. Seriousness of current survey findings;

2. Noncompliance history of facility; and

3. Use of other remedies that have failed to achieve or sustain compliance.

7508.2 - Duration and Resumption of Payments

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

Generally, if a facility achieves substantial compliance, CMS resumes payments to the facility **prospectively** from the date that it verifies (in accordance with §7317) as the date that the facility achieved substantial compliance. No payments are made to reimburse the facility for the period of time between the date the remedy was imposed and the date that CMS verifies as the date that the facility achieved substantial compliance. When CMS denies payment for all Medicare residents for three consecutive findings of substandard quality of care, the denial of payment cannot be lifted until the facility achieves substantial compliance and CMS believes that the facility will remain in substantial compliance.

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 *CMP* 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, *or both,* regardless of whether the deficiencies constitute immediate jeopardy. Additionally, per instance *CMPs* may be imposed for past noncompliance. An "instance *or instances of noncompliance" means a factual and temporal occurrence(s) when a facility is not in substantial compliance with the requirements for participation. Each instance of noncompliance is sufficient to constitute a deficiency and a deficiency may comprise of multiple instances of noncompliance*. There can be more than one instance of noncompliance identified during a survey. (See §7510.2 for guidance on past noncompliance.)

The CMS Location or State Medicaid Agency may impose a *CMP* between $3,050 and $10,000♦ per day of immediate jeopardy, or between $50 and $3,000♦ per day of non-immediate jeopardy *for each deficiency*, and/or "per instance" civil money penalties from $1,000 to $10,000 *(as adjusted for inflation at 45 CFR 102.3)* for each *instance of noncompliance*. *CMS and the State may impose a per day civil money penalty, a per instance civil money penalty, or both, in addition to the remedies specified in § 488.408(e)(2)(i). When a survey contains multiple instances of noncompliance, CMS and the State may impose any combination of per instance or per day CMPs, regardless of whether the deficiencies constitute immediate jeopardy (the aggregate daily amounts may not exceed the maximum amount). (See 7301.1 and 7302.1 for guidance on the civil money penalty amounts that may be imposed.)*

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*.

♦ *Federal CMPs are imposed in accordance with the instructions in the CMP Analytic Tool. Note that the CMP amount ranges that are noted here reflect the original statutory and regulatory amounts however, the amounts are subject to annual inflation adjustments under 45 CFR 102.3, see §7513 for more information.*

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 *previously cited* noncompliance since the last *three* standard survey*s*. When a CMP is recommended, the State 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.

7510.2 – Documentation of Past Noncompliance Citations on the CMS-2567

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

Past noncompliance may be cited on health and/or life safety code surveys of nursing homes. Past noncompliance may be cited on any type of survey (standard, recertification, abbreviated standard, e.g., complaint and revisit). Data about past noncompliance tags are not carried forward to subsequent revisit surveys.

Past noncompliance is documented at the actual deficiency tag (F-tags for health deficiencies or K-tags for life safety code deficiencies) where past noncompliance is identified. A scope and severity determination is assigned to a past noncompliance citation. Surveyors document on the CMS-2567 the nursing home's actions to correct the past noncompliance.

CMS or the State indicates in the appropriate data field in the *iQIES* whether a citation is past noncompliance. Tags cited as past noncompliance will appear in tag number order on the CMS-2567. The provider's plan of correction column on the CMS-2567 will print "Past noncompliance-no plan of correction required" for tags identified as past noncompliance.

The *iQIES CMS iQIES Survey & Certification User Manuals* include technical information about past noncompliance citations. This guide is located at the following Web site address: *https://qtso.cms.gov/software/iqies/reference-manuals.*

7510.3 – Applicability to Disapproval of Nurse Aide Training and Competency Evaluation Program

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

The provisions of §7809 (NATCEP Disapprovals) apply to findings of past noncompliance. (See also §7809.2.)

7512 - Compliance *w*ith 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.

7513 – The Federal Civil Penalties Inflation Adjustment Act Improvement Act of 2015

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act) requires federal agencies to publish annual penalty inflation adjustments (see sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. 114-74). The 2015 Act amends the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L 101-410) which was enacted to improve the effectiveness of federal CMPs and to maintain their deterrent effect. The 2015 Act adjustments only affects specific CMP amounts and not other related provisions, such as the factors reviewed for assessing CMPs. For SNFs, NFs and SNF/NFs, the CMP Analytic Tool instructions and calculations are updated to reflect the annual adjustments for inflation. For more information visit the CMS Civil Monetary Penalties (Annual Inflation Adjustment) webpage and https://qcor.cms.gov/main.jsp.

7514 - Special Procedures Regarding Compliance Decision and Overlap of Remedies

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

If CMS and the State Medicaid Agency both want to impose civil money penalties on any given facility, only CMS's civil money penalty is imposed. Special procedures specified in §7807 implement the provisions of *§1919(h)(6) and §1919(h)(7)* of the Act as well as *42 CFR 488.452* regarding whether the State or Federal remedy decision takes precedence in non-immediate jeopardy situations involving non-State operated nursing facilities and dually participating facilities.

7516 - Determining Amount of Civil Money Penalty

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

7516.1 - Range of Penalty Amounts

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

Civil money penalties are imposed in increments of $50.00 ♦.

1. Lower Range of Penalty Amounts for Per Day Civil Money Penalty

Penalties in the range of $50 to $3,000 ♦ per day may be imposed when immediate jeopardy does not exist, but the deficiencies either caused actual harm, or caused no actual harm, but have the potential for more than minimal harm. A civil money penalty may not be less than $50.00 per day ♦.

2. Upper Range of Penalty Amounts for Per Day Civil Money Penalty

Penalties in the range of $3,050 to $10,000 ♦ per day may be imposed for deficiencies constituting immediate jeopardy. Penalties may also be in the upper range of penalty amounts for deficiencies when immediate jeopardy does not exist if a penalty in the lower

range of penalty amounts was previously imposed and the deficiencies in the same regulatory grouping are repeated. Repeated deficiencies are defined in §7516.3.

3. Range of Per Instance Penalty Amounts

Penalties in the range of $1,000 to $10,000 ♦ per instance(s) may be imposed for noncompliance that constitutes actual harm, or for noncompliance that has the potential for more than minimal harm. The terminology "per instance" is not used to suggest that only one instance of noncompliance may be assigned a *CMP*. There can be more than one instance of noncompliance identified during a survey where the State utilizes the per instance *CMP* as an enforcement remedy. The total dollar amount of the civil money penalties for noncompliance *on **any single day*** may not exceed *the statutory and regulatory maximum amount and may not be less than the statutory and regulatory minimum amount for each day. When multiple per instance civil money penalties are imposed for **different days** of noncompliance, the total aggregate amount of all civil money penalties imposed for the survey may exceed the statutory and regulatory maximum (the statutory maximum only applies to the civil money penalty amount for any single day).*

NOTE: In situations of past noncompliance, see §7510.1 and §7510.2.

♦ *Federal CMPs are imposed in accordance with the instructions in the CMP Analytic Tool. Note that the CMP amount ranges that are referenced here are the original statutory and regulatory amounts, but these amounts are subject to annual inflation adjustments that are published at 45 CFR 102.3. See §7513 for more information.*

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 *iQIES* system *or subsequent system,* 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 *Administrative* 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. *Sections 7203.3.1 and 7410.2* 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.

7516.3 - Changing Amount of Civil Money Penalty

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

When the per instance civil money penalty has been selected as an enforcement remedy, the provision for changing the amount of the civil money penalty does not apply and no opportunity to correct is provided.

The amount of a per day civil money penalty can be adjusted within a given civil money penalty range.

The range of a per day civil money penalty amount may be decreased or increased in accordance with the guidance that follows:

1. Decreasing Per Day Civil Money Penalty Range

If a civil money penalty is imposed for a situation of immediate jeopardy and the immediate jeopardy is removed but the noncompliance continues, CMS or the State will shift the penalty amount to the lower range of penalty amounts. *When the civil money penalty amount is lowered following an immediate jeopardy, the lower level amount will accrue until substantial compliance or unless increased due to new noncompliance.*

2. Increasing Per Day Civil Money Penalty Range

Before the hearing, and following a revisit showing continued noncompliance, CMS or the State may propose to increase the penalty amount for facility noncompliance, which after imposition of a lower level penalty amount, becomes sufficiently serious to pose immediate jeopardy.

If a civil money penalty is imposed, CMS and the State must increase the penalty amount for any repeated deficiencies for which a lower level penalty amount was previously imposed, regardless of whether the increased penalty amount would exceed the range otherwise reserved for deficiencies when immediate jeopardy does not exist.

3. Repeated Deficiencies

(See *42 CFR 488.438(d)(3)*. These are deficiencies *in the same regulatory grouping of requirements cited since the last standard survey for which a CMP was previously imposed, subsequently corrected, and found again at the next survey. This includes any deficiencies cited on an intervening abbreviated standard survey for which a CMP was previously imposed since the last standard survey.* For example, a civil money penalty is imposed and sustained in some amount for deficiencies under Quality of Care related to hydration (see *42 CFR 483.25(g))* during a standard survey. These deficiencies are corrected at the time of the revisit. However, at the next survey, the facility has deficiencies in Quality of Care related to nutrition. (See *42 CFR 483.25(g)*)In this situation, if a civil money penalty is imposed for the repeated noncompliance, it should be higher than the civil money penalty that was previously imposed for the Quality of Care deficiencies pertaining to hydration.

