



Mary Myers, MS, RN
Chairman of the Board

William A. Dombi, Esq.
President

August 27, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1747-P
P.O. Box 8013
7500 Security Boulevard
Baltimore, Maryland 21244-8013

Submitted via: [regulations.gov](https://www.regulations.gov).

Re: CMS -1747-P The 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, 86 Fed. Reg. 35874 (July 7, 2021)

Dear Administrator Brooks-LaSure:

The Centers for Medicare and Medicaid Services (CMS) and the U.S. Department of Health and Human Services have proposed several reforms affecting the Medicare home health benefit, survey and enforcement requirements for the hospices, and the CY 2022 payment rates in the Notice of Proposed Rulemaking (NPRM). 86 Fed. Reg. 35874 (July 7, 2021).

The National Association for Home Care & Hospice (NAHC) respectfully submits these comments regarding the proposals contained within the NPRM. NAHC is the largest trade association representing

the interests of Medicare home health agencies (HHAs) and hospices nationwide including nonprofit, proprietary, urban and rural based, hospital affiliated, public and private corporate entities, and government run providers of home care since 1982. NAHC members provide the majority of Medicare home care services throughout the U.S.

NAHC is also an original provider-member of the Leadership Council of Aging Organizations (LCAO) as it has put patients first in its health policy and advocacy positions since its inception. Each year, NAHC members serve millions of patients of all ages, infirmities, and disabilities, providing an opportunity for individuals to be cared for in their own homes, the care setting preferred by virtually all people.

These comments are also supported by many members of our Forum of State Associations. We are specifically joined on this letter by numerous state home care associations listed on the final page. Many others are filing their own comments too. State associations are an important voice in understanding impact of the proposed rules in their local settings. Their “on the ground” perspective deserves special attention.

PAYMENT REFORM: PATIENT DRIVEN GROUPINGS MODEL (PDGM)

General Comments

We greatly appreciate the efforts that CMS has employed over the years to modernize the Medicare home health payment model. Further, the degree of transparency provided regarding the development of the Patient Driven Groupings Model (PDGM) has been crucial in permitting stakeholders to fully evaluate it and its potential impacts on patients and home health agencies. After nearly 20 months of operation of PDGM, it is most notable that the home health care environment is nothing like anyone could have forecast in 2019 when the original PDGM rule was finalized. Covid-19 has brought extensive changes in patient mix, significant alteration of the home health patient census, practice changes in all sectors of health care, and a response from patients and prospective patients that is unprecedented in terms of willingness to accept needed health care.

In NAHC comments to the CY2021 NPRM, we indicated that “the PDGM model has been tested in a manner we all hope is not repeated in 2021. At this stage, it is doubtful that anyone can confidently say that it works or does not work.” Unfortunately, the pandemic has continued throughout 2021, continuing the chaos in health care that began in March 2020. Accordingly, NAHC continues its support of a policy that maintains the general structure of PDGM without material modification in 2022. While CMS adopted this policy framework for CY2021, it proposes to diverge from it in CY2022 despite the continuing pressures of the Covid-19 pandemic and its unprecedented impact on health delivery nationwide. As discussed in more detail below, NAHC strongly recommends that CMS withdraw any changes proposed to

the PDGM model that are based on 2020 data, including those that relate to recalibration of the 432 case mix weights.

In the CY2021 rulemaking, NAHC recommended that CMS consider establishing a systemic methodology whereby future expedited adjustments can be made to accommodate impacts such as those triggered by the pandemic during a fiscal year so that access to care can continue for the usual population of home health patients while access can be established for a patient population that did not exist pre-pandemic. We repeat this recommendation this year as the continuation of the pandemic clearly demonstrates that expedited, temporary measures are essential to the continued provision of health care during a Public Health Emergency, including measures that ensure a fair level of payment from Medicare.

Specifically, NAHC survey data indicates that more than half of all HHAs provide service to actively infected Covid-19 patients throughout 2020 and to this point in 2021. In addition, all HHAs have provided services to the patient population that is considered at highest risk of serious complications, including death, from Covid-19. HHAs have admitted infected patients directly from hospital emergency rooms as no beds were available in the facility. HHAs also admitted patients who otherwise would have received care in a skilled nursing facility as infections and fatalities in SNFs rose across the country with some states prohibiting SNF admissions of any nature due to the risks posed. Notably, nearly 10% of Medicare home health admissions in December 2020 were patients with a primary diagnosis of Covid-19. PDGM was not built on that patient population.

While hospitals and SNFs saw significant adjustments made in payment models and payment amounts, HHAs have not. Instead, the Covid-19 patients have had to be fit into a payment model that had no such comparable patients in its foundational database. Further, while the costs of care rose generally for the entire patient population served by HHAs through such continuing cost increases as labor and PPE, the 2021 reimbursement rates did not change. If CMS had included a process for mid-year adjustments for unexpected cost increases, stabilization of home health care access would be more readily achievable.

NAHC offers detailed comments on several aspects of the PDGM-related NPRM in this letter. For purposes of clarity, we offer the following summary of PDGM-related recommendations that are further discussed following the summary.

SPECIFIC PDGM RECOMMENDATIONS:

- 1. CMS should maintain the structure and design of PDGM for 2022.**
- 2. CMS should withdraw its proposal to recalibrate PDGM case mix weights based on 2020 care utilization data. The purpose of recalibration is to reset case mix weights for subsequent years based on the premise that the base year used for recalibration reasonably reflects care delivery expected for the year when the recalibration applies. It is unreasonable to assume that the chaotic year of health care utilization in 2020 is an**

appropriate foundation for 2022. It is highly unlikely that home health care delivery in 2022 will be anything comparable to care delivery in 2020.

3. **CMS should replace its suggested methodology for assessing whether behavioral changes of HHAs resulted in PDGM achieved budget neutrality in comparison to the HHPPS HHRG payment model with a methodology that focuses on behavioral changes, not change in average case mix weight. The replacement model must include a recognition that PDGM triggered changes in behavior in the measures that affected case mix weights, particularly changes in therapy utilization, timing of visits, frequency of visits, and source of care. Any behavioral change impact on a budget neutrality determination cannot rely on a case mix weight comparison through a simple application of the HHPPS-HHRG payment model to 2020 care delivery as such ignores the PDGM behavioral changes that affected HHPPS-HHRG case mix weights. The proposed methodology is fatally flawed in that it does not assesses whether PDGM-driven HHA behavior changes impacted Medicare home health spending in 2020.**

4. **To comply with Medicare law, CMS must apply a PDGM-related budget neutrality adjustment methodology that exclusively is focused on PDGM-triggered behavioral changes. The change assessment methodology proposed by CMS encompasses changes unrelated to HHA behavioral changes under PDGM. Under 42 USC 1395fff(b)(3)(D), CMS may only make permanent or temporary rate adjustments related to the impact of assumed behavior changes and actual behavior changes on estimated aggregate expenditures. Other factors that impact expenditures, including any design flaws in the payment model or changes in patient case mix are not subject to the rate adjustment authority.**

5. **CMS should reconsider its decision to apply the new OMB geographic designations for CBSAs in the annual wage index. Alternatively, CMS should treat all provider types equally in the transition to an updated wage index by extending the 5% ceiling on negative changes in wage index values as it has done for inpatient hospitals. Otherwise, massive payment rate reductions in certain areas of the country will occur, jeopardizing access to home health care services as hospitals protected by the 5% cap will be able to have a more stable financial base, allowing them to recruit staff more successfully from the same pool of professionals that work in HHAs. With a significantly higher wage index, HHAs will be severely disadvantaged in retaining and recruiting staff in comparison to hospitals in the same geographic area. If it is appropriate for hospitals and HHAs to be placed in the same CBSA, CMS should not discriminate against HHAs by giving hospitals a wage index change protection that is not also applied to HHAs.**

- 6. CMS should establish a process and methodology to modify HHA payment systems and rates during a Public Health Emergency to address new costs triggered by the PHE or unpredicted limitations in payment models.**

CMS Should Maintain the Structure and Design of the Current PDGM Model

CMS proposes to maintain the existing structure and design of PDGM noting that full data is not yet available for 2020 and 2021. NAHC agrees with this proposed policy direction for 2022. With the extended Public Health Emergency (PHE) due to the Covid-19 pandemic, HHAs need stability and predictability in the Medicare fee-for-service home health benefit. Chaotic is an understated description of health care experiences in all sectors since the onset of the PHE in March 2020. Virtually all HHAs have taken on a patient population of Covid-19 infected patients that were not even contemplated when PDGM was designed and initiated as the payment model in 2020. In December 2020 alone, preliminary data indicates that over 9% of HHA Medicare admissions were patients with Covid-19 infection as a primary diagnosis.

The PHE also brought other significant changes in patients and patient care that continue today as the virus surges in many parts of the country. Hospital admission was closed off to elective surgeries for many months, including joint replacement patients that often need post-surgery services under the home health benefit. Nursing home admissions were blocked for months and are still restricted today, leaving HHAs with higher acuity patients. HHAs continue to employ significant use of unreimbursed telehealth services to reduce infection spreading risks to patients and staff in 2020 and 2021. Massive cost increases related to Personal Protective Equipment and infection control measures continue today.

In 2021, CMS recognized the wisdom of avoiding adding unnecessary pressures on HHAs that transitioned to a wholly different payment model during the pandemic in maintaining a stable PDGM. The pandemic pressures have unfortunately continued and, in recent weeks, have reached unprecedented levels within the pandemic as the Delta variant surges. While we all hope that the end of the pandemic or at least its control is within reach, now is not the time to modify PDGM in any material way.

Generally, CMS proposes to keep the framework of PDGM in place without significant alteration. NAHC fully supports that proposal. However, NAHC strongly counsels against the proposal to recalibrate all 432 case mix weights based on 2020 service resource utilization as discussed below.

RECOMMENDATION: CMS should maintain the structure and design of PDGM for 2022.

CMS Should Not Recalibrate PDGM Case Mix Weights for 2022

CMS proposes to recalibrate all 432 PDGM case mix weights for 2022. The proposed recalibration is based on perceived differences in the utilization of services and supplies in 2020 in comparison to utilization in the PDGM case mix weight base year. In recent years, CMS has recalibrated the case mix weights in the home health services payment model as frequently as on an annual basis. Recalibration is not mandated under 42 USC 1395fff. Further, in the 21 years of home health prospective payment, case mix weights have not been always annually recalibrated. CY2022 is not a year when recalibration is advisable.

It is axiomatic that 2020 was an unprecedented year in health care. It is highly unlikely that the experiences of 2020 will be repeated in 2022. Certainly, they will not be repeated in home health care as we have already seen significant signs of a return to the more usual manner and mode of care delivery in by HHAs. The most telling sign is the reduction in LUPAs that hit a high point in mid-2020 at levels that were as much as 3 to 5 times normal for individual HHAs. For the overall 2020 year, CMS in the NPRM reports just under 9% LUPAs in contrast to the predicted 5-6% incidence. However, the 9% annual level reflects a steady decline in LUPAs in the 4th quarter of 2020.

