



August 27th, 2021

Chiquita Brooks-LaSure
Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

RE: Comments on the Proposed Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Proposed Model Expansion; Home Health Quality Reporting Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; Inpatient Rehabilitation Facility Quality Reporting Program Requirements; and Long-Term Care Hospital Quality Reporting Program Requirements Rule (CMS-1747-P)

Dear Administrator Brooks-LaSure,

The National Partnership for Healthcare and Hospice Innovation (NPHI) is pleased to submit the following comments on the Survey and Enforcement Requirements for Hospice Programs section of the U.S. Department of Health and Human Services' (HHS) proposed Calendar Year 2022 Home Health Prospective Payment System Rate Update rule (CMS-1747-P).

NPHI is a collaborative of nearly eighty of the nation's most innovative, community-based, not-for-profit hospice and palliative care providers that serve as a critical safety net in communities across the United States. Our members collectively serve approximately 120,000 patients daily. Of the almost 5,000 hospice providers in the United States, only 21 percent are not-for-profit and willingly care for the sickest and most vulnerable patients. NPHI members are deeply embedded in their communities and have decades of experience providing the highest quality care for people facing serious illness. This includes providing a comprehensive scope of care to meet each patient's goals, values, and wishes, regardless of the patient's financial situation or prognosis.

The proposed rule, issued by the Center for Medicare and Medicaid Services (CMS) on June 28, largely focuses on home health providers, but includes significant provisions impacting hospice providers and their accompanying Accrediting Organizations (AOs). As was directed by Division CC, section 407(a) of the Consolidated Appropriations Act of 2021 (CAA 2021), CMS continues to review and revise survey processes to ensure high quality of care for Medicare beneficiaries who receive hospice care. Specifically, the rule proposes changes with respect to transparency, oversight, and enforcement of health and safety requirements for hospice providers. It also proposes a set of new enforcement remedies and establishes a Special Focus Program (SFP) for hospice providers with a history of inadequate compliance.

Based on these changes, we would like to highlight the following general comments and themes:

- We are broadly supportive of the provisions laid out in the proposed rule and share many of CMS’s concerns regarding hospice quality of care. We believe that these new enforcement remedies, if appropriately targeted and effectively operationalized to focus on hospice bad actors, will result in an improved standard of hospice care across the industry and will allow for a more effective use of CMS’s limited resources.
- We support the use of a Technical Expert Panel (TEP) for public reporting of survey data in a manner that is easily understood and of value to the public when selecting hospice service providers.
- We support the creation of a Special Focus Program (SFP) for those hospices found to be potentially placing patients at risk for poor care and encourage the use of a TEP to ensure that the SFP incorporates all of the unique aspects of hospice care delivery in its creation and implementation.
- We strongly support efforts to ensure the consistency of survey results among State Survey Agencies (SAs), and AOs, and encourage the use of surveyor staff with hospice industry experience and the requisite understanding of the core services to be delivered.

NPHI recognizes the important and timely changes made in the proposed rule and values the opportunity to offer the unique perspective of not-for-profit providers with respect to these specific proposals. We offer additional detail and commentary below.

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Application and Re-application Procedures for National Accrediting Organizations (§ 488.5)

Currently, regulations do not require AOs to utilize the same forms as SA surveyors when documenting survey findings of noncompliance. CMS is proposing to require that AOs, as part of the AOs application and re-application process for hospice programs, submit a statement acknowledging that the AO will include a statement of deficiencies (that is, the Form CMS-2567 or a successor form) to document findings of the hospice program Medicare conditions of participation (CoPs) and will submit such in a manner specified by CMS.

NPHI supports the provision as proposed.

Release and Use of Accreditation Surveys (§ 488.7)

CMS is proposing to add a new regulation which would require the posting of the Form CMS-2567 in a manner that is prominent, easily accessible, readily understandable, and searchable for the general public and allows for timely updates.

These proposed reforms will necessarily have far-reaching consequences and have the potential to drastically change the oversight and enforcement process for hospices. NPHI supports this proposal under the condition that given the potential impact of the changes, CMS recognizes it is critical to engage the requisite outside experts and key stakeholders necessary to inform implementation of the reforms and ensure the benefit of the changes to the public through the creation of a TEP. The TEP should be reflective of the hospice stakeholder community in general and include individuals representing patients, families, advocates, government, for-profit and not-for-profit providers, researchers, data experts, and others with appropriate expertise and experience to ensure that the information is prepared, presented, and communicated in a manner that the general public will find useful and balanced when selecting a hospice.

