2018 Hospice Regulatory Blueprint for Action

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INTRODUCTION

The Hospice Association of America (HAA) 2018 Regulatory Blueprint for Action identifies key regulatory issues of interest to hospice providers and includes a summary of each issue comprised of background information, recommendations, and the rationale behind the recommendations. This document provides a guide to the hospice industry's position on the issues addressed. The HAA Regulatory Blueprint for Action has been developed with input from the HAA Advisory Board, hospice agencies, and associations that represent hospice organizations at the state level, and was subsequently approved by the Board of Directors.

The 2018 Regulatory Blueprint for Action is divided into two parts – Part I contains hospice-specific issues and Part II contains issues that are applicable to both hospice and home health.

The Blueprint serves as HAA's regulatory plan of action for the forthcoming year. Issues that are identified as most important by members become the priorities in the plan of action. However, HAA recognizes that priorities may shift during the course of any year as a result of federal regulatory action or policy changes. HAA is an affiliate organization of the National Association for Home Care & Hospice (NAHC).

PART I: HOSPICE-SPECIFIC ISSUES

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 FY2016, 86% of hospice claims contained two or more diagnosis codes, and 77% 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 record 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. However, CMS is prohibiting hospices from using them. 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. 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.

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.

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. 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.

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.

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). Active communication 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 LOCATION 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 88 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 ($192.78 in 2018) for days one through 60 of hospice care and a lower rate ($151.41) 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 (CHC, paid at $40.68 in FY2018) 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.

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 provides 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. CMS indicated that while this is only preliminary data, it may mean that consideration of "recalibration" of payment rates would be appropriate at some time in the future.

An overriding concern, moving forward, is CMS' indication during 2014 that it believes rebasing of RHC rates (which would reduce them by approximately 10 percent) may be appropriate, and its continuing interest in reducing payments for care of patients in nursing facilities. While some hospices appear to reap financial benefits from care provided to facility patients, many hospices have a limited number of patients in individual facilities. These hospices could be discouraged from providing such care, which would further reduce access to hospice care for facility patients

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 has initiated changes in the hospice cost report for freestanding 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. 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. Changes such as rebasing and a site-of-service adjustment for NF patients may go well beyond what is needed, and create so much upheaval in the hospice payment system that they threaten the integrity of the hospice benefit and jeopardize access to care. Finally, any future discussion related to potential rebasing of hospice rates should not take place until a reasonable set of standards for rebasing has been developed and made public.

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 guides SNF/NFs and ICF/IID that they should tell the resident which hospices, if any, can provide care in the facility, but the guidance does not specify that this should occur at the time of admission and, again, at the time the resident is determined to be at the end of life.

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 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. 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.
- 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 slowdown 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 collects hospice visits and charge data as a first step in creating a database on hospice services provided. 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.

BASE SURVEY FREQUENCY FOR MEDICARE HOSPICE PROVIDERS ON PERFORMANCE

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. While the more frequent surveys are an essential step toward improving compliance with regulations and potentially higher quality of care, more frequent surveys for new Medicare hospice agencies and agencies with condition-level deficiencies or significant complaints would also help to elevate compliance and quality of care.

RECOMMENDATIONS: CMS should ensure that there are enough resources available for these hospice surveys and that timely and adequate training occurs for the surveyors; continuing education should be available as necessary. In addition, CMS should further target quality issues by adopting the following survey frequency guidelines:

- New Medicare hospice agencies should be surveyed annually for at least the first two years of certification.
- Agencies with condition-level deficiencies should be surveyed at least annually until they are deficiency free.
- Complaint surveys should be conducted following significant complaints. If deficiencies are found, annual surveys should be conducted until the hospice is deficiency free.
- CMS should continue surveying hospices at least every 36 months beyond September 30, 2025.

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. As the next step of this responsibility, there need to be regular surveys to ensure compliance with these regulations. Recipients of the MHB should be afforded the same protections provided to recipients of other Medicare benefits.

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. CMS began public reporting of some hospice quality data on the Hospice Compare site in 2017. CMS added two new measures to the HQRP in 2017 – Hospice Visits When Death is Imminent and Hospice and Palliative Care Composite Process Measure. CMS further commented in 2016 that it is considering a comprehensive standardized patient assessment instrument 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.

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.

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 rural hospices struggle to find and retain qualified social workers, as defined in the Medicare CoPs. Specifically, the number of social workers with MSW degrees is extraordinarily limited nationwide and especially in rural areas.