Similarly, patient hesitancy to allow HHAs into their homes changed in the second half of 2020 as they became more comfortable with and confident in the infection control measures of HHAs. This not only led to reduced LUPAs, that patient hesitancy also led to reduced reliance on telehealth as an alternative to in-person care and expanded patient populations.

In 2020, HHAs also had to manage their health care staff as their infection rates rose, staff departed for non-frontline jobs, care demands exceeded care supplies.

The purpose of recalibration of case mix weights is to align reimbursement with variations in resource use and costs in the delivery care. Such is well warranted as care gradually changes from one year to the next or when it is necessary to correct errors in case mix weight design as may occur in new payment models. However, it is rational to recalibrate case mix weights only when the data year is a fair representation of what is expected resource utilization in the recalibration year. Here, it cannot be expected that 2022 care will look anything like it did in 2020. Instead, any “new normal” is more likely to look fairly like the pre-Covid normal that the unprecedented experiences in 2020.

In such circumstances, the better course of action is stability rather than change. In the absence of solid evidence that the case mix weights caused significant difficulty in patients accessing care or triggered a material deterioration in the quality of care, it is time to be cautious and maintain the system that was designed to reflect a pre-Covid health care world rather than change to one that represents the unique Covid-world of 2020.

RECOMMENDATION: CMS should withdraw its proposal to recalibrate PDGM case mix weights based on 2020 care utilization data. The purpose of recalibration is to reset case mix weights for subsequent years based on the premise that the base year used for recalibration reasonably reflects care delivery expected for the year when the recalibration applies. It is unreasonable to assume that the chaotic year of health care utilization in 2020 is an appropriate

foundation for 2022. It is highly unlikely that home health care delivery in 2022 will be anything comparable to care delivery in 2020.

CMS's Proposed Methodology for Evaluating PDGM Budget Neutrality Impact is Flawed and Must be Replaced by an Appropriate Alternative Method

Under 42 USC 1395fff, CMS is required to engage in a reconciliation process to “true up” payment rates to achieve budget neutrality in comparison to the current HHPPS-HHRG payment model through 2026. In 2019, NAHC recommended that CMS establish the standards and process for future behavior adjustments and payment reconciliation at the outset of PDGM. Those standards were not established in the CY 2020 rulemaking. However, NAHC recognizes and very much appreciates that CMS has provided a detailed explanation of a proposed methodology in the CY 2022 rulemaking, offering interested parties with opportunity to evaluate that proposal and present recommendations on changes and/pr alternative methods. An appropriate methodology CMS should include standards for determining nominal versus real change in case mix, as well as changes that affect other aspects of Medicare home health spending such as Medicare enrollment, increased/decreased utilization of home health services, modification/improvement of enforcement of coverage standards (e.g. maintenance therapy; home infusion therapy), behavior changes in other PAC services that affect home health utilization, technological advances, and other factors that may contribute to Medicare spending changes not specifically related to PDGM. Crucially important, the methodology must recognize that 2020 Medicare aggregate spending on home health services in the absence of the PDGM reform would conform to the behavior practices that existed under HHPPS-HHRG, not PDGM. Such an approach is essential without regard to the impact of the Covid-19 pandemic. These are elements of a rational methodology even if the pandemic did not occur.

Applying appropriate standards and methods in this evaluation is not simple. It certainly is not as simple as comparing the average case mix weight under the PDGM system in 2020 with the calculated case mix weight under the predecessor system applied to a PDGM behavior changed 2020. NAHC very much recognizes the difficulties of estimating what would have happened in 2020 spending if PDGM never existed. Such an exercise is laden with a combination easy calculation along with nearly endless assumptions. In fact, the reliability of any method may be suspect. As such, the course of action may be to withhold from the evaluation altogether. However, one thing is abundantly clear, the methodology proposed by CMS fails to be rational on multiple counts and must be replaced.

A starting point in an appropriate methodology would be to evaluate the accuracy of the behavior change assumptions and calculations that CMS made in the CY2020 rulemaking. The NPRM indicates that such analysis has not been done. At the same time, data readily available to CMS indicates that the expected inflation in the primary diagnosis measure did not occur. Further, the expected reduction in LUPA instead ended up with a massive increase. Data on reported comorbidities appears to indicate a slightly higher scoring than anticipated. Together, the fact that the assumed behavior changes did not occur, warrant that

CMS discontinue the application of these assumptions through continued application of a 4.36% rate reduction in CY2022.

A second element of the evaluation must be an assessment as to extent to which those factors relevant to case mix categorization are affected or impacted by a “real” change in patients served by HHAs or a “nominal” change. CMS has multiple incidences where such an analysis has been performed. Without repeated past NAHC comments on the reliability and validity of the CMS assessment of real versus nominal change, some form of that assessment is essential when considering whether PDGM was a budget neutral reform.

The third element that is needed in any appropriate methodology may be the most difficult to apply but is the most crucial component. Any comparison of the outcome of PDGM on Medicare spending neutrality must be based on a “PDGM behavior change neutral assessment” of what would be the outcome spending under HHPPS-HHRG. CMS’s establishment of 2020 PDGM payment rates were based on a series of assumed behavior changes that the reimbursement model would trigger. The proposed methodology, however, is not based on the behaviors that would be reasonable to assume would continue if the HHPPS-HHRG model continued to apply in 2020.

There are many likely HHPPS-HHRG influenced behaviors that would have continued if PDGM did not come into operation. Some of these behaviors affected payment rates and others affected overall payments. These include, but are not limited to:

- The nature of the patients admitted into care
- The length of stay of admitted patients
- The timing of visit delivery
- The source of admission
- The volume and timing of therapy visits

Of these, the most notable is the volume and timing of therapy visits as such had a significant impact on payment rates, aggregate payments to individual HHAs and HHAs spending overall, and a provider’s focus on a preferred patient census. This should come as no surprise to CMS because a prime purpose of replacing HHPPS-HHRG with PDGM was to divorce the payment model from the highly criticized influence of the financial incentives of a model that offered higher payment rates tied to increases in therapy volume in an episode of care. The HHPPS-HHRG model also influenced the scheduling of therapy visits as significant increases in payment occurred with 14 and 20 visits during a 60-day episode. For example, it was financially advantageous for an HHA to schedule therapy visits such that no more than 20 were provided in an episode if it was clinically acceptable to schedule any additional therapy in a second episode. This is not to say that HHAs improperly served patients. However, it is a strong indication that CMS needs to recognize that PDGM might trigger certain behavior changes that increase payment while ending certain behaviors that CMS believed took place under the predecessor payment model that increased payments in the past.

The impact of the payment model changes on therapy services is addressed in detail in the attached analysis by the consultant group, Dobson-DeVanzo on behalf of the Partnership for Quality Home Healthcare. NAHC adopts this analysis in these comments. While the analysis makes a very convincing case on the impact of eliminating therapy volume on 2020 HHA service delivery practice, NAHC notes

that there are several other factors such as those listed above that also are behaviors that are impacted by the PDM reform that must be accounted for in a true budget neutrality analysis.

In summary, the flaws in the proposed methodology are as follows:

1. The methodology never evaluates the end accuracy of the behavior change assumptions that CMS employed in the CY2020 rate setting under PDGM
2. The methodology never analyzed the difference between real and nominal changes in case mix.
3. The methodology failed to compare PDGM spending outcomes to what would have occurred in 2020 without PDGM induced changes and the continuation of HHPPS-HHRG incentives and disincentives.

In NAHC's CY2021 comments, we recommended that CMS consider convening a Technical Expert Panel (TEP) to fully explore and design a consensus-based methodology to evaluate PDGM budget neutrality. The complexities evident is such an undertaking warrant such a process. The risk of adverse impact on home health services through an inaccurate assessment methodology further warrant a TEP process especially given the current CMS projection that HHAS have been overpaid by 6% in 2020 under the proposed assessment methodology. Certainly, there is sufficient time to convene a TEP in advance of the CY2023 rulemaking.

RECOMMENDATIONS:

1. **CMS should replace its suggested methodology for assessing whether behavioral changes of HHAs resulted in PDGM achieved budget neutrality in comparison to the HHPPS HHRG payment model with a methodology that focuses on behavioral changes, not change in average case mix weight. The replacement model must include a recognition that PDGM triggered changes in behavior in the measures that affected case mix weights, particularly changes in therapy utilization, timing of visits, frequency of visits, and source of care. Any behavioral change impact on a budget neutrality determination cannot rely on a case mix weight comparison through a simple application of the HHPPS-HHRG payment model to 2020 care delivery as such ignores the PDGM behavioral changes that affected HHPPS-HHRG case mix weights. The proposed methodology is fatally flawed in that it does not assesses whether PDGM-driven HHA behavior changes impacted Medicare home health spending in 2020.**
2. **CMS should restore the 4.36% reduction in payment rates as the assumed behavior changes have not occurred.**

Medicare Law Permits a PDGM Rate Adjustment Only to Offset Changes in Estimated Aggregate Expenditures Related to 2020 Behavior Adjustments

CMS's proposed methodology for assessment as to whether actual PDGM aggregate expenditures in 2020 equaled a budget neutral level in relation to the level of expenditures is not limited to a focus on PDGM triggered behavior changes. If CMS employs this methodology, it will violate 42 USC 1395fff(b)(3)(D). Specifically, section 1395fff(b)(3)(D)(i) provides that:

The Secretary shall annually determine the impact of differences between assumed behavior changes (as described in paragraph (3)(A)(iv)) and actual behavior changes on estimated aggregate expenditures under this subsection with respect to years beginning with 2020 and ending with 2026.

The referenced behavior changes in paragraph (3)(A)(iv) are those “that could occur as a result of the implementation of paragraph (2)(B) and the case-mix adjustment factors established under paragraph (4)(B) ...” Paragraph (2)(B) refers to the establishment of a 30-day episode of payment that began in 2020 under PDGM.

Permanent and temporary rate adjustments are authorized only for purposes of an “offset for such increases or decreases in estimated aggregate expenditures (as determined under clause (i)...” 42 USC 1395fff(b)(3)(D)(ii) and (iii).

Accordingly, CMS must utilize a PDGM budget neutrality methodology that is solely focused on assumed behavior changes that were incorporated into the original 2020 rate setting. Those assumed behavior changes were related to the primary diagnosis, LUPA volume, and incidence of comorbidities as each measure affected the 432 PDM case mix adjusted rates or payment. Notably absent from the proposed methodology is the mandated focus on assumed behavior changes. Instead, the proposed methodology is tied to changes in average case mix weights. As discussed above, the change in case mix weights is not consistent with a focus on assumed behavior changes. As further stated above, that methodology is fatally flawed in other respects in that it incorporates actual behavior changes both related and unrelated to the 2020 assumed changes under PDGM into the calculation as to what Medicare spending would be if the HHPPS-HHRG payment model remained in place in 2020. CMS must replace its budget neutrality assessment methodology with one that meets the mandated standards in 42 USC 1395fff(b)(3)(D).

RECOMMENDATION: CMS must apply a PDGM-related budget neutrality adjustment methodology that exclusively is focused on PDGM-triggered behavioral changes. The change assessment methodology proposed by CMS encompasses changes unrelated to HHA behavioral changes under PDGM. Under 42 USC 1395fff(b)(3)(D), CMS may only make permanent or temporary rate adjustments related to the impact of assumed behavior changes and actual behavior changes on estimated aggregate expenditures. Other factors that impact

expenditures, including any design flaws in the payment model or changes in patient case mix are not subject to the rate adjustment authority.

