
CMS Manual System

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

Transmittal 221

Date: May 10, 2024

SUBJECT: Revisions to the State Operations Manual (SOM) Chapter 10 –Informal Dispute Resolution (IDR) and Enforcement Procedures for Home Health Agencies and Hospice Programs

I. SUMMARY OF CHANGES: The Centers for Medicare & Medicaid Services (CMS) has revised the State Operations Manual (SOM) chapter 10 to provide procedures regarding the informal dispute resolution (IDR) process for both Home Health Agencies (HHAs) and hospice programs. The revisions also include guidance for State Agencies (SAs) and CMS Survey & Operations Group (SOG) Locations on recommending and imposing HHA alternative sanctions and hospice enforcement remedies.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: May 10, 2024

IMPLEMENTATION DATE: May 10, 2024

Or

MANUALIZATION/CLARIFICATION – EFFECTIVE/IMPLEMENTATION DATES: Not Applicable.

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
N	SOM/Chapter 10/ Informal Dispute Resolution and Enforcement Procedures for Home Health Agencies and Hospice Programs

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

Or

Funding for implementation activities will be provided to contractors through the regular budget process.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction

	Confidential Requirements
	One-Time Notification
	One-Time Notification - Confidential
	Recurring Update Notification

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

State Operations Manual
Chapter 10 – Informal Dispute Resolution and
Enforcement Procedures for Home Health Agencies and
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(Rev. 221; Issued: 05-10-24)

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10000 – Introduction

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

The Secretary has the responsibility to promote quality of care and the health and safety of patients receiving services through Medicare certified home health agencies (HHA) and hospice programs by ensuring that providers maintain compliance with the Conditions of Participation (CoP). The survey and certification process provides a method for CMS to evaluate HHA and hospice programs' compliance with the CoPs, ensuring that patient services provided meet the minimum health and safety standards and a basic level of quality. This process is explained in Appendix B of this manual for HHAs and Appendix M of this manual for hospice programs.

Chapter 10 provides guidance for the HHA and hospice program enforcement regulations at 42 CFR Part 488. No provisions contained in this chapter are intended to create any rights or sanctions not otherwise provided in law or regulation.

In accordance with 42 CFR §488.800 – §488.865 for HHAs and §488.1200-§488.1265 for hospice programs, in addition to termination of the HHA's or hospice program's provider agreement, sanctions such as civil money penalties (CMP), suspension of payment for all new admissions, temporary management, directed plans of correction, and directed in-service training can be imposed when an HHA or hospice program are out of compliance with Federal requirements.

Alternative sanctions in HHAs and enforcement remedies in hospice programs are recommended by the State survey agency (SA), and the CMS Location reviews the SA recommendation to ensure that it is supported by the SA findings. However, the CMS Location does not have the authority to delegate the imposition of sanctions to the State.

It should be noted that failure of CMS or the State to act timely does not invalidate otherwise legitimate survey and enforcement determinations.

10001 - Definitions and Acronyms

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

***Abbreviated standard** survey means a focused survey other than a standard survey that gathers information on an HHA's or hospice program's compliance with fewer specific standards or CoPs. An abbreviated standard survey may be based on complaints received or other indicators of specific concern such as reapplication for Medicare billing privileges following a deactivation. (HHA: 42 CFR §488.705; Hospice: SOM Appendix M, Task I)*

An abbreviated standard survey is a focused survey that examines any standard(s) related to the reason for the survey.

AO – National Accreditation Organization whose program is approved by CMS. (42 CFR §488.1)

***Certification of compliance** means that the HHA or hospice program is in compliance with the CoPs and is eligible to participate in the Medicare program. (HHA: 42 CFR §488.740)*

***CFR** - Code of Federal Regulations.*

***CMP** - Civil money penalty. (HHA: 42 CFR 488.845; Hospice: 42 CFR §488.1245)*

***CMS Location**- previously known as CMS Regional Office(s), the CMS Location(s) are part of the Survey & Operations Group (SOG) within CMS.*

***Complaint investigation**, previously known as a complaint survey, means an onsite review that is conducted to investigate specific allegations of noncompliance.*

***Condition-level deficiency** means noncompliance as described in 42 CFR §488.24. A condition-level deficiency is any deficiency of such character that substantially limits the provider's or supplier's capacity to furnish adequate care or which adversely affects the health or safety of patients.*

***Credible allegation of compliance** is a statement or documentation that is realistic in terms of the possibility of the corrective action being accomplished between the exit conference and the date of the allegation; and that indicates resolution of the problems.*

***Deficiency** is a violation of the Act and regulations contained in part 484 for HHAs, subparts A through C of this chapter, and §418 for hospice programs, subparts C and D of this chapter, is determined as part of a survey, and can be either standard or condition-level.*

***Directed plan of correction** means CMS or the temporary manager (with CMS/SA approval) may direct the HHA or hospice program to take specific corrective action to achieve specific outcomes within specific timeframes. (HHA: 42 CFR §488.805; Hospice: 42 CFR §488.1250)*

***Enforcement action** means the process of imposing one or more of the following alternative sanctions for HHAs or enforcement remedies for hospice programs: termination of a provider agreement; suspension of payment for all new admissions; temporary manager; civil money penalty; directed plan of correction; or directed in-service training. (HHA: 42 CFR §488.810-865; Hospice: 42 CFR §488.1200-1265)*

***Extended survey (HHA only)** means a survey that reviews additional CoPs not examined during a standard survey. It may be conducted at any time but must be conducted when substandard care is identified. (42 CFR §488.705)*

Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause serious injury, harm, impairment, or death to a patient(s).

iQIES – Internet Quality Improvement and Evaluation System.

New admission means an individual who becomes a patient or is readmitted to the HHA or hospice on or after the effective date of a suspension of payment sanction. (HHA: 42 CFR §488.805)

Noncompliance means any deficiency found at the condition-level or standard-level.

Partial extended survey (HHA only) means a survey conducted to determine if deficiencies and/or deficient practice(s) exist that were not fully examined during the standard survey. The surveyors may review any additional requirements which would assist in making a compliance finding. (42 CFR §488.705)

Per day means a CMP imposed for the number of days a facility is not in substantial compliance with the CoPs.

Per instance means a single event of noncompliance identified and corrected through a survey, for which the Act authorizes CMS to impose a sanction or remedy. (HHA: 42 CFR §488.805; Hospice: 42 CFR §488.1245(b)(6))

Plan of correction means a plan developed by the HHA or hospice program and approved by CMS that is the HHA's or hospice program's written response to survey findings detailing corrective actions to cited deficiencies and specifies the date by which those deficiencies will be corrected.

Repeat deficiency means a condition-level citation that is cited on the current survey and is substantially the same as or similar to, a finding of a standard-level or condition-level deficiency cited on the most recent previous standard survey or on any intervening survey since the most recent standard survey. Repeated non-compliance is not on the basis that the exact regulation (that is, tag number) for the deficiency was repeated. (HHA: 42 CFR §488.805; Hospice: 42 CFR 488.1205)

Standard-level deficiency means noncompliance with one or more of the standards that make up each condition of participation.

Standard survey means a survey conducted in which the surveyor reviews the HHA's or hospice program's compliance with a select number of standards and/or CoPs to determine the quality of care and services furnished by an HHA or hospice program. (HHA: 42 CFR §488.705)

State survey agency (SA) means the entity responsible for conducting most surveys to certify compliance with the Medicare participation requirements.

Substandard care means noncompliance with one or more CoPs identified on a standard survey, including deficiencies which could result in actual or potential harm to patients. (HHA: 42 CFR §488.705)

Substantial compliance means compliance with all condition-level requirements, as determined by CMS, the SA, or AO. (HHA: 42 CFR §488.705; Hospice: 42 CFR 488.1105)

Temporary management means the temporary appointment by CMS or by a CMS authorized agent, of a substitute manager or administrator. The HHA's or hospice program's governing body must ensure that the temporary manager has authority to hire, terminate or reassign staff, obligate funds, alter procedures, and manage the HHA or hospice program to correct deficiencies identified in the HHA's or hospice program's operation. (HHA: 42 CFR §488.805; Hospice 42 CFR 488.1235)

Validation survey means a survey of an accredited provider or supplier to validate the accrediting organization's CMS-approved accreditation process. These surveys are conducted on a representative sample basis, or in response to substantial allegations of non-compliance. (42 CFR 488.9(a))

10002 – Informal Dispute Resolution (IDR) for Home Health Agencies & Hospice Programs (Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

10002.1 – IDR Introduction & Purpose (Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

Section 488.745 and 488.1130 offers HHAs and hospice programs the option to request an informal opportunity to dispute condition-level survey findings warranting an alternative sanction following a facility's receipt of the official statement of deficiencies (Form CMS-2567).

Whenever possible, we want to provide every opportunity to settle disagreements at the earliest stage, prior to a formal hearing, conserving time and money potentially spent by the facility, the SA, and CMS. The goal of IDR is to offer the facility an opportunity to refute one or more condition-level deficiencies cited on the statement of deficiencies. An IDR between an HHA or hospice program and the SA or CMS Location, as appropriate, will allow the facility an opportunity to provide an explanation of any material submitted to the SA and respond to the reviewer's questions (77 FR 67141).

This IDR will occur with the agency who conducted the survey. The IDR process, as established by the State or CMS Location, must be in writing so that it is available for review upon request.

If the survey is conducted by the CMS Location, the CMS Location may conduct the IDR.

CMS has adopted the following elements to be incorporated in all cases involving deficiencies cited as a result of Federal surveys. They are designed to clarify and expedite the resolution process. States are free to incorporate these elements into their procedures.