RECOMMENDATIONS: 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. As with other professionals, in particular registered nurses, the average age of the social worker is increasing. According to a study completed by the National Association of Social Workers (NASW), in 2005 nearly 30% of social workers were over 55 years of age, compared with 14% of the US civilian labor force. At least 13% of these social workers have left the work force since the study was completed. While the majority of social workers have an 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 for contracting for supervision.

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 contract with the hospice. In fact, hospices in urban areas are reporting difficulties in hiring and retaining masters-level social workers, as well. The number of rural hospices without access to an MSW is expected to increase as the number of social workers in the United States decreases.

The hospice social work supervision requirement in the CoPs exceeds the standard most state licensure laws impose. The Medicare 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.

CLARIFY HOSPICE RESPONSIBILITIES RELATED TO DISPOSAL OF CONTROLLED MEDICATIONS

ISSUE: On October 9, 2014 the Controlled Substances Disposal Act (the Act) became effective. This rule governs the secure disposal of controlled substances by registrants and ultimate users. These regulations will implement the Secure and Responsible Drug Disposal Act of 2010 by expanding the options available to collect controlled substances from ultimate users for the purpose of disposal, including: Take-back events, mail-back programs, and collection receptacle locations. The Disposal Act provides that, ''if a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent's property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided'' for ultimate users (21 U.S.C. 822(g)(4)). An ultimate user includes ''a person who has lawfully obtained, and possesses, a controlled substance for his own use or for the use of a member of his household'' (21 U.S.C. 802(27)). Accordingly, a member of the hospice patient's household may dispose of the patient's pharmaceutical controlled substances, but the home hospice or homecare provider cannot do so unless otherwise authorized by law - for example, under state law - to dispose of the decedent's personal property and in cases where an ultimate user has given permission to the hospice to dispose of the medication.

Since their inception, the majority of hospice providers have developed and implemented procedures whereby a hospice staff member, usually a hospice nurse, disposes of at least controlled substances remaining after a patient's death when the patient resided in a personal community residence. This common practice of hospices typically involves documentation of the medications destroyed and destruction according to the recommendations of the FDA and EPA. There is also typically a documented witness to the destruction and there is a provision for family members of the decedent to refuse the destruction, but this is a rare occurrence. The purpose of this practice is to prevent the diversion of controlled substances. CMS has recognized the long-standing practice in regulations at CFR 418.106. Specifically, the regulations state:

§418.106(e)(2) Disposing.

(i) Safe use and disposal of controlled drugs in the patient's home. The hospice must have written policies and procedures for the management and disposal of controlled drugs in the patient's home. At the time when controlled drugs are first ordered the hospice must:

§418.106(e)(2)(A) - Provide a copy of the hospice written policies and procedures on the management and disposal of controlled drugs to the patient or patient representative and family;

§418.106(e)(2)(B) - Discuss the hospice policies and procedures for managing the safe use and disposal of controlled drugs with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe use and disposal of controlled drugs; and

§418.106(e)(2)(C) - Document in the patient's clinical record that the written policies and procedures for managing controlled drugs was provided and discussed.

While these federal regulations do not specifically require the hospice to actually dispose of/destroy the medications, there are some state laws that do require this. These state laws often do not expressly give authority to the hospice staff to "possess" the medications for destruction. Hence, there is confusion at the state level and hospice level regarding what, exactly, hospice staff can and should do with unused/unwanted medications in the home setting. Hospices in states with laws that require they destroy the medications are concerned that complying with state law will cause them to be out of compliance with the Controlled Substances Disposal Act. The DEA encourages home hospice and other homecare providers to assist their patients, and their patients' families, in disposing of pharmaceutical controlled substances in accordance with applicable regulations. However, assistance by the hospice provider may involve "possession". Additionally, the Controlled Substances Disposal Act addresses long term care facilities (LTCF) but does not address hospice inpatient units.

RECOMMENDATIONS: The DEA should provide clarification of the role hospices should and are able to play in preventing the diversion of controlled substances for those patients under their care in personal residences and in hospice inpatient facilities. CMS should consider the clarified role in light of CFR 418.106 and provide guidance accordingly.

RATIONALE: Clarification of the hospice's role is necessary in order for hospices to be in compliance with both state and federal rules and regulations. Clarification is also necessary for state DEA offices and state legislators to ensure state laws are not in direct conflict with the Act.

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 will begin 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. 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.

