



Center for Clinical Standards and Quality/ Quality, Safety & Oversight Group

Ref: QSO 18-18-NH

DATE: June 15, 2018

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Final Revised Policies Regarding the Immediate Imposition of Federal Remedies

Memorandum Summary

- **This memo replaces the following Survey & Certification (S&C) Memos: 16-31-NH released July 22, 2016 and revised on July 29, 2016, and S&C: 18-01-NH, released in draft on October 27, 2017.** The October 2017 memo solicited comments on a proposed directive requiring, for certain situations, immediate imposition of federal remedies on Medicare and Medicaid participating skilled nursing facilities. After reviewing comments, CMS is issuing a final version of the directive. Substantive revisions to the prior Immediate Imposition of Federal Remedies guidance include:
 - When the current survey identifies Immediate Jeopardy (IJ) that does not result in serious injury, harm, impairment or death, the CMS Regional Offices may determine the most appropriate remedy;
 - We clarified that Past Noncompliance deficiencies (as described in §7510.1 of this chapter) are **not** included in the criteria for Immediate Imposition of Remedies; and,
 - For Special Focus Facilities (SFFs), S/S level “F” citations under tags F812, F813 or F814 are excluded from immediate imposition of remedies.
- **Revisions to Chapter 7 of the State Operations Manual (SOM) (Attachment):** The Centers for Medicare & Medicaid Services (CMS) has revised guidance in Chapter 7 of the SOM related to the Immediate Imposition of Federal Remedies as noted in this memo and its attachment. Other sections of Chapter 7 have been revised to ensure conformity and consistency with these revisions.

Background

Skilled Nursing Facilities (SNFs), Nursing Facilities (NFs) and dually participating facilities (SNF/NFs) are required to be in substantial compliance with Medicare and Medicaid requirements at all times and are always responsible for the health and safety of their residents.

The purpose of federal remedies, which are imposed after finding a facility is out of substantial compliance with Medicare and Medicaid requirements, is to encourage quick action on the part of facilities to promptly achieve, sustain, and maintain compliance with all federal requirements.

When a facility fails to maintain compliance with federal Medicare and Medicaid participation requirements, there are specific statutorily mandated remedies under sections 1819 and 1919 of the Social Security Act that CMS is statutorily required to take that address higher scope and severity (S/S) harm level deficiencies, substandard quality of care and cases of extended noncompliance. To support the purpose of federal remedies, we are directing the immediate imposition of federal remedies in certain situations.

In addition to the required remedies that must be imposed when a facility is determined to be out of substantial compliance, CMS will select federal remedies that inspire a facility to act quickly in order to achieve compliance and maintain continued compliance with Medicare and Medicaid requirements. Noncompliance may occur for a variety of reasons; however, whenever a facility is out of substantial compliance, it is a danger to the health and safety of its residents and can result in harm or likely harm to residents.

The CMS Regional Offices (ROs) should consider the extent to which the cited noncompliance is a one-time mistake or accident, the result of larger systemic concerns, or a more intentional action or disregard for resident health and safety in order to select a remedy that protects the health, safety and well-being of patients by encouraging the facility to quickly achieve compliance with Medicare and Medicaid requirements. When facilities are out of substantial compliance for designated time periods, have deficiencies that harm residents in violation of quality of care regulations, have repeated deficiencies that harm residents or put them in immediate jeopardy, and when SFFs are cited for certain deficiencies, States must refer case information to CMS ROs for enforcement action as specified in Chapter 7 of the SOM.

Revisions to Chapter 7 of the State Operations Manual (SOM), Chapter 7 - Survey and Enforcement Process for Skilled Nursing Facilities and Nursing Facilities (Attachment)

- CMS has revised guidance relating to the Immediate Imposition of Federal Remedies in Chapter 7 of the SOM as reflected in the advanced copy attached to this memo. Substantive revisions to the prior Immediate Imposition of Federal Remedies guidance S&C: 16-31-NH include:
 - When the current survey identifies Immediate Jeopardy (IJ) that does not result in serious injury, harm, impairment or death, the CMS RO must immediately impose a remedy. Some of the possible remedies include a civil money penalty (CMP), directed in service training, directed plan of correction. A complete list of enforcement remedies can be found at <https://www.gpo.gov/fdsys/pkg/CFR-2014-title42-vol5/pdf/CFR-2014-title42-vol5-sec488-408.pdf>;
 - Clarifying that Past Noncompliance deficiencies (as described in §7510.1 of Ch. 7 of the State Operations Manual (i.e. Determining Citations of Past Noncompliance at the Time of the Current Survey) are **not** included in the criteria for Immediate Imposition of Remedies; and,
 - For SFFs, scope/severity level “F” citations under tags F812, F813 or F814 are excluded from immediate imposition of remedies. The complete list of all F-Tags is located at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/List-of-Revised-FTags.pdf>