7516.4 – Reduction of a Civil Money Penalty by 50 Percent for Self-Reporting and Prompt Correction of Noncompliance

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

CMS will reduce a civil money penalty by 50 percent when a facility self-reports and promptly corrects a deficiency for which a civil money penalty is imposed by CMS provided all of the following conditions are met:

a) The facility must have self-reported the noncompliance to CMS or the State before it was identified by CMS or the State and before it was reported to CMS or the State by means of a complaint lodged by a person other than an official representative of the nursing home;

b) Correction of the noncompliance must have occurred on the earlier of either 15 calendar days from the date of the self-reported circumstance or incident that later resulted in a finding of noncompliance or 10 calendar days from the date a civil money penalty was imposed;

c) The facility waives its right to a hearing;

d) The noncompliance that was self-reported and corrected did not constitute a pattern of harm, widespread harm, immediate jeopardy, or result in the death of a resident;

e) The civil money penalty was not imposed for a repeated deficiency that was the basis of a civil money penalty that previously received a 50 percent reduction; and

f) The facility has met mandatory reporting requirements for the incident or circumstance upon which the civil money penalty is based as required by Federal and State law.

Correction will be determined by CMS or the State with an on-site visit or based upon an examination of credible written evidence that CMS or the State can verify without an on-site visit.

NOTE: Under no circumstances will a facility receive both the 50 percent reduction for self-reporting and correcting and the 35 percent reduction for waiving its right to a hearing.

7518 - Effective Date of Civil Money Penalty

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

The per day civil money penalty may start accruing as early as the date that the facility was first out of compliance, as determined by CMS or the State. The per instance civil money penalty is for *an instance or instances of noncompliance* within a specific survey (i.e., standard, revisit, complaint) up to a maximum of $10,000♦ for ***each day*** *of noncompliance (see sections 7301.1 and 7301.2 for examples)*. The effective date of the per day civil money penalty will often be the date of the survey because it may be difficult to document precisely when noncompliance begins if before the date of survey. For purposes of recording the imposition of the per instance civil money penalty, the date of occurrence of the noncompliance may be used. However, for purposes of recording the deficiency on the Form CMS-2567, the effective date of the per instance civil money penalty must be the last day of the survey that identified the noncompliance against which it is being imposed. This will permit the input of deficiencies into the *iQIES, or subsequent system*.

A civil money penalty cannot be collected until a facility has an opportunity for a hearing if it properly requests one. Allowing an effective date for the accrual of a per day civil money penalty to be as early as the date of the noncompliance permits the noncompliance to be sanctioned promptly and requires that the facility be notified promptly of the imposition of the civil money penalty. However, if there is undue delay in notifying the facility of the civil money penalty, it is possible that the effective date of the penalty could be moved to a date later than the date of the noncompliance.

♦ *Federal CMPs are imposed in accordance with the instructions in the CMP Analytic Tool. Note that the CMP amount ranges that are referenced here are the original statutory and regulatory amounts, but these statutory and regulatory amounts are subject to annual inflation adjustments under 45 CFR 102.3. See §7513 for more information.*

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..

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.

7520.1 - Responsibility for Issuing Notice

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

CMS sends a written notice of the imposition of the civil money penalty when CMS is imposing the civil money penalty on a skilled nursing facility, nursing facility, or dually participating facility. The State Medicaid Agency sends a written notice of the imposition of the civil money penalty when the State Medicaid Agency is imposing a civil money penalty on a non-State operated nursing facility.

7520.2 - Content of Notice

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

In addition to the notice requirements in §7305, the following civil money penalty information is included:

1. The nature of the noncompliance (regulatory requirements not met);

2. The statutory basis for the civil money penalty;

3. The amount of the penalty per day of noncompliance *and/*or the amount of the penalty per instance of noncompliance during a survey;

4. The factors that were considered in determining the amount of the civil money penalty;

5. The date on which the per day civil money penalty begins to accrue;

6. A statement that the per day civil money penalty will stop accruing on the date on which the facility comes into substantial compliance or is terminated from participation in the program;

7. When the civil money penalty is collected;

8. Statement of the facility's right to a hearing and information about how to request a hearing; and

9. Implications of waiving the right to a hearing and information about how to waive the right to a hearing. (See §7526.2.)

7522 - Duration of Civil Money Penalty

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

The per day civil money penalty *may* accrue for the number of days of noncompliance from the date that the deficiency starts until the date that the facility achieves substantial compliance or, if applicable, the date of termination. For example, if a facility is found in substantial compliance or its provider agreement is terminated on May 18, the accrual of the civil money penalty stops on May 17.

The per instance civil money penalty is imposed for each instance of noncompliance based on a deficiency during a specific survey. It is applied to as many instances as is deemed appropriate during a specific survey up to a total of $10,000 *for each day of noncompliance (as adjusted for inflation by 45 CFR 102.3)*.

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 *F*-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*, or both,* 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 *example*, noncompliance was identified at *F689* during the original survey. During the revisit survey, a different problem dealing with the elopement of three residents was cited at *F689*. The per instance or per day civil money penalty*, or both, could* be selected for the noncompliance identified at *F689*. *A per instance civil money penalty may be imposed for each instance of noncompliance (refer to 7301.1)*.

7522.2 - Revisit Identifies New Noncompliance and a Different Data Tag is Selected

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

If a revisit identifies new deficiencies at a different data tag, a per instance or per day civil money penalty*, or both,* could be selected as an enforcement remedy.

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 *instances of noncompliance* during a survey for which the civil money penalty is determined to be an appropriate remedy. *For examples of per instance civil money penalties, see sections 7301.1 and 7301.2.*

7522.4 - Noncompliance - Immediate Jeopardy Exists
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

For noncompliance that poses immediate jeopardy, CMS or the State must terminate the provider agreement within 23 calendar days after the last day of the survey that identified the immediate jeopardy if the immediate jeopardy is not removed. If the life safety code survey found the immediate jeopardy, CMS or the State must terminate the provider agreement within 23 calendar days after the last day of the life safety code survey. The accrual of the per day civil money penalty stops on the date that the provider agreement is terminated. The per instance civil money penalty is limited to *the regulatory maximum amount for each day of noncompliance.*

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 - Appeal of Noncompliance That Led to Imposition of Civil Money Penalty
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7526.1 - Facility Requests Hearing on Noncompliance That Led to Imposition of Civil Money Penalty
(Rev. 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 *is considered to have w*aive*d its* right to a hearing *when CMS has not received a request for a hearing* within 60 calendar days from the date of the notice of imposition of the civil money penalty. (See 42 CFR 488.436).

If a facility waives its right to a hearing, the CMS Location or the State Medicaid Agency reduces the civil money penalty amount by 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 - When Penalty Is Due and Payable

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

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

(Rev. 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 and in accordance with 42 CFR 488.442. 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.

7528.3 - No Hearing Requested *(Constructive Waiver)*

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

Payment of a civil money penalty is due 15 calendar days after the time period for requesting a hearing has expired and a hearing request was not received when:

1. The facility achieved substantial compliance before the hearing request was due; or

2. The effective date of termination occurred before the hearing request was due.

7528.4 - After Waiver *of* Hearing

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

Payment of a civil money penalty is due 15 calendar days *after the 60 day timeframe that a facility has to request* a hearing *has passed* when:

1. The facility achieved substantial compliance before *the facility waived* its right to a hearing;

2. A per instance civil money penalty has been imposed. Since no opportunity to correct is available for the noncompliance against which a per instance civil money penalty is imposed, allowing time for the facility to achieve substantial compliance is not a factor in determining when the civil money penalty is due; or

3. The effective date of termination occurred before *the facility waived* its right to a hearing.

7528.5 - After Substantial Compliance is Achieved
(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

Payment of a per day civil money penalty is due 15 calendar days **after** substantial compliance is achieved when:

1. A final administrative decision, upholding the imposition of the civil money penalty, is made before the facility achieved substantial compliance;

2. The facility did not file a timely hearing request before it achieved substantial compliance; or

3. The facility waived its right to a hearing before it achieved substantial compliance.

However, the period of noncompliance covered by the civil money penalty may not extend beyond 6 months from the last day of the standard health survey.

7528.6 – After Effective Date of Termination
(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

Payment of a civil money penalty is due 15 calendar days after the effective date of termination, if before the effective date of termination:

1. The final administrative decision was made upholding the imposition of the civil money penalty; *or*

The time for requesting a hearing has expired and the facility did not request a hearing

7530 - Notice of Amount Due and Collectible
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7530.1 - Contents of Notice
(Rev. 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 *Baltimore* 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 *via Automated Clearing House (ACH) using the pay.gov portal or* by check to CMS if the *payment* 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 - Disposition of Collected Civil Money Penalty
(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

7534.1 - Collected From Medicare or Dually-Participating Facility
(Rev. 213; Issued: 02-10-23; Effective: 02-10-23; Implementation: 02-10-23)

A Federal civil money penalty (CMP) collected by CMS from a dually-participating facility is apportioned commensurate with the relative proportions of Medicare and Medicaid beds at the facility actually in use by residents covered by the respective programs on the date the CMP begins to accrue, per resident census data obtained at the time of the survey.

After this apportionment is made, the Medicaid portion of the CMP is returned to the State. For the Medicare portion, ten percent of the CMP funds that are subject to being held in escrow and that remain after a final administrative decision are deposited with the Department of the Treasury. The remaining ninety percent of the Medicare portion of the CMP funds that are subject to being held in escrow, and that remain after a final administrative decision, are subject to the same uses as the Medicaid-portion of the Federal CMP that is returned to the State (see §7535). For a Medicare-only facility, the entire collected CMP amount is still subject to the 10%/90% split. These Federal CMP funds may not be used for survey and certification operations or State expenses, except that reasonable expenses necessary to administer, monitor, or evaluate the effectiveness of projects utilizing CMP funds may be permitted. Funds must be used entirely for activities that protect or improve the quality of care or life of residents. These activities must be approved as specified under §7535.1).

