

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 18-01-NH

DATE: October 27, 2017

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Revised Policies regarding the Immediate Imposition of Federal Remedies- FOR ACTION

Memorandum Summary

- **This policy memo replaces S&C: 16-31-NH released July 22, 2016 and the revision on July 29, 2016.**
- **Revisions to Chapter 7 of the State Operations Manual (SOM) (Attachment):** The Centers for Medicare & Medicaid Services (CMS) has revised guidance relating to the Immediate Imposition of Federal Remedies. Other sections of Chapter 7 have been revised to ensure consistency with these revisions. Major revisions include:
 - We specify that when the current survey identifies Immediate Jeopardy (IJ) that does not result in serious injury, harm, impairment or death, the CMS Regions 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;
 - For Special Focus Facilities (SFFs), we now exclude any S/S level “F” citations under tags F812, F813 or F814 from the tags that require immediate imposition of remedies.
- **This memo is being released in draft. We seek comment on this policy by December 1, 2017.**

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 its residents.

The purpose of federal remedies is to promote the initiative and responsibility of facilities to continuously monitor their performance and 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.

In addition to the required enforcement action(s), remedies should be selected that will bring about compliance quickly and to maintain continued compliance. Noncompliance may occur for a variety of reasons and can result in various levels of harm or likely harm to residents. The CMS Regional Offices (ROs) should consider the extent to which the 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.

CMS is in the process of updating the SOM to reflect this revised guidance. The final version of this document when published in the on-line SOM may differ slightly from this interim advanced copy which is attached.

Contact: Please contact the CMS Regional Office or the dnh_triageteam@cms.hhs.gov to provide feedback on this draft by December 1, 2017.

Effective Date: CMS is seeking input on this draft and requests comments. CMS will review these comments before issuing a final version.

/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

Pub. 100-07 State Operations Provider Certification

Department of Health &
Human Services (DHHS)
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 7304 through 7304.3, 7306, 7308.3, 7313.2, 7400.5, and 7400.5.1 regarding policies related to Immediate Imposition of Federal Remedies (previously referred to as Opportunity or No Opportunity to Correct). Sections 7304.2.1 and 7304.2.2 have been deleted and incorporated into other sections noted above.

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 7/7304/ Mandatory Immediate Imposition of Federal Remedies |
| R | Chapter 7/7304.1/ Criteria for Mandatory Immediate Imposition of Federal Remedies |
| 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 when there is an Immediate Imposition of Federal Remedies |
| R | Chapter 7/7306/ Timing of Civil Money Penalties <i>(CMPs) for Immediate Imposition</i> |
| D | Chapter 7/7306.1/ I Imposition of a Civil Money Penalty when a Facility is not allowed an Opportunity to |
| 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 <i>Business</i> Day |
| R | Chapter 7/7309.2/ 5th <i>Business</i> Day |
| R | Chapter 7/7309.3/ 5th - 21st Calendar Day |
| R | Chapter 7/7309.4/ No Later Than 10th <i>Calendar</i> Day |
| R | Chapter 7/7309.5/ By 23rd Calendar Day |
| R | Chapter 7/7313/ Procedures for Recommending Enforcement Remedies When Immediate Jeopardy 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 7/7400/ <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/ Availability of State Medicaid Agency Remedies to the Regional Office in Dually Participating Facilities |
| R | Chapter 7/7400.5/ <i>Factors That Must Be Considered When Selecting Remedies</i> |
| D | Chapter 7/7400.5.1/ <i>Matrix for Scope & Severity</i> |

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.

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 encourage prompt compliance. The purpose of federal remedies is to promote the initiative and responsibility of facilities to continuously monitor their performance and 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 federal remedies for past noncompliance 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.)

A facility *shall not be offered* an opportunity to correct deficiencies before federal remedies are imposed 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 Substandard Quality of Care (SQC) regulatory sections that are not IJ but did result in injury, harm, or impairment; 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., be from different noncompliance cycles. In other words, level G or above deficiencies from multiple surveys within the same noncompliance cycle must not be combined to make this “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.*

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.

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 may or may not accept these recommendations.

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 achieve and maintain compliance. When making remedy choices, the CMS RO considers 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.

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.*

***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 are only 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.*

If a per instance CMP is imposed, the facility shall not be given an opportunity to correct any deficiency for which this CMP is imposed prior to the imposition of this remedy.

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 §7550 of this chapter. 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 must be imposed when a facility's deficiencies constitute IJ or widespread actual harm and a decision is made to impose an alternative remedy to 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. 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.)

The State Survey Agency must immediately inform its CMS RO when immediate imposition of remedies must be made so that the notice letter, from the State Survey Agency or the CMS RO, to the facility can promptly be sent out and meet the timelines for notice as outlined in §7305 of this chapter. This will ensure that remedies are imposed as soon as possible. Once a remedy is imposed, it becomes effective as of the date in the notice letter. All remedies remain in effect and continue until the facility is determined to be in substantial compliance (which may occur before the revisit date). Substantial compliance must be verified in accordance with §7317 of this chapter.

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 or not 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 §7304.1, *within five (5) business days from when the initial notice was sent to the facility by the survey agency*, the State Survey Agency **MUST**:

- Copy the CMS RO on its initial notice to the facility. The State Survey Agency does not need prior approval from the CMS RO before sending this notice to the facility; *and*
- Assure *all of* these cases are referred to the CMS RO for *their review and* action.

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.

7306 - Timing of Civil Money Penalties (CMPs)

(Rev.)