- 1. Notice to the facility will indicate that the IDR, including any face-to-face meetings, constitutes an informal administrative process that in no way is to be construed as a formal evidentiary hearing.*
- 2. Notice to the facility will indicate that counsel may accompany the HHA or hospice program. If the facility chooses to be accompanied by counsel, then it must indicate that in its request for IDR, so that CMS may also have counsel present.*
- 3. CMS will verbally advise the facility of CMS's decision relative to the informal dispute, with written confirmation to follow.*

10002.2 – IDR Process

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

When survey findings indicate a condition-level deficiency (or deficiencies), CMS or the State, as appropriate, will notify the facility in writing of its opportunity to request an IDR of those deficiencies. This notice will be provided at the time the Statement of Deficiencies is issued to the facility. The facility's request for IDR must be submitted in writing, should include the specific deficiencies that are disputed, and should be submitted within the same 10 calendar day period that the facility has for submitting an acceptable plan of correction.

A facility's initiation of the IDR process will not postpone or otherwise delay the effective date of any enforcement action. The failure to complete an IDR will not delay the effective date of any enforcement action. Further, if any findings are revised or removed based on IDR, the official Statement of Deficiencies is revised accordingly, and any enforcement actions imposed solely because of those revised or removed deficiencies are adjusted accordingly.

10002.3 - Mandatory Elements of IDR

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

Upon their receipt of the official Form CMS-2567, agencies must be offered one informal opportunity, if they request it in writing, to dispute condition level deficiencies. Deficiencies cited at the standard level are not subject to the IDR process.

The following elements must be included in each IDR process offered:

- 1. Agencies may not use the IDR process to delay the formal imposition of sanctions or to challenge any other aspect of the survey process, including:*

- *The severity assessment of a deficiency(s) at the standard level that constitutes substandard care or immediate jeopardy (IJ);*
 - *Sanctions imposed by the enforcing agency;*
 - *Alleged failure of the survey team to comply with a requirement of the survey process;*
 - *Alleged inconsistency of the survey team in citing deficiencies among agencies; and*
 - *Alleged inadequacy or inaccuracy of the IDR process.*
2. *HHAs or hospice programs must be notified of the availability of IDR in the letter transmitting the official Form CMS-2567. The letter should inform the facility of the following:*
- *It may request the opportunity for IDR, and that if it requests the opportunity, the request must be submitted in writing;*
 - *The written request for IDR, from the facility, must include an explanation of the specific condition-level deficiencies that are being disputed;*
 - *The written request must be made within the same 10 calendar day period the facility has for submitting an acceptable plan of correction to the surveying entity;*
 - *The name and address, e-mail, and phone number of the person to contact at the CMS Location or the SA to request the IDR;*
 - *The IDR process that is followed in that State, e.g., telephone conference, written communication, or face-to-face meeting; and*
 - *The name and/or position title of the person who will be conducting the IDR, if known.*

NOTE: *IDR is a process in which State agency officials make determinations of noncompliance. SAs should be aware that CMS holds them accountable for the legitimacy of the process including the accuracy and reliability of conclusions that are drawn with respect to survey findings. This means that while the SA may have the option to involve outside persons or entities they believe to be qualified to participate in this process, it is the SA, not outside individuals or entities that are responsible for IDR decisions. When an outside entity conducts IDR, the results of the IDR process may serve only as a recommendation of noncompliance or compliance to the SA. The SA will then make the IDR decision and notify the facility of that decision. CMS will look to the SA to*

assure the viability of these decision-making processes, and holds the SA accountable for them.

Since CMS has ultimate oversight responsibility relative to a SA's performance, it may be appropriate for CMS to examine specific IDR decisions or the overall IDR process to determine whether the decision is consistent with CMS policy. For dually participating or Medicare-only agencies, informal dispute findings are in the manner of recommendations to CMS and, if CMS has reason to disagree with those findings, it may reject the conclusions from IDR and make its own binding determinations of noncompliance.

- 3. Failure to complete IDR timely will not delay the effective date of any enforcement action against the facility.*
- 4. When a facility is unsuccessful during the process at demonstrating that a deficiency should not have been cited, the SA must notify the facility in writing that it was unsuccessful.*
- 5. When a facility is successful during the IDR process at demonstrating that a deficiency should not have been cited or should be revised:*
 - The deficiency citation should be marked "deleted," or "revised" as appropriate, and signed and dated by a supervisor of the surveying entity; and*
 - Any enforcement action(s) imposed solely because of that deleted or revised deficiency citation should be rescinded.*

***NOTE:** The facility has the option to request a clean (new) copy of the Form CMS-2567. However, the clean copy will be the releasable copy only when a clean (new) plan of correction is both provided and signed by the facility. The original Form CMS-2567 is disclosable when a clean plan of correction is not submitted and signed by the facility. Deficiencies pending IDR should be entered into iQIES but will not be uploaded to the national database system until IDR has been completed.*

- 6. An agency may request IDR for each survey that cites condition-level deficiencies. However, if IDR is requested for deficiencies cited at a subsequent survey, a facility may not challenge the survey findings of a previous survey for which the facility either received IDR or had an opportunity for it. Condition-level deficiencies that are not corrected and that are carried forward on a subsequent survey are not eligible for the IDR process. Condition-level deficiencies identified on a subsequent survey that are new are eligible to be reviewed through the IDR process.*

Additional information related to the effect of IDR on HHA alternative sanctions and hospice program enforcement remedies, including CMPs, is addressed in the appropriate sections of this chapter.

10003 – Enforcement Actions for Home Health Agencies and Hospice Programs

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

CMS certifies HHAs and hospice programs for participation in Medicare. The SAs then conduct standard and complaint surveys of certified providers to determine compliance with the CMS conditions of participation. If an HHA or hospice program is not in compliance with the Medicare conditions, CMS may impose an alternative sanction or enforcement remedy. The following sections describe the statutory authorities, considerations, and process for imposition of sanctions/remedies.

10003.1 - Statutory Basis

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

Alternative Sanctions for Home Health Agencies

Sections 1891(c) through (f) establish requirements for surveying and certifying HHAs as well as authorizes the Secretary to utilize varying enforcement mechanisms to terminate participation in the Medicare program and to impose alternative sanctions if HHAs are found out of compliance with the Medicare home health CoPs. The imposition of alternative sanctions specified in §488.820 allows for non-compliant HHAs to have additional time to come into compliance with the CoPs before being terminated.

Enforcement Remedies for Hospice Programs

Division CC, section 407 of the Consolidated Appropriations Act 2021, amended Part A of Title XVIII of the Act to add a new section 1822 of the Act, and amended sections 1864(a) and 1865(b) of the Act, establishing new hospice program survey and enforcement requirements. Section 1822(c)(5) of the Act authorizes the Secretary to utilize varying enforcement mechanisms to terminate participation in the Medicare program and to impose enforcement remedies if hospice programs are found out of compliance with the Medicare CoPs. The imposition of enforcement remedies specified in §488.1220 allows for non-compliant hospice programs to have additional time to come into compliance with the CoPs before being terminated.

10003.2 - General Provisions

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

Under section 1891(e)(1) of the Act for HHAs and section 1822(c)(5) of the Act for hospice programs, if CMS or a SA determines that condition-level deficiencies immediately jeopardize the health or safety of its patients, then CMS must take immediate action to notify the provider of the jeopardy situation and the provider must correct the deficiencies. If the IJ is not removed because the provider is unable or unwilling to correct the deficiencies, CMS will terminate the provider's provider agreement. In addition, CMS may impose one or more specified alternative sanctions or enforcement

remedies, respectively, including but not limited to CMPs and suspension of all Medicare payments before the effective date of termination.

If CMS finds that the provider is not in compliance with the Medicare CoPs and the deficiencies involved do not immediately jeopardize the health and safety of the individuals to whom the HHA or hospice program furnishes items and services, CMS may terminate the provider agreement and should consider the imposition of an alternative sanction(s)/enforcement remedy(ies)

The decision to impose one or more alternative sanctions for HHAs or enforcement remedies for hospice programs would be based on condition-level deficiencies or repeat deficiencies found in the provider during a survey.

While SAs are not required to recommend the types of sanction/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. To ensure effective communication and exchange of information, CMS encourages that all documentation is included in iQIES or any subsequent system. The CMS Location will consider these recommendations but ultimately makes the enforcement determination.

Not all situations require the same sanctions/remedies. The CMS Location should use the enforcement sanction/remedy most appropriate in considering the level/degree of harm, the context behind the facility noncompliance, and the type of enforcement that has the best chance of the facility achieving future compliance. While a range of sanctions/remedies are available, suspension of payment for all new admissions is likely to be the most effective at rapidly returning the provider to compliance.

10003.3 - Effect of Sanctions/Remedies on HHAs and Hospice Programs that Participate in Medicare via Deemed Status through an Accrediting Organization
(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

A deemed HHA or hospice program loses its deemed status when a condition-level finding is cited on a complaint or validation survey. When a condition-level deficiency (ies) is found, the CMS Location returns oversight of the accredited HHA or hospice program back to the SA until the HHA or hospice program can demonstrate compliance with the CoPs. During the time that the SA has jurisdiction over the HHA or hospice program, the SA, not the Accrediting Organization (AO), will follow the procedures for recommending the imposition of sanctions/remedies, if appropriate. Once the HHA or hospice program returns to compliance with the Medicare conditions and has not been terminated, the CMS Location will restore its deemed status and return oversight to the AO.