EXAMPLE: *In a dually-participating facility that has the capacity to provide care for 100 residents, 70 residents are in the facility on the date that the CMP begins to accrue. Of the 70 residents, Medicare is the primary payer for 15 residents, Medicaid is the primary payer for 45 residents, and 10 residents pay for their own care. Thirty of the total 100 beds are empty. There are 60 Medicare and Medicaid residents. The amount of the CMP is apportioned as follows:*

- *75 percent (45/60 residents= 75%) is returned to the State to benefit nursing home residents consistent with §7535 and 25 percent is the federal share;*
- *10 percent of the 25 percent (15/60= 25%) federal share of the CMP would be returned to the Department of the Treasury; and*
- *The remaining 90 percent of the 25 percent (15/60) federal share is used by CMS in accordance with §7535 for activities that protect or improve the quality of care or life of residents.*

NOTE: *All Federal CMPs are subject to being held in escrow and are disbursed as described above upon final administrative decision."*

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.

7534.2 - Collected From Medicaid Facility

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

One-hundred percent of the Federal civil money penalty collected from a nursing facility

is returned to the State. These Federal CMP funds may not be used for survey and certification operations or State expenses, except that reasonable expenses necessary to administer, monitor, or evaluate the effectiveness of projects utilizing civil money penalty funds may be permitted. Funds must be used entirely for activities that protect or improve the quality of care for residents (see §7535). These activities must be approved by CMS as provided in §1919(h)(3)(C)(ii)(IV)(ff) of the Social Security Act and 42 CFR 488.433.

7534.3 –Imposed and Collected by a State from a Medicaid Facility

(Rev. Issued:, Effective:, Implementation:

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

A civil money penalty imposed and collected by a State from a Medicaid certified facility (either dually certified for Medicare and Medicaid, or Medicaid-only certified) that the State or CMS find deficient must be applied to the protection of the health or property of residents of nursing facilities that the State or CMS find deficient (see §1919(h)(2)(A)(ii) of the Social Security Act). Per statute and regulation (42 CFR 488.442(g)), appropriate uses by the State of the collected civil money penalty funds include:

1. *State costs related to the maintenance of operations of a facility pending correction of deficiencies or closure;*

2. *Reimbursement of residents for personal funds or property lost at a facility as a result of actions by the facility or by individuals used by the facility to provide services to residents. Established procedures for the reimbursement of residents are followed; and/or,*

3. *Payment for the cost of relocating residents to other facilities.*

In contrast to funds collected under Federal authority, CMS does not have the authority to endorse, approve, disapprove, or otherwise make determinations about suggested uses for civil money penalties collected by a State. Instead, States have the authority to determine which activities constitute acceptable uses of the funds, as long they are applied to the protection of the health or property of residents of nursing facilities.

7534.4 – Collected Amounts from a Dually Participating Facility or Medicare Facility and Held in Escrow

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

A civil money penalty collected from a dually participating facility is apportioned between Medicare and Medicaid commensurate with the relative proportions of Medicare and Medicaid beds at the facility actually in use by residents covered by the respective programs on the date the civil money penalty begins to accrue, per resident census data in the *iQIES* at the time of the survey.

After this apportionment is made, ten percent of the Medicare portion of collected civil money penalty funds that are subject to be held in escrow and that remain after a final

administrative decision will be deposited with the Department of the Treasury. The remaining ninety percent of the collected civil money penalty funds that are subject to be held in escrow and that remain after a final administrative decision may not be used for survey and certification operations but must be used entirely for activities that protect or improve the quality of care for residents. These activities must be approved by CMS as provided in Sections *1819(h)(2)(B)(ii)(IV)(ff)* and *1919(h)(3)(C)(ii)(IV)(ff)* of the Act.

7535 - Use of Civil Money Penalty Funds

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

Sections 1819(h)(2)(B)(ii)(IV)(ff) and 1919(h)(3)(C)(ii)(IV)(ff) of the Act incorporate specific provisions of the Patient Protection and Affordable Care Act (the Affordable Care Act) pertaining to the collection and uses of CMPs imposed by CMS when nursing homes do not meet requirements for Long Term Care Facilities.

1. *42 CFR §488.433 further specifies that all activities and plans for utilizing federal civil money penalty funds, including any expense to administer projects utilizing civil money penalty funds must be approved in advance by CMS.* The Act provides that collected CMP funds may be used to support activities that benefit residents *and* include, but are not limited to:

a) Assistance to support and protect residents of a facility that closes (voluntarily or involuntarily) or is decertified (including offsetting costs of relocating residents to home and community-based settings or another facility);

b) Time-limited expenses incurred in the process of relocating residents to home and community-based settings or another facility when a facility is closed (voluntarily or involuntarily) or downsized pursuant to an agreement with the State Medicaid agency;

c) Projects that support resident and family councils and other consumer involvement in assuring quality care in facilities; and

d) 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).

e) Development and maintenance of temporary management or receivership capability, such as but not limited to recruitment, retention, training, or other system infrastructure expenses. However, as specified in §488.415(c), a temporary manager's salary must be paid by the facility. In rare situations, if the facility is closing, CMS plans to stop or suspend continued payments to the facility under 42 CFR § 489.55 during the temporary manager's duty period, and CMS determines that extraordinary action is necessary to protect the residents

until relocation efforts are successful, CMP funds may be used to pay the manager's salary (for unique situations, see exceptions in Section 3 below).

For more details about allowable uses of CMP funds within the regulatory provisions listed above, see section 7535.1 below (Allowable and Non-Allowable of the Use of Civil Money Penalty Funds)

Civil Money Penalty Use Applications

The specific use of CMP funds collected from SNF, NF, or SNF/NF as a result of Federally imposed CMPs must be approved in advance by CMS on behalf of the Secretary.

2. *Project application and budget requests are required to be submitted to the State Agency for initial review and recommendation. State Agencies make the initial decision if the requested project benefits nursing home residents and protect or improve their quality of care or quality of life. After the State Agency determines applications meet State requirements, the application and budget requests are sent to the CMS CMPRP team for review and final approval. After review of the application and budget request, CMS will provide one of the following notifications within 45 days of receipt*:*

    a) *An approval. The application has met all application and CMP funding criteria and is approved for the use of CMP funding;*
    b) *A denial, with an explanation. The application has not met all application and CMP funding criteria and cannot be approved for the use of CMP funding. The reason for the application denial is specific to the prohibited uses of CMP funding, and the applicant cannot resubmit the application; or*
    c) *Request for additional information through corrective actions. When CMS identifies issues or additional application information is required, CMS will request up to two corrective actions for the applicant to respond to the requested information within a 45-day period. If all information is not received with the time period, the application will be returned and will need to be resubmitted as a new application.*

**CMS generally provides a final application decision within 45 days of receipt of the application. However, CMS may delay or place applications on hold to ensure that the intent of the CMP funds is spent appropriately and in accordance with 42 CFR §488.433.*

NOTE: *For questions related to the status of an application, the State should contact the CMP-Info@cms.hhs.gov mailbox.*

3. *Applications for CMP fund approval should contain a description of the proposed use/project that may include but is not limited to the information below.*

***NOTE**: An application template is available on the CMS Civil Money Penalty Reinvestment Resource website at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/LTC-CMP-Reinvestment.html*:

a) ***Applicant Contact Information:*** *contact information of the applicant;*
b) ***Applicant Organization Information:*** *contact information for the organization requesting CMP funds;*
c) ***Organization History:*** *describe the history of the organization requesting CMP funds;*

d) ***Organization capabilities:*** *Describe the organization's capabilities, including products and services relevant to the proposed CMP project.*
e) ***Organization Website:*** *Provide the website address for the organization requesting CMP funds, if available.*
f) ***Other Funding Sources:*** *indicate whether the applicant or collaborating partners receive Federal or State funds or whether other funding sources, such as Federal or State funds have been requested or applied for and/or granted.*
g) ***Total CMP Fund Requested Amount:*** *The specific amount of CMP funds to be used for this project;*
h) ***Detailed Line-Item Budget:*** *detailed line-item budget to outline specific cost requirements for the project;*
i) ***Budget Narrative:*** *justify the indirect cost and cost sharing amounts included in the budget for the project;*
j) ***Project Title:*** *provide the title/name of the project;*
k) ***Project Time Period:*** *provide the numbers of years and specific dates of the project;*
l) ***Project Category:*** *identify the category that describes the focus of the project;*
m) ***Summary of the Project and its Purpose:*** *Describe the problem, gap, or nursing home need the project is aiming to address, provide goals and objectives;*
n) ***Benefits to Nursing Home Residents:*** *Describe how this project will directly benefit nursing home residents.*
o) ***Nursing Home and Community Involvement:*** *Describe 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. If the organization applying is not a nursing home, letters of support from all participating nursing homes are provided with the application submission.*
p) ***Other Partnering Entities:*** *Provide any other collaborating entity(ies) that will be partnering with the applicant on the project (e.g., individuals, organizations, associations, facilities);*
q) ***Project Deliverables:*** *List any items that will be deliverables as a result of funding the project (e.g., electronics, training materials, curricula);*

r) ***Performance Monitoring and Evaluation:*** *A description of the methods by which the project results will be monitored or evaluated (including specific metrics) and the intended outcomes. If the applicant and project have previously been approved for CMP funding, results from the prior project should be submitted with the current application;*

s) ***Duplication of Effort:*** *Provide information that demonstrates the project will not duplicate or overlap with the responsibility of the nursing home to meet existing Medicare and Medicaid requirements and other statutory and regulatory requirements, nor duplicate Federal or State services;*

t) ***Risks:*** *Potential risks or barriers associated with implementing the project and a plan to address these concerns;*

u) ***Sustainability:*** *A description of how the project will be sustained after CMP funding concludes; and*

v) ***Signature and Date:*** *Provide the name and signature of the applicant along with the date of the signature.*

NOTE: *State Agencies should provide information to and obtain prior approval from its CMS CMPRP team for any project for which the State wishes to use CMP funds, including projects greater than three years. CMS reserves the right to disapprove such projects.*

4. State Agencies 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, including but not limited to one with the entity(ies) who will benefit from the intended project(s) or use(s); and

c) Not a recipient of a contract, grant or other payment from Federal or State sources for the same project(s) or 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. Aside from nursing homes, 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, private contractors, etc.*

NOTE: *States may review resources for submitting CMP applications on the CMS Civil Money Penalty Reinvestment Resource website available at:*

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/LTC-CMP-Reinvestment.html.