Other sections of Chapter 7 have been revised to ensure conformity and consistency with these revisions. Specifically, the following sections, which include previous language that has been

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renumbered, moved and/or consolidated to provide better organized guidance:

- §7205 - Survey Frequency: 15-Month Survey Interval and 12-Month State-wide Average
- §7205.1 – Last Day of Survey
- §7205.1.1 – Setting the Mandatory 3-Month and 6-Month Sanction Time Frames
- §7310 - Immediate Jeopardy (IJ) Does Not Exist
- §7317 – Acceptable Plan of Correction
- §7400.4 - Other Factors That May Be Considered in Selecting Enforcement Remedy Within a Remedy Category
- §7510.1 – Determining Citations of Past Noncompliance at the Time of the Current Survey

The final version of these revisions to Chapter 7, when published in the SOM may differ slightly from this attached interim advanced copy.

Contact: For questions related to this memo, please contact the DNH Triage Team at dnh_triageteam@cms.hhs.gov.

Effective Date: This memorandum will be effective within 30 days of its publication date. Therefore, this guidance should be communicated with all survey and certification staff, their managers, and the State/RO training coordinators within 30 days of this memorandum.

/s/
David R. Wright

Attachment: Advanced Guidance Revisions to SOM Chapter 7

cc: Survey and Certification Regional Office Management
State Medicaid Agencies

CMS Manual System

Department of Health &
Human Services (DHHS)

Pub. 100-07 State Operations Provider Certification

Centers for Medicare &
Medicaid Services (CMS)

Transmittal- ADVANCE COPY

Date: XXXX

SUBJECT: Revisions to the State Operations manual (SOM 100-07) Chapter 7

I. SUMMARY OF CHANGES: Revisions to the State Operations manual (SOM 100-07) Chapter 7 – To provide revisions in sections 7205 through 7205.1.1, 7304 through 7304.6, 7306 through 7306.4, 7308 through 7308.3, 7309 through 7309.5, 7310 through 7310.2, 7311 through 7311.3, 7313 through 7313.2, 7317, 7400 through 7400.5.3 and 7510.1.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance

IMPLEMENTATION DATE: Upon Issuance

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

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Chapter 7/7205/ Survey Frequency: 15-Month Survey Interval and 12-Month State-wide Average
R	Chapter 7/7205.1/ <i>Last Day of Survey</i>
N	<i>Chapter 7/7205.1.1/ Setting the Mandatory 3-Month and 6-Month Sanction Time Frames</i>
R	Chapter 7/7304/ Mandatory Immediate Imposition of Federal Remedies
R	Chapter 7/7304.1/ Criteria for Mandatory Immediate Imposition of Federal Remedies Prior to the Facility's Correction of Deficiencies
R	Chapter 7/7304.2/ Effective Dates for Immediate Imposition of Federal Remedies
D	Chapter 7/7304.2.1/ Mandatory Criteria for Having No Opportunity to Correct
D	Chapter 7/7304.2.2/ Additional State Discretion
R	Chapter 7/7304.3/ Responsibilities of the State Survey Agency and the CMS Regional Office (<i>RO</i>) when there is an Immediate Imposition of Federal Remedies
D	Chapter 7/7304.4/ Acceptable Plan of Correction
D	Chapter 7/7304.5/ Last Day of Survey
D	Chapter 7/7304.6/ Setting the Mandatory 3-Month and 6-Month
D	Chapter 7/7306/ Timing of Civil Money Penalties
D	Chapter 7/7306.1/ I Imposition of a Civil Money Penalty when a Facility is not allowed an Opportunity to Correct