AOs are not authorized to impose federal sanctions/remedies. Therefore, HHAs or hospice programs participating in Medicare through deemed status are not directly subject to sanctions/remedies by the AO while under jurisdiction of the AO. However, the CMS location may, after reviewing the AO's survey findings and related

information, authorize the SA to conduct a focused validation survey to determine whether condition-level deficiencies, cited by the AO, have been corrected. If deemed status is withdrawn and/or the HHA or hospice program is placed under the jurisdiction of the SA, as may occur following a complaint investigation by the SA, the CMS Location may impose alternative sanctions/remedies on the HHA or hospice program per the usual procedures.

10003.4 - Effect of Sanctions/Remedies on HHA Branches and Hospice Multiple Locations

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

Regardless of whether the condition level non-compliance is identified at the branch (HHA), multiple location (hospice), or the parent location, all sanctions/remedies imposed would apply to the parent HHA or hospice and its respective branches or multiple locations.

10003.5 - Enforcement Action When IJ Exists

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

When there is IJ to patient health or safety, CMS must complete termination procedures within 23 days from the last day of the survey which found the IJ if it is not removed before then (following guidelines in Appendix Q of the State Operations Manual). The procedure must not be postponed or stopped unless the IJ is removed, as verified through onsite verification. If there is a written and timely credible allegation that the IJ has been removed, CMS or the State will conduct a revisit prior to termination, if possible.

In addition to termination, one or more alternative sanctions for HHAs or enforcement remedies for hospice programs may be imposed. While the use of alternative sanctions or enforcement remedies in addition to termination is permitted, the Act makes it clear that the enforcement action for noncompliant agencies with IJ deficiencies is intended to be swift. The imposition of alternative sanctions for HHAs or enforcement remedies for hospice programs in addition to termination does not extend the timeframe that the HHA or hospice program has to remove the IJ situation.

10003.6 – Enforcement Action When Condition-Level Deficiencies Exist That Do Not Pose IJ

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

If the HHA or hospice program is no longer in compliance with the CoPs, either because the deficiency(ies) substantially limit the HHA's or hospice program's capacity to furnish adequate care but do not pose IJ, or because the HHA or hospice program has repeat noncompliance that results in a condition level deficiency based on the HHA's or hospice program's failure to correct and sustain compliance, CMS will either terminate the provider agreement following the 90 day termination track or impose one or more alternative sanctions for HHAs or enforcement remedies for hospice programs as an alternative to termination. If alternative sanctions or enforcement

remedies are imposed, CMS terminates the HHA's or hospice program's provider agreement within 6 months of the last day of the survey if the HHA or hospice program is not in substantial compliance with the CoPs and the condition level deficiencies are not corrected.

10003.7 - Effect of Termination on the Patients

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

If an HHA or hospice program fails to correct deficient practices and sustain compliance, CMS may terminate the provider agreement. When this happens, an HHA or hospice program is required to appropriately and safely transfer its patients to another local HHA or hospice within 30 days of termination (see §488.825(c) & §488.830(e) for HHAs & §488.1225(c) & §488.1230(e) for hospice programs). The HHA or hospice is responsible for providing information, assistance, and any arrangements necessary for the safe and orderly transfer of its patients. The SA is required to provide oversight for all HHAs or hospices that are terminated to ensure the safe discharge and orderly transfer of all patients to another Medicare-approved HHA or hospice. Payment to terminated HHAs or hospices for services for current patients is provided up to 30 days after termination pursuant to §489.55.

10004- Available Sanctions/Remedies

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

To the greatest extent possible, the time between the identification of deficiencies and imposition of sanctions/remedies should be minimized. In accordance with §488.820 for HHA and §488.1220 for hospice programs, the following sanctions/remedies in addition to termination of the provider agreement are available:

- Civil money penalties;*
- Suspension of payment for all new admissions;*
- Temporary management;*
- Directed plan of correction; and*
- Directed in-service training.*

It is important to note that imposition of an alternative sanction or enforcement remedy is an available enforcement action, but it is not required when CMS may ultimately determine that termination is the most appropriate enforcement action to ensure patient health and safety. When CMS believes that an agency cannot promptly return to compliance, termination may be preferable.

10004.1 - Factors to be Considered in Selecting Sanctions/Remedies

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

When making sanction/remedy choices, the CMS Location should consider the extent to which the noncompliance is the result of a one-time mistake, larger systemic

concerns, or an action of disregard for patient health and safety. CMS bases its choice of sanction(s)/remedy(ies) on consideration of one or more factors that include, but are not limited to, the following:

- The extent to which the deficiencies pose IJ to patient health and safety.*
- The nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.*
- The presence of repeat deficiencies, the HHA's or hospice program's overall compliance history and any history of repeat deficiencies at either the parent or branch or multiple locations.*
- The extent to which the deficiencies are directly related to a failure to provide quality patient care.*
- The extent to which the HHA or hospice program is part of a larger organization with performance problems.*
- An indication of any system-wide failure to provide quality care.*

In addition, CMS reviews other factors including, but not limited to, the history of the HHA's or hospice program's compliance with the CoPs, specifically with reference to the cited deficiencies.

Once a sanction/remedy is imposed, it becomes effective as of the date specified in the notice letter for the sanction/remedy being imposed. All sanctions/remedies remain in effect and continue until the facility has demonstrated and is determined to be in substantial compliance with all CoPs.

The summary table below gives a high-level overview of the available sanctions/remedies and factors to consider for selection. Each of these are discussed in greater detail throughout the rest of this chapter.

Available Sanction/Remedies	Factors to Consider for Selection
For All Sanctions/Remedies	<ul style="list-style-type: none"> • <i>The extent to which the deficiencies pose IJ to patient health and safety.</i> • <i>The nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.</i> • <i>The presence of repeat deficiencies, the hospice program's overall compliance history and any history of repeat deficiencies at either the parent hospice program or any of its multiple locations.</i> • <i>The extent to which the deficiencies are directly related to a failure to provide quality patient care.</i> • <i>The extent to which the hospice program is part of a larger organization with performance problems.</i> • <i>An indication of any system-wide failure to provide quality care.</i>
Civil Money Penalty (CMP)*	<p><i>When repeat deficiencies exist.</i></p> <ul style="list-style-type: none"> • <i>Upper range of CMPs for IJ situations.</i> • <i>Middle range of CMPs for noncompliance that is directly related to poor quality patient care outcomes (non-IJ).</i> • <i>Lower range of CMPs for noncompliance that is related predominately to structure or process-oriented conditions.</i>
Suspension of payment for all new admissions (SPNA)*	<p><i>When condition-level deficiencies relate to poor patient care outcomes.</i></p>
Temporary Management*	<p><i>When failure to comply with the CoPs is directly related to management limitations, or</i></p> <p><i>When current management oversight is likely to impair the facility's ability to return to full compliance, or</i></p> <p><i>When needed, based on the above situations, to oversee orderly involuntary termination/closure and safe transfer of patients to another local HHA or hospice.</i></p>
Directed Plan of Correction (DPOC)	<p><i>When the HHA or hospice program has deficiencies that warrant direction for the provider to take specific actions, or</i></p> <p><i>When the HHA or hospice program fails to develop an acceptable plan of correction for condition-level deficiencies.</i></p>

Directed In-Service Training	<i>When education is likely to correct the deficiencies and help the HHA or hospice program achieve substantial compliance.</i>
<i>* For HHAs only: Please note that the imposition of one or more of these sanctions could prohibit an HHA from conducting home health aide training and competency evaluation program as noted in 42 CFR 484.80(f).</i>	

Summary Table of Available Sanctions/Remedies for HHAs & Hospice Programs

The following sections describe each possible alternative sanction or enforcement remedy and procedures for imposing them. In addition, the CMS Location and SA follow the procedures in Chapter 3 of the SOM if an adverse action is likely to be initiated against a Medicare participating provider.

10005 - Civil Money Penalties

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

10005.1 - Basis for Imposing Civil Money Penalties

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

CMS may impose a CMP against an HHA or hospice program based on noncompliance with one or more CoPs found through a survey or on the presence of repeat deficiencies (i.e., looking at the HHA’s or hospice program’s overall compliance history per 42 CFR 488.815(c) and 42 CFR 488.1215(c)).

Enforcement sanctions/remedies may be applied regardless of whether the HHA’s or hospice program’s deficiencies pose IJ to patient health and safety. CMS may impose a CMP for the number of days that an HHA or hospice program is not in substantial compliance with one or more CoPs, or for each instance that an HHA or hospice program is not in substantial compliance. In the case of unremoved IJ situations, the existing 23-day termination timeline still applies (See also Appendix Q of the State Operations Manual for IJ timelines).

The CMP amounts are based on §488.845 for HHAs and §488.1245 for hospice programs which lay out the ranges and amounts for CMPs. However, CMS is required by law to annually adjust the CMP amounts based on inflation in accordance with 45 CFR part 102. Therefore, while the original CMP amounts are located in the regulations, CMS Location staff will use the annually adjusted amounts that CMS posts on its website on the Quality, Safety & Oversight Group webpage (<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Civil-Monetary-Penalties-Annual-Adjustments.html>) to calculate the penalty. The maximum CMP amount is also posted on this website and will be regularly updated when annual inflation adjustments are made.

CMS may impose a CMP against an HHA or hospice program for either the number of days (per day CMP) the facility is not in compliance with one or more CoPs or for each instance (per instance CMP) that the facility is not in compliance.

Per Day CMP

“Per day” means a CMP imposed for the number of days a facility is not in substantial compliance with the CoPs.