The 2022 Wage Index Discriminates Against Certain HHAs in a Manner that Favors Hospitals that Employ Staff from the Same Geographic Area

In CY2021, CMS modified the wage index area designations for all providers subject to wage index adjustments in payment rates. In doing so, CMS reset the Core-Based Statistical Areas (CBSA) in a manner that reflects findings of the Office of Management and Budget (OMB) relative to economic marketplaces for labor. As some of the modified CBSA designations led to significant reduction of wage index values in certain areas of the country, CMS implemented a budget neutral cap on negative adjustments set at 5%.

To illustrate the depth of the potential reduction in wage index values, the example of CBSAs 35614 and 35154 stand out. CBSA 35614 generally encompasses the New York City metropolitan area including parts of New Jersey. The revised CBSA designation maintained an application to some New Jersey counties but excluded several previously included New Jersey counties. Those excluded New Jersey counties include Monmouth, Middlesex, and Ocean. The excluded counties had been included in the New York City CBSA for at least a decade. The redesignation has a dramatic effect on the applicable wage index for those excluded counties, reducing the CY2022 wage index from 1.3389 to 1.0578. If this proposed change is finalized, home health payment rates for services provided to residents of those counties will drop precipitously from the 5% reduction already experienced in CY2021 (1.2108) by an additional 11.5%.

The first question is whether it was appropriate to reclassify the New Jersey counties from CBSA 34614 to 35154. There are important indicia that the reclassification was not warranted. Health care employers in those newly designated CBSA 35154 counties routinely employ workers from the same employment pool as providers in those counties within CBSA 35614. In addition, the labor costs that are used to determine CBSA designations and wage index values remain comparable in the newly designated 35154 CBSA counties and those counties in CBSA 35614. Specifically, hospitals in Middlesex, Monmouth, and Ocean counties report average hourly wages of \$50.2173, \$50.4721, and \$50.5437 respectively. (CCN 310039; 310034; 310052). In comparison hospitals in the CBSA 35614 pool report average hourly wages of \$39.33 (Passaic CCN 3100060), \$48.25 (Bergen CCN 310008), \$52.35 (Bergen CCN 310012), and \$45.62 (Hudson CCN 310025). These data demonstrate that the CBSA reclassification for the affected New Jersey counties was unwarranted.

The second question is why CMS decided to extend the protective 5% cap on negative wage index changes for hospitals, but not HHAs or other Medicare providers. <https://public-inspection.federalregister.gov/2021-16519.pdf>. There is no basis for concluding that hospitals deserve special protection from the effects of the CBSA redesignations, but that HHAs, hospices, SNFs, and rehabilitation facilities do not. In fact, since all these providers compete for the same labor pool they warrant equal treatment, not discrimination. At the same time, due to the likely unprecedented reduction in wage index values triggered by the CBSA redesignation, all providers warrant a cap on any negative adjustment.

A payment rate reduction over two years of nearly 15% and a 2022 reduction over 11% is not sustainable without access to care consequences.

RECOMMENDATION: CMS should reconsider its decision to apply the new OMB geographic designations for CBSAs in the annual wage index. Alternatively, CMS should treat all provider types equally in the transition to an updated wage index by extending the 5% ceiling on negative changes in wage index values as it has done for inpatient hospitals. Otherwise, massive payment rate reductions in certain areas of the country will occur, jeopardizing access to home health care services as hospitals protected by the 5% cap will be able to have a more stable financial base, allowing them to recruit staff more successfully from the same pool of professionals that work in HHAs. With a significantly higher wage index, HHAs will be severely disadvantaged in retaining and recruiting staff in comparison to hospitals in the same geographic area. If it is appropriate for hospitals and HHAs to be placed in the same CBSA, CMS should not discriminate against HHAs by giving hospitals a wage index change protection that is not also applied to HHAs.

CMS Rate Setting Should Account for Costs Related to the Public Health Emergency That Can Be Expected to Continue in 2022

CMS has proposed a 1.7% rate adjustment for 2022 based on 2.4% Market Basket Index (MBI) and a 0.6% Productivity Adjustment (PA). NAHC is aware that CMS modified both the MBI and PA in other sectors in final rules that take effect on October 1, 2021. However, neither those changes in other sectors nor the proposed 2022 rate adjustment in home health services adequately account for the increased costs of care in 2021 that are highly likely to continue in 2022. Foremost among those cost increases that are not adequately represented in the MBI is Personal Protective Equipment and other infection control costs.

As indicated earlier, NAHC believes the PPE costs alone have increased per visit costs by approximately \$11.50 or nearly 5% of the current base episodic rate. The PPE cost increases began in 2020 and have continued in 2021. The MBI reflects increase in the cost of goods and labor, but it does not address new costs or volume increases in the use of such items as PPE.

While the end point of the Covid-19 pandemic is unfortunately not known, it is reasonable and fair to conclude that the use of PPE will be maintained at levels comparable to 2020 throughout CY2021 and into 2022. As such, the increased cost of care, as experienced in 2020-2021, as it relates to PPE will continue in 2022. CMS could include a PPE cost add-on to the 2022 payment episodic and per visit payment rates. Conceptually, an add-on has been used in Medicare home health services previously to reflect the administrative costs of OASIS and other administrative activities for LUPA-only patient care. HHAs are prepared to support the add-on costs of PPE to the point of reliable data. These are examples of a method CMS can employ to address unforeseen cost changes that are not reflected in the MBI.

RECOMMENDATION: CMS should establish a process and methodology to modify HHA payment systems and rates during a Public Health Emergency to address new costs triggered by the PHE or unpredicted limitations in payment models.

THE NOTICE OF ADMISSION POLICY REQUIRES FINE TUNING

NOA RECOMMENDATIONS:

- 1. CMS should not assess the late submission penalty for the NOA until the issues that negatively impact HHAs are resolved.**
- 2. CMS should provide clear and timely instructions to HHAs related to the identified system issues**
- 3. CMS should include payer changes to the list of exceptions to the NOA timely submission penalty. CMS should require the MACs to request an ADR if addition information is required to decide on a payer change exception.**
- 4. CMS should include other providers overlapping in the CWF as a listed exception to the NOA timely submission penalty. CMS should require the MACs to request an ADR if addition information is required to decide on whether the HHAs was prevented from submitting a timely NOA due other another provider's actions.**
- 5. Instruct the MACs to not apply the timely submission penalty if the original NOA is submitted timely but must be canceled and resubmitted.**

Beginning January 1, 2022, CMS will replace submission of the No Pay RAP with a Notice of Admission.

Like the No-Pay RAP the NOA carries a late submission penalty for HHAs. HHAs that do not submit the NOA within 5 calendar days of admission receive a reduction in payment that is equal to a one-thirtieth reduction to the wage and case-mix adjusted 30-day period payment amount for each day from the home health start of care date until the date the HHA submitted the NOA.

NAHC continues to hear from HHAs about significant issues with the No-Pay RAP timely filing policy that is unfairly penalizing HHAs. The following issues will continue to negatively impact HHAs with the implementation of the NOA.

Beneficiaries Switch from Medicare Advantage to Fee-For-Service Medicare

Patients often switch payers that is not communicated to the HHA by the plan or noted in the common working file (CWF) until several days after admission to the agency. For example, one agency reported that an MA plan had authorized services for the patient and paid the claim for a patient that had disenrolled from the plan prior to the HHA admission. The agency did not become aware of the disenrollment until the MA plan requested the payment be returned. The Medicare Administrative Contractor (MAC) did not allow an exception to the penalty even though the MA plan had the patient listed as an enrollee when admitted to the HHA. NAHC is aware that many times the MACs are applying penalty without requesting additional documentation, which would have provided the agency with proof that the late RAP was beyond the agency's control

Payer changes impacting the 5-day submission time frame was a concern that NAHC commented on when the NOA and No-pay RAP were proposed. CMS noted in their response that circumstances around payer changes would meet the exception.

A RAP is cancelled, and new RAP is submitted

The new RAP cannot be submitted until the original RAP is cancelled in the Medicare system. The RAP cancellation by the system can take several days. Contractors are not allowing an exception to timely RAP filing if the new RAP is submitted later than two days from when the HHA submits the cancelled RAP, regardless of how long it has taken the system to process the cancelled RAP. The contractors are not allowing an exception even when the RAP is submitted within two days of the system cancellation of the RAP. In addition to setting an impossible standard for resubmission of the RAP, there is no requirement to resubmit the RAP within two days from the cancellation. According to the CMS Manual it is a general expectation, not a requirement. In addition, prior to the initiation of the No-Pay RAP policy, CMS had informed HHAs that a late penalty would not be applied to resubmitted RAPs if the original RAP was submitted timely.

Overlapping periods with other HHA RAPs and hospice discharges

The HHA must wait for the other HHA provider to cancel the RAP or the hospice to enter the discharge. The need to work with other agencies outside the HHAs has caused delays in RAP submissions. The HHA does not have the ability to control or enforce administrative requirements for other providers.

Other Medicare system issues that raise concerns regarding the NOA implementation

When an agency discharges in a second 30-day period without visits to the patient but the first period claim end date from the "transferring from" agency is the through date of the claim vs. the true discharge

date. In this scenario, there would be a “gap” of days between the first agency claim through date (where that claim is changed to a discharge status of 06, transfer) and the second agency transfer in date. This could create an incorrect PEP adjustment

The current Medicare manual states to use the through date of a claim as the discharge date if the patient dies, but if the patient were to die after the period end date without any visits in that second period, the accurate date of death would not be reflected on the claim.

HHAs need additional guidance from CMS related to how providers are to handle situations when they enter a discharge in a second period, but no billable visits are provided. Since there is no claim submitted for the second period, the system does not register that the patient has been discharged. Therefore, an open admission period remains in the CWF. Current interim guidance on this situation for the No-Pay RAP is for providers to cancel their second period RAP, however, the NOA, cancelling an NOA will not be an option.

