E-Alliance Extra

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CMS Proposes Sweeping Hospice Survey Reforms *(from NAHC Report)*

In mid-2019, the Department of Health and Human Services' Office of the Inspector General (OIG) issued reports regarding hospice survey performance that raised considerable concerns in Congress, at the Centers for Medicare & Medicaid Services (CMS) and among hospice stakeholders. While the OIG's findings indicated that a relatively small percentage of hospice providers have serious deficiencies and/or substantiated complaints, the reports set off a firestorm of activity aimed at reforming the hospice survey process.

In late 2000, as part of the Consolidated Appropriations Act of 2021 (CAA 2021), provisions making sweeping changes to the hospice survey program were enacted. The National Association for Home Care & Hospice (NAHC) has developed a summary table outlining the hospice provisions of the CAA 2021, which is available **HERE**.

As part of the recently released Calendar Year 2022 Proposed Home Health Payment Rule, CMS issued proposed regulations designed to implement those reforms. This article provides NAHC's initial summary of the hospice survey regulations.

An initial review of the regulations raises a number of concerns, particularly with respect to CMS' proposed approach for developing a hospice-specific Special Focus Program, proposed use of the State Performance Standards System (SPSS) – which would entail increasing the number of validation surveys — to improve consistency of hospice surveys, and the fact that CMS has not proposed use of a technical expert panel (TEP) to help guide implementation of these significant changes to the hospice survey process. Over the coming weeks, NAHC will be conducting additional analysis and gathering input from member organizations on the proposed regulations with an eye toward development of comments for submission to CMS.

As part of the rule, CMS states, "…we are proposing a comprehensive strategy to enhance the hospice program survey process, increase accountability for hospice programs, and provide increased transparency to the public. Our goals include: (1) maintaining the public trust through addressing conflicts of interest and improving survey transparency; (2) addressing inconsistency within the survey process through training and survey team composition and use of common hospice program deficiency reporting mechanisms; and (3) ensuring hospice programs are held accountable for addressing identified health and safety issues. The statutory requirements outlined in the CAA 2021 will address CMS' goals and are in the best interest of patients who receive care in Medicare-participating hospice programs."

The CAA 2021 contains nine new survey and enforcement provisions for hospice programs. The law:

- Requires public reporting of hospice program surveys conducted by state agencies (SAs) and accrediting organizations (AOs), as well as enforcement actions taken as a result of these surveys, on CMS's website in a manner that is prominent, easily accessible, searchable and readily understandable format.
- Removes the prohibition at section 1865(b) of the Act of public disclosure of hospice surveys performed by AOs, requiring that AOs use the same survey deficiency reports as SAs (Form CMS-2567, "Statement of Deficiencies" or a successor form) to report survey findings.
- Requires programs to measure and reduce inconsistency in the application of survey results among all surveyors.
- Requires the Secretary to provide comprehensive training and testing of SA and AO hospice program surveyors, including training with respect to review of written plans of care.
- Prohibits SA surveyors from surveying hospice programs for which they have worked in the last 2 years or in which they have a financial interest.
- Requires hospice program SAs and AO to use a multidisciplinary team of individuals for surveys conducted with more than one surveyor (to include at least one registered nurse (RN).
- Provides that each SA must establish a dedicated toll-free hotline to collect, maintain, and update information on hospice programs and to receive complaints.
- Directs the Secretary to create a Special Focus Program (SFP) for poor-performing hospice programs, sets out authority for imposing enforcement remedies for noncompliant hospice programs.
- Requires the development and implementation of a range of remedies as well as procedures for appealing determinations regarding these remedies. These enforcement remedies can be imposed instead of, or in addition to, termination of the hospice program's participation in the Medicare program. These remedies include civil money penalties (CMPs), suspension of all or part of payments, and appointment of temporary management to oversee operations.

The provision requiring a new hospice program hotline is effective one year after the CAA 2021 enactment (that is, December 27, 2021). Most other provisions are effective on October 1, 2021, including the following—the requirement to use multidisciplinary survey teams, the prohibition of conflicts of interest, expanding CMS-based surveyor training to AOs, and the requirement for AOs with CMS-approved hospice accreditation programs to begin use of the Form CMS-2567 (or a successor form). The public disclosure of survey information and the requirement to develop and implement a range of enforcement remedies is effective no later than October 1, 2022. The other provisions in the legislation were effective upon enactment of the CAA 2021.

