CMS Issues Final Rule to Reform Hospice Survey Process

- **Special Focus Program to be Part of Future Rulemaking**

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. In response, as part of the Consolidated Appropriations Act of 2021 (CAA 2021), Congress enacted sweeping reforms that include expansion of enforcement remedies available to CMS for use in response to survey deficiencies, creation of a Hospice Special Focus Program, and requirements to make hospice survey findings publicly available. CMS issued proposed rules to implement the survey reforms as part of the **Calendar Year (CY) 2022 Proposed Home Health Payment Rule,** and has issued final rules in the recently-released CY 2022 Final Home Health Payment Rule. This article constitutes the National Association for Home Care & Hospice's (NAHC's) summary of those rules based on an initial review.

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.

As a reminder, the survey reforms have various implementation dates, ranging from "upon enactment" to October 1, 2021, to future dates. Based on a memo released on October 20, 2021, CMS is prohibited from conducting compliance monitoring activities using these policy changes until sixty (60) days from the effective date of the new regulations contained in the CY 2022 Home Health Payment Rule, which is January 1, 2022.

FINAL HOSPICE SURVEY REFORMS

AO Submission of Form CMS-2567 to Support Public Reporting of Survey Findings: CMS proposed that AOs agree, as part of their application and reapplication process, to submit 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 the CMS-2567 had not previously been utilized by AOs, CMS and the AOs must determine the systems process for the inclusion and collection of CMS-2567 as part of all hospice surveys completed by AOs. For now, AOs have been required to develop a way of incorporating the CMS-2567 into their documentation systems. Over the course of the summer, CMS modified the CMS-2567 to ensure that it can be used by the AOs.

In response to comments CMS indicated that it will be developing guidance to address many of the concerns raised by comments regarding the October 1, 2021, deadline, submission, and formatting/reporting by the AOs. CMS also indicated that if the agency decides to make additional changes to the CMS-2567, as recommended by some commenters, those changes will go through a public notice process. **CMS finalized the regulation as proposed.**

Release and Use of Accreditation Surveys: CMS proposed 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 indicated 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 sought 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 indicated it anticipates the need to develop 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.

CMS indicted that publication of the CMS-2567 is expected to be a "first step" in meeting the intent of this requirement, and that the agency is considering the recommendation that a TEP or other vehicle be convened to gather stakeholders' input on ways to define a more comprehensive metric or algorithm for public display of hospice survey information. **CMS finalized the regulation as proposed, with a minor technical change.**

Providers or Suppliers, Other than SNFs, NFs, HHAs, and Hospice Programs with Deficiencies: 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 proposed to include hospice programs as exempt from 488.28 since new enforcement remedies specific to hospice are being established under a new subpart N. **CMS finalized the regulation as proposed.**

Proposed New Subpart M – Survey and Certification of Hospice Programs

Basis and Scope: CMS proposed a new regulation at 488.1100 that specifies the statutory authority and general scope of the hospice program. **CMS finalized this regulation as proposed.**

Definitions: CMS proposed 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 standard level.
- ***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.

CMS finalized the Basis and Scope and Definitions regulations as proposed.

Hospice Program Surveys and Hospice Program Hotline: Under the new Subpart M, CMS proposed 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). These would apply to hospice programs going forward.

In response to comments CMS clarified that State or local agencies that have existing toll-free hotlines for home health agency complaints can utilize this hotline to also collect and maintain information on hospice programs. However, the State or local agency may decide to establish a separate toll-free hotline specific to hospice programs. **CMS finalized the regulations as proposed.**

Surveyor Qualifications and Prohibition of Conflicts of Interest: Prior to the CAA of 2021, both State and AO surveyors were required to undergo training but were not

subject to identical training requirements. CMS proposed that all SA and AO hospice program surveyors be required to take CMS-provided surveyor basic training that is publicly available at https://qsep.cms.gov, and additional training as specified by CMS. Until the rule is finalized, CMS proposed 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. CMS has updated the hospice program basic training to include enhanced guidance for surveyors. The updated training will 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; and Section 418.58 Condition of Participation: Quality assessment and performance improvement.

CMS clarified as part of the discussion in the final rule that a surveyor would be expected to take the training that is available when their individual need for training arises (that is, upon hiring, or if beginning to survey a provider they have not previously been trained to survey). CMS plans to post a training update of changes in the new version for surveyors who used the older version of the CMS training so that they will not have to take the new training in its entirety. CMS also indicated in response to recommendations related to ongoing training and competency that the agency relies on the managerial oversight of State agencies, with the assistance of State training coordinators to monitor surveyor abilities.

