

2011 Regulatory Blueprint for Action

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INTRODUCTION

The Regulatory Blueprint for Action identifies important regulatory issues for home care, hospice and durable medical equipment providers. It provides a summary of each issue, including background information, recommendations, and rationale for the recommendations. This document provides a guide to the home care industry's position on the issues addressed. The National Association for Home Care & Hospice (NAHC) 2011 Regulatory Blueprint for Action has been reviewed by the Regulatory Affairs Subcommittee and the Forum of State Association's Regulatory Affairs Advisory Committee and approved by the Board of Directors.

In order to identify the regulatory issues that are of importance to home care, hospice and durable medical equipment providers throughout the country, NAHC engages in a variety of activities. Member comments gathered from telephone calls, letters, and personal contact are analyzed. The current industry trends and government actions are evaluated. NAHC committees, the Forum of State Association's Regulatory Affairs Advisory Committee, and the Board of Directors participate in development of positions for the annual Regulatory Blueprint for Action. NAHC publishes a list of major issues in NAHC Report annually and asks members to score each issue from the least to most important. The results are tabulated and industry priorities identified.

The Blueprint serves as NAHC's regulatory plan for action for the upcoming year. Issues that are identified as most important by members become the priorities in the plan for action. However, NAHC recognizes that priorities may shift during the course of any year as a result of Federal regulatory action or policy changes. The Regulatory Priorities selected by the membership for 2010, are:

EXECUTIVE SUMMARY

The 2011 Regulatory Blueprint for Action and the priorities established by the membership reflect the impact of the major legislative and regulatory changes that have swept the home care community over the past several years. The Blueprint addresses current and anticipated regulations, provides insight into each problem and offers a proposed solution and rationale.

Financial survival is the greatest concern to home care providers today. Therefore, home health and hospice reimbursement issues are addressed in the first section of the Blueprint. This section is followed by sections on: survey and certification, administration, coverage and other. Beginning in 2000, separate sections were created for hospice and durable medical equipment issues. The top twenty home care priorities identified by NAHC members for 2011 are:

1. Establish reasonable policies and implementation procedures for the physician face to face encounter required for medicare home health certification
2. Make certain that home health agencies have a role in new health care delivery models
3. Establish fair and appropriate standards for rebasing of medicare home health rates
4. Ensure the provider enrollment, chain, and ownership system (pecos) is fully operational and adequately maintained prior to implementation
5. Require medicare to fully assess and report on the impact of its new rules
6. Ensure home health access for homebound beneficiaries
7. Establish reasonable therapy service requirements
8. Establish procedures for timely & accurate adjustments to the case-mix system that address changes in patient characteristics and home health resources
9. Improve the application of wage index for medicare home health agencies
10. Ensure fairness in government fraud and abuse activities
11. Reform medicare home health market basket index
12. Reimburse home health agencies for telehealth and provide for regulatory flexibility
13. Oppose public authorities or other measures that restrict consumer choice of provider in the provision of long term care services and fail to protect workers
14. Ensure access to Medicaid home health

15. Provide fair and targeted reimbursement for medical supplies
16. Refine guidance for selection and make appropriate decisions based on g codes
17. Ensure home care services under managed care
18. Ensure use of statistically valid sampling methodology for post-payment review
19. Ensure claims review decisions at all levels of appeal that are consistent and in compliance with medicare coverage requirements
20. Adopt due process provisions before suspending payment

I. REIMBURSEMENT REFORM

ESTABLISH PROCEDURES FOR TIMELY & ACCURATE ADJUSTMENTS TO THE CASE-MIX SYSTEM THAT ADDRESS CHANGES IN PATIENT CHARACTERISTICS AND HOME HEALTH RESOURCES

ISSUE: On August 29, 2007 CMS published a final rule updating the home health prospective payment (PPS) case-mix adjuster effective January 1, 2008. This is the first update to the payment system since CMS implemented it on October 1, 2000 was made to improve its power to predict resource utilization which had eroded to 20% since the start of PPS. In this update the case-mix adjuster was established based on 2005 and first quarter 2006 data. The data that was used reflects the resource use of care and supplies at that time.

A case-mix adjuster is used to distribute payments based on variations in patient care needs as determined by a variety of characteristics. The design is to provide higher payments for patients with needs for higher levels of care and lower payment for patients needing less care. Case-mix considerations include such variables as the health and functional status of the patients served. The final rule reforming PPS includes a case-mix adjuster with 153 case-mix groupings.