To implement the changes, CMS is proposing to add new subparts M and N to 42 CFR part 488. Subpart M would provide survey and certification processes while subpart N would provide the enforcement remedies for hospice programs with deficiencies that are not in compliance with Medicare participation requirements. The proposed enforcement remedies for hospice programs with deficiencies are similar to the alternative enforcement sanctions available for HHAs with deficiencies.

CMS is proposing to amend § 488.2 and § 488.28, where appropriate, to include the reference to hospice program. In addition, CMS proposes to amend terminations and appeals requirements based on the proposed enforcement remedies.

Following is a summary of the changes CMS is proposing:

AO Submission of Form CMS-2567 to Support Public Reporting of Survey Findings: CMS is proposing that AOs agree, as part of their application and reapplication process, to agree to submission of a statement of deficiencies (CMS-2567 or a successor form) to document hospice survey findings and that it will be submitted in a manner specified by CMS. As CMS-2567 is not currently utilized by AOs, CMS and the AOs must determine the systems process for the inclusion and subsequent collection of CMS-2567 as part of all hospice surveys completed by AOs. The current system used by the AOs to submit survey data (the ASSURE system) is not able to generate the CMS-2567, so CMS is assessing the revisions that would be needed for various systems to support AO submission of the form. This will take some time to address. For now, AOs will be required to develop a way of incorporating the CMS-2567 into their documentation systems. CMS also is in the process of modifying the CMS-2567 to ensure that it can be used by the AOs, and is seeking OMB approval of these revisions. As part of this section, CMS is seeking public comment on how AOs can customize their software systems to incorporate a version of the Form CMS-2567 and submit it via electronic data exchange to CMS.

Release and Use of Accreditation Surveys: CMS is proposing to add a new section 488.7(c) to require public posting of the CMS-2567 in a form that is prominent, easily accessible, readily understandable, and searchable for the general public, and that allows for timely updates. In addition to AO systems issues mentioned above, CMS indicates that there are limitations and additional data system changes to consider in order to display survey results in a meaningful and useful format. For this reason, CMS is seeking public comment as to how the data elements from the CMS-2567 might be utilized and displayed, and other recommendations of relevant provider information, to assist the public in obtaining a more comprehensive understanding of a hospice program's overall performance. CMS anticipates development of some type of standard framework that identifies key survey findings and other relevant data about hospice performance. CMS acknowledges the need to collaborate with stakeholders to assure that the release of national survey data is fair and equitable across hospice programs.

Providers or Suppliers, Other than SNFs, NFs, HHAs, and Hospice Programs with Deficiencies (Section 488.28): Section 488.28 requires a deficient supplier or provider to submit an acceptable plan of correction (POC) for achieving compliance. The regulation exempts SNFs, NFs, and HHAs from this requirement because similar provisions are set out in regulation for these specific providers. CMS is proposing to include hospice programs as exempt from 488.28 since new enforcement remedies specific to hospice are being established under a new subpart N.

Proposed New Subpart M – Survey and Certification of Hospice Programs

Basis and Scope (Section 488.1100): CMS is proposing a new regulation at 488.1100 that specifies the statutory authority and general scope of the hospice program.

Definitions (Section 488.1105): CMS is proposing to add definitions at Section 488.1105 for survey and enforcement terms for hospice programs; the definitions are as follow:

- ***Abbreviated standard survey*** would mean a focused survey other than a standard survey that gathers information on hospice program's compliance with specific standards or CoPs. An

abbreviated standard survey may be based on complaints received or other indicators of specific concern. Examples of other indicators include media reports or findings of government oversight activities, such as OIG investigations.

- ***Complaint survey*** would mean a survey that is conducted to investigate substantial allegations of noncompliance as defined in § 488.1.
- ***Condition-level deficiency*** would mean noncompliance as described in § 488.24 of this part.
- ***Deficiency*** would mean a violation of the Act and regulations contained in 42 CFR part 418, subparts C and D, is determined as part of a survey, and can be either standard or condition-level.
- ***Noncompliance*** would mean any deficiency found at the condition-level or standardlevel.
- ***Standard-level deficiency*** would mean noncompliance with one or more of the standards that make up each condition of participation for hospice programs.
- ***Standard survey*** would mean a survey conducted in which the surveyor reviews the hospice program's compliance with a select number of standards and/or CoPs to determine the quality of care and services furnished by a hospice program.
- ***Substantial compliance*** would mean compliance with all condition-level requirements, as determined by CMS or the State.

