

State Operations Manual

Chapter 9 – Survey and Enforcement Process for Home Health Agencies

Table of Contents

9000	Introduction.....	6
	9000.1 Expectations of the Regulations	6
9001	Definitions and Acronyms	7
9002	Home Health Agencies – Citations and Description	9
	9002.1 Citations	9
	9002.2 Description.....	10
	9002.3 Home Health Services.....	11
9003	Emphasis, Components, and Applicability.....	11
	9003.1 Introduction	11
	9003.2 Survey and Certification Responsibility	12
9004	Survey Team	12
	9004.1 Survey Team Size	12
	9004.2 Survey Team Composition	12
	9004.3 Length of Survey	13
	9004.4 Surveyor Qualifications.....	13
9005	Conflicts of Interest for Federal and State Employees	13
	9005.1 Introduction	13
	9005.2 Conflicts of Interest.....	13
	9005.3 Examples of Potential Conflicts of Interest.....	14
	9005.4 Report and Investigation of Improper Acts	14
9006	Survey Protocol.....	15
	9006.1 Introduction	15
	9006.2 Types of Surveys	15
	9006.3 Standard Survey.....	15
	9006.4 Initial Certification Surveys.....	16
	9006.5 Recertification of Participating Facilities	16

9006.6	Post Survey Revisit (Follow-Up).....	16
9006.7	Abbreviated Standard Survey.....	17
9006.8	Partial Extended Survey	18
9006.9	Extended Survey.....	18
9007	Survey Frequency	19
9007.1	Citation 19	
9008	Unannounced Surveys	19
9008.1	Citation 19	
9008.2	Scheduling Requirements.....	19
9008.3	CMS Review of State Scheduling Procedures.....	19
9008.4	Penalty for Announcing a Survey	19
9009	Informal Dispute Resolution (IDR)	20
9009.1	Introduction.....	20
9009.2	Purpose20	
9009.3	Mandatory Elements of IDR	21
9010	Alternative Sanctions for Home Health Agencies	22
9010.1	Statutory Basis.....	22
9010.2	General Provisions.....	23
9010.3	Effect of Sanctions on HHAs that participate in Medicare via Deemed Status through an Accrediting Organization	23
9010.4	Effect of Sanctions on HHA Branches.....	24
9010.5	Available Sanctions.....	25
9010.6	Factors to be considered in selecting sanctions.....	25
9011	Action when deficiencies pose immediate jeopardy.....	26
9011.1	Statutory and Regulatory Basis	26
9011.2	Purpose26	
9012	Enforcement Action When Immediate Jeopardy Exists	26
9013	Action When Deficiencies are Condition-level But Do Not Pose Immediate Jeopardy. 26	
9014	Guidance for Individual Sanctions.....	26
9015	Temporary Management.....	27
9015.1	Introduction.....	27

	9015.2	Purpose	27
	9015.3	Authority of Temporary Manager.....	27
	9015.4	Selection of Temporary Manager	27
	9015.5	Conditions of Temporary Management	27
	9015.6	Orienting and Supervising Temporary Manager	28
	9015.7	Notice of Imposition of Temporary Management.....	28
	9015.8	Duration of Temporary Management	28
9016		Suspension of Payment for All New Medicare Admissions.....	28
	9016.1	Introduction	28
	9016.2	Notice of Sanction.....	29
	9016.3	Effect of Sanction on Patients Admitted before the Effective Date of Sanction	29
	9016.4	Duration	30
9017		Civil Money Penalties.....	30
	9017.1	Basis for Imposing Civil Money Penalties	30
	9017.2	Determining Amount of Civil Money Penalty	31
	9017.3	Adjustments to penalties.....	31
9018		Range of Penalty Amounts	32
	9018.1	Upper range of penalty.....	32
	9018.2	Middle range of penalty.....	33
	9018.3	Lower range of penalty	33
	9018.4	Per instance civil money penalty	33
	9018.5	Decreased penalty amounts	33
	9018.6	Increased penalty amounts	33
	9018.7	Considerations in determining the penalty amount.....	34
9019		Suggested Penalty Amounts	34
	9019.1	Upper Range Civil Money Penalties for Immediate Jeopardy Citations.....	34
	9019.2	Middle Range Penalties for Non-Immediate Jeopardy Citations.....	34
	9019.3	Lower Range Penalties for Structure and Process Citations Not Directly Related to Patient Care	36
9020		Procedures.....	36
	9020.1	Notice of imposition of civil money penalty.....	36
	9020.2	Sending the Notice.....	37

9020.3	Appeal of Noncompliance That Led to Imposition of Civil Money Penalty.....	37
9020.4	HHA Waives Right to a hearing	37
9020.5	Accrual and duration of per day penalty.....	38
9020.6	Amount of per instance penalty.....	38
9020.7	Duration of Civil Money Penalty.....	39
9020.8	Duration of per day penalty when there is immediate jeopardy.....	40
9020.9	Duration of penalty when there is no immediate jeopardy.....	40
9020.10	When Penalty Is Due and Payable	41
	1. After Final Administrative Decision.....	41
	2. No Hearing Requested	41
	3. After Request to Waive Hearing.....	41
	4. After Substantial Compliance Is Achieved.....	41
9021	Notice of Amount Due and Collectible	42
	1. Contents of Notice	42
	2. Method of Payment.....	42
9021.2	Computation and notice of total penalty amount	42
9021.3	When a penalty is due and payable	43
9021.4	Method of Payment	45
9021.5	Settlement of Civil Money Penalty.....	45
9021.6	Offsets	45
9022	Disbursement of Recovered CMP funds.....	45
9023	Directed plan of correction	46
9023.1	Introduction.....	46
9023.2	Purpose	46
9023.3	Imposition of a Directed Plan of Correction.....	46
9023.4	Elements of a Directed Plan of Correction	46
9023.5	Achieving Compliance	47
9023.6	Notice of Imposition of Directed Plan of Correction.....	47
9024	Directed In-service Training.....	47
9024.1	Introduction.....	47
9024.2	Purpose	47
9024.3	Appropriate Resources for Directed In-Service Training Programs	48
9024.4	Further Responsibilities.....	48

	9024.5	Notice of Imposition of Directed In-Service Training.....	48
9025		Effect of termination on the HHA's patients	48

9000 Introduction

Chapter 9 implements the home health agency (HHA) survey, certification, and 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.

To participate as an HHA in the Medicare program, an agency or organization must meet the definition of an HHA as defined in section 1861(o) of the Social Security Act (the Act). Additionally, HHAs must meet the requirements in section 1891(a) of the Act. The regulations implementing sections 1861(o) and 1891(a) of the Act are known as health and safety standards, or conditions of participation (CoPs), for HHAs and are codified in §484.

The Secretary has the responsibility to promote quality of care and the health and safety of patients receiving services through Medicare certified HHAs by ensuring that providers maintain compliance with the CoPs. The survey and certification process provides a method for CMS to evaluate HHA 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.

9000.1 Expectations of the Regulations

The HHA survey, certification, and enforcement provisions of the Act and regulations establish several expectations. The first is that providers remain in substantial compliance with Medicare program requirements as well as State law. The regulation emphasizes the need for continued, rather than cyclical compliance. The enforcement processes require that policies and procedures be established to correct deficient practices and to ensure that correction is lasting; specifically, that HHAs take the initiative and responsibility for continuously monitoring their own performance to sustain compliance.

The second expectation is that all deficiencies will be addressed promptly. The standard for program participation mandated by the regulation is substantial compliance, which is defined at §488.705 as compliance with all condition-level requirements, as determined by CMS or the State. The State and the CMS regional office will take steps to bring about compliance quickly. In accordance with 42 CFR §488.800 – §488.865, in addition to termination of the HHA's provider agreement, sanctions such as civil money penalties, suspension of payment for all new admissions, temporary management, directed plans of correction, directed in-service training, and/or additional State alternative sanctions recommended and approved by CMS can be imposed when HHAs are out of compliance with Federal requirements. See also section 1891(f)(2)(B) of the Act.

The third expectation is that the individuals under the care of the HHA will receive the care and services they need to attain and maintain their highest practicable functional capacity. The process detailed in these sections provides incentives to HHAs for the continued compliance needed to enable these individuals to reach these goals.

Throughout this chapter, references to the State would be applicable, as appropriate, to the CMS RO when the CMS RO is the surveying entity. Alternative sanctions are recommended by the SA and the CMS RO reviews the recommendation to ensure that it is supported by the SA findings.

It should be noted that failure of CMS or the State to act timely does not invalidate otherwise legitimate survey and enforcement determinations. It should also be noted that in cases where the State is authorized by CMS, the State may provide notice of imposition of certain sanctions on CMS's behalf, within applicable notice requirements.

The Automated Survey Processing Environment (ASPEN) Enforcement Manager (AEM) is the data system used by CMS and all States for data entry and reporting on home health survey and enforcement activities.

9001 Definitions and Acronyms

Abbreviated standard survey means a focused survey other than a standard survey that gathers information on an HHA's compliance with fewer specific standards or conditions of participation. An abbreviated standard survey may be based on complaints received, a change of ownership or management, or other indicators of specific concern such as reapplication for Medicare billing privileges following a deactivation. (42 CFR §488.705)

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

AEM – ASPEN Enforcement Manager.

AO – national Accreditation Organization whose program is approved by CMS.

ASPEN – Automated Survey Processing Environment.

Certification of Compliance means that the HHA is in at least substantial compliance and is eligible to participate in the Medicare and Medicaid programs. (42 CFR §488.740)

Certification of Noncompliance means that the HHA is not in substantial compliance and is not eligible to participate in in the Medicare and Medicaid programs. (42 CFR §488.740)

CFR - Code of Federal Regulations.