When similar reforms were proposed for nursing homes, Congress encouraged CMS to establish a process under which the agency consulted with a wide variety of stakeholders to ensure accuracy, clarity of presentation, timeliness, and comprehensiveness of information. In the interest of ensuring consistency among post-acute care providers, hospices should be treated similarly. Also, a TEP will assist CMS in understanding the unique communication issues associated with terminally ill patients, their families, and their care providers.

Moreover, the survey process for all healthcare providers includes a plan of correction (COP) that is approved by either the SA or AO. Since survey reports are often complex and may be inherently confusing for the public to digest in a meaningful way, it is essential that the final version of the form, including reversed findings and approved corrective actions be included as evidence of ongoing improvement efforts. A TEP and subsequent final proposal should emphasize serious deficiencies and other findings that have the clearest impact on quality of care for patients. Disputed findings that have the potential to paint a provider in a negative light ought to be designated as such on Hospice Compare.

Additionally, as is the case for publicly reported nursing home surveys, a hospice that has reconciled a cited deficiency should be designated as such on Care Compare. It is important for the public to understand that the very existence of a deficiency does not necessarily equate to systemic issues impacting patient care. Our members often report observing a “see one, cite one” approach to deficiency identification. For instance, a surveyor may review 100 instances of hospice aide supervision. If one of these instances does not meet the standard, then a hospice receives a citation. Such a deficiency has the potential to be misleading to the general public.

Moreover, most hospices are sincerely interested in promptly remediating any deficiencies once brought to their attention or they may legitimately disagree with the initial survey finding. In summation, the stakeholder community desires fairness and transparency in the public reporting process so that consumers can see if, and to what extent, a hospice has remediated any identified and substantiated deficiency, and have confidence that bad actors in the industry are penalized and ultimately removed if necessary.

Hospice Hotline (§ 488.1110)

Prior to the amendments made by CAA 2021, section 1864(a) of the (Social Security) Act required that agreements between the Secretary and the State, under which SAs carry out the Medicare certification process, shall provide for the appropriate State or local agency to establish and maintain a toll-free hotline for Home Health Agencies (HHAs). The CAA 2021 amended this requirement to include hospice programs. Therefore, CMS proposes that the State or local agency is responsible for establishing and maintaining a toll-free hotline to receive complaints (and answer questions) with respect to hospice programs in the State or locality and for maintaining a unit to investigate such complaints.

NPHI supports this provision as proposed, with the recommendation that the State or local agency staff the hospice hotline with individuals who are appropriately trained on hospice care and the hospice philosophy.

Surveyor Qualifications and Prohibition of Conflicts of Interest (§ 488.1115)

Surveyor Qualifications

Section 1822(a)(4)(C) of the Act requires the Secretary to provide training for State and Federal surveyors, and any surveyor employed by an AO, including a training and testing program approved by the Secretary, no later than October 1, 2021. Further, no surveyor can conduct hospice program surveys until they complete training and testing. CMS notes that differences in standards and processes between AOs and what CMS provides to SA surveyors have the potential to create disparities in overall survey performance. With this in mind, CMS proposes that all SA and AO hospice program surveyors would be required to take CMS-provided surveyor basic training currently available, and additional training as specified by CMS.

NPHI is pleased that CMS is focused on addressing significant discrepancies in consistency across various surveying entities. It is critically important that all surveyors demonstrate a proficient understanding of the comprehensive array of integrated services covered by the Medicare CoPs for hospice providers. Likewise, surveyors must be determined competent to consistently apply the standards based on sound evaluative methods. NPHI appreciates the challenges of surveyors who often must rely on their trained observation, interview, and document review skills to discern if the standard of care is being met, which is precisely why broad and deep direct survey experience is so important. That said, NPHI remains skeptical of the assessment that online training modules alone will ensure consistency of survey results but nonetheless appreciates the intent behind the proposed regulation.

Regarding the development of basic training materials, we request that CMS include real-world examples of how various regulations could be met. Additionally, considering the wider variety of disciplines conducting surveys, as proposed later in the rule, CMS should include items of specific interest to social workers and chaplains. NPHI seeks to clarify whether these training materials would be considered evergreen or whether CMS has a plan and consistent timeline in place to update them as new information is gathered and real-world experience is gained.