Surveyors may come across information during the survey that identifies past noncompliance, but evidence exists that the noncompliance was corrected and is not an issue during the current survey. While we do not cite to past noncompliance (deficiencies identified and corrected since the last survey), if a surveyor finds current noncompliance and can trace the start of noncompliance back to a specific date prior to this current survey, a per day CMP may be imposed. In general, the CMS Location may impose a per day CMP from the time when the noncompliance occurred through the time when the noncompliance was corrected. For example, CMS may impose a CMP for the number of days an IJ situation exists.

The range of per day penalties is set forth at §488.845(b)(3)-(5) for HHAs and §488.1245(b)(3)-(5) for hospice programs. These base amounts are adjusted annually for inflation and are posted on the CMS website.

The CMP range amounts are based on three levels of seriousness—upper, middle, and lower. The lower range of permitted per day CMP amounts enables CMS to better correlate the seriousness of noncompliance with the amount of the CMP. The expanded lower end of the range may be particularly important if CMS imposes a CMP that begins at the lower or middle range and then increases in amount over time the longer the noncompliance remains uncorrected. In such a case, prompt remedial action by the HHA or hospice program can limit the total amount of per day CMP that accrues (See also 77 FR 67150).

Per Instance CMP

“Per instance” is defined at §488.805 and 42 CFR 488.1205 and means a single event of noncompliance identified and corrected during a survey, for which the statute authorizes CMS to impose a sanction/remedy.

For example, during a survey, CMS or a state may identify several instances of noncompliance, each in distinct regulatory areas. Generally, we anticipate imposing per instance penalties only in the situation where a surveyor identifies a condition-level deficiency during the survey and the HHA or hospice program took sufficient action to correct the deficiency during the time of the survey (see also 77 FR 67150).

The range of per instance penalties is set forth at §488.845(b)(6) for HHA and §488.1245(b)(6) for hospice programs, and the penalty amounts are adjusted annually

for inflation and are posted on the CMS website. The terminology “per instance” is not used to suggest that only one instance of condition-level noncompliance may be assigned a CMP. There can be more than one instance of condition-level noncompliance identified during a survey where the SA/CMS Location utilizes the per instance CMP as a sanction/remedy. However, the total dollar amount of the CMP for the instance or multiple instances of condition-level noncompliance may not exceed the maximum \$10,000 (as adjusted for inflation) for each day of that specific survey, and may not be less than \$1,000 (as adjusted for inflation) per instance.

NOTE: *A per day and a per instance civil money penalty cannot be used simultaneously for the same deficiency in conjunction with a survey (i.e., standard, revisit, complaint). However, both types of CMPs may be used during a noncompliance cycle if more than one survey takes place, and the per day CMP was not the CMP initially imposed. When a per day CMP is the CMP sanction initially imposed, a per instance CMP cannot be imposed on a subsequent survey within the same noncompliance cycle.*

For HHAs Only: *Please note that the imposition of a \$5,000 or more CMP on an HHA would prohibit that HHA from conducting health aide training and competency evaluation program for 2 years from the date this sanction is imposed (see also 42 CFR 484.80(f)). See Appendix B of the State Operations Manual for additional information for eligible home health aide training and competency evaluation organizations at §484.80(f).*

10005.2 - Determining Amount of Civil Money Penalty (Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

CMPs are intended as a tool to encourage the HHA or hospice program to rapidly return to compliance with program requirements to protect the health and safety of individuals under their care. As with all other enforcement sanctions/remedies, CMPs are a discretionary enforcement action and not required. CMS may ultimately determine that termination is the most appropriate enforcement action to ensure patient health and safety. While a provider may be given an opportunity to correct their deficiencies and return to compliance, if CMS determines that an agency cannot promptly return to compliance, termination may be preferable to an alternative sanction or enforcement remedy.

CMS bases its choice of sanction/remedy on consideration of one or more factors that include, but are not limited to the following:

- The extent to which the deficiencies pose IJ to patient health and safety.*
- The nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.*

- *The presence of repeat deficiencies, the HHA's or hospice program's overall compliance history and any history of repeat deficiencies at either the parent or branch or multiple location.*
- *The extent to which the deficiencies are directly related to a failure to provide quality patient care.*
- *The extent to which the HHA or hospice program is part of a larger organization with performance problems.*
- *An indication of any system-wide failure to provide quality care.*

In determining the amount of the civil money penalty, CMS considers certain factors in addition to those listed above which include:

- *The size of the HHA or the hospice program and its resources;*
- *Accurate and credible resources, such as PECOS, Medicare cost reports and Medicare/Medicaid claims information that provide information on the operation and resources of the HHA; and*
- *Evidence that the HHA or hospice program has a built-in, self-regulating quality assessment and performance improvement system to provide proper care, prevent poor outcomes, control patient injury, enhance quality, promote safety, and avoid risks to patients on a sustainable basis that indicates the ability to meet the conditions of participation and to ensure patient health and safety.*

In collaboration with other CMS components, CMS may consider an agency's financial condition on a case-by-case basis, and this evaluation may be made in part by considering the HHA's or hospice program's size and its resources. The CMS Location may need to consult with other CMS components such as Center for Program Integrity (CPI), Centers for Medicare (CM), and/or Office of Financial Management (OFM) as part of the process to consider the above factors. CMS considers whether the HHA or hospice program has the ability to pay the CMP without having to go out of business or compromise patient health and safety. An HHA or hospice program may be expected to satisfy its obligations to the federal government before making payments to its owners.

Information on the operations and resources of the HHA or hospice program may include items such as, but not limited to, historical patient census, staffing levels, and claims paid. Additionally, CMS may consider other aspects such as enforcement actions taken by CMS for enrollment or payment related issues (e.g., overpayment, pre/post-pay audits, suspensions, and revocations) and the impact these can have on HHA or hospice program resources.

When several instances of noncompliance are identified at a survey, either a per day or per instance civil money penalty could be imposed. By law, CMPs may not exceed

a set maximum amount per day. The maximum is a total, comprising per day and per instance penalties. This maximum amount is set forth at §488.845(b)(2)(iii) and at §488.845(b)(6) for HHA and §488.1245(b)(2)(iii) and at §488.1245(b)(6) for hospice programs, and the current adjusted maximum amount is posted on CMS's website on the Quality, Safety & Oversight Group webpage at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Civil-Monetary-Penalties-Annual-Adjustments>.

Per the Federal Civil Penalties Inflation Adjustment Improvements Act of 2015, inflationary adjustments to the CMPs are published annually and are effective immediately upon publication. The first of these adjustments was published in the Federal Register on September 6, 2016, at 81 FR 61538. A table located at 45 CFR 102.3 shows how the CMPs are adjusted for inflation. In addition, these adjusted CMP amounts are posted on the CMS website on the Survey and Certification Group webpage and are updated when future inflation adjustments are made. Adjusted amounts that are in effect when the CMP is imposed by CMS shall be applied, regardless of when noncompliance is identified. This means that the CMP amount per day or per instance imposed should be calculated using the most current adjusted amount noted in 45 CFR 102.3. For example, if a survey identifies condition-level noncompliance but CMS has not imposed a CMP yet (i.e., sent notice of intent to impose a CMP) and the next annual adjustment is published, then CMS must impose a CMP amount, either per day or per instance, using the newly adjusted amounts. For example: During a survey, a situation of IJ that is unremoved at survey exit, is identified, and CMS sends notice of the intent to impose a CMP. Upon receipt of an acceptable plan of correction, a revisit survey is completed, revealing the situation of IJ was removed but noncompliance at the condition level remains. CMS would move to lower the amount of the CMP imposed per day considering the survey findings and changes to the severity of identified noncompliance. However, if the daily penalty assessment of the CMP is adjusted under existing Federal law prior to CMS notifying the facility of the reduction in the per day amount of the CMP, CMS must lower the amount per day only to an amount that meets the newly adjusted totals (see also 42 CFR 488.845(b)(2)(iii) for HHAs and 42 CFR 488.1245(b)(2)(iii) for hospice programs).

In the event the ranges, minimum, and/or maximum amount of a CMP is adjusted for inflation during an entity's cycle of noncompliance, CMS must calculate the amount based upon the date the notice of intent is issued, not the date noncompliance was identified. These adjusted amounts shall be used until the next effective date for CMP inflation adjustments occurs.

The CMS Location consults with the regional attorney's office to ensure compliance with section 1128A of the Act and Department of Justice requirements. Section 1128A of the Act requires CMS to offer a hearing before collecting, but not before imposing, a CMP.

10005.3 - Penalty Amounts

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

The current adjusted penalty amounts are posted annually on the CMS website on the Quality, Safety & Oversight Group webpage at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Civil-Monetary-Penalties-Annual-Adjustments> and are regularly updated when inflation adjustments are made.

10005.4 - Range of Penalty Amounts

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

CMS bases the range of civil money penalty amounts on three levels of seriousness—upper, middle, and lower. The range of CMPs is identified at §484.485(b)(3) – (6) for HHA and §488.1245(b)(3) – (6) for hospice programs, and the amounts are adjusted annually for inflation and are posted on the CMS website. The specified CMP ranges mark the starting point in CMS’s determination of the CMP amount. First, CMS looks to the specific circumstances of the survey findings to determine whether a per day or per instance CMP is warranted and whether the facts point to a CMP rate in an Upper, Middle, or Lower range. After the CMP type and range are determined, CMS considers the additional factors described above at 10012.2.

When CMS is determining the rates for multiple CMPs, the rates must be evaluated collectively. By law, CMPs may not exceed a set maximum amount per day. The maximum is a total, comprising per day and per instance penalties. This maximum is set forth at §488.845(b)(2)(iii) and at §488.845(b)(6) for HHA and at §488.1245(b)(2)(iii) and at §488.1245(b)(6) for hospice programs.