RECOMMENDATIONS:

- 1. CMS should not assess the late submission penalty for the NOA until the above issues that negatively impact HHAs are resolved.**
- 2. CMS should provide clear and timely instructions to HHAs related to the system issues identified above**
- 3. CMS should include payer changes to the list of exceptions to the NOA timely submission penalty. CMS should require the MACs to request an ADR if addition information is required to decide on a payer change exception.**
- 4. CMS should include other providers overlapping in the CWF as a listed exception to the NOA timely submission penalty. CMS should require the MACs to request an ADR if addition information is required to decide on whether the HHAs was prevented from submitting a timely NOA due other another provider’s actions.**
- 5. Instruct the MACs to not apply the timely submission penalty if the original NOA is submitted timely but must be canceled and resubmitted.**

NAHC SUPPORTS AN EXPANSION OF MODIFIED HHVBP NATIONWIDE

HHVBP GENERAL RECOMMENDATIONS:

- 1. CMS should establish a Technical Expert Panel (TEP) to evaluate the proposed HHVBP measures to ensure that the measures appropriately consider the full scope of the patient**

- population served with the home health benefit, particularly patients not likely to experience condition improvement.
2. **CMS should consider extending the start date for an expanded HHVBP to provide HHAs with sufficient time to institute operational reforms that would fuel success under the program.**
 3. **CMS should establish HHVBP cohorts that reflect the wide variation in health care utilization rather than apply nationwide cohorts of large and small HHAs.**
 4. **CMS should reduce the level of payment at risk in the expanded HHVBP to 3% based on the rationale in starting with 3% in the original demonstration.**
 5. **CMS should include a “shared savings” component to HHVBP to enhance the incentives that led HHAs to achieve significant savings to Medicare.**
 6. **CMS should provide the 2022 bonus payments that would otherwise be due to the HHAs in the nine states in the original HHVBP demonstration project.**

Since initiation of the program, NAHC has supported the philosophy and concepts behind the Home Health Value-Based Purchasing (HHVBP) demonstration program. We have long believed that HHAs bring a dynamic value to health care, preventing cost-increasing hospitalizations, reducing use of institution-based post-acute care, maintaining individuals with multiple chronic illnesses, and slowing progression on functional deterioration of aged individuals with various neurological conditions. The four years of HHVBP have established this dynamic value that comes through appropriate use of the Medicare home health benefit. As such, an expansion of HHVBP is well warranted.

CMS estimates that HHVBP has saved \$141 million in annual Medicare spending because of reduced hospitalizations and use of SNF care, among other impacts. Equally important is the finding that the nine states in the original HHVP demonstration reached a 4.6% improvement in patient care quality scores. HHVBP is an unrivaled success for CMS in achieving both quality improvement and expenditure savings. Clearly, HHAs responded to the incentives built into HHVBP. Those incentives are a combination of potential financial reward and the opportunity to fully establish to Medicare what HHAs have known for many years—home health care means value to patients and payers.

CMS now proposes to expand HHVBP nationwide beginning in CY2022. Certainly, an expansion of the demonstration meets all the required criteria, such expansion also has the support of NAHC and the HHA community.

General Concerns with the Proposed Expansion of HHVBP

While NAHC supports a nationwide expansion, we also recommend that CMS consider several modifications to the proposed expansion. The NPRM indicates that CMS has taken a very thoughtful approach in determining the design of the expansion. We are especially appreciative of CMS's acknowledgement that the full Medicare home health patient population needs to be considered in the design. Too often patients with chronic illness or those at the end of life have not been addressed in policy action in Medicare. The original HHVBP does not adequately address the value of high-quality home health services for these populations. With the proposed nationwide HHVBP, CMS attempts to rectify this weakness. Still, we believe more can be done using additional measures along with a modified risk adjuster that accounts for this patient population. While CMS believes that the proposed combination of TNC Self-Care and TNC Mobility measures "represent a new direction" in how patients at risk of functional decline, these measures still have a primary focus on functional improvement. NAHC invites CMS to consider a Technical Expert Panel (TEP) for an ongoing evaluation of HHVBP measures throughout the proposed demonstration project.

Several other modifications should be considered.

First, as NAHC discussed with CMMI officials prior to the release of the NPRM we believe that one reason that HHVBP succeeded while other VBP demonstrations did not was the advance opportunity to fully educate on HHVBP and to determine and implement operational changes intended to contribute to HHVBP success. Nearly a year of advance preparation was available to the nine states in the original HHVBP. Here, CMS proposes a massive expansion of HHVBP with significant design modification including the nature of cohorts of competing HHAs and new performance measures, yet HHAs will effectively have only two months between the issuance of the CY2022 Final Rule and the start of the new HHVBP. It would be highly prudent for CMS to push back the start of HHVBP to provide the crucial prep time that can help with the program's success.

Second, NAHC is very concerned in the use of a nationwide cohort of HHAs in the project. The greatest concern is centered around the widely recognized variations in health care practice and utilization nationwide. As headlined on the website that displays the Dartmouth Atlas Project, this landmark annual study of health care utilization "has documented glaring variations in how medical resources are distributed and used in the United States" for more than 20 years. <https://www.dartmouthatlas.org/> CMS is well aware that such "glaring variations" notably include post-acute care services such as home health care.

Home health services utilization variations are extraordinarily wide. The average number of nursing, therapy, and home care aide visits per episode of care shows no commonality nationwide. For example, in 2019 Medicare cost report data that relies on inputs from PS&R reports indicate that Oregon HHAs provided an average of 14.8 visits per episode while 20.8 visits were provided on average in Utah. These data are only a small sampling of the wide variation in home health services. Such variation exists throughout the health care sectors.

HHAs do not operate in a vacuum. The patients they admit from multiple referral sources are affected by their pre-home health care. Likewise, patient outcomes are affected by the ancillary care

provided during an episode of home health services. There are also payer impacting effects, particularly for dual-eligibles and enrollees in Medicare Advantage. While not a perfect manner to address these care variations, the application of state-based cohorts goes a long way to so, far better than using a single nationwide cohort of large and small HHAs. It appears that CMS proposes a nationwide cohort model for the primary purpose of having enough “small” HHAs in a cohort. That is not sufficient justification to displace the concerns existing in the “glaring variations” in health care services utilization.

An additional concern arises with the proposal to use national cohorts of HHAs in the expanded HHVBP. Nine states began the current HHVBP four years ago. That gives those states a head start advantage in understanding the program and having adopted clearly successful changes in operations to succeed in HHVBP. It also advantages those states as they generally have performance scores already that exceed the average HHA.

Third, while CMS proposes a starting point of 5% of payment at risk in HHVBP as a middle ground between the 3% starting point in the original project and its current 8% level, it does not account for the reasoning that CMS used in starting the original HHVBP. Then CMS concluded—

we agree with commenters that providing some additional leeway for HHAs to ensure compliance with the model is important and would also address concerns associated with moving competing HHAs from FFS incentives to VBP financial incentives tied to quality measures. Accordingly, under our final policy, we are reducing the payment adjustment percentage in CY 2018 from 5-percent to 3-percent. Further, by responding to these practical concerns, the conceptual model remains intact with the capacity to test the effect of higher incentives on quality. 80 Fed. Reg. 68624, 68687 (Nov. 5, 2015).

Given the success of the original HHVBP it would be wise for CMS to follow the path previously travelled if CMS seeks to mirror that success in an expanded HHVBP.

Fourth, since CMS has proven that financial incentives provided to home health agencies to improve care quality and secure Medicare savings truly work, CMS should consider enhancing the positive financial incentives. Specifically, NAHC recommends that CMS provide a share of the savings Medicare achieves with those HHAs responsible for that savings. CMS estimates that over the five years of the proposed project, Medicare will achieve savings of \$3.154 Billion, primarily through reduced hospitalization costs. Notably, CMS estimated the original HHVBP project to reach savings of \$380 million over five years and the actual savings over four years is nearly \$600 million.

Other VBP demonstration projects have based incentives on a share of the Medicare savings. With over \$3 Billion in projected savings, CMS could improve the likelihood of success by providing any HHA that has contributed to the savings through performance improvement with a share of that savings. Such would be highly consistent with the finding that incentivized HHAs trigger material savings for Medicare. It would also rectify a weakness in the original HHVBP model where HHAs that achieved performance improvement and delivered savings to Medicare may have ultimately suffered a payment reduction because the improvements did not equal or exceed the average performance improvements of other HHAs in its cohort. NAHC recommends that contributing HHAs receive a 25% share of the HHVBP savings.

Fifth, the proposal to institute an early end to the original HHVBP raises questions of fairness. In doing so, CMS would deprive HHAs that bore the costs and burdens of performance improvement actions to be eligible for a performance bonus as high as 8%. Those costs and burdens have already occurred. The relevant performance year is already completed. Still, CMS proposes to retroactively end the program. In other words, Medicare got the benefit of the HHAs' quality improvement performance but does not want to keep up its end of the bargain to reward high performing providers. To the extent there is concern that the chaotic year of 2020 with the Covid-19 pandemic justifies an early end to the demonstration project, NAHC suggests that CMS apply some sort of risk adjustment to account for Covid driven impacts.

HHVBP GENERAL RECOMMENDATIONS:

- 1. CMS should establish a Technical Expert Panel (TEP) to evaluate the proposed HHVBP measures to ensure that the measures appropriately consider the full scope of the patient population served with the home health benefit, particularly patients not likely to experience condition improvement.**
- 2. CMS should consider extending the start date for an expanded HHVBP to provide HHAs with sufficient time to institute operational reforms that would fuel success under the program.**
- 3. CMS should establish HHVBP cohorts that reflect the wide variation in health care utilization rather than apply nationwide cohorts of large and small HHAs.**
- 4. CMS should reduce the level of payment at risk in the expanded HHVBP to 3% based on the rationale in starting with 3% in the original demonstration.**
- 5. CMS should include a "shared savings" component to HHVBP to enhance the incentives that led HHAs to achieve significant savings to Medicare.**
- 6. CMS should provide the 2022 bonus payments that would otherwise be due to the HHAs in the nine states in the original HHVBP demonstration project.**
- 7. CMS should develop measures that reward stabilization in patients with chronic and/or unstable conditions**
- 8. CMS must ensure that robust and effective risk adjustment models are applied to any measure selected for the HHVBP program to account for the variation in patient profiles admitted for home health services.**
- 9. NAHC supports aligning the measures in the HHVBP program with the measures reported in the HH QRP. However, CMS should give HHAs ample time, at least one year, to become familiar with the Home Health Within Stay Potentially Preventable Hospitalization measure, and to affect outcomes, if needed, before including it in the HHVBP program.**

HHVBP Quality Measures: General Considerations Used for the Selection of Quality Measures for the Expanded HHVBP Model

Current measure selection

Like the original HHVBP model the measures selected for the expanded model largely reflect a patient's improvement in function, mobility, and self-care. These improvement measures have been part of the home health quality reporting program for almost two decades. Since that time, it has been recognized that patients admitted to home health increasing have chronic and/or co-morbid conditions. This is a result of treatment advancements for chronic condition along with the oldest cohort of Medicare beneficiaries (ages 80-90) requiring home health care at a greater rate than younger Medicare beneficiaries. Therefore, commensurate with changing patient profiles the goal for home health care is to prevent decline rather than aim for improvement in health status. The emphasis on improvement measures couple with the higher weights assigned to the hospitalization and emergency department use measures may serve to disincentivize home health agencies from accepting onto service Medicare beneficiaries that have chronic and/or unstable conditions.

RECOMMENDATIONS:

- 1. CMS should develop measures that reward stabilization in patients with chronic and/or unstable conditions**
- 2. CMS must ensure that robust and effective risk adjustment models are applied to any measure selected for the HHVBP program to account for the variation in patient profiles admitted for home health services.**

Proposed future measure selection

CMS proposes to replace the Acute Care Hospitalization During the First 60 Days of Home Health measure and Emergency Department Use Without Hospitalization During the First 60 Days of Home Health measure with the Home Health Within Stay Potentially Preventable Hospitalization Measure beginning with the CY 2023 HHQRP. CMS plans to replace the two current measures with a new home health hospitalization measure because meets CMS' criteria to remove a when a measure is available that more strongly associated with desired patient outcomes.

