2021 Regulatory Blueprint for Action

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INTRODUCTION

The Regulatory Blueprint for Action identifies important regulatory issues for home care, hospice and home medical equipment providers. It provides a summary of each issue, including background information, recommendations, and rationale for the recommendations. This document provides a guide to the home care industry's position on the issues addressed. The National Association for Home Care & Hospice (NAHC) 2021 Regulatory Blueprint for Action has been reviewed by the NAHC Advocacy Council, the Public Policy Committee, the Forum of State Associations' Regulatory Affairs Advisory Committee, and has been approved by the Board of Directors.

In order to identify the regulatory issues that are of importance to home health and hospice providers throughout the country, NAHC engages in a variety of activities. Member comments gathered from telephone calls, letters, and personal contact are analyzed. The current industry trends and government actions are evaluated. NAHC publishes a list of major issues in the NAHC Report annually and asks members to score each issue from the least to most important. The results are tabulated and top industry priorities are identified.

I. REIMBURSEMENT REFORM

ENSURE THE DEVELOPMENT OF A FAIR AND EQUITABLE PATIENT DRIVEN GROUPER MODEL (PDGM)

ISSUE: The PDGM completely overhauls the current home health payment system. The PDGM is a wholesale payment reform measure that would replace a 17-year payment model with dramatic and wide ranging affects at the provider level. It will replace the historically used 60-day episodes with 30-day "periods" even though Medicare retains a 60-day standard for the patient assessment and plan of care. Although the Congress requires the model be implemented in a budget neutral manner, CMS is permitted to apply a presumptive behavior adjustment when calculating the base payment rate. Finalized for 2020, is a 4.36 % behavior adjustment related to changes in the clinical grouping (primary diagnosis), comorbidity (secondary diagnosis), and low utilization payments adjustments (LUPA) thresholds. CMS is required to analyze data for 2020 through 2026, after implementation of the PDGM to determine the impact of the differences between assumed behavioral changes and actual behavioral changes on estimated aggregate expenditures and adjust the payment amount either upwards or downwards accordingly.

During the COVID-19 PHE, agencies have seen a significant reduction in revenue related to patient refusals and no reimbursement for visits conducted remotely. The behavior adjustment unjustifiably further reduces reimbursement to home health agencies.

RECOMMENDATION: There are fundamental revisions that must be made to the proposed PDGM for it to be a workable payment model for the home health provider community. These changes will ensure that access to care is maintained for one of Medicare's most vulnerable beneficiary populations who are older, sicker and poorer, on average, than other Medicare patient groups.

1. PDGM must be revised to not include rate adjustments based on presumptive behavioral changes.
2. Behavior adjustments should only be made retrospectively using agency utilization data that proves "gaming".
3. Any adjustments related to true behavior changes should be limited to 2% in any given year.
4. Re-evaluate the behavior adjustment to accommodate for the decreased expenditures for Medicare home health services that have occurred due to the COVID-19 pandemic.
5. Reconcile payments to home health agencies that were based on the behavior adjustment

RATIONALE: CMS is permitted to apply behavior adjustment to the PDGM arbitrarily and presumptively, leading to unfair rate cuts. Additionally, agencies could be subject to significant rate cuts if reconciliation adjustments are applied without limits. The only fair application of behavioral adjustment to the PDGM is to apply them retroactively based on real changes in behavior.
Home health agencies could not have possibly reached expenditures presumed by the behavior adjustment with losses to reimbursements during the COVID-19 PHE.

REVERSE THE POLICY ON QUESTIONABLE ENCOUNTERS/UNACCEPTABLE DIAGNOSES

ISSUE: When developing the PDGM, CMS made the decision to exclude certain diagnoses codes in the home health case mix Grouper if listed as the primary diagnosis for home health services. These diagnoses are referred to as questionable encounters or unacceptable diagnoses. CMS maintains that these questionable encounters/unacceptable diagnoses do not provide adequate justification for skilled home health services when reported as the primary diagnoses. As a rule, questionable encounters/unacceptable diagnoses are diagnoses that indicate nonspecific conditions or symptoms, such as, muscle weakness and unsteady gait.

However, several of the excluded diagnoses, particularly the symptom diagnoses, are not uncommon as primary diagnoses for home health patients. The physician may not have enough definitive diagnostic information to provide an underlying cause for the symptom or the symptom could be a manifestation of several diagnoses, however, the treatment is the same regardless of the underlying cause.

If the HHA submits a claim with a questionable encounter/unacceptable diagnosis the claim will not process and is returned to the provider. Agencies must choose whether to admit the patient for care hoping the physician will provide an acceptable diagnosis or not admit the patient.

Agencies make every effort to obtain an acceptable diagnosis; however, there are occasions when the physician is not able to provide any additional information. In situations where all options to obtain an acceptable diagnosis have been exhausted, HHAs struggle with whether they can transfer the financial liability to beneficiaries. Additionally, since the claim will not process with the questionable encounter/unacceptable diagnosis, the patient does not have the option to request the HHA bill Medicare and have the Medicare Administrative Contractor (MAC) review the claim for a coverage determination; leaving the patient without any appeal rights.

RECOMMENDATIONS:

- CMS should reconsider its policy and modify the home health case mix Grouper to include all diagnoses
- Rather than reject claims, allow the MACs, through the medical review process, determine whether a questionable encounter/unacceptable diagnosis meets Medicare coverage criteria for reasonable and necessary skilled home health services.
- In the meantime, CMS should provide instructions to HHAs on the advance beneficiary notice requirements and process if the HHA must transfer financial liability to the beneficiary when an acceptable diagnoses cannot be obtained.

RATIONALE: CMS' policy to not allow certain diagnoses in the home health case mix Grouper could lead to beneficiaries who are otherwise eligible and may benefit for Medicare covered home health services to either go without home health care or be require to find another payer source for care that should be covered under the Medicare home health benefit. Beneficiaries in need of home health could be at risk for declining health and requiring more intensive care in other settings. Additionally, HHAs could be at financial risk if care is provide for which the claim will not process.

MONITOR MEDICARE HOME HEALTH OUTLIER POLICY

ISSUE: Medicare law requires that the home health prospective payment system (HHPPS) include a component for outlier payments, with 5% of the anticipated expenditures allocated to an outlier budget. In implementing this mandate, the Centers for Medicare & Medicaid Services (CMS) created an outlier payment methodology that includes shared losses with the provider of services through the use of an eligibility threshold and percentage payment on costs above that eligibility threshold. CMS analysis of outlier payments has shown that only a portion of the outlier budget was actually being spent each year since the inception of HHPPS.

Between 2005 and 2009, the amount of outlier spending increased considerably. During that time almost 40% of the outlier outlays were to one county in the country. As a result, CMS became concerned that outlier spending would exceed budget. CMS raised the fixed dollar loss ratio (FDL), effective January 1, 2008, from 0.67 to 0.89 with the intention of decreasing the number of episodes that will qualify for outlier payments.

In 2010, CMS promulgated new outlier policy designed to stem what it perceived to be abusive use of outliers in certain parts of the country. At the time, NAHC had been advocating for an agency-specific cap on outlier payment of 10%. CMS implemented such a cap beginning January 1, 2010, and applied the cap through rolling adjustments on claims payments designed to result in an end-of-year limitation of no more than 10% of Medicare home healthy revenue relating to outlier payments. CMS also returned the fixed dollar loss ratio to 0.67, thereby applying outliers to a larger patient segment.

The Patient Protection and Affordable Care Act (ACA) codified the outlier cap into Medicare law beginning January 1, 2011, removing section 1895(b)(5) of the Act so that estimated total outlier payments in a given fiscal year (FY) or years may not exceed 2.5% of total payments projected or estimated. The provision also makes permanent a 10% agency-level outlier payment cap. CMS implemented these new legislation requirements in 2011.

Since the implementation of the outlier cap, some concerns have been raised that certain patients may find barriers to access to care, as outlier patients are not always evenly distributed. Section 3131(d)(1)(A)(iii) of the ACA requires the Secretary to analyze potential revisions to outlier payments to better reflect costs of treating Medicare beneficiaries with high levels of severity of illness. CMS must deliver a Report to Congress regarding the results and recommendations of a home health study no later than March 1, 2014.

In 2014, CMS revised the eligibility threshold for outlier payment as a significant portion of the outlier budget was unspent in 2013. CMS maintains the 2014 outlier eligibility threshold despite continuing underspend on outlier episodes.

In the 2017 HHPPS rate update rule CMS finalized changes to the outlier methodology to calculate outlier payments, using a cost-per-unit approach rather than a cost-per-visit approach. Using this approach, the national per-visit rates would be converted into 15 minute unit rates. The per-unit rates by discipline would then be used, along with the visit length data by discipline reported on the home health claim in 15 minute increments (15 minutes = 1 unit), to calculate the

estimated cost of an episode to determine whether the claim will receive an outlier payment and the amount of payment for an episode of care. CMS has retained the 10 % cap on outlier payments.

RECOMMENDATIONS:

1. Monitor the outlier payment methodology to determine whether qualified patients have barriers to access to care; if barriers are found to exist, develop revisions to outlier standards that accommodate exceptional circumstances (e.g. use of an exceptions process and prior authorization);
2. Where the full allocated outlier budget is not utilized, CMS could make retrospective payments to providers with excess outlier subject to a pre-stated limit; and
3. Interest payments should be made on all outlier claims not paid within the 30-day required timeline.

RATIONALE: The hard cap on outlier spending was needed to address a unique abusive practice. With that practice essentially eliminated, CMS should determine what refinements may be needed to provided outlier payment support to HHAs that exceed the 10% cap while still providing appropriate care to its patient population. The cap should be viewed as a radical but short-term remedy rather than one that disqualifies patients in need without consideration of their needs.

IMPROVE APPLICATION OF WAGE INDEX FOR MEDICARE HOME HEALTH AND HOSPICE

ISSUE: Medicare home health and hospice payments have historically been adjusted to reflect varying wage levels across the nation through the application of a wage index. However, the wage index that has been utilized by the Centers for Medicare & Medicaid Services (CMS) has been based upon wages reported by hospitals across the nation. This index is derived from data that explicitly excludes any home health or hospice services costs. An attempt some years back to create and utilize a home health-specific wage index failed due to the unavailability of reliable wage data.

While home health and hospice payment rates are adjusted for wage variability through application of a hospital wage, the index utilized and its manner of application is significantly distinct from that utilized for hospital services payment rates. Of particular concern is the fact that a hospital may secure a geographic reclassification for application of the wage index by establishing that the hospital draws on an employment pool different from the geographical area to which it would otherwise be assigned for its wage index level. Home health agencies and hospices are not authorized to secure a wage index reclassification. As a result, a hospital may compete for the same health care employees as a hospice or home health agency but be approved for a relatively higher payment rate through the wage index reclassification. Additionally, Congress has established specific wage index criteria for certain geographic locations. However, these criteria apply only to hospitals. Hospitals also are provided extra protection against losses due to dramatic drops in their wage indices by a provision imposing a "rural floor" under which no hospital's wage index can fall below the state-specific rural wage index.

Finally, home health agencies and hospices are not afforded any type of stop-loss protections. As a result, changes in area wage indices from year to year are sometimes dramatic, and always difficult to plan for. For example, in recent years one area of Texas underwent a 12 percent drop in its wage index value one year, and a 14 percent increase the next year.

On a related note, concerns are on the rise that the home health PPS case-mix adjuster has proven difficult to refine sufficiently so that agencies are appropriately reimbursed for care. Refinement to the home health wage index calculation method could help in this regard.

During 2007 the Medicare Payment Advisory Commission (MedPAC) recommended to Congress that it give authority to the Secretary of the Department of Health & Human Services to fashion a new system for calculating the wage index for hospitals as well as several other providers, including home health. MedPAC's recommendation would base the wage indices for all providers on a different data set than the one currently in use by Medicare. In doing so, it also would eliminate any need for geographic reclassifications and the rural floor. MedPAC continues to support a new wage index model for all Medicare providers.

The Patient Protection and Affordable Care Act provides for comprehensive reform of the Medicare hospital wage index system that takes into account MedPAC's 2007 recommendations (PPACA Section 3137). This provision requires that CMS submit a report to Congress by December 31, 2011, setting out a plan to reform the wage index consistent with the 2007 MedPAC recommendations.

CMS issued the report to Congress on April 11, 2012. The report recommends the use of Commuting Based Wage Index (CBWI) that sets wage index values using the commuting patterns of hospital workers. The consulting group on the report expressed that the CBWI could be adapted for non-hospital providers including home health agencies. It stated: "Medicare could implement one of three options to adapt the index for use in these settings. First, Medicare could adapt the CBWI methodology to develop wage indices specifically for each one of the providers that use the Medicare wage index to adjust their payments. The administrative burden and resource requirements associated with this approach might be considerable. Second, as long as a hospital is located in close proximity to one of these other providers, Medicare could use the hospital's CBWI as the basis for the other healthcare provider's wage index. Using hospital wages assumes that the relative wage differences between areas are similar for hospital workers and for other healthcare provider workers. Third, Medicare could base providers' values on those of nearby hospitals using the nearest-neighbor method. For each healthcare provider, this method would approximate wage index values based on a weighted average of the wage index values for nearby hospitals."

The report did recognize the complexities of using a CBWI in home health and hospice "given that the Hospice and Home Health payment methods use the beneficiary residence or place of service to adjust payments, the relevant commuting patterns would be from the employee residence to the beneficiary residence. This would add a new level of complexity to the collection of commuting data and is unlikely to be feasible." CMS has not moved forward with any wage index reforms.

Most recently, in late 2018, the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) issued an in-depth report, "Significant Vulnerabilities Exist in the Hospital Wage Index System for Medicare Payments" identifying problems with the wage index system and recommending, among other actions, stepped-up oversight and comprehensive reform of the system.
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RECOMMENDATION: CMS should conduct further study to determine a wage index approach that can be most equitably applied to all Medicare providers – the goal should be to put all providers on a level playing field with their respective wage indexes. If the revised wage index allows for geographic reclassifications for one provider group, it should provide the same allowance for all. Any wage index weight changes in a reformed model, or in future years in applying the wage index model, should be subject to a transition limitation on increases and decreases from one year to the next.

RATIONALE: The current hospital wage index does not fairly reflect variations in wages in home health and hospice. In today's health care environment, health care providers of all types compete for employment of the same personnel. The adjustment of Medicare payment rates intended to reflect variations in wages across the nation should be consistent across all provider types. With increasing shortages of health care personnel, unequal wage index adjustments for health care providers in the same geographic region results in an uneven and discriminatory distribution of the employment pool of personnel. Prevention of wide swings in wage indexes will enable health care providers to more precisely project revenue and budget expenses.

PROVIDE FAIR AND TARGETED REIMBURSEMENT FOR MEDICAL SUPPLIES

ISSUE: In implementing the PGDM for Medicare home health services, CMS has modified how home health agencies are reimbursed for providing medical supplies. Under the current payment system, the provision of medical supplies by home health agencies is reimbursed as an add-on payment.

In the 2008 reform of HHPPS, CMS established separate payment for medical supplies in each full episode, with the amount of payment based on certain patient characteristics. Payment rates are tied to a six-level severity index. The decision to pay separately for supplies using a new medical supply case-mix adjustor, rather than by adding a set dollar amount to every episode, came about because the CMS HHPPS research identified that only 10% of home health claims included charges for medical supplies.

The PDGM model incorporates the cost of supplies into the base rate based on cost report data. Cost report data has been suspect for accuracy ever since the implementation of the home health prospective payment system (HHPPH) since reimbursement under HHPPS is not directly tied to cost reporting.

As with the HHPPS episodic model, PDGM will not include the cost of supplies for LUPA claims. These are reimbursed on a per visit rate. Additionally, technological advances in supplies for home health patients, such as chest tube drains, can be very expensive and may not be captured adequately on cost reposts

Because HHAs must provide all supplies while a beneficiary is under a home health plan of care, regardless of whether those supplies are part of the treatment plan, failure to adequately address the true costs of supplies could result in under payments for episodes with high supply costs.

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RECOMMENDATIONS:

1. Identify costs of supplies provided for which payment is inadequate;
2. Identify certain conditions routinely requiring supplies;
3. Study the fairness of the payment rates;
4. Make timely adjustments to the medical supply costs in order to provide accurate payment based on findings;
5. Apply supply costs to LUPA episodes;
6. Develop an outlier payment mechanism for high-cost medical supplies;

RATIONALE: HHAs have an expanded responsibility for medical supplies, the true costs of which have not been captured and reflected in the episodic payment rate. However, poor data resulting from HHAs' failure to include full supply charges on cost reports may have resulted in incorrect conclusions about supply needs, patient characteristics, and costs. Incorporating supply into the home health base rate, which was developed based on incomplete data, could be seriously flawed and the payment amount inadequate. Furthermore, because CMS failed to acknowledge the limit on coverage of supplies used by patients and their caretakers and failed to project added costs of new technologies, the Medicare benefit has been unfairly expanded on the

backs of HHAs. Many LUPA episodes, such as those for catheter changes, require the home health clinician to use costly supplies in the course of care. Often patients in LUPA episodes have the need for other supplies that must be provided by HHAs due to the bundled supply requirements.

ELIMINATE INEQUITIES IN PARTIAL EPISODE PAYMENTS

ISSUE: The implementation of a prospective payment system by CMS included the provision of partial payment in circumstances where the patient either (a) is discharged and readmitted, or (b) elects to transfer to another home health agency during an episode, as a disincentive to premature discharge from care. The partial episode payment (PEP) adjustments prorate the PPS episodic payment based on the number of days a patient is served between the first and last billable visit in relation to the 60-day episode. As a result of this interpretation, there are payment gaps that inequitably reduce the level of payment.

Current CMS policy and Medicare administrative contractors (MAC) actions in cases where two agencies bill for services provided within a 30 day period of time are confusing. CMS policy identifies the home health agency of record as the "primary agency." The primary agency is responsible for provision of all bundled services to the home health patient. However, in cases where a second agency bills for home health services, CMS has instructed its contractors to assume that this constitutes a "beneficiary elected transfer" resulting in a PEP of the first agency's episode. CMS failed to allow for exceptions to the policy, such as partial episodes due to relocation of Medicare beneficiaries during disasters.

CMS maintained the PEP policy with PDGM. PEPs will apply to 30 day periods rather than 60 day episodes.

RECOMMENDATIONS:

1. CMS should eliminate the payment gaps or carve-outs under its current interpretation of PEP payments.
2. Full 30 day period payments should be made when readmissions or beneficiary-elected transfers occur for conditions unrelated to the initial reason for care.
3. If readmission or transfer is required for the same condition, partial-episode payments should be prorated based on the total number of days out of 30 from the start of care or first day of the episode through the day prior to the date the patient was readmitted or came under the care of the second home health agency.
4. Fair and equitable policies and protocols should be established for providers to follow to avoid PEP episodes and conflicts when determining "primary agency."
5. Exceptions should be allowed to the PEP policy when home health patients require services after relocation during declared disasters.

RATIONALE: The use of a PEP adjustment is inconsistent with the manner in which CMS calculated average episode costs. CMS originally envisioned HHPPS as a system under which an agency would be paid prospectively for 60 days of care, now 30 days, regardless of the actual number of visits made during that episode. Under the current interpretation, CMS has chosen to carve out the days in between billable visits when paying for a partial episode. However, if there is no transfer or readmission, the agency receives a full episodic payment without the carve-outs, regardless of the length of stay. Providers should not be penalized when patients require treatment for a new condition unrelated to the original reason for care within a 30-day period. Reimbursement in this manner is more characteristic of per-visit payment rather than per-

episode. Unclear and conflicting policies and practices result in conflict and unfair payment reductions.

HHPPS should not exclude portions of episodic payment where there is a gap between intervening events since the nature of home care is the provision of part time or intermittent care. A patient is under a home health plan of care for the duration of the treatment plan. PEP episodes when patients receive services after relocation due to a disaster compounds the agency's financial losses.

REIMBURSE HOME HEALTH AGENCIES AND HOSPICES FOR TELEHEALTH AND PROVIDE FOR REGULATORY FLEXIBILITY

ISSUE: Interest in the concept of delivering home health and hospice services via telehealth (also known as telemedicine) has grown over the last few years. Quality Improvement Organizations (QIO) were charged in the 8th Scope of Work by CMS with urging and assisting home health agencies in the use of telehealth services, particularly as a tool in their efforts to reduce hospitalizations. The 2007 Home Health National Quality Improvement Campaign that was sponsored by CMS and the QIOs included telehealth as one of the twelve monthly best practices because of growing reports of greatly improved outcomes of care by home health agencies using telehealth. The 2011 Home Health Quality Improvement National Campaign included information on the benefits of telehealth in reducing hospitalization rates of home health patients. The use of telehealth has proven beneficial to hospice patients and their families, providing them with added security while allowing hospices to provide additional oversight of patients at a lower cost than additional home visits would require.

In December, 2000, Congress passed the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act (BIPA) which contained a telehealth provision for home health. This provision clarified that HHAs should not be prevented from providing telehealth services. However, BIPA reinforced that such services do not substitute for "in-person" home health services ordered by a physician, and are not considered "visits" for purposes of eligibility or payment.

Through the 2019 home health final rule, CMS made changes to allow home health agencies to include the costs of remote patient monitoring on cost reports in a way that allows these costs to be included in the per visit cost calculation. In the 2021 home health final rule, CMS promulgated regulations to permit HHAs include physician ordered telehealth and remote monitoring services in the plan of care (POC), as long as the technologies do not replace an ordered on-site visit. However, it is unclear whether CMS intended to permit hospice providers to include telehealth and remote monitoring visits on the hospice POC.

At this time, limited reimbursement is available from Medicaid, managed care plans and private insurance for telehealth services. Furthermore, CMS requirements to apply the conditions of participation (CoPs) to all individuals under the care of home health agencies (regardless of payer) creates a disincentive for home health agencies to use telehealth services for monitoring of stable individuals.

The cost of telehealth equipment and transmission of information can be prohibitive. Obstacles to the growth of telehealth services in home health and hospice include geographic practice limitations imposed by state professional licensure laws and liability laws.

During the COVID-19 pandemic home health and hospices agencies were almost exclusively providing care using remote technologies without reimbursement for the services. Additionally, there is no mechanism to capture visits conducted using telehealth or remote monitoring technologies on home health and hospice claims.

Congressional efforts have been undertaken to improve the status of telehealth within Medicare. However, to date the enacted legislation has not affected home telehealth services or telehealth within the home health and hospice benefits. Nevertheless, there are steps that CMS can take to address telehealth within Medicare that do not require further congressional authorization.

RECOMMENDATIONS: CMS should:

1. Expand telehealth demonstration projects to include home health and hospice services to Medicare beneficiaries to identify potential cost-savings to the Medicare program, appropriate patients, and the quality and effectiveness of telehealth services.
2. Develop payment mechanisms to reimburse home health and hospices agencies for equipment costs.
3. Recognize telehealth service as billable under home health PPS based on a discrete number of telehealth services per period.
4. Clarify if hospice providers may include in the POC visits conducted via telehealth and remote monitoring technologies.
5. Develop a method to capture visits conducted using telehealth and remote monitoring technologies on home health and hospice claims.
6. Not apply CoP requirements in instances where telehealth is used solely for monitoring stable individuals when Medicare is not the payer.

RATIONALE: Home health and hospice providers foresee application of telehealth as a means to improve quality and efficiency in the delivery of care in the home, provide greater access to specialists, and produce cost savings for specific types of patients. Telehealth has been identified as a best practice that leads to reduced hospitalization by providers participating in quality improvement initiatives with their Quality Improvement Organizations (QIO). Non-traditional services should be recognized and their use encouraged in the home care arena. CMS and the home health and hospice industries need data from claims, cost reports, quality reporting, and demonstration projects to support the expansion of telehealth services for the care of patients in the home, to justify expenditures, and ensure appropriate quality of care. Preliminary research results have demonstrated that telehealth results in cost-savings, prevent and shorten hospital stays, and improve patient outcomes and patient satisfaction. Additionally, CMS has been clear in its desire to advance the use of remote technologies in all sectors of healthcare. The COVID-19 pandemic further demonstrates the value of telehealth and remote monitoring technologies as part of the home health and hospice POC. However, to ensure expanded use of telehealth in home care, regulatory burdens must be minimized and payment must be guaranteed.

ENSURE USE OF STATISTICALLY VALID SAMPLING METHODOLOGY FOR MEDICAL REVIEW

ISSUE: Since July, 1992, the Centers for Medicare & Medicaid Services (CMS) has considered incorporating a revised sampling procedure for post-payment and audit reviews of Medicare claims. In 1999, CMS introduced a revised sampling procedure. The use of sampling procedures involves the MAC identifying a specific type of claim submitted for a specified period of time. The denial rate in the sample is extrapolated to all similar claim types for the period, resulting in denial of claims that were never reviewed individually. The validity of currently available sampling procedures has been questioned not only by providers but also by at least one CMS Region Office.

Congress limited the authorization to use sample adjudication and outcome extrapolation to circumstances where there is evidence of fraud or when efforts to correct a provider's misapplication of coverage standards through individual claim reviews and education have failed. However, CMS has not controlled the use of sampling in conformance with the congressional limitation, as Medicare contractors have extrapolated claims reviews to the universe of claims in a period of time without regard to a provider's claim compliance history. When these actions are subject to administrative review, the vast majority of claim denials are reversed, but only after providers have incurred great expense. The decision to apply sample adjudication is not subject to administrative review in an appeal.

RECOMMENDATIONS: CMS should strictly oversee the use of sampling and should prohibit all contractors from using sampling without specific authorization from CMS. In addition, CMS should:

1. Stop sampling until, and if, a valid methodology is identified.
2. Permit sampling only after there is a clear demonstration of program abuse.
3. Ensure statistically valid sampling procedures and overpayment methodology.
4. Refrain from extrapolating the denial rate to the entire population of claims submitted during that period of time until all appeals of the claims actually reviewed and denied have been exhausted.
5. Improve educational programs for providers and establish guidelines for minimum training of all Medicare contractor reviewers.
6. Expand contractor provider relations, services, and education to reduce claim errors.
7. Implement a time-limited prepay review.
8. Apply sampling to the population only after all appeals have been exhausted by the provider.
9. Require repayment only after all appeal rights are exhausted.
10. Permit providers to challenge the merits of the decision to apply sample adjudication under the standards set in CMS rules.
11. Develop criteria and standards for the exclusion from the program of providers that have a history or pattern of submitting claims for non-covered services after education has been provided.

RATIONALE: Sampling imposes significant risk of bankruptcy to agencies and reduces the protection available in an appeal. Even if CMS can develop a valid sampling methodology, extrapolation of denial rates to a large percentage of claims, with recovery of funds before

appeals have been exhausted, is unfair to agencies and patients. If sampling is used by CMS, safeguards as recommended are essential.

ENSURE HOME HEALTH CARE SERVICES UNDER MANAGED CARE

ISSUE: The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 increased payment to Medicare Advantage (MA) plans to encourage more beneficiaries to leave traditional Medicare and join private HMO and PPO plans. In addition, the Part D Medicare prescription drug plan has created policies that result in the automatic enrollment of special needs Medicaid enrollees into Medicare managed care plans. The Medicare plans have an obligation to provide the same scope of home health services as is available under traditional Medicare by agencies that meet Medicare quality standards. However, these plans have often covered home health services on a "per visit" basis while traditional Medicare covers episodic care. Further, some Medicare Advantage plans impose significant cost-sharing obligations on enrollees, while Medicare has no coinsurance requirements for home health services.

Managed care programs enrolling Medicare beneficiaries have been known to engage in questionable marketing practices, particularly in conjunction with marketing Part D prescription drug plans. These result in patients being unaware of their enrollment. Beneficiaries who wish to dis-enroll are faced with burdensome procedural requirements and delayed transfer back to fee-for-service Medicare.

Timely information is not available in the Common Working File (CWF) and home care providers have difficulty obtaining reimbursement for patients served when the patient did not inform them of their Medicare Advantage enrollment. Despite limitations on services and payments, Medicare certified providers are still responsible for meeting quality standards as outlined in the Medicare Conditions of Participation (CoPs).

In addition, several of the MA plans have contracted with medical review organizations that apply coverage criteria that are stricter than Fee-For-Service Medicare. This practice has left providers with claim denials and money recouped where the agency has provided the services in good faith and often with the plan's authorization.

RECOMMENDATIONS:

1. Require managed care plans and preferred provider organizations serving Medicare beneficiaries to provide home care services consistent with the coverage guidelines
2. Require Medicare and Medicaid managed care plans and preferred provider organizations to notify patients and their current providers of authorization of service requirements prior to the effective date of enrollment.
3. Require immediate notification of the HIPAA Eligibility Transaction System (HETS) by managed care plans and preferred provider organizations of Medicare fee-for-service enrollment and disenrollment, and improve the timing for updating HETS by CMS.
4. Clarify state laws regulating managed care plans and preferred provider organizations.
5. Establish an appropriate policy to encompass all disciplines of care, supplies, and HME within a definition of "home health services," and develop a reasonable definition of "custodial care."
6. "Hold harmless" providers, who in good faith provide physician-ordered, reasonable and necessary home health services to beneficiaries before notification of enrollment.

7. Ensure that preferred provider organizations and disease management programs assure access, adequacy of coverage and quality care.
8. Impose penalties on managed care organizations that fail to pay for authorized services in a timely manner to providers that meet quality requirements imposed in regulation
9. Ensure that Medicare and Medicaid managed care plans offer services through home health agencies that meet the Medicare conditions of participation.

RATIONALE: It is unfair to Medicare beneficiaries enrolled in managed care plans that limit the amount of home health service and impose co-pays and/or fail to authorize care. Further, different levels of benefits will result if new insurance models, such as preferred provider organizations and disease management programs, are not held to the same standards or required to ensure access to home health. Finally, home health agencies unfairly suffered, and will continue to suffer, serious financial problems caused by inadequate communication of beneficiary enrollment in these plans and failure of plans to pay for service provided.

ENSURE ACCESS TO MEDICAID HOME CARE SERVICES

ISSUE: Medicaid is the safety net to protect the poor. Generally, the Medicaid home care need is increasing, while available funding is decreasing. In many states, Medicaid rates for home health service and supplies are so poor that agencies cannot cover their costs, even after substantial subsidization from other payers. Budget problems in most of the states are leading to the initiation of payment rate and scope of coverage restrictions, as well as the imposition of co-pays on home care. The result is that access to home care is limited by the rates and by the reduction in benefits. Cost cutting is further encouraged by CMS through adoption of consumer-directed care programs in place of traditional home care services – programs that operate with few regulatory requirements and little oversight. While this is happening, compliance demands are increasing on Medicaid providers with the imposition of Medicare Conditions of Participation (CoPs), especially OASIS requirements.

Another cost-saving action taken by states is contracting with managed care organizations to manage all care provided to Medicaid clients, often resulting in even more limitations on home care services and payment rates. This has led to creation of a care dilemma for home care providers when faced with patients who have continuing needs beyond their benefit limit.

State associations indicate that multiple, state-specific reasons exist for the problems patients have in accessing home care services. States rarely use an objective and rational approach to rate-setting design. Some Medicaid programs operate with unwritten or incomplete coverage standards, thereby subjecting agencies and their patients to arbitrary coverage denials, the application of invalid sampling methodologies, and restricted appeals processes. NAHC has intervened in numerous state battles with Medicaid to improve rate-setting methodologies and the scope of home care benefits. To date, many of these efforts have been successful, but problems continue to arise in other states.

CMS is more active in managing Medicaid compliance by the states. CMS codified in the federal regulations a prohibition for states to require that Medicaid beneficiaries be homebound. CMS is pushing for better rebalancing of long term care spending in favor of home care. CMS recently published a Federal Register notice addressing new Medicaid federal rules on such topics as rate-setting standards. However, this notice included certain statements that could have a negative impact on payment to providers.

CMS is actively encouraging states to develop waiver programs that shift Medicaid home care to managed care systems. Early indications are that he managed care plans do not fully understand long-term services and support needs of the Medicaid population.

RECOMMENDATIONS:

1. Establish accountability and program integrity standards in Medicaid home care.
2. Develop appropriate rate-setting structures for use within the individual state Medicaid programs.
3. Enforce federal Medicaid law that requires states to set rates in a manner that secures access to necessary care and quality.
4. Curtail cuts in the scope of benefits.
5. Prohibit co-payment requirements.

6. Ensure that home health is included in every state Medicaid benefit package if block grants are established.
7. Address service and payment rate requirements that must be followed by managed care organizations serving Medicaid clients.
8. Ensure comprehensive reform of Medicaid home care consistent with the *Olmstead* decision.
9. Ensure compliance with the elimination of the homebound requirement at the state level.
10. Require that minimum standards be established for consumer-directed care programs.
11. Prohibit Medicaid from restricting coverage to a consumer-directed care model.

RATIONALE: Medicaid, in many instances, is the payer of last resort. The multiple barriers to access, due to low reimbursement rates, increased cost due to compliance demands, and a poorly designed benefit, inhibit home health agencies in providing care to the needy. Co-payments create increased administrative costs, bad debts, and an indirect reduction in reimbursement to the agency. State Medicaid agencies that impose homebound requirements are in violation of federal law.

Although consumer-directed care is ideal for some individuals, primarily young disabled persons, it should not be forced upon those unwilling and/or unable to direct their own care as a means for states to save Medicaid dollars.

Responding to the U.S. Supreme Court decision in *Olmstead*, CMS issued guidance to the states to take steps to provide alternatives to institutional care for the disabled, as mandated by the U.S. Supreme Court decision in *Olmstead* with home care as the central focus of CMS' actions. While there have been positive signs that the institutional bias of Medicaid is weakening, home care access has a long way to go.

PROMOTE MEDICARE-MEDICAID COORDINATION

ISSUE: Some patients are dually eligible for Medicare and Medicaid benefits. Their coverage may alternate between Medicare and Medicaid due to a change in their condition and the need for skilled services. Medicare is considered primary to Medicaid, so some Medicaid programs require a Medicare denial before making payment. Current CMS regulations require that third-party liability recovery programs demonstrate cost effectiveness and that liability be established to the third party prior to recovery from the provider.

In response to growing national concerns about the lack of coordination between Medicare and Medicaid for dually eligible persons, Section 2602 of the Affordable Care Act mandated the formation of the Federal Coordinated Healthcare Office. This office functions under the Centers for Medicare & Medicaid Services (CMS) "to make sure dual eligible beneficiaries have full access to seamless, high quality health care and to make the system as cost-effective as possible." The Medicare-Medicaid Coordination Office works with the Medicaid and Medicare programs, across federal agencies, states and stakeholders to align and coordinate benefits between the two programs, partnering with states to develop new care models and improve the way the dually eligible get health care.

It is the belief of the state Medicaid programs that Medicaid has incorrectly made payment on behalf of patients who were eligible for Medicare coverage. Medicaid programs across the nation have initiated projects designed to recover payments made for services to patients who are dually enrolled in both the Medicare and Medicaid programs. Others are requiring a formal Medicare claim determination before processing a Medicaid bill. In addition, some states are taking a hard line against Medicaid payment for any services rendered during any part of the 60-day period that includes some Medicare coverage of home health services. This position is taken even when the Medicaid claim concerns services after the close of Medicare coverage or when necessary care is provided beyond Medicare's scope of benefits.

Significant costs to providers, Medicare, and Medicaid are incurred because these projects require retrospective claims review, submission of claims to Medicare, and administrative appeals. Further, the unsupportable position that Medicare covers everything in the home for each day of the 30-day period leaves providers with unpaid services.

Problems exist with the demand bill process, sometimes taking three to four months when the payer (e.g., Medicaid) requires billing in a shorter time. Agencies have to bill without the Medicare denial, get rejected, and re-bill when the Medicare denial is received. This costs agencies considerable dollars. Some programs have required billing to Medicare for services clearly not covered (e.g., personal care only, housekeeping).

States have returned to individual claim submissions and appeals since the end of the sampling demonstration programs. This has led to high administrative costs and never-ending confusion. Additional states from the original ones pursuing Medicare-maximization are now instituting recovery programs or other barriers to Medicaid payment for dual-eligible patients. In addition, states have begun adopting "dual-eligible" demonstration programs that combine Medicare and Medicaid into a single managed care program. Concerns have arisen regarding the voluntary

nature of the enrollment of individuals into managed care plans, including whether the beneficiaries Medicare rights are compromised.

RECOMMENDATIONS: The Federal Coordinated Healthcare Office of CMS should take on the following work in pursuit of its goals to ensure Medicare-Medicaid coordination:

1. Modify third-party liability regulations to require that states utilize the most cost-effective method for recovering payment for dually eligible patients.
2. Implement a system of claims review that does not require individual claims submissions and appeals. Medicare and Medicaid claims submission should be combined with initial billing to Medicare and a transfer billing of remaining non-covered care to the respective state Medicaid program.
3. Require states to recoup incorrect payments from the Medicare program rather than the provider. No recovery should take place against a provider until after third party (Medicare's) liability is established.
4. Monitor the Medicaid third-party liability demonstration programs.
5. Establish clear coverage standards for Medicare and Medicaid that differentiate between the Medicare responsibilities in an episode of care and the Medicaid coverage obligations for additional services.
6. Eliminate regulatory conflicts between rules under the Medicare and Medicaid programs.
7. Improve care continuity and ensuring safe and effective care transitions for dual-eligible individuals.
8. Eliminate cost-shifting between the Medicare and Medicaid program and among related health care providers.
9. Carefully monitor any dual eligible demonstration programs and require full freedom of choice for beneficiaries regarding managed care enrollment

RATIONALE: While home health agencies make the best effort to determine whether a patient is covered under Medicare prior to submission of a claim to Medicaid, incorrect Medicaid payments have occurred. However, the use of an individual appeals system represents a costly, burdensome process for all parties concerned, including the provider of care, the Medicaid program, and Medicare. Strengthened rules and better enforcement would allow CMS to maintain improved oversight over state programs and to minimize the overall cost experienced by all parties. If the model demonstration programs are adopted nationwide, most of the burden of states' efforts to maximize Medicare will be eliminated.

ENSURE FAIRNESS IN GOVERNMENT FRAUD AND ABUSE ACTIVITIES

ISSUE: Fraudulent and abusive activity by a few home health/hospice providers taint the reputation of the industry as a whole. Current programs available to monitor fraud and abuse in home health/hospice are fragmented and often ineffective. These include CMS' program integrity and survey and certification activities, and enforcement activities of the Office of Inspector General (OIG).

CMS has supported the concept that all stakeholders in a Medicare benefit work together to protect both the beneficiary and the program from fraud and abuse. Although CMS recognizes that fraud and abuse is limited, it "must improve its ability to deter fraud and abuse and to detect it where it does exist." CMS has pursued the following as a means to control these problems: facilitate suspension of payment, ensure agencies have adequate financial reserves and business plans, require bonding, tighten certification requirements for abusive agencies, and establish joint consumer/provider workgroups, along with educating providers about their performance compared to peers in areas vulnerable to improper payment via the PEPPER as well as continuing adoption of stringent enrollment requirements in an attempt to identify and eliminate fraudulent providers.

CMS has developed a long-term strategy for detecting and preventing fraud and abuse in response to provisions in the Health Insurance Portability (HIPAA) and Accountability Act. The strategy involves separating program safeguard functions from the claims processing activities carried out by MACs and assigning them to Zone Program Integrity Contractors (ZPIC)/Unified Program Integrity Contractors (UPIC) and Recovery Audit Contractors (RAC).