CMS is finalizing the regulation related to surveyor qualifications as proposed.

CMS also proposed, 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 would be prohibited from conducting a survey of a specific provider. While the legislative provision applies to SA surveyors, CMS proposed applying the provision to AO surveyors, as well. Under the new regulation, 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.

In response to comments, CMS expressed appreciation for comments indicating that it would be impossible to identify all of the potential conflicts of interest that could arise in a survey situation, and will consider the recommendation put forth by NAHC and others that CMS create a code of ethics for surveyors or require an attestation by surveyors that they intend to judge providers objectively. CMS indicated that it would consider these recommendations as part of future policy changes affecting all surveyors. CMS also indicated that it would review existing training addressing roles and responsibilities of surveyors, including conflicts of interest, and make updates as needed. CMS also noted that the current CMS State Operations Manual requires that State agency administrators should require employees to make a declaration of any outside interests and update this declaration periodically. As a result, CMS believes that surveyors are responsible for disclosing and recusing themselves as needed.

CMS is finalizing the conflict of interest regulation with a modification that surveyors must disclose actual or perceived conflicts of interest prior to participating in a hospice program survey and be provided the opportunity to recuse themselves, as necessary.

Survey Teams: 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 proposed at 488.1120 that all survey entities (SAs or AOs) include diverse professional backgrounds among their surveyors to reflect the professional disciplines responsible for providing care to persons who have elected hospice care. Such multidisciplinary teams should include professions included in hospice core services (physicians, nurses, medical social workers, pastoral, or other counselors – bereavement, nutritional, and spiritual). To implement this requirement, CMS proposed that when a survey team is comprised of more than one person, the additional slots would be filled by professionals from among the disciplines specified.

In response to comments, CMS clarified that since an RN will be on every survey team, to ensure that the team is multidisciplinary the additional team member(s) mut be

selected from other disciplines included in the interdisciplinary group. **CMS finalized the proposed regulation without modification.**

Consistency of Survey Results: 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 believes this provision should be applicable not only to various SAs, but that discrepancies between SA and AO survey findings must also be addressed. CMS proposed at Section 488.1125 to enhance the requirements of the State Performance Standards System (SPSS) 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 plans to promulgate objective measures of survey accuracy, and sought public opinion on what measures would be feasible for States. 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 such issues found as a result of interstate analysis.

Currently CMS monitors consistency of SA surveys through review of an SA's CMS-2567 submissions (conducted by CMS regional location offices), 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 proposed to analyze trends in the disparity rates 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 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.

CMS is finalizing the regulation related to consistency of survey results as proposed.

Proposed New Subpart N – Enforcement Remedies for Hospice Programs with Deficiencies

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. The CAA 2021 provides for penalties for previous noncompliance and the implementation of alternative remedies not later than 10/2022. These include suspension of all or part of payments, temporary management, and civil money penalties (CMPs) not to exceed $10,000 for each day of noncompliance by a hospice program. CMS proposed the addition of a directed plan of correction and directed in-service training.

Notice: CMS proposed at § 488.1225(b), that for a deficiency or deficiencies that pose Immediate Jeopardy (IJ) it would provide the hospice program with at least 2 days advance notice of any proposed remedies, except CMPs (discussed at proposed § 488.1245). **This notice period was finalized with the clarification that these are calendar days.**

For a deficiency or deficiencies that do not pose IJ CMS proposed a notice of at least 15 days of any proposed remedies, except for CMPs (discussed at proposed § 488.1245). Such remedies would remain in effect until the effective date of an impending termination (at 6 months) or until the hospice program achieves compliance with CoPs, whichever is earlier. This 15-day period is consistent with the general rule for providers and suppliers in § 489.53(d)(1). **This notice period also was finalized with the clarification that these are calendar days.**

For terminations, CMS proposed a notice of the termination within 2 days before the effective date of the termination to hospice programs consistent with the requirement for Home Health Agencies (HHAs). CMS also proposed 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. **This was finalized as proposed.**

Factors to be Considered in Selecting Remedies: To determine which remedy or remedies to apply, CMS proposed 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.

CMS finalized these factors as proposed but also indicated that it will develop associated guidance and training for CMS staff and SA staff. The training will be publicly available.

Payment Suspension: CMS carefully considered payment suspensions for hospices. Specifically, CMS proposed at § 488.1240 that it may suspend all or part of the payments to which a hospice program would otherwise be entitled with respect to items and services furnished by a hospice program on or after the date on which the Secretary determines that remedies should be imposed. This language is consistent with the CAA 2021; however, it is not consistent with the payment suspensions applicable for other provider types. Specifically, the suspension for HHAs is limited to new admissions only. **CMS finalized this provision with modifications to limit the suspension of payments to all new patient admissions.** The payment suspension is to be for a period not to exceed 6 months and would end when the hospice program either achieves substantial compliance or is terminated.