CMP - Civil money penalty.

Complaint survey means a survey that is conducted to investigate specific allegations of noncompliance. (42 CFR §488.705)

Condition-level deficiency means noncompliance as described in 42 CFR §488.24 of this part. 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. SAs and ROs should refer to the State Operations Manual (SOM), Appendix B for further guidance on how surveyors determine condition-level and standard-level deficiencies. (42 CFR §488.705)

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. (See §3016A)

Deficiency is a violation of the Act and regulations contained in §484, subparts A through C of this chapter, is determined as part of a survey, and can be either standard or condition-level. (42 CFR §488.705)

Directed plan of correction means CMS or the temporary manager (with CMS/SA approval) may direct the HHA to take specific corrective action to achieve specific outcomes within specific timeframes. If a temporary manager establishes a plan of correction, then this is considered a directed plan of correction and the imposition of this sanction needs to be entered into AEM. (42 CFR §488.805)

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

Extended survey means a survey that reviews additional conditions of participation 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). (42 CFR §488.805)

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

Noncompliance means any deficiency found at the condition-level or standard-level. (42 CFR §488.705)

Partial extended survey 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 instance means a single event of noncompliance identified and corrected through a survey, for which the Act authorizes CMS to impose a sanction. (42 CFR §488.805)

Plan of correction means a plan developed by the HHA and approved by CMS that is the HHA's written response to survey findings detailing corrective actions to cited deficiencies and specifies the date by which those deficiencies will be corrected. (42 CFR §488.805)

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. (42 CFR §488.805)

Standard-level deficiency means noncompliance with one or more of the standards that make up each condition of participation for HHAs. SAs and ROs should refer to the State Operations Manual (SOM), Appendix B for further guidance on how surveyors determine condition-level and standard-level deficiencies. (42 CFR §488.705)

Standard survey means a survey conducted in which the surveyor reviews the HHA's compliance with a select number of standards and/or conditions of participation in order to determine the quality of care and services furnished by an HHA as measured by indicators related to medical, nursing, and rehabilitative care. (42 CFR §488.705)

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

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

Substantial compliance means compliance with all condition-level requirements, as determined by CMS or the State. SAs and ROs should refer to the State Operations Manual (SOM), Appendix B for further guidance on how surveyors determine condition-level and standard-level deficiencies. (42 CFR §488.705)

Temporary management means the temporary appointment by CMS or by a CMS authorized agent, of a substitute manager or administrator based upon qualifications described in §484.4 and §484.14(c). The HHA'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 to correct deficiencies identified in the HHA's operation. (42 CFR §488.805)

9002 Home Health Agencies – Citations and Description

9002.1 Citations

A HHA is defined in section 1861(o) of the Act. The conditions of participation for HHAs are found at 42 CFR 484.10 – 484.55.

9002.2 Description

An HHA is a public agency or private organization or a subdivision of such an agency or organization, which:

- (1) is primarily engaged in providing skilled nursing services and other therapeutic services;
- (2) has policies, established by a group of professional personnel (associated with the agency or organization), including one or more physicians and one or more registered professional nurses, to govern the services (referred to in paragraph (1)) which it provides, and provides for supervision of such services by a physician or registered professional nurse;
- (3) maintains clinical records on all patients;
- (4) in the case of an agency or organization in any State in which State or applicable local law provides for the licensing of agencies or organizations of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing agencies or organizations of this nature, as meeting the standards established for such licensing;
- (5) has in effect an overall plan and budget that meets the requirements of subsection (z);
- (6) meets the conditions of participation specified in section [1891\(a\)](#) and such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization;
- (7) provides the Secretary with a surety bond—
 - (A) effective for a period of 4 years (as specified by the Secretary) or in the case of a change in the ownership or control of the agency (as determined by the Secretary) during or after such 4-year period, an additional period of time that the Secretary determines appropriate, such additional period not to exceed 4 years from the date of such change in ownership or control;
 - (B) in a form specified by the Secretary; and
 - (C) for a year in the period described in subparagraph (A) in an amount that is equal to the lesser of \$50,000 or 10 percent of the aggregate amount of payments to the agency under this title and title XIX for that year, as estimated by the Secretary that Secretary determines is commensurate with the volume of the billing of the supplier; and
- (8) meets such additional requirements (including conditions relating to bonding or establishing of escrow accounts as the Secretary finds necessary for the financial security of the program) as the Secretary finds necessary for the effective and efficient operation of the program;

except that for purposes of part A such term shall not include any agency or organization which is primarily for the care and treatment of mental diseases. The Secretary may waive the

requirement of a surety bond under paragraph (7) in the case of an agency or organization that provides a comparable surety bond under State law.

NOTE: The surety bond requirement in the above paragraph is currently on hold.

9002.3 Home Health Services

Home health services are covered for the elderly and disabled under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program. Section 1861(m) of the Act defines the term “home health services” as items or services furnished to an individual, who is under the care of a physician, that must be furnished by, or under arrangement with, an HHA that participates in the Medicare program, under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician, and must be provided on a visiting basis to the individual’s home (unless provided on an outpatient basis, under arrangement by the HHA, at a hospital or skilled nursing facility, or at a rehabilitation center). Such items and services may include the following:

- Part-time or intermittent skilled nursing care furnished by or under the supervision of a registered nurse.
- Physical therapy, speech-language pathology, and occupational therapy.
- Medical social services under the direction of a physician.
- Part-time or intermittent home health aide services who have successfully completed an approved training program.
- Medical supplies (other than drugs and biologicals – unless osteoporosis drugs) and durable medical equipment.
- Medical services of interns and residents if the HHA is owned by or affiliated with a hospital that has an approved medical education program.
- Services at hospitals, skilled nursing facilities, or rehabilitation centers when they involve equipment too cumbersome to bring to the home.

Survey Process

9003 Emphasis, Components, and Applicability

Home health agencies must be in compliance with the requirements in 42 CFR Part 484, Subparts A, B, and C to receive payment under Medicare. To certify a HHA, surveyors follow the procedures in Appendix B of this manual.

9003.1 Introduction

The Secretary is authorized to enter into an agreement with a State survey agency (SA) under section 1864(a) of the Act or a CMS-approved national accreditation organization (AO) under section 1865(a) of the Act, with oversight by CMS ROs, to determine whether HHAs meet the Federal participation requirements for Medicare. Sections 1902(a)(9) and (33)(B) of the Act

provides for SAs to perform the same survey tasks for facilities participating in or seeking to participate in the Medicaid program. The results of Medicare and Medicaid-related surveys are used by CMS and the Medicaid State Agency, respectively, as the basis for a decision to enter into, deny, or terminate a provider agreement with the agency. To assess compliance with Federal participation requirements, surveyors conduct onsite inspections (surveys) of agencies. In the survey process, surveyors directly observe the actual provision of care and services to patients and the effect or possible effects of that care to assess whether the care provided meets the assessed needs of individual patients. A SA periodically surveys HHAs and certifies its findings to CMS and to the State Medicaid Agency if the HHA is seeking to acquire or maintain Medicare or Medicaid certification, respectively. The general requirements regarding the survey and certification process are codified at 42 CFR Part 488 and specific survey instructions are detailed in the SOM, Chapter 2, sections 2180- 2202, Appendix B and in policy transmittals.

Certain providers and suppliers, including HHAs, can be deemed by CMS to meet the Federal requirements for participation if they are accredited and recommended for participation in Medicare by an AO whose program is approved by CMS to meet or exceed Federal requirements under section 1865(a) of the Act. These deemed providers and suppliers are subject to complaint and validation surveys under §488.7.

9003.2 Survey and Certification Responsibility

Surveyors conduct the HHA survey in accordance with the applicable protocols. They look to the requirements in the statute and regulations to determine whether a deficiency citation of non-compliance is appropriate. Surveyors should base any deficiency on a violation of the statute or regulations, which is identified through clinical record reviews, interviews with the HHA's patients, staff, and others as appropriate and direct observations of the HHA's performance and practices. (See §2712.)

9004 Survey Team

9004.1 Survey Team Size

Survey team size will vary, depending primarily on the size of the agency being surveyed. The SA or CMS for Regional Office (RO) surveys determines how many members will be on the survey team. Survey team size is normally based upon the following factors:

- The average patient census of the agency to be surveyed;
- Whether the agency has a historical pattern of serious deficiencies or complaints;
- Whether the agency has branches; and
- Whether new surveyors are to accompany a team as part of their training.

9004.2 Survey Team Composition

Each home health survey team should include at least one RN with home health survey experience. Other qualified surveyors who have the expertise to determine whether the HHA is in compliance may be used as needed.

9004.3 Length of Survey

The length of a survey in terms of person hours is expected to vary, based on the actual patient census, presence of branches, number of home visits and travel time, and the number and complexity of concerns that need to be investigated.

9004.4 Surveyor Qualifications

Section 1891(c)(2)(C)(iii) of the Act requires that “an individual who meets the minimum qualifications established by the Secretary” to conduct a survey of an HHA. This means that each individual on a survey team must meet certain minimum qualifications. CMS criteria for surveyor minimum qualifications as well as circumstances that would disqualify a surveyor from surveying a particular agency are found at §488.735. In addition, before any State or Federal surveyor may serve on an HHA survey team (except as a trainee), he/she must have successfully completed the relevant CMS-sponsored Basic HHA Surveyor Training Course and any associated course prerequisites as determined by current CMS policy. New surveyors may accompany the team, in an observational role only, as part of their training prior to completing the CMS Basic HHA Surveyor Training Course.