Home health and hospice providers are under a national RAC contract, permitting one contractor to focus specifically on home health and hospice claims for improper payments and evidence of fraud.

RECOMMENDATIONS:

1. Establish and enforce minimum qualification and training requirements for CMS contractors, including knowledge of Medicare home health and hospice regulations and policies.
2. Closely monitor the work of ZPICs/UPICs and RACs to ensure appropriate fraud investigation and referrals.
3. Hold ZPICs/UPICs and RACs accountable to consistently and correctly applying Medicare home health and hospice regulations and policies by developing and implementing contractor performance criteria such as compliance with timeframes for review of records, inter-rater reliability, etc.
4. Establish a process for stakeholders to addresses inappropriate review requests with CMS.
5. Ensure timely processing of provider applications, whether for initial enrollment, revalidation, change of information, or change of ownership.
6. Offer timely guidance and assistance to providers when innocent errors lead to incomplete or erroneous applications.

7. Establish a Home Care Program Integrity Council composed of representatives from Medicare, Medicaid, providers, and beneficiaries to develop strategic efforts to avoid and control fraud, waste and abuse.
8. Establish a Hospice Program Integrity Council composed of representatives from Medicare, Medicaid, providers, and beneficiaries to develop strategic efforts to avoid and control fraud, waste and abuse.
9. Ensure coordination among the various audit contractors to reduce provider burden and duplication.

Further, the Office of Inspector General should:

1. Establish minimum training requirements for OIG and Department of Justice investigators, as well as working with the industry to address concerns regarding fraud and abuse, particularly under the new incentives of PPS.
2. Hold OIG and Department of Justice investigators accountable to consistently and correctly applying Medicare home health and hospice regulations and policies by developing and implementing investigator performance criteria such as compliance with timeframes for review of records, inter-rater reliability, etc
3. Streamline their enforcement procedures to minimize the investigative impact on non-fraudulent providers. They should seek assistance from NAHC/HAA in drafting "Fraud Alerts" and investigative procedures.
4. Provide timely responses to providers' legal questions, as well as access to published legal opinions.

RATIONALE: The direct and ongoing involvement of the home care industry in support of government fraud enforcement activities is necessary. This position is set out in NAHC's principles regarding provider fraud. At the same time, enforcement efforts must be balanced with adequate safeguards to ensure that innocent providers of care do not fall victim to inappropriate administrative actions.

ENSURE APPLICATION OF PROFESSIONAL AUDITING AND ACCOUNTING STANDARDS

ISSUE: Reports about the poor quality of auditing performed by home health MACs under the Medicare and Medicaid benefits are increasing. Of particular concern is the development of a Medicare "desk audit" to replace the required field audit. Auditing standards are not met when the audit is performed offsite, without the ability of the auditors to discuss issues with home health agency staff and to examine the full range of documents available at the home health agency. While CMS policy allows for a desk review, these reviews are only intended as precursors to full field audits.

The elimination of cost reimbursement raises concerns that MAC auditors will rush to "close the books" on providers. However, the audits remaining under cost reimbursement and any cost report auditing under HHPPS should be consistent with professional standards.

Medicare home health payment rates were subject to rebasing in 2014. In that action, CMS conducted a series of audits of home health agencies. Information indicates that these audits fell far short of professional auditing standards.

RECOMMENDATIONS:

1. Ensure that auditing standards comply with "Generally Accepted Accounting Principles" (GAAP) and CMS' published auditing standards.
2. Bear the burden of proving compliance with standards in the event of a dispute regarding the audit process.
3. Ensure that appropriate field audits are performed and that desk reviews are limited to pre-audit screening actions.
4. Assign adequate auditing resources where payment system reforms are developed.

RATIONALE: Poor quality audits lead to erroneous cost disallowances, premature or unnecessary recoupment, and delays in proper settlement. Shortcuts to auditing such as the "desk audit" create undue risks of error. In this context these are field audits done at the desk, not the traditional FI desk audit per se.

REFORM MEDICARE HOME HEALTH MARKET BASKET INDEX

ISSUE: Medicare law requires that payment rates for home health services be annually updated by a market basket index. Congress has left to Medicare the determination as to the makeup and calculation of the index. The Centers for Medicare & Medicaid Services (CMS) determines the market basket index by using inflation data from the Department of Labor Bureau of Labor Statistics (BLS) regarding the rate of inflation in a variety of cost sectors, including health care wages and benefits, transportation, insurance, and space rental. The cost items make up the home health market basket. Each cost category is weighted to reflect the proportionate impact that the respective items have on the overall cost of home health services. The proportionate impact is determined through a review of the cost of these items as set out in the cost reports filed by each home health agency. The annual index is determined by applying the BLS reported rate of inflation in the various cost categories to each category in proportion to its overall cost weight. CMS projects a rate of inflation using a proprietary forecasting system supplied by an outside commercial contractor.

Over the last several years, the Market Basket Index (MBI) has been significantly lower that the index calculated for other provider sectors. Even though these provider sectors share the same labor pool, the index shows a lower projected inflation rate for home health services than the other sectors. In addition, despite dramatically increased costs of transportation, the index reflected a small cost impact.

The current market basket index variables do not include consideration of new costs required by providers such as regulatory changes and employment cost changes. For example, CMS imposed new rules regarding documentation and oversight of therapy services that will increase provider service and administrative costs, yet these costs are not considered in calculating the MBI. Likewise, the Patient Protection and Affordable Care Act of 2010 (ACA) includes new administrative requirements, such as the face-to-face physician encounter, that will raise providers' operational costs.

The weaknesses in the current MBI calculation method is highlighted this year in the significant difference between the index rate applied to hospitals and the index rate proposed for home health agencies. A difference of .5 is, on its face, unsupportable. Home health agencies have experienced (a) significantly increased administrative costs for the face-to-face encounter rule, (b) a great increase in the requirements for professional therapist assessments of patients, and (c) increases in gas costs for a provider group that travels nearly five billion miles a year.

RECOMMENDATIONS: CMS should thoroughly review and evaluate all aspects of the home health MBI to ensure that is reasonably forecasts annual cost increases. That review and evaluation should include the appropriateness of the BLS proxy data choices, the choice of cost components, the accuracy of the cost component weights, and the reliability of the forecasting model.

The CMS review and evaluation should be made publicly available as part of the issuance of a proposed rule regarding the annual rate update. The index should incorporate a forecast of expected changes in costs resulting from new legislative and regulatory mandates. CMS must

include an element in the MBI to address the resulting cost changes when the home health services "product" changes because of new regulatory or administrative requirements.

RATIONALE: The MBI, as constructed by CMS, fails to include consideration of the direct cost increases that CMS rules may have on the delivery of care. Instead, it looks at general cost changes such as the cost of caregivers, transportation, insurance, and office space. This approach does not provide CMS with the information needed to adjust payment rates in relation to regulatory cost increases. Home health agencies compete with hospitals and skilled nursing facilities for nurses, therapists, medical social workers, and aides. Further, home health care is vulnerable to the swings in gasoline pricing and other transportation costs. Further, changes in law and regulations often increase the costs of care. An accurate inflation update is crucial to secure continued access to home health care. Failure to include these new costs in an MBI results in an unfunded mandate.

ESTABLISH FAIR AND APPROPRIATE STANDARDS FOR ANY FURTHER REBASING OF MEDICARE HOME HEALTH RATES

ISSUE: Section 3131 of the Patient Protection and Affordable Care Act of 2010 (ACA) requires that payment rates for Medicare home health services be rebased beginning in 2014, and that the rebased rates be phased in over a four-year period concluding in 2017. The legislation leaves much to the Centers for Medicare & Medicaid Services (CMS) to decide on the process and factors considered in the rate rebasing. The law itself provides that the rates "shall be adjusted by a percentage determined appropriate by the Secretary to reflect such factors as changes in the number of visits in an episode, the mix of services in an episode, the average cost of providing care per episode, and other factors that the Secretary considers to be relevant." The legislation also allows the Secretary to consider differences between hospital-based and freestanding providers, for-profit and not-for-profits, and urban and rural providers.

On November 23, 2013, CMS issued a Final Rule that sets Medicare home health payment rates based on a formula that ostensibly relates to the average cost of care. With this approach, CMS reduced base episode payment rates by the full 14% allowed under PPACA through a 4-year phase in of the rate changes. In addition , CMS limits the increases in per visit payment rates to 3.5% despite a finding that average costs of these visits is as much as 133% of the rates. 78 Fed. Reg. 72256 (December 2, 2013).

The rebased payment rates are founded in old data and based on a formula that ensures that aggregate payments to home health agencies is less than the cost of care. Forecasts of the impact of the new rates show that nearly 73% of all agencies will be paid less than their costs of care by 2017, the final year of the rate phase-in. In addition to the flawed data and rebasing formula, CMS failed to take into account all the costs of home care, the need for business capital by non-profit and proprietary agencies alike, and the wide variation in financial outcomes due to the unique aspects of delivery of care in individual's homes rather than a single site institution.

Although rebasing concluded in 2017, MedPAC continues to recommend to Congress additional rebasing of home health payments.

Any future discussion related to potential rebasing of HHA rates should not take place until a reasonable set of standards for rebasing has been developed and made public.

RECOMMENDATIONS: To ensure continued access to high-quality care, in its rebasing of home health payment rates, CMS should revise its rebasing rule to:

1. Ensure that all existing costs of home health care are known and considered, including telehealth, caregivers such as respiratory therapists and nutritionists, marketing, taxes, acquisition of capital, and new regulatory requirements.
2. Ensure that the rates are rebased in a manner that considers the aggregate financial consequences rather than a siloed approach to segments of the rates.
3. Recognize that a reasonable financial margin is needed for any business, including home health agencies, in order to meet cash flow needs and to incent efficiencies.

4 Convene a technical expert panel of home health agency representatives to provide advice and direction to CMS in determining rate rebasing standards.
5 Recognize differences in types and location of providers in setting rebased rates, but only to the extent that the difference relate to factors outside the control of the providers;
6 Publish the standards for rate rebasing with sufficient time for all stakeholders to fully evaluate and develop comments for consideration.
7 Evaluate the impact of rebased payment rates in a manner that considers short and long-term impact, the impact on the viability of the existing businesses, the impact on access to care, and the impact on clinical practices.

RATIONALE: Congress intentionally required a series of payment reforms in home health services to occur on a gradual and periodic basis to provide the opportunity for companies to adjust so that they might stay in business and allow continued access to care. The rebasing of payment rates is the single most important reimbursement action undertaken by Medicare. A well-informed and rationally developed set of rebasing standards can ensure that Medicare beneficiaries maintain access to high-quality care. Conversely, poorly devised rebasing standards can be a disaster for beneficiaries and the providers that serve them. The CMS rebasing rule will result in a loss of access to care as a result of its failure to consider all reasonable elements of cost, trends in Medicare margins, the wide variation in costs in home health care, and the need for capital.

The rebasing standards must be revised with the recognition that home health care is a health care business that needs to operate within reasonably normal business principles, which include the need to accumulate capital for growth and improvement, and the opportunity to secure a margin to justify the investment – whether from a for-profit enterprise or a non-profit entity that needs a margin to support any mission.

ENSURE A FAIR AND EQUITABLE HOME HEALTH VALUE BASED PURCHASING (HHVBP) SYSTEM

ISSUE: In the 2016 HHPPS rate update rule, CMS included a provision for a HHVBP pilot program for home health to begin in 2016. The VBP model for the program would increase or decrease payments by 3-8% depending on performance. Nine states have been selected to participate and all agencies in those states are subject to the VBP program. CMS has selected an array of quality measures that include outcome, process, HHCAHPS, and claims based measures that are currently reported on HHC or at the agency level through CASPER reports. In addition, three new quality measures have been included. These measures, however, will only be required to be reported. There is not a performance metric associated with the new quality measures.

In the 2017 HHPPS rate update rule, CMS made several positive changes to the HHVBP program: four measure were eliminated and benchmark and achievement thresholds will be calculated at the state-level rather than the smaller-and larger-volume cohort level; smaller-volume cohort must have a minimum of eight HHAs in order for the HHAs in that cohort to be compared only against each other, rather than against the HHAs in the larger-volume cohort; and modifications to the appeals process.

CMS continues to modify the HHVBP through the measure set. In the 2018 HHPPS rate update rule, CMS eliminated the Drug Education on All Medications Provided to Patient/Caregiver During All Episodes of Care measure and discussed developing three new composite measures for future consideration.

For reporting year 2019, payment year 2021, CMS dramatically revised the measures by eliminating the last two process measures from the measure set and is re-weighing the OASIS and claims based measures.

CMS proposes to weight the OASIS and claims based measures so that each accounts for 35 % of 90% of the total points scored (TPS) and the HHCAPHS will account for the remaining 30 % of the 90 % TPS. CMS proposes to further alter the weights of the claims based measures so that the Unplanned Hospitalization during first 60 days measure would carry three times the weight as the Emergency Department Use without Hospitalization measure; 26.25% / 8.75% respectively.

CMS is also proposing to replace the three activities of daily living measures (improvement in bathing, transfer and ambulation) with two composite measures that will carry a maximum possible score of 15 points each: Total Normalized Composite Change in Mobility and Total Normalized Change in Self Care.

The composite measure for change in mobility uses the assessment items from the OASIS measures CMS proposes to replace (improvement in bathing, transfer, and ambulation.) However, the composite measure for the change in self care uses the six OASIS measures, five of which are not currently included in the HHVBP model.

CMS did not provide sufficient time for agencies participating in the HHVBP model to prepare for such dramatic changes to the measure set.

Additionally, because the outcome and process measures are collected from the OASIS data set, performance on these measures reflect Medicare, Medicaid and Managed Care patients served by the agency, even though the payment adjustment applies only to Medicare payments.

Furthermore, CMS continues to block access to the HHVBP portal on the CMS web site to all entities except the participating agencies. Therefore, the national and state home health care associations do not have information that is communicated to the participants or the results of the participants' performance.

According the CMMI. the model has resulted in an average 4.6% improvement in home health agencies' quality scores in the nine states and an annual savings of $141 million to the Medicare program. On January 8, 2021, CMS announced its intent to expand the HH VBP demonstration project nationwide. CMS plans to issue a NPRM on the details of the expansion within the next several months.

RECOMMENDATIONS:

1. Ensure consultation with provider representatives in identification of appropriate HHVBP outcome and process measures, and in the development of a fair and equitable system.
2. Allow provider representatives access to the same information shared with the HHVBP participants.
3. CMS should allow agencies at least 6 months to prepare when significant changes to the model are implemented.
4. Base the system on measures that are under the control of, or reasonably susceptible to the influence of, the home health agency while the patient is on service with the agency.
5. Base selected measures on uniform patient outcome data that home health agencies have collected and reported for a sufficient period of time in order to ensure consistency and reliability.
6. Apply HHVBP based to Medicare patient data only.
7. Ensure that the risk adjustment methodology effectively adjusts for age, the number of co-morbidities, and Medicaid eligibility.
8. Base the system on measures that are meaningful to patients, providers, payers, and other stakeholders and represent value and important aspects of care and services rather than patient spending.
9. Spread reward payments throughout the calendar year.
10. Ensure stakeholder involvement and input is considered before finalizing any plans to expand the HHVBP demonstration.

RATIONALE: Identification of acceptable, fair and equitable measures can be problematic, especially in light of the many variations in the needs and social and economic status of Medicare beneficiaries. Therefore, development of a HHVBP system must be undertaken carefully, in concert with the provider community, and only after sufficient research has been

conducted in order to ensure that providers are rewarded appropriately and not unfairly penalized. Small providers do not have the reserve funds to invest in costly HIT. Furthermore, it would be unfair to providers to withhold monies needed for daily operation until in the end of the year in order to fund HHVBP.

It is generally accepted in government circles that, because of the outcome measures already available to home health providers, home health is a step closer than most other providers in preparing for VBP. However, many questions exist about the validity and reliability of OASIS in light of new changes and additions. In addition, CMS has not tested and validated the new quality measures to be used in the VBP program. In consideration of the P4P demonstration project, as well as any system adopted for implementation, variations of health status and practice patterns found in various parts of the country necessitate that performance thresholds be compared separately. Therefore, geographic areas that are smaller than entire states should be identified for comparison of agency performance. Core-based statistical areas (CBSAs) may serve as more appropriate for determining performance thresholds.

Furthermore, dramatic changes to the model while providing agencies little time to prepare places agencies participating in the HHVBP program at a significant risk for unfair rate reductions.

ESTABLISH REASONABLE POLICIES AND IMPLEMENTATION PROCEDURES FOR THE PHYSICIAN FACE-TO-FACE ENCOUNTER REQUIRED FOR MEDICARE AND MEDICAID HOME HEALTH CERTIFICATION

ISSUE: The Patient Protection and Affordable Care of 2010 (ACA) conditions Medicare payment for home health services on a physician or certain non-physician practitioner having a face-to-face encounter with the patient prior to certifying the need for care. The statute also called for application of this requirement to Medicaid home health services. The Centers for Medicare and Medicaid Services (CMS) promulgated a Final Rule on November 2, 2010, for Medicare that requires the encounter to occur no more than 90 days before or 30 days after the start of care. The rule includes significant, prescribed documentation requirements the physician must comply with, or the home health agency may not bill for the services. The effective date for implementation was to be January 1, 2011. CMS delayed enforcement of the rule until April 1, 2011, to provide agencies and other stakeholders with additional time to establish operational protocols necessary to comply with the regulation. A Medicaid face-to-face proposed rule was published during 2011 with similar requirements. Although some states have already implemented Medicaid face-to-face requirements, no federal final rule has yet been published.

As part of the certification form itself, or as an addendum to it, the physician must document that the physician or NPP saw the patient, and document how the patient's clinical condition supports a homebound status and need for skilled services. The form may not contain standardized language or check boxes, unless the documentation is done electronically. Although the physician or the physician's office staff may complete the form from the medical, documentation must include the date of the encounter, supporting evidence of homebound status, and evidence that home health services are medically necessary. CMS clarified that is not permissible for the physician to dictate the face to face encounter findings to the home health agency staff to transcribe and send for signature. The stringent documentation guidelines are proving to be burdensome to physicians. Many physicians have expressed frustration with the additional documentation requirement, and are resisting complying with the regulation. In response to physician complaints CMS advised them that documentation requirements are far less detailed than home health agencies are asking for, despite the fact that this information is contrary to Federal Register notices, policy manuals guidance and CMS issued Q&As.

CMS provided some flexibility regarding institutional physicians when patients are hospitalized or in skilled nursing facilities. Medicare will allow a physician who attended to the patient but does not follow patient in the community, such as a hospitalist, to certify the need for home health care based on their face to face contact with the patient. However, the documentation requirements and restrictions are the same, and many institutional physicians are not willing to certify patients for Medicare home health services. In addition, CMS took steps to reduce the burden on inpatient physicians by publishing revisions to the face-to-face regulation and policy in the 2012 PPs rate update notice, allowing community physicians to certify a patient for home health based on inpatient physicians' encounter documentation. CMS allowed for greater flexibility, in the 2013 PPS rate update, by permitting the allowed NPP to conduct the face-to-face encounter in an inpatient facility and communicate the findings to the inpatient physician who would the communicate to the findings to the community physician. However, this has resulted in even more confusion and many questions as to how these provisions are to be put into practice.

In addition, home health agencies have been subject to high denial rates for insufficient F2F encounter documentation. One of the contractors has reported a denial rate as high 80%. The high denial rates suggest a general misunderstanding by agencies and physicians as to what CMS expects physician's to include on the F2F encounter document.

Furthermore, home health agencies have been informed that they may not bill a patient for uncompensated care due to noncompliance with the new requirement. Therefore, agencies will be held financial responsible for any care provided to a patient where the face to face encounter has not occurred during the prescribed time frames or the physician's documentation does not satisfy CMS' requirements. Agencies will have to choose whether or not to admit patients that are referred but have not had the required face to face encounter, or to discharge patients on services that have not had a face to face encounter with the physician within 30 days of admission. Forcing agencies to choose between providing uncompensated care or not accept a patient onto service will likely result in a lack of access to home health services for certain Medicare beneficiaries. Beneficiaries without transportation or resources to facilitate a visit to the physician are placed at a disadvantage for receiving home care services for which they are entitled.

Finally, CMS imposed restrictions on the use of telehealth technologies for the conduct of face-to-face encounters that make it almost impossible for its application.

In the final rule for the 2015 PPS rate update, CMS revised the F2F encounter requirements. CMS eliminated the narrative requirement, which required the certifying physician to provide a detailed explanation on why the patient was homebound and in need of skilled services. CMS will still require that the face-to-face encounter occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care, be related to the primary reason the patient is receiving home health services, and be performed by a physician or allowed NPP.

In addition to eliminating the narrative requirement, CMS has also altered its medical review process for determining patient eligibility for home health services. CMS requires that the home health agency submit pertinent sections of the certifying physician's medical record when an agency's claim is requested for review. If the documentation in the physician's record is insufficient to support eligibility, the home health agency's claim will be denied

CMS will, however, permit the agency to inform the certifying physician of the agency's findings from their comprehensive assessment that supports the patient's eligibility for home health care. The certifying physician will need to sign the additional information and incorporate it into his/her medical record

In the 2019 HHPPS payment rate update rule, CMS codified into regulation that the home health plan of care may be used as agency documentation to be incorporated into the physician's clinical record.

CMS maintained the concept that documentation for home health eligibility must be contained solely in the physician's medical record rather than allowing for the entire medical record, including the home health record to be considered.

RECOMMENDATIONS:

1. Provide additional flexibility in the documentation requirements to:
    a. Limit the documentation to permit the physician to sign an attestation statement that the face to face encounter had occurred.
    b. Allow any physician to conduct a face-to-face encounter and certify eligibility for home health services, regardless of whether that physician or another physician is responsible for the plan of care.
    c. Require full consideration of the home health medical record documentation, when evaluating eligibility for Medicare home health benefits.
2. Apply "without fault" provisions, or permit the agency to bill the patient, when non-compliance is the fault of the physician or beneficiary.
3. Establish exemptions to face-to-face encounter requirements including but not limited to: patients receiving home health services after an inpatient stay; those patients living in medically underserved areas; and any persons with barriers to access to care, such as individuals incapable of leaving home and without access to a home visiting physician.
4. Remove the reference to section 1834(m) of the Social Security Act and substitute a definition of telehealth services that allows an individual to meet the face-to-face encounter requirements through modern technologies available in their home. These technologies should include two-way audio and video communications.
5. Include the changes referenced above as regulatory measures to the extent that CMS is able under the existing Section 6407 to implement the changes.
6. Establish a process to re-evaluate CMS policies for the face-to-face requirement that includes input from providers, physicians and beneficiaries.
7. Modify Medicare coverage rules to cover an ambulance transport to a physician's office for beneficiaries that require an ambulance.
8. Ensure adequate education is provided to agencies and physicians

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RATIONALE: A face-to-face encounter is an event outside of the home health agency's control. An agency can facilitate a visit to the physician, but whether or not the encounter takes place is within the control of the physician and/or patient. We believe that CMS has gone beyond statutory intent in the regulation on two fronts: requiring that the encounter be directly for the primary reason for the prescribed home health services, and conditioning home health payment on unprecedented physician documentation on the encounter including a rationalization of the certification as to how the patient meets Medicare coverage requirements.

Home health agencies are subject to nonpayment of their claim if physicians fail to meet the unprecedented documentation requirements. In other words, the non-compliance of a party outside the control of the agency will cause financial harm to the agency and be of no consequence to the physician. Home health agencies have no authority over the physician to guarantee that the documentation is properly composed in the first place.

Home health agencies must be held harmless for any non-compliant documentation by the physician or failure of the patient to comply that is outside of their control. CMS should automatically apply the "without fault" provisions in section 1870 of the Social Security Act where the HHA receives a properly completed certification statement from the physician but that the physician is non-compliant with requirements for documentation or the patient fails to see the physician. Also, the good faith efforts of the HHA should be protected against physician or beneficiary non-compliance through payment guarantees under section 1879 of the Social Security Act.

ENSURE A FAIR AND EQUITABLE POLICY FOR OASIS PAY-FOR-REPORTING

ISSUE: A "pay-for-reporting" requirement for home health agencies (HHAs) has been implemented since 2007. Agencies are required to submit the OASIS assessments to CMS in order to receive the full annual payment update (APU). Agencies that do not submit OASIS assessments receive a 2% reduction in payments. However, the quantity of OASIS assessment the agency must submit has never been established. If an agency submitted even one OASIS assessment they met the requirement and could avoid the 2% reduction on payments.

In the 2015 final rule for the HHPPS update, CMS finalized a requirement that sets a threshold for OASIS quality assessment submissions. HHAs will be required to submit at least 70 % of quality assessments during the first reporting year, which runs July1, 2015- June 30, 2016, in order to receive the full APU for the applicable payment year. CMS defines what constitutes a quality assessment in seven ways.

CMS' ultimate goal is to require HHAs achieve a pay-for-reporting performance requirement compliance rate of 90% or more. CMS originally proposed to phase-in the requirement over a three year period, the first year agencies would be required to submit 70%, the second year 80%, and the third year 90% of their quality assessments.

Agencies must have a 90% compliance rate in order to avoid a 2% penalty beginning in payment year 2019 and beyond.

RECOMMENDATIONS:

1. Provide agencies with a report showing their individual submission rate prior to the effective date.
2. Monitor HHA submission rates to ensure agencies are able to meet and maintain a 90% submission rate.
3. CMS should be transparent in reporting which assessments do not qualify for the QAO calculation so the providers can more effectively refute discrepancies.

RATIONALE: The ''pay-for-reporting'' OASIS submission threshold requirement is a new reporting requirement that can have a significant financial impact any HHA that is not able to meet the requirements. In addition, "quality assessment" is a new term that comprises a combination of assessments and is defined seven ways by CMS'. Many agencies do not have adequate data regarding a submission rate for "quality assessments".

ENSURE REASONABLE PRE-CLAIM REVIEW POLICIES FOR HOME HEALTH AGENCIES

ISSUE: The Centers for Medicare and Medicaid Services (CMS) had initiated a 3 year pre-claim review (PCR) demonstration project for Medicare home health services in 2016.

CMS initiated the demonstration in Illinois only in September 2016 and in April, 2017 CMS announced a pause in the pre-claim review demonstration project .with no indication when, or if, the demonstration project would be resumed.

In May 2018, CMS announced its proposal for a new 5 year demonstration project, renamed Review Choice Demonstration (RCD), which is very similar to the PCR demonstration. The revised demonstration has been modified in the following ways:

1. Home health agencies (HHAs) are given a choice of 100% pre-claim review, 100% post-payment review, or a 25% payment rate reduction and potential claim review by the Recovery Audit Contractor; and
2. HHAs can qualify for an exemption based on certain performance standards.

The targeted states have been partly changed to include Illinois, Texas, Florida, Ohio, and North Carolina while dropping Michigan and Massachusetts.

On June 1, 2019, RCD began in Illinois. On September 30, 2019, the RCD began in Ohio, and on March1, 2020 the RCD began in Texas. CMS delayed the start of the RCD in North Carolina and Florida, which was scheduled to begin on May 4, 2020, due to the COVID -19 PHE. CMS established a phased-in approach for RCD in North Carolina and Florida that has been extended through March 30, 2021 when CMS will reevaluate a start date for these states.

The phased-in approach to RCD for North Carolina and Florida gives providers the option to submit pre-claim review requests or submit claims without going through the pre-claim review process. Claims submitted without going through pre-claim review will process as usual and not be subject a 25% rate reduction. However, these claims are subject to 100% post-payment review.

For the states of Illinois, Ohio, and Texas, CMS permits a similar option to RCD. However rather than a post-payment review, these states are subject to 100% pre-payment review on claims submitted without going through pre-claim review.

RECOMMENDATION:

- CMS should officially modify the RCD project and restrict any pre-claim review activity to highly targeted designated providers that demonstrate a high risk of program abuse based on past claims history or new providers of services in high risk geographic areas. Alternatively, pre-claim review should be available to the HHAs as an option that can be used on a claim-by-claim basis.

- CMS should conduct an annual a cost benefit analysis of the RCD to evaluate the improper payment rate against the cost of the demonstration.
- Eliminate the 100% prepayment and post payment review for claims submitted during the PHE without pre-claim review.
- CMS should directly prohibit any of its contractors from re-reviewing claims approved through pre-claim review in the absence of fraud.

RATIONALE: Pre-claim review is an extraordinary action that triggers significant costs for all parties and could present barriers to the timely and effective use of home health services. CMS estimates that the costs associated with performing review for home health services under the revised demonstration would be approximately $392.9 million over the 5-year demonstration period. Past trials of similar programs, such as, prior authorization for certain Medicare services have shown that it has negligible impact on program abuse. Additionally, the improper payment rate for home health agencies continues to decrease. The improper payment rate for home health providers in 2020 dropped 7.9 percent, from the 2018 rate of 17.6 percent.
CMS' attempt to provide relief to HHAs required to participate in RCD falls short if claims are still subject to100% review (pre-payment or post- payment). Many HHAs have chosen to continue with pre-claim review rather than risk having 100% medical review on claims.

ENSURE FAIR IMPLEMENTAION OF THE TARGETED PROBE AND EDUCATE

ISSUE: On October 1, 2017 CMS implemented a revised medical review program applicable to all provider types including home health and hospice. The program, called Targeted Probe and Educate (TPE), will replace the current medical review programs conducted by the MACs.

The TPE focuses on providers that have been identified through data analysis as being a potential risk to the Medicare trust fund or who vary significantly from their peers in data indicating improper payments. As with previous probe audits the TPE review requires 20-40 claims be reviewed per round, for a total of up to three rounds of review. Each round will be a prepayment review. After each round, providers will be offered individualized education based on the results of their reviews.

Agencies with continued high error rates after three rounds of TPE may be referred to CMS for additional action, which could include 100 percent prepay review, extrapolation, referral to a Recovery Audit Contractor (RAC), etc. Providers may be removed from the review process after any of the three rounds of probe review if they demonstrate low error rates or sufficient improvement in error rates, as determined by CMS.

CMS' policy requiring a range of 20-40 claims for review does not consider that for small agencies even the low end of the range (20 claims) could represent a significant portion of total claims submitted. Additionally, depending on the focus of the review it may take a months to years for a home health agency or hospice to submit enough claims to reach the minimum 20-claim sample. For instance, a hospice under TPE for patients with a length of stay longer than 730 days may only have one patient per month that meets this criteria requiring 20 months of claims before the minimum claim sample is achieved. Also, home health and hospice providers vary in size with many having an average daily census of less than 100.

RECOMMNDATIONS:

1. CMS should closely monitor the TPE program to ensure small providers are not unfairly burdened with the prescribed number of claims that must be reviewed.
2. CMS should allow the contractors to review less than 20 claims based on the portion of claims Medicare received and the performance of providers on claims processed through TPE when it will take a significant amount of time to reach the 20-claim minimum.

RATIONALE: A high portion of prepayment claim review for small providers could represent an undo financial burden and places small providers at an unfair disadvantage for the TPE.

ESTABLISH AN EQUITABLE HOME INFUSION THERAPY BENEFIT

The 21st Century Cures Act (Act) included a provision that called for the development of new home infusion therapy benefit under Medicare Part B and this was finalized as part of the CY2019 Home Health Final Rule. The benefit provides professional services for beneficiaries receiving home infusion therapy through a pump that is an item of Durable Medical equipment (DME). Medicare covers certain infusion drugs under Part B when the drug requires infusion by a pump. These drugs include chemotherapy, inotropic medications, certain pain medications, immunoglobulin therapy, and anti-fungal medications.

The Act defines a qualified home infusion therapy supplier as a pharmacy, physician, or other provider licensed by the state where services are provided. Home health care and hospice providers are eligible to be accredited as home infusion therapy suppliers

The new benefit includes the professional service, such as nursing services, under a physician established plan of care that is periodically reviewed; training and education on infusion therapy, medications, disease management, and care of vascular access sites; remote monitoring; and 24/7 availability by the supplier. CMS would permit remote monitoring to be follow-up telephone calls or on-site visits.

CMS proposes payment for home infusion therapy to be a single payment for the day the nurse is in the home and the drug is infused.

Full implementation of the home infusion therapy benefit will begin in 2021, once the benefit becomes a permanent program; beneficiaries will not be able to receive Part B home infusion therapy services under the home health benefit. Beneficiaries will only be able to receive the services through a home infusion therapy supplier.

The 2018 Bipartisan Budget Act (BiBA) included a provision that provides payment for home infusion therapy services, under the new benefit, during a transitional period (2019-2020) to select providers. Only licensed pharmacies enrolled as a DME supplier will be eligible to offer the benefit to beneficiaries during the transitional period.

CMS is permitting HHAs to continue to provide the professional services associated with Part B infusion drugs under the home health benefit during 2019 and 2020 transitional period.

RECOMMENDATIONS:

1. CMS should provide clear guidance for on the coverage criteria for services provided under the home health benefit and the home infusion therapy supplier benefit when beneficiaries are receiving services under both benefits currently. .
2. CMS should work with Congress, the home health industry, an the home infusion industry to establish a more equitable home infusion benefit that takes into account the concerns of all stakeholders.
3. CMS should create a demonstration project to study expanding home infusion access to any Medicare Part D covered drug that is administered intravenously or subcutaneously for an

administration period of 15 minutes or more. Under the demonstration, drugs used in the home infusion therapy setting would be billed to Medicare Part D, while there would be a bundled payment billed through the A/B MACs for home infusion therapy services, and disposable equipment and supplies

RATIONALE: NAHC has serious concerns with CMS' proposal since it fails to recognize how home infusion therapy is currently provided to eligible beneficiaries under the home health benefit.

Currently, a beneficiary may receive home infusion therapy by combining the DME benefit for the pump, supplies and covered infusion drug with the skilled professional services covered under the home health benefit. The DME supplier bills Part B DME for the supplies, pump and infusion drugs, while the HHA bills Medicare for the professional services under the home health benefit.

If the home infusion therapy benefit is implemented as proposed, HHAs will not be able to bill for the profession services associated with the new benefit for home infusion therapy under the home health benefit, rather, these service will need to be provided and billed by a home infusion therapy supplier under Medicare Part B, whether or not the home infusion therapy supplier is also the Medicare certified HHA. This benefit structure disadvantages beneficiaries in terms of cost to the beneficiary, restricting entitled benefits, and fragmenting care.

Eligible beneficiaries are able to receive the professional services associated with infusion therapy under the home health benefit without incurring out of pocket costs. The new Part B home infusion therapy benefit will require 20 % beneficiary co-pay for the professional services that are otherwise covered in full under the home health benefit.

Additionally, some beneficiaries could see limitations in eligibility for home health services. For example, if a beneficiary is otherwise eligible for home health services and the only needed skilled service is nursing for infusion therapy, but also needs a dependent home health service(s)(occupational therapy, home care aide, social worker), the beneficiary will be precluded from receiving the other support services under the home health benefit. The qualifying service for Medicare home health services will be shifted to the home infusion therapy supplier. The home infusion therapy supplier will not be eligible to provide the support services nor will the beneficiary be eligible to receive the services under the home health benefit. Therefore, the beneficiary will be forced to go without the needed support services or pay for the care privately.

Furthermore, the proposal for the home infusion therapy benefit and the home health benefit to run concurrently could require two distinct service providers in the home under separate plans of care during the same spell of illness. For example, a beneficiary that requires skilled nursing for wound care and infusion services could potential be required to receive skilled nursing for the wound care from the home health agency and receive skilled nursing for the infusion from the home infusion therapy supplier. This fragmentation of care poses a clear risk to the quality of care provided to the beneficiary. Additionally, the burden of coordinating care to assure

beneficiary safety will be the responsibility of the home health agency since home health agencies are required to coordinate all care provided to patients under the HHCoPs.

ENSURE ADEQUATE REIMBUSEMENT FROM MEDICARE ADVANTAGE PLANS FOR HOME HEALTH SERVICES

ISSUE: With more Medicare beneficiaries enrolled in Medicare Advantage (MA) plans and the MA plan market saturation increasing, HHAs are currently out-leveraged in their ability to negotiate fair rates for services. There are multiple factors compounding this issue:

- MA plans largely do not reimburse on an episodic rate, but rather a per-visit negotiated rate,
- MA plans are subject to different quality metrics than home health agencies, and different plans may require different measures, thus requiring HHAs to provide many different measures and documentation,
- MA plans by and large require several reviews and prior authorizations throughout the time that an HHA is caring for the patient, and
- MA plans have not approached negotiations with home health agencies with an awareness of the expertise and value being offered and therefore have not appropriately valued the services from a payment perspective.

HHAs are under significant financial and administrative pressure from the variety of payer relationships from which they work. Insufficient MA plan payments for home health services are far too frequently being balanced by traditional Medicare fee-for-service payment. These factors coupled with the continuing growth of MA plans, suggest that coordination and education of the value of home health care needs to be established now.

RECOMMENDATIONS:

- Establish a working group to provide cross-educational opportunities for MA plans and HHAs to highlight best practices for both.
- Work to enable better interoperability for home health agencies and MA plans to lessen the administrative and reporting needs.
- Support value-based payments in MA plans that are implemented in a least burdensome manner. Value-based payments should use performance measures that are NQF-endorsed for use by home health agencies.
- Support annual overall and targeted governmental oversight of MA plan practices with public reporting including rate-setting, utilization management, claims processing, and appeals processes -- to ensure that Medicare beneficiaries have:
    - Access to high quality home health services;
    - Freedom of choice among providers; and
    - Services delivered in a manner that does not unnecessarily shift costs and burdens to patients and caregivers.
- Require MA plans reimburse on an episodic model.

RATIONALE: Medicare Advantage plans have played an increasingly larger role in the Medicare program over the past decade. More than 20 million Medicare beneficiaries (34%) were enrolled in Medicare Advantage plans in 2018. Enrollment in Medicare Advantage plans has grown every year since 2010 and is anticipated to continue to attract enrollment for Medicare beneficiaries. CMS continues to set policies that favor the MA plans' ability to offer innovative

benefit packages to enrollees but has done nothing to ensure the providers of services are able to negotiate with MA plans for fair rate structures and appeals. Additionally, CMS has long abandoned a per visit reimbursement model for home health services in Fee- for- Service Medicare, yet permits the MA plans to continue with this outdated reimbursement structure.

DELAY THE NO-PAY REQUEST FOR ANTICIPATED PAYMENT (RAP) SUBMISSION PENALTY

Issue: Effective January 1, 2021 HHAs will be required to submit a no-pay RAP within 5 days of the "from" date on the claim or be subject to a penalty that is 1/30 of the total payment for each day beyond the "from" date that the RAP is late. For example, if the HHA submits the RAP only one day late they are penalized for the days between the claim start date until the date the RAP was submitted and accepted into the system.

The RAP updates the Medicare Common Working File to enforce consolidated billing rules under the home health prospective payment system for HHAs. However, even if a claim for another outpatient provider is erroneously paid while a beneficiary is under a home health plan of care, the Medicare system is set up to eventually recoup those funds. Therefore, the Medicare program has built-in controls to prevent risks related to improper payments under home health consolidated billing.

This is a new process for agencies requiring operational and system changes effective January 1, 2021. There is great concern among HHAs as to whether they will be able to effectively implement the required changes with the additional burden of caring for an increased number of patients/reduced number of staff.

Recommendations: NAHC urges CMS to delay the late RAP submission penalty for the later of six months from the scheduled implementation date or three months after the public health emergency ends.