PART II: COMBINED HOME HEALTH AND HOSPICE ISSUES

IMPROVE APPLICATION OF WAGE INDEX FOR MEDICARE HOME HEALTH AND HOSPICE

ISSUE: Since the inception of the Medicare per-visit cost limits, home health payment rates have been adjusted to reflect varying wage levels across the nation through the application of a wage index. This payment rate adjustment continues under the Medicare home health prospective payment system (HHPPS), which was implemented effective October 1, 2000. However, the wage index that has been utilized by the Centers for Medicare & Medicaid Services (CMS) has been based upon varying wages within hospitals across the nation. The hospice benefit payment is also adjusted by the same hospital wage index, with a further adjustment known as the Budget Neutrality Factor (the BNAF is being phased out over fiscal years 2010 through 2015). The hospital index is derived from data that explicitly excludes any home health services costs. Furthermore, it is based on the mix of employees found in hospitals, rather than home health agencies and hospices. In addition, providers have seen wide swings in their wage index from one year to the next. An attempt some years back to create and utilize a home care-specific wage index failed due to the unavailability of reliable wage data.

While the home health and hospice payment rates are based upon the application of a hospital wage index, both the index utilized and its manner of application are significantly distinct from that utilized relative to hospital services payment rates. Hospitals may secure a geographic reclassification for application of the wage index by establishing that the particular 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. Congress has established specific wage index criteria for certain geographic locations. However, these criteria apply only to hospitals that are also protected from wide variations from one year to the next by establishment of a floor.

The Medicare Payment Advisory Commission (MedPAC) recommended that Medicare replace the hospital wage index with one that relies on data from the Bureau of Labor Statistics, and design the new wage index in a manner that allows for tailoring to other provider sectors, including home health and hospice.

The Patient Protection and Affordable Care Act of 2010 (ACA) directs CMS to reform the hospital wage index consistent with the recommendations of MedPAC, and to report to Congress on its plan for instituting a new wage index. CMS submitted its report on a commuting-based wage index (CBWI) to Congress in April, 2012; however, the report indicates that the complexities of applying the proposed wage index to providers whose payment varies based on the location where services are delivered would be prohibitive. As of January 2015, the only change that CMS has made to the wage index is to incorporate new CBSA area designations related to the 2010 census.

RECOMMENDATIONS: 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.

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.

Current Medicare home health regulations are limited to services provided as "visits." There is no separate payment mechanism for telehealth services under the Medicare home health despite the fact that home health agencies are required to comply with the conditions of participation regardless of the payer. The Centers for Medicare & Medicaid Services (CMS) has no current plans to extend the Medicare home health benefits to specifically include telehealth services. Under PPS, home health providers may look to telehealth as a possible mechanism to deliver services.

Telehealth services are not reported on home health or hospice claims. Telehealth services must be reported as non-allowable costs on Medicare cost reports. CMS plans to analyze telehealth cost report information in order to evaluate the use and cost of telehealth services. It is not known whether telehealth will be considered an allowable expense for future home health cost reports after CMS reviews costs and revises payment rates. At this time, limited reimbursement is available from Medicaid, managed care plans and private insurance for telehealth services. A few demonstrations are under way in rural areas.

Currently, 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. 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.

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:

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 agencies and hospices for equipment costs.
3. Recognize telehealth service as billable under home health PPS based on a discrete number of telehealth services per episode and consider telehealth costs as allowable for cost reporting purposes.
4. Include telehealth equipment and service delivery as allowable costs on home health and hospice cost reports.
5. Consult with industry representatives and develop guidelines under the current Conditions of Participation (CoP) to allow for telehealth services delivered by providers.
6. Do 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. 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 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 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) and Recovery Audit Contractors (RAC).

In 2017, a national RAC contract for all home heath and hospice providers was awarded 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 and RACs to ensure appropriate fraud investigation and referrals.
3. Establish a process for stakeholders to addresses inappropriate review requests with CMS.
4. Ensure timely processing of provider applications, whether for initial enrollment, revalidation, change of information, or change of ownership.
5. Offer timely guidance and assistance to providers when innocent errors lead to incomplete or erroneous applications.
6. 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.
7. 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. 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.
3. 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 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 will focus 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. Home health and hospice provider vary in size with many having average daily census of less than 100.

RECOMMNDATIONS:

1. CMS should closely monitor the TPE program to ensure small providers are not unfairly burden 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.

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.

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 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 S&C staff. However, not every state participates in CMS training.

CMS implemented revised Home Health Conditions of Participation (HHCoPs), effective January 13, 2018. New surveyor guidelines and protocols will soon be instituted by CMS. New requirements and varying interpretations will likely result an increase in both standard and condition-level deficiencies. In addition, alternative sanction regulations have been in effect since 2013 with h 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 in May, 2011, and ensure that all surveyors are adequately trained in the new protocols.