The revised case-mix system reallocates points for all clinical, functional and service utilization items, expands the diagnoses considered, and allows for case-mix points for both primary and secondary diagnoses. In addition, it provides for payment increases at three therapy thresholds (6, 14, and 20 visits), as opposed to a single 10 visit threshold, and offers graduated payment increases for therapy visits between the thresholds. Another major change made is the assignment of different case-mix points and payment rate based on whether a patient is in an early (1st or 2nd) episode of care, or a late (3rd or after) episode of care. The result is a four equation case-mix model that appears to offer more equitable payments based on actual resource utilization. CMS reported that the new case mix system will have resource utilization predictive rate of over 40%.

However, CMS based its case-mix revisions on data gleaned from OASIS submissions, and claims up to 2006. Home health agencies admitted to reporting incomplete information on home health claims, such as omission of visits and medical supplies.

CMS will continue to base payment on the number of therapy visits provided as a predictor of overall resource utilization. Also in the update of the case-mix adjuster, CMS made certain policy decisions, such as to continue exclusion of any consideration of informal caregiver services and consideration of the impact of poverty on level of services. Furthermore, rehabilitation considerations continue to be limited to the services of therapists and do not include rehab nursing. A number of system errors occurred during the first eight months after PPS refinements were implemented, leaving it impossible to conduct an accurate analysis of the impact of the changes.

Since the implementation of the 2008 adjuster CMS began use of OASIS-C which provides additional data on patient characteristics. CMS is studying how OASIS-C, which was implemented January 1, 2010, can serve in future changes to PPS case-mix.

Concerns have been raised about the continued reliability of the case mix adjuster and its integrity as well. In the proposed rule for 2011 payment rates, CMS planned to eliminate use of a diagnostic

variable that relates to hypertension. CMS explained that it no longer believed that the diagnoses affected a patient's resource needs. This proposal would have reduced revenues on average 1.78% because CMS did not propose to reconcile the elimination of the variable with the system as a whole. CMS withdrew its proposal in the Final Rule.

The Medicare Payment Advisory Commission (MedPAC) is recommending that CMS replace the case mix adjustment model with a new version that drops therapy utilization from the variables applied to the payment determination. MedPAC views therapy thresholds as problematic as they encourage unnecessary therapy utilization to increase payments. MedPAC is developing a new adjuster through an outside contractor that it expects would be ready for use in 2012.

Concurrently, CMS is researching the development of case mix adjuster reforms that also limit the impact of utilization thresholds. No details of the potential revisions are public at this point.

RECOMMENDATIONS:

1. Conduct ongoing analysis of the adequacy of the case-mix adjuster with input from providers and case-mix study contractors.
2. Consider revisions that eliminate the use of the volume of therapy visits to determine payment amounts while not discouraging therapy utilization.
3. Test any revised model prior to nationwide implementation
4. Validate that a proposed new model performs better than the existing case mix adjuster model/
5. Implement further refinements that would extend or increase the case-mix system reliability, in a timely manner, based on study findings.
6. Provide at least 4 months notice when making future adjustments to payment rates and the case-mix system.
7. Thoroughly analyze OASIS-C to ensure that the data is employed appropriately in future changes to the case-mix system.

RATIONALE: The revised case-mix adjuster established by CMS was based on data from 2005 and the first quarter of 2006. Home health patient characteristics and resource utilization will continue to change over time. In addition, testing of the new case-mix adjusters will not be complete until in place for some time in home health agencies with real patients. The therapy utilization thresholds are a "lightning rod" for concerns about abuse and objective clinical characteristics offer a higher integrity approach provided that the explanatory power of the model fairly reflects variations in resource intensity.

Continued refinements should be used only if there is an increase in the models' explanatory power capabilities. Research is needed into the impact of caregiver access and poverty on resource utilization, which was limited by CMS due to the political implications of inclusion of those items. Finally, failure to include rehab nursing services in the therapy adjustment to case mix, particularly in light of therapist shortages, does not accurately reflect true resource utilization and costs.

ESTABLISH PROCESSES FOR MODIFICATION OF PPS PAYMENT RATES AND CASE-MIX ADJUSTMENTS

ISSUE: Under the Balanced Budget Act of 1997, Congress mandated the creation of a Medicare home health prospective payment system (PPS). That system of PPS was implemented by the Centers for Medicare & Medicaid Services (CMS) on October 1, 2000. At that time, CMS was authorized to annually adjust payment rates solely through the use of a market basket index, which is intended to reflect cost inflation in the delivery of home health services. In addition, CMS is required to include a case-mix adjustment component to PPS to set payment rates in a manner which reflects the varying use of clinical resources among the population of patients receiving Medicare home health services.