Rationale: The No-Pay Rap policy was finalized in the calendar year 2020 HHPPPS rate update rule. At that time is was unimaginable that there would be a global pandemic lasting for the majority of 2020 and into 2021. HHAs have not had ample time to prepare for this new payment policy while managing the unpredictable events resulting from the COVID-19 public health emergency.

II. QUALITY

ENSURE TRAINING IS CONDUCTED AND CONSISTENT FOR HOME HEALTH AND HOSPICE SURVEYORS

ISSUE: State surveyors for Medicare certified providers often survey all types of providers, e.g., nursing homes, home health agencies, hospices, and hospitals. Each of these providers is governed by a different set of complex regulations. CMS requires that all new surveyors attend CMS-sponsored basic HHA and hospice training programs. In the past, state surveyors were trained by other state surveyors who may or may not have attended CMS surveyor training. Fraud and abuse initiatives have placed surveyors in the position of reviewing records for coverage compliance and determining what documentation should be submitted to Medicare Administrative Contractors (MACs), for which they have received little training. When surveyors inappropriately cite deficiencies as a result of misunderstood regulations, the burden is on the provider to prove the citation wrong. Although CMS-required projection of costs for training, including on-site, webcasts, and satellite broadcasts, there is no mechanism for enforcement or penalties for failure to participate. Surveyors have been restrained to computerized documentation of care, requiring home health agencies and hospices to print hard copies of records required for review.

CMS has taken steps over the past several years to improve on surveyor training and provide in-depth and consistent training to state surveyors by CMS Central Survey & Certification staff. However, not every state participates in CMS training. Accrediting Organization (AO) surveyors are not required to participate in CMS surveyor training. And, there are instances where CMS Region Office and CMS Central Office have provided conflicting guidance to AO and state survey entities.

CMS implemented revised Home Health Conditions of Participation (HHCoPs), effective January 13, 2018 and accompanying Interpretive Guidelines in August 2018. New requirements and varying interpretations will likely result in an increase in both standard and condition-level deficiencies. In addition, alternative sanction regulations have been in effect since 2013 with civil monetary penalties increasing significantly.

RECOMMENDATIONS: CMS should follow through on its stated plan to provide surveyor training on the Medicare Home Health and Hospice regulations. Training programs should:

1. Be required for all new surveyors, with refresher training every 3 years.
2. Be based on an established curriculum with specific learning objectives.
3. Emphasize survey citations are based on evidence of trends of a violation rather than a single violation.
4. Include information on Medicare coverage of services, adequate to identify possible problems to be referred to the MAC.
5. Ensure consistent interpretation and application of the regulations.
6. To reach all surveyors instead of only a small group, utilize technology such as webcasts, interactive training, etc.
7. Be available to providers.
8. Be based on interpretive guidelines as created and updated by CMS to reflect current regulations.

9. Include education in utilizing clinical information systems and performing online record review.
10. Evaluate the accuracy and effectiveness of surveyor guidance issued and ensure that all surveyors are adequately trained in the new protocols.

State agencies and AOs should be:

1. Required to show evidence of surveyor training for all new surveyors and provide ongoing continuing education to all surveyors.
2. Evaluated and penalized if they fail to have surveyors attend training programs.

ENSURE FAIR AND EQUITABLE POLICIES FOR THE APPLICATION OF THE REVISED CONDITIONS OF PARTICIPATION

ISSUE: Revised home health conditions of participation (HHCoPs) went into effect January 13, 2018. The new requirements are the first comprehensive revision of the HHCoPs in three decades. The revisions focuses on a patient-centered, outcome oriented approach to care planning. Although this approach may facilitate high quality home health care for patients served by Medicare certified agencies, it will require significant operational, process and cultural changes for home health providers.

CMS did not begin surveyor training until December 2017, and did not issue the final version of the interpretive guidelines until late August, 2018; 8 months after the implementation of the new requirements.

There remains inconsistent interpretations of the revised HHCOPs by surveyors two years after their implementation.

RECOMMENDATIONS:

1. Require CMS to make available to all home health care providers the same training as is provided to the surveyors.
2. CMS should ensure open communication with stakeholders related to any guidance issued on the revised HHCoPs.

RATIONALE: The final rule implements significant changes to Home Health Conditions of Participation (HHCoPs). The rule expands the standards for patient rights, care planning, and care coordination, and includes two new HHCoPs — one for a quality assessment and performance improvement (QAPI) program and another for an infection control program.

Although CMS has made several significant revisions to the HHCoPs throughout the years, many of the current HHCoPs had remained unchanged since their inception; therefore many of the revisions will present significant process, operational and cultural changes for agencies.

Home health agencies (HHAs) must meet the Medicare HHCoPs in order to participate in the Medicare program. Agencies that fail to meet any of the HHCoPs are at risk, at a minimum, for the imposition of a number of sanctions and potentially at risk for program termination. The interpretive guidelines, although helpful in understanding CMS' intent with applying the regulations, do not address all of the gaps in understanding. Agencies are still requesting additional clarification two years after the implementation of the revised HHCoPs.

INCREASE FLEXIBILITY IN THE APPLICATION OF THE CONDITIONS OF PARTICIPATION

ISSUE: CMS requires the application of all of the Medicare Conditions of Participation (CoP) to all patients served by the Medicare-certified agency, regardless of payer source or services. These requirements increase the cost of services to all payers. Yet, only one CoP (supervision of home health aides) has been written to provide flexibility in application based on service needs. Another, OASIS, varies depending on payer, but CMS addressed the possibility of applying OASIS requirements to all patients in the future.

RECOMMENDATIONS:

1. Allow HHAs flexibility in application of the CoP to payers other than Medicare.
2. Limit application of the following requirements to medically unstable patients and patients receiving medical interventions for treatment of diseases only:
    a. Plan of care (42 CFR §§484.60(a))
    b. Comprehensive assessment (42 CFR §484.55) at specific time points
3. Apply OASIS requirements to Medicare fee-for-service patients only.

RATIONALE: Some CoPs, in their full application, are excessive for the delivery of some services by home health agencies. With the introduction of PPS and OASIS, burdensome regulations that have been instituted since the BBA of 1997, it has become increasingly difficult for agencies to comply with the CoP for all patients and control costs. Building additional flexibility into the CoP would help contain costs of delivery of services to non-Medicare patients by certified agencies. As a result, non-Medicare patients would be more likely to continue to receive care from certified, regulated agencies rather than unregulated separate entities, and thus maintain quality.

It is not necessary for physicians to review and sign the plan of care for medically stable persons receiving health promotion and personal care services, according to state nurse practice acts. Physician order requirements were designed for legal authority to provide care and control of utilization. Nursing and therapy practice acts now recognize all but invasive procedures as independent aspects of practice, so orders are not usually required for legal coverage. Physicians' orders, with the intent of controlling utilization, are a payer issue rather than an operations or practice issue. If a payer wants to require this and assume the costs thereof, it should be a condition of payment. OASIS data collection and reporting is not covered by most payers. Medicaid payments do not cover the cost of care in most states before the added burden of OASIS. Managed care plans do not use the quality reports produced from OASIS data.

ENSURE FAIR APPLICATION OF IMMEDIATE JEOPARDY CITATIONS AND APPEAL RIGHTS

ISSUE: CMS issued a policy in August, 2000, to Federal and State Survey and Certification personnel and Complaint Investigators that can result in the termination of Medicare and Medicaid providers who fail to immediately correct and implement measures to prevent repeat jeopardy situations. This policy was published as Appendix Q of the interpretive guidelines for survey of skilled nursing facilities but is applied to all provider types. Immediate jeopardy is defined as "a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident."

A provider may be cited and placed on the fast track for termination as a Medicare or Medicaid provider if a single individual is at risk. Serious harm, injury, impairment or death does not have to occur, but merely have a high potential of occurrence. Some surveyors have used this policy to place home health agencies on the fast track to termination. In some of the cases, agencies were cited because they provided needed care in compliance with the requirements to patients who failed to comply with recommended health practices, or chose to remain in less than ideal social situations. Surveyors have gone so far as to suggest infringement of patients' rights by recommending that unsafe objects be removed from homes by providers. In addition, there is the potential that surveyors may interpret OASIS adverse event reports, which are intended to be potential indicators of problems, as a basis for immediate jeopardy.

The OIG released a report, Hospice Deficiencies Pose Risks to Medicare Beneficiaries (OEI-02-17-00020 July 2019) that highlighted the need for CMS to improve the survey process for hospices. This report showed that there are inconsistencies in the identification and citation of immediate jeopardy situations.

RECOMMENDATIONS:

1. Provide training to surveyors to help them identify real jeopardy and to differentiate it from standards of living that are different than their own. Surveyors should be provided with tools to help them identify jeopardy that results from the home health agency's failure to provide safe and effective care.
2. Surveyors should be trained to recognize patient right of choice and that home health agencies lack 24-hour control over patients' actions.
3. Agencies should not be cited when jeopardy results because patients choose to remain in less than ideal situations or engage in unhealthful practices. Citations should be clearly stated to ensure that agencies are able to identify the jeopardy and take steps necessary to remove it prior to the surveyor exit.
4. In cases where home health agencies disagree with an immediate jeopardy citation, the HHA should have the right to appeal the citation prior to termination through a dispute resolution process.
5. Any decision by a surveyor to terminate an agency based on immediate jeopardy should subject to expedited review by the CMS region office.

6. Surveyors should be trained to differentiate between OASIS adverse event reports as indictors of potential quality problems and true "immediate jeopardy" situations.
7. Work with the provider community to identify remedial factors and corrective actions should be undertaken.

RATIONALE: Surveyors are required to conduct surveys across multiple provider types. Untrained, inexperienced home health surveyors lack the skills necessary to differentiate between jeopardy resulting from poor quality care and that created by patients' personal life habits and chosen environment. Adequate training in the application of the survey process to the home setting is necessary to avoid citations and termination proceedings based on risky situations that result from patients' choices.

Beneficiaries often choose to remain in unsafe, non-therapeutic situations, and protective service agencies frequently fail to intervene in response to home health referrals.

If surveyors are not provided with sufficient training in the use of Adverse Events reports, any adverse event could inappropriately be identified as a potential situation for patient harm. A surveyor could almost do a "virtual" survey through the adverse events reports and claim immediate jeopardy.

DEVELOP APPROPRIATE POLICIES FOR EQUITABLE AND CONSISTENT IMPLEMENTATION OF SURVEY AND CERTIFICATION PENALTIES AND SANCTIONS

ISSUE: CMS has developed "alternate sanctions" that could be imposed in addition to, or in lieu of, termination from the Medicare program.

The type of sanctions CMS has made available include: civil money penalties, suspension of payment for new admissions, temporary management, a directed plan of correction, and directed in-service training. The criteria used in selecting which sanction(s) are to be applied and the severity of the sanctions is vague. And a combination of sanctions can be applied at one time. For example, CMP can be imposed per diem or per instant or a combination of both, along with other sanctions. In addition, the amounts of CMP can be as high as $20,111 per day for deficiencies. Further, sanctions are imposed until it has been determined that the agency has achieved substantial compliance. Surveyors must complete an on-site follow-up visit in order to make a compliance determination whenever an agency has been cited with a condition-level deficiency. Due to state survey workloads, there are instances where surveyors have not returned to the HHA for a resurvey for over 90 days.

Additionally, there has been persistent inconsistency in the interpretation of the CoPs among Medicare state surveyors. The level and severity of deficiencies can vary greatly from surveyor to surveyor. The rule is unclear on the degree of influence any surveyor will have in determining which sanctions apply; however, CMS traditionally has provided the State surveyors with a great deal of discretion in survey matters.

In the final rule, CMS provides for an IDR process when a condition level deficiency has been cited. However, this process did not go into effect until July, 2014. Its effectiveness in promoting a due process for HHAs is yet to be determined.

Further, CMS has issued a final rule that significantly revises the Conditions of Participation for home health agencies, effective January 13, 2018. Effective implementation of these new rules will be a learning curve for all stakeholders.

RECOMMENDATIONS:

1. Only condition-level deficiencies that impact quality of care should warrant sanctions.
2. Condition-level deficiencies should be differentiated from standard-level deficiencies and those that pose a threat to patients.
3. Complaint surveys should be based on "significant" complaints that affect patient health, safety, and rights (42 CFR §§484.10, 484.18, 484.30, 484.32, 484.34, and 484.36).
4. Personnel responsible for imposing sanctions should be trained and tested on the CoP.
5. An objective, structured system for imposing civil money penalties should be developed.

6. All surveys should conclude with an exit interview to permit the provider to clarify issues.
7. All recommendations for sanctions should be subject to region office review prior to imposition.
8. Sanctions should not be imposed for deficiencies that have been self-corrected by the provider prior to determination of noncompliance.
9. CMS to provide flexibility in enforcement of the revised CoPs for a reasonable amount of time when all agencies can be expected to come into compliance

RATIONALE: It is important that the sanctions and appeals process assure equitable application of the statute provisions and they protect agencies from unwarranted penalties. The type of sanctions, levels of civil money penalties, and the correlation between the sanctions and specific deficiencies is critical in assuring that the provisions are implemented appropriately and equitably. Therefore, any alternate sanction should be subject to objective standards for application and review. Furthermore, specific guidelines for surveyors are essential to ensure equitable imposition of sanctions.

DEVELOP FAIR POLICIES FOR ESTABLISHING CIVIL MONEY PENALTIES

ISSUE: The Department of Health and Human Services (HHS) published in the Federal Register on February 3, 2017, a final rule which adjusts for inflation CMP amounts authorized under the Social Security Act. The final rule significantly adjusts new CMP amounts and ranges effective on February 3, 2017 for many of the agencies under HHS. The CMP for home health agencies increased from $10,000 per day maximum to over §20,000 per day.

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 requires HHS to:
• Adjust the level of applicable CMPs with an initial "catch-up" adjustment, through interim final rulemaking (IFR); and,
• Make subsequent annual adjustments for inflation.

The "catch-up" adjustments are based on the percentage change between the Consumer Price Index for all Urban Consumers (CPI-U) for the month of October in the year a CMP was originally established, and the CPI-U for October 2015. Because of the "catch-up" adjustment the amount of civil monetary penalties has more than doubled from the original assessment for home health agencies.

RECOMMENDATION: CMS should apply the "catch-up" amount to the CMP rates issued in the 2013 HHPPS rate update rule when intermittent sanctions, including CMP, for home health agencies became effective. Adjust for inflation on the percentage change from the implementation date for the CMP rates issued in the 2013 HHPPS rule, rather than applying inflation adjustments for the past 16 years (1999) when the regulation was originally issued.

RATIONALE: CMS has the discretion to apply the "catch up" amount so that the increase in CMP is not so dramatic. CMS' initial maximal amount of 10,000 per day is a daunting amount for many agencies. A two fold increase in the CMP would pose a significant financial burden for the average home health agency.

IDENTIFY INDEPENDENT SPECIALISTS TO RESOLVE SURVEY DISCREPANCIES THROUGH THE INFORMAL DISPUTE RESOLUTION (IDR) PROCESS

ISSUE: CMS may issue alternative sanctions for home health agencies in lieu of or in addition to termination from the Medicare program when a HHA has a condition-level deficiency. CMS also provides agencies with an opportunity for an IDR. Agencies may submit a request for an IDR for a condition-level deficiency to the state survey agency. However, the IDR process is conducted internally by the same state survey agency that initially cited the HHA, and although the state survey agency may use independent contractors for their IDR process, there is no requirement for an independent review.

The variance in the surveyors' interpretations of the Conditions of Participation for Home Health Agencies and the subjective nature of the Medicare survey have created survey problems in many parts of the country. The resulting controversies had not been adequately addressed in prior guidelines and regulations. The new IDR process is a welcome step in the right direction, but must be implemented to objectively address discrepancies in interpretations of when a condition-level deficiency has occurred.

RECOMMENDATIONS:

1. Retain final responsibility for interpretation and application of federal regulations rather than abdicate authority to states.
2. Work with industry representatives to develop an effective communications process among CMS, surveyors and the industry.
3. Identify one or more persons to be available to answer questions and resolve conflicts between surveyors and providers prior to issuance of statements of deficiency.

RATIONALE: While it is important that agencies' services meet appropriate standards of care, the CoPs by their nature are general in nature and subject to various interpretations. In addition, surveyors and providers are often not privy to past interpretations and clarifications that affect agency operations. Most disagreements could be readily resolved by a person with extensive knowledge of the regulations and requirements, and those that escalate to a higher level would be few in number – but important in nature.

By establishing an IDR process that requires independent specialists in resolving CoP deficiency disputes, the state survey agency and the HHA can be assured of accurate compliance interpretations and appropriate methods for corrections.

REQUIRE REGION OFFICE REVIEW OF CHALLENGES TO STANDARD-LEVEL DEFICIENCIES

ISSUE: Home health agencies and hospices are subject to Conditions of Participation (CoP) and regular surveys to participate in the Medicare program. Due to the complexity of Medicare regulations, interpretive guidelines, and limited surveyor training, inconsistent and highly subjective interpretations of these requirements continue and are likely to exacerbate as new proposed CoPs are eventually implemented. Also, CMS has not published adequate criteria for differentiating condition-level from standard-level deficiencies, and immediate jeopardy from conditions/standards results in arbitrary classifications by state survey agencies. CMS has an Informal Dispute Resolution (IDR) process for condition-level deficiencies in home health; however, agencies do not have any appeals process for standard-level deficiencies and there is not an IDR process for hospices. State surveyors often cite agencies with deficiencies based on a single incident, rather than based on trends. State agencies have been known to use outdated policies or inappropriate interpretations.

Some surveyors continue to provide exit conferences that are less than helpful to providers. The deficiencies appearing on the written statement are not always consistent with the information provided during the exit conference, thus denying agencies the opportunity to present rebuttal documentation during the exit. Some survey agencies require providers to attend an exit conference in the survey agency's offices, making it impossible for the provider to point out contradictory information available in patient records.

The current CMS instructions require that survey entities complete and send the Statement of Deficiencies to home health/hospice providers within 10 business days and the providers are required to respond to statements of deficiencies within 10 calendar days. The State Operations Manual includes contradictory language, in one site indicating that providers have the option to submit their objections to deficiencies with no plan of correction, but at another site suggesting that a plan of correction is required in all instances. Providers are instructed to indicate their disagreement with a citation on the right site of the statement of deficiency form. Since statements of deficiencies in some states are paper, rather than electronic, providers must hand print or type responses using a typewriter, which is labor intensive. Furthermore, because of the limited information surveyors can share during an exit interview, providers are often surprised by the citations on the Statement of Deficiencies, and the limited timeframe providers have to develop and submit a plan of correction further complicates the process for provider correction of deficiencies. Survey entities are sometimes not compliant with the timeframe for sending out the Statement of Deficiencies. In fact, some Statements of Deficiencies have been so late that the provider is placed in a tenuous position of possibly being decertified due to condition-level deficiencies they were not aware existed because the receipt of the Statement of Deficiencies is so close to the 90-day correction timeframe. Some survey entities also require that the provider correct any deficiencies within 30 days of the date of survey exit for surveys with condition-level deficiencies in order to allow the survey entity to complete a revisit within 90 days. However, the Statement of Deficiencies is sometimes not received within this 30 days making it impossible for the provider to meet surveyor expectations and be recommended for termination of their Medicare certification.

If agencies submit both a corrective action and their disagreement, the disagreement is often ignored since the corrective action is included. If they submit only their disagreement, the plan of correction is considered unacceptable and the agency is at risk of termination. This essentially nullifies providers' ability to refute a deficiency citation. Ordinarily, the provider is expected to achieve compliance within 60 days of notice of the deficiency unless the seriousness warrants quicker corrective action.

Region Offices (ROs) differ in their willingness to work with providers in resolving disputes regarding interpretations of requirements. Some will offer to take issues to CMS Central; others are offended by requests for such additional reviews.

RECOMMENDATIONS:

1. Surveyors should be required to advise agencies of deficiencies during the exit conference or require that the quality review of the surveyor findings be completed within three calendar days of the survey and the Statement of Deficiencies sent to the provider no later than 10 business days after the survey CMS should hold survey entities to this requirement or allow the provider additional days in which to submit corrections.
2. CMS should require that all challenges to a deficiency citation be reviewed by the RO and a response given to the HHA/hospice within 30 days.
3. Challenges to a deficiency should stop the clock until the RO responds.
4. For standard-level deficiencies and condition-level deficiencies that pose no immediate threat to patients, the HHA/hospice should not be required to submit the corrective action initially. If the RO upholds the deficiency, the HHA/hospice would then be required to submit the corrective action plan.
5. For deficiencies considered to pose a threat to patient safety, the HHA/hospice would be required to submit and begin corrective action. If the RO reverses the determination, then the HHA/hospice can abandon the corrective action plan.
6. RO determinations need to be included in the file for public disclosure. If an agency is able to produce evidence (policies, etc.) demonstrating incorrect policy interpretation by the RO, they should be able to appeal to CMS central.
7. A provider ombudsman system to resolve differences should be instituted.
8. Providers should be permitted to submit objections and/or plans of correction on computer- generated attachments, or provide electronic statements of deficiencies that providers may respond on, directly opposite each deficiency.

RATIONALE: Without an objective review of the providers' objections, the agencies have no recourse but to accept the determination of a surveyor even if that determination is wrong. This is of particular concern for home health agencies where new CoPs went into effect January 13, 2018 without final guidance for compliance.

Creating and implementing plans of correction may involve costly or time-consuming procedures that are not necessary. Since policy is established at CMS central, ROs should be required to adhere to the Division of Survey and Certification positions on survey finding differences.

Responses to deficiencies are detailed and often require more space than allocated on the statement of deficiency. In addition, because deficiencies cascade from one standard to another, the same plan of correction is often applicable to multiple deficiencies and thus may be repeated. The use of available technology, including electronic reports and responses, should be incorporated into the survey process in order to minimize burden.

REQUIRE FEDERALLY FUNDED CRIMINAL BACKGROUND CHECKS AND ESTABLISH A NATIONAL REGISTRY SYSTEM

ISSUE: At times, media attention has focused on the unacceptable, but few, cases of abuse of home care clients, fueling consumer anxiety and industry concern about the need for better consumer protections. Although any fraud and abuse is unacceptable, it's important to note that cases of consumer abuse in home care are rare, certainly the exception rather than the rule. The overwhelming majority of home care workers perform their duties with compassion and integrity; likewise, the vast majority of home care agencies provide reputable, legitimate, quality care. However, as in any industry, there are a few unscrupulous individuals who defraud and abuse the system and its patients.

The 2008 Hospice CoP require hospices to conduct a criminal background check on all hospice employees and contracted workers providing direct patient care or with access to patient records. Criminal background checks cannot be relied on as the sole method of keeping consumers safe. No matter how effective, the criminal background check should not substitute for the most basic and prudent personnel practices that any responsible employer would undertake to establish the appropriateness, safety and suitability of an applicant.

Under a provision in the fiscal year 1999 Omnibus Appropriations legislation, a home care agency or a nursing facility is permitted but not required to submit a request to the Attorney General (through the appropriate state agency) to conduct a criminal background check on applicants who would be involved in direct patient care. This provision, which does not mandate criminal background checks, is an important step toward making criminal history information more accessible. It is very likely that Congress will continue to consider mandatory criminal background check provisions as the capacity of federal systems to process such requests is improved.

In the 106th Congress, Senator Herb Kohl (D-WI) and Representative Pete Stark (D-CA) introduced "The Patient Abuse Prevention Act" (PAPA) to require criminal background checks for long term care workers. Senator Kohl renewed the effort by reintroducing the bill in the 107th and 108th Congresses, the latest version of which was S.958. Provisions of the bill were included as an amendment to S.1, the Senate version of the Medicare Prescription Drug, Improvement, and Modernization Act. The amendment was dropped in conference with the House and replaced by a pilot program before final passage of the legislation (Public Law 108-173).

Section 307 of P.L. 108-173 required the Secretary of HHS to establish pilot projects in no more than 10 states for the purpose of expanding background checks for workers with direct patient access who are employed by Medicare and Medicaid long term care providers. CMS selected seven states to participate in the Background Check Pilot Program: Alaska, Idaho, Illinois, Michigan, Nevada, New Mexico, and Wisconsin. Long term care facilities or providers include nursing homes, home health agencies, hospices, long term care hospitals, and other entities that provide long term care services (except for those paid through a self-directed care arrangement). Separate funds were earmarked to conduct an independent evaluation of the background check pilot which has now been completed.

Senator Kohl introduced legislation in the 110th and 111th Congress to expand the pilot projects to make the program available to every state. His legislation was included in the Patient Protection and Affordable Care Act (H.R. 3590; Public Law 111-148) in March 2010. Twenty-five states have participated in the National Background Check Program, which entered its ninth and final phase in 2018.

RECOMMENDATIONS:

1. Congress should establish efficient, effective, and economical criminal background check requirements based on the findings of the pilot.
2. Efforts to establish a national registry and background check system administered by the states for all health and long-term care workers, including independent providers, who provide direct care to patients, should be supported.
3. Such a system should be voluntary until an efficient and accessible background check system is in place.
4. Federal and state background check requirements should not be duplicative.
5. New requirements should not impose burdensome supervisory requirements on home care agencies while a background check is pending, and must protect providers from liability during a provisional period of employment.
6. Requirements should mandate that agencies be adequately reimbursed for the cost of the background checks.
7. A standard definition of abuse, neglect, or misappropriation of patient property should be used for purposes of establishing a national registry.
8. Close monitoring and careful analysis of the project should take place with attention to: (a) access to criminal background information, (b) time requirements to carry out background checks, (c) costs to providers, and (d) accuracy of criminal information.
9. The Department of Justice and the FBI should work with provider representatives to establish an educational program that can increase the awareness of background check capabilities.
10. The FBI should decrease the cost of their background check service.
11. Efforts should be coordinated with review of the OIG and GSA exclusion lists.

RATIONALE: As the demand for high-quality home care increases, it is critical that all services are delivered with care and compassion by ethical providers. Fraud and abuse cannot be tolerated in any form. The care environment must be safe for patients and caregivers and free of abuse, exploitation, and inappropriate care. Criminal background checks and a national registry are important components of ensuring consumer safety. Criminal background checks cannot be relied on as the sole method of keeping consumers safe. No matter how effective, the criminal background check should not substitute for the most basic and prudent personnel practices that any responsible employer would undertake to establish the appropriateness, safety, and suitability of an applicant.

In state laws, the trend is toward background check requirements for nursing and home health aides only; however, there is currently no consistent systematic mechanism through which other direct care staff members are checked. It is in the best interest of consumers of home care and other health services for all direct care staff to be screened. However, state and federal requirements should not be cumulative and overly burdensome.

ENSURE THE USE OF APPROPRIATE QUALITY INDICATORS AND ACCURACY OF HOME HEALTH COMPARE

ISSUE: Since 2003, CMS has operated a web-based information tool for consumers to aid in their selection of home health agencies for themselves or loved ones. This tool, entitled Home Health Compare, is being used by consumers and other health care professionals, such as discharge planners, to make informed choices. CMS also believes that public reporting through Home Care Compare will stimulate providers to try to continuously improve the quality of the care they deliver.

CMS, in conjunction with the National Quality Forum (NQF), will identify and analyze all available home health quality indicators in order to determine which ones are most appropriate for public reporting. Currently, there are 23 quality indictors publicly reported. The indicators consist of 9 outcome measures and 13 process measures. Public reporting of the claims-based measures and patient perception of care measures (Home Health Consumer Assessment of Healthcare Providers and Systems) have been added to Home Health Compare.

Home Health Compare provides a listing of Medicare participating home health agencies and the geographic area that they serve along with information regarding the performance of the agencies in terms of certain patient outcomes. Actual use of this tool as a guide to provider selection is unknown. Further, there have been some questions raised regarding the accuracy and relevance of the information contained in Home Health Compare. The fact that agencies are listed alphabetically could lead consumers to select agencies that appear early, rather than thoroughly reviewing the full list for the best provider. Testing of the site with Medicare beneficiaries has led to concerns about how it is formatted and whether enhancements are needed to the Medicare.gov site for Home Health Compare.

RECOMMENDATIONS:

1. Continue to work with the home care industry, including providers, to ensure the use of valid, reliable quality indicators.
2. Avoid adding unnecessary and burdensome requirements to collect data on quality indicators that have not been researched and proven to be necessary for public awareness and quality assessment.
3. Present measures in ways that are useful and understandable to the public.
4. Continuously evaluate and update measures.
5. Ensure that measures are adequately risk-adjusted before being reported.
6. Establish thresholds or trigger points for quality reporting instead of averages.
7. Provide assistance to home health agencies in identification and implementation of best practices for improved care.
8. Conduct research into home health appropriate structure measures.
9. Consider alternate ways to list agencies other than alphabetically.
10. Include the average number of patients served by each agency in the profile.
11. Identify the time period during which the data the data was collected for the outcomes reported.

RATIONALE: The usefulness of quality reporting hinges on the accuracy of the quality measures selected, as well as the ability of consumers to relate to them. Measures should not be

static, but rather need to change with advances in health care. A system of reporting that does not provide opportunities for improvement does little to help consumers in the long run.

A combination of structure, process, and outcome measures are needed to adequately determine whether care is provided in accordance with currently acceptable standards. However, ongoing scrutiny of publicly reported measures is essential. Large numbers of quality indicators are not necessarily helpful to the public, and can be confusing when trying to identify an appropriate provider of care. In addition, unless proven essential to quality, collection of data is unnecessarily costly and burdensome.

The Medicare Home Health Compare website must be user friendly and provide home health agency information in the most useful manner and with sufficient detail to prove helpful to anyone seeking information about the quality of Medicare providers.

ALLOW HOME HEALTH AGENCIES AND HOSPICES TO PROVIDE UNLIMITED SERVICES UNDER ARRANGEMENTS

ISSUE: The Medicare Conditions of Participation (CoP) require that a home health agency (HHA) must provide at least one of the qualifying services directly through agency employees, but may provide the second qualifying service and additional services under arrangements with another agency or organization (42 CFR §484.14(a)). CMS published proposed home health conditions of participation in March, 1997, that require HHAs to provide directly, by employees, 50% of all professional and home health aide services. Since the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003 required final rules must be published within three years of the proposed rule, a new proposed rule for the conditions of participation for home health providers is anticipated in the near future. Medicare hospice regulations require the provision of all core services by employees. CMS interprets service "directly through agency employees" as meaning providing the services "by employees in its entirety," which essentially inhibits contract arrangements even when needed for emergencies or staffing shortages. The MMA of 2003 permits hospices to enter into arrangements with another hospice program to provide core services in certain extraordinary, exigent, or other non-routine circumstances. Although the legislation provides some increased flexibility, additional relaxation of contracting requirements is needed. Furthermore, home health has not been offered a similar exception.

Home health and hospice experience shows that subcontracting is necessary when temporary staffing shortages exist, community demands result in increased referrals, and patients require the skills of specialty nurses and therapists. The current health care environment has resulted in an increase in managed care and numerous organizational relationships. In order to remain competitive for managed care contracts, providers must contract for services to control costs while enabling patients to receive specialty services. Mergers, acquisitions, and joint ventures are taking place at a rapid pace, resulting in the need for greater flexibility in the provision of services to ensure HHA and hospice survival. Finally, HHPPS requires HHAs to contract for therapy services when their patients need special equipment not available in the home, leaving nursing, aides and social workers as the only possible direct service providers.

The Secretary's Advisory Committee on Regulatory Reform adopted a resolution in 2002, asking for issuance of a "revised policy declaring that due to the national nursing shortage we are in a period of extraordinary circumstances."

RECOMMENDATIONS: HHAs and hospices should be permitted to provide unlimited services under arrangements both by individuals or other agencies or organizations. CMS should enforce the home health and hospice regulations that require oversight and control of services by the certified providers regardless of whether the persons providing care are employees or contractors.

RATIONALE: This requirement does not fit within the current health care service economy and workforce market. The "service directly requirement" is a proxy for establishing quality assurance in the provision of care. Medicare maintains an outdated and unfounded belief that an employed caregiver is more capable of providing high quality services to patients than a contracted caregiver. Arbitrary staffing/contractor ratios do not ensure quality of care. Existing

and proposed quality, coordination, and supervision regulations and guidelines, if enforced, can serve to ensure quality of care to Medicare beneficiaries.

ENSURE THE EMERGENCY PREPAREDNESS PLAN REQUIREMENTS ADEQUATELY ADDRESSES THE NEEDS OF PROVIDERS OF SERVICES IN THE HOME

ISSUE: The Centers for Medicare & Medicaid Services (CMS) issued a final rule Federal Register that establishes national emergency preparedness requirements as part of the conditions for coverage and the conditions of participation for Medicare and Medicaid providers and suppliers to ensure that they adequately plan for both natural and man-made disasters. The rule has an effective date of November 16, 2016 with an implementation date of November 16, 2017.

The rule addresses emergency preparedness requirements that 17 provider and supplier types must meet in order to participate in the Medicare and Medicaid programs. Home health and hospice provides are among the provider types that will be required to implement the emergency preparedness plan as outlined in the proposed rule.

CMS recognizes the variations that exist among the different provider and supplier types and takes those differences into account, while also providing generally consistency in emergency preparedness requirements. The requirements for home health and hospice providers are essentially modifications to the requirements for acute care hospitals. CMS requires that emergency preparedness for all the designated provider and supplier types include the following four core elements:

- Risk assessment and planning;
- Policies and procedures;
- Communication plan; and
- Training and testing

RECOMMENDATIONS:

1. CMS should ensure adequate guidance for compliance is available for providers on an ongoing basis.
2. Ensure emergency preparedness requirements and guidance take into account the unique nature of providing health care services in the home.
3. Ensure home health and hospice providers are represented in training and education sessions and materials.
4. Ensure surveyors are adequately trained on what CMS expects for compliance.
5. CMS should monitor the effectiveness of the requirements in emergency preparedness for home health and hospice providers against the burden to implement the requirements.

RATIONALE: National emergency preparedness plans such as the Homeland Security Council's "National Strategy for Pandemic Influenza: Implementation Plan," the Department of Health and Human Services' "Pandemic Influenza Plan," and the first draft of the S&C "Emergency Preparedness Plan" address mass causality events as it relates primarily to inpatient settings. Recommendations for action in many disaster-planning models do not consider the uniqueness of home care.

Any emergency preparedness requirements as a Condition of Participation for home health care must be tailored appropriately for home health care and hospice providers, in order to avoid unrealistic expectations that will ultimately subject an agency to unfair deficiency citations.

ENSURE ADEQUATE FUNDING FOR MEDICARE SURVEY AND CERTIFICATION TO PROTECT QUALITY OF CARE

ISSUE: Medicare is responsible for determining whether home health agencies and hospices meet their respective Conditions of Participation (CoPs). That responsibility includes surveying providers in response to quality of care complaints, periodic resurveys of providers to review continued compliance with the CoPs, and the initial survey and certification of applicants for Medicare provider participation. Medicare uses contracted state agencies to fulfill these responsibilities.

In recent years, Medicare has been under-funded for many of its administrative responsibilities. This trend is expected to continue. With respect to survey and certification, Medicare has found that the contracted state agencies have not been able to handle all of the complaints, periodic surveys, and initial certifications on a timely and comprehensive basis. The main reason for that shortcoming is inadequate administrative funding. As a result, Medicare has curtailed initial certifications in many states, and backlogs on complaint response and the periodic surveys continue to grow. In addition, a follow up survey is required when ever a condition level deficiency has been cited. Now that agencies are subject to alternates sanction, they are at risk for prolonged sanction impositions while waiting to be resurveyed. While initial certification applicants can use the alternative of a private "deemed status" entity, that alternative is costly and fails to address the required resurveys for condition level deficiency citations.

RECOMMENDATIONS: Medicare should take all steps necessary to secure adequate funding from Congress to undertake the full range of survey and certification responsibilities set out in Medicare law.

RATIONALE: Quality of care is the only goal in Medicare survey and certification. There is no reasonable basis for under-funding Medicare survey and certification activities. Further, providers should not need to pay directly to finance the oversight responsibilities of Medicare or be subject to protracted sanctions.

ESTABLISH APPROPRIATE PROCESS FOR APPROVAL OF BRANCH OFFICES BY ACCREDITING BODIES

ISSUE: The Centers for Medicare & Medicaid Services (CMS) instructs state Medicare survey agencies to prioritize federal survey functions into four priority tiers. Tier 1 consists of statutory mandates, such as surveys of existing home health agencies and surveys related to complaints. State survey agencies must complete the work in Tier 1 before conducting initial surveys of new home health care providers or approving new branches.

Home health care providers seeking initial Medicare certification are advised to attain deemed Medicare status conducted through a CMS-approved accreditation organization in lieu of Medicare surveys by the state survey agencies. The accreditation organizations have processes in place to conduct an initial Medicare deemed status survey for home health agencies (HHAs); however, they do not have the authority or processes to approve a branch location. State survey agencies traditionally approved HHA branches even for those agencies that were deemed Medicare certified through an accreditation organization. If the state survey agency does not provide a branch approval, the agency may not serve Medicare beneficiaries from that location.

RECOMMENDATIONS:

1. CMS should authorize the accrediting organizations to assume branch approvals for HHAs when the state survey agencies are not able to conduct new agency surveys.
2. Require the accrediting organizations to establish CMS approved procedures for approving a HHA branch.

RATIONALE: CMS has traditionally assumed the role of approving branches even for agencies that have deemed status. As a result, accrediting organizations do not have the authority or procedures for approving branches. Agencies seeking branch approval will either have to wait until the state survey agency can resume this survey activity or provide services to only non-Medicare patients, which may result in access to care problems for Medicare beneficiaries in areas served by the branch.

ENSURE A FAIR PROCESS FOR A FIVE STAR RATING SYSTEM

ISSUE: CMS intends to implement a five star rating system for home health agencies beginning sometime in 2015. A Special Open Door Forum call was held where CMS announced the quality measures it plans to use along with the proposed methodology for obtaining the five star rating,

CMS includes 8 quality measures that are currently reported on Home Health Compare. Six of the measures show improvement in functional status or clinical condition. The remaining selected measures consist of one process measures and the measure for acute care hospitalization. A star rating for the HHCAPHs is included on HHC as a separate rating. In addition, although all measures selected are risk adjusted, the risk adjustment model does not account for all variances among the patient population served by home health agencies.

CMS applies a star rating model that scores each of the 8 quality measures, sorts them low to high and then divides the scores into ten approximately equal size groups (deciles). The HHA's score on each quality measure is then assigned a rating from 0.5 -5 in 0.5 increments.

The preliminary rating is then adjusted according to the statistical significance of the difference between the agency's individual quality measure score and the national average for that quality measure. If the agency's preliminary rating for a measure is <2.5 the score is adjusted up by 0.5. If the preliminary rating is >3 the score is adjusted down by 0.5. No adjustment is made to an initial score between 2.5 and 3. In other words, if the score is anything other than a 2.5 or 3 and there is no significant difference from the national average the rating is adjusted up or down by 0.5 accordingly. For each HHA, the adjusted preliminary ratings are then averaged across all the 9 proposed measures to obtain an overall average rating for the agency. The overall average rating is then translated into a star rating for reporting on HHC.

CMS finalized its plan to remove the *Improvement In Pain Interfering with Activity* measure from the Home Health Quality Reporting Program (HH QRP) next year, and therefore, will not be collected or reported in the HH QRP or Star Rating calculation.