7535.1 –Allowable and Non-Allowable of the Use of Civil Money Penalty Funds

(Rev. Issued:, Effective:, Implementation:)

1) ***Allowable uses of CMP funds***

Examples of generally allowable uses of CMP funds are listed below. While the purpose of the project may be allowable, specific details of the project might not be not be allowable. Also, CMS may establish maximum funding amounts for projects. However, CMS will not automatically approve the maximum amount allowable for a project. Applicants must continue to clearly demonstrate the need and reasonableness for any funds requested. CMS will consider adjusting the dollar amounts over time (e.g., for inflation). Information on maximum funding amounts is available at the CMS Civil Money Penalty Reinvestment Program (CMPRP) CMS CMPRP website.

For applicants proposing to implement projects in nursing homes, letters of support from all participating nursing homes should be submitted with the application. The commitment letter must display the project title, time frame, the nursing home's CMS certification number (CCN), and the signature of an individual authorized to commit the nursing home. In the instance of a corporation submitting a project request on behalf of its nursing home(s), a single letter containing the above criteria for all participant facilities will suffice. Exceptions in rare cases to reduce or eliminate the need for letters of support may be available for programs such as state-based conferences where all nursing homes are invited to attend.

CMP funds may be generally used for projects within the following categories:

a) ***Resident or Family Councils:*** *CMP funds may be used for projects by not-for-profit resident advocacy organizations that:*

- *Assist in the development of new independent family councils;*
- *Assist resident and family councils in effective advocacy on their family member's behalf;*
- *Develop materials and training sessions for resident and family councils on state implementation of new federal or state legislation.*

b) ***Consumer Information****: CMP funds may be used to develop and disseminate information that is directly useful to nursing home residents and their families in becoming knowledgeable about their rights, nursing home care processes, and other information useful to a resident.*

c) ***Training to Improve Quality of Care****: CMP funds may be considered for training in facility improvement initiatives that are open to multiple nursing homes, including joint training of facility staff and surveyors, technical assistance for facilities implementing quality assurance programs, training for resident and/or family councils, LTC ombudsman or advocacy organizations and other activities approved by CMS.*

d) ***Activities to Improve Quality of Life****: CMP funds can be used for projects to foster social interaction, movement, and minimize loneliness.*

e) ***Emergency Use for States:*** *States can use CMP funds for time-limited assistance to support and protect residents of a facility that closes (voluntarily or involuntarily) or is decertified. Funding cannot be used for meeting regulatory requirements (e.g., see 42 CFR §483.73 Emergency preparedness). Allowable uses for emergency activities to assist and protect residents when a facility closes or is decertified may include, but are not limited to:*

- *Resident expenses such as food, supplies, medical equipment or medications necessary during the transfer and relocation process;*
- *Expenses for seeking resident guardianship for purpose of transfer, if required;*
- *State insurance expenditures, workmen's compensation, general liability insurance;*
- *Resident and family interactions to discuss transfer;*
- *Information for residents about facilities and working with facilities to discuss residents who may be transferring;*
- *Receivership costs (e.g., staff salaries, vendor payments). See subsection (j) (CMP Funds During Facility Closure Or Receivership) below for more information on receivership;*
- *Medical records copying; and,*
- *Transportation expenses if needed for resident and family to visit other facilities.*

Other requested uses not listed above must be reviewed by CMS to determine if they are appropriate and allowable or prohibited. Please see the Civil Money Penalty Reinvestment State Plans section (§7535.2) for further detail.

NOTE: States must obtain prior approval of use of CMP funds from CMS except for temporary use in the case of sudden nursing home relocations, natural disasters, or similar emergencies. In such emergency cases, the State must seek CMS approval within 10 working days of the emergency use of CMP funds. States shall report all CMP funds spent on emergencies in

accordance with its approved plan for the effective use of CMP funds. States shall report all CMP funds spent on emergencies (see §7535.2 State Plans,2(e) Emergency Reserve Fund Plans). CMP funding cannot be used for meeting regulatory requirements (e.g., see 42 CFR §483.73 Emergency preparedness) or for functions states are required to perform.

f) ***Administrative Use for States**: CMP funds can be requested by the state for certain reasonable costs of administering the CMP funds as part of the annual CMP State Plan process. For example, states may request funds for personnel required to solicit and review CMP Applications. The request should include adequate detail and justification for the requested amount including position descriptions and the breakdown of salary and benefits for each position. Funds may not be used for survey and certification operations or state expenses other than a reasonable amount for the actual administration of grant awards including the tracking, monitoring, and evaluating of approved projects.*

g) ***Travel Costs**: Travel costs are permitted when it is required to implement the project and must not exceed the maximum funding per category. Travel expenses must be reasonable. Examples of reasonable rates include, but are not limited to, the published U.S. government allowance rates (available from the www.gsa.gov website) for mileage and per diem; and standard commercial rates for airfare. Nursing home staff **,**may not apply for travel costs. Travel for state staff will be evaluated with each application.*

***h) Temporary Manager Salaries**: A temporary manager (or State appointed manager or monitor for a nursing home or other form of State administrative management) salary cannot be paid with CMP funds* except *as allowable under facility closure section below.*

i) ***CMP Funds During Facility Closure Or Receivership**: CMP funds can be used, only upon CMS approval, in those rare situations where a facility is closing or in receivership and CMS determines that extraordinary action is necessary to protect the residents until relocation efforts are successful or Medicare and Medicaid payments can be accessed. While in receivership, the limitation of the use of CMP funds will be decided on a case- by- case basis.*

In rare situations, if the facility is closing, CMS plans to stop or suspend continued payments to the facility under 42 CFR § 489.55 during the temporary manager's duty period, and CMS determines that extraordinary action is necessary to protect the residents until relocation efforts are successful, CMP funds may be used to pay the manager's salary and other items noted in the Emergencies section above.)

While §489.55 permits Medicare and Medicaid payments to a facility to continue for up to 30 days after the effective date of a facility's termination or possibly longer (or shorter) if a facility has submitted a notification of closure under §483.70(l) in order to promote the orderly and safe relocation of residents, if the continued Medicare and Medicaid payments are not being used to pay for facility operations during the relocation period, then residents may be placed at increased risk.

Furthermore, there may be situations where CMS concludes that it is otherwise infeasible to ensure timely payment for a temporary manager by the facility and CMS determines that extraordinary action is necessary in order to protect the residents until relocation efforts are successful. For this reason, and because CMS places a priority on resident protection and protection of the Trust Fund, CMS would allow the use of CMP funds to pay for a temporary or State-appointed manager salary for a limited time, as long as CMS also intends to stop payments to the facility under §489.55 or redirect the flow of Medicare/Medicaid payments to accounts accessible to the receiver or temporary manager. If access to these funds is not available, States should work with CMS to take actions that would stop the improper flow of Medicare/Medicaid funds directly to the facility and to redirect to accessible accounts.

2) ***Non-allowable uses of CMP funds***

The non-allowable uses of CMP funds include, but not limited to, the following categories listed below. States should review these items to ensure they are not incorporated into applications prior to forwarding to the CMPRP team.

a) ***Conflict of Interest Prohibitions:*** *CMS will not approve projects for which a conflict of interest exists or the appearance of a conflict of interest. Generally, projects greater than three years may not be approved. However, the CMS CMPRP team will review projects on an as needed basis. By obliging the State to fund a long and large multi-year expense, we consider such projects to raise the appearance of a conflict of interest for the purpose of levying future CMPs, rather serving the statutory and regulatory purpose to impose remedies on a nursing home for failure to meet the federal requirements.*

b) ***Duplication:*** *States may not use CMP funds to pay entities to perform functions for which they are already paid by State or Federal sources. CMP funds, for example, may not be used to enlarge an existing appropriation or statutory purpose that is substantially the same as the CMP project. Also, CMP funds may not be used to fund State legislative directives for which no or inadequate state funds have been appropriated.*

c) ***Capital Improvements:*** *CMP funds may not be used to pay for capital improvements (a durable upgrade, adaptation, or enhancement of a property that increases its value, often involving a structural change or restoration to a nursing home, or building a nursing home, as the value of such capital improvement accrues to a private party (the owner). Federal and State payments also already acknowledge the expense of capital costs, so the use of CMP funds for such a purpose is prohibited. Capital improvements include replacing a boiler, redesigning a nursing home, landscaping, parking lot or sidewalk construction, adding a concrete patio, etc.*

d) ***Nursing Home Services or Supplies:*** *CMP funds may not be used to pay for nursing home services or supplies that are already the responsibility of the nursing home, such as laundry, linen, food, heat, staffing costs, medical equipment, resident transportation, resident beds, etc. would duplicate an existing responsibility of the nursing home. Please consult the State Operations Manual (SOM) Appendix PP.*