7306.1 - Immediate Imposition of a Civil Money Penalty (CMP)

(Rev)

If a per instance CMP is imposed, the facility shall not be given an opportunity to correct any deficiency for which this CMP is imposed prior to the imposition of this remedy.

While the State Survey Agency is not required to recommend that a CMP (or the amount of a CMP) be imposed as a result of the noncompliance referenced in §7304.1, they may do so. This recommendation must be sent to the CMS regional office (RO) and the State Medicaid Agency.

The *CMS RO* and *the* State Medicaid Agency *must respond* to the State survey agency's recommendation and, if accepted, *the CMS RO* sends out the formal notice *of the immediate imposition of a CMP to the facility* in accordance with the requirements in §§7305, 7309 and 7520.

7308 - Enforcement Actions When Immediate Jeopardy (IJ) Exists

(Rev.)

When the State *Survey Agency* identifies *IJ*, *no later than two business days following the survey date which identified the IJ*, it must notify;

- The *CMS* Regional Office (*RO*) *and* the State Medicaid Agency *of its survey findings by telephone, e-mail, or other means acceptable to the CMS RO and the State Medicaid agency: and,*
- *The facility of the IJ findings in writing. A written notice or letter to the facility in lieu of a Form CMS 2567 would be acceptable.*

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 to the imposition of enforcement remedies, the *CMS RO* terminates the *Medicare* 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 *no more than* 23 calendar days of the last date of the survey. When the *CMS RO* imposes termination of a Medicare provider agreement, it *must* notify the State Medicaid Agency.

In order *to prevent* termination *from occurring within 23 days*, the *IJ must be removed, even if the underlying deficiencies have not been fully corrected*. When *IJ* is identified, the facility must submit an allegation that the *IJ* has been removed, *including a specific plan detailing* how and when the *IJ* was removed.

Documentation 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).

If the facility alleges that the *IJ* is removed and *the survey agency verifies this* but the facility is still not in substantial compliance, *then complete a full Statement of Deficiencies (CMS Form 2567)*, which requires a plan of correction for all *remaining deficiencies*.

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 *Business* Day **(Rev.)**

When the State *Survey Agency* identifies *IJ*, *no later than two business days following the survey date which identified the IJ*, it must notify;

- The *CMS Regional Office (RO) and the State Medicaid Agency of its survey findings by telephone, e-mail, or other means acceptable to the CMS RO and the State Medicaid agency: and,*
- *The facility of the IJ findings in writing that the State is recommending to the CMS RO (for skilled nursing facilities and dually participating facilities) or to the State*

Medicaid Agency (for nursing facilities) that the provider agreement be terminated and that a Civil Money Penalty (CMP) or other remedies may be imposed, refer to §§7304 and 7304.1. A temporary manager may be imposed in lieu of or in addition to termination. Procedures pertaining to the imposition of CMPs and temporary management can be found in §§7510-7536 and §7550, respectively.

This letter *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.

7309.2 - 5th *Business* Day **(Rev.)**

Within five business days from when the initial notice was sent to the facility by the State Survey Agency, they must assure these IJ cases are forwarded and referred to the CMS RO for their review and action, including all documentation (e.g., notice letter, contact reports, Forms CMS-1539 and CMS-2567, if completed). *This information may be transmitted and referred to the CMS RO via the Automated System Processing Environment (ASPEN)/ASPEN Enforcement Manager (AEM) system.*

7309.3 - 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 (see §7305). 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 as specified in §7550, 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.

7309.4 - No Later Than 10th *Calendar* Day **(Rev.)**

If the survey entity verifies that the IJ has been removed, then the survey agency must send the Statement of Deficiencies (Form CMS-2567) to the facility, the CMS RO, and, if the facility participates in Medicaid, the State Medicaid Agency.

NOTE: The facility is not required to submit a *PoC* in order to verify the removal of the *IJ*. The facility *should* 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-CMS-2567)* from the survey agency.

The CMS RO must impose a Civil Money Penalty (CMP) if the IJ resulted in serious injury, harm, impairment or death on the current survey.

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 whichever type of remedy best achieves the purpose of achieving and sustaining compliance and address various levels of noncompliance.

7309.5 - By 23rd Calendar Day

(Rev.)

Termination takes effect unless the *IJ* has been removed. If the *IJ* has been removed *and verified by the survey agency however additional deficiencies remain and* substantial compliance has not been achieved, the facility may be given up to 6 months from the last day of survey during which to achieve substantial compliance. (See §7316 for key dates when immediate jeopardy does not exist.)

7313 - Procedures for Recommending Enforcement Remedies When Immediate Jeopardy 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.*

The State Survey Agency, or the CMS regional office (RO) for federal surveys, provides the initial notice to the facility that failure to correct cited deficiencies may result in the recommendation or imposition of remedies. The State Survey Agency may provide formal notice in its initial notice to the facility or in its notice letter related to the first revisit survey of the imposition of Category 1 remedies and the denial of payment for new admissions if authorized by its CMS RO.

If at the time of the first revisit the facility has not achieved substantial compliance, remedies may be imposed and will be effective once formal notice has been provided to the facility. In these circumstances, the State Survey Agency recommends to the CMS RO and the State

Medicaid Agency that remedies be imposed and/or *become* effective. The *CMS RO* and *the* State Medicaid Agency should establish procedures with the State *Survey Agency* as to when and how the documentation of noncompliance is to be communicated *and how and when responses regarding these recommendations will be made.*

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 as long as 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.)

In order 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 encourage the provider to achieve and sustain substantial compliance. 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.)

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

Substandard 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).