Current information on the range of CMPs and the maximum amount per day is posted on the CMS website on the Quality, Safety & Oversight Group webpage at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Civil-Monetary-Penalties-Annual-Adjustments.html>.

10005.5 - Upper Range of Penalty

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

Upper range penalty amounts are imposed for a condition-level deficiency that is IJ. The CMP upper ranges are set forth in §§488.845(b)(3)(i), (ii), and (iii) for HHA and §488.1245(b)(3)(i), (ii), and (iii) for hospice programs and will vary based on the following:

- a. If the IJ is cited for actual harm;*
- b. If the IJ is cited for potential for harm; and*
- c. If the IJ is cited for a violation of established HHA or hospice program policies and procedures*

Note: The following examples contain findings that could become a part of an HHA's or hospice program's IJ citation. Please note that the citation of IJ is only made after careful investigation of all relevant factors as detailed in Appendix Q. An IJ decision requires a determination that the situation meets all required IJ components.

1. Section 488.845(b)(3)(i) for HHAs and §488.1245(b)(3)(i) for hospice programs address CMPs for a deficiency or deficiencies that are determined to be IJ and that results in actual harm. **Examples:** The facility fails to report to a physician, episodes of severe hyperglycemia, resulting in ketoacidosis and hospitalization of diabetic patient; and the facility fails to timely and accurately assess a patient's pressure ulcers, which deteriorate to Stage 4 and sepsis prior to their recognition.
2. Section 488.845(b)(3)(ii) for HHAs and §488.1245(b)(3)(ii) for hospice programs address CMPs for a deficiency or deficiencies that are determined to be IJ and that result in a potential for harm. **Examples:** The facility fails to intervene after patient verbalizes threats of suicide, resulting in potential for self-harm; and the facility fails to administer ordered intravenous antibiotic to patient with diagnosed infection, resulting in potential for development of sepsis.
3. Section 488.845(b)(3)(iii) for HHAs and §488.1245(b)(3)(iii) for hospice programs address per day penalties for an isolated incident of noncompliance that is in violation of the HHA's or hospice program's established policies and procedures. **Example:** One of the facility's nurses did not follow the infection control policies and procedures when performing wound care requiring sterile technique on an immunocompromised patient.

Current information on the range of CMPs and the maximum amounts is posted on the CMS website on the Quality, Safety & Oversight Group webpage at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Civil-Monetary-Penalties-Annual-Adjustments.html>

The penalty in this upper range will continue until the IJ is removed and substantial compliance can be determined per the usual procedures. (See Appendix Q for IJ removal process and timelines)

During the revisit survey, the SA will determine if the IJ is removed. If the IJ situation has been removed, but condition level deficiencies still exist, the penalty amount may be decreased to the middle or lower range of penalties based on the deficiency.

Note: In accordance with 42 CFR 488.830(a)(2) for HHAs and 42 CFR 488.1230(c) for hospice programs, if one or more alternative sanctions are imposed as an alternative to termination, the delay in termination may not exceed 6 months from the last day of the survey identifying condition-level noncompliance.

10005.6 - Middle Range of Penalty

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

Section 488.845(b)(4) for HHA and §488.1245(b)(4) for hospice programs set forth the middle range of penalties. Middle range amounts are imposed for a repeat and/or condition-level deficiency that does not constitute IJ but is directly related to poor quality patient care outcomes.

10005.7 - Lower Range of Penalty

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

Section 488.845(b)(5) for HHA and §488.1245(b)(5) for hospice programs set forth the lower range of penalties. CMPs in the lower range are imposed for a repeat and/or condition-level deficiency that does not constitute IJ and that is related predominately to structure or process-oriented conditions (such as OASIS submission requirements) rather than directly related to patient care outcomes.

10005.8 – CMP Imposition and IDR in HHAs and Hospices

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

Per §488.745 for HHAs and §488.1130, CMS's or the State's failure to complete IDR (as described in section 10002 of this manual) shall not delay the effective date of any enforcement action, including the imposition of CMPs. In those occasions where an IDR may occur after a CMP is imposed, the IDR results will nevertheless be considered in the enforcement action. We specify at §488.745(c) for HHAs and §488.1130(c) for hospices that if any findings are revised or removed by CMS or the State (for surveys conducted by the SA) based on IDR, the CMS-2567 is revised accordingly and any enforcement actions imposed solely because of those cited deficiencies are adjusted accordingly.

10005.9 - Adjustments to Penalties

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

CMS has the discretion to increase or reduce the amount of the CMP during the period of noncompliance depending on whether the level of noncompliance changed at the time of a revisit survey.

CMS may increase a CMP based on the following:

- *The HHA's or hospice program's inability or failure to correct deficiencies;*
- *The presence of a system-wide failure in the provision of quality care; or*
- *A determination of IJ with actual harm versus IJ with potential for harm.*

CMS may decrease a CMP to the extent that it finds, pursuant to a revisit, that substantial and sustainable improvements have been implemented even though the HHA or hospice program is not yet in full compliance with the conditions of participation.

10005.10 - Decreased Penalty Amounts

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

If a penalty was imposed in the upper range and the IJ is removed or abated but the HHA or hospice program continues to have condition-level noncompliance that is not IJ, CMS will shift the penalty amount imposed per day from the upper range to the middle or lower range based on the conditions that are out of compliance. SAs and CMS Locations should follow the same guidelines above to determine new penalty amount. An earnest effort to correct any systemic causes of deficiencies and sustain improvement must be evident.

10005.11 - Increased Penalty Amounts

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

Following the imposition of a lower level penalty amount (either the middle range or the lower range), CMS may increase the per day penalty amount for any condition-level deficiency or deficiencies which become sufficiently serious to pose potential harm or IJ.

CMS increases the per day penalty amount for deficiencies that are not corrected and found again at the time of revisit survey(s) for which a lower level penalty was imposed.

For repeated noncompliance with the same condition-level deficiency or for uncorrected deficiencies from a prior survey, CMS may impose an increased CMP amount.

10005.12 - Accrual and Duration of Per Day Penalty

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

<i>Available Sanction/Remedies</i>	<i>Timeframe for Notice of Imposition</i>
<i>Civil Money Penalties (CMP)*</i>	<p><i>Notice of intent to impose – provided with statement of deficiencies</i></p> <p><i>Notice includes: the amount of the CMP being imposed, the basis for such imposition and the proposed effective date of the sanction.</i></p>

10005.13 - Duration of Per Day Penalty when there is IJ
(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

The per day CMP would begin to accrue on the last day of the survey that identified the noncompliance and would continue to accrue until the HHA or hospice program achieves substantial compliance with all requirements or the date of termination, whichever occurs first. In the case of noncompliance that poses IJ, CMS must terminate the provider agreement within 23 calendar days after the last date of the survey if the IJ is not removed.

10005.13A - Duration of Penalty when there is no IJ
(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

In the case of noncompliance that does not pose IJ, the daily accrual of per day CMP is imposed for the days of noncompliance, i.e., from the day the penalty starts (based on the survey completion date and this may be prior to the notice), until the HHA or hospice program achieves substantial compliance based on a revisit or the provider agreement is terminated, but for a period of no longer than 6 months following the last day of the survey.

If the HHA or hospice program has not achieved substantial compliance with all the conditions of participation, CMS will terminate the provider agreement. The accrual of civil money penalty stops on the day the HHA or hospice program agreement is terminated or the HHA or hospice program achieves substantial compliance, whichever is earlier.

10005.14 – Range of Penalty Amounts - Per Instance
(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

Penalties imposed per instance of noncompliance may be assessed for one or more singular events or instances of condition-level noncompliance that are identified and where the noncompliance was corrected during the onsite survey. The terminology “per instance” is not used to suggest that only one instance of noncompliance may be the basis to assess a CMP. There can be more than one instance of noncompliance identified during a survey. The current adjusted range for per instance CMPs, as well as the adjusted maximum amount per day, is posted on the CMS website on the Quality, Safety & Oversight Group webpage at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Civil-Monetary-Penalties-Annual-Adjustments>.

10005.15 – Accrual and Duration of Per Instance Penalty
(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

As set forth in §488.845(b)(6) for HHA and §488.1245(b)(6) for hospice programs, a per instance CMP is imposed for each instance of noncompliance based on a deficiency(ies) during a specific survey. It is applied to as many instances as is deemed appropriate and in a specific amount for that deficiency(ies). The current adjusted range for per instance CMPs, as well as the maximum adjusted amount per day, is posted on the CMS website on the Quality, Safety & Oversight Group webpage.

