
CMS Manual System

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

Transmittal 161

Date: September 28, 2016

Transmittal 160, dated September 23, 2016 is being rescinded and replaced by Transmittal 161, dated September 28, 2016 to correct minor formatting edits within the transmittal table and table of contents pages. All other information remains the same.

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

I. SUMMARY OF CHANGES: To provide revisions in sections 7304 through 7304.3, 7306.1, 7308.3, 7400.5.1, 7400.6.2 and 7313.2 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: September 23, 2016

IMPLEMENTATION DATE: September 23, 2016

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	7/Table of Contents
R	7/7304 Mandatory Immediate Imposition of Federal Remedies
R	7/7304.1 Criteria for Mandatory Immediate Imposition of Federal Remedies
R	7/7304.2 Effective Dates for Immediate Imposition of Federal Remedies Prior to the Facility's Correction of Deficiencies
D	7/7304.2.1 Certification- Related Terms/ Mandatory Criteria for Having No Opportunity to Correct
D	7/7304.2.2 Additional State Discretion
R	7/7304.3 Responsibilities of the State Survey Agency and the CMS Regional Office when there is an Immediate Imposition of Federal Remedies
R	7/7306.1 Imposition of a Civil Money Penalty when a Facility is not allowed an Opportunity to Correct
R	7/7308.3 /Enforcement Action That Must Be Taken
R	7/7313.2 Facilities Given an Opportunity to Correct Deficiencies prior to the Immediate Imposition of Federal Remedies

R	7/7400.5.1 /Factors That Must Be Considered When Selecting Remedies
R	7/7400.6.2- - Category 2

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.**

State Operations Manual

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

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

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7304 - Mandatory Immediate Imposition of Federal Remedies
(Rev.161, Issued: 09-28-16, Effective: 09-23-16, Implementation: 09-23-16)

The CMS Regional Office (RO) or the State Survey Agency has no obligation to provide a facility (SNF, SNF/NF or NF) an opportunity to correct its deficiencies prior to immediately imposing federal remedies. Federal remedies **must** be immediately imposed in accordance with the criteria identified in §7304.1 below and must meet the minimum notice requirements in §7305 of this chapter that are applicable to the imposition of remedies. The State Survey and/or Medicaid Agencies **shall not** permit changes to this policy and **shall not** offer a facility an opportunity to correct cited deficiencies before federal remedies are imposed if the situation meets the criteria in §7304.1.

7304.1 - Criteria for Mandatory Immediate Imposition of Federal Remedies Prior to the Facility's Correction of Deficiencies
(Rev.161, Issued: 09-28-16, Effective: 09-23-16, Implementation: 09-23-16)

The CMS RO must immediately impose, prior to affording a facility an opportunity to correct deficiencies, one or more federal remedies for a facility (SNF, SNF/NF or NF) in any one or more of the following circumstances:

- Immediate Jeopardy (IJ) (scope and severity levels J, K, and L) is identified on the current survey; **OR**
- Deficiencies of SQC that are not IJ are identified on the current survey; **OR**
- Any G level deficiency is identified on the current survey in 42 C.F.R. §483.13, Resident Behavior and Facility Practices, 42 C.F.R. §483.15, Quality of Life, or 42 C.F.R. §483.25, Quality of Care; **OR**
- Deficiencies of actual harm or above (level G or above) on the current survey as well as having deficiencies of actual harm or above on the previous standard health or LSC survey **OR** deficiencies of actual harm or above on any type of survey between the current survey and the last standard survey. These surveys must be separated by a period of compliance (i.e., from different noncompliance cycles); **OR**
- A facility is classified as a Special Focus Facility (SFF) **AND** has a deficiency citation at level “F” or higher for the current health survey or “G” or higher for the current Life Safety Code (LSC) survey.

NOTE: The “current” survey is whatever Health and/or Life Safety Code (LSC) survey is currently being performed, i.e., standard, revisit, or complaint.