9005 Conflicts of Interest for Federal and State Employees

9005.1 Introduction

Conflicts of interest may arise within the Medicare certification and survey process when public employees’ duties give them the potential for private gain (monetary or otherwise) or the opportunity to secure unfair advantages for outside associates. This includes all Federal and State surveyors and their supervisors. There are a number of Federal and State laws setting forth criminal penalties for abuses of privileged information, abuses of influence, and other abuses of public trust. Federal employees are required to make a declaration of any outside interests and to update it whenever such interests are acquired. The same should be required of State employees whose positions may produce possible conflicts of interest. Both CMS and the State are responsible for evaluating the need for preventive measures to protect the integrity of the certification program. When survey and certification work is performed by agencies other than CMS or the State, the State administrators and the sub-agency administrators have a shared responsibility for this surveillance.

In the case of States, it is not necessary to inform CMS of all potential conflict situations. However, if an overt abuse requires corrective action, the CMS RO must be informed.

9005.2 Conflicts of Interest

Section 488.735(b) sets out the circumstances that would disqualify a surveyor from surveying a particular HHA. A surveyor is prohibited from surveying an HHA if the surveyor currently works, or within the past two years has worked for the HHA to be surveyed. Specifically, the surveyor could not have been a direct employee, employment agency staff at the HHA, or an officer, consultant or agent for the surveyed HHA regarding compliance with CoPs. A surveyor

would also be prohibited from surveying an HHA if he or she has a financial interest or an ownership interest in that HHA. A financial interest is defined as salary, fees, commissions, honoraria, or any other source of income. The surveyor would also be disqualified if he or she has a family member who has a financial interest or ownership interest with the HHA to be surveyed or has an immediate family member who is a patient of the HHA to be surveyed. An immediate family member is defined in §488.301 as husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

9005.3 Examples of Potential Conflicts of Interest

CMS and the States must consider all relevant circumstances that may exist beyond the benchmarks given in this section to ensure that the integrity of the survey process is preserved. For example, a surveyor may not have worked for the agency to be surveyed for more than two years, but may have left the HHA under unpleasant circumstances, or, may not currently have an immediate family member who receives services from, but may have recently received services from the HHA who the surveyor considers to have received inadequate care.

The following are typical of situations that may raise a question of possible conflicts of interest for Federal or State employees; however, they do not necessarily constitute conflicts of interest:

- i. Participation in ownership of an HHA located within the employing State;
- ii. Service as a director or trustee of an HHA;
- iii. Service on a utilization review committee for an HHA;
- iv. Private acceptance of fees or payments from a health facility or group of health facilities or association of health facility officers for personal appearances, personal services, consultant services, contract services, referral services, or for furnishing supplies to a health facility;
- v. Participation in a news service disseminating trade information to a segment of the health industry; and
- vi. Having members of one's immediate family engaged in any of the above activities.

9005.4 Report and Investigation of Improper Acts

Any acts of employees in violation of Federal or State laws or regulations regarding conflicts of interest should be handled in accordance with applicable Federal or State procedures. In the case of State employees, conflicts of interest violations must be reported to the CMS RO, and the CMS RO must be kept advised of the corrective actions. States should ask for assistance or advice from CMS in the case of any impropriety involving a conflict of interest that cannot be handled immediately under an applicable State procedure. The regional office of the Inspector General, along with the CMS RO, will then work in close cooperation with the responsible State officials until the matter is resolved.

9006 Survey Protocol

9006.1 Introduction

Surveys conducted on a HHA must be based upon protocols developed, tested, and validated by the Secretary under section 1891(c)(2)(C)(ii) of the Act. Survey protocols are established to provide guidance to surveyors of HHAs. They serve to clarify and/or explain the intent of the regulations. The purpose of the protocols and guidelines is to direct the surveyor's attention to avenues of investigation in preparing for the survey, conducting the survey, and evaluating the survey findings. All surveyors are required to reference the protocols in assessing compliance with Federal requirements.

These protocols represent the policies of CMS on relevant issues that must be inspected or reviewed under each requirement. The use of these protocols promotes consistency in the survey process. The protocols assure that a HHA's compliance with the requirements is reviewed in a thorough, efficient, and consistent manner to produce sufficient information to make compliance decisions. The survey protocols are found in Appendix B of this manual.

9006.2 Types of Surveys

Sections 1891(c)(1)-(2) of the Act specify the requirements for types and frequency of surveys, identifying standard, and abbreviated standard, partial extended, and extended surveys. These surveys are generally defined in §488.705.

9006.3 Standard Survey

A standard survey is conducted not later than 36 months after the date of the previous standard survey, as is specified in section 1891(c)(2)(A) of the Act. A standard survey may also be conducted within 2 months of any change of ownership, administration, or management of the HHA to determine whether the change has resulted in any decline in the quality of care furnished by the HHA and it shall be conducted within 2 months of when a significant number of complaints have been reported as specified in section 1891 (c)(2)(B)(i) and (ii). Section 1891(c)(2)(C) of the Act requires that a standard survey, to the extent practicable, reviews a case-mix stratified sample of individuals to whom the HHA furnishes services. Actual visits to the homes of sampled patients must be conducted and a survey of the quality of services being provided as measured by indicators of medical, nursing, and rehabilitative care must be conducted. Minimum requirements for standard surveys are specified in §488.710.

Standard surveys are conducted for initial certifications and for re-certifications. During a standard survey, the surveyor reviews compliance with Level I standards as designated in the SOM Appendix B.

Deficiency findings of any Level I standard will trigger a partial extended survey. Deficiencies at the condition-level will trigger an extended survey.

9006.4 Initial Certification Surveys

All HHAs are required to successfully complete an initial standard survey before they can be certified as meeting the Medicare requirements. The initial Medicare certification survey begins as a standard survey. Before this initial Medicare survey takes place, the prospective HHA must send written documentation to the SA requesting an initial certification survey. Follow Appendix B - Guidance to Surveyors: Home Health Agencies for conducting initial certification surveys.

9006.5 Recertification of Participating Facilities

An HHA is subject to a recertification survey no later than 36 months from the previous recertification survey. All recertification surveys begin (and may end) as a standard survey, unless a problem is identified with a Level 1 standard as described in Appendix B of this manual. Each State must follow CMS instructions for survey frequency within this 36-month interval commensurate with the need to assure the delivery of quality home health services. Follow Appendix B - Guidance to Surveyors: Home Health Agencies for standard surveys.

9006.6 Post Survey Revisit (Follow-Up)

The SA follows up on all deficiencies cited in PoCs. In some cases, the cited deficiencies may be of a nature that a mail or telephone contact will suffice in lieu of an onsite visit (e.g., the HHA amended its written policies). A mail or telephone contact is acceptable as long as the SA has no reason to question the validity of the reported corrections. However, an onsite visit is generally required for deficiencies concerning quality of care.

If the SA has cited condition level deficiencies, they must conduct a post survey revisit to determine if the HHA now meets the CoPs.

At the time of the follow-up visit to verify corrections of deficiencies previously cited on Form CMS-2567 and/or when corrections are verifiable by telephone contact or mail, the SA completes Form CMS-2567B for the corrections that have been completed. The SA enters:

1. HHA identification information;
2. Date of the revisit or date of verification;
3. Data tag;
4. Corresponding regulatory reference cited on the original Form CMS-2567; and
5. Date the correction was accomplished.

If documentation or onsite verification is warranted, the SA obtains appropriate verification before reporting a deficiency as corrected. The revisit requires that the SA complete a Post-Certification Revisit Report (Form CMS-2567B).

If possible, the revisit is to be conducted by a member(s) of the survey team who cited the original findings. The SA has the completed form initialed by the reviewing official and signed

by the surveyor and retains the fourth copy for its provider file, mails a copy to the HHA, and forwards a copy to the RO or SMA, as appropriate.

If, at the time of the revisit, some deficiencies have not been corrected, follow the instructions at Section 2732B.

9006.7 Abbreviated Standard Survey

An abbreviated standard survey is limited in its scope and does not cover as many aspects of HHA operations and services as are covered in a standard, partial extended, or extended survey but rather concentrates on a particular area of concern(s). This survey focuses on particular tasks that relate, for example, to complaints received, or a change of ownership, management, or administration, or reapplying for Medicare billing privileges following a deactivation. The survey team (or surveyor) may investigate any area of concern and make a compliance decision regarding any regulatory requirement, whether or not it is related to the original purpose of the survey.

9006.7A Complaint Investigations

If the State's review of a complaint allegation(s) identifies possible non-compliance with one or more of the requirements and only a survey can determine whether a deficiency(ies) exist, an abbreviated standard survey will be conducted. During an abbreviated standard survey, the standards identified as being related to the allegations of noncompliance are reviewed. If a condition is found to be out of compliance during the survey, the surveyor should move into a partial extended or extended survey depending on the findings identified. Follow the guidelines in Chapter 5: Complaint Investigations and Appendix B of this manual.

If an accredited HHA is deemed to meet the requirements and a deficiency(ies) is found at the condition level during a complaint or validation survey, the RO will remove deemed status and oversight authority reverts back to the SA until the organization returns to substantial compliance with all requirements or is terminated. Once the HHA is in compliance, the RO will restore deemed status and turn oversight authority back to the AO.

For example, S&C-09-08 (Question V-4) provides for two processes:

1. If the SA finds condition-level noncompliance as a result of a full survey conducted on a representative sample basis and the RO agrees with this finding, the provider/supplier is: notified of the deficiencies via the CMS 2567 and also of the removal of its deemed status; placed under the jurisdiction of the SA; and, placed on track for termination of its provider agreement. The RO also notifies the provider's/supplier's AO of the removal of deemed status and that the facility has been placed on a termination track. CMS will terminate the provider agreement unless the provider/supplier submits an acceptable POC and the SA verifies through a revisit survey that the provider/supplier has come into compliance. The revisit survey focuses on the conditions that were previously deficient. The timeframe for coming into compliance depends on whether the deficiencies posed an immediate jeopardy to patient health and safety. If the provider/supplier fails to make

timely correction of its deficiencies, the RO terminates the provider agreement. If the provider/supplier has been determined to have achieved compliance, the RO notifies the provider/supplier that its deemed status has been reinstated.