State agencies 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.
3. Required to have a healthcare background.
4. Required to compensate surveyors commensurate with area standards.

CMS should promote communication between survey agencies and MACs:

1. A formal procedure for sharing information between the Medicare Administrative Contractors (MACs) and state survey agencies (SAs) should be developed.
2. SAs should report suspected coverage problems to the MACs, and the MACs should report suspected quality problems to the SAs.
3. MACs should be cross-trained on basic coverage and regulatory principles, reporting procedures, and the bounds of their individual authority.
4. Training should be ongoing to maintain current knowledge.

RATIONALE: Surveyors for the Medicare Home Health and Hospice benefits need full knowledge of the provisions and requirements of the benefits to avoid inappropriately citing hospice and home health providers with deficiencies and to ensure the highest quality of care. This is of critical importance with the revised HHCoPs that went into effect January 13, 2018. In addition, recent legislation requires hospice providers to undergo triennial surveys. Prior to this, surveys of hospice providers were infrequent.

A healthcare background is essential for proper assessment of quality care. Underpaying surveyors limits a state's ability to recruit quality personnel. In addition, providing current interpretive guidelines to providers will foster understanding and compliance with regulatory requirements. It is by knowing what is required that providers can maintain compliance with requirements. Surveyors are not adequately trained to make coverage decisions, especially in light of the fact that some agencies may have a different MAC, with different coverage policy interpretations, than the one normally assigned to providers in that state. Surveyors must become adept at accessing and reviewing clinical records online as more home health agencies move to e-health records.

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 IDR process for condition-level deficiencies in home health; however, agencies do not have any appeals process for standard-level deficiencies. 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 home health/hospice providers respond to statements of deficiencies within 10 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 are paper, rather than electronic, providers must hand print or type responses using a typewriter, which is labor intensive.

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.
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 – and in many cases involve caregivers not affiliated with a home care agency. 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.

Some states have enacted laws requiring criminal background checks. These laws vary from state to state, and compliance with them is costly for home health agencies. In some states, an individual may not work until a criminal background check has been completed, and completion may take more than 60 days. The resulting delay may dissuade workers from entering the home health field. Furthermore, criminal background check systems are expensive, cumbersome, and often do not reflect the overall background of the individual screened.

The Centers for Medicare & Medicaid Services (CMS) included a provision for criminal background checks on home health aides in the 1997 proposed CoP. In the meantime, Congress has considered passing legislation mandating criminal background checks on all long-term care workers. Neither CMS nor Congress has implemented mandatory criminal background check requirements. However, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 included a provision that calls for establishment of "a pilot program to identify efficient, effective, and economical procedures for long term care facilities or providers to conduct background checks on prospective direct patient access employees."

CMS selected several states and initiated the MMA provision to establish a Criminal Background Check Pilot Project for the purpose of expanding background checks for workers with direct patient access employed by Medicare and Medicaid long-term care providers. 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). Long-term care providers in these states are required to fingerprint applicants and conduct registry and state and federal criminal background checks on all direct patient access employees. Under the project, employees are permitted to provide provisional care (care under supervision as defined by the state) until the background check has been completed. Providers are required to disqualify from direct access employment any individual who has been convicted of a "relevant crime" or patient abuse. The Criminal Background Check Pilot Project was completed in September 2007, and an evaluation report of project was published in August 2008.

This was expanded through the National Background Check Program which was established based on a legislatively mandated federal program, as part Affordable Care Act (ACA). The purpose of the program, which is voluntary and open to all states that wish to participate, is to identify efficient, effective and economical procedures for long term care facilities and providers to conduct background checks on prospective direct patient/resident access employees. Grant funding is available to states.

The Department of Health and Human Services Office of Inspector General (OIG) is conducting a congressionally-mandated evaluation of the Nationwide Program for National and State Background Checks on Direct Patient Access Employees of Long-Term Care Facilities and Providers. The OIG is required to evaluate the impact of conducting background checks to determine whether there are any unintended consequences, including a reduction in the available workforce for long-term care providers. OIG has decided that the best way to ensure identification of problems is to gather information and opinions from long-term care providers as well as the organizations that represent them.

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.

ALLOW HHAs 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 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 will require that emergency preparedness for all the designated provider and supplier types will 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 are represented in training and education sessions and materials.
4. Ensure surveyors are adequately trained on what CMS expects for compliance.