Under the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), CMS is authorized to make adjustments in the standard prospective payment amount if it is determined that the changes in the overall case mix result in a change in aggregate payments, whether the result of “upcoding” or classification in different units of service that do not reflect real changes in case-mix. In addition to this payment rate adjustment authority, CMS intends to regularly adjust the case-mix weights with system refinements based upon an expanded database.

CMS revised PPS, including a modified case mix adjustment model, with implementation in January 2008. The changes included an 11.75% rate reduction phased in over four years triggered by a finding that coding weights had increased beyond levels justified by changes in patient characteristics. An additional 2.71% rate reduction was originally included for 2011. In 2010, CMS proposed increasing the 2011 adjustment to 3.79% and adding a 3.79% adjustment in 2012 as well. Ultimately, CMS finalized just the 2011 adjustment while leaving 2012 an open threat. These significant policies did not include comprehensive information about changes and the underlying basis for those changes.

In response to the regulatory rate reductions, legislation was introduced in both houses of Congress during 2007 that would require CMS to utilize a rational and transparent process for adjusting rates under the BIPA authority. That legislation, H.R. 3865 and S. 2181, proposed detailed standards such as the use of a Technical Advisory Group, consideration of service utilization through service reviews rather than statistical assumptions, and a full public display of the data and analysis prior to the finalization of rate adjustments. Unfortunately, the proposed legislation did not advance because a repeal of the regulatory cuts came with a cost estimate of over \$7 billion by the Congressional Budget Office. S. 2181 was refiled in the 111th Congress (S. 3315); the House companion bill was also filed (H.R.4950). These bills expired with the 111th Congress and are expected to be refiled in 2011. In its 2011 rulemaking, CMS promised to revisit its process for evaluating changes in case mix weights. However, CMS did not agree to voluntarily utilize the process prescribed in S. 3315.

The payment rate adjustment authority weakens the financial security of the home health benefit since the stability of the payment rates is uncertain and subject to vague or ambiguous standards left to the discretion of CMS.

RECOMMENDATION: CMS should modify payment rates only with adequate advance notice of at least 12 months and that CMS should develop reliable and accurate criteria for application of the BIPA case-mix adjustment correction authority through public rulemaking. The procedural standards set out in S. 3315 should be adopted by CMS in regulation without waiting for a legislative mandate immediately and applied prospectively to any further coding weight adjustments.

RATIONALE: An intended consequence from the transition of cost reimbursement to prospective payment is stability and reasonable certainty regarding Medicare home health service payment rates. With cost reimbursement principles allowing for retroactive payment adjustments, home health agencies suffered through an environment of financial instability. PPS should operate with at least a modicum of stability of payment rates and CMS should not be allowed to arbitrarily adjust payment rates through the

application of vague and ambiguous standards.

MONITOR AND REFINE MEDICARE HOME HEALTH OUTLIER POLICY

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

Between 2005 and 2009 the amount of outlier spending increased considerably. During that time almost 40% of the outlier outlays were to one county in the country. As a result CMS became concerned that outlier spending would exceed budget. As a result, CMS raised the fixed dollar loss ratio, effective January 1, 2008, from 0.67 to 0.89 with the intention of decreasing the number episodes that will qualify for outlier payments. In its analysis of data to update the outlier policy for 2009 CMS acknowledged the existence of unusual trends in outlier payments to certain parts of the country. Therefore, CMS decided to retain the FDL at 0.89 until further analysis can be carried out and other actions implemented to remedy problems identified.

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

The Patient Protection and Affordable Care Act (PPACA) codified the outlier cap into Medicare law beginning January 1, 2011. Since the implementation of the outlier cap some concerns have been raised that certain patients may find barriers to access to care as outlier patients are not always evenly distributed.

RECOMMENDATION: Monitor the outlier payment methodology to determine whether qualified patients have barriers to access to care. If barriers are found to exist, develop revisions to outlier standards that accommodate exceptional circumstances. The revisions could include use of an exceptions process and prior authorization. Further, where the full allocated outlier budget is not utilized CMS could make retrospective payments to providers with excess outlier subject to a pre-stated limit.