2. If the SA finds condition-level noncompliance as a result of a validation survey based on a substantial allegation and the RO agrees with this finding, the provider/supplier is notified of the deficiencies via the CMS-2567 and also of the removal of its deemed status and placement under SA jurisdiction; the RO notifies the AO of its removal of deemed status.

9006.7B Substantial Changes in an HHA's Organization and Management

If an HHA notifies the SA of a change in organization or management, review the change to ensure compliance with the regulations. Request copies of the appropriate documents, e.g. written policies and procedures, personnel qualifications and agreements, etc., if they were not submitted with the notification. If changes in an HHA's organization and management are significant and raise questions of its continued substantial compliance, determine, through a survey, whether deficiencies have resulted. Collect information about changes in the HHA's organization and management on the "Medicare and other Federal Care Program General Enrollment," Form CMS-855A.

9006.8 Partial Extended Survey

The partial extended survey is conducted to determine if a deficiency (ies) and/or deficient practice exists at standard or condition levels in the CoPs that were not fully examined during the standard survey and there are indications that a more comprehensive review of the CoPs would determine if a deficient practice exists. The surveyors may review any additional standards or conditions which would assist in making a compliance decision. Partial extended surveys are also conducted when the surveyor's off-site preparation determines a concern. At that point there is not a determination of a deficient practice. For example, the surveyor may have a concern about the HHA's transmission of OASIS data and want to review that area during the survey.

During the partial extended survey, the surveyor reviews, at a minimum, the Level 2 standards under the same conditions which are related to the Level 1 standard(s) that are out of compliance. The surveyors may review any additional standard(s) under the same condition or other related or unrelated condition(s) which would assist in making a compliance decision. Follow the guidance in Appendix B of this manual.

9006.9 Extended Survey

The extended survey consists of a review of additional conditions of participation not reviewed during a standard survey. At a minimum, review any related conditions of participation or standards to the condition found to be deficient, as defined in Appendix B of the SOM. Extended surveys may be conducted at any time at the discretion of CMS or the SA, and must be conducted when any condition level deficiency is found. This survey also reviews the HHA's policies, procedures, and practices that produced the substandard care. An extended survey must

be conducted not later than 14 calendar days after the completion of a standard survey which found the HHA out of compliance.

9007 Survey Frequency

9007.1 Citation

Section 1891(c)(2) of the Act requires HHAs to be subject to a standard survey not later than every 36 months from the previous standard survey and the frequency of a standard survey to be commensurate with the need to assure the delivery of quality home health services. Surveys may be conducted as often as necessary to ascertain compliance or confirm correction of deficiencies.

9008 Unannounced Surveys

9008.1 Citation

Section 1891(c)(1) of the Act requires that standard surveys be unannounced. Moreover, under §488.725, all HHA surveys must be unannounced, including standard surveys, complaint surveys and onsite revisit surveys.

9008.2 Scheduling Requirements

The SA has the responsibility for keeping surveys unannounced and their timing unpredictable. This gives the SA greater ability to obtain valid information because it increases the probability that the surveys will observe conditions and care practices that are typically present. While the Act and implementing regulations in §488.725 require that standard surveys be unannounced, it is CMS's intention and expectation to not announce **any** type of HHA survey such as an abbreviated standard, complaint, or onsite revisit surveys. Therefore, if CMS conducts standard surveys or validation surveys, the CMS RO must follow the same procedures as required of the SA to not announce surveys.

9008.3 CMS Review of State Scheduling Procedures

Section 1891(c)(1) of the Act requires CMS to review State scheduling and survey procedures to ensure that the agency has taken all reasonable steps to avoid giving notice of impending surveys through these procedures. The CMS RO reviews annually each of its State's procedures for assuring that HHA surveys are not announced through the methods by which they are scheduled or conducted.

9008.4 Penalty for Announcing a Survey

Section 1891(c)(1) of the Act provides that any individual who notifies (or causes to be notified) an HHA of the time or date of the standard survey is subject to a civil money penalty not to exceed \$2,000. Section 488.725 reflects these requirements.

If any individual has, in any way, given prior notification to a HHA of the date of a standard survey, the State or CMS is to contact the regional Office of the Inspector General and report the name of the individual and what has occurred. The Office of the Inspector General will further investigate and make a determination as to whether or not a Federal civil money penalty will be imposed. A civil money penalty of up to \$2,000 may be imposed. The provisions of section 1128A of the Act, other than subsections (a) and (b), apply to civil money penalties. The imposition of a civil money penalty applies only when a standard survey is announced. See §1005 for policy developed by the Office of the Inspector General regarding administrative appeals of Federal civil money penalties.

9009 Informal Dispute Resolution (IDR)

9009.1 Introduction

Section 488.745 offers HHAs, upon their receipt of the official Form CMS-2567, the option to request an informal opportunity to dispute condition-level survey findings warranting a sanction. This IDR will occur with the agency who conducted the survey. A State does not need to create any new or additional processes if its existing process meets the requirements described in this section. The IDR process, as established by the State or CMS RO, must be in writing so that it is available for review upon request.

If the survey is conducted by the CMS RO, the RO 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 HHA 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 HHA will indicate that counsel may accompany the HHA. If the HHA 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 HHA of CMS's decision relative to the informal dispute, with written confirmation to follow.

9009.2 Purpose

IDR offers a HHA the opportunity to refute one or more condition level deficiencies cited by the State on the Form CMS-2567 Statement of Deficiencies. An HHA's initiation of the IDR process or failure of CMS or the State, as appropriate, to complete an IDR will not postpone or otherwise delay the effective date of any enforcement action.

9009.3 Mandatory Elements of IDR

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(ies) at the standard level that constitutes substandard care or immediate jeopardy;
- 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;
- Alleged inadequacy or inaccuracy of the IDR process.

2. HHAs must be notified of the availability of IDR in the letter transmitting the official Form CMS-2567. (See Exhibit 139 in this manual for transmission of Form CMS-2567.) The letter should inform the agency 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 must include an explanation of the specific deficiencies that are being disputed.
- The written request must be made within the same 10 calendar day period the HHA 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 in order to request the IDR;
- The IDR process that is followed in that State, e.g., telephone conference, written communication, or face-to-face meeting.
- 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 HHA 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 agency.

4. When an HHA is unsuccessful during the process at demonstrating that a deficiency should not have been cited, the SA must notify the agency in writing that it was unsuccessful.

5. When an HHA 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 HHA 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 agency. The original Form CMS-2567 is disclosable when a clean plan of correction is not submitted and signed by the agency. Deficiencies pending IDR should be entered into AEM but will not be uploaded to the Certification and Survey Provider Enhanced Reporting system (CASPER) 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, an HHA may not challenge the survey findings of a previous survey for which the HHA 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.

Enforcement Process

9010 Alternative Sanctions for Home Health Agencies

9010.1 Statutory Basis

Sections 1891(e)-(f) of the Act authorizes the Secretary to utilize varying enforcement mechanisms to terminate participation and to impose alternative sanctions if HHAs are found out of compliance with the Medicare home health conditions of participation. Prior to the implementation of alternative sanctions, the only sanction that CMS used for enforcement actions of HHAs that were not meeting the participation requirements was termination within 90 days. The imposition of alternative sanctions specified in §488.805 would allow for noncompliant HHAs to have additional time to come into compliance with the CoPs before being terminated.

9010.2 General Provisions

Under section 1891(e)(1) of the Act, if CMS or a SA determines that the HHA's condition-level deficiencies immediately jeopardize the health or safety of its patients, then CMS must take immediate action to notify the HHA of the jeopardy situation and the HHA must correct the deficiencies. If the IJ is not removed because the HHA is unable or unwilling to correct the deficiencies, CMS will terminate the HHA's provider agreement. In addition, CMS may impose one or more specified alternative sanctions, including but not limited to civil money penalties and suspension of all Medicare payments before the effective date of termination. These provisions are incorporated in §488.810. The purpose of enforcement sanctions is to ensure prompt compliance with program requirements in order to protect the health and safety of individuals under the care of an HHA.

Sections 1891(e)(1) and (2) of the Act provide that if CMS finds that an HHA is not in compliance with the Medicare home health CoPs and the deficiencies involved do not immediately jeopardize the health and safety of the individuals to whom the agency furnishes items and services, CMS may terminate the provider agreement, impose an alternative sanction(s), or both. While section 1891(e)(2) of the Act provides for termination of the HHA's provider agreement as an enforcement option in non-immediate jeopardy situations, CMS provides incentives for HHAs to achieve and maintain full compliance with the participation requirements before termination becomes necessary.

The decision to impose one or more sanctions would be based on condition-level deficiencies or repeat deficiencies found in an HHA during a survey. Determinations on deficiencies would not be limited to findings from the mandated surveys specified in the statute or the regulations. Rather, deficiency findings that are based on other reporting or evaluative programs, procedures, or mechanisms, such as OASIS reporting and validated complaints, would be sufficient to determine whether Medicare requirements are met.

Survey agencies should make a recommendation to the RO on which sanction(s) may be effective in prompting the HHA to return to compliance. The RO considers the SA's recommendations and makes a determination to agree with or impose a different sanction(s) for the HHA.

9010.3 Effect of Sanctions on HHAs that participate in Medicare via Deemed Status through an Accrediting Organization

HHAs can acquire certification for participation in Medicare via a SA survey or via deemed status through a CMS-approved AO. Deemed status through a CMS-approved AO is voluntary and not necessary to participate in Medicare. Deemed status HHAs remain under the jurisdiction of their AO rather than SAs for oversight of their ongoing compliance with health and safety standards, unless SAs conducting a validation survey at the direction of CMS find evidence of serious noncompliance. In such case, the HHA is placed under the jurisdiction of the SA.