CMS seeks public comment on whether to align the expanded HHVBP Model with the proposed changes for HH QRP by proposing to remove the same two measures from the expanded Model and replacing it with the new hospitalization measure in a future year.

NAHC supports aligning the measures in the HHVBP program with the measures reported in the HH QRP. However, CMS should give HHAs ample time to become familiar with the Home Health Within Stay Potentially Preventable Hospitalization measure, and to affect outcomes, if needed, before including it in the HHVBP program.

Additionally, there is concern with including observation stays in the measure. Observation stays function more as an extension of an emergency department stay rather than an alternative to an inpatient stay. As noted in the proposed rule, experts raised concerns that there were several drivers of emergency department use outside the control of an HHA. Furthermore, hospital policies vary on when to admit a patient to observation vs. discharge to home.

RECOMMENDATIONS:

- 1. Provide HHAs with a least one year to transition to the Home Health Within Stay Potentially Preventable Hospitalization measure before applying it to the either the HHVBP or HH QRP programs.**
- 2. Exclude observation stays from the Home Health Within Stay Potentially Preventable Hospitalization measure.**

PROPOSED CHANGES TO THE HOME HEALTH CONDITIONS OF PARTICIPATION

§484.80 (h)(1)(i)

The regulations at §484.80(h)(1)(i) requires that the 14-day supervisory assessment be conducted by the registered nurse (RN) or other appropriate skilled professional who is familiar with the patient, the patient's plan of care and the written care instructions CMS proposes that HHAs be permitted to use

interactive two-way, audio-visual telecommunications systems for purposes of aide supervision, on occasion, not to exceed 2 virtual supervisory assessments per HHA in a 60-day period.

NAHC supports and appreciates the flexibility CMS proposes for the HCA supervisory visits. NAHC also agrees that on-site HCA supervisory visits in conjunction with an occasional telecommunications HCA supervisory visit provides an appropriate balance for use of the two modalities to ensure compliance with 14-day HCA supervisory visit requirement. However, limiting the number of telecommunications visits to 2 per HHA in a 60-day period is not practical to be of much value for agencies, particularly for large providers. Additionally, it would be difficult, if not impossible, for HHAs to track these visits at the agency level to ensure compliance. Since the telecommunication visits are to be through two-way, audio-visual, technology, NAHC believes the HCA could be assessed for all the required skills, at §484.80(h)(4)(i-vi) with similar sufficiency as an on-site visit to the patient. Therefore, CMS could reasonably apply the number of permitted telecommunication supervisory visits at the patient level with an acceptable limitation on the number of visits per patient.

RECOMENDATION: Modify the limit for the HCA supervisory telecommunication visit to 1 visit per patient in a 60- day period.

§ 484.80(h)(2)

At § 484.80(h)(2), if home health aide services are provided to a patient who is not receiving skilled care, the RN must make an on-site visit to the location where the patient is receiving care from such aide. Such visits must occur at least once every 60 days to observe and assess each home health aide while he or she is providing care.

CMS is also proposing to add a new requirement to 42 CFR 484.80(h)(2) that would require the RN to make a semi-annual on-site visit to the location where a patient is receiving care to directly observe and assess each home health aide while he or she is performing care. This would apply to patients who are not receiving skilled services.

NAHC supports and appreciates CMS' proposals for the HCA supervisory visits for patients receiving nonskilled service. The change will significantly reduce the burden associated with a requirement for a 60-day on-site HCA supervisory visit, with the aide present. Several HHAs, however, have expressed concern with the logistics of conducting a semi-annual onsite visit, aide present, for all HCAs. HHAs that

provide aide services to patients not receiving skilled care may have multiple home health aides providing care to the same patient.

RECOMMENDATION: CMS should monitor the feasibility for HHAs to conduct a semi-annual on site, aide present, supervisory visit on their non-skilled patients.

§484.80(h)(3)

§484.80(h)(3) requires that the agency conduct, and the home health aide complete, retraining and a competency evaluation related to the deficient skill(s). CMS proposes to maintain this requirement at 484.80(h)(3), but to modify it by adding “and all related skills.” For example, if the patient informs the nurse that they almost fell when the aide was transferring them from bed to a chair, the nurse should assess the aide’s technique for transferring a patient in other circumstances beyond transfer to a chair, such as transferring from a bed to bedside commode or to a shower chair.

NAHC agrees that any related skills identified as deficient would require retaining and a competency evaluation. However, there are concerns regarding how the term “all related skills” will be interpreted among HHAs and among surveyors.

RECOMMENDATION: CMS should provide more clarity around skills that would be considered related, such as additional examples, to promote consistency for applying this requirement.

CLOSING THE HEALTH EQUITY GAP IN POST-ACUTE CARE QUALITY REPORTING PROGRAMS—REQUEST FOR INFORMATION

HHAs will be required to report Standardized Patient Assessment Data Elements on certain social determinants of health (SDOH), including, ethnicity, preferred language, interpreter services, health

literacy, transportation, and social isolation. CMS is seeking guidance on any additional Standardized Patient Assessment Data Elements that could be used to assess health equity in the care of HHA patients, for use in the HH QRP.

Although the above elements are important SDOH, there are several other SDOH elements that could be captured by CMS.

RECOMMENDATION: CMS should consider capturing information related to food insecurity, income, education, and housing. These SDOH elements are in align with the those outlined in HHS, Office of Disease Prevention and Health Promotion, Healthy People 2030.

CMS are also interested in feedback regarding whether including HHA-level quality measure results stratified by social risk factors and social determinants of health (for example, dual eligibility for Medicare and Medicaid, race) in confidential feedback reports could allow HHAs to identify gaps in the quality of care they provide.

RECOMENDATIONS: NAHC supports providing HHAs with confidential reports that report quality measures stratified by social risk factors and SDOH. This information will be necessary to effectively establish strategies, such as the following, to mitigate health disparities and gaps in health care.

- **Track the social needs that impact their patients, allowing for personalized care that addresses patients medical and social needs;**
- **Aggregate data across patients to determine how to focus a social determinants strategy; and**
- **Identify population health trends and guide community partnerships.**

CMS seeks information on the methods that commenters or their organizations use in employing data to reduce disparities and improve patient outcomes, including the source(s) of data used, as appropriate.

Most HHAs collect a variety of SDOH information in order develop a comprehensive and individualized patient plan of care. Outside of the required SPADES for SDOH, however, there is no standardize data collection for other important SDOH.

RECOMMENDATION: CMS should consider adopting the use of Z codes for SDOH on home health claims. The data used on claims is more accessible to those who may have a need for the data, such as, research and academic institutions, and other stakeholders.

Fast Healthcare Interoperable Resources (FHIR) for Digital Quality Measures (dQMs)

In many cases, the delivery of quality care, including home health services, relies on the collaboration and exchange of health information across the continuum of care with physician practices, hospitals, and long-term post-acute care (LTPAC) providers such as SNFs and rehabilitation hospitals. Therefore, we believe it is imperative that CMS consider home health providers as vital partners in the overarching pursuit of interoperable health information exchange across the continuum of care. Interoperable exchange of health information is a necessary goal to achieve the overarching goal of person-centric longitudinal coordination of care. We believe that standardizing data elements that are part of clinical documents to exchange information based on high-value use will support the case for health IT adoption. For example, there is no standard for the electronic documentation of a face-to-face physician encounter. Consequently, each connection in a network may define the structure and type differently, preventing true information exchange.

To advance interoperability, it is necessary to clearly specify the defined set of FHIR-APIs and/or HL7 messages that each health IT vendor must support to meet interoperability standards of practice. This will ensure consistent, objective methods to reliably request and retrieve information from other systems. FHIR could be adopted for new clinical documents that are being developed, the OASIS-E, for instance.

RECOMMENDATION: CMS should standardize data elements that are part of clinical documents to exchange information based on high-value use and clearly specify the defined set of FHIR-APIs and/or HL7 messages that each vendor must support for interoperability.

Although home health providers were not among the health care providers that were incentivized to adopt The Office of the National Coordinator for Health Information Technology (ONC)-certified Health Information Technologies (CEHRT), we have remained engaged in the pursuit of interoperability and the development of strong business cases for health information exchange. While the exact number of HHAs

utilizing EHR systems today is unknown, it is fair to say that most utilize such a system. For those that do not, significant costs would be incurred if CEHRT was required and FHIR were adopted. However, we do consider such requirements advancements.

Providers already using EHR systems will inevitably incur additional costs, as vendors will be required to implement significant improvements to their solutions and, in turn, a percentage of these costs will inevitably be passed along to their provider customers. In addition, providers will require additional staffing and training to support, administer, and configure new software solutions that support interoperability. Also, incentives to offset these new imposed costs will help sustain adoption rates.

Lastly, post-acute providers typically align with health systems in various referral relationships. Considerations for further incentives to referring partners (e.g., hospitals in a referral network) should be made, to ensure alignment with their interoperability strategies. The success of achieving high levels of CEHRT adoption and use by inpatient and ambulatory providers owes much to the incentives and resources that were provided as part of Meaningful Use. NAHC reminds CMS that no provisions were made for home health agencies in the Meaningful Use initiative.

RECOMMENDATION: CMS and the Congress should account for and implement such incentives for home health agencies (and hospices) as interoperability is advanced in these provider types. We urge CMS to allow for a minimum of 6 months from the date final specifications are available for EMR and other vendors to respond to any changes in the interoperable exchange of health information. This means that in most cases changes that are implemented through rulemaking must be finalized in rule governing the previous year for vendors to have sufficient lead time for implementation.

Adequacy of Aide Staffing

CMS is seeking information about the adequacy of aide staffing and requests comments on the following:

- Whether home health agencies employ or arrange for (under contract) home health aides to provide aide services;
- The number of home health aides per home health agency (both directly employed and under contract), and whether the number has increased or decreased over the past 5–10 years;
- The average number of aide hours per beneficiary with aide service ordered on the plan of care;
- The effect of the public health emergency on the ability of HHAs to employ home health aides or arrange for (under contract) the provision of home health aide services.

NAHC queried HHAs through a survey seeking feedback on CMS's information request. In summary, the majority of HHAs offer home care aide (HCA) services. While the number of HCAs employed varies, the majority of HHAs reported having 10 or less HCAs. Additionally, the number of aide hours provided per beneficiary varies greatly and the responses lack context in terms of organization size and the time frame that the total hours the HCA services were provided. The majority of HHAs report having difficulty hiring qualified HCAs, which has increased due to the public health emergency

Below is a summary of the data for each question within the survey

1. Does your home health agency employ or arrange for (under contract) home health aides to provide aide services?

Total respondents = 109

Yes = 87.07% of respondents

No = 11.93% of respondents

2. How many home health aides does your agency employ (both directly employed and under contract),

The size of the organizations responding is not specified and therefore my account for the variation in responses.

Total responses = 108 with 102 responses that could be quantified

0-10 HCAs = 62 respondents /61%

11-20 HCAs = 17 respondents /17%

21-50 HCAs = 14 respondents /13%

51-100 HCAs = 6 respondents /6%

>100 HCAs = 3 respondents 3%

In addition to the numeric responses there were 6 narratives responses that were not quantified.