e) ***Supplementary Funding of Federally Required Services:*** *CMP funds may not be used, for example, to provide Long-Term Care Ombudsman certification training for staff or volunteers or investigate and work to resolve complaints as these are among the responsibilities of Long-Term Care Ombudsman programs under the federal Older Americans Act (OAA), regardless of whether funding is adequate to the purpose. On the other hand, there is no prohibition to an Ombudsman program receiving CMP funds to conduct or participate in approved projects, or to carry out other quality improvement projects that are not within the Ombudsman program's existing set of responsibilities under the OAA. Nor is there any prohibition to Ombudsman program staff or volunteers to participate in training that is paid by CMP funds but open to a broad audience, such as nursing home staff, surveyors, consumers, or others.*

f) ***Complex Technology:*** *CMP funds cannot be used to purchase high-dollar, complex, or sophisticated technologies, such as telemedicine, alert systems, virtual reality, artificial intelligence, etc. Please review the list of non-allowed technology at:* ***https://www.cms.gov/files/zip/allowable-and-non-allowable-uses-cmp-funds.zip***

g) ***Research:*** *Conducting descriptive, analytical, experimental, or integrative research studies on nursing home residents/staff, often consists of projects where the benefit to nursing home residents is unknown or concentrated on the research entity, or a large portion of the budget does not directly benefit nursing home residents. Additionally, research often uses a large portion of the project budget for the development and testing of an intervention or activity, rather than the implementation of the project.*

h) ***Quality Innovation Network-Quality Improvement Organization (QIN/QIO) Approved Projects:*** *CMP funds cannot be used to fund activities for which QIN-QIOs are already receiving federal funding to complete. Check with the State or CMS Location regarding active QIN/QIO projects and activities.*

i) ***Nursing Home Employee Salary:*** *CMP funds cannot be used for salaries (all or part) of nursing home staff.*

j) ***Palliative Care Services:*** *CMP funds cannot be used for palliative care services. Palliative care services are billable medical services consistent with general medical care; therefore, all services are potentially billable to Medicare, Medicaid, private insurance, and private payer systems.*

k) ***Dental, Vision, and Hearing Services:*** *CMP funds are not intended to bridge the gap in coverage for services Medicare does not currently provide.*

Note: Some dental projects may be allowable, such as training, or based on the extent of the state's current dental coverage.

l) ***Incentives:*** *CMP funds cannot be used for monetary and non-monetary gifts to motivate or encourage individuals to do something, including but not limited to providing monetary incentives for attending trainings or for completing surveys.*

m) ***Overlap with State Functions:*** *CMP funds cannot be used to pay for state salaries and for functions that states are required to perform. This category also includes funding for survey and certification operations. The exception is the administrative use of CMP funds by the State Agency necessary to administer, monitor, or evaluate the effectiveness of CMP projects.*

n) ***Previously Denied CMPRP Projects:*** *CMP funds cannot be used to reactivate denied projects.*

o) ***Telemedicine Services and Equipment:*** *Telemedicine services and telemedicine equipment are not an appropriate use of CMP funds, as States may not use CMP funds to pay entities to perform functions for which they are already paid by State or Federal sources.*

p) ***Prohibited Budget Items:*** *CMP funds should not be used to include items or services that are not related to directly improving the quality of life and/or care of nursing home residents. Budget items should not contain excessive costs, items already considered a nursing home responsibility, or services/items being paid for by a state or federal agency. Also, infection control supplies, purchasing food and drinks are prohibited. Please review the complete list located on the Nonallowable Uses of CMP Funds document accessible here: https://www.cms.gov/files/zip/allowable-and-non-allowable-uses-cmp-funds.zip*

7535.2 – State Civil Money Penalty Reinvestment Plans

(Rev. Issued:, Effective:, Implementation:)

1. *As specified at 42 CFR 488.433(e), States must maintain an acceptable plan, approved by CMS, for the effective use of CMP funds.. Plans must be submitted to the CMS CMPRP team no later than October 31st of each year, unless otherwise*

specified by CMS. Plans will be reviewed by CMS for compliance with §488.433(e) and allowable uses of CMPs (§7535.1). If there are issues with the plan, States will be contacted for possible revisions. As part of plan requirements, an annual CMP project tracking sheet must be submitted by each State. An optional CMP Reinvestment State Plan Template and CMP Project Tracking Sheet are available for States' use on the CMS CMP Reinvestment Resource Website at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/LTC-CMP-Reinvestment.html.

2. *Acceptable plans should include:*

   a) ***Plan Timeline:*** *The start date and end date for the plan (i.e., month and year). This should follow the upcoming calendar year (CY) (e.g., January 1, 20XX – December 31, 20XX).*

   b) ***Contacts:*** *Name of the State contact person(s) responsible for the plan and their contact information.*

   c) ***Current CMP Balance:*** *The projected CMP balance in the State's Federal CMP reinvestment account as of January 1 for the CY covered by the plan.*

   d) ***CMPs Returned to the State:*** *The projected or actual Federal CMPs returned to the State during the CY prior to the covered plan period.*

   e) ***Emergency Reserve Fund Plans:*** *The amount of CMP funds that a State will hold in reserve for emergencies during the CY. States must indicate the intended use for the funds, such as the relocation of residents pursuant to an involuntary termination from Medicare and Medicaid. This amount should be sufficient to indicate that a State is prepared to respond to emergencies while at the same time is not maintaining a large unused amount of CMP funds. Details should be sufficient to understand how this amount was reached. The State should take an all-hazards approach to emergencies, including natural disasters that are likely to occur in their area and corresponding expenses. The State should provide adequate detail and justification for the amount they are requesting to include emergency use history, and other applicable details such as number of certified beds and applicable expenses (e.g., relocation expenses). CMP funds cannot be used for facilities to meet emergency preparedness requirements.*

   f) ***Annual Administrative Use****: If using CMP funds for administration and management of grant awards (tracking, monitoring, and evaluating approved projects), list the amount of CMP funds that will be used during the CY covered by the plan. These funds must be of a reasonable amount. States should provide a*

description of how these funds will be used that includes a position description(s) and corresponding costs (e.g., salary and benefits for one full-time staff (1 FTE) to oversee the evaluation of approximately 60 submitted CMP applications as well as the administration and monitoring of approximately 20 CMP awards). States must avoid potentially prohibited or problematic costs (e.g., administrative expenses beyond those necessary to administer, monitor, evaluate, or report on the effectiveness of projects utilizing CMP funds).

g) ***Obligated Funds Plan:*** *A list of continuing and/or new projects planned for the CY. List each project title, amount obligated for approved CY projects, start and end dates of the project, and recipient of funds. Provide the total amount of obligated funds for all continuing and/or new projects planned for the CY.*

h) ***Available Funds:*** *Provide the State's available funds for new CMP projects for the CY. This does not include the amount of funds for emergency use, administrative use, or for obligated projects.*

A reasonable amount of available funds must be awarded each year for projects that benefit nursing home residents and are consistent with the Act and CMS regulations. CMS considers it a reasonable goal to award at least 50% of CMP funds beyond those held in emergency reserve to projects benefiting nursing home residents.

i) ***Public Information:*** *States must make standard information about CMP-funded projects publicly available. Project information should be updated annually. Provide the specific web address for the publicly available website where the State will post this information. If a State prefers not to maintain its own website, and instead rely on the CMS CMP Reinvestment Resource Website, the State should include information on its website to direct stakeholders to the CMS site where the state CMP fund use is available. The information posted should include:*

- *Project title,*
- *Duration of the project,*
- *Dollar amount awarded for each approved project,*
- *Project summary (i.e., purpose/goals and objectives),*
- *Awardee name,*
- *Results of projects (i.e. the outcome of completed projects), and*
- *Other key information, such as whether improvements have been institutionalized as a result of the project.*

CMS will obtain this information from the State through the CMP Project Tracking Sheet and post it to the CMS CMP Reinvestment Resource Website. States are encouraged to also include this information on their own website for use by potential CMP reinvestment applicants.

j) Solicitation Methods: *A description of the method that will be used to solicit projects utilizing CMP funds (e.g., websites, notices to the Ombudsman's office, presentations to the nursing home provider community). Provide relevant details for each solicitation method (i.e., who is responsible, when, where, and who the target audience is). If applicable, provide information on the types of projects intended to be solicited (e.g., dementia care, music therapy).*

k) Review Methods: *A description of the method that will be used to review and evaluate incoming applications to determine if the proposal meets the criteria for acceptable uses of CMP funds. Include relevant details (i.e., personnel reviewing applications, criteria the State will use to evaluate applications, expected review timeframe, and process for submitting applications to CMS).*

l) Monitoring and Tracking Methods: *A description of the methods that will be used to monitor and track projects utilizing CMPs including any funds used for administrative use. Provide information on how the State will assure monies paid out for CMP projects were spent on the items identified by the CMP fund recipient in their application (e.g., site visit, invoices, timecards, receipts for supplies and travel). Describe how the State will track project results (e.g., periodic or standard reporting deadlines, deliverables, final report, tracking of metrics).*

m) CMP Project Tracking Sheet: *At the end of the CY, States should complete and submit to the CMS CMPRP team by February 1 of the subsequent year (e.g., On February 1, 2023, States should submit tracking sheets with information on projects that took place during CY 2022). The information submitted should include:*

- *CMP funds balance (obligated and available) as of the beginning of the calendar year (CY) (e.g., January 1, 20XX);*
- *CMP funds expended for administrative uses during the CY (e.g., CY 20XX);*
- *CMP funds expended for emergency uses during the CY;*
- *CMP funds spent on CMP projects during the CY;*
- *CMP funds added during the CY;*
- *CMP funds balance at the end of the CY (e.g., December 31, 20XX); and*
- *Information on each project implemented during the CY, including:*