Hospice Program Surveys and Hospice Program Hotline (Section 488.1110): Under the new Subpart M, CMS is including a new regulation at 488.1110(a) to require that a standard survey must be conducted not later than 36 months after the date of the previous standard survey. CMS further proposes a regulation at 488.1110(b)(1) requiring that a standard or abbreviated standard survey be conducted when complaint allegations against the hospice program were reported to CMS, the State, or local agency.

Preexisting statute at Section 1864(a) requires that, under survey agreements between HHS and the States, State or local agencies must maintain a toll-free hotline for home health agencies. The CAA 2021 amended Section 1864(a) to include hospice programs. The hotline must be maintained for the following purposes:

1. to collect, maintain, and continually update information on HHAs and hospice programs located in the State or locality that are certified to participate in the program established under this title; and
2. to receive complaints (and answer questions) with respect to HHAs and hospice programs in the State or locality.

Section 1864(a) also provides that the State or local agency must maintain a unit for investigating such complaints, and that unit must possess enforcement authority and have access to survey and certification reports, information gathered by AOs, and consumer medical records (with consent of the consumer or legal representative). CMS intends to build on these requirements and make them applicable to hospice programs going forward.

CMS is seeking public comment on current experiences with the HHA toll-free hotline as required by section 1864(a) of the Act. This information will inform CMS of future enhancements to the toll-free hotline. CMS is specifically interested in recommendations as to what data elements and processes should be included to assure confidentiality and immediate communication with relevant SAs in order to permit them to respond promptly.

Surveyor Qualifications and Prohibition of Conflicts of Interest (Section 488.1115): While both State and AO surveyors are currently required to undergo training, they are not subject to identical training requirements, which CMS believes could be a contributing factor to disparity in overall survey performance. CMS is proposing that all SA and AO hospice program surveyors be required to take CMS-provided surveyor basic training that is currently available, and additional training as specified by CMS. Until the rule is finalized, CMS is proposing to accept existing AO training as this training was previously approved by CMS during the application process.

CMS notes that basic surveyor online training is currently publicly available to all free of charge through the QSEP website at https://qsep.cms.gov, and CMS is in the process of updating the hospice program basic training and including enhanced guidance for surveyors. The updated training is expected to emphasize assessment of quality of care, including the requirements for establishing individualized written plans of care, and regularly updating these plans of care with the full involvement of the interdisciplinary team, patients, and their families.

CMS also notes that pending revisions to the CMS State Operations Manual (SOM) (Pub 100-7) will emphasize four "core" hospice program CoPs, as follow:

- **Section 418.52 Condition of Participation: Patient's rights**
- **Section 418.54 Condition of Participation: Initial and comprehensive assessment of the patient**
- **Section 418.56 Condition of Participation: Interdisciplinary group, care planning and coordination of care**
- **Section 418.58 Condition of Participation: Quality assessment and performance improvement**

CMS invites comment regarding the trainings, and also seeks comment on the continued SA and AO surveyor training as CMS releases additional basic course updates.

CMS also proposes, as part of the regulations, to set out circumstances that will disqualify a surveyor from surveying a particular hospice, as required under the CAA 2021. Under the legislation, SA surveyors considered to have a conflict of interest (including with regard to hospice programs for which they have worked in the last two years or in which they have a financial interest). While the legislative provision applies to SA surveyors, CMS is proposing to apply this provision to AO surveyors, as well.

Specifically, CMS is proposing that a surveyor would be prohibited from surveying a hospice program if the surveyor currently serves, or within the previous two years has served, on the staff of or as a consultant to the hospice program undergoing the survey. The surveyor could not have been a direct employee, employment agency staff at the hospice program, or an officer, consultant, or agent for the surveyed hospice program regarding compliance with the CoPs. A surveyor would be prohibited from surveying a hospice program if he or she has a financial interest or an ownership interest in that hospice. The surveyor would also be disqualified if he or she has an immediate family member who has a financial interest or ownership interest with the hospice program to be surveyed or has an immediate family member who is a patient of the hospice program to be surveyed. CMS will use the definition of "immediate family member" located at § 411.351, which includes 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.