- 2 budgeted, can't fill vacancies
- 2 employees, under contract varies
- 2-3 per agency average
- All employed
- We provide through LPNs n because aides are too unreliable
- We've gone from 50 to 12

3. Has the number of HCAs in your agency increased or decreased over the past 5–10 years?

Total responses = 109

17.43% responded an increase over the past 5-10 years

64.22% responded a decrease over the past 5-10 years

18.35% responded no change over the past 5-10 years

4. The average number of aide hours provided per beneficiary when aide service are ordered on the plan of care?

Several of the respondents reported the hours in ranges of hours per week, or example 1-2, 2-4 hour per week, while others responded with a single numerical value without reference to a time frame. Therefore, the variation in response makes it difficult provide a coherent summary of the data.

Total responses – 103 with 97 responses that could be quantified.

The responses are group in ranges from the data

0-2 hours = 36 respondents/ 37%

3-6 hours = 27 respondents/ 28%

8-12 hours = 19 respondents /20%

14-18 hours =8 respondents / 8%

20-40 hours = 5 respondents /5%

One respondent reported 80 hours and another reported 140 hours, neither specified the time frame. Each response equals 1% each

5. What effect has the public health emergency had on the ability for your agency to employ home health aides or arrange for (under contract) the provision of home health aide services?

13% of respondents stated that there was no change in the HHA's ability to employ HCAs as a result of the PHE. Although several respondents noted difficulty in hiring HCAs prior to the PHE. The remaining 87% responded as having increased difficulty in employing HCAs. The reasons cited for the difficulty in employing HCAs included competition from other higher payer industries, receipt of COVID relief payments, and an unavailability of qualified applicants.

Conforming Regulations Text Changes Regarding Allowed Practitioners

CMS notes that when implementing plan of care changes in the CY 2021 HH PPS final rule (85 FR 70298), the term “allowed practitioner” was inadvertently deleted from the regulation text at § 409.43. Therefore, CMS is proposing conforming regulations text changes at § 409.43 to reflect that allowed practitioners, in addition to physicians, may establish and periodically review the plan of care.

However, CMS maintains in the regulations that it is expected that the allowed practitioner to also perform the face-to-face encounter for the patient for whom they are certifying eligibility; except if a face-to-face encounter is performed by a physician or an allowed non-physician practitioner (NPP), as set forth in § 424.22(a)(1)(v)(A), in an acute or post acute facility, from which the patient was directly admitted to home health, the certifying allowed practitioner may be different from the provider physician or allowed practitioner that performed the face-to-face encounter.

The CARES also provides the following flexibility for whom may conduct the face-to-face encounter for any beneficiary admitted for home health services. The change in statute eliminates the requirement that the certifying practitioner conduct the face-to-face encounter when a beneficiary is admitted for Medicare home health services from the community.

(ii) in clause (iv), by striking “after January 1, 2010” and all that follows through “face-to-face encounter” and inserting “made by a physician after January 1, 2010, or by a nurse practitioner, clinical nurse specialist, or physician assistant (as the case may be) after a date specified by the Secretary (but in no case later than the date that is 6 months after the date of the enactment of the CARES Act), prior to making such certification a physician, nurse practitioner, clinical nurse specialist, certified nurse-midwife, or physician assistant must document that a physician, nurse practitioner, clinical nurse specialist, or physician assistant has had a face-to-face encounter”;

RECOMMENDATION: CMS should immediately issue conforming regulations to implement the provision of the CARES Act that changes the requirements for who may conduct the Medicare home health face to face encounter.

SURVEY AND ENFORCEMENT REQUIREMENTS FOR HOSPICE PROGRAMS

NAHC has a deep appreciation for the manner that the hospice benefit has transformed our nation's approach to end-of-life care, and a commitment to ensuring the continued provision of high-quality hospice

care to terminally ill individuals throughout the Nation. For this reason, we have been actively engaged in discussions with the Health and Human Services Office of the Inspector General (OIG), Congress and the Centers for Medicare & Medicaid Services (CMS) over the most appropriate ways to address the concerns that were raised as part of the OIG’s 2019 reports on hospice survey performance and quality of care.

Most recently, CMS proposed Survey and Enforcement Requirements for Hospice Programs that implement hospice survey reform provisions of the Consolidated Appropriations Act of 2021 (CAA 2021) and were included in [CMS-1747-P](#). These are complex changes that have the potential to dramatically impact the provision of hospice care and the integrity of CMS’ oversight of survey operations. Given such consequences, we have closely reviewed and given serious consideration to the proposed changes. We offer the following comments.

Subpart A – General Provisions

Under Subpart A, CMS proposes (at Section 488.5) to require Accrediting Organizations (AOs), as part of their application and reapplication process, to agree to submit a hospice’s statement of deficiencies from health and safety surveys on the Form CMS-2567 or a successor form in such a manner as specified by CMS. This provision would become effective on October 1, 2021. To meet this requirement, AOs must customize their documentation systems to allow for incorporation of the CMS-2567 and for electronic submission of the form to CMS. CMS must also modify the CMS-2567 to allow for identification of the AO and arrange for a means by which the AOs are able to electronically submit the CMS-2567.

Also under this Subpart, CMS is adding a new Section 488.7(c) to require public posting of the Form CMS-2567 in a manner that is “prominent, easily accessible, readily understandable, and searchable by the general public and allows for timely updates.” CMS acknowledges that there are “limitations and additional data system changes to consider for survey results from the Form CMS-2567 to be displayed in a meaningful and useful format” and that is “readily understandable and useable by the public in a meaningful way.” CMS “anticipate[s] the need...to develop some type of a standard framework that would identify salient survey findings in addition to other relevant data about the hospices,” and that “the implications of releasing national survey data will require collaboration with industry stakeholders to assure the development is fair and equitable across all hospice programs.”

COMMENTS AND RECOMMENDATIONS

AO Submission of CMS-2567 and Modification of the CMS-2567

We understand that the hospice AOs are working intensely toward compliance with the CMS-2567 submission requirement in the time frame specified, and that there are multiple complex technological issues that must be addressed as part of that effort. Once those technological issues have been addressed it will be necessary for the AOs to provide sufficient training to familiarize surveyors and other staff with any new processes and procedures that allow for proper completion and submission of the CMS-2567. We also understand the need for CMS to move swiftly to modify the CMS-2567 in time for the October 1, 2021, effective date.

RECOMMENDATION: It is our expectation that CMS will provide all support and flexibility necessary to the AOs throughout this process so that they are able to address these changes effectively.

Looking forward, CMS has indicated that major systems changes will be undertaken to migrate the CMS-2567 reporting system; we also expect that there will be future changes to the CMS-2567.

RECOMMENDATION: We encourage CMS to involve stakeholders in the process for developing changes and ensure that sufficient time is built into the process for a smooth transition. Where technological and systems changes are needed, we urge that CMS allow at least 3 months lead time from complete finalization of routine Form CMS-2567 changes to implementation; complex changes may require additional time.

Posting of Survey Findings

As part of its 2019 reports, the OIG recommended that CMS post survey findings to ensure greater transparency. An important goal of transparency is ensuring that the public has access to information that adequately allows for informed choices about providers. However, actual survey reports are complex and may be confusing and misleading to the public. Public posting of survey reports (Form CMS-2567) will provide limited utility to the public and posting of such reports in the absence of additional educational information could create confusion. Further, the sheer volume of information that is available on the CMS-2567 may serve as a deterrent to public review or may mislead viewers relative to the performance of a

hospice. The OIG recommended that survey information be “more readily available – and accessible – in a user-friendly way.”

We note, as referenced previously, that as part of the proposed rule CMS has indicated that some type of standard framework that identifies key survey findings may be needed. We believe that the most effective means for achieving this level of transparency is through engagement in a deliberative process which identifies for display key elements related to Medicare survey performance that will be most useful to the public, along with establishment of a means for conveying survey performance on hospice Conditions of Participation (CoPs) that are most closely linked to quality of patient care (specifically the four core CoPs), and from which a summary report or metric could be created and posted online. When such an effort was undertaken for nursing facilities, CMS convened a technical expert panel (TEP) comprised of a wide variety of stakeholders to address this and other relevant tasks.

While we recognize that actions taken by CMS while implementing nursing home survey reforms provide valuable experience and insight into means for implementing the hospice survey reforms, nursing home reforms were undertaken long enough ago, and hospice is sufficiently different that we believe that CMS must also bring a “fresh eye” to its implementation of the hospice survey reform.

RECOMMENDATIONS:

- 1. We strongly urge CMS to establish a TEP comprised of a wide array of stakeholders (including various types of hospice programs) to help identify the most relevant hospice survey performance information (examples of such could include date of most recent survey, number of condition-level deficiencies, the average number of hospice survey citations, whether a citation posed Immediate Jeopardy (IJ), date the hospice came back into compliance, whether the hospice is a Special Focus hospice, whether the hospice has had a substantiated serious complaint within a given time period, etc.) and the most effective way to share such findings with the public, as well as to provide input on other aspects of these survey reforms including the Special Focus Program for Hospices.**

2. It is our expectation that hospice survey findings will be linked from Care Compare in a manner like that currently used for nursing home surveys. We support posting of survey summary information along with a link to survey report(s) in a single location that is easily accessible by the public. For this reason, we believe that inclusion of access to survey findings from the Care Compare website is likely the most appropriate location currently.
3. We note that nursing home survey reports do not include the facility's plan of correction or information indicating that the provider has come into compliance, leaving a viewer with questions about the facility's compliance status. We strongly recommend that any posting related to survey findings in which a provider was cited for failure to meet the hospice CoPs includes a notation that the provider has corrected any deficiencies and is in full compliance with the hospice CoPs, and the date that the hospice achieved full compliance. If a hospice is deemed by an accrediting organization, the notation should include notice that once compliance was achieved the hospice was once again accredited by the AO.
4. Hospices with inpatient units have more CoPs for which they are surveyed, including a substantial number of Life Safety Code (LSC) requirements. We recommend that as part of any metric representing survey performance that CMS distinguish between hospices that provide inpatient care directly and those that do not to ensure appropriate comparison. Further, we recommend that such a display provides information related to the difference between LSC violations and other CoPs, including that LSC violations are not always directly related to patient care but may be failure to meet a technical requirement.
5. Given the complexity of the survey process, we strongly recommend that any posting of survey findings be accompanied by guidance about the hospice CoPs, how to read and interpret a Form CMS-2567 report, and the survey process that are geared toward a population that may not be familiar with the process. We also strongly recommend that CMS include an explanation that a single citation is not an indication that a hospice has systemic quality of care concerns.

6. **We note with some concern that there appears to be a lag in posting time for nursing home survey finding reports. It would be helpful if, as part of the final rule, CMS could provide a clear indication of the anticipated timeline for posting of hospice survey reports (especially the anticipated time frame between completion of the survey and posting of the report online) and that CMS consider enforcement provisions for survey entities to submit reports.**

NEW SUBPART M – SURVEY AND CERTIFICATION OF HOSPICE PROGRAMS

As part of the new Subpart M, CMS has developed regulations governing changes to the hospice survey and certification processes. The subpart permanently mandates that routine surveys occur minimally every 36 months and codifies the requirement that states/localities establish a dedicated toll-free hotline to collect, maintain, and update information on hospice programs and to receive complaints. It also addresses surveyor qualifications (including training), prohibits surveyor conflicts of interest, addresses the composition of survey teams, requires programs to improve the consistency of surveyor findings, and establishes a Special Focus Program for hospice.