NOTE: *The per day and per instance CMP would not be imposed simultaneously for the same CoPs in a survey. In no instance will the period of noncompliance be allowed to extend beyond 6 months from the last day of the original survey that determined the HHA's or hospice program's noncompliance. If the HHA or hospice program has not achieved substantial compliance with all the participation requirements within those 6 months, CMS will terminate the HHA or hospice program. The accrual of the per day CMP stops on the day the HHA's or hospice program's provider agreement is terminated or the HHA or hospice program achieves substantial compliance, whichever is earlier.*

Example: *When the per instance CMP is used on the original survey, the revisit survey is used to determine compliance. If noncompliance is identified at the revisit survey and a CMP is selected as the enforcement remedy/sanction, either the per instance or per day remedy may be selected.*

10005.16 - Accrual and Duration Examples

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation: 05-10-24)

- a. Revisit Survey Identifies New Noncompliance and Same Data Tag is Selected - If the same data tag is selected to identify noncompliance, the State (or CMS Location) could choose to utilize either the per instance or per day CMP. It would not matter whether the same data tag was selected to identify the new noncompliance. The issue is whether noncompliance is present and whether the deficient practice rises to a level that will support selecting a CMP as a sanction. For example, noncompliance was identified at HHA Tag G406 (Condition of participation: Patient rights) during the original survey. During the revisit survey, a different problem dealing with the patient rights of three patients was cited at Tag G406. The per instance or per day CMP would be selected for the noncompliance identified at Tag G406. If the per instance civil money penalty was used, the amount of the CMP might be influenced by factors relating to the violations of patient rights. However, only one per instance CMP would be appropriate. It would not be appropriate to assign a separate CMP for each of the violations related to patient rights (findings) identified at Tag G406.*
- b. Revisit Survey Identifies New Noncompliance and a Different Data Tag is Selected - If a revisit identifies new deficiencies at a different data tag, either a per instance or per day CMP could be selected as a sanction.*

- c. *Noncompliance - IJ Does Not Exist (Per Day)- For noncompliance that does not pose IJ, the per day CMP is imposed for the days of noncompliance, i.e., from the day the penalty starts (and this may start accruing as early as the beginning of the last day of the survey that determines the HHA or hospice program was out of compliance), until the HHA or hospice program achieves substantial compliance, or the provider agreement is terminated. However, if the HHA or hospice program has not achieved substantial compliance at the end of 6 months from the last day of the original survey, the CMS Location terminates the provider agreement. The accrual of the CMP stops on the date that the provider agreement is terminated.*
- d. *Noncompliance - IJ Does Not Exist (Per Instance)- For noncompliance that does not pose IJ, the per instance CMP is imposed for the number of deficiencies during a survey for which the per instance CMP is determined to be an appropriate sanction. For example, HHA Tag G510 (Condition of participation: Comprehensive assessment of patients) and HHA Tag G370 were cited on a survey. A per instance CMP of \$2,000 is imposed for Tag G370 and a per instance CMP of \$8,000 is imposed for Tag G510. No civil money penalty could then be imposed for additional deficiencies because the total “per instance CMP” may not exceed \$10,000 as adjusted annually for each day of noncompliance.*
- e. *Noncompliance - IJ Exists - For noncompliance that poses IJ, CMS must terminate the provider agreement within 23 calendar days after the last day of the survey that identified the IJ if the IJ is not removed. The accrual of the per day CMP stops on the date that the provider achieves substantial compliance, or the provider agreement is terminated.*

10005.17 - Computation and Notice of Total Penalty Amount
(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

*When a CMP is imposed on a **per day** basis and the HHA or hospice program achieves compliance with the conditions of participation as determined by an onsite revisit survey, CMS sends a final notice to the HHA or hospice program containing all the following information:*

- *The amount of penalty assessed per day.*
- *The total number of days of noncompliance.*
- *The total amount due.*
- *The due date of the penalty.*
- *The rate of interest to be assessed on any unpaid balance beginning on the due date. The rate of interest is the higher of either the rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest*

prevailing on the date of the notice of the penalty amount due and this rate is published quarterly in the “Federal Register” by the Department of Health and Human Services under 45 CFR 30.13(a); or the current value of funds rate which is published annually in the “Federal Register” by the Secretary of the Treasury, subject to quarterly revisions. (The CMS Locations are notified by the CMS Office of Financial Management for the rate of interest information.)

- *Instructions for submitting payment (see also “Method of Payment” section).*

*When a CMP is imposed on a **per day** basis and the HHA’s or hospice program’s provider agreement has been involuntarily terminated, CMS will send the penalty information, including the total amount of the CMP due, after one of the following actions has occurred:*

- *A final administrative decision is made;*
- *The HHA or hospice program has waived its right to a hearing in accordance with the regulations; or,*
- *The time for requesting a hearing has expired and CMS has not received a hearing request from the HHA or hospice program.*

*When a **per instance** CMP is assessed, a notice is sent to the HHA or hospice program containing all of the following information after the provider is in substantial compliance or its provider agreement has been terminated:*

- *The amount of the penalty or penalties that was assessed;*
- *The total amount due;*
- *The due date of the penalty;*
- *The rate of interest to be assessed on any unpaid balance beginning on the due date. The rate of interest is the higher of either the rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of the notice of the penalty amount due and this rate is published quarterly in the “Federal Register” by the Department of Health and Human Services under 45 CFR 30.13(a); or the current value of funds rate which is published annually in the “Federal Register” by the Secretary of the Treasury, subject to quarterly revisions. (The CMS Locations are notified by the CMS Division of Financial Management for the annual rate of interest information); and*
- *Instructions for submitting payment (see also “Method of Payment” section).*

10005.18 - Notice of Imposition of Civil Money Penalty
(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

If CMS or the SA imposes a CMP, it provides the HHA or hospice program with written notice of the intent to impose the sanction/remedy, including the amount of the CMP being imposed, the basis for such imposition and the proposed effective date of the sanction/remedy. The notice includes:

- I. The nature of the noncompliance (regulatory requirements not met);*
- II. The statutory basis for the CMP;*
- III. The amount of the penalty per day of noncompliance or the amount of the penalty per instance of noncompliance during a survey;*
- IV. The factors that were considered in determining the amount of the CMP;*
- V. The date on which the per day CMP begins to accrue;*
- VI. A statement that the per day CMP will accrue until substantial compliance is achieved or until termination from participation in the program occurs.*
- VII. When the CMP payment is due;*
- VIII. **For HHAs only:** Implications of the CMP imposition on the home health aide training and competency evaluation program (see also 42 CFR 484.80(f)).*
- IX. Instructions for responding to the notice, including a statement of the HHA's or hospice program's right to a hearing and information about how to request a hearing; and*
- X. Implications of waiving the right to a hearing and information about how to waive the right to a hearing (see §10013.20 below).*

10005.19 - Sending the Notice

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

The notice of CMP imposition shall be in writing and shall be addressed directly to the HHA or hospice program, or to an individual, an officer, managing or general agent, or other agent authorized by appointment or law to receive the notice.

The notice shall be dispatched through first-class mail, or other reliable means. Other reliable means refers to the use of alternatives to the United States mail in sending notices. Electronic communication, such as facsimile transmission or email, is equally reliable and on occasion more convenient than the United States mail. If electronic means are employed to send notice, the sender should maintain a record of the transmission to assure proof of transmission if receipt is denied.

It should be noted that in cases where the State is authorized by the CMS location, the State may send the initial notice of imposition of certain sanctions on CMS's behalf, within applicable notice requirements.

10005.20 - Appeal of Noncompliance That Led to Imposition of Civil Money Penalty

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

Before collecting a CMP, section 1128A of the Act requires the Secretary (CMS) to conduct a hearing when properly requested by the HHA or hospice program pursuant to §498.40. An HHA or hospice program may request a hearing with the Administrative Law Judge (ALJ) on the determination of the noncompliance that is the basis for imposition of the CMP.

The procedures to request a hearing specified in 42 C.F.R. § 498.40 are followed when CMS imposes a CMP on an HHA or hospice program. Once an appeal hearing is requested, CMS cannot collect the CMP until a final agency determination. Additional procedures are set forth at 42 CFR 488.845(h) for HHA and at 42 CFR 488.1245(g) for hospice programs. Per these regulations, when an ALJ or state hearing officer (or higher administrative review authority) finds that the basis for imposing a CMP exists, the reviewing authority may not— (1) Set a penalty of zero or reduce a penalty to zero; (2) Review the exercise of discretion by CMS to impose a CMP; and (3) Consider any factors in reviewing the amount of the penalty other than those specified at §488.845(b) for HHA or §488.1245(b) for hospice programs.

10005.20A – HHA or Hospice Program Waives Right to a Hearing

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

An HHA or hospice program may waive the right to a hearing, in writing, within 60 days from the date of the notice imposing the CMP. If an HHA or hospice program timely waives its right to an appeal hearing within 60 calendar days of their receipt of CMS' notice imposing the CMP, CMS will approve the waiver and reduce the CMP by thirty five percent (35%). Payment of the reduced CMP must be made within 15 days of the HHA's or hospice program's receipt of CMS's notice approving the waiver and reducing the CMP. If the HHA or hospice program does not waive its right to an appeal hearing in writing within 60 calendar days of their receipt of CMS original request for payment under §488.845(c)(2)(ii) for HHA and §488.1245(c)(2)(ii) for hospice programs, it will not receive the CMP reduction.

NOTE: *Each time a survey is conducted within an already running noncompliance cycle and a CMP is imposed, the HHA or hospice program is given appeal rights and may exercise its waiver of right to a hearing.*

When a per day CMP is imposed and then is increased or decreased at subsequent surveys during an already running noncompliance cycle, an HHA or hospice program may elect to either appeal each separate CMP imposition or waive the right to appeal

each imposition. Each CMP imposition is computed separately for a set number of days. The final CMP amount is established after the final administrative decision.

Example: *An HHA is cited on the original recertification survey for non-compliance with 42 CFR 484.60 Condition of participation: Care planning, coordination of services, and quality of care. Findings include evidence that the HHA did not follow the plan of care, the plan of care did not include all pertinent diagnoses, and the HHA failed to notify the physician of changes in the patient's condition. On the first revisit survey, the incidence of these deficiencies increased. On both surveys, the condition is cited as out of compliance and CMPs are imposed. The CMP will be increased following the revisit survey. The HHA may choose to appeal one or both citations, or waive one or both citations, or waive one citation and appeal the other.*

When several per instance CMPs are imposed during a noncompliance cycle, an HHA or hospice program may choose to appeal or waive the right to appeal one or more of the CMPs, in the same manner as illustrated above for the per day CMPs.