CMS also notes that the updated training will emphasize assessment of quality of care. CMS is emphasizing four “core” hospice program CoPs:

- §418.52 Condition of Participation: Patient’s rights
- §418.54 Condition of Participation: Initial and comprehensive assessment of the patient

- §418.56 Condition of Participation: Interdisciplinary group, care planning and coordination of care
- §418.58 Condition of Participation: Quality assessment and performance improvement.

NPHI supports the proposal to focus updated training materials on the four core hospice program CoPs. We note here, as we do elsewhere, that these materials should be updated by hospice and palliative care subject matter experts who have real-world experience complying with the CoPs and not just those familiar with the stated CoP language.

Conflict of Interest

In addition to training requirements for surveyors, CMS proposes to set out the circumstances that will disqualify a surveyor from surveying a particular hospice in accordance with section 1822(a)(4)(B) of the Act. CMS proposes to codify long-standing policies for both SA and AO surveyors to ensure there is no conflict of interest between the organization and the surveyor. In this vein, CMS proposes that a surveyor would be prohibited from surveying a hospice program if the surveyor currently serves, or within the previous 2 years has served, on the staff of or as a consultant to the hospice program undergoing the survey.

NPHI supports this proposed regulation but believes it should be extended to include anyone who has interviewed for key management positions within the same timeframe or similar positions at other hospice providers in the same service area. Additionally, a surveyor in a given geography should be prohibited from having a financial interest in a competitor to the hospice being surveyed using the same parameters and timeframe as proposed for those with a financial interest in the hospice itself.

NPHI suggests that perhaps CMS consider requiring surveyors to professionally attest that they are aware and will comply with the prohibition on conflicts of interest. Furthermore, NPHI would be supportive of a provision requiring surveyors to attest that they intend to judge providers objectively, within the bounds of the COPs, and refrain from relying on any personal convictions about what end-of-life care should be or ought to entail. Lastly, we would propose that individuals with a personal and direct experience with a given hospice be prohibited from surveying that hospice for the duration of their employment by an AO or SA.

Survey Teams (§ 488.1120)

The CAA 2021, adding section 1822(a)(4)(A) of the Act, calls for the use of multidisciplinary survey teams when the survey team comprises more than one surveyor, with at least one person being a Registered Nurse (RN). CMS proposes under a new subpart M to require that all survey entities—SA 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 at 42 CFR § 418.64, and may include physicians, nurses, medical social workers, pastoral, or other counselors—bereavement, nutritional, and spiritual. The interdisciplinary group or IDG, must include, but not be limited to a physician, a registered nurse, a medical social worker, and pastoral or other counselor. Therefore, CMS proposes that when the survey team comprises more than one surveyor, the additional slots would be filled by professionals from among these disciplines.

NPHI is broadly supportive of the proposal to ensure that survey teams reflect the composition of the professional staff of the hospice IDG. We believe this is a positive step that will increase the likelihood that survey results will include a comprehensive evaluation of the integrated nature of the IDG and take into account the unique role that various professions play in the provision of the Medicare hospice benefit. That said, as currently constructed, it is unclear whether the proposed changes are required of the AO or simply discretionary. NPHI requests that CMS clarify the meaning of “if the (survey) team is more than one surveyor” by indicating if and when a survey team is required to be comprised of multiple individuals, both for AOs and SAs.

Regarding the composition of the survey team, we suggest that CMS consider the inclusion of a former hospice administrator or quality improvement professional as an additional discipline to potentially be included by an SA or AO team. A former administrator would bring a perspective and breadth of knowledge to the survey team that cannot be found in other clinically focused disciplines.

Finally, given that CMS is encouraging the usage of multiple disciplines among survey teams, CMS should also require that these individuals be demonstrably knowledgeable about the hospice COPs and end-of-life care more broadly. However constituted, a survey team should collectively understand the full background and concept of the hospice IDG, including the social work, bereavement, and volunteer-related aspects of the benefit. Beyond that, in new training materials for survey teams, CMS should ensure there is proper attention paid to the psychosocial and spiritual aspects of hospice care and that said training is conducted by someone familiar with the hospice context in which this work occurs.