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

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

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 §488.404:

42 C.F.R. §488.404 - Factors to be considered in selecting remedies:

- (a) Initial assessment. In order to select the appropriate remedy, if any, to apply to a facility with deficiencies, CMS and the State determine the seriousness of the deficiencies.*
- (b) Determining seriousness of deficiencies. To determine the seriousness of the deficiency, CMS considers and the State must consider at least the following factors:*
 - (1) Whether a facility's deficiencies constitute—*
 - (i) No actual harm with a potential for minimal harm;*
 - (ii) No actual harm with a potential for more than minimal harm, but not immediate jeopardy;*
 - (iii) Actual harm that is not immediate jeopardy; or*
 - (iv) Immediate jeopardy to resident health or safety.*
 - (2) Whether the deficiencies—*
 - (i) Are isolated;*
 - (ii) Constitute a pattern; or*
 - (iii) Are widespread.*
- (c) Other factors which may be considered in choosing a remedy within a remedy category.*

Following the initial assessment, CMS and the State may consider other factors, which may include, but are not limited to the following:

- (1) The relationship of the one deficiency to other deficiencies resulting in noncompliance.*
- (2) The facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.*

Mandatory Criteria for Immediate Imposition of Federal Remedies

<i>Mandatory Criteria for Immediate Imposition of Federal Remedies</i>	<i>Immediate Jeopardy is identified on the current survey</i>	<i>Deficiencies of SQC that are not IJ are identified on the current survey</i>	<i>Any G level deficiency is identified on the current survey in 42 C.F.R. §483.13, Resident Behavior and Facility Practices, 42 C.F.R. §483.15, Quality of Life, or 42 C.F.R. §483.25, Quality of Care</i>	<i>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</i>	<i>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</i>
<i>Types of Remedy(ies) that, at a minimum, should be considered for immediate imposition by CMS in addition to the CMPs when immediate jeopardy is cited, mandatory 3-month DPNA for new admissions or mandatory 6-month termination, as required. NOTE: Multiple remedies may be imposed for any situation as appropriate.</i>	<ol style="list-style-type: none"> 1. Termination 2. CMPs <u>must</u> be imposed immediately 3. DDPNA¹ 4. Temp. Mgmt. 5. State Monitoring 6. Directed Plan of Correction 7. Directed In-service 8. Denial of Payment for ALL Individuals² 	<ol style="list-style-type: none"> 1. Termination 2. CMPs 3. DDPNA 4. Directed Plan of Correction 5. Directed In-service Training 6. Denial of Payment for All Individuals 	<ol style="list-style-type: none"> 1. Termination 2. CMPs 3. DDPNA 4. Directed Plan of Correction 5. Directed In-service Training 6. Denial of Payment for All Individuals 	<ol style="list-style-type: none"> 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 	<ol style="list-style-type: none"> 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
<i>Decisions, Responsibilities & Actions (refer to §7304.3)</i>	<i>Within 5 business days from when the initial notice was sent to the facility the survey agency must assure that all cases that meet the criteria outlined in 7304.1 above are entered into ASPEN/AEM and that all of these cases are referred to the CMS RO for their imposition of remedies. The CMS RO must take the necessary action to impose remedies as appropriate, regardless of a State's recommendation for imposition of remedies, based on the seriousness of the deficiencies following the criteria set forth in 42 C.F.R. §488.404 - Factors to be considered in selecting remedies. Civil Money Penalties (CMPs) must be imposed in accordance with instructions in the CMP Tool.</i>				

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

¹ DDPNA = Discretionary Denial of Payment for New Admissions

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

7304.2 - Effective Dates for Immediate Imposition of Federal Remedies
(Rev.161, Issued: 09-28-16, Effective: 09-23-16, Implementation: 09-23-16)

Once an enforcement remedy is imposed, it is in effect as of the date in the notice letter (i.e., as soon as the minimum notice requirements are met as outlined in §7305 of this chapter). All remedies remain in effect and continue until the facility is in substantial compliance and in accordance with 42 C.F.R. §488.414(a)(3) - Repeated Substandard Quality of Care, until it has demonstrated to the satisfaction of CMS or the State Survey Agency that it is in substantial compliance with all requirements and will remain in substantial compliance with all requirements, or is terminated from Medicare and/or Medicaid participation. Substantial compliance must be verified in accordance with §7317 of this Chapter.