RECOMMENDATIONS

1. Develop stabilization measures to be included in the Star Rating.
2. Develop a model that projects a star rating which more accurately reflects the agency's actual performance by establishing objective performance benchmarks rather than utilizing a star distribution model that automatically results in most HHAs grouped in a mid-range of star ratings.
3. Avoid using star ratings for measures where the distribution of scores lacks variation and is skewed.
4. CMS must measure consumer comprehension and interpretation based on like-kind models.
5. CMS should use the formal rulemaking process for public notice and comment on any Star Rating system.

RATIONALE: The expected outcome for many patients admitted to home health care is to stabilize or prevent decline of a condition or functional limitation. In addition, the settlement in the lawsuit in Jimmo v. Sebelius further confirms that the improvement standard does not apply to all Medicare home health patients. Further, an agency's ability to affect a patient's

improvement in any measure depends largely on the services provided and the length of time the patient spends on service with the agency. The quality measures for home health agencies include data from four different payment sources: Medicare Fee for Service (FSS); Medicare Advantage (MA); Medicaid; and Medicaid managed care. Each such patient population and the applicable payers have widely varying utilization patterns.

A star rating model that requires providers be placed in deciles even when the performance variation between the providers may be slight, compounds that weakness by grading "on a curve". The result is that all agencies are moved to a middle (2.5-3) regardless of their unadjusted star rating. Poor performers could rate higher than their actual performance while good or excellent performers could rate lower than their actual performance, with the potential for both performers to be rated as the same star grade.

In addition, a star rating of 3 or less is universally recognized to mean an average" or "poor rating. The resulting five star rating system is misleading and could have significant consequences for patients and home health agencies. Not only will consumers be misled, but private insurance plans, referral sources, and state survey agencies could misjudge the quality of care the agency provides.

Going forward NAHC recommends that CMS use the formal rulemaking process for public notice and comment on any star rating system.

ENSURE AN ADEQUATE QUALITY MEASURE DEVELOPMENT AND IMPLEMENTATION PROCESS RELATED TO THE IMACT ACT

ISSUE: On September 18, 2014, Congress passed the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The Act requires the Centers for Medicare & Medicaid Services (CMS) to develop standardized assessment data and quality measures across the post acute care (PAC) settings that include inpatient rehabilitation facilities (IRFs), skilled nursing facilities (SNFs), long term care hospitals (LTCHs) and home health agencies (HHA).

The Act specifies both the domains and time frames for which each PAC provider must begin to submit the cross setting quality measures. The quality measure domains include functional status, cognitive function, and changes in functional and cognitive function; skin integrity and changes in skin integrity; medication reconciliation; incident of major falls; and communicating the existence of and providing for the transfer of health information and care preferences. Resource use and other measures such as total Medicare spending per beneficiary, discharge to community, and potentially preventable hospital readmission rates are also part of the quality measures required by the IMPACT Act.

CMS had been on a fast track to develop quality measures and assessment data in order to comply with the tight deadlines for implementation of the Act. Not only were the quality measures being developed quickly, the public comments periods for the newly developed quality measures had very short turnaround time frames; many less than two weeks. In addition, several of the comment periods for the quality measurand assessment items overlapped.

CMS completed their work to develop cross setting measure and assessment items for home health agencies required by the IMPACT Act in 2019. In addition to concerns with the measure development process, there are also concerns around cross setting measure and assessment item comparisons with post-acute care institutional providers. Several of the assessment items are very complex and are new to home health providers. Additionally, several of the quality measures place home health agencies at a disadvantage when comparing to institutional settings. Home health providers do not have the same degree of control over patient behaviors as these institutional providers.

RECOMMENDATIONS:

1) CMS should ensue any new quality measure is tested and validated in the home health care setting prior to implementation of the measure.
2) CMS should develop a mechanism that ensures fair comparison with institutional providers.
3) CMS should allow stakeholder input and provide transparency with any plans to use the cross setting measures and assessment items.

RATIONALE:

Any new quality measure CMS develops as part of the home health quality reporting program (HHQRP) could have a direct impact on payments for HHAs. In addition to the HHQRP, these measures could also become part of the home health value based purchasing program (HHVBP) and/or the home health Star Rating System. How agencies perform on quality measures can have

significant payment implication under the HH VBP, while the Star Rating system can misguide the public on the quality performance of agencies.

The IMPACT Act pulls home health care into the post-acute care arena, however, over 50% of patients admitted to home health are referred from the community, and therefore, not post-acute care patients. Additionally, the home health care environment is very different than institutional care settings in that home health clinicians are not able to monitor their patients 24/7.

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ENSURE TIMELY DELIVERY OF DURABLE MEDICAL EQUIPMENT TO MEDICARE BENEFICIERS

ISSUE: Prior to Medicare competitive bid implementation, homecare agencies were able to (1) assess needs of homebound patients, (2) contact patient's Physician, and (3) contact local durable medical equipment (DME) vendor regarding needed equipment for patients. Recommended DME would typically be delivered within 2-7 days to home once a physician's order was sent to vendor.

With recent changes made by Medicare, beneficiaries often have to wait 4-6 weeks to have DME delivered to home after a prescription has been sent to a vendor. Delays are most often related to the vendor and physician not communicating and/or coordinating receipt of the necessary documentation to support medical necessity for the equipment. This is of particular concern for homebound Medicare beneficiaries that require the DME to facilitate optimal health and functional.

Per current Medicare guidelines, delivery of DME is required to be "timely". However, vendors universally claim that they are only required to deliver DME timely once all needed paperwork is in place. CMS does not require DME vendors to deliver equipment within a specified time frame from the time of the order is received.

RECOMMENDATIONS:

- CMS should require DME vendors provide ordered equipment to Medicare beneficiaries within a specified timeframe from the time the physician's order is received.
- CMS should conduct a study to determine the average time that DME is delivered to Medicare beneficiaries.

RATIONALE: Lack of accountability for delays in delivery of DME to Medicare beneficiaries receiving home health services has a negative impact on patient care and may increase the risk for falls/pressure ulcers and prevent timey discharge. These delays also increase the administrative burden for home health agencies.

APPLY REASONABLE REQUIREMENTS FOR CLINICAL RECORD REQUESTS

ISSUE: During the PHE ,CMS is extending the deadline for completion of the requirement at 42 CFR 484.110(e), which requires HHAs to provide a patient a copy of their medical record at no cost during the next visit or within four business days when requested by the patient. CMS will allow HHAs ten business days to provide a patient's clinical record, instead of four days.

NAHC supports the extension in the time frame to respond to patient requests for medical records. The requirement at §484.110(e) does not provide sufficient time for agencies to produce a medical record in many cases even during ordinary times. Many HHAs centralize medical record requests and have a detailed process for review prior to releasing any protected health information. Additionally, if the record is to be mailed, the agency will have only one or two days to reproduce the record, otherwise they will be out of compliance with time frame

RECOMMENDATION: NAHC urges CMS to maintain this regulatory change beyond the PHE. Ideally, CMS should align §484.100(e) with the requirements of the Health Insurance Portability and Accountability Act at §164.524(b) (2). §164.524(b) (2) which provides 30 days for a health care entity to act upon on a request for a copy of the medical record.

RATIONALE: NAHC supports providing patient with their medical records upon request. However, the regulatory time frame for responding to medical record requests should be within reason in order for or HHAs to comply with the requirement. Additionally**,** aligning regulations is always preferred in order to lessen provider burden.

PHYSICAL THERAPISTS (PT), AND SPEECH LANGUAGE PATHOLOGISTS (SLPs) TO PERFORM INITIAL AND COMPREHENSIVE ASSESSMENT IN ALL THERAPY CASES

CMS is waiving the requirements in 42 CFR §484.55(a)(2) and § 484.55(b)(3) that rehabilitation skilled professionals may perform the initial and comprehensive assessments when only therapy services are ordered. The waiver permits any therapy discipline to perform the initial and comprehensive assessment on all patients receiving therapy services as part of the plan of care. The waiver applies regardless of whether or not the service establishes eligibility for the patient to receive home health care.

HHAs have long advocated for change in the regulation to permit therapists to conduct the initial and comprehensive assessment for all patients when therapy is ordered at the start of care. The requirement for the RN to conduct the initial and comprehensive assessments when nursing and therapy are ordered results in the waste of valuable resources (extra RN visits that are not reimbursable) in cases where the plan of care does not require the RN to visit prior to the therapist.

The Consolidated Appropriations Act of 2021 included a provision that permits occupational therapists to conduct the initial and comprehensive assessments in cases where occupational therapy is ordered along with physical therapy or speech language pathology services and no nursing services. The change goes into effect no later than January 1, 2022.

Recommendation: NAHC urges CMS to maintain this regulatory modification beyond the PHE as a permanent change to §484.55(a)(2) and §484.55(b)(2) to permit PTs and SLPs to conduct the initial and comprehensive assessments whenever therapy services are ordered

Rationale: The waiver has been very beneficial in expanding HHA staff availability to accommodate patient surges related to the COVID-19 PHE. Additionally, a therapist may conduct the initial and comprehensive assessment if therapy is the only discipline ordered. Therefore there has been precedent for PTs ad SLPs to conduct the initial and comprehensive assessments.

III. ADMINISTRATION

ENSURE THE ROLE OF HOME HEALTH IN IMPROVED AND INTEGRATED CARE DELIVERY MODELS

ISSUE: The Patient Protection and Affordable Care Act (ACA) calls for sweeping health reform. New health delivery models to be tested under the health reform bill include: (a) chronic care coordination services to high-cost Medicare beneficiaries, (b) better transitions, (c) paying for performance, and (d) increased involvement of primary care physicians. The majority of projects currently under way envisioned in the ACA are the Accountable Care Organizations and the Episode-Based Payment Initiatives conducted through the CMMI. Home health agencies can play a large role in fostering efficiencies in these models

However, home health agencies are not always treated as equal participants in these models. Service delivery is often dictated to agencies by the convener organizations and the physician participants. For example, physicians participating in the Comprehensive Care for Joint Replacement Model, are only ordering 3-4 home therapy visits for beneficiaries. These patients are not provided a nurse for medication management or a home care aide if needed. The patient is very quickly referred to outpatient therapy to continue the therapy plan of treatment. This practice leads to a LUPA payment for the episode and poor quality measure reports for agencies, since beneficiaries are discharged from home health without an opportunity to improve in pain and mobility. Additionally, beneficiaries are at risk for substandard care due to an inability to receive the full complement of services under the home health benefit.

Another innovative payment model that is gaining momentum is a unified post-acute care payment model. The IMPACT Act of 2014 directed CMS and the Medicare Payment Advisory Commission (MedPAC) to begin developing models for a unified post-acute care payment model using at least two years' worth of patient assessment and quality measure data for each setting. Under a unified post-acute care payment model all post -acute care services, which includes post-acute institutional care and home health care, are covered under one payment amount.

Similar to other innovative payment models, home health care is not recognized for its uniqueness and contribution to the health care continuum. There are a couple of key aspects that differentiates home health care from other post-acute care settings. Health care provided in the home presents unique challenges that cannot be equated with care provided in an institution. Additionally, over half of the patients admitted to home health care are referred from the community, and therefore, are not "post- acute" care patients. However, the majority of patients that receive post-acute care receive that care in the home.

Furthermore, a unified post-acute payment model would be difficult to incorporate into the other innovative models that test value based, cost sharing payment schemes.

RECOMMENDATIONS: CMS should:

1. Require that home health agencies are included in planning and opportunities to be leaders and active participants in CMMI models, projects, and programs.

2. Monitor quality data from home health agencies to assess appropriate utilization of home health services.
3. Monitor re-hospitalization rates and emergency department visit use for beneficiaries participating in these bundled programs.
4. Any unified post-acute care payment model must recognize that only a portion of home health services are post-acute care thereby warranting an exclusion of home health services from any such model altogether.
5. Any unified post-acute payment model must be based in home health care rather than institutional services as the majority of post-acute care is provided at home
6. Congress must keep open the option to not enact a post-acute care payment model as it may not have a place in all the other health care innovation efforts

RATIONALE: Home health care is the natural alternative to the costly institutional care that has been the focus of Medicare health care expenditures. Medicare home health providers are positioned to care for high-cost beneficiaries in their homes. They are experienced in treating chronic illness in the home setting and coordinating health care based on a plan of treatment.

Leaders in home health are well positioned to participate in and develop new health delivery models. NAHC envisions a future where the integration of electronic health records, remote patient monitoring, and community based skilled nursing services will be the backbone of the national health care delivery system.

ENSURE EFFECTIVE EMERGENCY PREPAREDNESS COMMUNICATION AND REGULATORY RELIEF FOR HOME CARE AND HOSPICE

ISSUE: The COVID -19 pandemic has set an unprecedented challenge for emergency preparedness and response for both providers and the federal government.

To ensure that sufficient health care items and services are available to meet the needs of individuals in an emergency area, the Secretary of Health and Human Services is authorized under Section 1135(d) of the Social Security Act to temporarily waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements. These waivers are referred to as the 1135 waivers. The 1135 waiver authority, is limited to certain Conditions of Participation and HIPAA requirements. During the COVID -19 pandemic HHS issued blanket regulatory waivers and policy flexibilities for healthcare providers in recognition of the urgency for the our healthcare system to respond to a national pandemic

During previous regional PHEs the Secretary has been quick to invoke 1135 waiver authority when necessary. However, where HHS has not issued blanket waivers, such as in 2018 during the massive flooding in Texas, obtaining 1135 waivers is a cumbersome and confusing process, particularly when providers are in the midst of a disaster response. The federal government is reluctant to grant blanket waivers for specified provider types when regional disasters occur. Provides are expected to individually request waivers through the Region Office even though many disasters impact large regions with the need for common waivers across provider types.

The greatest impediment to efficient health care delivery is burdensome regulations. CMS has the authority to waive many of these regulations but does not do so as a routine response to disasters. In addition, CMS has never requested from Congress authority to waiver additional regulations that would be beneficial to home health and hospice providers such as payment policies, which are not covered under the current 1135 waivers authority. Additional considerations are needed to truly ensure uninterrupted service delivery and provider viability during disasters.

RECOMMENDATIONS:

1. Provide the leadership and resources to ensure fail-safe communication, collaboration, and coordination between Health and Human Services, and healthcare providers impacted by the disaster.
2. Make federal resources available to ensure coordinated disaster planning among the entire spectrum of health care providers.
3. Establish an algorithm for when blanket waivers should be implemented
4. Establish additional regulatory relief measures for home care providers that can be activated at the time that disaster areas are designated.

RATIONALE: The COVID-19 pandemic has proven the effectiveness of swift and decisive action in providing regulatory relief and flexibilities during the PHE. In previous years where CMS has been reluctant to issue blanket waivers when larges areas of the country impacted has brought into question the federal government's responsibilities and response policies related to

providing regulatory relief when 1135 waiver authority is in effect. Although CMS had developed several resource materials regarding waiver authority and when waivers are permissible there is confusion when a waiver is "blanketed" to a certain area in response to specific disasters. In addition, during these recent events CMS seemed reluctant to issue "blanket" waivers and issued very few relative to past disasters.

During a public health emergency healthcare providers should be free to ensure continuity of safe patient care and not be burdened with a cumbersome administrative process to obtain necessary regulatory relief.

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ESTABLISH REFERRAL STANDARDS AND DISCHARGE PLANNING REGULATIONS THAT ENSURE PATIENT CHOICE AND EQUAL ADVANTAGE TO ALL PROVIDERS

ISSUE: The home health and hospice industry has expressed concern about regulations and practices that may result in steering patients to certain providers. The root issue is patients' ability to freely choose a qualified home health provider and ensure a level playing field for providers of all types. The Balanced Budget Act (BBA) of 1997 Section 4321(a) requires discharge planning to include provision of a list of all Medicare certified HHAs that request to be listed in the patient's geographic area. In addition, the discharge plan may not specify or limit qualified HHAs, and must identify cases in which the hospital has a disclosable financial interest in entities to which the patient is referred. Some hospitals have misinterpreted HIPAA regulations, using them as the basis for restricting access of outside home health agencies to hospital patients.

The hospital and Critical Access Hospitals (CAHs) must assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but not limited to, HHA, SNF, IRF, or LTCH data on quality measures and data on resource use on measures. Hospitals must also include in the discharge plan a list of Medicare-participating HHAs that wish to be listed and are available to the patients in the geographic area in which the patient resides. The list must be presented to all patients for whom home health care is indicated. Managed care patients must be advised of the availability of home health services through entities with contracts with their managed care organizations.

Furthermore, hospitals must inform the patient of their freedom to choose among participating Medicare providers and must document in the patient's medical record that the list was presented to the patient. Finally, the discharge plan must identify any HHAs in which the hospital has a financial interest. A similar requirement for Critical Access Hospitals (CAH) was not included in the final rule Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies, and Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care [CMS–3317–F and CMS–3295–F], There have been concerns expressed about the limitations of patient choice and reported cases where physician's orders requesting that patients be referred to specific home health agencies have not been followed.

BBA 97 at Section 4321(b) included a provision whereby hospitals will be required to report information on the numbers of patients referred for home health services, the number referred to home health agencies or other entities in which the hospital had financial interest, and the number referred to home health agencies that had financial interest in the hospital.

CMS published a Notice of Proposed Rulemaking (NPR) in December, 2002, to implement this reporting requirement. However, CMS failed to publish a final rule within three years of the proposed rule as required by statute. CMS' reasoning for failure is that the plan proposed was not feasible due to federal information system limitations. CMS has not issued another proposed rule.

RECOMMENDATIONS: Educate surveyors about the discharge planning requirement and their responsibility to assess for compliance.

1. Have surveyors identify instances whereby physician orders for specific home health agencies were violated.
2. Ensure that enforcement of compliance with discharge planning regulations is carried out in the survey process.
3. Make all hospital discharge planning regulations applicable to Critical Access Hospitals.
4. Initiate a study to determine whether patients are denied access to home health services.
5. Require consideration of other possible solutions to implementation of referral reporting requirements and publications of a new proposed rule.

RATIONALE: The Social Security Act, at 42 USCS §1395a, guarantees freedom of choice by requiring that "any individual entitled to insurance benefits under this title (42 USCS §§1395 et seq.) may obtain health services from any institution, agency, or person qualified to participate under this title if such institution, agency, or person undertakes to provide him such services." Discharge planning regulations and referral standards ensure compliance with patient rights legislation. Hospital discharge planning regulations for ensuring patient choice, where such regulations provide for the dissemination of information to consumers about home health services available in their communities, help guarantee that all providers will have an opportunity to compete in the market. Reporting of hospital referral data will offer a record of what is actually happening in regard to home health referrals. Patients served by Critical Access Hospitals, many of which have their own home health agencies, should be guaranteed the same freedom of choice as other Medicare beneficiaries.

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CONTROL PAPERWORK BY REQUIRING CMS TO FOLLOW THE PAPERWORK REDUCTION ACT

ISSUE: Excessive and duplicative paperwork both increases costs and has a detrimental impact on quality, as it takes more and more staff time away from patient care. The Paperwork Reduction Act of 1980 (PRA) requires that before a government agency begins or revises an information collection, it must make sure the information is not collected elsewhere and reduce, to the extent possible, the burden on the persons required to provide the information. Approval must be obtained from the Office of Management and Budget (OMB). Paperwork requirements multiplied for home health agencies with the adoption of OASIS and its accompanying notice requirements. New process measures, face-to-face encounters, and physical therapy assessment requirements further increase home health agency paperwork.

RECOMMENDATIONS:

1. Promote paperwork reduction by eliminating duplicative information and establishing efficient procedures.
2. New policies and forms that may increase paperwork should not be instituted without a cost-benefit analysis that supports implementation and appropriate payment to compensate providers for the added paperwork.
3. Providers should be appropriately compensated for added costs.
4. Electronic crosswalks should be created that allow for automatic transfer of information from required forms, such as OASIS, to any new assessment tools.

RATIONALE: Paperwork reduction and the development of efficient and effective documentation tools and procedures should be a vital part of CMS' efforts to improve Medicare home health and promote more efficient use of limited financial resources. CMS' failure to pay providers for added paperwork results in fewer resources for direct care services. The reimbursement system must be adjusted for any new requirements. Needless and duplicative documentation requirements decrease the amount of time clinicians can spend in direct patient care.

SUPPORT PHYSICIANS IN ADOPTION OF E-PRESCRIBING AND E-HEALTH RECORDS RELATED TO HOME HEALTH AND HOSPICE SERVICES

ISSUE: The federal government is promoting the adoption of electronic prescribing and electronic health records by the health care system. Key to this change is physician adoption of electronic prescribing and electronic health records. Physicians have been slow to make this change to the electronic world, and both CMS and the OIG have issued safe harbors/exceptions to permit health care providers, without running afoul of the Stark or Anti-kickback provisions, to furnish non-monetary support to physicians to encourage physicians to make the transition to electronic prescribing and electronic health records. These provisions do not go far enough, and they need to be expanded to hasten physician adoption of electronic prescribing and electronic health records. Both CMS and the OIG have limited the type of providers that can furnish support to a physician regarding electronic prescribing. Only hospitals and group practices may furnish this support. Home health agencies and hospices were excluded.

With regard to electronic health records, the CMS and OIG guidance, which includes home health agencies and hospices, is too restrictive. The software must be interoperable at the time it is provided to the physician, and must include an electronic prescribing capability. Interoperability means generally that the software is not limited to communicating or exchanging data only within a limited health care system or community. Both restrictions hinder home health agencies and hospices from furnishing non-monetary support to physicians to encourage them to adopt e-prescribing and electronic health records.

RECOMMENDATIONS:

1. Include home health agencies and hospices as provider-types that may furnish non-monetary support to a physician under the electronic prescribing safe harbor/exception.
2. Permit home health agencies and hospices to furnish non-monetary support to physicians to adopt electronic health records under a two-step approach:
    a. **Step 1:** Assistance to permit the physician and the agency/hospice to have electronic communication regarding orders and medical records for home health and/or hospice services.
    b. **Step 2:** Assistance for fuller interoperability and electronic prescribing capability as defined under the current safe harbor/exception.

RATIONALE: Direct and ongoing involvement of the home care industry in support of electronic prescribing and electronic health records is necessary to encourage timely adoption of these systems by physicians. The approach by CMS and the OIG is based upon an outdated facility model that ignores the current preeminence of home care in the health care system.

PROHIBIT PUBLICATION OF MULTIPLE PROVIDER REGULATIONS IN A SINGLE NOTICE UNLESS ADEQUATE NOTIFICATION IS PROVIDED

ISSUE: CMS has been addressing an issue to a single provider type in a Federal Register Notice, which then is applied to multiple provider types upon adoption of the Final Rule. In other instances, CMS listed more than one provider type in the Notice description, but commingled the discussion so that NAHC could not determine which issues were applicable to home health agencies and hospices. Some recent examples of this situation include provider enrollment issues, claims and documentation requirements, and Stark compliance.

In regard to provider enrollment, CMS issued proposed rules regarding enrollment appeals, 72 Fed. Reg. 9479 (March 2, 2007), and commingled the discussion of home health and DME issues. NAHC was unable to clearly discern which proposals affected home health agencies and hospices and which did not, and NAHC so advised CMS in our comments.

CMS adopted rules affecting home health agencies and hospices in the 2009 Physician Fee Schedule final rule. The final rules contained provisions applicable to home health agencies and hospices that govern provider enrollment and document retention that affects claims.

The 1,700 page 2009 Hospital Inpatient Prospective Payment System Final Rule (August 18, 2008) contained changes to the Stark physician self-referral rules that are not limited to hospitals or hospital issues. NAHC found one change regarding the timing of a physician's signature on contracts that affects compliance, with an exception to the Stark provisions that applies to home health agencies and hospices, as well as to hospitals. In 2010 and 2012, hospice rules were published in the Home Health PPS Update for 2011 and 2013 respectively, and clinical laboratory rules were published in the 2010 Physician Fee Schedule.

Most recently, CMS issued changes to the requirements for the Quality Improvement Organization contractors in the 2021 Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System Inpatient final rule that impacted home health and hospice providers.

CMS has expressed concerns regarding the long amount of time it takes for a proposed rule to become a final rule. CMS has justified its practices on the ground of expediency.

RECOMMENDATIONS:

1. Clearly list in any notice headings all provider types or issues that will be addressed in the rulemaking.
2. In a rulemaking resulting from a single provider notice, such as a Hospital IPPS Rule or a Physician Fee Schedule, do not finalize rules applicable to other provider types that were not made aware that issues affecting them would be addressed.
3. In a rulemaking resulting from a single provider notice, if new issues arise that are applicable to other provider types, split these issues into a new rulemaking, and give notice to all affected provider types, as well as an opportunity to comment prior to finalizing the rules.

RATIONALE: NAHC appreciates the opportunity to comment upon proposed rules that affect the home care industry, allowing us to raise issues that CMS can address prior to adoption of final rules. NAHC is unable to perform this function when final rules applicable to the home care industry are adopted in a rulemaking seemingly applicable to other provider types. Nor can NAHC meaningfully comment when the discussion in the notice is not clear regarding which issues affect home health agencies and hospices. Although giving meaningful notice and comment may cause some delay in the adoption of final rules, CMS must bear this delay to comply with due process.

REQUIRE MEDICARE TO FULLY ASSESS AND REPORT ON THE IMPACT OF ITS NEW RULES

ISSUE: Most home health agencies and hospices are considered small businesses under federal law. The Small Business Regulatory Flexibility Act requires that any federal rule affecting a small business must undergo a regulatory impact analysis that is prepared and published at the proposed and final rule stages of rulemaking. Medicare rulemaking has failed to include an adequate, in-depth impact analysis in any of its home health services and hospice rulemaking. Instead, Medicare has simply published a statement of the broad financial impact of the rules rather than a comprehensive evaluation of the rule's impact on the provider's ability to maintain its operation and meets its responsibilities of providing care to Medicare beneficiaries.

This continually perpetuated in the annual HHPPS rate update NPRM rule by simply quantifying the percentage cut in rates on a geographic basis, and broadly evaluating the impact of the proposed changes in case-mix weights on categories of home health agencies such as freestanding, hospital-based, nonprofits, and urban and rural providers. Further, the NPRM impact analysis offers little substantive understanding of the cost impact of existing and proposed rules such as the physician face-to-face encounter requirement, revisions to therapy assessment, coding change proposals, and OASIS and CAHPS compliance. The estimated costs are vastly understated because they do not include the sizeable administrative expenses that home health agencies will incur to implement any of the changes beyond the cost of some of the form revisions. The most recent examples are the final rules for the emergency preparedness and the revised CoPs for home health agencies.

RECOMMENDATIONS:

1. The Small Business Administration should take steps to define the responsibilities of federal agencies regarding the regulatory impact analysis requirements to ensure that a full and reasonable analysis is developed and presented for public review.
2. CMS should modify its impact analysis approach to include an in-depth evaluation of a rule's impact on business viability, as affected by any and all changes triggered by a rule. The impact analysis should:
    a. Begin with the highest of priority concerns which is impact on access to care.
    b. Continue with an evaluation of the effect of the NPRM on Medicare spending in a whole sense, not just the effect on home health services spending.
    c. Evaluate the impact of the NPRM on the ongoing viability of the individual businesses and the industry as a whole.
    d. Include impact on workforce.
    e. Address access to capital.

RATIONALE: A rulemaking impact that is limited to aggregate effects regarding businesses that operate individually in diverse locales is of no value to understanding the impact of a rule. Further, an analysis that is limited to one year of a multi-year rule fails to display the true impact of the rule. That method of evaluating the impact of a proposed rule falls far short of adequacy in relation to the impact on the businesses that provide home health services. A valid and useful impact analysis starts with an understanding of the results of the combination of rate cuts and cost increases that the NPRM will bring to home health agencies.

Impact on access to care is the central purpose of Medicare and the HHAs that provide the care. For example, if the analysis of the NPRM's impact on access to care shows that thousands of Medicare beneficiaries who need therapy services will no longer have home health care available, or that it will be significantly delayed, Medicare spending will rise as a result of a shift to higher-cost care such as skilled nursing facility services or extended inpatient stays.

Among the many elements that should be reviewed is whether the business will be paid less than the cost of the delivery of care. It is critical to determine whether health care workers will take their talents to other care sectors because of reductions in compensation and benefits.

If the proposed rule changes restrict access to capital, there may be reduced use of efficiency-related technologies or business expansions to achieve economies of scale. Lack of access to capital could also mean an inability to meet ongoing payroll obligations because of cash flow problems.

ENSURE REASONABLE SCREENING, MORATORIA AND COMPLIANCE PLAN PROVISIONS FOR HOME HEALTH AGENCIES AND HOSPICES

ISSUE: CMS has expressed growing concerns about the entry of fraudulent providers into the Medicare program. Congress addressed some of these concerns in the Affordable Care Act, adopting (a) provisions requiring screening of new providers, (b) the assessment of application fees to cover this expense, (c) temporary moratoria, and (d) compliance plans. CMS issued a final rule governing these provisions.

CMS has strengthened provider and supplier screening through establishment of a risk matrix that assigns providers and suppliers to risk levels based upon findings and experiences of CMS and other enforcement agencies. The nature of the intensified provider screening is dependent on the risk level assigned to that provider/supplier sector. In the rule, home health agencies are assigned to a risk level depending on whether they are an existing home health agency (Moderate) or a new applicant for participation in Medicare (High). Hospice is assigned the Moderate risk level.

Each risk level is subject to three screening elements: (1) verification of provider/supplier specific Medicare requirements, (2) license verifications, and (3) database checks. Moderate risk level screenings add unscheduled or unannounced site visits. For high level screenings, two additional screening elements include criminal background checks and fingerprinting of certain owners and managers.

The risk categorizations of home health agencies and hospices are based on some oversight activities by the Office of Inspector General (OIG) and others over the years. Most of these providers are proposed for the Moderate risk level, thereby subjecting them to unscheduled or unannounced site visits. Reports of "phantom" home health agencies are likely the result of site visitors' failure to understand that home health services are provided in the home and that offices are not required to be staffed at all times as long as operating hours are posted and a contact number is displayed for visitors.

Since services are delivered in the home and providers are subject to initial on-site surveys in their offices and the homes of patients, NAHC raises the question as to whether anything is gained by such on-site visits. If there is anything that might be productive as a means to uncover the rare instance where a home health agency or hospice is fraudulently billing for "phantom" patients, it would be to conduct visits with existing or recent patients in their homes, since most care is provided to patients in their homes.

CMS issued a six month moratoria on new home health agencies for Miami–Dade, Florida and Cook Counties, Chicago, effective July 30, 2013. CMS has the authority to continue the moratoria for unlimited extensions in six-month increments and apply it to additional locations. CMS continued and expanded the moratoria in 2014 and 2015 to included counties within the Detroit, Fort Lauderdale, Dallas, and Houston metropolitan areas. On August 3, 2016, CMS expanded the moratoria statewide for enrollment of new HHAs in Florida, Illinois, Michigan, and Texas. The moratoria were extended for every six months until January 20, 2019 when CMS allowed the moratoria to expire.

The OIG continues to review recommendations submitted in response to a solicitation for corporate compliance plan requirements, and plans to issue a new proposed rule specifically addressing compliance plans, with opportunity to comment.

RECOMMENDATIONS:

1. Include competency credentialing in the provider screening model.
2. Establish a credentialing screen at the "Limited" risk level for all new providers and suppliers. The credentialing should include minimum training and competency testing of owners and managers in all areas of Medicare/Medicaid operations, including coverage standards, claim submission, cost reporting and compliance requirements under the anti-kickback laws and the Stark law provisions.
3. Coordinate screening standards with other rules regarding Medicare program participation.
4. Ensure that its enrollment requirements are consistent with its conditions of participation (CoP).
5. Allow providers that have submitted the appropriate CMS Form 855A prior to the public notice of any moratorium to proceed to acceptance and enrollment.
6. Apply any home health agency moratoria based on services area rather than office location.
7. Apply certain standard exceptions to a moratorium such as:
    a. The state has a Certificate of Need program, and the state determines that there is a need for additional providers.
    b. The provider is establishing a branch office or multiple locations within its geographic service area.
8. The seven core elements of a compliance plan (as set forth in the Sentencing Guidelines) should provide the framework and should be the basis for mandatory compliance plan requirements for all providers, ensuring consistency across provider types.
9. Effective compliance plans should begin with these core elements, which are tailored to address provider-specific risk areas.
10. Compliance plan requirements must be periodically re-evaluated and revised as needed.
11. The cost of the compliance plans must be included as part of the factors when developing the payment rates under the new reimbursement models.
12. Provide sufficient outreach and education, and at least 12 months for providers to implement a compliance plan following the publication of any final rule.

RATIONALE: Denial or revocation of billing privileges is too severe a punishment for what is merely a mistake in the inclusion of all documentation with its application.

While there have been instances where certain "phantom" suppliers have been uncovered through surprise site visits, there is no evidence of abusive, fraudulent phenomena occurring in home health services or hospices.

The home care industry strongly supports the use of temporary home health agency moratoria authority in targeted geographic areas. In the past decade, certain areas of the country have had dramatic growth in the number of home health agencies. Evidence suggests that in certain areas, the demand for home health services follows the supply of the agencies, with utilization levels far in excess of other parts of the country.

Coordination of screening efforts in consideration of other requirements reduces burden and confusion. For example, a hospice that requests approval to operate in multiple locations may not furnish services to Medicare patients at that location until CMS approves the location pursuant to 42 CFR 418.100(f)(1)(i). As a result, an on-site visit to an expanded hospice location before it was approved would not find it fully "operational" in the sense of 42 C.F.R. §424.502.

For providers of services participating in Medicare, maintaining a comprehensive compliance plan as part of their Medicare enrollment requirements goes a long way to reducing fraud, waste and abuse. However, imposing compliance plan requirements that are overly burdensome will only add to increased costs without decreasing abuses.

ENSURE REASONABLE ENROLLMENT AND PARTICIPATION REQUIREMENTS FOR HOME HEALTH AGENCIES

ISSUE: CMS has adopted a series of regulations and manual provisions governing the enrollment of home health agencies to address concerns of fraudulent providers entering the Medicare program. In 2010, CMS adopted revised provisions governing the capitalization, also known as the initial reserve operating funds (IROF), to be maintained by new home health agencies, and also significantly revised the 36-month rule applicable to changes of ownership and sales of stock of home health agencies.

In regard to capitalization, CMS has adopted a burdensome approach that requires the agency to have the IROF available at the time the 855A is filed, when the contractor recommends approval to the Regional Office (RO), before the RO approves the application, and before the contractor conveys Medicare billing privileges and issues the billing number. Due to the lengthy time for processing the enrollment application, this is burdensome on agencies, and contractor enforcement of this provision may impose additional burdens and delays in processing new HHA enrollments.

CMS has adopted various versions of the 36-month rule to address concerns about the new owner of a home health agency. In 2010, CMS adopted multiple versions of its interpretation of the rule, causing a freezing of the financial markets. These interpretations included versions that made the rule effective upon a 5% or more change in ownership, a 100% change in ownership, indirect ownership changes, or stock sales; it also required the termination of an agency and the filing of an initial enrollment if one of the owners died.

NAHC and others worked with CMS throughout the year to bring to the attention of CMS the numerous problems caused by their various interpretations of the rule. CMS has retained the so-called 36- month rule, with significant exceptions. If there is a change in majority ownership of an HHA by sale (including asset sale or sale of stock, mergers, and consolidations) within 36 months after the effective date of the HHA's initial enrollment in Medicare or within 36 months of the HHA's most recent change in majority ownership, the HHA's provider agreement does not convey to the new owner. The new owner must enroll in Medicare as a new (initial) agency and obtain state survey or accreditation.

However, CMS adopted significant exceptions to the 36-month rule in cases where:

1. The HHA has submitted two consecutive years of full cost reports (low utilization cost reports or no utilization cost reports do not quality). This is a reduction from five years of cost reports to two years of cost reports.
2. An HHA's parent company is undergoing an internal corporate restructuring such as a merger or consolidation.
3. The owners of an existing HHA are changing its business structure such as from a corporation to a partnership, from an LLC to a corporation, or from a partnership to an LLC, in each case where the owners remain the same.
4. An individual owner of an HHA dies.

CMS further clarified that:

1. Indirect ownership changes are not subject to the 36-month rule.
2. If there is a change in ownership between partners that changes one person's ownership interest from 40% to greater than 50%, the rule applies unless an exception applies.
3. The exception for submitting two full years of cost reports applies to both public and private companies.
4. The 36-month rule applies to nonprofit as well as for-profit entities.
5. CMS would comply with court orders approving the sale of an HHA, including from a bankruptcy court, regarding an HHA that would otherwise be subject to the 36-month rule. CMS would not adopt a bankruptcy exception, nor would CMS adopt an exception to permit a bank or lender to foreclose on a defaulted loan and permit the lender to sell the HHA.

RECOMMENDATIONS:

1. Monitor for appropriate application of the 36-month rule and its impact on access to home health services.
2. Require each contractor to post an IROF calculator on its website so that HHAs can determine the capitalization amount as part of their business analysis regarding whether to open a new HHA.
3. Monitor its four-time contractor review of IROF. NAHC believes that this quadruple review of IROF is unnecessary, unduly burdensome, and will further delay the processing of new HHAs. NAHC recommends that CMS have contractors check the IROF twice: when the application is filed and prior to conveying billing privileges.

RATIONALE: The wholesale revisions of the exceptions may be viewed as a wholesale revision of the rule. As devised, the final 36-month rule may allow most bona fide transactions to take place and permit lenders and investors to stay involved with home health care, with a reasonable degree of security that their collateral or investment does not become worthless. Due to significant problems with past implementation of the 36-month rule, it is important to monitor implementation of the rule to address any potential problems that arise.

ENSURE REASONABLE APPLICATION AND IMPLEMENTATION OF HOME HEALTH SURETY BOND REQUIREMENT

ISSUE: The Balanced Budget Act of 1997, P.L. 105-33, mandated that all home health agencies and certain other entities participating in Medicare and/or Medicaid secure a minimum surety bond of $50,000 in order to protect the programs from fraud. The provision was effective January 1, 1998.

The Centers for Medicare & Medicaid Services (CMS) published implementing regulations for home health surety bonds in the Federal Register on January 5, 1998, that went far beyond the intent of Congress. While the legislation required a minimum $50,000 bond and allowed CMS to waive the requirement in states where a similar requirement already exists, CMS expanded on that authority in the regulations by requiring a bond which is the greater of $50,000 or 15% of previous year's Medicare and/or Medicaid revenues. CMS placed no cap on the amount of the bond. Additionally, the regulations were crafted so that the length of time for which the surety company was liable could be as long as six years. As a result, many surety companies would not write surety bonds for home health; other companies required that agency administrators or owners provide personal guarantees or post collateral two or three times the full value of the bond. Most home health agencies were unable to secure bonds. In the regulations, CMS waived the requirement for government-run agencies (even though the statute did not expressly allow this), but CMS made no attempt to exempt providers with proven good track records.

In an effort to address concerns about the January, 1998, regulations, CMS published changes that responded to the criticisms of the surety industry, but that failed to address home health agencies' concerns. The Small Business Administration (SBA) petitioned CMS to withdraw the rules, citing, among other concerns, the threat the regulations posed to agencies as small businesses.