Survey Teams (Section 488.1120): The CAA 2021 requires that when a survey is conducted by more than one surveyor that the survey must be conducted by a multidisciplinary survey team, and at least one person must be a RN. In response, CMS is proposing at 488.1120 that all survey entities (SAs or AOs) must include diverse professional backgrounds among their surveyors to reflect the professional disciplines responsible for providing care to persons who have elected hospice care. CMS indicates that such teams should include professions included in hospice core services, and may include physicians, nurses, medical social workers, pastoral or other counselors – bereavement, nutritional, and spiritual. When a survey team is comprised of more than one person, the additional slots would be filled by professionals from among these disciplines, and CMS is seeking comments on this approach. CMS notes that survey entities may need additional time to hire and train professionals to meet this new requirement. In order to track compliance with this provision, CMS proposes to establish a baseline knowledge by asking survey entities to tell CMS:

- The extent to which their surveys are conducted by one professional, who by regulation must be a RN;
- The professional makeup of their current workforce; and
- Estimate a timeframe in which they could effectuate multidisciplinary teams if not already in place.

Consistency of Survey Results (Section 488.1125): CAA 2021 requires that each State and HHS implement programs to measure and reduce inconsistency in the application of hospice program survey results among surveyors. CMS indicates that they believe this should be applicable not only to various SAs, but that discrepancies between SA and AO survey findings must also be addressed. CMS proposes at Section 488.1125 to enhance the requirements of the State Performance Standards System (SPSS) (currently used for skilled nursing facilities) to direct States to implement processes to measure the degree or extent to which surveyors' findings and determinations are aligned with federal regulatory compliance and with an SA supervisor's determinations. There is significant variation among SAs relative to the number of surveyors deployed for a particular survey, or the distribution of survey professional backgrounds. To address this variation, CMS expects to promulgate objective measures of survey accuracy, and seeks public opinion on what measures would be feasible for States. CMS is interested in measures that are both specific and utilize currently collected data, if possible. Accuracy could include whether a survey finding aligns with the selected regulatory deficiency, as well as failing to cite such findings. When applied to survey findings, the measures should allow CMS to determine the need for corrective action or education for individual surveyors or for a group of surveyors. If systemic issues are found, CMS indicates that it is prepared to enhance its training to address systemic issues found as a result of interstate analysis.

Currently CMS monitors consistency of SA surveys through review of an SA's CMS-2567 submissions, and consistency of AOs through validation surveys conducted by SAs. Validation surveys report disparate findings as the percentage of validation surveys that have conditions identified by the SA but were missed by the AO survey team. This percentage is called the "disparity rate", and is tracked by CMS as an indication of the quality of AO surveys. The disparity rate is reported annually to Congress. Using the disparity rate approach — under which surveyors are reviewed for condition-level deficiencies the AO fails to identify — CMS is proposing to analyze trends in the disparity rate among States, as well as among AOs. State survey results would be reviewed to identify findings that were potentially worthy of condition-level citation but were not cited.

CMS believes that some of the variation in deficiency citations may be attributable to the differences in training that AO and SA surveyors receive, and that uniform training will help to increase the consistency in surveyor performance and have a positive impact on high disparity rates. CMS also indicates that it wants to align its processes more closely to those that have been found effective for other provider types, and the process it is proposing for hospice is similar to one currently employed with skilled nursing facilities under which a sufficient number of validation surveys are conducted to allow for inferences about the adequacies of surveys. CMS indicates that while AOs are not currently included in the CMS SPSS, a similar methodology would be applied to all hospice surveying entities, including AOs. If CMS finds that SAs or AOs do not meet performance standards, they would be required to develop and implement a corrective action plan.

Special Focus Program: CMS is proposing at § 488.1130 to develop a Special Focus Program (SFP) to address issues that place hospice beneficiaries at risk for poor quality of care through increased oversight, and/or technical assistance. CMS is proposing a program similar to the long-term care SFP. The following criteria would be used to determine whether a hospice would need to participate in the SFP:

- a history of condition-level deficiencies on two consecutive standard surveys,
- two consecutive substantiated complaint surveys, or
- two or more condition-level deficiencies on a single validation survey (the validation survey with condition-level deficiencies would be in addition to a previous recertification or complaint survey with condition-level deficiencies).

Only a subset of hospice programs that meet the proposed criteria would be selected to be in the SFP, and those hospice programs would be surveyed every 6 months, which may result in additional enforcement remedies and/or termination. Once an SFP hospice program has completed 2 consecutive 6-month SFP surveys with no condition-level deficiencies cited, the facility would graduate from the SFP. If the hospice program did not meet the requirements to graduate, it would be placed on a termination track.