For Immediate Jeopardy Situations:

Removal of the conditions that are IJ may, at CMS's discretion, result in the rescission of the 23-day termination that was imposed against the facility. However, once the minimum notice requirements are met, CMS **shall not** rescind any remedies imposed. Any cited deficiency of a S/S level of J or higher must have remedies effectuated against the facility. The CMP must be imposed and be in effect, irrespective of when the IJ is removed, unless otherwise rescinded as a result of legal proceedings. Remedies will be immediately imposed and effectuated whether or not the immediate jeopardy was:

- past noncompliance, or,
- 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 when there is an Immediate Imposition of Federal Remedies
(Rev.161, Issued: 09-28-16, Effective: 09-23-16, Implementation: 09-23-16)

When a facility is **NOT** provided an opportunity to correct deficiencies prior to the imposition of federal remedies as outlined in §7304.1 above, the State Survey Agency **MUST** copy the CMS RO on its initial notice to the facility and assure these enforcement cases are referred to the CMS RO for action no later than five (5) business days from the date the notice is sent to the facility. The State Survey Agency does not need prior approval from the CMS RO before sending this notice to the facility.

The State Survey Agency and the CMS RO for Federal Monitoring surveys must ensure these enforcement cases are entered into the ASPEN-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.

7306.1 - Imposition of a Civil Money Penalty when a Facility is not allowed an Opportunity to Correct

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

A facility is not given an opportunity to correct any deficiency against which a per instance civil money penalty is imposed. The State may recommend that a per day civil money penalty be imposed without an opportunity for the facility to correct deficiencies as a result of the types of noncompliance referenced in §7304.1 In this case, the State notifies the regional office and/or State Medicaid Agency of its recommendation (that the regional office or State Medicaid agency impose a civil money penalty) within 10 working days from the last day of the survey which determined noncompliance when immediate jeopardy does not exist, or 2 calendar days (one of which must be a working day) when immediate jeopardy exists. The regional office and/or State Medicaid Agency responds quickly to the recommendation, and if accepted, sends out the formal notice in accordance with the notice requirements in §7305, and any additional requirements in §7520.

7308.3 - Enforcement Action That *Must* Be Taken

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

The State *Survey Agency may* recommend to the *CMS Regional Office and* the State Medicaid Agency, as appropriate, remedies *that* it believes will achieve and maintain compliance, *in addition to the required enforcement action(s).*

The CMS RO must immediately impose a Civil Money Penalty (CMP) for any deficiency cited at a Scope and Severity (S/S) level of J or higher on the current survey, without permitting an opportunity to correct deficiencies. Irrespective of a state recommendation or no recommendation of a remedy, the CMS RO may also impose additional remedies as warranted.

7313.2 - Facilities Given an Opportunity to Correct *Deficiencies prior to the Immediate Imposition of Federal Remedies*

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

The State may provide an opportunity for the facility to correct its deficiencies and defer the imposition of remedies *only when the criteria outlined in §7304.1 of this Chapter is not met.* The State requests a plan of correction and provides initial notice that failure to correct cited deficiencies will result in a recommendation of remedies to CMS or the State Medicaid Agency, and/or, as appropriate and, as authorized by CMS and/or the State Medicaid Agency, provides a

formal notice of imposition as category 1 remedies to be effective no sooner than 15 days from the date of this notice. If authorized by the regional office, the State may provide formal notice of the imposition of denial of payment for new admissions in this initial notice or it may provide such formal notice in its first revisit letter. (See also [§7301](#), [§7305.1](#), [§7311](#), [§7314](#), [§7316.2](#), and [§7506.1](#)) If the facility is in substantial compliance as determined by the State in accordance with instructions in [§7317](#) for verifying compliance, **no remedies will be imposed**. If it is determined that the facility has not achieved substantial compliance, the State recommends that remedies be imposed and/or, that remedies be effective when notice of remedies has already been provided. If a civil money penalty is being recommended, the effective date of the civil money penalty is generally the last day of the original survey as described in [§7518](#). The regional office and/or State Medicaid Agency responds to the recommendation within 14 working days and sends out the formal notice to the facility imposing the remedy(ies). (See [§7305](#) for notice requirements.)