After the facility achieves substantial compliance or its provider agreement is terminated, it is notified of the revised CMP amount due.

10005.21 - When a CMP is Due and Payable

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

In accordance with HHA (42 CFR 488.845(f)) and hospice program (42 CFR 488.1245(f)) regulations, payments are due for all CMPs within 15 days from any of the following:

- *After a final administrative decision when the HHA or hospice program achieves substantial compliance before the final decision or the effective date of termination before final decision,
 - *A final administrative decision includes an ALJ decision and review by the Departmental Appeals Board, if the HHA or hospice program requests a review of the ALJ decision.**
- *After the time to appeal has expired and the HHA or hospice program does not appeal or fails to timely appeal the initial determination,*
- *After CMS receives a written request from the HHA or hospice program requesting to waive its right to appeal the determinations that led to the imposition of a CMP,*
- *After substantial compliance is achieved, or*
- *After the effective date of termination.*

Note: The regulations at §488.845 for HHA and §488.1245 for hospice programs do not include a provision for extended payment plans for HHA or hospice program CMPs.

An HHA or hospice program has two options for action following the imposition of a CMP:

- The HHA or hospice program could pay the amount due for all CMPs imposed prior to the date a CMP is due and payable; or*
- The HHA or hospice program could request a hearing based on the determination of noncompliance with Medicare CoPs.*

When an HHA or hospice program provides timely notice waiving its right to a hearing, CMS reduces the final CMP amount by 35%. This reduction is reflected once the CMP stops accruing, that is, when the HHA or hospice program achieves substantial compliance before CMS receives its request to waive a hearing, or the effective date of the termination occurs before CMS received the waiver request.

Impact of Hearing Requests:

Within 60 days of receipt of the notice of imposition of a penalty, the HHA or hospice program may file a request directly to the Departmental Appeals Board in the Office of the Secretary, Department of Health and Human Services with a copy to the State and CMS. In accordance with §498.40(b), the HHA's or hospice program's appeal request would identify the specific issues of contention, the findings of fact and conclusions of the law with which the HHA or hospice program disagreed, and the specific basis for contending that the survey findings and determinations were invalid. A hearing would be completed before any penalty was collected. However, sanctions/remedies would continue regardless of the timing of any appeals proceedings if the HHA or hospice program had not met the CoPs.

Requesting an appeal would not delay or end the imposition of a sanction/remedy but can only affect the collection of any final CMP amounts due. A CMP would begin to accrue on the last day of the survey which identified the noncompliance. These include penalties imposed on a per day basis, as well as penalties imposed per instance of noncompliance.

10005.22 - Method of Payment

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

HHAs and hospices may select one of the following payment options: (1) Pay.gov; or (2) Electronic transfer of funds. CMS Office of Financial Management (OFM) prefers the use of Pay.gov because it is the federal government's secure portal for web-based collection and billing services which has been implemented by OFM to collect any money due to CMS. Questions related to use of pay.gov, please contact the OFM's Division of Collections via email at OFMDPBCCMPGeneralMailBox@cms.hhs.gov.

HHAs and hospices are not to send CMP payment checks to the CMS Locations. If an HHA or hospice requests to pay by check, it will be considered on a case-by-case basis with collaboration from the CMS Location's division of financial management.

10005.23 - Settlement of Civil Money Penalty

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

The CMS Location has the authority to settle CMP cases at any time prior to a final administrative decision. If a decision is made to settle, the settlement should not be for a better term than had the HHA or hospice program opted for a 35 percent reduction.

10005.24 - Offsets

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

If payment was not received by the established due date, CMS will collect the CMP through offset of monies then owed or later owing to the HHA or hospice program. To initiate such an offset, CMS will instruct the appropriate Medicare Administrative Contractors (MAC), when applicable, the State Medicaid agencies, to deduct unpaid CMP balances from any money owed to the HHA or hospice program. To maintain consistency in recovering a CMP among other types of providers who are subject to a CMP, the amount of any penalty can be deducted (offset) from any sum CMS or the State Medicaid Agency owes to the HHA or hospice program.

Interest would be assessed on the unpaid balance of the penalty beginning on the due date. The rate of interest assessed on any unpaid balance would be based on the Medicare interest rate published quarterly in the Federal Register, as specified in §405.378(d). CMS Locations are notified by CMS OFM of the current interest rate and any changes.

10005.25 - Debt Referral to the Department of the Treasury via the Debt Collection System

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

Those CMP amounts not recovered due to HHA or hospice program failure to pay or inadequate funds for offset will be collected through the Debt Collection Improvement Act of 1996 which requires all debt owed to any Federal agency that is more than 180 days delinquent to be transferred to the Department of the Treasury for debt collection services. Prior to initiating a CMP debt referral to the Department of the Treasury, the CMS Location must first exhaust all collection options through the MAC and the State Medicaid Agency.

The Debt Collection System (DCS) is the data system that is used by the Division of Medicare Debt Management (DMDM) in OFM to transmit debt referrals to the

Department of the Treasury via the Program Support Center (PSC), a separate component within the Department of Health and Human Services.

10005.26 - Disbursement of Recovered CMP funds

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

The CMP amounts and any corresponding interest recovered from HHAs, and hospice programs will be divided between the Medicare and Medicaid programs, based on a proportion that is commensurate with the comparative Federal expenditures under Titles XVIII and XIX of the Act, using Medicaid Statistical Information System (MSIS) and HHA or hospice program Prospective Payment System (PPS) data for a three-year fiscal period. The amounts are disbursed in accordance with § 488.845(g). Penalty funds may not be used for survey and certification operations nor can they be used as the State's Medicaid non-Federal medical assistance or administrative match. The CMS Locations are not responsible for disbursement of recovered CMP funds.

10006 - Suspension of Payment for All New Medicare Admissions

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

10006.1 - Introduction

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

Suspension of payment for all new Medicare admissions is conducted in accordance with §488.840 for HHA or §488.1240 for hospice programs when the provider is not in substantial compliance with the CoPs. The SA should consider recommending this sanction/remedy for deficiencies related to poor patient care outcomes, regardless of whether cited deficiencies pose IJ to patient health and safety. Suspension of payment for new admissions is likely to be the most effective sanction/remedy to influence rapid change to facilitate compliance with the CoPs and may be imposed alone or in combination with other sanctions/remedies.

10006.2 - Notice of Sanction

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

Suspension of payment for new Medicare admissions may be imposed anytime an HHA or hospice program is found to be out of substantial compliance, as long as the HHA or hospice program is given written notice at least 2 calendar days before the effective date in IJ situations and at least 15 calendar days before the effective date in non-IJ situations. The notice of suspension of payment for new admissions must include the following: the nature of the non-compliance; the effective date of the sanction/remedy; and the right to appeal the determination leading to the sanction. In addition to notifying the HHA or hospice program of this proposed sanction/remedy, CMS will also notify the State Medicaid Agency, if applicable.

For HHAs Only: Please note that the imposition of suspension of payment for new admissions on an HHA would prohibit that HHA from conducting health aide training and competency evaluation program for 2 years from the date this sanction is imposed (see also 42 CFR 484.80(f)). See Appendix B of the State Operations Manual for additional information for eligible home health aide training and competency evaluation organizations at §484.80(f).

10006.3 - Effect of Sanction/Remedy on Patients Admitted before the Effective Date of Sanction/Remedy
(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

The patient's status on the effective date of the suspension of payment sanction/remedy is the controlling factor. This sanction/remedy would not apply to patients who have been receiving care from the HHA or hospice program before the effective date of this sanction/remedy. This sanction/remedy would apply only to new Medicare admissions. CMS will suspend payments for new Medicare patient admissions to the HHA or hospice program that are made on or after the effective date of the imposition of the sanction/remedy for the duration of the sanction/remedy. Payments for individuals who are already receiving services could continue. CMS defines a "new admission" as the following:

- A patient who is admitted to the HHA or hospice program under Medicare on or after the effective date of a suspension of payment sanction/remedy; or*
- A patient who was admitted and discharged before the effective date of the suspension of payment and is readmitted under Medicare on or after the effective date of suspension of payment sanction/remedy.*

As part of this sanction/remedy, the HHA or hospice program would be required to notify any new patient admission, before care is initiated, of the fact that Medicare payment would not be available to this HHA or hospice program because of the imposed suspension. The HHA or hospice program would be precluded from charging the Medicare patient for those services unless it could show that, before initiating the care, it had notified the patient or representative both orally and in writing in a language that the patient or representative can understand that Medicare payment is not available.

The suspension of payment sanction/remedy will end when CMS finds that the HHA or hospice program is in substantial compliance with all the CoPs or when the HHA or hospice program is terminated. That is, the suspension of payment sanction/remedy would end when the HHA or hospice program has corrected all condition-level deficiencies, and the correction has been verified by the SA. Any Medicare patients admitted during the suspension of payment period would require a new start of care (SOC) date after the suspension of payment for new admissions has ended. This is required for the HHA or hospice program to begin receiving payments for those patients.

10006.4 - Duration

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

The suspension of payment would end when CMS terminates the provider agreement or when CMS finds the HHA or hospice program to be in substantial compliance with all of the CoPs. No payments are made to reimburse the HHA or hospice program for the time between the date the sanction/remedy was imposed and the date that substantial compliance was achieved. CMS accomplishes the suspension of payment sanction/remedy through written instructions to the appropriate MAC. The CMS Location will send the letter with instructions to the MAC indicating the beginning or ending date of the payment suspension. Generally, if the HHA or hospice program achieves substantial compliance and it is verified by CMS, CMS will resume payments to the HHA or hospice program prospectively from the date it determines that substantial compliance was achieved.