COMMENTS AND RECOMMENDATIONS

Hospice Program Surveys and Hospice Program Hotline

We strongly support the provision in the Consolidated Appropriations Act (CAA) 2021 that makes permanent the requirement that routine hospice surveys be conducted, at a minimum, every 36 months. Relative to establishment of dedicated toll-free hospice hotlines, we understand that many states have already established and operate such hotlines but are supportive of codifying and making the requirement uniform throughout the United States.

Surveyor Qualifications and Prohibition of Conflicts of Interest

We appreciate that CMS included in this section details related to the agency's ongoing work to update hospice surveyor training modules and guidance to surveyors included in the State Operations Manual so that greater emphasis is placed on assessment of quality of care. We have some concerns that the timing of the effective date for the surveyor qualifications – particularly the requirement that all Federal, State Agency and AO surveyors successfully complete CMS' training and testing program by October 1, 2021, to be qualified to conduct hospice surveys – could be problematic. It is our understanding that given the ongoing COVID Public Health Emergency (PHE), some organizations are lagging behind the requirement that routine surveys be conducted every 36 months, at a minimum.

To meet the training/testing requirements, survey entities (states and AOs) could be required to pull staff from the field to ensure that they meet the training requirements, which could add further to the survey backlog. Additionally, CMS has indicated that it has in development new training modules for hospice surveyors, but CMS has not indicated when those modules will be released. To meet the effective date of the training requirements, it appears possible that AO (and SA) surveyors may be trained and tested on the older educational modules.

Surveyor Training: Given the impending release of revised surveyor training, we believe that it would be optimal for surveyors to meet the training and testing requirements utilizing the updated training modules, which we assume will coincide with release of the revised Interpretive Guidelines/Survey Protocols.

RECOMMENDATIONS:

- 1. In order to achieve this goal, we recommend that CMS provide, as part of the final rule, a timeline for when the new training modules will be released and establish a schedule for completion of the updated surveyor training for all surveyors (Federal, State, and AO) that allows a reasonable amount of time (for example, a minimum of 3 months following release of the new training) for surveyors to successfully complete the training/testing.**
- 2. Survey entities would benefit from receiving information about how their surveyors have performed on CMS' training modules. We encourage you to share details of surveyors' performance on the various testing modules so that the employing survey entity has knowledge of a surveyor's knowledge base and areas of strength and weakness.**

In some states the number of surveyors is limited, and surveyors may conduct surveys on a variety of provider types.

RECOMMENDATION: CMS should establish an ongoing requirement for continuing surveyor eligibility that includes continuing education requirements and ensures that a surveyor conducts a minimum number of surveys on a provider type annually to maintain credentials.

In addition to formal training modules and memoranda issued by the Quality, Safety and Oversight Group (QSOG), we understand that SAs, AOs, CMS Location offices and CMS Central communicate throughout the course of the year regarding various hospice survey issues. These communications yield clarifications and interpretations that help to shape surveyors' perspectives and impact the overall survey process. These communications are not available to all surveyors, nor are they publicly available. We believe that access to such clarifications and interpretations is, in many instances, critical to improving hospice surveyors', hospice providers' and other stakeholders' understanding of the CoPs and the survey process.

RECOMMENDATION: In the interest of improved quality of care and greater transparency in the survey process we strongly recommend that CMS develop a means for communicating informal guidance specific to interpretation of CoPs or the survey process to Location offices, SAs, AOs, and all stakeholders (including hospice providers) in an organized way.

Given the significant emphasis in the CoPs on the appropriate delivery of quality care, including a RN on the survey team is critical to effective review of a hospice's compliance. However, we also recognize that much of the value of hospice care comes from the variety of disciplines that are represented on the multi-disciplinary team. As CMS continues to update its hospice surveyor training, we offer the following recommendations.

RECOMMENDATIONS:

- 1. Education and training should adequately address psychosocial, emotional, and spiritual components of hospice care. These elements of the training should be**

- developed and conducted, wherever possible, by social workers and chaplains with education and experience in these specific areas of hospice;**
- 2. Education and training should be updated when there are new or revised CoPs or interpretations; and**
 - 3. Training modules should emphasize that survey citations are based on evidence of trends of a violation rather than a single violation.**

Conflicts of Interest: We appreciate CMS' proposals related to implementation of the conflict-of-interest provisions of the CAA 2021 and believe this is an important element in ensuring fairness in the survey process. As part of our discussions with hospice providers several examples of additional potential conflicts of interest were raised, including a surveyor's potential conflict of interest arising out of a work history that includes an employment arrangement with a hospice's competitor. It may be challenging to address this issue as it would be necessary to define competitor and, in the case of a hospice with multiple locations, how far the prohibition would extend. We are interested, however, in whether CMS has considered this potential conflict of interest and how it might best be addressed. Further, objectivity is an important part of the survey process.

RECOMMENDATIONS:

- 1. CMS should develop materials to help guide surveyors and survey entities regarding potential conflicts of interest.**
- 2. CMS should develop, in collaboration with the AOs, a code of ethics for hospice surveyors. Surveyors should be given the opportunity to recuse themselves from the survey process in instances where there is a potential conflict of interest.**

Survey Teams

CAA 2021 calls for the use of multidisciplinary survey teams when the survey team is comprised of more than one surveyor. We appreciate CMS' call, under section 488.1120, for diverse professional backgrounds among surveyors to reflect the professional disciplines responsible for providing hospice care, and its recognition of the disciplines included in the hospice core services requirement. We also appreciate CMS' call for additional input from appropriate entities regarding the current professional makeup of survey entities' workforces to establish a baseline knowledge of this area.

Relative to the new survey team composition requirement it would be helpful if CMS could clarify/consider the following:

- Does CMS intend to require that any hospice survey team of more than one individual include one RN and one from among the following disciplines: physician, RN, a medical social worker, and pastoral or other counselor?
- Would this prohibit an LPN from being part of the hospice survey team?

RECOMMENDATIONS:

- 1. Based on CMS' explanation of this provision, we believe it would be permissible for a hospice survey team of 2 individuals to be comprised of 2 RNs.**
- 2. We encourage CMS to strongly consider requiring that all surveyors have experience in hospice care.**
- 3. Specialty surveyors should be engaged when appropriate.**

Consistency of Survey Results

The CAA of 2021 requires that each state and the Secretary of HHS establish programs to measure and reduce inconsistency in hospice survey results among surveyors. We agree with CMS' comment that the variation in training requirements for SA and AO surveyors may well contribute to inconsistent performance among SA and AO surveyors and are hopeful that pending revisions to the training and the new requirement that all surveyors meet the same training and testing standards will, indeed, contribute to increased consistency of surveyor findings.

CMS has indicated that it believes it is important that in addition to ensuring consistency of hospice survey results across SAs, that discrepancies between SA and AO surveys of hospice providers be

addressed. CMS plans to make several changes to implement this new requirement, including expansion of the State Performance Standards System (SPSS) such that states must implement processes to measure the degree to which surveyors' findings and determinations are aligned with federal regulatory compliance and with an SA supervisor's determinations.

CMS also indicates a desire to promulgate objective measures of survey accuracy and seeks public opinion on what measures would be feasible for states. CMS intends to expand calculation of survey entities' "disparity rates" – a calculation currently used with AOs that measures the degree of missed condition-level deficiencies -- to include SAs, to notify each survey entity of its disparity rate, require a corrective action plan, and take remedial action if the survey entity's disparity rate is above a certain level.

CMS also plans to conduct random sample validation surveys for both SAs and AOs to ensure they meet specified performance standards. In cases where SAs or AOs do not meet such standards, they would be required to develop and implement corrective action plans. Following are some of our comments relative to CMS' plans to improve survey consistency:

- While it is important that any program to improve surveyor consistency ensures that surveyors are identifying all condition-level deficiencies, we are concerned that the "disparity rate" calculation does not include review of imposed citations to ascertain that surveyor-identified condition level citations are accurate and appropriate.
- While we understand the need to conduct validation surveys as part of CMS' efforts to address consistency of survey findings, in almost all cases validation surveys are conducted some time after the survey, and any change in the hospice can significantly alter a surveyor's findings. In such cases this does not necessarily mean that the initial surveyor failed to identify or overlooked existing deficiencies. Instead, the difference may be due to changes that have occurred at the hospice since the time the initial survey was conducted. Additionally, under current practice where federal, state and AO surveyors are subject to different training and have access to different guidance and regulatory interpretations, survey findings can vary. (New requirements for identical training programs, and an effort by CMS to provide access to informal policy interpretations, as recommended above, could help to address some of these factors.) We believe that validation surveys are best conducted simultaneously wherever possible. We understand that in recent years CMS conducted a pilot under which surveys were conducted simultaneously. While such simultaneous surveys can be challenging to coordinate, it is our understanding that the pilot yielded greater accuracy.

- As part of any effort to improve the consistency of survey findings, we believe that the creation of protocols for deficiency citations could be helpful in providing decision-making support for all hospice surveyors, provided they include sufficient flexibility to allow for surveyor judgment. Such protocols could suggest that a certain level of compliance is needed to convey that a hospice has met the goals of the CoPs and that a single instance of non-compliance may not be indicative of a systemic problem. The protocol would need to consider the manner and degree of the offense when deciding that a citation is appropriate.

RECOMMENDATIONS:

- 1. In the interest of addressing the accuracy of surveyor findings, we believe that any review of a surveyor's report must also include confirmation that there is sufficient evidence that imposed citations are fully justified and appropriately imposed.**
- 2. We recommend that CMS try to encourage that validation surveys be conducted concurrent with routine or other surveys. Where such is not possible, such surveys should occur within a shorter period following the standard survey (weeks as opposed to months, as is generally now the case).**
- 3. We strongly recommend that CMS explore the potential to create protocols for deficiency citations for hospice surveyors.**

Special Focus Program

CMS proposes to develop a hospice Special Focus Program (SFP), as required by the CAA 2021, to address issues that place hospice beneficiaries at risk for poor quality of care through increased oversight, and/or technical assistance. NAHC supports a targeted focus on hospice providers needing additional oversight and technical assistance.

CMS proposes the following criteria for hospice SFP eligibility:

- 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).

The amount of time in which there could be two consecutive substantiated complaint surveys was not specified in the proposed rule, and because the nature of the complaint was not listed as a factor it is presumed it does not have an effect. Depending on the nature and severity of the complaint, it could be some time before complaints are investigated. In fact, it could be years. Survey entities may receive complaints that are not of an urgent nature and investigation of the complaint is held until the next scheduled survey.