- *Project start date,*
- *Project end date,*
- *Total amount of CMP funds approved for the project,*
- *Project title,*
- *Project summary [i.e., specific purpose of the project, description of what the project will achieve, explanation of how the project will benefit nursing home residents, and target audience beyond nursing home residents, if applicable],*
- *Funded entity(ies),*
- *Results/Outcomes of the project, and*
- *Total amount of CMP funds expended during the CY for the project.*

3. *As specified at 42 CFR 488.433(f), if CMS finds that a State does not spend its CMP funds in accordance with 42 CFR 488.433; fails to use its funds to improve the quality of care or quality of life of nursing home residents; or fails to maintain a CMS-approved CMP reinvestment state plan, then CMS may withhold future CMP fund disbursements to the State until an acceptable plan is submitted and approved by CMS. There may be several scenarios where this might occur, for example:*

   - *If CMS has information that a State is using Federal CMP funds for projects or activities that are not in conformance with our law or regulations, which may also include situations where a State is approving projects without obtaining prior CMS approval;*

   - *If a State has a significant fund balance and they have not solicited any requests for proposed projects within the past year, nor have they submitted any project for approval to CMS within the past year; or*

   - *If a State fails to submit an acceptable plan for the use of civil money penalty funds.*

   In these instances, when CMS receives information that a State has misspent CMP funds or fails to make use of funds to benefit the quality of care or life for residents, or fails to maintain an acceptable plan for the use of CMP funds that is approved by CMS, CMS should first contact the State to confirm that this information is accurate. In the case of the State's failure to submit an acceptable plan, the State should be given the opportunity to do so in a timely manner. If CMS determines that the State is not in compliance with 42 CFR 488.433, CMS will notify the CMS Office of Financial Management to withhold Medicaid CMP disbursements until an acceptable CMP reinvestment state plan and/or CMP spending practices are reviewed and approved by CMS.

7536 - Loss of Nurse Aide Training and Competency Evaluation Program or Competency Evaluation Program as a Result of Civil Money Penalty

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

Sections *1819(f)(2)(B)* and *1919(f)(2)(B)* of the Act and *42 CFR 483.151(b)* use the term "assessed" to state that the approval of a nurse aide training and competency evaluation program or competency evaluation program is prohibited in a facility which, within the previous 2 years, has been assessed a civil money penalty of not less than $5,000. Section 7809 provides additional information regarding nurse aide training and competency evaluation program and competency evaluation program disapprovals.

7536.1 - Definition of "Assessed"

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

The term "assessed" is defined to reflect the fact that the civil money penalty may be revised on administrative appeal. The assessed amount of the civil money penalty is the final amount determined to be owed after a hearing, waiver of right to a hearing, or settlement.

7536.2 - Effective Date for Prohibition of Nurse Aide Training and Competency Evaluation Program or Competency Evaluation Program When Civil Money Penalty of $5,000 or More Is Assessed

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

If a civil money penalty of $5,000 (*as adjusted for inflation at 45 CFR 102.3)* or more is assessed on a facility as a result of current or past noncompliance found during a survey, the effective date of the prohibition of the nurse aide training and competency evaluation program or competency evaluation program specified in the notice cannot be before the time frame for requesting a hearing has expired, or after receipt of the written waiver, or later than the date on which a civil money penalty of $5,000 or more (*as adjusted for inflation at 45 CFR 102.3)* is upheld on administrative appeal. In accordance with *42 CFR 483.151,* the State notifies the program in writing, indicating the reason(s) for withdrawal of approval of the program. However, students who have started a training and competency evaluation program for which approval has been withdrawn must be allowed to complete the course.

It is possible for a facility to experience two or more separate disapprovals of its nurse aide training and competency evaluation program or competency evaluation program that could run concurrently for at least part of the same period of time. When two periods of program disapproval overlap, the program will not be restored until the second 2-year disapproval period has been completed. (See §7809.7)

7550 - Temporary Management

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

7550.1 - Introduction

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

This remedy is established pursuant to *§1819(h)(2)(A)(I), §1819(h)(B)(iii), §1919(h)(1)(A), §1919(h)(2)(A)(iii), §1919(h)(3)(B)(I), and §1919(h)(3)(C)(iii)* of the Act and *42 CFR 488.415*.

7550.2 - Purpose

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

A temporary manager may be imposed anytime a facility is not in substantial compliance. However, when a facility's deficiencies constitute immediate jeopardy or widespread actual harm and a decision is made to impose an alternative remedy to termination, the imposition of temporary management is required. It is the temporary manager's responsibility to oversee correction of the deficiencies and assure the health and safety of the facility's residents while the corrections are being made. A temporary manager may also be imposed to oversee orderly closure of a facility.

7550.3 - Authority of Temporary Manager

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

A temporary manager has the authority to hire, terminate, or reassign staff; obligate facility funds; alter facility procedures; and otherwise manage a facility to correct deficiencies identified in the facility's operation.

7550.4 - Selection of Temporary Manager

(Rev. 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 *iQIES* 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.

7550.5 - Conditions of Temporary Management
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The facility's management must agree to relinquish control to the temporary manager and to pay his/her salary before the temporary manager can be installed in the facility.

The facility cannot retain final authority to approve changes of personnel or expenditures of facility funds and be considered to have relinquished control to the temporary manager. The temporary manager must be given access to facility bank accounts that include Medicare and Medicaid receipts.

The temporary manager's salary must be at least equivalent to the prevailing annual salary of nursing home administrators in the facility's geographic area, plus the additional costs that would have reasonably been incurred by the facility if the temporary manager had been in an employment relationship, e.g., the cost of a benefits package, prorated for the amount of time that the temporary manager spends in the facility. The State is responsible for determining what constitutes a facility's geographic area.

If the facility refuses to relinquish control to the temporary manager, the facility will be terminated within 23 calendar days of the last day of the survey if the immediate jeopardy is not removed.

7550.6 - Orienting and Supervising Temporary Manager
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The State should provide the temporary manager with an appropriate orientation that includes a review of the facility's deficiencies. The State may request that the temporary manager periodically report on the actions taken to achieve compliance and on the expenditures associated with these actions.

7550.7 - Notice of Imposition of Temporary Management
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A temporary manager may be imposed 15 calendar days after the facility receives notice in non-immediate jeopardy situations and 2 calendar days after the facility receives notice in immediate jeopardy situations.

7550.8 - Duration
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Temporary management continues until a facility is terminated, achieves substantial compliance and is capable of remaining in substantial compliance, or decides to discontinue the remedy and reassume management control before it has achieved substantial compliance. In the latter case, the facility faces termination.

7550.9 - Alternatives to Temporary Management
(Rev. 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.

7552 - Transfer of Residents and Transfer of Residents with Closure of Facility
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7552.1 - Introduction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

This section implements §1819(h)(4), §1919(h)(2)(A)(iv), and §1919(h)(5) of the Act in conjunction with §1819(c)(2) of the Act and *42 CFR 488.426*.

7552.2 - Responsibility for Transferring Residents
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The State has the ultimate responsibility for transferring Medicare and Medicaid residents when a facility is terminated. In some instances, a facility may assume responsibility for the safe and orderly transfer of residents when it is closed or its provider agreement is terminated. However, this does not relieve the State of its ultimate responsibility to transfer residents. The goal must be to minimize the period of time during which residents are receiving less than adequate care. CMS is specifying that transfer requirements apply only to Medicare and Medicaid residents and **not** to private pay residents. However, when a facility is closed, regardless of whether the closure is a result of action taken by the State or by the facility, the State may have plans available to provide assistance in the relocation of private pay residents.

7552.3 - State's Prerogative to Close Facility and Transfer Residents
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A finding of immediate jeopardy will not, in and of itself, require the State to close a facility and transfer Medicare and Medicaid residents. It could, however, result in the immediate termination of a Medicare and/or Medicaid provider agreement and the subsequent transfer of Medicare and/or Medicaid residents. During an emergency, the State can permanently or temporarily transfer residents to another facility until the original facility is able to care for its residents.

7556 - Termination Procedures for Skilled Nursing Facilities and Nursing Facilities When Facility Is Not in Substantial Compliance *w*ith Participation Requirements

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

7556.1 - Introduction

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

Sections 1819(h)(4) and 1919(h)(5) of the Act and *42 CFR 488.456* and 489.53 provide for termination of skilled nursing facility and nursing facility provider agreements. Title *42 CFR Part 431, Subpart D*, provides the appeals process for nursing facilities subject to enforcement actions by the State.

Under certain circumstances, Federal regulations provide for payment to a facility beyond the effective date of termination as follows:

- Under *42 CFR 489.55*, Medicare payment is available for up to 30 days after the effective date of termination for inpatient hospital services (including inpatient psychiatric hospital services) and post-hospital extended care services furnished to a beneficiary who is admitted before the effective date, and home health services and hospice care furnished under a plan established before the effective date.

- Under *42 CFR 441.11*, Federal financial participation may be continued for up to 30 days after the effective date of termination or expiration of a provider agreement, or after an administrative hearing decision that upholds the agency's termination or nonrenewal action, as long as the Medicaid payments are for those residents admitted to the facility before the effective date of termination or expiration, and the Medicaid agency is making reasonable efforts to transfer the residents to other facilities or to alternate care.

7556.2 - When There Is Immediate Jeopardy

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

When there is immediate jeopardy to resident health or safety, the enforcing agency must complete termination procedures within 23 days from the last day of the survey which found the immediate jeopardy if it is not removed before then. (See §7309 for time frames.) The procedure must not be postponed or stopped unless the immediate jeopardy is removed, as verified through onsite verification or review of verifiable documentation.

If there is a written and timely credible allegation that the immediate jeopardy has been removed, CMS or the State will conduct a revisit prior to termination, if possible.