A deemed HHA 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 RO returns oversight of the accredited HHA back to the SA until the HHA can demonstrate compliance with the CoPs. During the time that the SA has jurisdiction over the HHA, the SA, not the AO, will follow the procedures for recommending the imposition of sanctions, if appropriate. Once the HHA returns to compliance with the Medicare conditions and has not been terminated, the RO will restore its deemed status and return oversight to the AO.

In accordance with 42 CFR 488.7, CMS may require a survey of an accredited HHA to validate the AO's accreditation process. There are two types of validation surveys:

- Surveys conducted on a representative sample basis, which may be either comprehensive surveys of all Medicare conditions or focused surveys on a specific condition or conditions; or
- Surveys in response to a “substantial allegation” – generally a complaint. These surveys focus on those Medicare conditions related to the allegations.

SAs conduct validation surveys of accredited providers/suppliers only when they are specifically authorized to do so by the RO. In the case of representative sample surveys, CMS selects the providers/suppliers to be surveyed and the RO assigns the SA to conduct the validation survey within 60 days of the AO survey. In the case of substantial allegations, most complaints are received by the SA, which then forwards to the RO complaints that they believe make substantial allegations of noncompliance with Medicare conditions. The RO reviews the complaint and determines whether it will authorize the SA to conduct a survey, and also determines which conditions the SA should focus its survey on. CMS also receives complaints directly. Information raising substantial allegations of noncompliance may also come to CMS' attention via means other than complaints, such as press reports. In such cases the RO reviews the information and makes a determination as to whether the SA should conduct a validation survey, and of which conditions. (See Section 5100 of the SOM for more details about procedures for substantial allegation surveys of accredited, deemed providers/suppliers).

9010.4 Effect of Sanctions on HHA Branches

An HHA's branch office is part of the HHA and is located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the branch independently to meet the conditions of participation as an HHA. An HHA's branch location may be included in, or be the focus of, the unannounced standard survey of a parent HHA, and any deficiencies found at a branch of the HHA will apply to the entire HHA. Therefore,

regardless of whether the deficiency or deficient practice is identified at the branch or the parent location, all sanctions imposed would apply to the parent HHA and its respective branches. For example, if a deficient practice is found in one branch of an HHA and CMS imposes sanctions, the sanctions would apply to the parent and all branch offices that are affiliated with that HHA. However, these sanctions would not apply to any non-branch subunit that was associated with an HHA since a subunit is independently required to meet the CoPs for HHAs. Such subunit instead could have sanctions imposed on it based on deficient practices found at that subunit. For HHAs that operate branch offices in multiple states, CMS would base enforcement decisions on surveys conducted by the State in which the parent office is located.

Definitions for “parent HHA,” “branch office,” and “subunit” are found at 42 CFR 484.2. See also section 2182 for additional information on parent, branch and subunit.

9010.5 Available Sanctions

In accordance with §488.820, the following sanctions in addition to termination of the provider agreement are available:

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

9010.6 Factors to be considered in selecting sanctions

Consistent with section 1891(f)(3) of the Act, procedures for selecting the appropriate sanction, including the amount of any fines and the severity of each sanction have been designed to minimize the time between the identification of deficiencies and the final imposition of sanctions.

In order to select the appropriate sanction(s) for an agency’s noncompliance, the seriousness of the deficiencies must first be assessed and the determination made as to whether the deficiencies pose immediate jeopardy to patient health and safety. The factors CMS considers include:

- I. The extent to which the deficiencies pose immediate jeopardy to patient health and safety.
- II. The nature, incidence, manner, degree, and duration of the deficiencies or non-compliance.
- III. The presence of repeat deficiencies, the HHA’s overall compliance history and any history of repeat deficiencies at either the parent or branch location.
- IV. The extent to which the deficiencies are directly related to a failure to provide quality patient care.
- V. The extent to which the HHA is part of a larger organization with performance problems.
- VI. 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 compliance with the CoPs, specifically with reference to the cited deficiencies.

9011 Action when deficiencies pose immediate jeopardy.

9011.1 Statutory and Regulatory Basis

Sections 1891(e)(1) of the Act and §488.825 provide how situations involving immediate jeopardy will be processed. In addition, Appendix Q of this manual discusses immediate jeopardy.

9011.2 Purpose

Immediate action is required to remove the immediate jeopardy to patient health or safety and to subsequently correct the deficiencies. Termination is required to address immediate jeopardy situations and occurs within 23 days if the immediate jeopardy is not removed. CMS may also choose to impose alternative sanctions in addition to termination. While the use of alternative sanctions in addition to termination is permitted, the Act makes it clear that the enforcement action for noncompliant agencies with immediate jeopardy deficiencies is intended to be swift. The imposition of alternative sanctions in addition to termination would not extend the timeframe that the HHA has to abate the immediate jeopardy situation.

9012 Enforcement Action When Immediate Jeopardy Exists

When the State identifies immediate jeopardy to patient health or safety, the State must notify the RO and follow the procedures in Appendix Q of this manual. When immediate jeopardy exists, the HHA's provider agreement is immediately terminated in accordance with §489.53 and §488.825. In addition to termination, one or more alternative sanctions may be imposed.

9013 Action When Deficiencies are Condition-level But Do Not Pose Immediate Jeopardy.

If the HHA is no longer in compliance with the CoPs, either because the deficiency(ies) substantially limit the HHA's capacity to furnish adequate care but do not pose immediate jeopardy, or because the HHA has repeat noncompliance that results in a condition level deficiency based on the HHA'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 as an alternative to termination. If alternative sanctions are imposed, CMS terminates the HHA's provider agreement within 6 months of the last day of the survey if the HHA is not in substantial compliance with the CoPs and the condition level deficiencies are not corrected.

9014 Guidance for Individual Sanctions

The following sections describe each possible alternative sanction and procedures for imposing them. In addition, the CMS RO 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.

9015 Temporary Management

9015.1 Introduction

This sanction is established pursuant to §1891 of the Act and §488.835. CMS may choose to impose temporary management in situations where the failure to comply with the CoPs is directly related to poor management or lack of management such that it is likely to impair the HHA's ability to correct deficiencies and return the agency to full compliance within the necessary timeframe.

9015.2 Purpose

A temporary manager may be imposed if it is determined that an agency is not in substantial compliance. 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 agency's patients while the corrections are being made. A temporary manager may also be imposed to oversee orderly closure of an agency including the proper and safe transfer of patients to another local HHA.

9015.3 Authority of Temporary Manager

A temporary manager has the authority to hire, terminate, or reassign staff; obligate agency funds; alter agency policies and procedures; and otherwise manage an agency to correct deficiencies identified in the agency's operation.

9015.4 Selection of Temporary Manager

Each SA should compile a list of individuals who are eligible to serve as temporary managers. When CMS decides to impose this sanction, 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 management will not exceed a period of six months.

The SA should reject a candidate who has demonstrated difficulty maintaining compliance in the past.

9015.5 Conditions of Temporary Management

CMS notifies the HHA that a temporary manager is being appointed. The HHA'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. A contract or memorandum of understanding should be completed between the temporary manager and the HHA 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.

The HHA cannot retain final authority to approve changes of personnel or expenditures of HHA funds and be considered to have relinquished control to the temporary manager. The temporary manager must be given access to all HHA bank accounts. If the HHA does not relinquish control to the temporary manager and/or provide access to bank accounts and available assets, the HHA will be terminated. It should be noted that the HHA'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 administrators in the HHA's geographic area (Geographic Guide by the Department of Labor, BLS Wage Data by Area and Occupation), plus any additional costs that would have reasonably been incurred by the HHA 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. The HHA 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.

9015.6 Orienting and Supervising Temporary Manager

The State should provide the temporary manager with an appropriate orientation that includes a review of the HHA'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.

9015.7 Notice of Imposition of Temporary Management

A temporary manager may be imposed 15 calendar days after the HHA receives notice in non-immediate jeopardy situations and 2 calendar days after the HHA receives notice in immediate jeopardy situations.

9015.8 Duration of Temporary Management

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

9016 Suspension of Payment for All New Medicare Admissions

9016.1 Introduction

Sections 1891(f)(2)(A)(ii) of the Act and §488.840 provide for the suspension of payment for all new Medicare admissions when a HHA is not in substantial compliance, regardless of whether cited deficiencies pose immediate jeopardy to patient health and safety. This suspension of payment for new admissions may be imposed alone or in combination with other sanctions to encourage prompt compliance.

9016.2 Notice of Sanction

Suspension of payment for new admissions may be imposed anytime a HHA is found to be out of substantial compliance, as long as the HHA is given written notice at least 2 calendar days before the effective date in immediate jeopardy situations and at least 15 calendar days before the effective date in non-immediate jeopardy situations. 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; and the right to appeal the determination leading to the sanction. In addition to notifying the HHA of this proposed sanction, CMS will also notify the State Medicaid Agency if the HHA is dually certified.

9016.3 Effect of Sanction on Patients Admitted before the Effective Date of Sanction

The patient's status on the effective date of the suspension of payment sanction is the controlling factor. This sanction would not apply to patients who have been receiving care from the HHA before the effective date of this sanction. This sanction would apply only to new Medicare admissions. CMS will suspend payments for new Medicare patient admissions to the HHA that are made on or after the effective date of the imposition of the sanction for the duration of the sanction. Payments for individuals who are already receiving services could continue. In accordance with §488.805, CMS define a "new admission" as the following:

- A patient who is admitted to the HHA under Medicare on or after the effective date of a suspension of payment sanction; 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.