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 the home setting 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 EFFECTIVE EMERGENCY PREPAREDNESS COMMUNICATION AND REGULATORY RELIEF FOR HOME CARE AND HOSPICE

ISSUE: 2017 was one of the most active years for natural disasters. Several category 4 and 5 hurricanes along the Gulf Coast and Caribbean and massive wildfires in California 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. In recent years, the Secretary has been quick to invoke 1135 waiver authority when necessary during declared emergencies. However, the process for requesting 1135 waivers remains cumbersome and confusing particularly when providers are in the mist of a disaster response. The federal government is reluctant to grant blanket waivers for specified provider types. 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.

CMS has issued two resource documents for healthcare providers during emergencies: Policies and Procedures that may be Implemented Without an 1135 waiver and Policies and Procedures that may be Implemented Only With 1135 Waivers. Although these documents provide valuable information, CMS is unclear when they are to be activated. Those procedures that do not need waiver authority may be initiated by the CMS Region Office or Medicare Administrative Contractor but that is not clear in the document or any of CMS' instructions on their web pages. Waivers that require 1135 authority still need to be individually requested by providers, even thought CMS frequently references the document in its emergency response communications as though they are in effect. Providers do not know whether these represent blanket waivers.

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 disaster events that impacted many areas of the country in recent years 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 has 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.

Hospitals must 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. Although CMS indicated that it will evaluate establishment of a similar requirement for Critical Access Hospitals (CAH), compliance is not required at this time because CAHs have separate regulations. 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:

1. Educate surveyors about the discharge planning requirement and their responsibility to assess for compliance.
2. Have surveyors identify instances whereby physician orders for specific home health agencies were violated.
3. Ensure that enforcement of compliance with discharge planning regulations is carried out in the survey process.
4. Make hospital discharge planning regulations applicable to Critical Access Hospitals.

5. Initiate a study to determine whether patients are denied access to home health services.
6. 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.

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.

In 2011, President Barack H. Obama issued executive order (E.O.) 13563. E.O 13563 instructs federal agencies to periodically review their significant regulations with the goal of making their regulatory programs more effective or less burdensome. E.O. 13563 requires that the regulatory agencies conduct a retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them.

In May 2014 CMS issued a final rule reforming several Medicare regulations that were identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers. However, none of reforms included any regulations affecting home health or hospice providers.

. **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.

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 another 6 months, effective January 29, 2017, and was further extended into 2018.

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.

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 will have to become self-sustaining after their grants expire in FY-2013, 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 changed 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.

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. Identify a subset of OASIS-C 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.);
5. Support standards of interoperability to exchange health information with hospitals and physician practices;
6. Revise the (Consolidated-CCD) clinical document standard for the exchange of the HH-PoC and summary care record between home health care providers, physician groups, hospitals and other LTPAC providers;
7. 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.
8. Identify technical assistance and resources needed by home health care and hospice providers to support EHR adoption and the electronic exchange of health information;
9. Encourage homecare and hospice providers to engage in HIE governance and taskforces.
10. Provide educational resources to homecare and hospice providers for 5010 and ICD-10 conversions;
11. Explore strategies to incorporate interfaces for telehealth and remote monitoring data into EHRs, and;
12. 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: Both the existing and the proposed rules on suspension of Medicare/Medicaid payments fall far short of reasonable due process.

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).

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), Program Safeguard Contractors (PSC), Zone Program Integrity Contractors (ZPIC), 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, 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 new audit contract 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.

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.

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 insufficient documentation on the F2F encounter document. 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 most recently, by the 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.

As of May 31, 2016 there were 83, 203 home health and 5,153 appeals pending out of 716,442 total pending appeals.

In early 2018, CMS launched a Low Volume Appeals (LVA) Initiative under which eligible providers whose appeals are validated can receive payments equal to 62 percent of the net Medicare approved amount. Additionally, CMS also announced plans to expand its Settlement Conference Facilitation Process, which is applicable to larger appeals, beginning in April 2018.

CMS is to be commended for initiating the LVA Initiative and for its plans to expand the Settlement Conference Facilitation Process, 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. CMS should provide a settlement option to all appellants with claims pending before an ALJ in order to reduce the backlog. That settlement should be based on historical data on ALJ reversal rates and the cost savings achieved by Medicare coming through the avoidance of an ALJ appeal.
4. 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.

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.

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.

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.

APPLY REGULATORY RELIEF FAIRLY TO INCLUDED 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.

RECOMMENDATIONS: 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.

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.