CMS is seeing public comment regarding the SFP, specifically the following issues:

- Should CMS utilize a similar criteria/process/framework for the SFP as outlined in the current Long-Term Care Program. What if any differences should CMS consider to enhance the overall impact of the hospice SFP?
- Additional selection criteria that CMS should consider for the identification and participation in the SFP. This may include use of current or future data elements that could be incorporated into a more comprehensive algorithm.
- Utilization of a Technical Expert Panel (TEP) to enhance the SFP in terms of selection, enforcement and technical assistance criteria while in the program. Furthermore, a TEP may assist CMS by assisting in identifying contextual data and relevant information to assist the public in obtaining a more comprehensive understanding of the Form CMS-2567 survey data and the overall performance of a hospice provider, in addition to what data to include, how to make this information useful and meaningful on a CMS website.

Proposed New Subpart N – Enforcement Remedies for Hospice Programs with Deficiencies: CMS would expand the Secretary's options to impose additional enforcement remedies for hospice programs failing to meet Federal requirements in the same way it has done for home health agencies. These additional enforcement remedies may be used to encourage poor-performing hospice programs to come into substantial compliance with CMS requirements before CMS is forced to terminate the hospice program's provider agreement. Instead of using the term "intermediate sanctions" as is done with home health agencies, CMS proposes to the use the term "remedies" or "enforcement remedies" for the additional enforcement options.

If CMS determines that a hospice program is not in compliance with the Medicare hospice programs conditions of participation (CoPs) and the deficiencies involved may immediately jeopardize the health and safety of the individual(s) to whom the hospice program furnishes items and services, then CMS may terminate the hospice program's provider agreement, impose one or more enforcement remedies, or both. The decision to impose one or more remedies, including termination, would be based on the degree of noncompliance with the hospice program Federal requirements. With the proposed provisions, CMS would be able to impose one or more remedies for each discrete condition-level deficiency constituting noncompliance.

It is important to note that hospices may receive initial certification as well as recertification in the Medicare program through an Accrediting Organization (AO). AOs do not have the authority to recommend or implement enforcement remedies. Therefore, if an AO finds deficiencies during an accreditation survey, it communicates any condition-level findings to the applicable CMS Survey Operations Group (SOG) location. Based on the survey findings, CMS makes any determinations regarding the imposition of Federal enforcement remedies. For those agencies operating under deemed status with an AO, CMS may remove the deemed status due to condition-level findings found by the SA or Federal survey team during a complaint or validation survey. Once an enforcement remedy is imposed on a formerly accredited hospice program and deemed status is removed, oversight and enforcement of that hospice program will be performed by the SA until the hospice program achieves compliance and the condition(s) causing the noncompliance are removed or until the hospice program is terminated from the Medicare program.

Remedies available to CMS would include:

- CMPs in an amount not to exceed $10,000 for each day of noncompliance by a hospice program with the requirements specified in section 1861(dd) of the Act;
- suspension of all or part of the payments to which a hospice program would otherwise be entitled under this title for items and services furnished by a hospice program, on or after the date on which the Secretary determines that remedies should be imposed; and
- appointment of temporary management to oversee the operation of the hospice program and to protect and assure the health and safety of the individuals under the care of the program while improvements are made to bring the program into compliance with all such requirements.

In addition to these remedies which are specified in the statute, CMS proposes to add a directed plan of correction (POC) and directed in-service training as additional enforcement remedies.

CMS is proposing that a hospice would be required to submit an acceptable POC to the SA or CMS within 10 calendar days from receipt of the statement of deficiencies (which is the current practice in most cases when a deficiency is cited). CMS would provide a notice of intent to the hospice program that would include the intent to impose a remedy, the statutory basis for the remedy, the nature of the noncompliance, the intent to impose a payment suspension and which payments would be suspended (if applicable), the intent to propose a CMP and the amount being imposed (if applicable), the proposed effective date of the sanction, and appeal rights. CMS proposes that for all remedies imposed, except for CMPs, when there is Immediate Jeopardy (IJ) (to be defined by CMS) the notice period is at least 2 calendar days before the effective date of the enforcement action and when there is no IJ, that the notice period is at least 15 calendar days before the effective date of the enforcement action. For terminations, CMS would give notice of the termination within 2 days before the effective date of the termination, to hospice programs consistent with the requirement for HHAs. CMS also proposes to amend § 489.53(a)(17) to indicate that it will terminate a hospice program's (as well as an HHA's) provider agreement if the hospice program failed to correct a deficiency or deficiencies within the required time frame.