Both the Senate Special Committee on Aging and the Senate Committee on Small Business held hearings on home health surety bonds. Witnesses from the SBA, home health and the surety industries all expressed concern over CMS' regulations. Finally, in the wake of overwhelming Congressional objection and the threat of passage of resolutions introduced by Senator Kit Bond (R-MO) and Representative Jim Nussle (R-IA) formally disapproving the surety bond regulations, CMS was forced to withdraw the compliance date for agencies to meet the bonding requirement. CMS agreed to await the results of a Congressionally-requested General Accounting Office (GAO) study prior to developing new regulations.

The GAO study was issued in January, 1999, and recommended the following:

1. Retaining the "financial guarantee" nature of the bond, rather than restricting it to a fraud bond.
2. Eliminating the requirement for separate bonds for Medicare and Medicaid participation.
3. Exploring the possibility of exempting agencies that have demonstrated financial stability.
4. Eliminating the option of substituting a Treasury note or other federal public debt obligation in place of a surety bond.

As part of efforts during 1999 to refine the BBA, the Congress made the following changes to the home health surety bond requirements:

1. Limiting the bond to the lesser of $50,000 or 10% of previous year's program revenues.
2. Requiring that agencies secure bonds for four consecutive years, rather than for the full length of Medicare and/or Medicaid program participation.
3. Requiring that agencies secure only one bond to fulfill their obligations under Medicare and Medicaid.

The Affordable Care Act, section 1128J(g), expanded the Medicare authority to impose surety bonds on home health agencies in allowing the bonds to be set at amounts "that the Secretary determines is commensurate with the volume of the billing of the home health agency." The purpose of this change was to overcome any perceived obstacle to the imposition of a bond in excess of $50,000.

The HHS Office of Inspector General followed the ACA amendment with a report entitled, "Surety Bonds Remain an Unused Tool to Protect Medicare from Home Health Overpayments" (September 27, 2012. The OIG suggested that a surety bond on home health agencies would reduce the amount of uncollected overpayments in Medicare.

On April 16, 2015, President Obama signed into law the Medicare Access and CHIP Reauthorization Act (MACRA), which modifies the home health surety bond requirements, setting the bond minimum at $50,000 and allowing Medicare to scale the bond value above $50,000 commensurate with a home health agency's volume of Medicare revenue. Under this provision, the Centers for Medicare & Medicaid Services (CMS) has considerable discretion to implement the requirement and set the scaled bond amount for those bonds greater than the minimum of $50,000. Even without the legislation, CMS had the authority to implement a bond requirement on home health agencies but chose not to do so up to this point.

NAHC opposed the inclusion of the surety bond provision in the MACRA legislation. Among NAHC's arguments against the surety bond requirement include: it would further hurt providers currently struggling to comply with expensive regulations; it would threaten access to care especially in rural areas; it is effectively a tax on the vast majority of providers to cover the cost of a few bad actors; it provides too much discretion to CMS in setting the bond amount and implementing the requirement; any surety bond requirement should be time-limited and targeted to new providers only. Long-standing providers rarely present a risk to Medicare. The Congressional Budget Office estimated the bond requirement would achieve only $10 million in Medicare savings over 10 years, while costing an estimated $130 million over that same 10 years. The small estimated savings indicate that virtually all home health agencies fully repay any Medicare overpayments

RECOMMENDATIONS: CMS should:

1. Look to better program integrity alternatives than the surety bond as a bond simply becomes a tax on compliant providers to cover the unreimbursed overpayments from a few noncompliant providers.
2. Apply any surety bond requirements only to agencies with poor records of repayment to Medicare and/or Medicaid or to new agencies wishing to participate in the program(s).

3. Apply any surety bond requirement for a time-limited period of no more than three years consistent with the recommendation of the GAO.
4. Utilize the surety bond only as a screen to bar inappropriate providers from the programs to protect against fraud, not as insurance against any programmatic losses through unrecouped overpayments.
5. Honor the notice and comment requirements in the Administrative Procedures Act in promulgating regulations to implement the surety bond requirement.
6. Comply with all procedural requirements of the Small Business Regulatory Enforcement Act in developing regulations for the surety bond requirement.
7. Establish objective criteria for agency eligibility for a repayment plan.
8. Explore more targeted approaches to resolving the root causes of problems related to recoupment of overpayments, including requiring that agency operators have sufficient knowledge of Medicare prior to opening an agency. Serious consideration should be given to alternatives that are better measures of an agency's competence and worthiness to participate in Medicare than imposing surety bond and similar requirements. Alternatives to a surety bond approach include requiring the demonstration of financial management ability and knowledge of Medicare coverage and participation requirements.

RATIONALE: Unrecouped Medicare home health overpayments amount to less than 0.2% of home health outlays and are the result of issues presented by a very small number of providers. Also, CMS has many tools available to avoid overpayments altogether and to significantly reduce the risk of uncollected overpayments, such as strengthened authority to suspend payments and real-time data access to catch overpayments quickly. Given these facts, applying an across-the-board surety bond requirement that is onerous and difficult for many agencies to meet is counterproductive and will limit the availability of important home health services. Home health, for the most part, is not a capital-intensive industry. Rather, many agencies are small businesses that are established because of a commitment to providing vital services to needy beneficiaries. These agencies have limited financial reserves. Meeting any requirement that focuses primarily on capital does not necessarily demonstrate an agency's understanding of Medicare policies, nor does it gauge an agency's motivations for getting into the home health business. Unrealistic or excessive requirements could preclude all but the most highly-capitalized providers from entering the program, discouraging many highly scrupulous and capable providers from participating in the program and threatening beneficiary access to care.

ADVANCE THE ADOPTION AND USE OF HEALTH IT IN HOME HEALTH AND HOSPICE

ISSUE: Over the past decade, health information technology (HIT) has been promoted as an essential tool to improve quality, reduce preventable medical errors, and contain rising costs in the U.S. healthcare system. Despite the infusion of government funding to support HIT adoption through the HIT Adoption Initiative, HITECH Act, and the Patient Protection and Affordable Care Act of 2010 (ACA), home health and hospice providers have not greatly benefited from the implementation of key programs, including: the Meaningful Use EHR Incentive program, state health information exchanges (HIEs), regional extension centers (RECs), and other new standards for interoperable health information exchange.

Meaningful Use eligible professionals (EPs) and hospitals have been the primary recipients of federally subsidized HIT investments and programs. In addition to receiving fiscal incentives, hospitals and physicians are also eligible to receive technical assistance from regional extension centers (RECs). The RECs were created to provide guidance, training, and support services to assist EPs in adopting EHRs. However, because of their focus on assisting EPs, RECs are unaware of the similar technology needs of home health and hospice providers. Since RECs have to been self-sustaining for several years now, there is an opportunity for them to develop and execute comparable outreach and technical assistance strategies to engage and assist home health care and hospice providers.

The Office of the National Coordinator for Health Information Technology (ONC) has made an impact on the inclusion of home health care and hospice providers in the Beacon Community Program and through their state HIE Challenge Grants. ONC is providing $250 million over three years to 17 selected communities throughout the United States that have already made inroads in the development of secure, private, and accurate systems of EHR adoption and health information exchange. Several of the Beacon projects, such as in Western New York and Eastern Maine, have participation from home health agencies. Also, the HIE Challenge Grants were awarded specifically awarded to HIEs that were engaging home health and hospice agencies and Long-Term Post-Acute Care (LTPAC) providers in the exchange of clinical data with other providers.

ONC has also provided resources and expertise through the S&I Framework in order to engage stakeholders that were not incentivized by the Meaningful Use Program. In December of 2011, ONC launched a new community initiative within their established Standards & Interoperability (S&I) Framework called the Longitudinal Coordination of Care (LCC) Workgroup (WG). The LCC WG was chartered to represent the data exchange needs of Long-Term Post-Acute Care Providers (LTPAC) and its work has focused on three primary areas of interest: patient assessments, care transitions and the longitudinal care plan. The LCC WG is charged with the development of standards of health information exchange that support these main objectives, and with seeking their integration into the Meaningful Use program objectives. Therefore, NAHC, through its affiliated Home Care Technology Association of America (HCTAA), has been collaborating within the S&I LCC WG and advocating for funding for the development of standards to support the electronic Home Health Plan of Care (HH-PoC) and Care Transition standard for the benefit of home health care and hospice providers. As of fall 2013, both standards have been developed by HL7 and are entering the piloting phase. Also, the Health IT

Policy Committee has recommended the Care Transition standard for inclusion in Meaningful Use Stage 3.

Although no federal funds have ever been allocated to support EHR adoption among home health and hospice providers, a group of stakeholders worked with the Certification Commission for Health IT (CCHIT©) to develop an initial set of standards and certification criteria for a LTPAC EHR. These standards were designed to satisfy special care requirements among LTPAC (e.g. SNF, home health, etc.) while also going beyond Meaningful Use EHR certification criteria in order to meet clinicians' health IT needs across the care spectrum. The CCHIT© Certified EHR Home Health Add-On was released in July, 2010, and to date, only three EHR products have been certified under this program. Despite the regulatory-compliant standards of the CCHIT© LTPAC EHR Certification, ONC and CMS have not recognized or incorporated these standards. However, HHS/ONC is considering the development of a voluntary EHR certification program for long-term post-acute care (LTPAC) and behavioral health providers. HCTAA has been active in advocating for the development of a voluntary program as well as an expansion of the definition of interoperable health information exchange to include providers currently outside the scope of the Meaningful Use EHR Incentive program.

Interoperability among EHR system is paramount in home health care. A significant financial challenge remains with unsigned physician orders.

RECOMMENDATIONS:

1. Coordinate with ONC and CCHIT to ensure that the LTPAC Certified EHR standards for home health are updated to support EHR standards (e.g. Consolidated CDA, SNOMED-CT, LOINC, RxNORM);
2. Promote the development and adoption of a certified LTPAC EHR standard for home health and hospice and seek recognition of the certification program from CMS/ONC;
3. Expand the scope of HITECH programs to include ineligible providers, such as home health and hospice, in the Meaningful Use Program;
4. Develop cross-care standard for requesting a physician signature on any documentation from agencies that require a physician signature;
5. Identify a subset of OASIS data that are the essential clinical measurements required for safe and efficient transfers between ambulatory and post-acute settings, and home health care / hospice providers (e.g. summary of care record, etc.);
6. Mandate use of LOINC mapping of the items identified in item 4, per the CMS Data Element Library.
7. Support standards of interoperability to exchange health information with hospitals and physician practices;
8. Revise the (Consolidated-CCD) clinical document standard and Fast Healthcare Interoperability Resources (FIHR) standards for the exchange of the HH-PoC and summary care record between home health care providers, physician groups, hospitals and other LTPAC providers;

9. Ensure that the HH-PoC is supported as a national standard of exchange by state IHEs and also supported in EMR/EHR products in use in home care providers and by physicians.
10. Identify technical assistance and resources needed by home health care and hospice providers to support EHR adoption and the electronic exchange of health information;
11. Encourage homecare and hospice providers to engage in HIE governance and taskforces.
12. Provide educational resources to homecare and hospice providers for 5010 and ICD-10 conversions;
13. Explore strategies to incorporate interfaces for telehealth and remote monitoring data into EHRs, and;
14. Collaborate with CMS/ONC to provide REC technical assistance to home health care and hospice providers, especially in rural areas.

RATIONALE: In most cases, the delivery of quality homecare services is very dependent upon the collaboration and sharing of health information amongst various health care providers across the continuum of care (e.g. physician practices, hospitals, skilled facilities, rehab facilities, case managers, etc.). Therefore, information sharing amongst physicians and hospitals with home health care and hospice providers will be critical to advancing care coordination efforts, reducing costs and improving care transitions. NAHC envisions a future where the integration of advanced communication technologies and community-based skilled nursing services is leveraged in the home setting as the backbone of the national health care delivery system.

ADOPT DUE PROCESS PROVISIONS BEFORE SUSPENDING PAYMENT

ISSUE: Existing rules on suspension of Medicare/Medicaid payments fall far short of reasonable due process. In addition, there has been an increase in payment suspensions issued by the unified program integrity contractors (UPICs). The suspension are for extended periods of time and not support by the UPIC audit review results.

RECOMMENDATION:

1. Notice of the proposed payment suspension prior to the imposition of the suspension, except in cases where there is reliable evidence of fraud.
2. The notice must provide the specific basis for the suspension with detailed explanation as to the evidentiary basis for the action. All standards for suspension should be fully disclosed and should not be vague and indefinite. The standards in the proposed rule fail that test.
3. Reliable evidence of fraud must be established through concurrence of at least two independent government agencies/departments.
4. A party subject to a payment suspension must be entitled to a fair hearing before an administrative body with a right of judicial review within a reasonable time period following the suspension, but no greater than one payment cycle. The hearing and judicial review includes evaluation of the basis and authority for the payment suspension.
5. The grounds for "good cause" not to suspend payment should be more fully articulated and focus, at a minimum, on access to care for beneficiaries and the history of claims reversals in the administrative appeals process.
6. The standards for terminating a suspension also should be articulated more fully and provide the benefit of the doubt to the provider.

RATIONALE: A payment suspension for home health agencies and hospices is generally a death sentence as Medicare/Medicaid is usually the sole or primary payer. NAHC has reviewed a number of instances where the claim determinations that trigger a suspension of payments or the consideration of a suspension are clearly erroneous or unreliable.

ENSURE THAT HOME HEALTH AND HOSPICE ARE INCLUDED AS REQUIRED HEALTH BENEFITS BY HEALTH PLANS

ISSUE: Section 1302 of the Affordable Care Act requires qualified health plans to include the following ten essential health benefits (EHBs): (1) ambulatory patient services, (2) emergency services, (3) hospitalization, (4) maternity and newborn care, (5) mental health and substance use disorder services, (6) prescription drugs, (7) rehabilitative and habilitative services and devices, (8) laboratory services, (9) preventive and wellness services and chronic disease management, and (10) pediatric services. Home health and hospice coverage is not included in the ten essential health benefits.

The Affordable Care Act instructs the Secretary that the EHB must equal the scope of benefits provided under a typical employer plan. The Centers for Medicare & Medicaid Services (CMS) announced an intended regulatory approach of utilizing a reference plan based on typical employer-sponsored coverage in the marketplace today, supplemented as necessary to ensure that plans cover each of the ten statutory categories. CMS invited public input to this intended approach through solicitation of comments. However, at this point CMS believes that the following four benchmark plan types for 2014 and 2015 would best reflect the statutory standards for EHB:

1. The largest plan by enrollment in any of the three largest small group insurance products in the state's small group market.
2. Any of the largest three state employee health benefit plans by enrollment.
3. Any of the largest three national federal employee health benefits plan options by enrollment.
4. The largest insured commercial non-Medicaid health maintenance organization operating in the state.

RECOMMENDATIONS:

1. Require the inclusion of home health and hospice benefits in health plans adopted by states.
2. Avoid cost sharing for home health and hospice services.
3. Update benefits as new information becomes available about interventions and consumer preferences.

RATIONALE: According to a recent national study, home health is a benefit in 77% of health plans and hospice in 66%. Home health has proven to be effective in reducing health care expenditures by reducing hospitalizations, shortening hospital stays, and serving as an alternative to costly post-acute inpatient stays. In addition, cost savings are realized at end of life through the delivery of hospice services. Failure to include home health and hospice coverage will result in increased cost and fewer options to enrollees. Furthermore, failure to include home health and hospice benefits is inconsistent with the Administration's focus on home and community based services and could be in violation of the American with Disabilities Act (ADA).

DEVELOP COORDINATED PHASED IN IMPLEMENTATION PLAN FOR PROVIDER ENROLLMENT CHANGES AND PROVIDE INDUSTRY GUIDANCE AND EDUCATION

ISSUE: In September 2019 CMS finalized a rule that was proposed in 2015, Program Integrity Enhancements to the Provider Enrollment Process (CMS-6058-FC). This rule creates several new revocation and denial authorities to bolster CMS' efforts to stop waste, fraud and abuse. A new "affiliations" authority in the rule allows CMS to identify individuals and organizations that pose an undue risk of fraud, waste or abuse based on their relationships with other previously sanctioned entities. The rule implements a provision of the Act that requires Medicare, Medicaid, and CHIP providers and suppliers to disclose any current or previous direct or indirect affiliation with a provider or supplier that has uncollected debt; has been or is subject to a payment suspension under a federal health care program; has been excluded from Medicare, Medicaid, or CHIP; or has had its Medicare, Medicaid, or CHIP billing privileges denied or revoked(all of which are hereafter occasionally referred to as "disclosable events"), and that permits the Secretary to deny enrollment based on such an affiliation when the Secretary determines that it poses an undue risk of fraud, waste, or abuse. The rule provides CMS with the authority to do the following:

- Deny or revoke a provider's or supplier's Medicare enrollment if CMS determines that the provider or supplier is currently revoked under a different name, numerical identifier, or business identity, and the applicable reenrollment bar period has not expired.

- Revoke a provider's or supplier's Medicare enrollment –including all of the provider's or supplier's practice locations, regardless of whether they are part of the same enrollment – if the provider or supplier billed for services performed at, or items furnished from, a location that it knew or should reasonably have known did not comply with Medicare enrollment requirements.

- Revoke a physician's or eligible professional's Medicare enrollment if he or she has a pattern or practice of ordering, certifying, referring, or prescribing Medicare Part A or B services, items, or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements.

- Increase the maximum reenrollment bar from 3 to 10years, with exceptions as stated in this rule.

- Prohibit a provider or supplier from enrolling in the Medicare program for up to 3years if its enrollment application is denied because the provider or supplier submitted false or misleading information on or with (or omitted information from) its application in order to gain enrollment in the Medicare program.

- Revoke a provider's or supplier's Medicare enrollment if the provider or supplier has an existing debt that CMS refers to the United States Department of Treasury.

- Deny a provider's or supplier's Medicare enrollment application if–(1) the provider or supplier is currently terminated or suspended (or otherwise barred) from participation in a

state Medicaid program or any other federal health care program; or (2) the provider's or supplier's license is currently revoked or suspended in a state other than that in which the provider or supplier is enrolling.

How CMS will implement the provisions of this final rule are not yet clear. CMS stated in its comments to the final rule that it will provide additional sub-regulatory guidance; however, this guidance has not been provided even though the implementation date of the rule was in November 2019. CMS acknowledges it will take some time to develop the guidance and that the CMS Form 855 will need to be revised in order to serve as a collection mechanism for the data CMS is required to obtain per this rule. CMS also asked for feedback from providers and other stakeholders to for help in identifying the best ways to incorporate the greater than 1.7 million providers in the implementation of the final rule.

Providers must gather extensive amounts and types of information from some of their employees, governing body members, and contractors. It will take a significant amount of time for providers to gather the information as they must first determine exactly what they need, from whom, and how and when it must be collected. Providers have numerous and varied questions about all of these components and need further guidance in order to be prepared and to provide CMS with accurate and timely information.

RECOMMENDATION:

1. CMS should develop a schedule of providers due for mandatory disclosure that coincides with the providers' revalidation dates and phase providers in gradually over the course of 5-10 years.
2. Allow providers an ample opportunity to appeal final decisions, and NAHC strongly recommends that CMS observe a timeframe of 180 days to fully adjudicate the appeal
3. Provide detailed and timely sub-regulatory guidance for providers and educate enrollees and applicants on the guidance. CMS should also ensure MACs are educated on the guidance in order to facilitate consistency in application of the final rule provisions.

RATIONALE: Currently instructions are not consistent with information contained in the Program Integrity Manual (PIM) regarding the completion and submission of information during initial enrollment and revalidation. The risk for providers, if inaccurate or incorrect information is provided, is extensive. The more explicit the sub-regulatory guidance provided by CMS, and the more real-life examples used in provider training, the more accurate and timely the information will be that is submitted to CMS.

REVISE THE HHCAHPS TO FACILITATE PARTICIPATION

ISSUE: The Home Health Care Consumer Assessment of Healthcare Providers and Systems® (HHCAHPS) Survey is designed to measure patients' perspectives of the care they receive from Medicare-certified home health agencies (HHAs).

The national implementation of the HHCAHPS Survey began in October 2009 with agencies participating on a voluntary basis prior to when quality reporting requirements for the home health annual payment update (APU) began in the third quarter of calendar year 2010. The Centers for Medicare & Medicaid Services (CMS) began publicly reporting results from the HHCAHPS Survey on Home Health Compare in April of 2012.

The HHCAHPS Survey instrument contains 34 questions covering topics such as access to care, communications, and interactions with the agency and agency staff. There are two global questions: one asks the patient to rate the care provided by the HHA, and the other asks the patient about his or her willingness to recommend the HHA to family and friends. The survey also contains questions that ask for self-reported health status and basic demographic information (race/ethnicity, education attainment level, language spoken in the home, etc.). The survey can be administered either by mail or telephone interview

Since the implementation of the HHCAPHS, HHAs and patients have raised concerns regarding the length of the survey. HHAs have also expressed concern regarding the patient's willingness and ability to complete the survey.

In July 2018, CMS, through their HHCAHPS contractor, convened a technical expert panel (TEP), to revise the HHCAPHS. The TEP reconvened on April 17, 2019 to continue the work. NAHC is represented on that TEP.

The contractor and TEP agreed on some revisions to the questions for clarity and eliminated several of the questions. The CMS contractor is continuing the work with no time frame for completion that has been communicated to date.

RECOMMENDATIONS: CMS should continue the work on revising the HHCAPHs in order to facilitate ease with completing the survey. CMS' initial work with the goal to simplify the survey, with particular attention to reducing the number of survey questions, is a step in the right direction.

RATIONALE: A survey designed that measures the patient perception of the care they receive is an important aspect to consider when measuring the overall quality of care rendered by any health care provider. However, the HHCAHPS is an extended survey that the typical Medicare beneficiary served by home health agencies often find too burdensome and complex to complete. CMS has been collecting the HHCAHPS almost for 10 years and should have ample data to support improvements to the survey.

MONITOR DIRECT CONTRACTING MODELS TO ENSURE ACCESS TO QUALITY CARE

ISSUE: CMS has developed two Direct Contracting models under the Centers for Medicare and Medicaid Innovation (CMMI). A Professional model and a Global model. Both of the models have varying elements but similar goals and include a value based, risk sharing approach to payment for participating and preferred providers. The models use a direct contracting entity (DCE) that is responsible for managing beneficiaries' care. The Professional DC model focuses on primary care services while the Global model includes all Part A and Part B services. Both models align beneficiaries with participating providers.

CMMI has explicitly developed the models based on the Medicare Advantage(MA) plans operations and incentives for cost savings. Beneficiaries can be enrolled under a DCE through their primary care provider without realizing they are part of a CMMI demonstration project. A beneficiary can only opt-out of the model by changing their primary care provider.

RECOMMENDATIONS: CMS should:

1. Closely monitor the Direct Contracting models through targeted and frequent evaluations related to beneficiary care.
2. Obtain stakeholder input on the evaluations obtained from the DC models.
3. Conduct extensive beneficiary outreach and education on the DC models.
3. Require, at a minimum, the same program integrity activities as required by the MA plans.
4. Establish a quality measurement system aimed at assessing care adequacy for access and quality of care for beneficiaries.
5, Evaluate pricing strategies to ensure adequate payments to providers and the impact on Medicare Fee-for-Service pricing.

RATIONALE: The CMMI has been very aggressive in its developing and implementing value- based payment models despite the fact that these value- based payment models have not shown significant overall savings to the Medicare program. The DC models are designed to provide the coordinating entity (i.e. DCE) more control over health care utilization, providers of service with less autonomy, and questionable accountability for the care provided to beneficiaries. The similarity to the DC models with Medicare Advantage plans and the negative experience HHAs have had with many of the MA plans warrants CMS to strengthen quality oversight and beneficiary education.

ABANDON THE IMPLEMENTATION OF THE GEOGRAPHC DIRECT CONTRACTING MODEL

ISSUE: In addition to the Professional and Global Direct Contracting models, CMMI has developed a Geographic Direct Contracting model. Similar to the other two direct contracting models the Geographic Direct contracting model includes a value based, risk sharing approach to payment for preferred providers. Additionally, the model has a direct contracting entity (DCE) that is responsible for managing beneficiaries care.

The Geographic DC model includes all Part A and Part B services and requires all beneficiaries within a set geographic area to participate in the model regardless of whether their primary provider is a participating provider. Although beneficiaries may continue to see a provider of their choice, the beneficiary may not op-out of the model. The DCE is at risk for all the beneficiary's Medicare expenditures and for managing the care.

To encourage provider participation and provide flexibilities in managing the beneficiary's care, the DCEs have the option to offer a variety of beneficiary engagement incentives and certain enhanced Medicare benefits which include vouchers for transportation to medical appointments; home visits for care management; increased access to home health care by waiving the homebound requirement, access to curative care while receiving the hospice benefit; and allowing NPs to certify beneficiaries for hospice services. However, these enhancements may only be offered by the DCE's preferred providers in order to incentivize beneficiaries to use the contracted preferred providers.

For the Model, CMS will define a region as a Core Based Statistical Area (CBSA), which includes both metropolitan and micropolitan communities. The CBSAs CMS is considering for the model are:

- Atlanta
- Dallas
- Denver
- Detroit
- Houston
- Los Angeles
- Miami
- Minneapolis
- Orlando
- Phoenix
- Philadelphia
- Pittsburgh
- Riverside
- San Diego
- Tampa

The model raises obvious concerns regarding beneficiary choice and the implications for care. There is also concerns around steering beneficiaries to preferred providers through incentives. Furthermore, the beneficiary enhancements and flexibilities in the model are

intended to provide the DCEs with the ability to better manage the care of beneficiaries while reducing costs. However, a consequence of these increased incentives could be rate reductions to providers and/or curtailing the full scope of Medicare benefits to beneficiaries.

Additionally, two notable organizations (the National Association for Accountable Care Organizations and the Center for Medicare Advocacy) have raised other concerns regarding the Geographic DC model. The Geographic DCEs are not required to submit claims or encounter data to CMS as required by the Medicare Advantage plans. This data is used to uncover potential fraud and to ensure beneficiaries are receiving appropriate care. Furthermore, the only quality measurement method for the model a star rating system, has been called into question.

RECOMMENDATIONS:
CMMI should abandon the Geographic Direct Contacting model as currently designed..

RATIONALE: NAHC supports testing innovated health care models and in the past has encouraged CMMI to test beneficiary incentives and flexibilities in other CMMI projects. However, the Geographic model raises several concerns for providers and beneficiaries. The coordinating entity (i.e. DCE) will have significant control over health care utilization while providing beneficiaries no freedom of choice for model particiaption. Additionally, incentivizing beneficiaries towards certain providers without ensuring the quality of care of those providers places beneficiaries at risk for substandard care. Furthermore, the model offers a number of enhancement and incentives the could have negative consequences for providers and beneficiaries.

IV. COVERAGE AND APPEALS

ENSURE CLAIMS REVIEW DECISIONS AT ALL LEVELS OF APPEAL THAT ARE CONSISTENT AND IN COMPLIANCE WITH MEDICARE COVERAGE REQUIREMENTS

ISSUE: Recent claims denials by Medicare Administrative Contractors (MAC), Zone Program Integrity Contractors (ZPIC)/Unified Program Integrity Contractors (UPIC), Recovery Audit Contractors (RAC), Supplemental Medical Review Contractors (SMRC) and review of claims denials by Qualified Independent Contractors (QIC) and Administrative Law Judges (ALJ), are inconsistent and are not in compliance with Medicare coverage requirements as stated in the statute, regulations, and manuals.

In addition to the Medicare Administrative Contractors, which process claims and conduct pre-payment and post-payment reviews, CMS has implemented four other audit contractor types – all of which have essentially the same function and serve the same purpose.

There is growing concern about inappropriate ZPIC/UPIC, RAC, SMRC and CERT coverage interpretations, denials, and sampling. Below are several examples:

The CERT Program produces a national Medicare FFS improper payment rate. Often CERT requests for documentation are sent to incorrect addresses.

In addition, CERT contractors have inappropriately requested home health agencies to provide physicians' medical records to support his/her face-to-face encounter documentation in addition to the agencies' face-to-face encounter documentation and clinical records.

ZPICs in certain areas are denying claims for beneficiaries they believe to be not homebound. The homebound status of the beneficiary is based on a previous claim denial for non-homebound status and does not include a review of the medical record for the services being denied.

RAC issues approved by CMS have a number of problems, such as:
1.The overly broad Medical Necessity and Conditions to Qualify for Services that provides the RAC with discretion to deny claims based on their interpretation of all qualifying and coverage criteria; and
2. Payment denial of claims where the OASIS was not completed within the five-day window despite CMS policy that payment would be based on OASIS timely submission, not completion.

Finally, the SMRC is an additional audit contractor that has been tasked to perform a large volume of Medicare Part A, Part B, and Durable Medical Equipment reimbursement claims reviews nationally. The focus is to lower improper payments in Medicare fee-for-service programs and increase efficiencies in medical review functions. One example of inconsistent coverage determination by this contractor has been denials related to physicians failing to include credentials as part of their signatures.

RECOMMENDATIONS:

1. Train each of these contractors on the coverage contained in the statute, regulations, and manuals, and require the contractors to apply these coverage requirements in their review of claims.
2. Monitor compliance with their sub-contractors by auditing a statistically valid random sampling of the claims decisions of each contractor. CMS should discuss inconsistencies and coverage errors with each sub-contractor. High coverage errors should be taken into account when the contractor requests a subsequent contract with Medicare. ALJs who have high coverage errors should receive additional coverage training.
3. Monitor the various contractors for redundancies in claims review and provider burden.
4. Hold these contractors accountable to consistently and correctly applying Medicare home health and hospice regulations and policies by developing and implementing contractor performance criteria such as compliance with timeframes for review of records, inter-rater reliability, etc

RATIONALE: Medicare is a national federal program. Determination of coverage should be consistent across the country so that beneficiaries are guaranteed access to all services to which they are entitled. Inconsistencies lead to confusion and unfair eligibility determinations by home health agencies.

ENSURE HOME HEALTH ACCESS FOR HOMEBOUND BENEFICIARIES

ISSUE: In order to qualify for home health services, Medicare beneficiaries must be confined to their home. CMS recently issue clarifying guidance on the definition for homebound. CMS defines a beneficiary as homebound "because of illness or injury, need the aid of supportive devices; the use of special transportation; or the assistance of another person in order to leave their place of residence or have a condition such that leaving his or her home is medically contraindicated……and leaving home must require a considerable and taxing effort". According to the longstanding Medicare policy, if a person leaves their home, "absences must be infrequent or for periods of relatively short duration," unless for medical purposes. Congress attempted, but failed, to impose strict numerical limitations on how often a home health beneficiary could leave home for non-medical reasons at "no more than approximately 5 times a month and no more than about 3 hours each time."

The Balanced Budget Act of 1997 (PL105-33) replaced this earlier legislative proposal and recognizes persons absent from home for adult day care and religious services as homebound if certain criteria are met. CMS revised its homebound policy to allow for unlimited absences to attend adult day care and religious services. In addition, adult day programs must be licensed, accredited or certified in order to meet CMS criteria. However, many states do not license or certify adult day programs, leaving beneficiaries who attend adult day care in those states without the ability to access the home health benefit.

Face-to-face encounter requirements legislated by the Affordable Care Act became effective January 1, 2011. According to CMS regulations to implement the statute, physicians must not only certify that patients are homebound, but must ensure there is documentation in their medical records to support a patient's home bound status. However, most physicians are ill-equipped to do so in light of the complexity of homebound rules and lack of education on the homebound policy.

For the most part, medical review staff at the CMS contractors (MAC, RAC, SMRC, and UPIC,) do not have an acceptable understanding of homebound criteria. These contractors have been known to issue inappropriate denials because of their lack of understanding of Medicare "confined to home" policies.

In an attempt to improve understanding of homebound requirements, CMS revised the Medicare Benefit Policy Manual to clarifying the homebound definition.

Most recently, CMS clarified that beneficiaries whose physician advises them not to leave the home because of a confirmed or suspected COVID-19 diagnosis or if patient has a condition that makes them more susceptible to contract COVID-19 will meet the homebound criteria for Medicare home health services. With this clarification CMS demonstrates how the Medicare homebound criteria apply to beneficiaries during the COVID-19 pandemic. The clarification provided home health agencies (HHAs) with the guidance needed to make affirmative determinations regarding a beneficiary's eligibility for Medicare home health services.

RECOMMENDATIONS:

1. Work with the industry to establish homebound definition and guidelines that:
    a. Ensure access to home health services, as intended by the Social Security Act, based on functional limitations and the clinical condition of the patient as documented in the patient record rather than arbitrary number and duration of absences.
    b. Do not impose burdensome documentation requirements, such as detailed information about reasons, frequency, and duration of non-medical absences from the home.
    c. Expand the definitions of "licensed" and "certified" adult day programs.
    d. Ensure that analysis of the impact of any expansion of the homebound definition addresses the financial impact on providers as well as the Medicare program.
2. Require CMS to provide educational information to physicians and all of its contractors, and oversee their application of the homebound policy.
3. CMS should continue to reinforce the application of the Medicare homebound definition for beneficiaries with conditions where leaving the home is contraindicated, particularly when there is a high risk for the beneficiary to contract an infectious and/or communicable disease

RATIONALE: Congress rejected the inflexible definition proposed by the Administration for "homebound" that prescribed limits to the frequency and duration of non-medical absences from the home. Functional status and medical condition are appropriate criteria for determining whether a person can leave home, without undue hardship or negative health consequences. Practitioners' failure to understand the flexibility of CMS' homebound policy will incorrectly deny access to home health services to beneficiaries. Inappropriate denials and subsequent appeals based on homebound status are costly to providers and the Medicare program. Erroneous denials issued by Medicare contractors for services to beneficiaries who do meet homebound criteria could result in access problems. Failure to expand the definition of "licensed" or "certified" adult day care centers creates access barriers to beneficiaries living in states without these processes.

PROMOTE CONSISTENT APPLICATION OF COVERAGE RULES AND ABANDON LOCAL COVERAGE POLICIES

ISSUE: The Centers for Medicare and Medicaid Services (CMS) issued revised home health coverage guidelines in 1996 that incorporated the codified coverage rules published in December of 1994 (42 CFR §§409.40 to 409.50). Coverage rules were further expanded by the addition of existing polices on management and evaluation, and teaching services to regulations in the 2010 HHPPS payment update. Interpretation of the coverage rules and explanations varies among Medicare contractors and managed care organizations. As a result, home health utilization and coverage varies dramatically among regions and among Medicare managed care enrollees. In many instances, CMS contractors and MA plans create their own set of policies.

One of the official responsibilities assigned to CMS contractors is the development of local medical review policies (LMRP), now called local coverage decisions (LCD), for the purpose of clarifying Medicare coverage policies. In addition, CMS urges contractors to adopt LCDs developed by others, thus creating national coverage policies without completing the formal process required for National Coverage Decisions. CMS has instructed its contractors to ensure that LCDs are "consistent with all statutes, rulings, regulations, and national coverage, payment and coding policies."

According to CMS, more than 8,000 LCDs have been developed over the last 11 years. There are numerous examples where LCDs have resulted in more stringent interpretations of coverage than is spelled out in the Medicare Benefit Policy Manual (Pub 100-2). These LCDs are intended to apply in a particular contractor's jurisdiction. In the case of home health, where three Home Health MACs serve the entire country, LCDs are applied to large geographic areas.

Local policies are reviewed by CMS regional offices upon request only. They are not subject to review by CMS central office. However, CMS central has been called upon to intervene on numerous occasions when MACs developed inappropriate local policies. Many local policies were contrary to Medicare policy and/or limited beneficiaries' access to care. Examples of local policies that required CMS intervention include diabetic supplies, physical therapy, foot care, psychiatric nursing, and homebound status.

Furthermore, managed care organizations have reinterpreted coverage rules, resulting in enrollees in MA plans being deprived of entitled services.

RECOMMENDATIONS:

1. Abandon use of local coverage decisions (LCD) and prohibit CMS from abdicating its responsibility to establish coverage policies to its contractors.
    a. Educate contractor staff on coverage rules.
    b. Instruct MACs to provide clarifications using existing Medicare Benefit Policy Manual (Pub 100) coverage and payment rules, rather than new and potentially more restrictive policy.
2. Until LCDs are abandoned:
    a. Require Medicare contractors to receive CMS approval for new local coverage decisions.

b. Establish formal procedures that allow providers to seek CMS review of questionable contractor interpretation of coverage policies.
c. Ensure compliance with procedures that enable providers to review and comment on proposed local medical review policies.
d. Establish procedures that enable providers to challenge inappropriate local policies.

3. Require MCOs to provide home care services consistent with Medicare guidelines.

RATIONALE: Policies developed and implemented by Medicare contractors are not local due to the extensive geographic areas that they serve. Medicare contractors do not have the legal resources that are available to CMS and essential to ensuring appropriate interpretation of the Medicare benefit and establishment of coverage policy. Federal law requires adherence to formal processes for the establishment of national coverage decisions. Coverage policies that are applied to large areas of the country, and in some cases the entire country, should be established only through this process.

Medicare coverage is a complex issue. Although treatment standards and practices vary from one part of the country to another, Medicare is a national program and beneficiaries should receive all services to which they are entitled. When contractors do not adopt LCDs from other MACs, inconsistency in coverage results within geographic areas since provider assignment to Medicare contractors is not on a strictly geographic basis.

Medicare beneficiaries that enroll in managed care plans should be guaranteed the same home health benefit as fee-for-service beneficiaries.

REFINE CLAIMS REVIEW AND ADDRESS TECHNICAL ERRORS

ISSUE: Claims denial must be based on the information contained in forms and records and based on the individual beneficiary's medical condition. Those claims that are reviewed require submission of extensive records that is costly and time-consuming for providers, suppliers and Medicare contractors. Payment is often delayed when MACs fail to review records in a timely manner.

Top billing errors in home health and hospice have consistently included: failure to submit requested records, lack of physician signature prior to billing, and most recently lack of certification information. . These billing errors represent technical mistakes as opposed to fraudulent billing practices. Other examples of claims that result in issuance of technical denials include: failure to record the date of verbal order on the plan of care, lack of physicians' signatures on all verbal orders prior to billing (including minor treatment changes), lack of a date of the providers' receipt of signed orders in cases where physicians have not dated their signature, and SMRC, denials related a lack of credentials for physician signatures. These denials are often appealed and overturned, a process that is time-consuming and costly for providers, contractors, and ultimately, the Medicare program. A new regulation was promulgated at 42 CFR 424.22(b)(1) eliminating the option of date of receipt by home health agencies of a physician's undated signature. Agencies may not bill for home health services unless the physician affixes the date to his/her signature.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003, Sections 931-940, included a number of provisions related to appeals, recovery and contractor reform. In one provision the Secretary was to establish a process so that providers and suppliers can correct minor errors and omissions in claims that were submitted for payment. However, CMS has not interpreted and implemented this provision as intended by Congress. What CMS has done is limit the application of this provision to denied claims, rather than all claims that have been adjudicated, whether paid or denied.

CMS has instructed Medicare contractors to direct medical review efforts towards claims where there is the greatest risk of inappropriate program payment. Under this approach, called "Targeted Probe and Educate (TPE)", CMS contractors must review 20-40 claims per topic. However, this number of claims does not take into account small providers where 20 claims could represent a high percentage of claims submitted.