Consistency of Survey Results (§ 488.1125)

New section 1822(a)(3) of the Act requires that each State and the Secretary implement programs to measure and reduce inconsistency in the application of hospice program survey results among surveyors. CMS proposes 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.

CMS monitors the consistency of SA surveys through a review of an SA’s Form CMS-2567, which is conducted by its assigned CMS Survey Operations Group (SOG) Location, and consistency among AOs through validation surveys conducted by SAs. The SAs perform validation surveys on a sample of providers and suppliers accredited by the AOs. Validation surveys report disparate findings as the percentage of validation surveys that have conditions identified by the SA but missed by the AO survey team. This percentage is referred to as the “disparity rate” and is tracked by CMS as an indication of the quality of the surveys performed by the AO. Using the disparity rate approach used with AOs, where surveys are reviewed for condition-level deficiencies the AO fails to identify, CMS proposes 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.

Finally, to reduce inconsistencies in survey results among surveyors, CMS proposes to require agencies that review other entities’ survey findings for missed condition-level deficiency citations (disparities), to notify each survey entity of its disparity rate annually, and to require a formal corrective plan as part of the survey entity’s Quality Assurance program.

NPHI strongly supports uniform surveyor training across the board. Given that approximately half of all hospices are surveyed by AOs and that information from all survey findings is proposed to be made public, it is vital that surveyor determinations are based on a consistent understanding of the hospice COPs. Further, NPHI supports the proposed analysis of survey entities' findings, and would request that a report on those findings be made available to hospice providers on an annual basis. We do suggest that CMS add a provision noting that validation surveys be conducted in a timely manner by the AO or SA.

Special Focus Program (§ 488.1130)

Section 1822(b) of the Act requires the Secretary to conduct a Special Focus Program (SFP) for hospice programs that the Secretary has identified as having substantially failed to meet applicable requirements of the Act. CMS proposes to develop a hospice SFP to address issues that place hospice beneficiaries at risk for poor quality of care through increased oversight, and/or technical assistance.

NPHI supports the concept of a SFP that provides additional oversight and technical assistance to providers requiring supplementary help. Our overarching comment regarding this proposal is for CMS to utilize a TEP to inform the creation of the SFP. Importantly, the TEP ought to represent the hospice community as currently constructed, meaning at least one member should be a representative of a not-for-profit hospice provider. In many, if not most instances, not-for-profit hospices serve a critically important function as safety-net providers, ensuring end-of-life care services are available to underserved populations and anyone, regardless of their ability to pay. The very nature of not-for profit hospice providers frequently leads them to focus on priorities that are different but no less important than for-profit organizations. Their patient care practices and administrative practices also tend to differ. Failing to include this important voice on the TEP disadvantages the efforts of CMS to create a valuable and effective SFP that is able to effectively assist underperforming hospices. It is NPHI's position that no design or implementation of the proposed SFP should occur before the TEP is allowed to complete its work.

Regarding the criteria employed to determine whether a hospice program is eligible for participation in the SFP, CMS proposes "two consecutive substantiated complaint surveys." NPHI seeks to clarify the timeframe for the substantiated complaint surveys as proposed.

The proposed rule states that, "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." NPHI seeks to clarify what parameters or priorities a state may or may not employ to determine which hospice programs are included in the state's SFP. We seek this clarification due to the fact that without a set of guidelines or minimum thresholds, significant variation could occur from state to state on how and why a hospice program is chosen for the SFP. This potential degree of variation is not in alignment with the efforts undertaken by CMS in this proposed rule to encourage and ensure consistency across the survey and enforcement landscape.

Regarding the survey frequency for a hospice program in a state's SFP, the proposed rule states that "the SA would survey the facility at least once every six months, as required by the CAA 2021." NPHI suggests that CMS consider whether six months is an appropriate timeframe. Current processes operate such that once a hospice is surveyed, the SA has 10 business days to return the report to the hospice. The hospice then has 10 calendar days to submit a corrective action plan. If the hospice has received a

Condition Level deficiency, the SA will return in 30-45 days. The two 10-day cycles then repeat. Thus, it could take 60 days or more before the corrective action plan is approved. Certainly, a hospice should be working to correct deficiencies from the day they are identified. That said, a survey conducted two months after the corrective action plan is approved would force a hospice to spend substantial time on the structured survey and corrective action plan process, taking time away from actual implementation of the corrective actions driving quality outcomes.