CMS proposes to require a hospice program whose provider agreement is terminated to appropriately and safely transfer its patients to another local hospice program within 30 days of termination, unless a patient or caregiver chooses to remain with the hospice program as a self-pay or with another form of insurance (for example, private insurance). In addition, the hospice program would be responsible for providing information, assistance, and any arrangements necessary for the safe and orderly transfer of its patients.

With respect to CMPs, CMS proposes that once the administrative determination to impose the CMP is final, CMS would send a final notice to the hospice program with the amount of the penalty assessed, the total number of days of noncompliance (for CMPs imposed per day), the total amount due, the due date of the penalty, and the rate of interest to be charged on unpaid balances. A hospice could appeal the determination of noncompliance leading to the imposition of a remedy. A pending hearing would not delay the effective date of the remedy against the hospice program and remedies would be in effect regardless of any pending appeals proceedings. Civil money penalties would accrue during the pendency of an appeal but would not be collected until the administrative determination is final.

To determine which remedy or remedies to apply, CMS proposes to consider the following factors that are consistent with the factors for HHA alternative sanctions:

- The extent to which the deficiencies pose IJ to patient health and safety.
- The nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.
- The presence of repeat deficiencies (defined as condition-level), the hospice program's compliance history in general, and specifically concerning the cited deficiencies, and any history of repeat deficiencies at any of the hospice program's additional locations.
- The extent to which the deficiencies are directly related to a failure to provide quality patient care.
- The extent to which the hospice program is part of a larger organization with documented performance problems.
- Whether the deficiencies indicate a system-wide failure of providing quality care

Temporary Management: The term "temporary management" means the temporary appointment by CMS or a CMS authorized agent, of a substitute manager or administrator, who would be under the direction of the hospice program's governing body and who would have authority to hire, terminate or reassign staff, obligate hospice program funds, alter hospice program procedures, and manage the hospice program to correct deficiencies identified in the hospice program's operation. The substitute manager or administrator would be appointed based on qualifications described in § 418.100 and § 418.114 and would be under the direction of the hospice program's governing body. Temporary management would be required to be provided at the hospice program's expense and would be imposed when a hospice program is determined to have condition-level deficiencies and that the deficiencies or the management limitations of the hospice program are likely to impair the hospice program's ability to correct the deficiencies and return the hospice program to compliance with all of the CoPs within the required timeframe. CMS proposes to impose temporary management to bring a hospice program into compliance with program requirements within 6 months of the date of the survey identifying noncompliance.

If the hospice program refuses to relinquish authority and control to the temporary manager, CMS will terminate the hospice program's provider agreement. If a temporary manager was appointed, but the hospice program failed to correct the condition-level deficiencies within 6 months from the last day of the survey, the hospice program's Medicare participation would be terminated. Additionally, if the hospice program resumes management control without CMS's approval, CMS would impose termination and could impose additional enforcement remedies. Temporary management would end when:

- CMS determines that the hospice program has achieved substantial compliance and has the management capability to remain in compliance;
- The hospice program provider agreement is terminated; or
- The hospice program resumes management control without CMS approval.
- Temporary management will not exceed a period of 6 months from the date of the survey identifying noncompliance.

Suspension of Payment for All or Part of the Payments: If a hospice program has a condition-level deficiency or deficiencies (regardless of whether or not an IJ exists), CMS may suspend payments for all or part of the payments to which a hospice program would otherwise be entitled for items and services furnished by a hospice program on or after the effective date of the enforcement remedy. Suspension of payment would be for a period not exceed 6 months and would end when the hospice program either achieved substantial compliance or was terminated.

Civil Money Penalties: CMS would impose CMPs against a hospice program that is determined to be out of compliance with one or more CoPs, regardless of whether the hospice program's deficiencies pose IJ to patient health and safety. CMS could also impose a CMP for the number of days of IJ. CMPs are not to exceed $10,000 for each day of noncompliance. CMS proposes both "per day" and "per instance" CMPs. The per day CMPs would be imposed for each day of noncompliance with the CoPs. Additionally, should a survey identify a particular instance or instances of noncompliance during a survey, CMS proposes to impose a CMP for that instance or those individual instances of noncompliance. CMS proposes to define "per instance" as a single event of noncompliance identified and corrected during a survey, for which the statute authorizes CMS to impose a remedy. For penalties imposed per instance of noncompliance, CMS is proposing penalties from $1,000 to $10,000 per instance. 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.