Finally, MACs have been known to down-code home health claims when documentation contained in the patient's OASIS assessment is not duplicated elsewhere in the medical record, or when the medical record does not contain documentation of treatments and interventions corresponding to every OASIS item. This down-coding continues to occur in spite of clarification from CMS that other parts of medical records need not contain information duplicative of what is found in OASIS. Furthermore, OASIS assessments capture information about a patient's condition at a particular point in time. Therefore, it is unreasonable to deny ordered and provided services when a problem is not identified in OASIS if that problem developed subsequent to completion of the patient assessment. At the same time, CMS is increasing its efforts to oversee the contractors that process and pay Medicare claims for providers and suppliers. Each year, CMS publishes and/or revises the criteria and standards for

evaluating contractor performance. CMS has identified at least one measurable standard as "the rate of reversals of denied claims at the Administrative Law Judge (ALJ) level." This standard defines an acceptable reversal rate as one that is at or below 5%. Data from CMS found the percentage of reversals for home health and hospice denials at both the reconsideration and ALJ levels far exceeded 5%.

RECOMMENDATIONS:

1. Identify data elements that can be submitted electronically in response to a request for medical review.
2. Direct TPE medical review efforts at non-technical issues and allow providers to correct minor technical errors without denials, including dating of physician signatures.
3. Ensure use of the principles of progressive corrective action (PCA) guidelines established by CMS to guarantee provider-specific focused review, as well as cost-effective utilization of limited resources.
4. Commit resources to educational activities and timely dissemination of information.
5. Establish minimum standards for Medicare contractor medical review staff.
6. Develop a procedure for providers to explain utilization variations prior to making decisions to place them on TPE.
7. Limit medical review to 4% of claims except in cases of demonstrated cause.
8. Require additional education of Medicare contractor medical review staff in the appropriate and correct review of OASIS documentation as a part of the medical record as a whole.
9. Correct the instructions to contractors and providers to accurately reflect the intent of Congress.
10. Involve the provider community in defining "minor errors."
11. Treat claims that are presently issued as technical denials because they are missing information as "incomplete claims."
12. Notify providers of the reason their claims cannot be processed and require resubmission, rather than issue denials.
13. In cases where a technical problem is discovered on post-pay review, require repayment and allow providers to resubmit these claims for payment once the incorrect or incomplete information has been received.

RATIONALE: Claims review must be refined in its targeting to become productive, rather than to remain a labor-intensive and cost-intensive activity. However, claims review must continue to act as both an ongoing educational device and a deterrent to abusive claims submission.

Providers and suppliers are under severe financial hardships when payments are delayed inappropriately for weeks and, in some cases months, while under the review process. Prompt response to inquiries and access to educational materials and programs will improve accuracy in submission and payment of Medicare claims. Denials based on technical errors result in unnecessary and costly appeals. However, should providers identify an underpayment resulting from a technical error, they should be permitted to correct that error through claims processing rather than appeals procedures for up to the four-year limit as allowed by statute.

While the OASIS is the sole basis for determining case-mix and, therefore, appropriate payment to a home health agency, it is not the sole determinant of the scope of services an agency is responsible to provide. The medical record as a whole should support the patient's unique medical, nursing and social needs.

Treating claims with missing information as "incomplete claims" is more efficient than issuing a denial, and could reduce the number of costly appeals filed by providers. Congress' intention was that providers should have the right to correct all technical errors and omissions, and not just those related to claim submission or denials. Congress intended to expand provider rights. It is financially burdensome and non-productive to the Medicare program to subject providers to focused medical review without first identifying significant numbers of billing errors and without taking into account appeal reversals.

ELIMINATE DELAYS IN MEDICARE APPEALS TO ADMINISTRATIVE LAW JUDGES

ISSUE: Under Medicare law, a decision must be issued by a Medicare Administrative Law Judge (ALJ) within 90 days following the filing of the appeal by the Medicare beneficiary or provider. However, the appeal system is irreparably backlog with nearly 900,000 appeals pending review before a handful of ALJs. Despite efforts by the Office of Medicare Hearings and Appeals to expanded the number of ALJs and achieve greater efficiencies in processing appeals, with 14,000 new appeals filed every week, a decision on any current ALJ appeal is years away.

In February 2016, the Office of Medicare Hearings and Appeals (OMHA) expanded the Settlement Conference Facilitation (SCF) pilot to all Medicare Part A providers, including home health and hospice. The SCF is an alternative dispute resolution process designed to bring the appellant and CMS together to discuss the potential of a mutually agreeable resolution for claims appealed to the Administrative Law Judge (ALJ) hearing level of the Medicare claim appeals process. If a resolution is reached, a settlement document is drafted by the settlement conference facilitator to reflect the agreement.

In early 2018, CMS launched a Low Volume Appeals (LVA) Initiative under which eligible providers can receive payments equal to 62 percent of the net Medicare approved amount. The LVA process ended in June 2018. However, CMS expanded its Settlement Conference Facilitation Process to all providers. Providers and suppliers whose appeals have a total billed amount less than $10,000 may participate in a new SCF Express process.

In May 2019, CMS expanded its Part A East (PAE) QIO Appeals Demonstration to home health and hospice providers within the PAE states. Eligible providers are offered a telephone conference with the QIO to discuss the claim and submit additional documentation for reconsiderations of claim denials. In addition, the demonstration offers a reopening process for appeals waiting at ALJ level. The demonstration will run until the end of 2020.

CMS is to be commended for initiating the various projects to reduce the appeals at the ALJ, but these efforts may not fully address concerns over the long term, particularly in light of expanded contractor review efforts.

RECOMMENDATIONS:

1. CMS should take all necessary steps to improve the quality and accuracy of initial claim determinations to limit need for an administrative appeal.
2. CMS should monitor its contractors that handle early-stage administrative appeals to ensure a high degree of accuracy and to reduce the number of appeals that end up before an ALJ.
3. OMHA should increase its resources to handle the level of demand and establish alternative dispute resolution processes to resolves some appeals

RATIONALE: With stepped up claims reviews in all provider sectors in Medicare, the number of appeals has increased exponentially. Alternative remedies must continue to be explored and implemented as a means to reduce erroneous claim denials and resulting appeals.

PROVIDE HEALTH IT VENDORS SUFFICIENT TIME TO IMPLEMENT NEW REGULATIONS

ISSUE: CMS is required to provide agencies at least 60 days notice prior to the implementation on annual rate updates to the HHPPS. The 60 day time frame is provided for agencies and CMS to make any necessary system changes. The regulatory environment has become more complex, thus a 60 day timeframe to review, analyze, design, code, test and deliver an updated software product is extraordinarily difficult while still trying to meet end of year and other requirements.

RECOMMENDATIONS: CMS should take into consideration the complexities, cost and resources required by software developers when issuing deadlines for the implementation of final rules that effect home care and hospice providers. NAHC should also work with the health IT vendor community to develop a model for implementing regulatory changes as well as a means to educate and illustrate to CMS the effort that health IT vendors make to respond to regulatory changes.

RATIONALE: In today's electronic health care environment it is becoming increasingly difficult to implement changes to health IT software and deliver them in a timely manner to providers especially when these regulatory changes are combined with the demands of multiple regulations.

ENSURE EQUITABLE POLICES FOR BENEFICIARIES IN FEE-FOR-SERVICE MEDICARE AND MEDICARE ADVANTAGE PLANS

ISSUE: CMS is expanding the traditional benefit package for Medicare beneficiaries under the MA plans. MA plans may offer its members supplemental benefits that include services, such as, transportation, adaptive equipment for the home and home support services. CMS has reinterpreted the definition of "primary health benefits" to permit these types of services if they contribute to the health and well-being of the beneficiary.

In addition to providing flexibility in the types of services the MA plan may offer, CMS has reinterpreted uniformity requirements for Part C benefits offered to MA enrollees. These changes allow MA plans the ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer different deductibles for beneficiaries that meet specific medical criteria.

In November, 2018, CMS issued a rule proposing to lift the restricting of telehealth services to only beneficiaries in rural areas and to permit the originating site for telehealth services to include the beneficiary's home.

RECOMMEDATIONS: CMS should**:**

1. Monitor the impact of the new benefit packages on MA plans members, particularly how these services relate to any reductions in emergency department visits and re-hospitalizations.
2. Consider developing similar models for Fee-for- Service Medicare through the Centers for Medicare & Medicaid Innovation.

RATIONAL:
CMS recognizes the importance of testing innovative strategies for improving the quality of care and program satisfaction of Medicare beneficiaries. These new benefits should be considered for Medicare beneficiaries who wish to remain in the Fee- for-Service program and have the same advantages as beneficiaries enrolled in MA plans.

BROADEN ACCESS TO COMMUNITY-BASED PALLIATIVE CARE UNDER MEDICARE

ISSUE: Palliative care is increasingly recognized as an important component on the health care continuum with the number of palliative care programs increasing within the health care system. Palliative care fills the gap between Medicare-covered curative and restorative interventions and hospice care. However, there is no explicit palliative care benefit under the Medicare program.

The World Health Organization defines palliative care as follows:

Palliative care is an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.

Palliative care:

- provides relief from pain and other distressing symptoms;
- affirms life and regards dying as a normal process;
- intends neither to hasten or postpone death;
- integrates the psychological and spiritual aspects of patient care;
- offers a support system to help patients live as actively as possible until death;
- offers a support system to help the family cope during the patients illness and in their own bereavement;
- uses a team approach to address the needs of patients and their families, including bereavement counseling, if indicated;
- will enhance quality of life, and may also positively influence the course of illness;
- is applicable early in the course of illness, in conjunction with other therapies that are intended to prolong life, such as chemotherapy or radiation therapy, and includes those investigations needed to better understand and manage distressing clinical complications.

Distinguishing palliative care from traditional hospice care can be difficult since both approaches to care follow a similar philosophy. Where palliative care ends and hospice care begins is typically defined by Medicare coverage criteria for life expectancy and program design for hospice care. Palliative care is provided to those beneficiaries who either do not fit the Medicare eligibility criteria for hospice care or who choose to not receive care through the hospice model.

Currently, palliative care services are billed to Medicare by by various provider types, including hospitals, physician group practices, hospice organizations (through separately-owned home health agencies or physician practices), and skilled nursing facilities, with varying program designs.

Because Medicare does not offer palliative care as a distinct benefit, many home health agencies do not believe palliative care is covered under the Medicare home health benefit; irrespective of the fact that many of the services within palliative care are reasonable and necessary skilled services covered under Medicare. Additionally, certified hospice entities are not permitted to bill Medicare for palliative care services that are administered to patients outside of the hospice

benefit, unless they offer such services through separately-operated group practices or home health programs. As a result, Medicare beneficiaries that could benefit from palliative care delivered in the home are not fully serviced.

Palliative care should be delivered by clinicians who have specialized training in treating patients that are in need of pain and symptom management. Any HHA wanting to develop a palliative care program must recognize that staff serving the palliative care patients will require specialized training for which there are currently no federal guidelines.

RECOMMENDATIONS: CMS should:

- Outline and provide education on the design of a palliative care program that would be appropriate for HHAs to offer and that may be billed as reasonable and necessary skilled services under the Medicare home health benefit.
- Develop guidelines for staff training and experience appropriate for the care of patients under a palliative care program.
- Establish a community-based palliative care model under the Center for Medicare & Medicaid Innovations (CMMI) under which hospices, home health agencies, and other appropriate entities are authorized to provide interdisciplinary palliative care in the home to patients with serious illness.

RATIONALE: Home health agencies and hospices are well positioned to offer palliative care programs. Palliative care programs include skilled nursing for symptom management, such as pain control and psychiatric counseling. Physical, occupational and speech therapy are often part of palliative care programs, along with home care aide services. The agency can decide how it will include services that are not offered under traditional Medicare outside of hospice, such as spiritual counseling and bereavement supports..

The home health palliative care program will be a combination of Medicare covered skilled home health services and non-Medicare covered home health services for which patients may choose to purchase with another pay source.

CMS could require that palliative care provided under the home health benefit be provided by nursing staff that have special training and/or experience beyond the standard curriculum required for a registered nurse, similar to CMS' requirement for psychiatric nursing care provide by Medicare certified home health agencies. The specialized training requirements could be prescribed through the local coverage determination (LCD) process, as is with home health psychiatric nursing care.

ENSURE REGULATIONS FOR NPPS TO CERTIFY HOME HEALTH SERVICES ALIGNS WITH THE STATUTE

ISSUE: The Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed into law on March 27, 2020 This relief package provided critical support to the to the Nation in response to the order to respond to the COVID -19 pandemic. A provision in the CARES Act promulgated the Improving Care Planning for Medicare Home Health Services Act. The Act permits non-physician practitioners (NPPs), nurse practitioners, physician assistants, and clinical nurse specialists, the authority to certify eligibility and write orders under the Medicare Home Health benefit.

On March 30, 2020, CMS issued the Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, interim final rule with comments (IFC). The IFC included revisions to the regulations at §424.22 around the new authority for NPPs to certify and order home health services for Medicare beneficiaries.

However, the revised regulations at §424.22 are conflicting and confusing regrading who may conduct the face -to face encounter for Medicare home health certifications. Section §424.22(a)(v)(A)(2) permits an NPP collaborating with the physician to conduct the F2F encounter when beneficiaries are admitted to home health from the community, while section §424.22(a)(v)(C) limits who may conduct the F2F encounter to the certifying physician or practitioner when beneficiaries are admitted to home health from the community.

Additionally, the regulations at §424.22 and §484.4 retains a "collaborative" requirement with the physician for NPPs who certify and order home health services.

The CARES Act does not include a requirement for collaboration between the physician and NPP, nor does it require that only the certifying practitioner may conduct the F2F encounter for beneficiaries referred to home health from the community. The statute requires NPPs practice in accord with state laws and that the certifying practitioner document that a physician or NPP has conducted a F2Fencounter.

RECOMMENDATION: CMS should modify the regulations to reflect the flexibilities permitted by the CARES Act.

1. Modify §424.22 and §484.4 to permit NPPs to certifying beneficiaries for home health service in accord with state laws
2. Modify §424.22 to eliminate the requirement that the certifying practitioner conduct the F2F encounter. Permit the certifying practitioner to document that **a** physician or allowed NPP has conducted the F2F encounter.

RATIONALE: The CARES Act clearly demonstrates Congress' intent to permit NPP to certify and order home health service for Medicare beneficiaries in accord with state laws. Congress also clearly provided flexibility around who may conduct the F2F encounter for Medicare home health certifications.

V. OTHER

ENSURE THERE IS AN ADEQUATE NUMBER OF CMS CERTIFICATION NUMBERS (CCN) FOR CERTIFIED PROVIDERS

ISSUE: There is a defined process for the assignment of CCNs to newly certified providers and providers needing new numbers. This process uses a finite number of available CCNs based on the state where the provider is located. In 2018, CMS depleted the available CCNs for hospice providers in California. CMS then had to request new numbers be made available and update the CMS software systems to allow the CCNs to be used. This resulted in significant delays in the assignment of CCNs which resulted in providers having to wait many months before being able to submit claims.

RECOMMENDATION:

1. Annually review the growth of home health providers and hospice providers in each state and estimate the number of CCNs needed for the following year.
2. Request additional CCNs proactively and ensure software systems are updated to accept them.

RATIONALE: There is a significant cash outlay involved in a home health or hospice start up as providers must deliver care to a certain number of patients without Medicare payment until they are certified. Providers should not have to incur unnecessary costs in addition to this while they wait for CMS to request, obtain and disseminate CCNs and ensure CMs systems can accept them. The unanticipated time this takes and the additional costs providers must incur may result in some providers not accepting patients or even closing their business which may mean patients do not receive care.

PROMOTE PROVIDER RIGHTS AND OPPORTUNITIES TO COMPETE THROUGH EFFECTIVE ENFORCEMENT OF ANTITRUST LAWS

ISSUE: The health care reform environment has brought about the advent of new systems of delivery of health care services. Mergers of health care providers, vertical and horizontal integration of health care entities, entrance of insurance companies into the provider market, and the growth of managed care plans have resulted in intensified competition, closed markets for provision of services, and new challenges for health care providers to adjust to the reform systems. Managed care, in particular, presents risks of monopolization that do not exist in the traditional fee for service market. Individual home health and hospice providers with limited geographic coverage or limitations relative to the extent of services provided may not adequately compete in this new age. Antitrust laws are designed to foster competition and prevent restraints on trade by competitors. The Federal Trade Commission (FTC) and Department of Justice (DOJ) have, until recently, focused little on health care services in their antitrust law activities. However, public statements from the federal government indicate an intention to reevaluate its efforts in health care.

The Patient Protection and Affordable Care Act of 2010 (ACA) includes authority to develop and support integrated care delivery through such arrangements as accountable care organizations and bundling of payments. Whenever integrated care occurs, the competitive marketplace among providers is impacted. The FTC and DOJ issued a "Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating In The Medicare Shared Savings Program" 76 Fed. Reg. 67026 (October 28, 2011). The Policy Statement describes (1) the ACOs to which the Policy Statement will apply, (2) when the agencies will apply rule of reason treatment to those ACOs, (3) an antitrust safety zone, and (4) additional antitrust guidance for ACOs that are outside the safety zone, including a voluntary, expedited antitrust review process for newly formed ACOs. Home health services and hospice care are not specifically addressed in the Statement. However, the general principles appear to require that any restraint of trade analysis examine such services separate and distinct from inpatient care or physician services.

Similarly, CMS has initiated several projects with "bundled" Medicare payment of post-acute care services. The bundling of payment may require the integration of competing providers in order to properly manage the bundled payment in a manner that allows for economies of scale and sharing of business information. The DoJ antitrust guidelines do not provide adequate guidance on these new delivery models from the perspective of PAC.

RECOMMENDATIONS: The FTC and the DOJ should promote rights and opportunities to compete through effective antitrust laws by issuing additional guidance and further "safety zones" that directly focus on the changing relationship between home health and hospice providers, bundled payment service providers, managed care systems, and payer sources. Specifically, there should be guidelines that define acceptable activities involving the integration of payers with home health and hospice providers. State regulations should provide similar protection.

RATIONALE: Home care providers are looking toward changes in their delivery of services in order to compete for contracts with managed care systems and to participate in the integrated

care approaches encouraged by ACA such as ACOs and PAC bundled payment initiatives. Further, individual home care providers are at a disadvantage in the market, in comparison to vertically integrated health care systems that can offer a managed care plan and a range of services that fit the managed care plan's overall design. Collaborative activities among home care providers can bring about efficiencies and economies of scale that are pro-competition. However, continued and vigorous enforcement of antitrust laws is necessary to insure continued survival of competition in home care services.

DEVELOP QUALITY OF CARE STANDARDS AND ACCOUNTABILITY FOR MEDICAID PERSONAL CARE SERVICES

ISSUE: CMS has encouraged states to give Medicaid beneficiaries more control over the long-term care services they receive. The Patient Protection and Affordable Care Act of 2010 (ACA) includes provisions expanding support for Medicaid home care services. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 included development of a demonstration project for consumer-directed personal care under the Medicare home health benefit. In 2008, CMS promulgated a rule allowing for the provision of consumer-directed care as part of the optional benefits that can be elected by a state Medicaid program. This rule leaves great discretion to states in establishing quality of care protections. Still, this new benefit option requires states to allow a Medicaid beneficiary to choose an agency model for the delivery of personal care. However, no such requirement exists for the many Medicaid home care programs (such as waiver programs) provided under other authority. The ACA includes numerous provisions to expand home and community services.

Some states contract directly with individuals to provide paraprofessional services ranging from social support to “"hands-on” personal care rather than using home care organizations for the provision of such services. In some cases, the services delivered by these individual providers require highly trained health care workers, such as in cases where insulin injections, catheter care, nasogastric tube insertion and feeding are needed. These services are financed through a variety of programs at the federal, state, and county levels. Many states have determined these workers to be employees of the client, thereby delegating the traditional duties of the employer (such as hiring, training, supervising, firing, securing backup workers when the primary care provider is not available, performing background checks, and, in some cases, transmitting payment for services and making employer tax contributions) to the client.

Some states have also required home health providers to act as fiscal agencies for consumer-directed caregivers. This arrangement has resulted in a great deal of confusion as to the role and responsibilities of the home health agency. Legal liability, such worker’s compensation responsibility and liability for clinical errors, has resulted.

Advocates for people with disabilities strongly support growth in personal care services and consumer direction of personal care, and have worked diligently to make the model more widely available. Clearly, it provides recipients who are capable of directing their care more choice and greater independence. NAHC also supports the availability of high-quality, accountable, consumer-directed care for Medicaid beneficiaries who are capable of and choose to use a self-directed care model. However, states’ decisions to use this model are too often driven by cost considerations rather than consumer needs or quality.

RECOMMENDATIONS:

1. Beneficiary participation in consumer-directed care should be strictly voluntary.
2. All states that contract with individuals to provide paraprofessional home care services through publicly-funded programs must provide adequate assurances that consumers receiving care from such individuals are assessed to be capable (for example, a person receiving highly skilled services such as catheter care must be

capable of directing the caregiver in the performance of that task) and willing to assume the required employer responsibilities, such as payment of overtime.

3. Consumers should also be given the option to choose among service models (consumer-directed, home care agency, etc.) to ensure what best meets an individual's needs.
4. States should provide a mechanism for resolving any problems that arise between a consumer and providers, and should devise a method for ensuring that backup workers are available.
5. Consumers directing their own care and their caregivers should be afforded the same important protections (such as those recommended by the Centers for Disease Control and those imposed by OSHA regarding blood-borne pathogens) that are required when care is provided through an agency.
6. Consumers should be educated as to their responsibilities if a private caregiver model is chosen.
7. Caregivers should be trained, tested, and competent to provide services.
8. Home care providers must be freed from responsibility and liability for care provided by consumer-directed caregivers.
9. Require all models of care to comply with applicable state and federal labor laws and health and safety regulations.
10. States should be required to maintain well-defined and effective systems for program integrity and accountability to ensure that beneficiaries receive high quality of care consistent with their needs, and without any wasteful spending that puts the program at risk for all.
11. Criminal background checks should be required commensurate with those applied to other provider organizations.

RATIONALE: A goal of home care is to foster independence in the least restrictive environment while safely meeting the consumer's needs. Consumers have the right to choose the model of care that best suits those needs. Individuals who are capable and choose to do so should be permitted to self-direct care. However, those who are unwilling or unable to assume the many responsibilities associated with this model should be able to select other options. For the safety of consumers and caregivers, the training, testing, and quality standards to which agencies are held should apply to all models of care. It is unfair to require agencies to be responsible for services over which they have no control. Further, as these programs grow in size and scope, evidence of abuses has surfaced. CMS and state Medicaid programs need to take steps to secure full accountability in these programs in order to preserve them for qualified beneficiaries.

OPPOSE CHANGES TO COMPANIONSHIP SERVICES AND LIVE-IN DOMESTICE SERVICES EXEMPTIONS TO THE FAIR LABOR STANDARDS ACT

ISSUE: In 1974, Congress established an exemption for companionship services from the Minimum Wage and Overtime Requirements of the Fair Labor Standards Act. Congress made a societal choice in balancing the interests of the worker relative to the needs for care to the elderly and the infirm. Current law provides the Secretary of the US Department of Labor (DOL) the authority to define and determine the scope of the companionship exemption.

In June, 2007, the US Supreme Court ruled that the DOL companionship services exemption regulation was valid, thereby reversing the Court of Appeals in a final decision.

Since the Supreme Court ruling, there has been a re-focusing of efforts by some opposed to the DOL rule. Currently, they are attempting to get Congress to change the law while also seeking legislative and/or regulatory remedies at the state level. Legislative efforts in the 110th, 111th and 112th Congresses intended to eliminate the current companionship services exemption for home care aide workers are opposed by NAHC because they do not go far enough to protect workers.

Some states already have passed laws that eliminated the companionship services exemption. In others, there are efforts to interpret the regulations in a manner different than the federal rules.

Advocates for changing the exemption have expanded their efforts with the Obama administration to encourage DOL to change the regulation. These efforts include enlisting the aid of 15 Senators to send a letter to the Secretary of Labor requesting that the exemption be modified through regulation to exclude home care aides employed by agencies or family of the client. DOL issued a proposed rule on December 27, 2011, that would significantly restrict the companionship and live-in domestic services exemptions and make them inapplicable to workers employed by home care companies.

The proposed rule was made final on October1, 2013 with an effective date delayed until January 1, 2015, 78 Fed. Reg. 60453 (October 1, 2013). In the absence of a mandate that government payment programs increase payment rates to cover the added cost of wages that would result from these efforts, home care aide employers are expected to restrict working hours to avoid overtime pay. Further, these efforts do nothing to create career opportunities for home care aides or to address their need for health insurance. This isolated action related to a single element of the home care aide working conditions will have a reverse negative impact on those workers.

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Legislation was introduced in the 112th Congress that intended to codify the current definition

of companionship services. NAHC was supportive of the "Companionship Exemption Protection Act" (H.R.3066) because it creates certainty for home care providers and patients rather than leaving the definition open to changes through the regulatory process.

In June 2014, NAHC and others filed a lawsuit in federal district court challenging the validity of the Department of Labor rules that restricted the definition of "companionship services" and excluded application of the companionship services and live-in domestic services exemption to individuals employed by home care companies and other third-party employers. In rulings issued in late 2014 and early 2015, the court vacated the challenged rules, reinstating the longstanding standards on the exemption. The Department appealed the rulings.

On August 21, 2015, the U.S. Court of Appeals for the DC Circuit reversed the District Court rulings concluding that the FLSA exemptions were ambiguous and permitted the DOL to establish limiting standards through rulemaking. NAHC and its co-plaintiff sought a stay of the appeal court's ruling with the U.S. Supreme Court. Chief Justice Roberts denied the stay request and the challenged rules went into affect on October 13, 2015.

With the rules going into affect, few states have adjusted Medicaid rates to accommodate new overtime costs. As a result, access to appropriate care scheduling has been compromised as home care employers rely on work hour limitations to avoid overtime. With respect to private pay services, charges have been increased for clients wishing to retain caregivers who provide overtime hours. Otherwise, employers have restricted working hours to limit overtime costs.

RECOMMENDATIONS: The companionship services and live-in domestic services exemptions under wage and hour laws should be restored at the state and federal level until a comprehensive plan can be implemented that addresses service funding, worker health insurance, and career development. The Department of Labor should reverse its rule change that effectively eliminated the application of the companionship services exemption to home care. Alternatively, the Administration and Congress should ensure that govern-funded home care programs adequately reimburse Employers for an added cost of overtime compensation and provide financial protection to consumers of private pay services through tax credits or other subsidies. Finally, the Department of Labor should develop and the Congress should enact reforms to the FLSA that establish a reasonable compensation structure for home care that respects the uniqueness of that employment setting where the patient/client is the primary focus of responsibility. That reformed structure should also properly address the unique aspects of "live-in" care where employees reside in the home of the client, receive room and board, and take on caregiving responsibilities throughout a 24 hour day.

RATIONALE: Most home care providers are small business with limited resources. The companionship exemption result would be to reduce the availability of care to the elderly and the infirm, and to increase the costs of service delivery with no corresponding increase from third-party payers, such as Medicaid. A comprehensive rather than a piecemeal approach to worker compensation and working conditions is necessary if access to high quality of care and continuity of services are to be achieved.

MONITOR EFFORTS TO AUDIT IMPROPER EMPLOYEE CLASSIFICATIONS AS INDEPENDENT CONTRACTORS

ISSUE: The US Department of Labor (DOL) initiated an education, oversight and audit project in 2010 related to the misclassification of employees as independent contractors. Among the employment areas targeted by the DOL is home health care.

A major step was taken in September, 2011, with the signing of a Memorandum of Understanding (MOU) between the DOL and the Internal Revenue Service (IRS). Under this agreement, the agencies will work together and share information to reduce the incidence of misclassification of employees, to help reduce the tax gap, and to improve compliance with federal labor laws.

Additionally, labor commissioners and other agency leaders representing 11 states have signed MOUs with the Department's Wage and Hour Division, and in some cases, with its Employee Benefits Security Administration (EBSA), Occupational Safety and Health Administration (OSHA), Office of Federal Contract Compliance Programs (OFCCP), and the Office of the Solicitor. Colorado, Connecticut, Hawaii, Illinois, Maryland, Massachusetts, Minnesota, Missouri, Montana, Utah and Washington have signed similar agreements. More information is available on the U.S. Department of Labor's misclassification Web page at http://www.dol.gov/misclassification. MOUs are being actively pursued with additional states.

According to the DOL, misclassifying employees as independent contractors results in employees being denied access to benefits and protections such as family and medical leave, overtime compensation, minimum wage pay and unemployment insurance. The DOL further asserts that misclassification can create economic pressure for law-abiding business owners, who often find it difficult to compete with those who are skirting the law.

While most home health agencies employ their caregiving staff or contract entities that employ the staff assigned to the home health agency, there are situations when home care providers treat workers as independent contractors. This approach has been known to exist within home health agencies, particularly with individual therapists.

At the same time, other home care programs that are not home health agencies may classify workers as independent contractors. These include state-run consumer-directed care programs, staffing registries, and individuals themselves. Most often these home care operations involve personal care services.

Whether an individual can be classified as an independent contractor or must be classified as an employee is not a simple determination in home care. Likewise, with the widely varying models of home care delivery, it is not possible to easily conclude that a particular work category is an employee or can be an independent contractor.

Home care employers compliant with DOL standards for worker classification are at a competitive disadvantage with entities that improperly classify individuals as contractors.

RECOMMENDATIONS: The DOL should issue comprehensive standards specific to home care that allow for consistent application of worker classifications. The DOL should recognize the variations in home care programs when proceeding with its education, oversight and auditing efforts. In its guidance, DOL should account for circumstances where the home care worker is not the employer of a home care company, but rather is either an independent contractor or the employee of the home care consumer.

RATIONALE: Employers that misclassify their employees may not be paying the proper overtime compensation, FICA and unemployment insurance taxes, or workers' compensation premiums. According to the DOL, misclassifying employees as independent contractors results in employees being denied access to benefits and protections such as family and medical leave, overtime compensation, minimum wage pay and unemployment insurance. The DOL further asserts that misclassification can create economic pressure for law-abiding business owners, who often find it difficult to compete with those who are skirting the law. Hence, misclassification of workers as independent contractors harms the worker and the employers that comply with classification standards. At the same time, DOL needs to be careful to avoid an overbroad approach to home care worker classification to recognize that certain skilled, professional caregivers can correctly operate as independent contractors.

ENSURE ACCEPABLE STANDARDS FOR CULTURALLY AND LINGUISTICALLY APPROPRIATE HEALTH SERVICES

ISSUE: The Department of Health and Human Services (DHHS) Office of Minority Heath has prepared standards for Culturally and Linguistically Appropriate Health Services. These standards require providers to have a comprehensive management strategy to address culturally and linguistically appropriate services including goals, plans, policies, procedures, and designated staff. Providers must establish a formal mechanism for community and consumer involvement in the design and execution of service delivery, planning, policy making, operations, evaluation, training and treatment planning. In addition, providers must recruit qualified, diverse and culturally competent staff trained to address the needs of the racial and ethnic community they serve and provide all clients with limited English proficiency access to bilingual staff or interpretation services.

RECOMMENDATION:

1. Develop and make available to providers translated materials to inform Medicare and Medicaid beneficiaries of their rights in all languages (e.g. patient rights, advance directives, notice of non-coverage, OASIS data set).
2. Require CMS to produce beneficiary notices, OASIS privacy notices, and other required, federally developed forms in multiple languages.

RATIONALE: Most home health agencies are small businesses and lack the financial resources needed to comply with the proposed standards. The cost of hiring bilingual staff or interpreters is compounded for home care providers because services are delivered in the patient's home. To exclude family and friends from the role of interpreter is counter to the philosophy of home care. Global standards requiring providers of health care services to effectively communicate and recognize cultural issues of their patients already exist.

ENSURE REASONABLE POLICIES FOR PROVIDERS SERVING PERSONS WITH LIMITED ENGLISH SKILLS

ISSUE: On April 15, 2016, the Department of Health and Human Services (HHS) issued a final rule implementing the prohibition of discrimination under Section 1557 of the Affordable Care Act (ACA). Under the rule, covered entities are required to take reasonable steps to provide meaningful access to each individual with limited English proficiency (LEP). In addition, covered entities are encouraged to develop and implement a language access plan.

The final rule requires covered entities to post in a conspicuous location a notice of individual rights related to nondiscrimination with taglines for, at least, the top 15 non-English languages spoken in the State in which the entity is located or does business. The notice may be in English and must contain information that alerts LEP individuals to the availability of language assistance services. Covered entities must also include the notice, along with the taglines, in significant publications targeted at patients such as, patient handbooks or notices pertaining to patient rights. The same notice and taglines must also be in a conspicuous location on the covered entity's Web site accessible from the home page.

To reduce burden and costs for covered entities, the Office of Civil Rights has a sample notice and taglines in over 60 languages.

Last year, CMS proposed to reverse several of the more burdensome LEP requirements. However, until those proposals are finalized providers must continue to comply with the current LEP regulations.

RECOMMEDATIONS: The Office of Civil Rights (OCR) should assist providers in effectively implementing the rule. Rather than take a punitive stance for providers that might be struggling to comply with the extensive requirements outlined in these regulations, the OCR should assess where provider might be need more education or assistance and make those resources available.

RATIONALE: The final rule has extensive requirements for providers servicing individual with limited English proficiency. Many home health providers serve areas that have significant diversity; some can represent hundreds of different languages and dialects. Assuring that all patients have access to a notice of rights will be overwhelming for many agencies that, by definition, are small businesses. Difficulty in adequately complying with provision 1557 of the ACA may be the effect of the magnitude of the requirement rather than failure on the part of the provider.

OPPOSE PUBLIC AUTHORITIES OR OTHER MEASURES THAT RESTRICT CONSUMER CHOICE OF PROVIDER IN THE PROVISION OF LONG TERM CARE SERVICES AND FAIL TO PROTECT WORKERS

ISSUE: California and other states have implemented a state-sponsored public authority system that requires that home care aides providing services under the Medicaid program be employed by the public authority. This arrangement was sought by employee unions to facilitate the organization of home care aides. Consumers in these states are required to obtain home care aide services from the public authority.

Similarly, legislation was introduced in New Jersey to establish such a system for that state, but was rejected. Washington State has established a public authority that permits home care agencies to compete with the public authority, but discourages agency participation in the provision of Medicaid home care services by paying more for services provided by the public authority. There is a growing effort by unions to expand the public authority model of delivering home care aide services and to mandate its adoption in any new federal long-term care program.

The public authority model of care delivery often is promoted as a means to give consumers greater control in caregiver selection and supervision. However, this model does not fit for all the disabled or elderly in need of home care, as it is a model that can deter individuals from seeking care, limit options for continuity of care, and weaken quality of care standards. By providing consumers with a public authority model, choice is limited to the public authority as the provider. The public authority model raises additional concerns related to accountability and quality of services. Some of these programs operate without appropriate standards for client eligibility, service verification, and the employee's entitlement to wages earned. They fail to provide workers with basic protections related to workers compensation, collective bargaining choices, and other rights afforded most other workers. Finally, the programs operate without quality of service standards that are comparable to an agency model of care delivery.

The Patient Protection and Affordable Care Act (ACA), P.L. 111-148, contains numerous improvements in federal Medicaid support for home and community-based care. Fortunately, Congress resisted calls for the expanded use of a public authority model in the expansion of Medicaid home care, and the states have the full authority to devise any suitable delivery model that secures accessible, high quality home care.

RECOMMENDATION: All federal agencies, including the Centers for Medicare & Medicaid Services (CMS), should reject proposals that restrict or discourage home care aides from working for home care agencies or consumers from obtaining home care aide services through agencies, and should require the use of a public authority model of care delivery. In any new or existing long-term care program, the federal government should ensure that consumers have the right to choose to receive home care aide services according to the delivery model that they are most comfortable with. In addition, home care aides should have the opportunity to choose their employer instead of being relegated to a "one-employer" model that can restrict their employment rights.

RATIONALE: Workers are not well served by mandating participation in a public authority,

which is at heart a monopoly composed of a union combined with an employer with the authority of government. There is no compelling evidence that imposing a public authority is the best way to achieve increased wages and benefits for employees; there are other means for attaining this goal.

Under the public authority system, home care aides are stripped of their right to choose their employer and the protection of working under professional supervision. Home care agencies are better equipped than public authorities to provide worker training and oversight of the home care aide. Many agencies also provide career ladders. Home care agencies assume liability for services and can be held accountable, unlike large government-sponsored monopolies.

The quality of care and service accountability concerns have been exposed in the California model, where patients have lost care, workers have received wages for care undelivered, and payments are made on behalf of ineligible clients.

The public authority model either eliminates or makes it difficult for patients to choose to receive home care aide services from an agency, limiting free enterprise and in some cases causing agencies to close their doors. It stifles private sector competition that can lead to improvements in quality and price. A California district attorney recently said their program is so "riddled with fraud it's approaching state-subsidized elder and dependent-adult abuse." A California state analysis for 2003-04 said the council system is so out of control that the state proposed pulling state funding out of the public authority home care system.

Given the myriad problems that have arisen where the public authority model has been tried, it would be particularly inappropriate for the federal government to impose this model on any federal long-term care program. A federal mandate imposing this model on state programs such as Medicaid would run counter to ongoing efforts by the federal government to give the states greater flexibility in how they run their programs.

APPLY REGULATORY RELIEF FAIRLY TO INCLUDE HOME HEALTH AND HOSPICE PROVDERS

ISSUE: The Department of Health & Human Services has an initiative called "Patients over Paperwork" that aims to reduce regulatory burden on providers while increasing efficiencies. CMS has eliminated several burdensome requirements for all provider types but seems biased towards physicians and hospitals when looking for areas to provide regulatory relief. In 2018, CMS requested feedback on unnecessary regulatory burdens including those for home health and hospice agencies that, if eliminated, could increase efficiencies. Suggestions were provided and CMS proposed some reliefs. The hospice industry was surprised that the proposed relief did not appear to be consistent with the stakeholder input regarding the most burdensome and unnecessary regulations. Furthermore, the hospice industry does not find all the regulations that were proposed for revision/removal to be nearly as burdensome as some others, and NAHC found that many hospices would not change their policies and procedures based on CMS' proposed revisions/deletions.

CMS began holding listening sessions in 2018 with home health and hospice providers and key stakeholders.

RECOMMENDATIONS:

1. CMS should consider the scope of impact rather than size of the provider type or volume of beneficiaries served when determining when a regulation is burdensome for providers.
2. CMS should continue its listening sessions and work more directly with providers and key stakeholders in developing proposed regulatory relief and increased efficiencies.

RATIONALE: Although regulatory burdens on large provider types, such as acute care and institutional care providers, garner attention, the need for relief from burdensome requirements also extends to small providers such as home health and hospice. Hospitals are typically seen by the regulators as the driver of health care delivery and therefore are perceived as having a higher need for regulatory relief. However, home health and hospice providers have seen significant regulatory activity leading to increased cost, impediments to operations, and decrease productivity.

VII. HOSPICE

WORK WITH STAKEHOLDERS TO CLARIFY "RELATEDNESS" AND ADDRESS CODING ISSUES UNDER HOSPICE CARE

ISSUE: While analyzing data to reform the hospice payment system, the Centers for Medicare & Medicaid Services (CMS) was concerned to find that nearly 80% of hospice claims it received had only a single diagnosis listed. Over time and in response to CMS' expressed concerns, diagnosis reporting on claims improved such that during FY2018, 100% of claims included more than one diagnosis, 89% of hospice claims contained two or more diagnosis codes, and 81% of claims contained at least three diagnoses. As part of the FY2016 payment rule, CMS clarified that hospices are expected to include all diagnoses (related or unrelated) identified during the initial and comprehensive assessment on the hospice claim. CMS has also indicated that the hospice physician should record in the clinical records which diagnoses are considered related to the terminal condition and which are believed to be unrelated to the terminal or related conditions. For unrelated conditions, it is expected that the clinical rationale for why the diagnosis or condition is considered unrelated will be recorded.