D	Chapter 7/7306.2/ Per Day Civil Money Penalty Imposed Upon Failure to Correct
D	Chapter 7/7306.3 When State Recommends a Civil Money Penalty for Past Noncompliance
D	Chapter 7/7306.4/ Amount
R	Chapter 7/7308/ Enforcement Actions When Immediate Jeopardy (<i>IJ</i>) Exists
D	Chapter 7/7308.1/ Action That Must Be Taken
D	Chapter 7/7308.2/ Enforcement Action That Must Be Taken
D	Chapter 7/7308.3/ Action That Must Be Taken
R	Chapter 7/7309/ Key Dates When Immediate Jeopardy (<i>IJ</i>) Exists
R	Chapter 7/7309.1/ 2nd Calendar Day
R	Chapter 7/7309.2/ <i>5th - 21st Calendar Day</i>
R	Chapter 7/7309.3/ No Later Than 10th <i>Business</i> Day
R	Chapter 7/7309.4/ <i>By 23rd Calendar Day</i>
D	Chapter 7/7309.5/ By 23rd Calendar Day
R	Chapter 7/7310/ Immediate Jeopardy (<i>IJ</i>) Does Not Exist
D	Chapter 7/7310.1/ Introduction
D	Chapter 7/7310.2/ General
D	Chapter 7/7311/ Enforcement Action When Immediate Jeopardy Does Not Exist
D	Chapter 7/7311.1/ Actions to Be Taken
D	Chapter 7/7311.2/ Validation Authority
D	Chapter 7/7311.3/ Additional Action That Must Be Taken When Substandard Quality of Care Is Identified
R	Chapter 7/7313/ Procedures for Recommending Enforcement Remedies When Immediate Jeopardy (<i>IJ</i>) Does Not Exist
R	Chapter 7/7313.1/ <i>Facilities Given an Opportunity to Correct Deficiencies prior to the Immediate Imposition of Federal Remedies</i>
D	Chapter 7/7313.2/ Facilities Given an Opportunity to Correct Deficiencies prior to the Immediate Imposition of Federal Remedies
R	Chapter 7/7317/ <i>Acceptable Plan of Correction</i>
R	Chapter 7/7400/ <i>Enforcement Remedies for Skilled Nursing Facilities (SNFs), Nursing Facilities (NFs) and Dually Participating Facilities (SNFs/NFs)</i>
R	Chapter 7/7400.1/ <i>Available Federal Enforcement Remedies</i>
R	Chapter 7/7400.2/ <i>Enforcement Remedies for the State Medicaid Agency</i>
R	Chapter 7/7400.3/ <i>Selection of Remedies</i>
R	Chapter 7/7400.3.1/ <i>Matrix for Scope & Severity</i>
D	Chapter 7/7400.3.2/ Mandatory Enforcement Remedies
D	Chapter 7/7400.3.3/ Availability of State Medicaid Agency Remedies to the Regional Office in Dually Participating Facilities
R	Chapter 7/7400.4/ <i>Other Factors That May Be Considered in Selecting Enforcement Remedy Within a Remedy Category</i>
D	Chapter 7/7400.5/ Selection of Remedies
D	Chapter 7/7400.5.1/ <i>Matrix for Scope & Severity</i>
D	Chapter 7/7400.5.2/ Other Factors That May Be Considered in Selecting Enforcement Remedy Within a Remedy Category
D	Chapter 7/7400.5.3/ Requirement for Facility to Submit Plan of Correction

R	Chapter 7/7510.1/ Determining Citations of Past Noncompliance at the Time of the Current Survey
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III. FUNDING: No additional funding will be provided by CMS.

IV. ATTACHMENTS:

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

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

7205 - Survey Frequency: 15-Month Survey Interval and 12-Month State-wide Average **(Rev.)**

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.*

7205.1 - Last Day of Survey **(Rev.)**

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.)**

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.

7304 - Mandatory Immediate Imposition of Federal Remedies **(Rev.)**

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

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

7304.1 - Criteria for Mandatory Immediate Imposition of Federal Remedies Prior to the Facility's Correction of Deficiencies **(Rev.)**

*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 RO **must also** immediately impose **one or more additional** remedies for any situation that meets the criteria identified above. The State Survey and/or Medicaid Agencies **shall not** permit changes to this policy.*

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

*For IJ citations where there is **no resultant** serious injury, harm, impairment or death but the likelihood is present, the CMS RO must impose a remedy or remedies that will best achieve the*

purpose of attaining and sustaining compliance. CMPs may be imposed, but they are not required.