RECOMMENDATIONS:

1. NAHC strongly supports additional and targeted oversight and termination of Medicare certification, as appropriate, for hospices not delivering quality care and putting patients at risk. Due to the potential significant impact on the delivery of hospice care we reiterate 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. A TEP should, at a minimum, consist of consumers, hospice providers, SA and AO surveyors, and stakeholders who have had extensive experience with the hospice survey process. It is important that the SFP not be implemented until the TEP completes its work. Due to the complexity of an SFP, it would be most beneficial if the TEP were to address at least the following:

- **Criteria for inclusion in and graduation from the SFP**
 - **Should survey data be the only criteria for inclusion or should a combination of survey and program integrity data be utilized (i.e., Hospice Care Index performance, proportion of live discharges, etc.)**
 - **How the additional conditions of participation for those hospices providing inpatient care directly can equitably be incorporated into the SFP inclusion and graduation criteria**
 - **Whether the deficiency(ies) was widespread or isolated**
 - **Whether the deficiency(ies) resulted in patient harm and the level of harm**
 - **Should repeated eligibility/inclusion in the SFP result in termination**
 - **Length of time between being put on the termination track and actual termination and what steps should be part of this process.**

- **Whether ‘promising progress’ (i.e., sale of the hospice to a company with a strong compliance and quality of care track record) should impact if a hospice continues in the SFP/termination decision.**
 - **Public display of SFP information and ensuring it is updated timely**
 - **Level and types of technical assistance to be provided**
 - **Experience, training, and ongoing education of SFP surveyors**
 - **Evaluation of the efficacy and effectiveness of the SFP**
- 2. **The amount of time between substantiated complaint surveys should not be so long that the hospice has resolved the reason for the complaint and is not out of compliance with the conditions of participation related to it. Also, a complaint that is of a nature such that the survey entity does not see the need to address it for potentially 36 months should not affect SFP eligibility.**
- 3. **Under the proposed design, CMS would generate the Candidate List. The SA would then work with the CMS SOG location to select hospice programs from the list provided by CMS that would be selected for the SFP based on State priorities. If no hospice programs in a State meet the established criteria, then the SA would not have a hospice program in the SFP at that time. NAHC strongly supports a standardized, centralized approach, using objective criteria to determine which subset of hospices will be placed into the SFP. This builds an SFP that targets the poorest performing hospices. CMS does not comment on what type of State priorities may influence which hospices are chosen from the Candidate List for the SFP but introducing factors at the State or local level defeats the goal of providing oversight and/or technical assistance to the poorest performing hospices. We are pleased that the proposed SFP design does not utilize a quota system as is used in the Special Focus Facility (SFF) program for long term care and thank CMS for this, however, we strongly recommend CMS reconsider decentralizing the SFP selection process.**
- 4. **The purpose of the SFP is to provide oversight and/or technical assistance to the poorest performing hospices, to ultimately improve the quality of care provided to beneficiaries. The role of surveyors is essential and critical for the SFP to achieve this goal. The surveyors will be assessing compliance with the conditions of participation while**

simultaneously providing technical assistance to the hospice. Therefore, the surveyors must be well trained in the interpretive guidelines of the hospice conditions of participation and how to provide technical assistance and must also be well trained in working with those providers needing assistance. This is not the approach or the structure of any other survey. Therefore, SFP surveyors should be required to complete additional training. There should be an implementation timeframe for the SFP that accommodates this additional training. At a minimum, surveyors should have completed the updated basic surveyor training prior to the implementation of the SFP.

5. Careful consideration should be given to the information publicly reported about a hospice provider in the SFP. Graphics and details about the special focus program should be carefully developed to convey information accurately and without undue alarm. When a provider corrects the deficiencies that placed it in the SFP and meets any other criteria for moving out of the SFP, public reporting of this information should be timely.

Enforcement, Remedies and Civil Monetary Penalties (CMPs)

CMS is proposing general rules pertaining to enforcement actions against a hospice program that is not in substantial compliance with the CoPs. The Act 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 is proposing the addition of a directed plan of correction and directed in-service training. NAHC appreciates these proposed additions, and it aligns the enforcement remedies with the alternative sanctions available for HHAs. NAHC appreciates that CMS may desire to utilize the same structure and processes for the enforcement remedies in hospice as is used in other provider types. We take this opportunity to remind CMS that there is not any type of dispute resolution process available to hospices for a deficiency(ies) cited upon survey as there are for other provider types.

RECOMMENDATION: We strongly urge CMS to incorporate a dispute resolution process into the reforms, particularly since hospices will be subject to more severe consequences for noncompliance.

We also urge CMS to carefully consider payment suspensions for hospices. Specifically, CMS is proposing 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 Act; however, we draw to CMS' attention the following:

- The OIG recommended in a July 2019 report that the enforcement remedies be consistent with post-acute care providers and imposing suspension of payment beyond new admissions is not consistent with other provider types.
- OBRA 1987, the Act that established the Home Health Agency (HHA) alternative sanctions, uses language that is nearly identical to the Consolidated Appropriations Act by stating "...all or a part of the payments to which a home health agency...". In 2012, CMS proposed that suspension of payment for new Medicare admissions and new PPS episodes of care be applied to HHAs in certain circumstances. In response to comments received on the proposal CMS stated "We agree with comments submitted in response to the proposal that the use of suspension of payment for new patient admissions would be an effective sanction while suspension of new payment episodes may be disruptive to patients as they would have to transfer to different HHAs with different staff. It would also be difficult for the HHA to maintain a caseload of patients to ensure compliance with requirements. Therefore, we will keep the suspension of payment for new patients as an option but remove references to new payment episodes from the suspension of payment sanction as well as the definition of "new admission" in § 488.805." Suspension of all payments to which a hospice would otherwise be entitled would also be disruptive to patients and difficult for the hospice. There are far fewer hospices than there are home health agencies.
- More than 90% of payments for hospice services come from Medicare. Also, hospice providers have a higher volume of new admissions annually than most other post-acute care providers. Smaller, independently owned hospice providers may be disproportionately burdened financially by imposition of payment suspensions as well as other remedies as compared with larger hospice providers or hospice providers that are part of a larger healthcare network. This could result in less choice for the hospice consumer as smaller providers are increasingly pushed out of the hospice marketplace. In those states with Certificate of Need (CON) requirements for hospices, suspending all or a portion of the payments to which the hospice would otherwise be entitled could result in the

only hospice in a region of the state closing due to financial constraints instead of working towards performance improvement and the delivery of quality hospice care. The same could occur in non-CON states especially in rural areas and inner-city areas.

RECOMMENDATIONS:

- 1. NAHC strongly urges CMS to limit the suspension of payments to new admissions only and to consider the impact on access to care when imposing other remedies.**
- 2. The CAA 2021 provided for the Secretary to utilize money collected for hospice program improvements; however, this was not part of what CMS proposed. NAHC urges CMS to develop specifications for penalties collected to be used at the national level and/or state level as the Act intends – for hospice program improvements. This may include education programs and competency testing for state and AO surveyors as well as grant programs for provider performance improvement activities and the like.**
- 3. Consider hospice provider-initiated improvement plans resulting in positive outcomes and sustained compliance over the course of the “look back” period in determining whether to cite a deficiency and/or assign a CMP for previous noncompliance. For example, a survey occurs in January 2022 and includes a review of records, etc. from January 2021 through January 2022. Surveyor identifies a regulatory deficiency occurring in February 2021. Hospice provider can provide a documented internal action plan demonstrating that the problem was identified internally, a process improvement was put in place, and no additional deficiencies were noted following the implementation of the internal improvement plan. The hospice would not be cited for previous noncompliance in this situation.**
- 4. The proposed notice period for enforcement remedies when Immediate Jeopardy (IJ) is present is 2 days and when IJ is not present is 15 days. We believe CMS intends for these to be calendar days and ask CMS to clarify this in the final rule. CMS should consider the method that will be used to deliver the notices and consider whether 2**

days is reasonable. NAHC is aware of situations in recent years where it has taken CMS an extraordinarily long time to provide the Statement of Deficiencies to providers. In some cases, this has taken more than 30 days after a survey is completed (the requirement is 10 business days). These instances are not tied to the current Public Health Emergency (PHE) and there is significant concern from providers that these types of delays will continue and occur when enforcement remedies are being applied. NAHC recommends that CMS investigate the reasons for these delays and implement processes to remedy the situation. If delays cannot be avoided in some instances, hospices should be granted an extension equal to the number of days the Statement of Deficiencies was delinquent in submitting its plan of correction in response to a Statement of Deficiencies. In situations where enforcement remedies are applied, the implementation date of the remedy should be delayed for the same number of days that the notice was delinquent.

5. When temporary management is imposed, NAHC recommends CMS ensure the temporary manager/administrator goes through basic CMS surveyor training before beginning their assignment in the hospice organization and have hospice management/administrator experience. It is expected that temporary managers/administrators will likely be consultants. CMS needs to ensure that these individuals have an advanced command of the hospice conditions of participation and what is expected of hospice providers by CMS. Also related to temporary management, we do not believe there is a prohibition against using an individual within the hospice organization that has proven success in leading a compliant hospice program, i.e., a hospice administrator for a different hospice agency within the corporation; a senior executive in the organization who has not been directly involved in the hospice's day to day operations, etc. There are several advantages to using such an individual including but not limited to, that he/she is familiar with the organization and its policies and procedures so could delve into performance improvement sooner than someone from outside the organization and likely already has the credentials and licenses that may be required by the state. We ask CMS to clarify that a temporary manager/administrator is not required to be external to the hospice organization.

- 6. We understand that the SOG CMS Location will determine if and when to apply an enforcement remedy(ies) and which remedy(ies) to apply. In general, determinations of when enforcement remedies are to be imposed and which remedy to impose are quite subjective. We recommend CMS provide training to the Location staff in the factors to be used in making these determinations and that CMS develop processes to ensure these remedies are consistently applied by all the Location offices.**

CONCLUSION

NAHC appreciates the opportunity to submit these comments. Please do not hesitate to contact us if you need any clarification of these comments.

National Association for Home Care & Hospice

State Association Co-signers

Arizona Association for Home Care

Association for Home & Hospice Care of North Carolina

California Association for Health Services at Home

HomeCare Association of Arkansas

Home Care Alliance of Massachusetts

Home Care Association of Colorado

Home Care Association of Florida

Home Care Association of Louisiana

Home Care & Hospice Association of New Jersey

Home Care Association of New York State

Home Care and Hospice Association of Utah

Home Care Association of Washington

Home Care, Hospice, & Palliative Care Alliance of New Hampshire

Idaho Health Continuum of Care Alliance

Illinois HomeCare and Hospice Council

Indiana Association for Home and Hospice Care
Kentucky Home Care Association
Maryland National Capital Home Care Association
Michigan HomeCare & Hospice Association
Minnesota HomeCare Association
Missouri Alliance for Home Care
Ohio Council for Home Care & Hospice
Ohio Health Care Association
Oregon Association for Home Care
Nebraska Association for Home Healthcare and Hospice
South Carolina Home Care & Hospice Association
Virginia Association for Home Care and Hospice
West Virginia Council of Home Care Agencies

Very truly yours,



William A. Dombi



Theresa M. Forster

Vice President, Hospice Policy

Mary C. Carr

Vice President, Regulatory Affairs

Katie Werhi

Director, Regulatory Affairs