The National Association for Home Care & Hospice and its affiliate, the Hospice Association of America, have provided education to hospices regarding proper coding practices per the ICD-10-CM Official Guidelines for Coding and Reporting and the companion publication, ICD-10-CM Coding Manual. The terms 'comorbid', 'coexisting', 'secondary', and 'related/unrelated' are used by CMS to provide guidance to hospices on which diagnoses should be on the hospice claims. This terminology (i.e. secondary, co-morbid, and co-existing) and other coding vernacular are causing confusion for hospices nationally. Some of the terms come from the outpatient coding guidelines of the ICD-10-CM Coding Manual. Outpatient coding guidelines are not applicable to hospice patients as stated in the Manual. Some others are not recognized in coding guidance.

Beginning October 1, 2014 CMS began returning to provider (RTP) hospice claims that use the diagnosis adult failure to thrive, and other specified diagnoses, as the principle diagnosis. Some of the diagnosis codes listed as prohibited, i.e., adult failure to thrive, are not manifestation codes and according to the ICD-10-CM Coding Manual can be used as principle diagnoses on medical claims when no other diagnosis is identified as the principle diagnosis. At least one of the Medicare Administrative Contractors (MACs) has a current Local Coverage Determination (LCD) for Adult Failure to Thrive. It continues to confuse hospice providers and vendors because it appears as though the Adult Failure to Thrive diagnosis can be used as a principal diagnosis due to the fact that it remains an LCD. The MAC holding this LCD has clarified that the LCDs are not intended to be used as principal diagnosis categories, but instead to be used as conditions supporting a terminal illness. Because of this lack of clarity hospices cannot consistently and properly apply the terms and the coding guidelines. In addition, CMS and the MACs do not use consistent language in the guidance they release. This lack of clarity results in inconsistent interpretation of the coding guidelines leading to inaccurate data on claims that CMS may use to make payment revision decisions.

Of particular concern is the interpretation of 'related/unrelated'. These terms are used in the hospice industry for not only coding but also decisions regarding what medications and treatments are part of the hospice plan of care and paid for by the hospice. In 2013, CMS and its

representatives communicated CMS' view on what is/is not related to a patient's terminal illness and related conditions through the Final Wage Index and to Part D Plan Sponsors through several memos. This view was repeated again in comments in the FY2016 Final Wage Index and subsequent fiscal year wage index comments. Specifically, the following statement CMS made in its comments in 1983 when the Medicare hospice benefit was drafted has been reiterated: It is our general view that ... "hospices are required to provide virtually all the care that is needed by terminally ill patients." This statement and comments by CMS and its representatives has led some to the conclusion that ALL care for terminally ill patients on hospice is the responsibility of the hospice. This has led to significant confusion in the health care sector. We also believe that for hospices, it is not so much the case that they are uncertain of the definitions of terminal condition and related conditions, as each hospice's clinical team makes these determinations on a daily basis; rather, hospices are increasingly concerned that medical determinations related to the hospice's responsibility that are made by their trained clinical teams may not mesh with what CMS, its contractors, or other care providers believe to be related to the terminal condition and any related conditions CMS continues to track and analyze Medicare spending outside of the hospice benefit when a beneficiary is actively enrolled in hospice care. CMS views much of this spending as possibly related to the patient's terminal prognosis and therefore, the payment responsibility of the hospice. CMS specifically commented in the FY2019 Proposed Wage Index that it expects "… it would be unusual and exceptional to see services provided outside of hospice for those individuals who are approaching the end of life

In the FY2020 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Program (FY2020 Hospice Final Rule), CMS finalized plans for hospices to modify their Medicare
Hospice Election Statement and complete a Hospice Election Statement Addendum (Addendum), when requested, beginning FY2021. Hospices will need to identify any items, services, or drugs that are unrelated to the patient's principal diagnosis and any related conditions and communicate the availability of this information to the patient (or their legal representative). Upon request, the hospice will need to provide information about any unrelated items, services or drugs to the patient (or their legal representative) within a certain time frame and include an explanation of why the item, service or drug is unrelated. CMS indicates the reasons for this are greater transparency and to hold hospices accountable. Clear and consistent communication about diagnosis coding and relatedness are necessary in this effort.

RECOMMENDATION: CMS should work with the hospice industry to clarify the terminology applicable to coding for hospice patients. CMS should also work with industry stakeholders such as NAHC and HAA in development of educational tools that help hospices consistently and accurately apply ICD-10-CM coding guidelines.

CMS should collaborate with the hospice and medical fields to help bring greater clarity to the important area of establishing relatedness in end-of-life care. This would result in significant benefit to all involved. NAHC and HAA welcome the opportunity to work with CMS toward resolution on this issue.

RATIONALE: CMS stated in a December 6, 2013 memo "In order for services to be covered under the Medicare hospice benefit, those services must be reasonable and necessary for the

palliation and management of the terminal illness and related conditions. We have not made a regulatory specification of services that are unrelated to hospice care because of the wide variation of individual patient circumstances. These clinical decisions are to be made on a case-by-case basis." This is consistent with the Social Security Act and the approach that CMS has historically applied in its administration and oversight of the hospice benefit. It appears that recent statements by CMS and its representatives are not consistent with this basic premise of the Medicare benefit – that clinical decisions are made on a case-by-case basis by the physician and the hospice interdisciplinary group (IDG). This has caused confusion in hospice and other sectors of healthcare. In addition, lack of consistency across MACs in guidance provided to hospices regarding patient eligibility for the hospice benefit, coupled with inconsistent application of the hospice benefit and hospice financial responsibility, have created confusion and disruption in the hospice industry. CMS collaboration with the hospice and medical fields regarding clarification of terminology and determining "relatedness" will level the inconsistencies and help hospices properly apply the hospice benefit.

In order to determine what is/is not related to the principal hospice diagnosis and related conditions and, therefore, what items, services, and drugs will be covered under the Medicare Hospice
Benefit, the hospice must first determine which diagnoses/conditions are related and which are unrelated to the principal diagnosis. As stated above, this has been a source of inconsistency in the hospice industry as it is a subjective determination. The industry, and ultimately beneficiaries, will benefit from further guidance and clarity from CMS on "relatedness" and further guidance and clarity from CMS to non-hospice providers about how to handle unrelated cases and cases where an item, service, or drug may be related but is not reasonable and necessary.

PROTECT HOSPICE PATIENT ACCESS TO PART D DRUGS FOR CONDITIONS UNRELATED TO THE HOSPICE DIAGNOSES

ISSUE: There is ongoing concern that drugs considered to be a hospice provider's responsibility are being billed to Part D inappropriately. This was identified as a concern in a report by the Office of the Inspector General (OIG) and in investigations by the CMS Office of Program Integrity. As a result, the Medicare Drug Benefit C & D Data Group and the Medicare Program Integrity Group provided direction to all Part D Plan Sponsors to (1) recover from hospices payment for any analgesics paid for by Part D plans in 2011 and 2012 while a beneficiary was enrolled in hospice and (2) develop a prior authorization (PA) process for four classes (antiemetics, analgesics, anxiolytics, and laxatives) of medications requested to be covered by a Part D plan while a beneficiary is receiving hospice services. Hospices continue to receive recoupment requests from Part D plans for medications paid for by Part D plans in current years. There is no opportunity for the hospice to appeal the Part D plan decisions on prior-year recoupments. We believe these actions run counter to current law and regulation that grants hospice beneficiaries coverage outside of the hospice benefit for services and medications that are needed for treatment of conditions unrelated to their terminal condition(s).

Under direction from CMS, some Part D plans use credit and collection companies to request hospices reimburse the plan for specific drugs covered by the plan while a beneficiary was enrolled in hospice. By instructing Part D Plan sponsors to recover from hospices payment for specific medications, it implies that CMS assumes these drugs are related to the hospice prognosis. This is not always the case, nor is it in line with the Medicare Hospice Benefit as under the benefit, coverage for various items and services is determined on a case-by-case basis. Further, in cases where a hospice is not responsible for some of these drugs as they are determined to be unrelated to the terminal prognosis and does not pay the plan, the hospice may be at risk of having its credit score and financial stability adversely impacted.

While institution of the PA process has reduced the level of spending outside of hospice for drugs that fall under the four categories, other Part D spending — specifically for drugs classified by CMS as "maintenance" drugs — has continued to increase. The OIG issued an audit report – Medicare Part D Is Still Paying Millions for Drugs Already Paid for Under the Part A Hospice Benefit (Report No. A-0556-17-08004) – designed to follow up and expand upon the audit conducted in 2012. OIG determined that during 2016, approximately 6.7 million prescription drug events (PDEs) were logged for patients while they were on hospice care, and that a total of $422,693,830 in Part D total costs were expended for those PDEs The OIG then pulled a random stratified sample of 200 PDEs and sought information directly from the hospice provider as to whether or not the drug should have been the financial responsibility of the hospice provider.

The hospice providers indicated that drugs associated with 86 of the 200 PDEs should have been covered by the hospice, and that 108 of the PDEs were for drugs that were not the responsibility of the hospice. In extrapolating the impact, the OIG estimates that PDEs for which the hospices acknowledged responsibility would comprise approximately $160.8 million of the total Part D drug spending for hospice patients during 2016. The hospices identified reasons why the drugs were erroneously submitted to Part D for payment and some included situations where the Part D plan was not aware of the patient's hospice election. NAHC has been part of a collaborative of

the National Council of Prescription Drug Plans (NCPDP) that has identified this essential lack of communication between the hospice and the Part D plan as partly related to the amount of time it takes for the information about the patient's election of hospice care to flow through the CMS system and reach the Part D plan. This process frequently takes days.
Even with the existing PA process, difficulties continue to arise, but these instances have greatly reduced in number since the PA was originally implemented. However, any complications that result in delayed access to medications or conflict over payment could increase the risk that some individuals at end of life may not elect hospice care, which, in turn, may diminish their quality of life and increase Medicare costs.

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RECOMMENDATION: CMS should work with the hospice and Part D industries to enhance education and communications to improve understanding of respective coverage responsibilities and to ease tensions that may arise relative to appropriate responsibility for coverage of prescription medications. Additionally, CMS should develop additional education and oversight practices that hold hospices and Part D plans accountable for proper administration of the Medicare benefits they deliver and active participation in the PA process, while protecting the rights of hospice patients to treatment for conditions that are not related to their care under hospice.

RATIONALE: The wide variation of individual patient conditions and circumstances require that, under hospice, care be based on an individualized plan of care. There are many examples brought to our attention by providers where an analgesic or other medication is reasonable and necessary for pain or symptoms unrelated to the patient's terminal prognosis. It is only through review of the individual patient's plan of care and medical records that clear determination of responsibility can be definitively established and this is clearly the responsibility of the hospice's interdisciplinary group (IDG).

The annual PEPPER (Program for Evaluating Payment Patterns Electronic Report) provides hospices with information on their performance in various "target" areas. The "target" areas are identified by CMS as those that are vulnerable to improper Medicare payment, and the report compares a hospice's performance in each area to the performance of hospices in the state, the Medicare Administrative Contractor (MAC) jurisdiction and the nation. This information helps a hospice identify when its performance is outside the norm for the comparison areas. The 2021 hospice PEPPER will include a new "target" area related to Part D spending outside of the Medicare hospice benefit, Average Number of Part D Claims per Hospice Episode. This is highly anticipated data that is expected to enlighten hospices about Part D claims submitted for the patients they are serving. Other than requests for payment by Part D plans, hospices have not had a way of knowing what Part D claims were submitted for their patients. Armed with this knowledge, hospices may be able to impact claims submitted in error.

Gaps in the electronic transfer of hospice election information to Part D plans contributes to erroneous Part D claims for hospice beneficiaries because it may take days, a week or longer in some cases, for the electronic notification that a beneficiary has elected the MHB to be viewable in CMS systems to the Part D plan.. A pilot program undertaken in 2021 by the NCPDP and CMS may tighten electronic communication and result in reduced Part D spending outside of the hospice benefit.

Active communication such as the PEPPER and pilot programs between CMS, hospice providers and Part
D plans will advance mutual understanding of their respective benefits and promote greater involvement in established processes to eliminate coverage confusion. This will benefit Medicare, providers, plans, pharmacies and, most importantly, patients.

ESTABLISH TIME FRAMES FOR APPROVAL OF HOSPICE MULTIPLE LOCATIONS AND CHANGES

ISSUE: Certification requirements dictate that, in cases where a hospice plans to move from its surveyed, certified location to a new site or open a new location, a hospice must receive approval for the change from the Centers for Medicare & Medicaid Services (CMS) before it is permitted to provide Medicare services from the new address. As part of the process, the hospice must:

1. Submit all required documentation and an amended Form CMS-855A to its Medicare Administrative Contractor (MAC).
2. Notify CMS and its state survey agency in writing of the planned change.
3. If under deemed status, notify its national accrediting organization (AO) in writing.
4. Receive formal approval of the change in writing.

The CMS Regional Office (RO) may grant or deny the address change without a survey, or may determine that a survey is needed to establish that the new address complies with all applicable requirements. The opening of a new office (a "multiple location") requires that the new location be surveyed. CMS is expected to advise the provider of its findings. However, CMS has not specified time frames within which a hospice can count on receipt of a definitive determination on its request for approval of change.

Under separate provider enrollment requirements, a hospice is required to notify CMS of address or other changes through submission of the 855 enrollment form within 90 days of the change.

RECOMMENDATIONS: CMS should establish and enforce reasonable time frames within which state survey agencies, ROs, and MACs must respond to requests for approval of an address change or establishment of a new multiple location. CMS should also consider automatic approval for address changes in cases where a hospice is moving within the same geographical area and has a positive track record relative to its surveys. In cases where surveys are required to facilitate approval of the address change, CMS should establish a clear-cut process that includes access to expedited surveys and is minimally disruptive to the delivery of patient care.

RATIONALE: Different divisions of CMS require varying notifications and approvals of hospice office changes; these requirements are at times inconsistent, creating confusion for providers. CMS failed to consider business practices and the operational and financial burden this policy could impose on providers. Establishment and enforcement of explicit time frames for response by CMS and its agents would help hospice organizations better meet their responsibilities for notice and approval of office changes. Where approval of such changes reasonably requires a survey, CMS should develop an expedited process that ensures delivery of high-quality care that simultaneously supports continuity of care.

ENFORCE REQUIREMENT THAT MEDICAID HOSPICE BENEFITS MIRROR THOSE IN MEDICARE

ISSUE: States are not required to offer hospice services to adult Medicaid beneficiaries, but most states currently have hospice included under their State Medicaid Plan. While states have some flexibility related to the structure of the hospice benefit periods provided under Medicaid, Section 1902(a)(10)(VI) of the Social Security Act requires that Medicaid hospice services must be provided in the same amount, duration and scope as those offered under Medicare fee-for-service. However, as states grapple with increasing budget deficits, some are considering elimination of hospice benefits for adult Medicaid beneficiaries, while others have talked of limiting the hospice benefit to a "lifetime" limit of 210 days, despite numerous studies indicating that hospice services, when used appropriately, result in savings rather than increased health care costs. Some states are participating in demonstration projects and Medicaid expansion projects that move the Medicaid hospice benefit under managed care plans which may allow the amount, duration and scope of hospice services to be different than that offered under Medicare.

When an individual elects the Medicare or Medicaid benefit and resides in a nursing home, the nursing home room and board is covered by the Medicaid nursing home room and board benefit. The hospice bills Medicaid for the room and board and receives at least 95% of the facility's daily Medicaid rate. The hospice then passes this payment on to the nursing home, often having to pay the additional 5% so the nursing home receives 100% of its Medicaid daily rate. Under Medicaid managed care some plans are not paying the hospice anywhere near the 95%. Some are paying at less than 50% of the daily Medicaid rate, placing significant undue hardship on the hospice to pay the nursing home the difference between the Medicaid managed care payment and the facility's daily Medicaid rate. Furthermore, some Medicaid managed care plans are trying to contract with hospices for a bundled payment that includes the room and board payment with the total bundled payment being significantly less than the existing Medicare daily rate for the hospice routine home care level of care. Hospices are pressured into entering into inadequate payment contracts with Medicaid managed care organizations in order to ensure individuals have the option of receiving hospice care.

RECOMMENDATIONS: The Centers for Medicare & Medicaid Services (CMS) should ensure that states comply with the requirement that Medicaid hospice services be provided in the same amount, duration and scope as those offered under Medicare.

RATIONALE: Hospice holds great potential to enhance the lives of individuals with terminal illness and assist loved ones in dealing with the death of a family member or friend; use of hospice services frequently results in health care savings. NAHC believes that this valuable care model should be accessible to all Medicaid enrollees. Efforts to address concerns in hospice care should be directed at ensuring patients receiving services meet eligibility criteria rather than denying access to care.

WORK WITH HOSPICE INDUSTRY TO EVALUATE IMPACT OF HOSPICE PAYMENT REFORM; REJECT REBASING AND SITE-OF-SERVICE ADJUSTMENT FOR NF RESIDENTS

ISSUE: The Medicare Hospice Benefit (MHB) was created in 1982 to care for terminally ill cancer patients. Currently, hospice patients with a cancer diagnosis represent only about 30 percent of those being served by hospices, according to the Medicare Payment Advisory Commission (MedPAC).

Over the years the average length of stay (LoS) has increased to about 80 days, but the more important median LoS remains at about 18 days, according to MedPAC. In 1983, 20 percent of patients received hospice services for seven days; this has increased to about 30 percent. Additionally, 25 percent of hospice patients are on care for five days or less before expiring. The current reimbursement structure was created by estimating the original cost of delivering routine home care (RHC) -- 96 percent of hospice days of care -- by analyzing data collected during the 1980-1982 Medicare Hospice Benefit Demonstration Project.

Despite the changes noted by MedPAC and significant technological, pharmaceutical, and medical care delivery advances over the first 33 years of the hospice program, there had been no associated reimbursement adjustment to reflect the changes. In March 2009 MedPAC recommended that Congress mandate revision of the hospice reimbursement system to better reflect variation in costs over a patient's length of stay and expansion of data collection efforts. The final 2010 health care reform legislation (Public Law 111-148) authorized payment system reforms to be enacted no earlier than October 1, 2013. The Centers for Medicare & Medicaid Services (CMS) expanded collection of data related to visits and costs in 2008, 2010, and then again in April 2014. CMS also significantly revised the hospice cost reporting requirements to gather more detailed information related to hospice costs by level of care. While analyzing data for its payment reform efforts, CMS "floated" a seven-tiered payment system for RHC and also suggested that it may be appropriate to "rebase" hospice payments and reduce reimbursement for RHC provided to patients in nursing facilities.

During 2015, CMS promulgated and finalized reforms to payments for RHC under hospice that sets out two payment rates -- a higher rate for days one through 60 of hospice care and a lower rate for days 61 and over. Despite a break in service, unless a patient is off hospice care for more than 60 days, the "count of days" for purposes of determining the appropriate RHC rate includes previous hospice service days. CMS also created a Service Intensity Add-on (SIA) applicable to in-person RN and Social Worker visits that are provided during the final seven days of life. The SIA is payable at the hourly rate for Continuous Home Care for up to four hours per day. CMS was required to make the payment system changes budget neutral in the first year of application. However, given that provision of RN and Social Worker visits in the payment changes, CMS has indicated that in future years it will apply budget neutrality to account for changes in SIA utilization, but this may be eliminated if utilization of the SIA remains relatively constant over the years.
Public Law 111-148, the final health reform bill, also included a productivity adjustment to the annual market basket inflation update beginning in FY2013 and reduces the market basket index by 0.3 points in FY2013 through 2019, but makes provision to eliminate the market basket cut in

each of FY2014 – 2019 if growth in the health insurance-covered population does not exceed 5 percent in the previous year. The Medicare Access and CHIP Reauthorization Act of 2015 limited the hospice update for FY2018 to 1 percent.

As part of its FY2018 hospice payment rule, CMs published some initial analysis of data received from freestanding hospice providers using the new hospice cost report. CMS noted that this initial data indicates that hospice cots for the RHC level of care are, on average, significantly below payments, while costs incurred for other levels of care generally exceed payment rates. This was also noted in the FY2019 hospice payment rule, and in the FY2020 hospice payment rule CMS rebased the RHC payment rate. This rebasing allowed for an increase in the general inpatient, inpatient respite care and continuous home care level of care payment rates more closely aligning with the costs of providing these levels of care. The rebasing of rates applies to all patients regardless of the site of service.

RECOMMENDATION: CMS should closely monitor the impact of payment reform changes on access and quality of hospice care, and include NAHC and the hospice industry in discussions of advisable future reforms for the hospice payment system. CMS should resist efforts to overstep its charge to refine the hospice payment system by including changes like rebasing of RHC or reduced payments for care provided to NF residents that could go far beyond the payment refinement sought by the health reform bill and threaten future access to the full hospice benefit as it was conceived.

RATIONALE: To effectively revise the hospice payment system for all four levels of care, CMS must have an accurate and rich data set that reflects the full scope of services currently provided by hospices. To address these gaps, CMS initiated changes in the hospice cost report for all hospices and, additional data on hospice claims it believes can be used in hospice payment revision decisions. However, concerns remain that these expanded data collections may not provide a full and accurate depiction of true hospice costs, which could lead to inaccurate payment revision decisions.

Introduction of a payment approach to better synchronize the payment system with actual costs is appropriate, and the first steps toward this end were implemented in January 2016 and additional steps taken in FY2020.. These reforms will change incentives in the hospice payment system and, as a result, patterns of enrollment and care, and may be all that is needed to address inappropriate incentives in the current system. CMS must address payment reform in a measured and deliberate manner so as not to jeopardize access to care.

PROVIDE FULL DISCLOSURE OF HOSPICE AVAILABILITY AND CHOICE OF PROVIDER TO TERMINALLY ILL BENEFICIARIES RESIDING IN SNFs/NFs

ISSUE: In 1989, Public Law 101-239 mandated the ability of terminally ill Medicare beneficiaries residing in skilled nursing facilities/nursing facilities (SNF/NFs) and intermediate care facilities for individuals with intellectual disabilities (ICF/IID) to access services under the Medicare hospice benefit (MHB). As SNF/NF and ICF/IID residents become aware of the MHB, more of them are seeking hospice services. However, the SNF/NF and ICF/IID is not required to offer hospice services, nor is it required to disclose at admission if residents will be able to access hospice services without the need to transfer to another facility. Further, if the facility does have an arrangement to provide hospice, it is not required to disclose the hospice program with which it has a contract to provide services to residents. Finally, a resident does not have the right to choose the hospice program that he/she will receive hospice services from in the facility. In 2012, CMS released revised SNF/NF and ICF/IID Medicare conditions of participation interpretive guidelines related to end-of-life care; however, these are interpretive guidelines rather than requirements and they do not specifically address notifying SNF/NF and ICF/IID residents upon admission whether or not hospice services are available at the facility. In 2016, CMS released new conditions of participation for SNF/NFs and ICF/IID that also did not address notification to residents about hospice services in the facility. CMS interprets, in the most current version Appendix PP of the
State Operations Manual dated 11-22-2017, that SNF/NFs and ICF/IID should tell the resident which hospices, if any, can provide care in the facility at the time the resident is admitted; however, this remains only part of the interpretive guideline and not specifically required in the conditions of participation, but the guidance does not specify that this should occur not only at the time of admission but, again, at the time the resident is determined to be at the end of life. This guidance does not include disclosure of any financial relationships that may exist between the SNF/NFs and ICD/IID and the hospice(s).

RECOMMENDATIONS: CMS should require that SNF/NFs and ICF/IID disclose upon admission, and at the time residents are determined to be nearing the end of life, whether or not hospice services are available at the facility, and the name(s) of all the hospice(s) with which the facility has contracted to provide hospice services on site. CMS should also require that SNF/NFs and ICF/IID disclose upon admission, and at the time residents are determined to nearing the end of life, common ownership and any financial relationship between the contracted hospice(s) and the SNF/NF to the resident. Additionally, CMS should mandate that eligible Medicare beneficiaries residing in SNF/NFs and ICF/IID have the right to receive hospice services from the Medicare-certified hospice of their choice.

RATIONALE: SNF/NFs and ICF/IID should provide full disclosure regarding the availability of hospice services and the relationship between the hospice and the facility at admission and again as the resident approaches end-of-life so that potential residents are fully aware of whether or not they will be able to access hospice services at some time during their stay if needed and residents
would be reminded of all end-of-life resources available to them as they enter this stage of life. Such disclosure could help to avoid the significant upheaval and trauma that could result from a

resident's transfer to a different facility in order to exercise his/her right to the hospice benefit. Potential residents should also be notified regarding the names of the program(s) through which hospice services would be provided if they elect the hospice benefit while in residence at the facility. Finally, Medicare beneficiaries eligible for the hospice benefit should have the right to choose which hospice will serve them. Currently, a terminally ill SNF/NF and ICF/IID resident may only access the Medicare hospice benefit if the SNF/NF and ICF/IID has a formal arrangement with a hospice program to provide services in the facility.

REVISE FACE-TO-FACE REQUIREMENTS FOR HOSPICES

ISSUE: Section 3132(b) of the Affordable Care Act of 2010 requires a hospice physician or nurse practitioner (NP) to have a face-to-face encounter with every hospice patient prior to the patient's 180th-day recertification, and each subsequent recertification.

In the Home Health Prospective Payment System Rate Update for Calendar Year (CY) 2011, the Centers for Medicare & Medicaid Services (CMS) finalized its implementation approach for this hospice provision. The final rule, codified at 42 C.F.R. 418.22(a)(4) (75 Fed. Reg. 70463, November 17, 2010) states that the encounter must occur no more than 30 calendar days prior to the start of the hospice patient's third benefit period. The regulation requires that the hospice physician or nurse practitioner attest that the encounter occurred, and the recertifying physician must include a narrative that describes how the clinical findings of the encounter support the patient's terminal prognosis of six months or less. Both the narrative and the attestation must be part of, or an addendum to, the recertification. In 2011, CMS allowed hospices to delay the face-to-face encounter up to two days after a patient's hospice election under certain documented exceptional circumstances.

A number of concerns have arisen relative to the hospice face-to-face requirement:

- Hospices must complete the face-to-face encounter prior to the beginning of the applicable benefit period and the encounter must be arranged by the hospice. As the result, a patient's care may be delayed while the hospice identifies a physician or NP available and schedules the encounter. For many hospices, those in rural areas in particular, this delay can be much longer than two days. This is because these areas do not have access to physicians and NPs that meet the employment/contract requirements of CMS. However, these hospices may have access to physician's assistants and other non-physician practitioners. Even though the Bipartisan Budget Act (the Act) of 2018 revised the Social Security Act (SSA), and thereby the criteria of the Medicare Hospice Benefit, to allow physician's assistants to be chosen by hospice patients as their attending physician for hospice care, the Act did not modify the SSA to allow a PA to complete a face-to-face encounter.
- The face-to-face requirement is applicable to a patient's full time on hospice regardless of when the previous hospice service was provided. A patient may have been off hospice service for a lengthy period of time, then begin rapid deterioration and need admission very quickly. In such cases, the face-to-face requirement may not only delay admission but forces the patient to unnecessarily be subjected to an assessment.
- Centers for Medicare & Medicaid Services (CMS) data systems are not all available 24 hours, seven days a week, to access patient information and frequently do not have up-to-date information related to a patient's history on hospice care to allow a hospice to establish with absolute certainty whether a face-to-face encounter is required. CMS has clarified that if the data systems are not available, and because of this the hospice is not aware that the patient is entering his/her third or subsequent benefit period, the hospice has two days in which to obtain this information and complete the face-to-face. This two-day time period is insufficient time for the hospice to get the face-to-face scheduled as the two days, in essence, could be only one working day. For instance, those patients admitted on a Friday or holiday when the CMS data systems are not available don't have

access to the CMS data systems until the next business day, which could be Monday, or in the case of some holidays, Tuesday. The hospice accesses the data system the morning of the next CMS business day, sees that the patient is in his/her third or subsequent benefit period, and then has to get a hospice physician or NP to conduct the face-to-face. Getting the face-to-face scheduled can, as mentioned above, take several days, especially in rural areas.

- There are situations where CMS data systems do not display a beneficiary's previous service on hospice due to the fact that the previous hospice provider has not timely filed its Notice of Election (NOE), Notice of Termination/Revocation (NOTR), or claims. In such situations, the current hospice provider is not able to tell that a face-to-face encounter is required and often does not know this until after the two-day exceptional circumstance period has passed. These hospices are technically not permitted to bill Medicare for those days of service, which could mean a significant financial loss. Through no fault of its own and completely out of its control, the current hospice cannot get paid for care it has provided in good faith to the patient.
- Hospices will not be reimbursed for costs related to the face-to-face requirements, which may be prohibitive – particularly for small hospices in rural areas.
- Hospices may not utilize telehealth services to meet the face-to-face requirement.
- If a patient is on continuing hospice care but the hospice is not able, due to not being able to quickly access a physician or NP meeting the CMS requirements or other complications, to conduct the face-to-face prior to the benefit period for which the encounter is required, the hospice will not be paid for services provided until the face-to-face has been completed.

RECOMMENDATIONS: CMS should work with the hospice industry to ensure that regulations and guidance governing the hospice face-to-face provide sufficient flexibility that hospice programs are able to comply with the requirements without any threat of delayed access to care for beneficiaries in need of hospice services, and without undue financial burden on the hospice.

RATIONALE: The intent of the face-to-face requirement is to ensure adequate and appropriate involvement and accountability of physicians relative to certification of eligibility for hospice care. However, as currently written and interpreted by CMS, it may delay access to care and serve as a deterrent for some hospices to take eligible patients in need of immediate care onto service. This was neither its intent nor an advisable result of the requirement.

ADDRESS PAYMENT DELAYS AND INCREASED REGULATORY BURDENS CAUSED BY SEQUENTIAL BILLING POLICY FOR HOSPICE

ISSUE: The Centers for Medicare and Medicaid Services (CMS) implemented the longstanding hospital sequential billing policy on hospice claims. The policy prohibits providers from submitting claims for care to beneficiaries where previously submitted claims are pending. Claims processing can be delayed for weeks or months for many reasons, including medical review activities, common working file problems, CMS or Medicare Administrative Contractor (MAC) claims processing problems and pending claims from other providers, etc. Hospices have continued to serve patients even though Medicare payments have been delayed. CMS requires that hospices only submit one bill per beneficiary per month.

Imposition of the five-day timely filing requirement for Notices of Election (NOEs) and Notices of Termination/Revocation (NOTR) have added to the issues that hospices face relative to sequential billing.

RECOMMENDATION: Require hospices to submit claims in chronological order but process and pay all clean claims as submitted, regardless of whether previous claims have been processed.

RATIONALE: Most hospice programs are small businesses with little financial reserve, dependent on uninterrupted payment for services delivered. The type of patient for whom the number of lines on the claim is expected to be high is the patient who receives a significant number of medications with frequent doses and frequent visits by hospice team members. This is typically the hospice patient requiring higher levels of care such as the general inpatient level of care or continuous care. These are usually the more expensive levels of care for hospices to provide. Interruption of payment and slow down of payment for weeks or months, while requiring agencies to continue services to patients, can result in severe financial hardships.

ENCOURAGE ACCOUNTABILITY FOR HOSPICE UTILIZATION

ISSUE: Without outcomes linked to hospice utilization data, it is impossible to determine the appropriate utilization in terms of length of stay and level of care. It should be recognized that there is probably some under- and over-utilization of services. CMS collected hospice visits and charge data as a first step in creating a database on hospice services provided. This was expanded in 2017 to include more detailed hospice visit data for patients in the final days of life via the addition of the Visits When Death is Imminent measure in the Hospice Item Set (HIS) Due to the rapid growth in hospice expenditures, the hospice medical director and the attending physician's authorization for hospice services are being questioned by Medicare's contractors, and payments are being withheld based on Medicare's contractors' determinations of prognosis.

RECOMMENDATIONS:

- CMS should work with NAHC and the hospice industry to analyze hospice utilization data and identify problem areas.
- For identified problem areas, develop uniform protocols of care based on outcomes against which utilization can be measured. These should not be used as the basis for automatic denials, but to indicate the need for justifying hospice services.
- Direct equal attention toward under-utilization as well as over-utilization.
- Require Medicare's contractors to offer training at least twice a year, open to all providers who wish to attend.

RATIONALE: Variation in utilization points not so much to abuse as much as it does to physician concerns about giving a prognosis of six months or less for terminally ill patients and the differences in health care practices. Development of uniform protocols and the education of providers are the keys to compliance with eligibility criteria and the control of inappropriate utilization.

PROMOTE NATIONWIDE CONSISTENCY OF LCDs THAT REFLECTS CURRENT HOSPICE CODING AND DIAGNOSIS REQUIREMENTS

ISSUE: The current hospice local coverage decisions (LCD) promulgated by CMS (Guidelines) limit the policies to a set of medical variables and clinical signs and symptoms that are used to predict a prognosis of six months or less for terminally ill Medicare beneficiaries. Not all claims reviewers using the LCDs are given instructions or guidance to take into account the physician's clinical judgment or the psychosocial dimensions of the illness for determination of coverage decisions.

The multiple Medicare Administrative Contractors (MACs) for hospices do not have consistent requirements and guidance on hospice eligibility and how the diagnosis(es) are to be identified on the hospice claim. Specifically, the terms "comorbid," "coexisting," "secondary," and "related/unrelated" are not defined, so hospices are unable to consistently apply them. There is also some question regarding the degree to which inpatient coding guidelines take hospice care into consideration. This increases the likelihood that data received by CMS and upon which payment decisions are made is inaccurate.

RECOMMENDATIONS: CMS should perform annual reviews of all LCDs and revise the policies based on available research, industry input, and other pertinent findings relevant to the determination of a prognosis of six months or less. Additional steps that should be taken relative to LCDs include the following:

- Add the following criteria to LCDs to provide additional guidance to medical reviewers in determining the appropriateness of hospice admissions or re-certifications:
    - Encourage the use of multiple LCDs or one general LCD to document co-morbidities so that all conditions, and not just the primary diagnosis, are being reviewed.
    - Require review of documentation of the clinical judgment and psychosocial dimensions of the terminal illness by medical reviewers.
    - Require documentation by the reviewer of the date of patient's death, as appropriate, while enrolled in the hospice benefit or after discharge from hospice care if that death occurs within six months of the discharge.
- CMS should conduct research to validate the accuracy of the LCDs, including an analysis of their specificity and sensitivity.
- Publish future hospice medical review policies in the *Federal Register* for public review and comment, or allow broad dissemination of proposed policies through national and state associations representing the hospice industry, so that comments can be compiled and recommendations returned to CMS.
- Require that when making Medicare claims determinations, greater weight be given to the opinion of the treating physician.
- Require review or additional documentation prior to issuing denials.

CMS requires that all diagnoses be included on hospice claims. In order to obtain accurate and consistent data, CMS should determine in collaboration with industry experts what coding

guidelines are applicable to hospice and clearly define the terms associated with those guidelines (i.e. comorbid or related/unrelated).

RATIONALE: CMS annual reviews of the policies are needed in order to keep them informed and up-to-date. Criteria for determining a prognosis of six months or less (eligibility for hospice services) is not a matter to be decided at the local level, but rather by a set of scientifically determined variables, signs, and symptoms for discrete diagnoses based on research and clinical judgment. With the broad dissemination of proposed policies, either in the *Federal Register* or through national or state associations, the resulting LCDs will better reflect the current state of the art of prognostication and best practices in determining a life expectancy of six months or less for Medicare beneficiaries.

COMPENSATE PHYSICIANS FOR HOSPICE CERTIFICATIONS

ISSUE: One of the primary requirements for Medicare beneficiaries to access the Medicare hospice benefit is certification by the patient's attending physician and the hospice medical director that the patient has a limited life expectancy of six months or less if the disease runs its normal course. The length of stay for many beneficiaries on the Medicare Hospice Benefit (MHB) is still too short. The number of short lengths of stay for hospice patients is increasing which means some Medicare beneficiaries are not afforded the opportunity to take advantage of all of the end-of-life care available to them and that could potentially decrease Medicare outlays. At the request of Congress, the Government Accountability Office (GAO) conducted a study on the MHB that was released in 2000. Another report was issued in December, 2007: "End-of-Life Care: Key Components Provided by Programs in Four States." The reports concluded that the most significant influence on patient use of hospice is the physician. "Physicians initiate most referrals to hospice, and they may continue to care for their patients after enrollment as part of the hospice team. Because patients and their families rely heavily on physician recommendations for treatment, including recommendations for end-of-life care, physicians are an influential factor in a patient's entry into hospice." Medicare Payment Advisory Commission (MedPAC) data shows that the median length of stay remains consistent over recent years -- at about 18 days -- which is far too short to be of the greatest benefit.

The original health reform legislation approved by the House of Representatives (H.R. 3962) provided for payment to physicians and other health care professionals to provide a voluntary advance care planning consultation (Section 1233); it also contained a provision regarding the dissemination of advance care planning information (Section 240).

NAHC applauds CMS' activation of HCPCS codes GO179 and GO180 for physician certification and recertification of Medicare-covered home health services. The codes help home health agencies secure greater physicians involvement in home health care. Similar codes were developed for advance care planning in 2014; CMS associated payment with those codes beginning January 1, 2016.

RECOMMENDATIONS: CMS should create, recognize and provide payment for a new HCPCS code to compensate physicians for patient certification of eligibility for the MHB.

RATIONALE: In the past, CMS has expressed concern about the decreasing length of stay on the Medicare hospice benefit, and asked how they can help alleviate the problem. It is imperative to get physicians to focus on end-of-life care much earlier than is now occurring. Although the Medical Director of a Medicare-certified hospice is covered under Part A as an employee of the hospice, the patient's attending physician continues to bill under Part B for care plan oversight and direct patient services. At a time when the length of stay on the MHB is still too short for many hospice patients, it is important to encourage physicians to refer patients sooner by encouraging their efforts to educate patients on the availability of hospice care, and compensating them for hospice certification. Increasing the hospice length of stay for short-stay patients would allow the patient and their families to get the full benefit of holistic hospice services and save Medicare dollars by keeping patients at home rather than in traditional aggressive institutional care.

PROCEED WITH A THOUGHTFUL AND DELIBERATE EXPANSION OF THE HOSPICE QUALITY REPORTING PROGRAM

ISSUE: The June, 2008, hospice conditions of participation require hospices to develop, implement, maintain, and evaluate an effective, data-driven quality assessment and performance improvement program. The Centers for Medicare & Medicaid Services (CMS) requires hospices to either develop their own or use currently available systems of measures to track patient outcomes as well as optimum functioning at every level of a hospice's operations. The requirement includes retaining the information in a database that permits analysis over time.

The final 2010 health care reform legislation provided a strong start toward the development and implementation of a quality reporting program, by (a) mandating that the Department of Health and Human Services (HHS) publish hospice quality measures covering all dimensions of hospice quality and care efficiency by October 1, 2012, and (b) requiring that hospices begin reporting these measures. Failure to submit quality measures by a hospice would result in a two-point reduction in the annual market basket index update beginning with FY 2014 (Section 3004).