As part of this sanction, the HHA 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 because of the imposed suspension. The HHA 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 will end when CMS finds that the HHA is in substantial compliance with all of the CoPs or when the HHA is terminated. That is, the suspension of payment sanction would end when the HHA has corrected all condition-level deficiencies. Any Medicare patients admitted during the suspension of payment time 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 to begin receiving payments for those patients.

9016.4 Duration

The suspension of payment would end when CMS terminates the provider agreement or when CMS finds, in accordance with section 1891(f)(2)(C) of the Act and §488.840(c), the HHA to be in substantial compliance with all of the CoPs. If CMS terminates the provider agreement or determines that the HHA is in substantial compliance with the CoPs, the HHA would not be able to recoup any payments for services provided to Medicare patients admitted during the time the suspension was in place.

Generally, if the HHA achieves substantial compliance and it is verified by CMS, CMS will resume payments to the HHA prospectively from the date it determines that substantial compliance was achieved. No payments are made to reimburse the HHA for the period of time between the date the sanction was imposed and the date that substantial compliance was achieved. CMS accomplishes the suspension of payment sanction through written instructions to the appropriate Medicare Administrative Contractor (MAC). The RO will send the letter with instructions to the MAC.

9017 Civil Money Penalties

9017.1 Basis for Imposing Civil Money Penalties

Under sections 1891(e) and 1891(f)(2)(A)(i) of the Act and §488.845, CMS may impose a civil money penalty against an HHA that is determined to be out of compliance with one or more CoPs, regardless of whether the HHA's deficiencies pose immediate jeopardy to patient health and safety. CMS may impose a civil money penalty for the number of days that a HHA is not in substantial compliance with one or more CoPs, or for each instance that a HHA is not in substantial compliance. The civil money penalty amount cannot exceed \$10,000 for each day of non-compliance.

CMS defines "per instance" in §488.805 as a single event of noncompliance identified and corrected during a survey, for which the statute authorizes CMS to impose a sanction. While there may be a single event which leads to noncompliance, there can also be more than one instance of noncompliance identified and more than one civil money penalty imposed during a survey. For penalties imposed per instance of noncompliance, CMS has established penalties from \$500 to \$10,000 per instance. The sum of all penalties cannot exceed \$10,000 per day. Such penalties would be assessed for one or more singular events of condition-level noncompliance that were identified at the survey and where the noncompliance was corrected during the onsite survey. Since the range of possible deficiencies is great and depends upon the specific circumstances at a particular time, it would be impossible to assign a specific monetary amount for each type of noncompliance that could be found. SAs and ROs may use the chart found in section 9020 of this chapter for guidance in determining a per instance amount.

A per-day and a per instance civil money penalty cannot be used simultaneously for the same deficiency. However, both types of civil money penalties may be used during a noncompliance cycle if more than one survey takes place and the per day penalty was not the civil money penalty initially imposed.

9017.2 Determining Amount of Civil Money Penalty

In determining the amount of the civil money penalty, CMS considers certain factors in addition to those listed in §488.815 which include:

- The size of the agency and its resources.
- Accurate and credible resources such as PECOS and Medicare cost reports and claims information, that provide information on the operations and the resources of the HHA.
- Evidence that the HHA 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.

When several instances of noncompliance are identified at a survey, more than one per-day or per-instance civil money penalty could be imposed as long as the total civil money penalty did not exceed \$10,000 per day.

The regional office 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 civil money penalty.

9017.3 Adjustments to penalties

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

CMS may increase a civil money penalty based on the following:

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

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

No penalty assessment shall exceed \$10,000 for each day of noncompliance.

9018 Range of Penalty Amounts

9018.1 Upper range of penalty

Penalties in the upper range of \$8,500 to \$10,000 per day of noncompliance are imposed for a condition-level deficiency that is immediate jeopardy. The penalty in this range will continue until compliance can be determined. In the event of noncompliance with the CoPs, a “credible allegation of compliance” is required before a revisit is conducted. Once the credible allegation of compliance has been received, the SA will conduct a revisit. If the HHA makes an additional credible allegation that the deficiency(ies) is corrected following an earlier revisit or between the 46th and 90th calendar day prior to the effective date of termination, the RO must be notified by telephone. The SA submits all evidence or documentation regarding the HHA’s allegation and its recommendation regarding the HHA’s alleged compliance. The RO makes a determination whether a second revisit is appropriate. (See §3016A.)

During the revisit survey, the SA will determine if the immediate jeopardy situation has been abated. If the immediate jeopardy situation has been abated, but condition level deficiencies still exist, the penalty amount may be decreased to the middle or lower range of penalties based on the deficiency. The civil money penalty ranges are set forth in §§488.845(b)(3)(i),(ii), and (iii) and are as follows:

- a. \$10,000 per day for a deficiency or deficiencies that is determined to be immediate jeopardy and that results in actual harm;
- b. \$9,000 per day for a deficiency or deficiencies that is determined to be immediate jeopardy and that result in a potential for harm; and
- c. \$8,500 per day for an isolated incident of noncompliance that is in violation of established HHA policies and procedures

Note: The following examples contain findings that could become a part of an HHA’s immediate jeopardy citation. Please note that the citation of immediate jeopardy 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. The SA considers recommending a \$10,000 per day civil money penalty for a deficiency or deficiencies that is determined to be immediate jeopardy and that results in actual harm. **Examples:** HHA fails to report to physician episodes of severe hyperglycemia, resulting in ketoacidosis and hospitalization of diabetic patient; HHA fails to timely and accurately assess a patient’s pressure ulcers, which deteriorate to Stage 4 and sepsis prior to their recognition.
2. The SA considers recommending a \$9,000 per day civil money penalty for a deficiency or deficiencies that is determined to be immediate jeopardy and that result in a potential for harm. **Examples:** HHA fails to intervene after patient verbal threats of suicide, resulting in potential for self-harm; HHA fails to administer ordered intravenous antibiotic to patient with diagnosed infection, resulting in potential for development of sepsis

3. The SA considers recommending \$8,500 per day for an isolated incident of noncompliance that is in violation of established HHA policies and procedures.

Example: One of the HHA's nurses did not follow the HHA's infection control policies and procedures when performing wound care. Patient developed infection which could not be controlled at home and hospitalization was needed.

9018.2 Middle range of penalty

Civil money penalties imposed in the range of \$1,500 to \$8,500 per day of noncompliance are imposed for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy, but is directly related to poor quality patient care outcomes.

9018.3 Lower range of penalty

Civil money penalties in the range of \$500 to \$4,000 per day of non-compliance are imposed for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy and that is related predominately to structure or process-oriented conditions (such as OASIS submission requirements) rather than directly related to patient care outcomes.

9018.4 Per instance civil money penalty

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 civil money penalty. There can be more than one instance of noncompliance identified during a survey. When penalties are imposed for per instance of noncompliance, or for multiple instances of noncompliance, the penalties will be in the range of \$500 to \$10,000 per instance, and will not exceed a total of \$10,000 for each day of noncompliance.

9018.5 Decreased penalty amounts

If a penalty was imposed in the upper range and the immediate jeopardy is removed or abated but the HHA continues to have condition-level noncompliance that is not immediate jeopardy, 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 ROs 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.

9018.6 Increased penalty amounts

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 immediate jeopardy.

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 civil money penalty amount .

9018.7 Considerations in determining the penalty amount

SAs and ROs should review all applicable findings and consider the factors in §488.845 in determining the final amount of the CMP to be imposed.

9019 Suggested Penalty Amounts

9019.1 Upper Range Civil Money Penalties for Immediate Jeopardy Citations

Immediate Jeopardy – results in harm	\$10,000
Immediate Jeopardy – results in a potential for harm	\$9,000
Immediate Jeopardy – isolated event of non-compliance in violation of an established HHA policy	\$8,500

9019.2 Middle Range Penalties for Non-Immediate Jeopardy Citations

	Amount imposed in Recertification Survey	1 st Revisit Survey	2 nd Revisit Survey
Repeat Deficiency related to direct patient care. Consider citing for the following conditions: §484.18 Acceptance of patients, plan of care, and medical supervision §484.30 Skilled Nursing Services	\$5,000 - \$6,000	\$6,000 - \$7,000	\$8,500

<p>§484.32 Therapy Services</p> <p>§484.34 Medical Social Services</p> <p>§484.36 Home Health Aide Services</p> <p>§484.38 Qualifying to Furnish Outpatient Physical Therapy or Speech Pathology Services</p> <p>§484.55 Comprehensive Assessment of Patients</p>			
<p><u>Initial Citation</u> related to direct patient care. Consider citing for the following conditions:</p> <p>§484.18 Acceptance of patients, plan of care, and medical supervision</p> <p>§484.30 Skilled Nursing Services</p> <p>§484.32 Therapy Services</p> <p>§484.34 Medical Social Services</p> <p>§484.36 Home Health Aide Services</p> <p>§484.38 Qualifying to Furnish Outpatient Physical Therapy or Speech Pathology Services</p> <p>§484.55 Comprehensive Assessment of Patients</p>	\$2,000 - \$3,000	\$3,000 - \$4,000	\$5,500
<p><u>Citation for structure or process deficiencies.</u> Consider citing for the following conditions:</p> <p>§484.10 Patient Rights</p> <p>§484.12 Compliance with federal, state, and local laws, disclosure and ownership information, and accepted professional standards and principles.</p> <p>§484.14 Organization, services, and</p>	\$1,500 - \$2000	\$2,000 - \$3,000	\$3,500

administration			
§484.48 Clinical records			

9019.3 Lower Range Penalties for Structure and Process Citations Not Directly Related to Patient Care

	Amount imposed in Recertification Survey	1 st Revisit Survey	2 nd Revisit Survey
<p><u>Repeat Deficiency</u> related to structure or process deficiencies. Consider citing for the following conditions:</p> <p>§484.11 Release of patient identifiable OASIS information</p> <p>§484.16 Group of professional personnel</p> <p>§484.20 Reporting OASIS information</p> <p>§484.52 Evaluation of the agency’s program</p>	\$2,000	\$3,000	\$4,000
<p><u>Initial Citations</u> of structure or process deficiencies. Consider imposing for deficiencies related to CoPs:</p> <p>§484.11 Release of patient identifiable OASIS information</p> <p>§484.16 Group of professional personnel</p> <p>§484.20 Reporting OASIS information</p> <p>§484.52 Evaluation of the agency’s program</p>	\$500 - \$800	\$800 - \$1,000	\$1,500