When the State determines noncompliance at the revisit, it will recommend imposition of the remedies proposed. The State notifies the regional office and the State Medicaid Agency of its recommendation of choice of remedy and the timing for imposing such remedies.

The regional office and State Medicaid Agency establish procedures with the State as to when and how the documentation of noncompliance is to be communicated.

7400.5.1 - Factors That Must Be Considered When Selecting Remedies *(Rev.161, Issued: 09-28-16, Effective: 09-23-16, Implementation: 09-23-16)*

In order to select the appropriate remedy(ies) for a facility's noncompliance, the seriousness of the deficiencies must first be assessed, because specific levels of seriousness correlate with specific categories of enforcement responses. *Assessment factors that must be used to determine the seriousness of deficiencies are presented on [the following](#) matrix.* These factors relate to whether the deficiencies constitute:

- No actual harm with a potential for minimal harm;
- No actual harm with a potential for more than minimal harm but not immediate jeopardy;
- Actual harm that is not immediate jeopardy; or
- Immediate jeopardy to resident health or safety.

AND, whether deficiencies:

- Are isolated;
- Constitute a pattern; or
- Are widespread.

**ASSESSMENT FACTORS USED TO DETERMINE
THE SERIOUSNESS OF DEFICIENCIES MATRIX**

Immediate jeopardy to resident health or safety	J [redacted] PoC [redacted] Required: Cat. 3 Optional: Cat. 1 and Cat. 2 [redacted]	K [redacted] PoC [redacted] Required: Cat. 3 Optional: Cat. 1 and Cat. 2 [redacted]	L [redacted] PoC [redacted] Required: Cat. 3 Optional: Cat. 1 and Cat. 2 [redacted]
Actual harm that is not immediate	G PoC Required Cat. 2 Optional: Cat. 1	H [redacted] PoC [redacted] Required Cat. 2 Optional: Cat. 1 [redacted]	I [redacted] PoC [redacted] Required Cat. 2 Optional: Cat. 1 and Temporary Mgmt.
No actual harm with potential for more than minimal harm that is not immediate jeopardy	D PoC Required* Cat. 1 Optional: Cat. 2	E PoC Required* Cat. 1 Optional: Cat. 2	F [redacted] PoC [redacted] Required* Cat. 2 Optional: Cat. 1 [redacted]
No actual harm with potential for minimal harm	A [redacted] No PoC [redacted] No remedies Commitment to Correct [redacted] Not on CMS-2567	B [redacted] PoC [redacted] <i>No remedies</i> [redacted]	C [redacted] PoC [redacted] <i>No remedies</i> [redacted]
	Isolated	Pattern	Widespread

Substandard quality of care is any deficiency in **42 C.F.R. §483.13**, Resident Behavior and Facility Practices, **42 C.F.R. §483.15** Quality of Life, or **42 C.F.R. §483.25**, Quality of Care, that constitutes immediate jeopardy to resident health or safety; or a pattern of or widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm that is not immediate jeopardy, with no actual harm.

[redacted] *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).*

**This is required only when a decision is made to impose enforcement remedies instead of or in addition to termination.*

REMEDY CATEGORIES

Category 1 (Cat.1)	Category 2 (Cat.2)	Category 3 (Cat.3)
Directed Plan of Correction State Monitoring Directed In-Service Training	Denial of Payment for New Admissions Denial of Payment for All Individuals imposed only by CMS Civil money penalties: <i>Lower range per day Per instance³</i>	Temp. Mgmt. Termination Civil money penalties: <i>Upper range per day Per instance</i>

7400.6.2 - Category 2

(Rev.)

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

- Widespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or
- One or more deficiencies (regardless of scope) that constitute actual harm that is not immediate jeopardy.

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

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

CATEGORY 2 remedies include:

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

³ *Nursing home CMP amounts are subject to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (P.L. 114-74).*