CMS initiated a voluntary quality measure collection and reporting program in late 2011 and early 2012; mandatory quality measure data collection began October through December 2012, with mandatory data reporting beginning in January and April of 2013. Starting January 2013 hospices were required to collect and report the first full year of data. In July 2014, the Hospice Quality Reporting Program (HQRP) entered a new phase with the requirement that hospices collect and submit data for a patient-specific Hospice Item Set (HIS). Subsequently, beginning in January 2015, hospices had to contract with an outside vendor to collect responses to a hospice experience of care survey. Failure to report data results in a 2 percent payment reduction. This reduction will increase to 4% in 2022 per the Consolidated Appropriations Act of 2020. CMS began public reporting of some hospice quality data on the Hospice Compare site in 2017. The contents of this site were incorporated into Care Compare in 2020.

CMS is developing a comprehensive standardized patient assessment instrument, HOPE (Hospice Outcomes and Patient Evaluation) The HOPE is intended to replace the HIS and will be used for future hospice quality initiatives and may be used for future payment reform in hospice and indicated that this instrument may be used for future hospice quality initiatives and payment reform. CMS ultimately plans to develop a hospice star rating program, as well.

RECOMMENDATIONS: CMS should advance the HQRP through work with the hospice industry to select additional appropriate measures for reporting and establish a reasonable time frame for incorporating new measures. CMS should ensure that the quality measures currently under development for hospice incorporate:

- Reliable and valid indicators.
- Outcome measures limited to those that most accurately predict quality.
- A method for risk adjustment.
- A simple system with clinical utility.
- A mechanism enabling CMS to validate agency data.
- An ongoing evaluation of the entire system.
- A broad range of stakeholders in development of the assessment instrument and the star

- rating program.

RATIONALE: The ideal hospice quality assessment program must be based on what happens to the patients. In addition, research and demonstration projects are not factored into the current per diem reimbursement structure. The proposed quality system will require massive data collection and reporting unless purposely controlled. Every effort must be made to keep data collection and the paperwork burdens to a minimum so resources can be used for patient care rather than paperwork The HQRP must not comingle program integrity measures with quality measures. Consumers are the ultimate users of the HQRP to help inform decisions on hospice care and consumers do not have the contextual understanding to recognize and interpret measure results that are more of an indicator program integrity behavior than quality of care provision.

REINSTATE PRESUMPTIVE STATUS FOR HOSPICE WAIVER OF LIABILITY

ISSUE: Section 1879 of the Social Security Act provides protection from liability for charges for certain denied claims to beneficiaries who, acting in good faith, receive inpatient or outpatient services from Medicare providers. Similarly, providers may also be protected from liability under Section 1879 of the Act when it is determined that they did not know and could not reasonably have been expected to know that Medicare would deny payment. The waiver of liability is applicable to hospice claims denied on the basis of the "not reasonable and necessary" and "custodial care" exclusions. The presumptive status of the waiver of liability, which expired at the end of 1995, protected hospices by allowing them to be compensated under the waiver presumption when their overall denial of claims rate was less than 2.5% of Medicare services provided. Any agency that exceeded this 2.5% denial rate was not reimbursed under waiver. This requirement forced agencies to use due diligence in determining eligibility and coverage, but also protected them from financial loss for care that was provided in good faith.

Subsequent to the expiration of the presumptive status of waiver, Section 1879(g) of the Social Security Act was amended by Section 4447 of the Balanced Budget Act of 1997 to extend limitation on liability protection to a beneficiary enrolled in a hospice when there is a denial of claims due to a determination that the individual is not terminally ill. This took effect for services furnished on or after August 5, 1997. The MAC is to apply the usual procedures (not presumptive status) of the limitation on liability provision contained in the Medicare manual, and the indemnification procedures to determine whether or not the beneficiary is protected from liability and whether the hospice is protected from liability under Section 1879(g)(2) of the Act.

RECOMMENDATIONS: The Centers for Medicare & Medicaid Services (CMS) should reinstate waiver presumption for providers of the Medicare hospice benefit.

RATIONALE: The waiver presumption acts to protect providers who render services to Medicare beneficiaries in good faith, believing that they will be covered. The cushion for error is crucial in the Medicare hospice benefit due to the physician's inherent difficulty in determining that a patient will likely die within six months if the disease runs its normal course. This is particularly true for non-cancer diagnoses. Claims are susceptible to vagaries of interpretation by the MAC. Certifying terminal illness is an inexact science and extremely difficult for the physician, patient and family. A MAC determination that a patient is not terminally ill is also devastating.

STUDY HOSPICE REIMBURSEMENT FOR DUALLY ELIGIBLE PATIENTS RESIDING IN NURSING FACILITIES

ISSUE: Since 1986, terminally ill Medicare patients living in nursing homes could elect the Medicare hospice benefit (P.L. 99-272, Sec. 9505(a)(2). When a patient is entitled to both Medicare and Medicaid, the state Medicaid program must pay the hospice at least 95 percent of the nursing home charge for room and board services. The hospice then reimburses the nursing home for room and board: personal care, assistance with activities of daily living, administration of medications, socialization activities, maintenance of a resident's room, supervision and assistance in the use of home medical equipment and prescribed therapies.

The contractual relationship between hospice programs and nursing homes has been under scrutiny by the Department of Health and Human Services Office of the Inspector General (OIG). In its report "Hospice Patients in Nursing Homes," the OIG made recommendations to reduce the Medicare or Medicaid payments for hospice patients living in nursing homes. MedPAC is also focused on hospices that have many of their patients in nursing homes, and believes that these hospices may be taking advantage of a situation that is less resource intensive, thereby increasing their financial margins. MedPAC and the Centers for Medicare & Medicaid Services (CMS) have both indicated an adjustment in payments for hospice patients in NFs of between 3 and 5 percent may be appropriate.

Furthermore, many states are moving their Medicaid hospice benefits to Medicaid managed care plans. Absent state rule otherwise, payment mechanism/level is at the discretion of the managed care organization. This may have the unintended consequence of limiting access to hospice care for beneficiaries as hospices in some states are reporting that the payment mechanism/level of payment is so poor that it prevents the hospice from being able to deliver services to these beneficiaries.

Finally, some states impose "provider taxes" that help provide additional revenue to cover the costs of Medicaid services and increases in payment rates. In some states, hospices are being "taxed" on nursing home room and board payments but these payments do not accrue to the hospices -- instead they are being paid directly to the nursing facilities.

RECOMMENDATIONS: The Centers for Medicare & Medicaid Services (CMS) should not reduce payment to the hospice for patients residing in nursing homes unless data collected and analyzed unequivocally demonstrates duplicate payment for dually eligible patients residing in nursing facilities. Further, a thorough examination of the advisability of current CMS policy requiring that state Medicaid programs reimburse the hospice for the combined cost of nursing home and hospice (and that hospices then convey payment to the nursing home) may be in order at this time.

RATIONALE: If this action is taken without further data gathering and analysis of the nature and cost of hospice care provided in the nursing home, it could result in the complete lack of, or diminished access to, appropriate hospice services for these individuals. Changes to the hospice reimbursement and nursing home room and board reimbursement prior to an in-depth study (including analysis of the services provided and the cost of those services) will, in effect, deny

access to a humane and compassionate approach to care for eligible terminally ill residents of nursing homes. Any adjustments to Medicare or Medicaid payments should be made only after performing appropriate data collection and analysis.

EXPAND THE USE OF AND REIMBURSEMENT FOR TECHNOLOGIES IN HOSPICE

ISSUE: Hospice care is for terminally ill patients who are expected to live six months or less if their disease takes its normal course. This care is typically provided in the patient's home by a hospice interdisciplinary team (IDT), frequently with involvement of family caregivers or friends.
The IDT usually includes a physician, nurse, aide, social worker, and chaplain. Thus, hospice care
is a very personal, intimate service that is tailored to the specific needs of the patient and family members. While some hospices have developed sophisticated programs that utilize advanced technologies for clinical consultation, development of online support groups, and better communication with patients and their families, many hospices lack the financial capital to invest in technologies that could lead to better care management and enhanced patient satisfaction.

Family caregivers are responsible for giving medication to the patient, and they often have questions about patient care. The use of information technology would allow family caregivers to communicate changes and concerns, or to get advice from their hospice provider about specific care needs. For example, one study found that caregivers' concerns about giving pain medication decreased when they were able to join team meetings via video conferencing technologies. Family
caregivers and hospice staff reported improvements in communication and decision-making as a direct result of using the technology.

The COVID-19 pandemic has caused hospices to become more creative in assessing patient's and caregiver's needs, delivering interventions and performing subsequent follow-up via telehealth/telecommunications which include audio and visual communications as well as audio-only communications. The pandemic resulted in hospices not being able to perform face to face visits with many patients residing in facilities as facilities often had to limit the number of individuals coming into the facility. In addition, hospices needed to limit the number of face to face visits with patients residing in their own homes to reduce the risk of infection for patients/caregivers and staff. This spurred hospices to utilize technologies that were not widely employed prior to the pandemic. While this was not the ideal delivery method of care, it turned out to be more effective than expected. Data on the long term impact of the use of these technologies will be conducted with CMS encouraging more technological innovation in the interim.

RECOMMENDATIONS: The Administration should recognize the potential for improvements in communication, decision-making and care coordination by hospices as a means to provide higher quality care to hospice patients and support of family caregivers. Therefore, demonstration programs, grants, and other forms of reimbursement for tele-hospice and advance communication technologies in hospice should be tested along with new models of health care delivery to improve the delivery of hospice care in the home.

RATIONALE: Hospice care has a long standing tradition of providing care through coordinated teams of health care providers and family caregivers. Therefore, improvements in the communication, coordination and interaction among these caregivers will enable more timely and improved patient care, as well as allow for more efficient use of community services through

engaging family caregivers and patients in the delivery of hospice care.

OPPOSE EFFORTS TO REQUIRE PHYSICIAN CERTIFICATION FORMS TO INCLUDE A FALSE CLAIMS WARNING

ISSUE: The Department of Health and Human Services Office of Inspector General (OIG) issued its final report on hospice audits under Operation Restore Trust (ORT). The report, "Enhanced Controls Needed to Assure Validity of Medicare Hospice Enrollments," recommended, among other things, to make "hospice physicians more accountable for their certifications of terminal prognosis by requiring that the certification/recertification forms signed by these physicians contain a statement concerning the penalties for false claims." In its response, CMS stated, "Although CMS concurred with the intent of the recommendation, it did not agree with a warning statement. Instead, it indicated that a more affirmative flavor to the wording of the hospice certification would achieve the desired results."

RECOMMENDATIONS: CMS should continue to refrain from including a warning statement concerning penalties for false claims on physician certification and recertification forms for terminal prognosis. In its stead, CMS should develop educational information about the requirement of a six-month prognosis and make resources available to determine a prognosis. Additionally, CMS should encourage the use of interdisciplinary clinical judgment and appropriate documentation.

RATIONALE: The Conditions of Participation (CoPs) require that the hospice obtain written certification of terminal illness for each of the benefit periods. The hospice medical director or physician member of the hospice interdisciplinary group and the patient's attending physician, if the patient has one, must sign the initial certification; the hospice physician is then required to sign subsequent re-certifications. The certification must specify that the patient has a prognosis of six months or less if the terminal illness runs its normal course. Additional language addressing the validity of the six-month prognosis would be redundant, unnecessary, and potentially harmful in limiting access to patients who would otherwise be eligible for hospice services.

The science of prognostication is in its infancy and physicians must use whatever tools are available, including medical guidelines developed by the industry, local coverage decisions developed by the MACs, and their own best clinical judgment. Physicians tend to be cautious about certifying terminally ill patients for hospice care; the median length of stay has remained relatively constant and is currently 18 days. Placing a warning or other statement on the certification of terminal illness could further deter physicians from enrolling appropriate patients, thus denying access to this compassionate, humane, patient-and family-centered care at the end of their lives.

CREATE WAIVER FOR EXCEPTION TO SOCIAL WORK SUPERVISION REQUIREMENT

ISSUE: The 2008 revisions to the Hospice Conditions of Participation (CoPs) require that, effective December 2, 2008, a hospice social worker either have a master's degree in social work (MSW) or be supervised by an individual with a MSW unless hired prior to December 2, 2008. Many hospices struggle to find and retain qualified social workers, as defined in the Medicare CoPs. Specifically, the number of social workers with MSW degrees meeting the requirements is extraordinarily limited in some pockets of the nation and especially in rural areas.

There currently are hospices that have a vacancy for the required MSW supervisory position and have been looking to fill the vacancy for a significant number of months, or even a year or longer. The extensive distance between the rural hospice provider and its closest urban area is too great for the hospice to find an MSW-level social worker in the urban area who is willing to work with the hospice. In fact, hospices in urban areas are reporting difficulties in hiring and retaining masters-level social workers, as well.

RECOMMENDATION: CMS should create a waiver program under which hospices experiencing hardship in employing a MSW-level social worker may obtain an exception to the social work supervisory requirement.

RATIONALE: Most hospices across the nation serve fewer than 100 patients per day and many of these hospices are located in rural areas where they do not have access to qualified MSW-prepared social workers. While the majority of social workers nationally have a MSW degree, many states do not require this level of education in order to obtain a state social worker license. Therefore, such states tend to have an extremely limited supply of MSWs available to the hospices. The hospice social work supervision requirement in the Medicare hospice CoPs exceeds the standard most state licensure laws impose. The CoPs allow waivers of the requirement that all nursing services be provided directly and waiver of the requirement that physical therapy, occupational therapy, and speech-language pathology be provided by a hospice. The reasons for these waivers are the same reason a waiver of the MSW supervision requirement should be implemented – a shortage of qualified professionals.

ENSURE APPROPRIATE DEVELOPMENT OF PERFORMANCE-BASED PAYMENT FOR MEDICARE HOSPICE SERVICES

ISSUE: The latest advance in health care payment policy revolves around tying providers' health care payments to the quality or effectiveness of care they provide, based on patient-related outcomes. Value-based or "Pay for performance" (P4P) systems acknowledge financial remuneration as one of the strongest incentives available; they can be designed to reward providers based on use of certain processes of care, outcomes of care, or patient satisfaction. Incentives to provide high quality health care can be crafted in a variety of ways – for example, payers could impose a "withhold" of a certain amount on each payment until such time as performance can be assessed and the payer determines which providers will receive the incentive payments based on their performance. P4P can also take the form of a penalty for not reaching a required level of performance. P4P has been used in the private sector for some time and has more recently gained the attention of federal policymakers.

As part of the Affordable Care Act, Congress included several provisions that advanced development and implementation of value-based purchasing programs for a variety of provider types under Medicare, including hospice. Relative to hospice, under section 10326 of the Health Care and Education Reconciliation Act of 2010, Congress requires that no later than Jan. 1, 2016, the Secretary of Health and Human Services must establish a pilot program to test value-based purchasing under hospice care, but to date this pilot has not been implemented.

There are several key considerations in development of any value-based performance program, including determination of what measures should be used, what scoring rules will be applied to those measures, the size of the incentive pool, whether the incentive payments are derived from a payment "withholds" or some other source, and the manner in which performance will be linked to the incentive payments. It is advisable that selected measures are ones with which participating providers are familiar, that they represent key factors related to the desired outcomes in hospice, and that the measures are properly risk-adjusted and adequately validated to ensure that they measure what they seek to measure. Of equal importance is ensuring that the measures and the payment structure do not result in negative, unintended consequences -- for example, if a payment withhold approach is utilized, the withhold should not be so large that it affects adequate provider cash flow and, consequently, the ability to supply needed care to patients on service.

The Centers for Medicare & Medicaid Services (CMS) has worked diligently to develop quality reporting programs for a number of Medicare provider types; quality and outcomes-based measurement programs are at varying levels of development. The Hospice Quality Reporting Program (HQRP) is still at a relatively early stage in its evolution: hospices began reporting Hospice Item Set (HIS) data in July 2014, and CMS began to examine the validity of the HIS data during the third quarter of 2015. During the second quarter of 2015, hospices began full-time participation (with involvement of an approved vendor) in the hospice Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey, which was designed to measure and assess the experiences of patients who died while receiving hospice care, as well as the experiences of their informal primary caregivers. CMS developed a standardized comprehensive assessment instrument and began testing it in 2018. In August 2017 CMS

launched a Hospice Compare site on which quality measures for hospice are now publicly reported and updated on a quarterly basis.

RECOMMENDATION: CMS must give highest priority to ensuring that selected measures are relevant, have gone through the proper validation process and are familiar to hospice providers. Incentives should be geared toward positive reinforcement rather than penalizing providers. Given that the HQRP and Hospice Compare are currently in an early stage of development, CMS should wait to develop a value-based purchasing pilot program. When it does, the program should be tested on volunteer participants, but ensure that it is tested on a variety of hospices relative to size, type, geographical location and patient makeup. Full analysis of the pilot program and its impact on patients and providers must be conducted. As hospice quality measure development continues, future demonstration or pilot programs in value-based purchasing may be appropriate prior to launch of a nationwide value-based purchasing program for hospice.

RATIONALE: CMS has been methodical and thorough in its development of the HQRP, but the program is still in its infancy. Development of a pilot program in value-based purchasing for hospice requires equal deliberation and consideration. Value-based purchasing, with its focus on desired outcomes, has the potential to revolutionize health care delivery but must be based on a solid foundation of appropriate measure development, testing, and provider education.

ALLOW PHYSICIAN ASSISTANTS TO PRESCRIBE MEDICATIONS FOR HOSPICE PATIENTS REGARDLESS OF EMPLOYMENT STATUS

ISSUE: Attending physicians for hospice patients are chosen by the patient and identified in the CMS interpretive guidelines as "having the most significant role in the determination and delivery of the individual's medical care". The Bipartisan Budget Act of 2018 amended the Social Security Act (SSA) to allow physician assistants (PA) to be attending physicians for hospice patients effective January 1, 2019. And, the CY2020 Physician Fee Schedule final rule expanded a PA's role in hospice further by allowing hospices to accept medication orders from some PAs although the PA cannot be employed or contracted by the hospice. According to a January 2019 article on Health Leaders Media (4 Physician Assistant Trends to Watch in 2019, January 2, 2019), physician assistants are a dynamic segment of the healthcare sector workforce, per the National Commission on Certification of Physician Assistants NCCPA) statistics released in July 2018. From 2015 to 2017, the number of PAs grew more than 13%. Further, the number of PAs per physician rose 23% from 2015 to 2017, increasing to 128 PAs per 1,000 physicians. Increasingly, hospice providers are indicating that they are dealing with PAs on a daily basis.

Because physicians are increasingly using NPs and PAs as physician extenders, NPs and PAs are often the primary care practitioner for hospice patients. Hospices are often met with physician insistence upon the agency's first contact that all contact must be through the physician's NP or PA. The additional layer of communication before obtaining a certification for the patient is burdensome for the agency and the physician, and may result in a delay to the patient's care. Physicians, of course, oversee the care of any non-physician practitioner (NPP) and deal with more complex cases. Certainly patients at the end of life do have complex care needs and physicians are needed, but there is also a strong need for NPPs to serve as extenders of physician services.

RECOMMENDATION: CMS should allow hospices to accept orders for medications from any PA that is a hospice beneficiary's chosen attending physician whether or not this PA is employed or contracted by the hospice.

RATIONALE: Limiting allowed medication orders to only PAs chosen as the attending physician by the beneficiary and not employed or under contract with the hospice not only limits the practice of the PA, but also increases the burden to providers and physicians which ultimately impacts beneficiaries. As stated above, hospices are often met with physician insistence upon the hospice's first contact that all contact must be through the physician's NPP. Physicians do this because they recognize the skill set of the NPPs with whom they have chosen to work. Hospices then have to go through at least one extra layer of communication before obtaining an order for the beneficiary, which may result in a delay to the beneficiary. Furthermore, a PA's employment status does not in any way impact the skill set of the PA or the care the PA is able to provide.

ENSURE EQUITABLE POLICES AND QUALITY OF CARE FOR BENEFICIARIES IN FEE-FOR-SERVICE MEDICARE AND MEDICARE ADVANTAGE PLANS

ISSUE: Since its inception the Medicare Hospice Benefit (MHB) has only been offered under Medicare fee-for-services (FFS). In 2019, one-third (34%) of all Medicare beneficiaries – 22 million people – are enrolled in Medicare Advantage plans, similar to the rate in 2017 and 2018. Between 2018 and 2019, total Medicare Advantage enrollment grew by about 1.6 million beneficiaries, or 8 percent – nearly the same growth rate as the prior year. The Congressional Budget Office (CBO) projects that the share of beneficiaries enrolled in Medicare Advantage plans will rise to about 47 percent by 2029. In 2017, about 50 percent of Medicare FFS decedents and about 52 percent of MA decedents used hospice. In March 2014, MedPAC recommended that hospice be included in the MA benefits package (Medicare Payment Advisory Commission 2014)

In late January 2019, CMS' Center for Medicare and Medicaid Innovation (CMMI) announced its intent to allow MA plans (as part of the already-established Value-Based Insurance Design (VBID) Model), to voluntarily opt to cover hospice beginning in CY2021. According to CMMI, the proposal is intended to increase appropriate and timely access to hospice services, facilitate better coordination of care, and enable innovation. CMMI created the original VBID model so that MA plans could tailor benefit coverage for chronic conditions so as to encourage better treatment adherence, thereby reducing costly complications that can accompany poor care management (RAND VBID Year One Evaluation Report). Since the MA program places a strong emphasis on utilization control and financial savings, there are widespread concerns that carving end-of-life care into the MA benefit package poses serious risks and will negatively impact the scope and quality of services patients currently receive as part of the hospice benefit. Upon release of the CY2021 and CY2022 Requests for Application (RFAs) for MA VBID and the CY2021 Technical Specifications these concerns remain.

The development of measures to assess the quality of care provided by hospice entities is well under way but is still a relatively young program. Hospice providers are subject to a small albeit growing number of quality measures, including a hospice-specific CAHPS survey that is completed by an informal family caregiver. Quality measure scores and additional hospice data are publicly posted on a Care Compare website, and CMS continues to add more data to improve the website's value. In addition, CMS has in development a hospice assessment instrument (HOPE – Hospice Outcomes & Patient Evaluation) that is intended to assist both hospices and CMS in achieving a fuller understanding of patient care needs. Information gleaned from the assessment and other sources will play an important role in enhancing the Hospice Quality Reporting Program (HQRP) and utility of the CareCompare website in future years.

To meaningfully assess the quality of care provided at end-of-life and to thoroughly evaluate the impact of carving hospice care into MA on the breadth of services and quality of care provided to patients, CMS must do the following:

- Utilize a robust set of cross-setting end-of-life measures that can be utilized under
- original Medicare and MA to assess quality of care, adequacy of care coordination
- and transitions, and patient/family satisfaction
- Require reporting of full patient encounter data for all services and treatments that
- can be compared with existing Medicare claims data to evaluate plan performance

- and beneficiary outcomes
- Ensure full transparency around the benchmarks to be used for any model evaluation
- measure and must evaluate all outcomes of the model against the experience of MA
- patients outside the model who elect hospice care and patients enrolled in hospice under
- fee-for-service, as well as provide Congress with annual updates on the model.

RECOMMEDATIONS: CMS should:

1. Support creation of a robust set of cross-setting end-of-life measures that can be
1. utilized for all of Medicare; such measures should have the capacity to assess quality
2. of care, adequacy of care coordination and transitions, and patient/family satisfaction
3. and allow for public review and comment on these measures CMS must be required
4. to expand the quality measures it uses as part of the model to include a focus on the
5. percent of patients that die in hospice care.
2. Require full reporting of MA plan encounter data to assess the effectiveness of
6. advanced illness and end-of-life care CMS must ensure that MA plans report all
7. patient visits and services in a comprehensive manner.
3. Ensure that plans, assess the VBID Hospice model, provide for transparent analysis
8. of the impact of the model on patient care and the hospice benefit using a wide array
9. of quality and claims-based measures and through comparison of findings from the model against the experience of patients under regular MA coverage as well as under the FFS benefit.

CMS must monitor the impact of the new benefit packages on MA plan members, particularly how these services relate to the quality of care and timely provision of hospice care.

RATIONALE:

CMS recognizes the importance of testing innovative strategies for improving the quality of care and program satisfaction of Medicare beneficiaries. MAO (Medicare Advantage Organizations) quality measures do not currently encompass end of life quality measures, such as those used in the Hospice Quality Reporting Program. In fact, the measures currently used by CMS for MAOs are HEDIS measures. These measures are grouped into five different domains, some of which appear on the surface to be appropriate for end-of-life care, (i.e. effectiveness of care, access/availability of care, etc.); however, the measures under these domains are primarily related to prevention and screening or utilization of services. None of the measures relate directly to end-of-life care. Without a robust set of quality measures there is no baseline and no point of comparison for the effected populations.

CMMI has not indicated how it will demonstrate the degree to which the carve-in is effective and improves care quality for MA-enrolled hospice patients and/or reduces spending (while providing care of comparable quality with that available in original Medicare) over coverage. The Technical Specifications released indicate there will be a comparison of the MA-enrolled hospice patients with other MA-enrolled patients, but not hospice patients enrolled in the traditional MHB.

APPROPRIATELY PENALIZE HOSPICES FOR UNTIMELY PROVISION OF THE ELECTION STATEMENT ADDENDUM

ISSUE: Beginning FY2021 a new condition of payment was implemented for hospices, the hospice election statement addendum. The addendum contains all of the conditions, items, services and drugs the hospice determines to be unrelated to the beneficiary's terminal illness and related conditions and, therefore, not covered under the Medicare hospice benefit. Hospices must notify beneficiaries of the right to request the addendum and, if requested, provide it within the specified time frame. If the hospice does not comply with the required timeframe when the addendum is requested, payment for the claim associated with the addendum is denied. Because hospices submit claims monthly, a payment denial would encompass all of the days of hospice care during the month which could be a full 31 days instead of just the days the addendum is delinquent. The penalty is not commensurate with the infraction and has the unintended consequence of incentivizing hospices to discharge patients when the addendum was not provided timely.

RECOMMENDATION: CMS should only deny payment for the days of care for which a requested addendum was delinquent.

RATIONALE: Under the current requirements, the hospice does not have an avenue of correction for a delinquent addendum. Once the timely provision period for a requested addendum has passed, the only way a hospice can receive payment for any of the days after the addendum was provided is to end the beneficiary's election and begin a new one where the addendum can be provided timely. The penalty has the unintended consequence of incentivizing hospices to discharge beneficiaries from the Medicare hospice benefit in order to end the election and get paid for future days of care. This creates an unnecessary burden on beneficiaries and hospices.

DEVELOP STREAMLINED AND COHESIVE PROCESSES FOR HOSPICES TO NOTIFY BENEFICIARIES OF NON-COVERED ITEMS, SERVICES AND DRUGS AND FOR BENEFICIARY APPEAL

ISSUE: The Medicare hospice benefit does not include coverage of any items, services and drugs determined by the hospice interdisciplinary group (IDG) to be unrelated to the beneficiary's terminal illness and related conditions. Such items, services and drugs may be covered under traditional Medicare benefits. The benefit also excludes coverage of items, services and drugs that are determined by the IDG to be unreasonable and unnecessary under the hospice plan of care. Since Medicare does not cover items, services and drugs considered to be unreasonable and unnecessary payment for these are the responsibility of the beneficiary. This has been part of the hospice benefit structure since its inception.
In FY2021 CMS implemented a new process whereby hospices notify beneficiaries of their right to request an election statement addendum that details the items, services, and drugs determined by the IDG to be unrelated to the beneficiary's terminal illness and related conditions. This has created confusion since there are now two different processes to follow and different rights afforded to beneficiaries for each of the two types of non-covered items, services and drugs.

RECOMMENDATION: CMS should work with hospice industry stakeholders to develop a cohesive process for notifying beneficiaries of non-covered items services and drugs and a streamlined and cohesive set of beneficiary rights for non-covered items, services and drugs

RATIONALE: These two different categories of non-covered items, the unrelated category and the unreasonable and unnecessary category, are handled under different Medicare requirements and provide for different rights of the beneficiary. When disagreeing with items, services, and drugs that the hospice has determined to be unrelated, the beneficiary has the right to Immediate Advocacy. Under this process which is administered by the BFCC-QIO, the QIO cannot change the decision of the hospice. When disagreeing with items, services and drugs that the hospice has determined to be related yet unreasonable and unnecessary but still provided by the hospice (i.e. brand name drugs requested by the beneficiary when there is no medical reason that the generic form of the drug should not be tried), the beneficiary is provided with an Advance Beneficiary Notice (ABN) by the hospice and has the right to appeal the decision. The ABN transfers potential financial liability for the related but unreasonable and unnecessary item, service or drug to the beneficiary. Beneficiaries may understand that something is not be covered, but grasping the fine detail of why something is not covered - unrelated or unreasonable and unnecessary - and how to address any disagreement with the decision of non-coverage is difficult. .

The current process also creates unnecessary burden on the hospice and the beneficiary by requiring two or more forms to be completed by the hospice and signed by the beneficiary. This increases instances of confusion for the beneficiary. One document laying out all non-covered items, services and drugs and streamlined processes for the beneficiary to follow if disagreeing

with the non-coverage determination would minimize confusion and reduce beneficiary and provider burden.

WORK WITH INDUSTRY STAKEHOLDERS TO IMPLEMENT SURVEY REFORMS MANDATED BY THE CONSOLIDATED APPROPRIATIONS ACT OF 2020

ISSUE: Prior to October 6, 2014 there was no legislative requirement for the frequency of surveys
for providers of the Medicare hospice benefit (MHB). Failure to require that hospice providers be
surveyed on a regular basis can result in lack of compliance with regulations and poor quality of care. Some hospice providers went more than 10 years without a survey. On October 6, 2014 the IMPACT Act of 2014 was signed into law. The Act requires that hospices be surveyed no less than every 36 months beginning April 6, 2015 through September 30, 2025. With the passing of the Consolidated Appropriations Act in December 2020, surveys no less than every 36 months was made permanent. The Act also requires other hospice survey reforms including:

- Increased transparency of survey results by posting survey/certification information online
- Modifying the make-up of the survey team if more than one surveyor conducts the survey
- Providing for education of surveyors and reduction of survey inconsistencies
- Modifying enforcement options available to surveyors
- Creating a special focus facility program
- Implementing Civil Monetary Penalties (CMP)

Implementation of these reforms begins October 2021 and spans several years. Exactly how each of these provisions will be implemented is tasked to CMS. Funding of $10 million is provided CMPs and a special focus facility program have been part of the survey process in other provider types; however, there are concerns with these programs that could be avoided in hospice.

RECOMMENDATIONS: CMS should ensure that there are enough resources available for these survey reforms and should work with hospice industry stakeholders to design and implement the reforms to achieve the greatest degree of effectiveness and efficiency.

RATIONALE: When the MHB was created by the Congress, in order to assure quality of care and implement the benefit, CMS was given the responsibility of creating regulations to be followed by providers of hospice services. Recipients of the MHB should be afforded the same protections provided to recipients of other Medicare benefits. As the next step of this responsibility, there need to be regular surveys administered consistently across the nation to ensure compliance with these regulations.

IMPLEMENT FAIR CONSEQUENCES FOR INSTANCES WHEN HOSPICES DO NOT PROVIDE THE ELECTION STATEMENT ADDENDUM TIMELY

ISSUE: Beginning FY2021 a new condition of payment was implemented for hospices, the hospice election statement addendum. The addendum contains all of the conditions, items, services and drugs the hospice determines to be unrelated to the beneficiary's terminal illness and related conditions and, therefore, not covered under the Medicare hospice benefit. Hospices must notify beneficiaries of the right to request the addendum and, if requested, provide it within the specified time frame. If the hospice does not comply with the required timeframe when the addendum is requested, payment for the claim associated with the addendum is denied. Because hospices submit claims monthly, a payment denial would encompass all of the days of hospice care during the month which could be a full 31 days instead of just the days the addendum should have been provided but was not. This penalty is unnecessarily excessive.

RECOMMENDATION: CMS should only deny payment for the days of care for which a requested addendum should have been provided but was not.

RATIONALE: Under the current requirements, the hospice does not have an avenue of correction and all days of care after the timely provision period has passed are not payable. The only way to make days after this period payable is to end the beneficiary's election and begin a new one where the addendum can be provided timely. The penalty has the unintended consequence of incentivizing hospices to discharge beneficiaries from the Medicare hospice benefit in order to end the election and get paid for future days of care. This creates an unnecessary burden on beneficiaries and hospices.

SAFEGUARD THE INTEGRITY OF THE HOSPICE BENEFIT AS PART OF THE MA VBID HOSPICE DEMONSTRATION MODEL

ISSUE: The hospice benefit was the first bundled benefit package authorized under Medicare. Since its inception, the Medicare hospice benefit has been excluded from the Medicare private plan (Medicare Advantage-MA) benefit package and in 1997, as part of the Balanced Budget Act, Congress established in statute that hospice is carved out of the Medicare managed care benefits package. In 2014, the Medicare Payment Advisory Commission (MedPAC) recommended that hospice coverage be incorporated as part of the MA benefit package. MedPAC's rationale was based on the following:

- Concerns about the complexity of current coverage rules for MA patients that elect hospice;
- The desire for greater symmetry in Medicare coverage regardless of whether a beneficiary receives Medicare under fee-for-service, through an accountable care organization (ACO) or through a MA plan;
- The belief that MA plans should have full responsibility for coverage of Medicare benefits, including responsibility for coverage of all care delivered at the end of life; and
- The possibility that MA plans may be willing to offer additional services to patients who elect hospice – such as concurrent care – that is not available under standard Medicare coverage.

In December 2015 the Bipartisan Chronic Care Working Group of the Senate Finance Committee issued a Policy Options Document that suggested MA plans should be required to include hospice as part of the MA benefit package. The working group's proposal elicited significant concerns about the impact of this potential change on hospice patients and the integrity of the hospice benefit. As a result, when chronic care legislation authored by the Working Group (S. 870 -- the Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act of 2017) was introduced in April 2017, it did not propose inclusion of hospice as part of the MA benefit package.

During January 2019, the Centers for Medicare & Medicaid Services (CMS) announced plans to test inclusion of hospice under MA as part of its Value-Based Insurance Design (VBID) model for four years starting in CY2021. Under the model, MA plans are required to offer advance care planning (ACP) services to all enrollees, palliative care services (described by CMS as "largely medical services" already available under Parts A and B of Medicare) for patients not yet eligible for hospice or who choose not to elect hospice care, and concurrent care (expected to be time-limited) to assist with the transition to hospice care. Concurrent care will be offered only to patients choosing an in-network provider, and plans are encouraged to provide patient consultations to explain the benefit limitations of selecting an out-of-network hospice. Plans may not increase their bids to address the costs of palliative or concurrent care.

Plans are also permitted to offer a hospice- and beneficiary-specific set of supplemental benefits, access to which can be limited to a specific dollar value as well as to patients based on their choice of an in-network hospice provider. While the model requires that the "full" hospice benefit be provided, it also places a heavy emphasis on management by the MA plan and on utilization controls. CMS and plans will have the ultimate authority for determining whether services are "unrelated" to the terminal condition and related conditions, rather than the hospice physician. Further, plans are permitted to implement "program integrity safeguards",

suggestions for which include requiring prepayment review of drugs ordered by out-of-network hospices and prepayment review to address long lengths of stay (more than 180 days).

CMS initially signaled plans for potential bonus payments in later years of the model for those plans that reduce spending outside of hospice while patients are on service (unrelated services), reduce long lengths of stay (over 180 days), reduce the frequency of very short lengths of stay (less than 7 days), and reduce live discharges from hospice followed by hospitalization or death. Plans will cover services provided by all hospices in an area for the first two years of the model. In the third year of the program, plans will be subject to a network adequacy standard that was initially expected to be as low as one hospice per county, although CMS has more recently indicated it is seeking input on how to establish an appropriate network adequacy standard.

Inclusion of hospice as part of the MA benefit package raises significant concerns for hospice providers and beneficiary advocates; among them are the following:

- The success of MA has been largely due to imposition of utilization controls. Bringing coverage of end-of-life care under this model runs counter to the hospice model, which emphasizes team-based, patient-centered care;
- Medicare beneficiaries enrolled in MA who elect hospice will no longer have a choice of the hospice provider that will care for them in their final days of life;
- Many hospices provide additional services beyond the scope of the hospice benefit (such as massage, music, and other therapies) because these services have been shown to improve the quality of life for many patients on hospice. Continuing availability of these services may be at risk if MA payment rates do not adequately compensate the hospice;
- Medicare hospice eligibility rules require that a patient be determined to be terminally ill with a prognosis of six months or less if the disease follows its normal course. Tensions could arise between the MA plans and a hospice relative to whether a patient does or does not meet Medicare's eligibility requirements;
- The hospice per diem payment rate is intended to cover all care determined to be reasonable and necessary for the palliation and management of the terminal illness and related conditions, and hospice medical personnel have extensive experience in making determinations of what diagnoses and treatments are related and unrelated to the terminal diagnosis. However, under the model, these decisions are superseded by the MA plan, and may be driven by an MA plan's financial incentives to shift responsibility for unrelated services to the hospice provider.

There are also significant concerns that CMS' plans for evaluation of the model are not sufficient to ensure that the model will not negatively impact the integrity and scope of the hospice benefit.

RECOMMENDATION: The details for the VBID hospice model that have been released by CMS have done little to allay concerns around bringing hospice under MA. It is incumbent on CMS and other policymakers to ensure that the model addresses concerns regarding patient freedom of choice, addresses perverse incentives that will contribute to patient steering and could lead to reductions in services for hospice patients, and ensures that plans for a thorough and transparent evaluation of the impact of the model have been developed. As part of its efforts to monitor the model, CMS must ensure that MA plans report all patient visits and services in a comprehensive manner so that service utilization can be compared with hospice care under fee-for-service. Further, CMS must be required to expand the quality measures it uses as part of the model to include a focus on the percent of patients that die in hospice care. Finally, CMS must

ensure full transparency around the benchmarks to be used for each measure and evaluate all outcomes of the model against the experience of MA patients outside the model who elect hospice care and patients enrolled in hospice under fee-for-service, as well as provide Congress with annual updates on the model.

As part of the demonstration, CMS should test alternative models, including:

- Allowing MA plans to cover all services (including services unrelated to the terminal illness and related conditions) except hospice services; and
- Creating an end-of-life services bundle that provides hospices the opportunity to manage all care needs once a patient enrolls in hospice care.

Finally, given the breadth of concerns regarding the demonstration model, CMS should not expand MA coverage of hospice services outside of the VBID demonstration model on its own motion. Any consideration of expansion of the model must be contingent upon assurance that the model has demonstrated improved access to and quality of hospice care and that MA coverage of hospice services has not impacted the scope of the hospice benefit negatively.

RATIONALE: The Medicare hospice benefit was created to respond to the broad array of care needs that patients and families experience in the final months and days of life. While use of hospice was limited in its early days, the benefit has now become the foundation for the nation's end-of-life care system. The greatest challenges to hospice at this time are ensuring that patients enter service in sufficient time to fully reap the benefit that hospice has to offer and maintaining the integrity of the existing benefit.

Beneficiaries entering MA are, as a general rule, anticipating their needs for curative rather than end-of-life care. Decisions about care at the end of life are deeply personal and of great significance to patients and their families, and patients must retain the right to determine what level of care to pursue and under what provider's care.