9020 Procedures

9020.1 Notice of imposition of civil money penalty

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

- I. The nature of the noncompliance (regulatory requirements not met);
- II. The statutory basis for the civil money penalty;
- 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 civil money penalty;
- V. The date on which the per day civil money penalty begins to accrue;
- VI. A statement that the per day civil money penalty will accrue until substantial compliance is achieved or until termination from participation in the program occurs.
- VII. When the civil money penalty is collected;
- VIII. Instructions for responding to the notice, including a statement of the HHA's right to a hearing and information about how to request a hearing;
- IX. Implications of waiving the right to a hearing and information about how to waive the right to a hearing (see §9021.4 below).

9020.2 Sending the Notice

The notice shall be in writing and shall be addressed directly to the HHA; 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.

9020.3 Appeal of Noncompliance That Led to Imposition of Civil Money Penalty

Before collecting a civil money penalty, section [1128A](#) of the Act requires the Secretary (CMS) to conduct a hearing for an HHA that properly requests. An HHA may request a hearing with the Administrative Law Judge (ALJ) on the determination of the noncompliance that is the basis for imposition of the civil money penalty. The procedures to request a hearing specified in 42 C.F.R. §498.40 are followed when CMS imposes a civil money penalty on an HHA. Once an appeal hearing is requested, CMS cannot collect the CMP until a final agency determination.

9020.4 HHA Waives Right to a hearing

An HHA may waive the right to a hearing, in writing, within 60 days from the date of the notice imposing the civil money penalty. If an HHA timely waives its right to an appeal hearing within 60 calendar days of their receipt of CMS' notice imposing the civil money penalty, 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 receipt of CMS's notice approving the waiver and reducing the CMP. If the HHA 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), it will not receive the CMP reduction.

NOTE: Each time a survey is conducted within an already running noncompliance cycle and a civil money penalty is imposed, the HHA is given appeal rights and may exercise its waiver of right to a hearing.

When a per day civil money penalty is imposed and then is increased or decreased at subsequent surveys during an already running noncompliance cycle, an HHA may elect to either appeal each separate imposition of civil money penalty or waive the right to appeal each imposition. Each civil money penalty imposition is computed separately for a set number of days. The final civil money penalty amount is established after the final administrative decision.

Example: An HHA is cited on the original recertification survey for non-compliance with 42 CFR 484.18, Acceptance of patients, plan of care, medical supervision. Findings include evidence that the HHA did not follow the plan of care (G158), the plan of care did not include all pertinent diagnoses (G159) and the HHA failed to notify the physician of changes in the patient's condition (G164). 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 of the citations, or waive one or both citations, or waive one citation and appeal the other.

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

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

9020.5 Accrual and duration of per day penalty

The per-day civil money penalty would begin to accrue on the last day of the survey that identified the noncompliance and would continue to accrue until the HHA achieves substantial compliance with all requirements or the date of termination, whichever occurs first.

9020.6 Amount of per instance penalty

A civil money penalty 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 particular deficiency(ies), with an amount not to exceed \$10,000 each day.

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 noncompliance. If the HHA has not achieved substantial compliance with all the participation requirements within those 6 months, CMS will terminate the HHA. The accrual of the per day CMP stops on the day the HHA's provider agreement is terminated or the HHA achieves substantial compliance, whichever is earlier.

Example: When the per instance civil money penalty is used on the original survey, the revisit is considered another survey to determine compliance. If noncompliance is identified at the revisit and a civil money penalty is selected as the enforcement response, either the per instance or per day remedy may be selected.

9020.7 Duration of Civil Money Penalty

The per day civil money penalty accrues for the number of days of noncompliance from the date that the deficiency starts until the date that the HHA achieves substantial compliance or, if applicable, the date of termination. For example, if a HHA is found in substantial compliance or its provider agreement is terminated on May 18, the accrual of the civil money penalty stops on May 17.

The per instance civil money penalty is imposed for each instance of noncompliance based on a deficiency during a specific survey. It is applied to as many instances as is deemed appropriate during a specific survey up to a total of \$10,000.

EXAMPLE: When the per instance civil money penalty is used on the original survey, the revisit is considered another survey to determine compliance. If noncompliance is identified and a civil money penalty is selected as the enforcement response, either the per instance or per day penalty may be selected.

- a. **Revisit Identifies New Noncompliance and Same Data Tag is Selected** - If the same data tag is selected to identify noncompliance, the State (or regional office) could choose to utilize either the per instance or per day civil money penalty. It would not matter whether the same data tag was selected to identify the new noncompliance. The issue is whether noncompliance is present and whether the deficient practice rises to a level that will support selecting a civil money penalty as a sanction. For instance, noncompliance was identified at Tag G100 during the original survey. During the revisit survey, a different problem dealing with the patient rights of three patients was cited at Tag G100. The per instance or per day civil money penalty would be selected for the noncompliance identified at Tag G100. If the per instance civil money penalty was used, the amount of the civil money penalty might be influenced by factors relating to the violations of patient rights. However, only one per instance civil money penalty would be appropriate. It would not be appropriate to assign a separate civil money penalty for each of the violations related to patient rights (findings) identified at Tag G100.
- b. **Revisit 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 civil money penalty could be selected as a sanction.

- c. **Noncompliance - Immediate Jeopardy Does Not Exist** - For noncompliance that does not pose immediate jeopardy, the per day civil money penalty is imposed for the days of noncompliance, i.e., from the day the penalty starts (and this may be prior to the notice), until the HHA achieves substantial compliance or the provider agreement is terminated. However, if the HHA has not achieved substantial compliance at the end of 6 months from the last day of the original survey, the regional office terminates the provider agreement. The accrual of the civil money penalty stops on the date that the provider agreement is terminated.

For noncompliance that does not pose immediate jeopardy, the per instance civil money penalty is imposed for the number of deficiencies during a survey for which the civil money penalty is determined to be an appropriate sanction. For example, Tag G330 and Tag G320 were cited on a survey. A civil money penalty of \$2,000 is imposed for Tag 320 and a civil money penalty of \$8,000 is imposed for Tag 330. No civil money penalty could then be imposed for additional deficiencies because the total “per instance civil money penalty” may not exceed \$10,000 for each survey.

- d. **Noncompliance - Immediate Jeopardy Exists** - For noncompliance that poses immediate jeopardy, CMS must terminate the provider agreement within 23 calendar days after the last day of the survey that identified the immediate jeopardy if the immediate jeopardy is not removed. The accrual of the per day civil money penalty stops on the date that the provider agreement is terminated.

9020.8 Duration of per day penalty when there is immediate jeopardy

In the case of noncompliance that poses immediate jeopardy, CMS must terminate the provider agreement within 23 calendar days after the last date of the survey if the immediate jeopardy is not removed.

A penalty imposed per day of noncompliance will stop accruing on the day the provider agreement is terminated or the HHA achieves substantial compliance, whichever occurs first.

9020.9 Duration of penalty when there is no immediate jeopardy

In the case of noncompliance that does not pose immediate jeopardy, the daily accrual of per day civil money penalties is imposed for the days of noncompliance, i.e., from the day the penalty starts (and this may be prior to the notice), until the HHA 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 has not achieved substantial compliance with all of the conditions of participation, CMS will terminate the provider agreement. The accrual of civil money penalty stops on the day the HHA agreement is terminated or the HHA achieves substantial compliance, whichever is earlier.

9020.10 When Penalty Is Due and Payable

1. After Final Administrative Decision

When CMS imposes a civil money penalty, a final administrative decision includes an Administrative Law Judge decision and review by the Departmental Appeals Board, if the HHA requests a review of the Administrative Law Judge decision. Payment of a civil money penalty is due 15 calendar days **after** a final administrative decision, upholding the imposition of the civil money penalty, when:

- a. The HHA achieved substantial compliance before the final administrative decision; or
- b. The effective date of termination occurred before the final administrative decision.

2. No Hearing Requested

Payment of a civil money penalty is due 15 calendar days **after** the time period for requesting a hearing has expired and a hearing request was not received when:

- a. The HHA achieved substantial compliance before the hearing request was due; or
- b. The effective date of termination occurred before the hearing request was due.

3. After Request to Waive Hearing

Payment of a civil money penalty is due 15 calendar days **after** receipt of the HHA's written waiver of a right to a hearing when:

- a. The HHA achieved substantial compliance before receipt of the HHA's written waiver of its right to a hearing;
- b. A per instance civil money penalty has been imposed. Since no opportunity to correct is available for the noncompliance against which a per instance civil money penalty is imposed, allowing time for the HHA to achieve substantial compliance is not a factor in determining when the civil money penalty is due; or
- c. The effective date of termination occurred before receipt of the HHA's written waiver of its right to a hearing.