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 - Continuation of Payments During Correction

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

7600.1 - Introduction

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

These procedures are established pursuant to *§1819(h)(2)(C)* and *§1919(h)(3)(D)* of the Act and are implemented at *42 CFR 488.450*. States use these procedures when they determine that a non-State operated skilled nursing facility, nursing facility, or dually participating facility is not in substantial compliance with Federal participation requirements, and that an alternative remedy is preferred **instead** of termination. If the State decides to impose alternative remedies **in addition to termination,** it does **not** follow these procedures. (See §7556 for termination procedures.)

7600.2 - Purpose

(Rev. 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.

7600.5 - Facility Takes Corrective Action According to Its Approved Plan of Correction and Has Achieved Substantial Compliance
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Once the State has determined that a facility has made corrections according to its approved plan of correction and the facility has achieved substantial compliance, the facility may be certified in substantial compliance and the agreement to repay is void.

7600.6 - Facility Does Not Take Corrective Action According to Its

Approved Plan of Correction and Has Not Achieved Substantial Compliance

(Rev. 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 *b*ut 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.

7600.8 - Facility Does Not Take Corrective Action According to Its Plan of Correction and Has Achieved Substantial Compliance

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

The facility would not be required to repay the Federal funding received because it achieved substantial compliance.

7600.9 - When State Opts for Alternative Remedies in Lieu of Termination and Criteria Are Not Met

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

If termination is not sought, either by itself or along with another remedy (or remedies), or if any of the applicable criteria set forth in subsection 3 are not met, the facility or State Medicaid Agency will receive no Medicare or Federal Medicaid payments, as applicable, from the last day of the survey until the date that substantial compliance is achieved.

If the State recommends an alternative remedy instead of termination and the Medicare facility refuses to sign an agreement to repay, CMS has no authority to pay for services after the last day of the survey. If funding has ceased, the State must determine if the facility is in substantial compliance before funding can resume.

7700 - Nurse Aide Registry and Findings of Abuse, Neglect, or Misappropriation of Property

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

7700.1- Notification Procedures- Preliminary Determinations

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

If the State makes a preliminary determination, based on oral or written evidence and its investigation, that resident neglect, abuse, or misappropriation of property has occurred, the State completes the following notification procedures:

1. **Individuals Notified** - The State notifies the following individuals in writing within 10 working days of the investigation:

   a. Individual(s) implicated in the investigation; and

   b. The current administrator of the facility in which the incident occurred.

2. **Notice Information** - The following information is included in the notice:

   a. Nature of the allegation (specific facts);

   b. Date and time of the occurrence;

   c. A statement that the individual implicated in the investigation has a right to a hearing and must request the hearing within 30 days from the date of the notice. Provide the individual with the specific information needed to request

a hearing, such as the name and address of a contact in the State to request a hearing;

d. Statement that if the individual fails to request a hearing, in writing, within 30 days from the date of the notice, the findings will be reported to the nurse aide registry or the appropriate licensure authority;

e. The intent to report *the* findings *in writing, once the individual has had the opportunity for a hearing,* to the nurse aide registry and/or to the appropriate licensure authority;

f. Consequences of waiving the right to a hearing;

g. Consequences of a finding through the hearing process that the resident abuse or neglect, or misappropriation of property did occur; and

h. Right of the accused individual to be represented by an attorney at the individual's own expense.

7700.2 - Conduct of Hearing for Nurse Aides

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

1- Time frame to Complete Hearing

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

2 - Hearing Location

The State must hold the hearing in a manner consistent with State practice at a reasonable place and time convenient for the individual.

7700.3- Reporting Findings

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

1 - Reporting to Entities

If the individual waives the right to a hearing or the time to request a hearing has expired, or if the hearing finding is that the individual neglected or abused a resident or misappropriated a resident's property, the findings must be reported in writing within 10 working days to:

1. The individual;

2. Current administrator of the facility in which the incident occurred;

3. The administrator of the facility that currently employs the individual, if it is not the same facility in which the incident occurred;

4. Applicable licensing authorities; and

5. The nurse aide registry for nurse aides as specified in *42 CFR 483.156* and discussed in *Chapter 4* of this manual. *Chapter 4 also* discusses the function of the registry, the information contained in the registry, and responsibility for the registry.

2 - Information Submitted to the Nurse Aide Registry

The following information must be included and remain in the registry permanently, unless the finding was made in error, the individual was found not guilty in a court of law, or the State is notified of the individual's death. See *Chapter 4* of this manual.

a. Documentation of the investigation, including the nature of the allegation and the evidence that led to the conclusion that the allegation was valid;

b. The date of the hearing, if the individual chose to have one, and its outcome; and

c. A statement by the individual disputing the allegation if the individual chose to make one.

3- Information Retained in the Nurse Aide Registry Permanently

The registry removes entries for individuals who have performed no nursing or nursing-related services for 24 consecutive months, **unless** the individual's registry entry includes documented findings of abuse, neglect, or misappropriation of resident property.

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

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

When the CMS Location or SA *identifies noncompliance related to* finding*(s)* of abuse, the CMS Location or SA must report the findings to local law enforcement and, if appropriate, the Medicaid Fraud Control Unit.

Program Management

7800 - Consistency of Survey Results
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7800.1 - Introduction
(Rev. 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.

7801 - Sanctions for Inadequate State Survey Performance
Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

(Moved to Chapter 8 of this manual.)

7803 - Educational Programs
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7803.1 - Introduction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

This section implements §1819(g)(1) and §1919(g)(1) of the Act and *42 CFR 488.334.*

7803.2 - Purpose
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The purpose of this section is to ensure that long-term care facility staff and residents (and their representatives) are knowledgeable about current regulations, procedures, and policies relative to survey, certification, and enforcement processes.

7803.3 - Methodology
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The development of educational programs and the methods of presentation are within the purview of the agency providing the training as long as the programs cover long-term care regulations and the survey and enforcement process.

7803.4 - Suggested Training Modalities
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Suggested training modalities include the following:

- Video tapes;
- Satellite communication;
- Newsletters developed by the State;
- Formal presentations; and
- Informal sessions during or after onsite visits.

7805 - Criteria for Reviewing State Plan Amendments for Specified and Alternative Enforcement Remedies
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7805.1 - Introduction
(Rev. 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).*

7805.2 - Specified Remedies
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Specified remedies are those remedies defined in §1919(h) of the Act as well as *42 CFR 488.406(b).* The State plan must specify the State law or regulations that establish these remedies, pursuant to §1919(h)(2)(A) of the Act.

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.

7805.4 - Additional Remedies
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

If a State wishes to impose additional remedies to those specified in regulations, the State must describe:

- Whether the additional remedy is in category 1, 2, or 3 (see §7400 for description of remedy categories); and

- State law or regulations that established these additional remedies.

7807 - State/Federal Disagreements About Timing and Choice of Remedies
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7807.1 - Introduction
(Rev. 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 agency's findings.

While CMS expects that in most cases the CMS Location will agree with the State agency's findings of compliance or noncompliance and the timing of the State 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 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 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 agency's findings, that the facility is in substantial compliance, the State agency's finding prevails.

If the State agency finds a facility is in substantial compliance, but the CMS Location finds, either through an onsite survey or review of the State 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 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 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 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*.)

7809 - Nurse Aide Training and Competency Evaluation Program and Competency Evaluation Program Disapprovals

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

7809.1 - Introduction

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

Sections *1819(f)(2)(B)(iii)* and *1919(f)(2)(B)(iii)* of the Act, as well as *42 CFR 483.151(b)(2)* and *483.151(e)*, require denial or withdrawal of approval of facility-based Nurse Aide Training and Competency Evaluation Programs and Competency Evaluation Programs offered by or in a facility which, within the previous 2 years:

- Has operated under a *§1819(b)(4)(C)(ii)(II)* or *1919(b)(4)(C)(ii)* waiver (see *Chapter 4* of this manual);

- Has been subject to an extended or partial extended survey under *§1819(g)(2)(B)(i)* or *§1919(g)(2)(B)(i)* of the Act; or

- Has been assessed a civil money penalty described in the Act at *§1819(h)(2)(B)(ii)* or *§1919(h)(2)(A)(ii)* of not less than $5,000 or has been subject to a denial of payment, the appointment of a temporary manager, termination, or, in the case of an emergency, been closed and/or had its residents transferred to other facilities. (See §7536 for additional information regarding civil money penalties.)

The program will not be approved if it is offered by or in a facility unless the State makes the determination, upon an individual's completion of the program in the facility, that the individual is competent to provide nursing and nursing related services in skilled nursing facilities or nursing facilities.

Any reversals of *NATCEP/CEP* denials or withdrawals are limited to the informal dispute resolution *or Independent informal dispute resolution* process*es*.

In accordance with *42 CFR 483.151*, the State notifies the program in writing, indicating the reason(s) for withdrawal of approval of the program. However, students who have started a program for which approval has been withdrawn must be allowed to complete the course.

7809.2 - Applicability to Past Noncompliance

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

The provisions of this section apply to findings of past noncompliance when a civil money penalty of $5,000 or more is assessed.

7809.3 - Waiver of Program Disapproval

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

See *Chapter 4* of this manual.

7809.4 - Notice

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

The State agency must notify the State agency responsible for Nurse Aide Training and Competency Evaluation Programs/Competency Evaluation Program when it determines that denial or withdrawal of program approval is necessary. That agency, in turn, notifies the facility. If the noncompliance which caused a sanction to be imposed, or which caused an extended or partial extended survey to be performed, is successfully refuted by the facility or otherwise determined by the State to have been improperly cited, the facility's appeal to restore the Nurse Aide Training and Competency Evaluation Program/Competency Evaluation Program approval will be granted.