If CMS terminates the provider agreement or determines that the HHA or hospice program is in substantial compliance with the CoPs, the HHA or hospice program would not be able to recoup any payments for services provided to Medicare patients admitted during the time the suspension was in place.

10007 - Temporary Management

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

10007.1 – Introduction, Purpose & Imposition

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

Temporary management is established in accordance with §488.835 for HHAs and §488.1235 for hospice programs. The following situations should be used as a general guide for imposing temporary management when:

- *CMS determines the failure to comply with the CoPs is directly related to management limitations, or*
- *Deficient management oversight that is likely to impair the HHA's or hospice program's ability to correct deficiencies and return the HHA or hospice program to full compliance within the necessary timeframe, and*
- *When needed, based on the above situations, to oversee orderly involuntary termination/closure of an HHA or hospice program including the proper and safe transfer of patients to another local HHA or hospice program.*

Notice of intent to appoint a temporary manager must be given at least 15 calendar days before the effective date of the enforcement action. When there is an IJ, notice of intent must be given at least two calendar days before the effective date of the enforcement action. The notice of intent from CMS provides the intent to impose the enforcement action, the statutory basis for the enforcement action, the nature of the

noncompliance, the proposed effective date of the enforcement action, and the appeal rights. The final notice will be provided once the administrative determination is final.

For HHAs only: Please note that the imposition of temporary management on an HHA would prohibit that HHA from conducting health aide training and competency evaluation program for 2 years from the date this sanction is imposed (see also 42 CFR 484.80(f)). See Appendix B of the State Operations Manual for additional information for eligible home health aide training and competency evaluation organizations at §484.80(f).

The maximum period for use of the temporary manager is six months. It is the temporary manager's responsibility to oversee correction of the deficiencies and assure the health and safety of the HHA's or hospice program's patients while the corrections are being made. An HHA or hospice program that fails to relinquish authority and control to a temporary manager will have its provider agreement terminated in accordance with §488.865 (HHA) or §488.1265 (Hospice).

10007.2 - Selection of Temporary Manager (Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

Each SA should compile a list of individuals who are eligible to serve as temporary managers. When CMS decides to impose this sanction or remedy, it considers the SA's recommendation for a temporary manager whose work experience and education qualify the individual to oversee the correction of deficiencies to achieve substantial compliance. The temporary manager must have the experience and education that qualifies the individual to oversee the HHA or hospice program. The temporary manager can be either internal or external to the HHA/hospice program and will be appointed by CMS or the SA based on qualifications described in §§ 484.105(b) and 484.115 for HHAs and §§ 418.100 and 418.114 for hospice programs. The SA should reject a candidate who has demonstrated difficulty maintaining compliance in the past.

10007.3 – Authority and Conditions of Temporary Management (Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

CMS notifies the HHA or hospice program that a temporary manager is being appointed. The temporary manager must have the authority to hire, terminate, or reassign staff; obligate the provider's funds; alter provider policies and procedures; and otherwise manage an HHA or hospice program to correct deficiencies identified in the provider's operation. The HHA's or hospice program's management must agree to relinquish authority and control to the temporary manager and to pay his/her salary before the temporary manager can be installed in the HHA or hospice program. A contract or memorandum of understanding should be completed between the temporary manager and the HHA or hospice program prior to the temporary manager beginning any work or incurring any costs. Failure to relinquish authority and control to the temporary manager will result in termination of the HHA or hospice program.

The HHA or hospice program cannot retain final authority to approve changes of personnel or expenditures of HHA or hospice program funds and be considered to have relinquished control to the temporary manager. The temporary manager must be given access to all HHA or hospice program bank accounts. If the HHA or hospice program does not relinquish control to the temporary manager and/or provide access to bank accounts and available assets, the HHA or hospice program will be terminated. It should be noted that the HHA's or hospice program's governing body remains ultimately responsible for achieving compliance. The responsibility does not transfer to the temporary manager, SA, or CMS.

The temporary manager's salary must be at least equivalent to the prevailing annual salary of HHA or hospice program administrators in the HHA's or hospice program's geographic area based on the bureau of labor statistics, plus any additional costs that would have reasonably been incurred by the HHA or hospice program if the temporary manager had been in an employment relationship, e.g., the cost of a benefits package, prorated for the amount of time that the temporary manager spends in the HHA or hospice program. The HHA or hospice program is also responsible for any other costs incurred by the temporary manager in furnishing services under such an arrangement or as otherwise set by the State. Failure to pay the salary and other costs is considered a failure to relinquish authority and control to temporary management and will result in termination of the provider agreement.

The State should provide the temporary manager with an appropriate orientation that includes a review of the HHA's or hospice program's deficiencies and compliance history. The State may request that the temporary manager periodically report on the actions taken to achieve compliance and, on the expenditures associated with these actions.

10007.4 - Duration of Temporary Management (Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

Temporary management continues until an HHA or hospice program is terminated by CMS, or achieves substantial compliance via an onsite survey, and is capable of remaining in substantial compliance, or decides to discontinue the sanction/remedy and reassume management control before it has achieved substantial compliance. If the HHA or hospice program reassumes control before achieving substantial compliance, CMS would initiate termination of the provider agreement and could impose additional sanctions or remedies during the time period between HHA or hospice program resumption of management and termination. Temporary management will not exceed six months from the date of the survey identifying noncompliance.

10008 - Directed Plan of Correction (DPOC) (Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

10008.1 – Purpose (Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

The purpose of the DPOC is to achieve correction and continued compliance with Federal requirements. A DPOC is a plan that the State, with CMS Location approval, or the CMS Location develops to require an HHA or hospice program to take corrective action to achieve specific outcomes within specified time frames. The requirements for DPOC are specified at §488.850 for HHA and §488.1250 for hospice programs.

10008.2 - Imposition of a Directed Plan of Correction

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

Whether the facility has standard-level or condition-level deficiencies, an HHA or hospice program must submit an acceptable plan of correction to CMS. If the HHA or hospice program is unable to develop an acceptable plan of correction, CMS may impose a DPOC for condition level deficiencies. CMS must provide written notification of the intent to impose a DPOC sanction/remedy.

Notice of intent to impose a DPOC must be given at least 15 calendar days before the effective date of the enforcement action in non-IJ situations and at least 2 calendar days before the effective date in IJ situations. The date the DPOC is imposed, that is, the date the sanction/remedy becomes effective, does not mean that all corrections must be completed by that date.

10008.3 - Elements of a Directed Plan of Correction

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

A DPOC should address all of the elements required for an HHA- or hospice program-developed plan of correction. These elements include, but are not limited to, the following:

- I. How an HHA or hospice program will correct each deficiency;*
- II. How the HHA or hospice program will act to protect patients in similar situations;*
- III. How the HHA or hospice program will ensure that each deficiency does not recur;*
- IV. How the HHA or hospice program will monitor performance to sustain solutions; and*
- V. The timeframe in which corrective actions will be taken.*

10008.4 - Achieving Compliance

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

Achieving compliance is the HHA's or hospice program's responsibility, whether or not a DPOC is followed. If the HHA or hospice program fails to achieve compliance within the timeframes specified in the DPOC, CMS may impose one or more

additional alternative sanctions/remedies until the HHA or hospice program achieves compliance or is terminated from the Medicare program.

10009 - Directed In-Service Training

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

10009.1 – Purpose & Imposition

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

Directed in-service training may be used when the State, CMS, or the temporary manager believes that education is likely to correct the deficiencies and help the HHA or hospice program achieve substantial compliance. The requirements for directed in-service training are specified at §488.855 for HHA and §488.1255 for hospice programs.

Directed in-service training requires the staff of the HHA or hospice program to attend a specific in-service training program(s). The purpose of directed in-service training is to provide knowledge to achieve and remain in compliance with Federal requirements. For example, in circumstances where some, but not all, compliance problems are a result of a lack of knowledge on the part of the health care provider relative to advances in health care technology and expectations of favorable patient outcomes, directed in-service training would benefit the agency. Also, directed in-service could be used in situations where staff performance results in deficient practice. A directed in-service training program would correct this deficient practice through retraining the staff in the use of clinically and professionally sound methods to produce quality outcomes.

Notice of intent to impose directed in-service training must be given at least 15 calendar days before the effective date of the enforcement action in non-IJ situations and at least 2 calendar days before the effective date in IJ situations.

10009.2 - Appropriate Resources for Directed In-Service Training Programs

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implemetation:05-10-24)

HHAs or hospice program should use programs developed by well-established centers of health education and training such as continuing education programs offered by schools of medicine, nursing, public health, community colleges, state health departments, centers for the aging, and other available area centers which have established continuing education programs for health professionals. The programs may also be conducted by consultants with background in education and training with Medicare HHA or hospice program providers, as applicable, or as deemed acceptable by CMS and/or the SA (by review of a copy of the curriculum vitas and/or resumes/references in order to determine the educator's qualifications). The SA or CMS Location may also compile a list of resources that can provide directed in-service training and may make this list available to HHAs or hospice programs.

10009.3 - Further Responsibilities

(Rev. 221; Issued: 05-10-24; Effective: 05-10-24; Implementation:05-10-24)

The HHA or hospice program bears the expense of the directed in-service training for its staff. After the training has been completed, the SA will assess whether substantial compliance has been achieved. If directed in-service training was the sanction imposed and the HHA or hospice program does not achieve substantial compliance, CMS may impose one or more additional sanctions/remedies as specified at §488.820 for HHA or at §488.1220 for hospice programs.