Continuation of Payments to a Hospice program with Deficiencies: CMS proposed 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. The language proposed is consistent with that for HHAs. **CMS finalized this section with one modification. Because CMS is finalizing payment suspension to apply only to payments for all new patient admissions, it is removing the portion of the proposed language for this section that excepted the suspension of all payment.**

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 finalized this provision as proposed.**

Temporary Management: CMS proposed regulations to implement Section 1822(c)(5)(B)(iii) of the Act that specifies the use of appointment of temporary management as an enforcement remedy 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 in order to bring the program into

compliance with all such requirements. The temporary manager must have the experience and education that qualifies the individual to oversee the hospice program and can be internal or external to the hospice program. This portion of the proposed rule was detailed and included the definition of a temporary manager as well as details about the role of such individual and how CMS would handle situations where the hospice refused to relinquish administrative authority and control to the temporary manager. T**hese provisions were finalized as proposed.**

Civil Money Penalties: CMS proposed requirements for the imposition of CMPs at § 488.1245. They were consistent with the requirements of the Act and similar to what has been instituted for HHAs. Any funds collected as a result of CMPs imposed upon a hospice are distributed to the State Medicaid Agency and to the US Treasury under section 1128A(f) of the Act. Additionally, the CAA 2021 included a provision at section 1822(c)(5)(C) that allows the Secretary to use a portion of the CMPs collected to support activities that benefit individuals receiving hospice care, including education and training programs to ensure hospice program compliance. NAHC encourages CMS to utilize any collected CMPs in this manner. CMS will consider using its authority to support improvement activities in hospices in the future and will consider developing interpretive guidance for clarification as needed.

CMS pointed out that when the amount of the CMP penalty is determined, one factor that is considered is evidence that the hospice program has an internal quality assessment and performance improvement system to ensure patient health and safety and compliance with the CoPs. CMS can take into account that the hospice program has evidence of a self-regulating quality assessment and improvement plan when determining the amount of the penalty, and it can decrease the CMP penalty amount from the upper range to the middle or lower range if a condition-level deficiency exists and the hospice program shows an earnest effort to correct systemic causes of the deficiencies and sustain improvement. **The provisions of the CMP portion of the enforcement remedies was finalized as proposed.**

Directed Plan of Correction: This particular remedy is one of two proposed by CMS that are not required by the CAA 2021 (the other is directed in-service training). NAHC appreciates these proposed additions, and it aligns the enforcement remedies with the alternative sanctions available for HHAs. A directed POC remedy would require the hospice program to take specific actions to bring the hospice program back into compliance and correct the deficient practice(s). As indicated in § 488.1250(b)(2) a hospice program's directed POC would be developed by CMS or by the temporary manager, with CMS approval. **CMS has found the directed plan of correction successful in the home health and long-term care settings and finalized the addition of this remedy for hospices as proposed.**

Directed In-Service Training: This is the second remedy proposed by CMS that was not required by the CAA 2021 and aligns the enforcement remedies with the alternative sanctions available for HHAs. directed in-service training 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. **Commenters were supportive of this proposed addition and CMS finalized it as proposed.**

Special Focus Program: CMS proposed 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. The proposed structure of the program was similar to the long-term care SFP. Commenters recommended that CMS utilize a Technical Expert Panel (TEP). Due to the potential significant impact on the delivery of hospice care the need for and benefits of a TEP to enhance the SFP in terms of selection, enforcement, and technical assistance criteria for hospices in the program was suggested.

While CMS did not explicitly indicate as part of the rule any intent to utilize a TEP in development of the SFP, it did respond that it intends to work on a revised proposal and will seek additional collaboration with stakeholders to further develop the structure and methodology for implementing the SFP, which CMS hopes to include in a proposal for FY 2024 rulemaking. Further, as part of its press release announcing release of the regulation, CMS indicated the following: "…we are not finalizing our proposal for the Special Focus Program for poor-performing hospice programs that have repeated cycles of serious health and safety deficiencies. Numerous comments indicated CMS should not finalize the proposed provision until a Technical Expert Panel (TEP) is convened to further define the parameters and provide a targeted approach based on national measures. Therefore, we are establishing a TEP with stakeholder engagement that integrates the public comments and will finalize this program through future rulemaking."