7809.5 - Change of Ownership

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

If a facility undergoes a change of ownership after having had approval of its nurse aide training and competency evaluation program or competency evaluation program withdrawn for 2 years before the 2-year period has expired, the remainder of the 2-year period does not carry over to the new owner. If the facility meets all the other requirements for the nurse aide training and competency evaluation program or competency evaluation program, its program(s) will be approved.

7809.6 - Ability to Appeal a Finding of Substandard Quality of Care that Resulted in the Disapproval of a Nurse Aide Training and Competency Evaluation Program

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

A facility may appeal the finding of substandard quality of care that resulted in the disapproval of its nurse aide training and competency evaluation program.

There are instances when a Medicare-only or dually participating facility has been found to have provided substandard quality of care but has not experienced any other adverse consequence other than the disapproval of its ability to conduct a nurse aide training and competency evaluation program. These situations provide for a hearing under *42 CFR Part 498* even though it is the State that is the responsible party for removing the approval of the facility to conduct a program at the facility. When CMS makes a determination of substandard quality of care that leads to the disapproval of a nurse aide training and competency evaluation program, this determination provides for a hearing under Part 498. For Medicaid-only nursing homes, it is left to the State to determine whether to provide a hearing to challenge the substandard quality of care determinations that have resulted in the disapproval of a nurse aide training and competency evaluation program. Accordingly, notices from States advising Medicare-only or dually participating facilities of their loss of approval to conduct a nurse aide training and competency evaluation program must provide notice of the appeal rights available under *42 CFR Part 498*.

Under the regulations, it is the State, not CMS, that disapproves a facility's nurse aide training and competency evaluation program. While the hearings authorized under *42 CFR Part 498* are directed at actions initiated by CMS, they are expressly designed to confer hearing rights on Medicare-only or dually participating facilities that lose their nurse aide training and competency evaluation program authority even when no other Federal remedies have been imposed. If the appeals regulations at *42 CFR Part 498* were to be interpreted to permit challenges to a disapproval of nurse aide training and competency evaluation programs only when such disapprovals are a result of actions taken by CMS, these hearing rights would never be triggered since it is not CMS that takes these actions. This is not a result that was intended by the nurse aide training and competency evaluation program appeals regulation that was published on July 23, 1999 (64 "Federal Register" 39934).

7809.7 – Effective Date of Disapproval of Nurse Aide Training and Competency Evaluation Program or Competency Evaluation Program

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

The effective date of program disapproval is based on the actual occurrence of each of the triggering events, i.e., on the date that a nurse staffing waiver was effective; on the last day of the extended (or partial extended) survey; or, when the specified enforcement remedy or termination was effective. The disapproval is not delayed pending the outcome of any appeal. (See §7536.2 for the effective date of disapproval of a nurse aide

training and competency evaluation program or competency evaluation program resulting from a civil money penalty.)

It is possible for a facility to experience two or more separate disapprovals of its nurse aide training and competency evaluation program or competency evaluation program that could run concurrently for at least part of the same period of time. When two periods of program disapproval overlap, the program(s) will not be restored until the second 2-year disapproval period has been completed.

A facility's nurse aide training and competency evaluation program or competency evaluation program will be restored when the facility prevails at informal dispute resolution or at a formal hearing where the noncompliance is overturned that either caused the extended (or partial extended) survey to be conducted, or caused a specified remedy or termination to be imposed.

Disclosure

7900 - Information Disclosed to Public

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

(Also see "Handling Public Inquiries", §§3300-3320 of this manual.)

As provided in *§1819(g)(5)* and *§1919(g)(5)* of the Act and *42 CFR 488.325*, the State agency, the State Medicaid Agency, or CMS must make the following information available to the public, upon the public's request, for all surveys and certifications of skilled nursing facilities and nursing facilities:

- The fact that a facility does or does not participate in the Medicare/Medicaid program;

- The official "Statement of Deficiencies and Plan of Correction", Form CMS-2567. If it contains the name of any individual, medical information about any identifiable resident, the identity of a complainant, or the address of anyone other than an owner of the facility, that information must be blocked out before the Form CMS-2567 is released to the public;

- Approved plans of correction, Form CMS-2567. If the plan of correction contains the name of any individual, medical information about any identifiable resident, the identity of a complainant, or the address of anyone other than an owner of the facility, that information must be blocked out before the Form CMS-2567 is released to the public;

NOTE: The Statement of Deficiencies can be released before the facility has completed its plan of correction portion. However, after a plan of correction is submitted and approved, the two portions are released simultaneously since they appear on the same form.

- When applicable, a Notice of Isolated Deficiencies Which Cause No Actual Harm With the Potential for Minimal Harm (Form A) will be included with the Form CMS-2567;

- Facility comments;

- Statements that the facility did not submit an acceptable plan of correction or failed to comply with the conditions of imposed remedies, if appropriate;

- Official notices of provider terminations;

- Statistical data on facility characteristics that does not identify any specific individual. *42 CFR 401.120* states that records will not be created by compiling

selected items from the files to give the requester data such as ratios or percentages. However, if existing documents contain such statistical data (e.g., Certification and Survey Provider Enhanced Reporting (CASPER) reports), they are subject to release;

- Final appeal results;
- Medicare and Medicaid cost reports; and
- Names of individuals with direct or indirect ownership interest in a skilled nursing facility or nursing facility, as defined in *42 CFR 420.201*, who have been found guilty by a court of law of a criminal offense in violation of Medicare or Medicaid law.

7901 - Requesting Public Information

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

The public may request information in accordance with disclosure procedures specified in *45 CFR Part 5.*

7902 - Charges for Information

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

If the public requests copies of the records and information described in §7900 from CMS, there will generally be a charge. Charges should be in accordance with *42 CFR 401.140* for Medicare and applicable State procedures for Medicaid.

7903 - Time Periods for Disclosing Skilled Nursing Facility/Nursing Facility Information

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

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

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

Upon the public's request, the State 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 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 agency or CMS Location makes the determination about the appropriateness of the timing of the disclosure.

In situations generating media interest, the State agency should notify the CMS Location prior to the initial public release of 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.

7904 - Information Furnished to State's Long Term Care Ombudsman
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7904.1 -Information Given to Long Term Care Ombudsman
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

In accordance with *§1819(g)(5)(B)*, *§1919(g)(5)(B)* of the Act, and *42 CFR 488.325(f)*, the State agency must provide the State's long-term care ombudsman with the following:

- A Statement of Deficiencies reflecting facility noncompliance and, if applicable, a separate list of isolated deficiencies that constitute no actual harm with the potential for minimal harm;
- Reports of adverse actions specified in *42 CFR 488.406* imposed on a facility;
- Any written response by the facility, including plans of correction and facility requests for informal dispute resolution; and
- A facility's request for an appeal and the results of any appeal.

7904.2 - Federal Surveys
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

For Federal surveys, CMS will contact the State agency and provide the information needed for the State to notify the ombudsman on CMS's behalf.

7905 - Information Furnished to State by Facility with Substandard

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

7905.1 - Information Provided to the State Agency by Facility

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

To provide for the notice to physicians required under *§1819(g)(5)(C)* and *§1919(g)(5)(C)* of the Act, not later than 10 working days after receiving a notice of substandard quality of care (as defined in *42 CFR 488.301)*, a skilled nursing facility or nursing facility must provide the State agency with a list of:

- Each resident in the facility with respect to whom a finding of substandard quality of care was made; and

- The name and address of his/her attending physician.

7905.2 - Failure to Provide Information Timely
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A facility's failure to disclose the information as required in §7905.1 above will result in termination of participation or imposition of alternative remedies.

7905.3 - Federal Surveys
(Rev. 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 agency.

7906 - Information Furnished to Attending Physician and State Board
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7906.1 - State Notification of Noncompliance
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Not later than 20 calendar days after a skilled nursing facility or nursing facility complies with §7905.1, the State agency must provide written notice of the noncompliance to:

- The attending physician of each resident in the facility with respect to whom a finding of substandard quality of care was made; and

- The State board responsible for licensing the facility's administrator.

7906.2 - Federal Surveys

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

If the finding of substandard quality of care is based on a Federal survey, the State agency will provide notification of noncompliance to the above parties after receiving the necessary information from the skilled nursing facility or nursing facility. (See §7905.3.)

7907 - Access to Information by State Medicaid Fraud Control Unit

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

In accordance with the procedures in *42 CFR 455.21*, the State agency must provide access to any survey and certification information incidental to a skilled nursing facility's or nursing facility's participation in Medicare or Medicaid to a State Medicaid Fraud Control Unit as defined at *42 CFR Part 1007*, consistent with current State law and the operating agreement between the State agency and the State Medicaid Fraud Control Unit.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R213SOM	02/10/2023	Revisions to State Operations Manual (SOM), Chapter 7	02/10/2023	N/A
R161SOM	09/30/2016	Revisions to the State Operations Manual (SOM) Chapter 7	09/23/2016	N/A
R160SOM	09/23/2016	Revisions to the State Operations Manual (SOM) Chapter 7 – Rescinded and replaced by Transmittal 161	09/23/2016	N/A
R118SOM	06/12/2014	New Guidance Added to Chapter 7 – Survey and Enforcement Process for Skilled Nursing Facilities and Nursing Facilities	01/01/2012	N/A
R113SOM	04/25/2014	New Guidance Added to Chapter 7 – Survey and Enforcement Process for Skilled Nursing Facilities and Nursing Facilities – Rescinded and replaced by Transmittal 118	01/01/2012	N/A
R97SOM	12/13/2013	State Operations Manual (SOM) Chapter 7, Revisions for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)	12/13/2013	N/A
R63SOM	09/10/2010	Chapter 7-“Survey and Enforcement Process for Skilled Nursing Facilities and Nursing Facilities”	09/10/2010	N/A
R01SOM	05/21/2004	Initial Issuance of Pub 100-07	N/A	N/A