The size of the hospice program and its resources as well as evidence that the hospice program has a built-in, self-regulating quality assessment and performance improvement system to provide proper care, prevent poor outcomes, control patient injury, enhance quality, promote safety, and avoid risks to patients on a sustainable basis that indicates the ability to meet the CoPs and to ensure patient health and safety would be considered in determining the amount of the CMP. CMS would have the discretion to increase or reduce the amount of the CMP during the period of noncompliance, depending on whether the level of noncompliance had changed at the time of a revisit survey. CMS proposes to establish a three-tier system with subcategories that would establish the amount of a CMP.

Whether per instance or per day CMPs are imposed, once the hospice program has received the notice of intent to impose the CMP, it would have 60 calendar days from the receipt of the written notice of intent to either request an administrative hearing or to provide notice to CMS of its intent to waive its right to an administrative hearing in which case is would receive a 35 percent reduction in the CMP amount.

A CMP would become due and payable 15 calendar days from

- The time to appeal had expired without the hospice program appealing its initial determination;
- CMS received a request from the hospice program waiving its right to appeal the initial determination;
- A final decision of an Administrative Law Judge or Appellate Board of the Departmental Appeals Board upheld CMS's determinations; or
- The hospice program was terminated from the program and no appeal request was received.

Directed Plan of Correction: This remedy is utilized in both home health agencies and long-term care facilities. A direction plan of correction would require the hospice program to take specific actions to bring the hospice program back into compliance and correct the deficient practice(s). The directed POC would be developed by CMS or by the temporary manager, with CMS approval. If the hospice program failed to achieve compliance within the timeframes specified in the directed POC, CMS could impose one or more additional enforcement remedies until the hospice program achieved compliance or was terminated from the Medicare program.

Directed In-Service Training: This remedy could be used for hospice programs with condition-level deficiencies. It would be required where staff performance resulted in noncompliance, and it was determined that 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. The instructors for this type of program would be those with an in-depth knowledge of the area(s) that would require specific training. Hospice programs would be required to participate in programs developed by well-established education and training services. These programs would include, but not be limited to, schools of medicine or nursing, area health education centers, and centers for aging. CMS would only recommend possible training locations to a hospice program and not require that the hospice program utilize a specific school/center/provider. In circumstances where the hospice is subject to the SFP, additional technical assistance and/or resources could be made available. The

hospice program would be responsible for payment for the directed in-service training for its staff. If the hospice program did not achieve substantial compliance after such training, CMS could impose one or more additional remedies.

Continuation of Payments to a Hospice program with Deficiencies: CMS proposes the continuation of Medicare payments to hospice programs not in compliance with the requirements specified in section 1861(dd) of the Act over a period of no longer than 6 months. Medicare payments will continue for 6 months if:

- An enforcement remedy or remedies (with the exception of suspension of all payments) have been imposed on the hospice program and termination has not been imposed;
- The hospice program has submitted a POC which has been approved by CMS; and
- The hospice program agrees to repay the Federal government the payments received under this arrangement should the hospice program fail to take the corrective action as outlined in its approved POC in accordance with the approved plan and timetable for corrective action.

If any of these three requirements were not met, a hospice program would not receive any Federal payments from the time that deficiencies were initially identified. CMS would also terminate the agreement before the end of the 6-month correction period.

Termination of Provider Agreement: Termination of the provider agreement would end all payments to the hospice program. Termination would also end enforcement remedies imposed against the hospice program, regardless of any proposed timeframes for the remedies originally specified. CMS would terminate the provider agreement if—

- the hospice program failed to correct condition-level deficiencies within 6 months unless the deficiencies constitute IJ;
- the hospice program failed to submit an acceptable POC;
- the hospice program failed to relinquish control of the temporary manager (if that remedy is imposed); or
- the hospice program failed to meet the eligibility criteria for continuation of payments.

CMS proposes using the procedures for terminating a hospice program at § 489.53 and providing appeal rights in accordance with 42 CFR part 489. Additionally, CMS proposes using the procedures for payments 30 days post termination for hospice programs at § 489.55. Payment is available for up to 30 days after the effective date of termination for hospice care furnished under a plan established before the effective date of termination (§ 489.55(a)(2)).