4. After Substantial Compliance Is Achieved

Payment of a per day civil money penalty is due 15 calendar days after substantial compliance is achieved when:

- a. A final administrative decision, upholding the imposition of the civil money penalty, is made before the HHA achieved substantial compliance;
- b. The HHA did not file a timely hearing request before it achieved substantial compliance; or
- c. The HHA waived its right to a hearing before it achieved substantial compliance. However, the period of noncompliance covered by the civil money penalty may not extend beyond 6 months from the last day of the survey.

5. After Effective Date of Termination

Payment of a civil money penalty is due 15 calendar days **after** the effective date of termination, if before the effective date of termination:

- a. The final administrative decision was made upholding the imposition of the civil money penalty;
- b. The time for requesting a hearing has expired and the HHA did not request a hearing; or
- c. The HHA waived its right to a hearing.

9021 Notice of Amount Due and Collectible

1. Contents of Notice

The following information is included in a notice of the amount due which is sent to the HHA after the final amount due and collectible is determined:

- a. The amount of the penalty per day or the amount of the penalty per instance;
- b. For the per day civil money penalty, the number of days involved;
- c. The total amount due;
- d. The due date of the penalty; and
- e. The rate of interest to be assessed on the unpaid balance on the due date as follows:

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 regional office contacts CMS Central Office for the rate of interest information.)

2. Method of Payment

- a. The civil money penalty is payable by check to CMS if the check is rendered by the due date.
- b. After the due date of the penalty, the regional office or the State Medicaid Agency deducts the civil money penalty plus any accrued interest from money owed to the HHA.

9021.2 Computation and notice of total penalty amount

When a civil money penalty is imposed on a per day basis and the HHA achieves compliance with the conditions of participation as determined by a revisit survey, CMS sends a final notice to the HHA containing all of 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 regional office contacts CMS Central Office for the rate of interest information.)
- Instructions for submitting payment to CMS CO with the reference number on the check.

When a civil money penalty is assessed per instance of noncompliance, a notice is sent to the HHA containing all of the following information:

- 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 regional office contacts CMS Central Office for the rate of interest information.)
- Instructions for submitting payment to CMS CO with the reference number on the check.

9021.3 When a penalty is due and payable

Total civil money penalty amounts are computed after a final administrative decision; that is, after:

- I. Compliance is verified;
- II. The HHA provider agreement is involuntarily terminated; or
- III. Administrative remedies have been exhausted.

When the regional office imposes a civil money penalty, a final administrative decision includes an Administrative Law Judge decision and review by the Departmental Appeals Board, if the facility requests a review of the Administrative Law Judge decision. A civil money penalty is due and payable 15 days from the final administrative decision upholding the imposition of the penalty when (1) the facility achieved substantial compliance before the final administrative decision, or (2) the effective date of termination occurred before the final administrative decision.

Final administrative decision is when:

- The time to request a hearing has expired and a hearing request was not received when the HHA achieved substantial compliance before the hearing request was due or the effective date of termination occurred before the hearing request was due;
- CMS receives a request from the HHA waiving its right to appeal the initial determination and (1) the HHA achieved substantial compliance before CMS's receipt of the request, or (2) a per instance penalty has been imposed and the facility has achieved substantial compliance before CMS's receipt of the request; or (3) the effective date of termination occurred before receipt of the HHA's written request waiving its right to a hearing;
- A final decision of an Administrative Law Judge and/or Departmental Appeals Board Appellate Board upholding the imposition of the penalty; or
- The HHA is terminated from the program and if before the effective date of termination (1) the final administrative decision was made upholding the imposition of the penalty, (2) the time for requesting a hearing has expired and the HHA did not request a hearing, or (3) the HHA waived its right to a hearing.

A request for hearing will not delay the imposition of the civil money penalty, but can only affect the collection of any final amounts due to CMP. If an HHA timely waives its right to a hearing, CMS reduces the final CMP amount by 35%. This reduction would be reflected once the CMP stops accruing: when the HHA 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.

The final penalty receivable amount would be determined when the per-day CMP accrual period ends (either when the HHA achieves substantial compliance or is terminated).

An HHA has two options for action following the imposition of a penalty:

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

Within 60 days of receipt of the notice of imposition of a penalty, the HHA 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 appeal request would identify the specific issues of contention, the findings of fact and conclusions of the law with which the agency 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 would continue regardless of the timing of any appeals proceedings if the HHA had not met the CoPs. Requesting an appeal would not delay or end the imposition of a sanction. A civil money penalty 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.

9021.4 Method of Payment

The civil money penalty is payable by check to CMS if the check is rendered by the due date. After the due date of the penalty, the regional office deducts the civil money penalty plus any accrued interest from money then or later owed to the HHA by CMS or the State Medicaid Agency (see section 9022 below).

9021.5 Settlement of Civil Money Penalty

The regional office has the authority to settle civil money penalty 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 opted for a 35 percent reduction.

9021.6 Offsets

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

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).

Those civil money penalty amounts not recovered due to HHA 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.

9022 Disbursement of Recovered CMP funds

The CMP amounts and any corresponding interest recovered 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 an average of years 2007 to 2009 based on Medicaid Statistical Information System (MSIS) and HHA Prospective Payment System (PPS) claims. Based on the proportions of HHA claims attributed to Medicare and Medicaid, respectively, for the FY 2007-2009 period, approximately 63 percent of the CMP amounts recovered would be deposited as miscellaneous receipts to the U.S.

Department of the Treasury and approximately 37 percent will be returned to the State Medicaid Agency to improve the quality of care for those who need home-based care. Beginning one year after the effective date of §488.845 (which is July 1, 2014), these proportions shall be updated annually based on the most recent 3-year fiscal period in which the CMP is imposed, for which CMS determined that the Medicare and Medicaid expenditure data were essentially complete. The portion corresponding to Medicare payments is returned to the Department of Treasury as miscellaneous receipts and the portion corresponding to Medicaid payments is returned to the State Medicaid Agency. Penalty funds may not be used for survey and certification operations nor can it be used as the State's Medicaid non-Federal medical assistance or administrative match.

9023 Directed plan of correction

9023.1 Introduction

These procedures implement the regulatory requirements at [§488.850](#) for imposing a directed plan of correction. A directed plan of correction is one of the sanctions that the CMS regional office can select when it finds a HHA out of compliance with Federal requirements.

9023.2 Purpose

The purpose of the directed plan of correction is to achieve correction and continued compliance with Federal requirements. A directed plan of correction is a plan that the State, with RO approval, or the RO develops to require a HHA to take corrective action to achieve specific outcomes within specified time frames.

Whether it has standard-level or condition-level deficiencies, an HHA must submit an acceptable plan of correction to CMS. If the HHA is unable to develop an acceptable plan of correction, CMS may impose a directed plan of correction for condition level deficiencies.

9023.3 Imposition of a Directed Plan of Correction

The HHA's directed plan of correction may be imposed by CMS when the HHA has deficiencies that warrant directing the HHA to take a specific action(s) or when the HHA fails to submit an acceptable plan of correction for condition level deficiencies.

9023.4 Elements of a Directed Plan of Correction

A directed plan of correction should address all of the elements required for a HHA-developed plan of correction. These elements include, but are not limited to, the following:

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

9023.5 Achieving Compliance

Achieving compliance is the agency's responsibility, whether or not a directed plan of correction is followed. If the HHA fails to achieve compliance within the timeframes specified in the directed plan of correction, CMS may impose one or more additional alternative sanctions until the HHA achieves compliance or is terminated from the Medicare program.

9023.6 Notice of Imposition of Directed Plan of Correction

CMS must provide written notification of the intent to impose a directed plan of correction sanction.

A directed plan of correction may be imposed 15 calendar days after the HHA receives notice in non-immediate jeopardy situations and 2 calendar days after the HHA receives notice in immediate jeopardy situations. The date the directed plan of correction is imposed, that is, the date the sanction becomes effective, does not mean that all corrections must be completed by that date.

9024 Directed In-service Training

9024.1 Introduction

These instructions implement §488.855. Directed in-service training is one of the sanctions the SA may recommend and the RO may select when it finds an HHA out of compliance with Federal requirements.

9024.2 Purpose

Directed in-service training is a remedy that may be used when the State, CMS, or the temporary manager believe that education is likely to correct the deficiencies and help the HHA achieve substantial compliance. Directed in-service training requires the staff of the HHA to attend a specific in-service training program. The purpose of directed in-service training is to provide basic knowledge to achieve and remain in compliance with Federal requirements. 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.

9024.3 Appropriate Resources for Directed In-Service Training Programs

Home health agencies 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 providers, 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 RO may also compile a list of resources that can provide directed in-service training and may make this list available to HHAs.

9024.4 Further Responsibilities

The HHA 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 does not achieve substantial compliance, CMS may impose one or more additional sanctions as specified in [§488.808](#).

9024.5 Notice of Imposition of Directed In-Service Training

Directed in-service training may be imposed 15 calendar days after the HHA receives notice in non- immediate jeopardy situations and 2 calendar days after the HHA receives notice in immediate jeopardy situations.

9025 Effect of termination on the HHA's patients

Under the provisions of §§1866(b)(2)(A) and (B) of the Act (also 42 CFR 489.53), the Secretary may terminate an agreement with a provider of services if it is determined that the provider fails to comply substantially with the terms of the provider agreement, the provisions of title XVIII, or regulations promulgated thereunder, and that the provider fails to meet the applicable provisions of section 1861.

Under §488.830 (e), an HHA that has its provider agreement terminated is required to appropriately and safely transfer its patients to another local HHA within 30 days of termination. The HHA is responsible for providing information, assistance and any arrangements necessary for the safe and orderly transfer of its patients. The SA is required to work with all HHAs that are terminated to ensure the safe discharge and orderly transfer of all patients to another Medicare-approved HHA. Payment to terminated HHAs for services for current patients is provided up to 30 days after termination pursuant to §489.55(b).