Finally, NPHI thanks CMS for listening to stakeholder input and ultimately determining not to propose the inclusion of a quota structure in the SFP for hospices. We believe this is a meaningful and positive change compared to how the SFP operates for other types of providers.

Enforcement Remedies (§§ 488.1200 through § 488.1265)

General Provisions (§ 488.1210)

CMS proposes to set out the statutory basis for the proposed new subpart at § 488.1200, which are the new sections 1822(c)(1) through 1822(c)(5) of the Act. The requirements under this new subpart would expand the Secretary's options to impose additional enforcement remedies for hospice programs failing to meet Federal requirements. 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. CMS proposes at § 488.1210 general rules pertaining to enforcement actions against a hospice program that is not in substantial compliance with the CoPs.

NPHI is generally supportive of the newly proposed enforcement remedies derived from CAA 2021. We appreciate CMS proposing the additions of a directed POC and directed in-service training as additional enforcement options for the Secretary to consider given the range of potential citations that a hospice may incur. Although punitive measures, including termination from the Medicare program, are appropriate for the most egregious and systemic violations, CMS should seek first to apply proportional remedies that stimulate learning and quality improvement activities that will benefit patients and families.

a. Factors to be Considered in Selecting Remedies (§ 488.1215)

CMS proposes at § 488.1215, consistent with section 1822(5)(B)(i) of the Act, to establish procedures for selecting the appropriate enforcement remedy, including the amount of any CMP and the severity of each remedy, which have been designed to minimize the time between the identification of deficiencies and the final imposition of remedies, as required under section 1822(c)(5)(A)(ii) of the Act.

NPHI requests that CMS consider creating a scope and severity grid for providers reference, similar to what now exists for nursing homes. This is important because deficiencies that are administrative in nature very often do not rise to the same level of threat to patient safety as those that directly impact patient care and thus, should be treated with significant nuance in each individual case. Additionally, we would ask that CMS finalize a clear and stated protocol for the application of enforcement remedies to ensure consistency across the spectrum of potential deficiencies.

b. Suspension of Payment for All or Part of the Payments (§ 488.1240)

CMS proposes in § 488.1240 provisions describing when and how they would apply a suspension of payment of all or part of the payments for items and services furnished by a hospice program on or after the date on which the Secretary determines that remedies should be imposed under § 488.1225 or § 488.1230.

NPHI seeks to clarify whether a suspension of payment would apply to all patients served by the hospice program or only new patients, admitted after the determination was made to impose a suspension of payment. Given that the vast majority of a hospice program's revenue is derived from Medicare fee-for-service payments, a suspension of Medicare payment for all patients would cause dramatic financial instability for the hospice and in turn create a difficult situation for patients and their families. We hope and anticipate that CMS will only choose to utilize this enforcement remedy in limited circumstances where patient safety is in Immediate Jeopardy (IJ), but nonetheless we recommend CMS move forward with a process and procedure for suspension of payments that takes this factor into account and considers the impact such an action may have on providers almost entirely dependent on these payments. Moreover, for not-for-profit hospices operating at an average margin of 3 percent, this issue is even more pronounced.

c. CMPs (§ 488.1245)

CMS proposes at § 488.1245 requirements for the imposition of CMPs. CMS proposes to impose a CMP 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.

NPHI seeks to clarify how the collected CMPs will be stored, for what purpose they will be used, and the timeframe for those decisions to be made. CMS created the Civil Money Penalty Reinvestment Program (CMPPR) for nursing homes that allows states to reinvest some CMP funds to support activities that benefit nursing home residents and that protect or improve their quality of care or quality of life. A similar program for hospices would help support quality improvement and align with the goal of creating parity in enforcement remedies across care settings. We suggest that CMS's finalized policy include a requirement that CMPs be used in the ways outlined above.

Conclusion

Thank you again for the opportunity to provide comment on CMS's proposed CY 2022 Home Health rule. Moreover, we would like to thank CMS for its leadership and essential efforts throughout the ongoing COVID-19 PHE. As always, NPHI appreciates the opportunity to provide insight and commentary into how various proposed regulatory, compliance, and quality reporting changes may impact the not-for-profit hospice and palliative care provider community. If you have any questions concerning these comments or would like to discuss these issues further, please contact NPHI President Carole Fisher at carole@hospiceinnovations.org.

Sincerely,



Tom Koutsoumpas
Founder and CEO
NPHI