***NOTE:** “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 RO will consider these recommendations but ultimately makes the enforcement determination. To ensure effective communication and exchange of information, CMS encourages that all documentation is included in the ASPEN -Enforcement Manager (AEM) system or any subsequent system.*

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

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

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

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

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

***Directed In-Service Training** – Refer to §7502 of this chapter. Consider this remedy in cases where the facility has deficiencies where there are knowledge gaps in standards of practice, staff competencies or the minimum requirements of participation and where education is likely to correct the noncompliance. Depending on the topic(s) that need to be addressed and the level of training needed, facilities should consider using programs developed by well-established centers of geriatric health services such as schools of medicine or nursing, centers for the aging, and area health education centers which have established programs in geriatrics and geriatric*

psychiatry. If it is willing and able, a State may provide special consultative services for obtaining this type of training. The State or regional office may also compile a list of resources that can provide directed in-service training and could make this list available to facilities and interested organizations. Facilities may also utilize the ombudsman program to provide training about residents' rights and quality of life issues.

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

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

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

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

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

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.*

7304.2 - Effective Dates for Immediate Imposition of Federal Remedies **(Rev.)**

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

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

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

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

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

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

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

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

7308 - Enforcement Actions When Immediate Jeopardy (IJ) Exists (Rev.)

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 constitute IJ, the team leader must contact, while on-site, its management to discuss the findings. If it is determined that IJ exists the team must notify the facility administration, while on-site, of the IJ findings.

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

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

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

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

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

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

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

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

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

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

7309.1 - 2nd Calendar Day **(Rev.)**

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

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

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

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

7309.2 - 5th - 21st Calendar Day **(Rev.)**

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

7309.3 - No Later Than 10th Business Day **(Rev.)**

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.)**

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

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

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 I 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 Regional Office 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 Regional Office 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).

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

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.)**

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).

7317 - Acceptable Plan of Correction **(Rev.)**

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.

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.

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

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.)**

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.)**

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

- *Temporary management;*
- *Denial of payment for all new admissions;*
- *Civil money penalties;*
- *Transfer of residents;*

- *Transfer of residents with closure of facility; and*
- *State monitoring.*







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


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


7400.3 - Selection of Remedies
(Rev.)

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.

7400.3.1 - Matrix for Scope & Severity
(Rev.)

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

 *Substandard Quality of Care (SQC) is defined in 42 C.F.R. §488.301 as one or more deficiencies which constitute either immediate jeopardy to resident health or safety; a pattern of or widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm, related to certain participation requirements.*

 *Substantial compliance means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm. Substantial compliance constitutes compliance with participation requirements (42 C.F.R. §488.301).*

7400.4 - Other Factors That May Be Considered in Selecting Enforcement Remedy Within a Remedy Category
(Rev.)

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

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

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

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

(Rev.)

Past noncompliance may be identified during any survey. For the purpose of making determinations of current noncompliance or past noncompliance, the survey team is expected to follow the investigative protocols and surveyor guidance. To cite past noncompliance with a specific survey data tag (F-tag or K-tag), all of the following three criteria must be met:

1. The facility was not in compliance with the specific regulatory requirement(s) (as referenced by the specific F-tag or K-tag) at the time the situation occurred;
2. The noncompliance occurred after the exit date of the last standard (recertification) survey and before the survey (standard, complaint, or revisit) currently being conducted; and
3. There is sufficient evidence that the facility corrected the noncompliance and is in substantial compliance at the time of the current survey for the specific regulatory requirement(s), as referenced by the specific F-tag or K-tag.

A nursing home does not provide a plan of correction for a deficiency cited as past noncompliance because the deficiency is already corrected; however, the survey team documents the facility's corrective actions on the CMS-2567.

Regulations at 42 CFR 488.430(b) provide that a civil money penalty (**CMP**) may be imposed for past noncompliance since the last standard survey. CMS strongly urges States to recommend the imposition of a **CMP** for past noncompliance cited at the level of immediate jeopardy.

When a **CMP** is recommended, the State **Survey Agency** notifies the **CMS Regional Office (RO)** and/or State Medicaid Agency within 20 days from the last day of the survey that determined past noncompliance of its recommendation to impose a **CMP**. The **CMS RO** and/or State Medicaid Agency responds to the recommendation within 10 days, and if accepted, sends out the formal notice in accordance with the notice requirements in §7305 and §7520.