RATIONALE:

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

IMPROVE APPLICATION OF WAGE INDEX FOR MEDICARE HOME HEALTH AND HOSPICE

ISSUE: 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 (PPS), which was implemented effective October 1, 2000. However, the wage index that has been utilized by the Centers for Medicare and Medicaid Services (CMS) has been based upon varying wages within hospitals across the nation. The hospice benefit payment also is adjusted by the same hospital wage index with a further adjustment known as the Budget Neutrality Adjustment Factor (the BNAF is being phased out between FY2010 and 2016). 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, the index utilized and its manner of application is significantly distinct from that utilized relative to hospital services payment rates. Hospitals are allowed to 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 which are also protected from wide variations from one year to the next by establishment of a floor.

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

In the Patient Protection and Affordable Care Act of 2010 (PPACA) Congress directed Medicare to reform the hospital wage index consistent with the recommendations of MedPAC and to report to Congress no later than December 31, 2011 on its plan for instituting a new wage index.

RECOMMENDATION: CMS should move quickly to develop the wage index reforms as directed in PPACA. The goal should be to put all providers on a level playing field with their respective wage indexes. If the revised wage index allows for geographic reclassifications for one provider group it should provide the same allowance for all. Any wage index weight changes in a reformed model or in future years in applying the wage index model should be subject to a transition limitation on increases and decreases from one year to the next.

RATIONALE: The current hospital wage index does not fairly reflect variations in wages in home health and hospice. In today's health care environment, health care providers of all types compete for employment of the same personnel. The adjustment of Medicare payment rates intended

to reflect variations in wages across the nation should be consistent across all provider types. With increasing shortages of health care personnel, unequal wage index adjustments for health care providers in the same geographic region results in an uneven and discriminatory distribution of the employment pool of personnel. Prevention of wide swings in wage indexes will enable health care providers to more precisely project revenue and budget expenses.

PROVIDE FAIR AND TARGETED REIMBURSEMENT FOR MEDICAL SUPPLIES

ISSUE: In implementing the prospective payment system (PPS) for Medicare home health services, CMS significantly modified the responsibilities of home health agencies for providing medical supplies to individuals receiving care under the Medicare home health benefit. Under the previous payment system the provision of medical supplies by home health agencies was not required. Provision of non-routine medical supplies and covered medical supplies was optional and limited to those non-routine supplies that were ordered as part of the plan of care. Under PPS, home health agencies must provide all supplies. Bundling of medical supplies has been the most problematic component of the home health prospective payment system.

In the 2008 reform of HH PPS, CMS decided to provide separate payment for medical supplies in each full episode, with the amount of payment based on certain patient characteristics. However, additional supply payments are not allowed for LUPA episodes. Payment rates are tied to a six level severity index. The decision to pay separately for supplies using a new medical supply case-mix adjustor, rather than by adding a set dollar amount to every episode, came about because the CMS PPS research identified that only 10% of home health claims included charges for medical supplies.

Policies and billing procedures were established to require home health agencies to report billing codes to correlate to the case mix level and whether or not supplies are provided. Claims must reflect supply charges in cases where supplies are provided. However, analysis of supply payment data will not be available until early in 2009 since the new information collection requirements did not go into effect until October 2008.

Despite the move to establish a more equitable payment methodology for supplies, concern remains that the amount of money allotted for medical supplies will not be adequate. The amount of money allocated for medical supplies is based on pre-PPS data. Large numbers of HHAs did not provide supplies pre-PPS and Part B files did not account for supply costs for beneficiaries who did not have Medicare B coverage. Furthermore, many required supplies under PPS were not included in the payment calculation since the Medicare B supply benefit guidelines are more restrictive than those for home health. CMS did not build in inflationary considerations for new, high cost supplies such as those needed for chest drainage and complex wound care. Finally, many home health agencies admit that they did not bill for supplies provided to patients since payment was not affected by the inclusion of supply charges on claims.

Because HHAs must provide all supplies while a beneficiary is under a home health plan of care, regardless of whether those supplies are part of the treatment plan, some patients are forced to accept different brands of supplies than those to which they are accustomed. In addition, they are required to interrupt relations they have had with their suppliers or pay out of their pockets for their supplies while under a home health plan of care.

CMS and MedPAC are now working to devise reforms to the case mix adjustment model. However, there is no indication that either effort includes modifications to the medical supply element of home health services.

RECOMMENDATION:

1. Monitor the new policy for unbundled payment of non-routine supplies from the episodic payment rate.
2. Identify costs of supplies provided for which payment is inadequate because of failure of the supply case-mix adjuster to identify certain conditions routinely requiring supplies.
3. Study the fairness of the payment rates found in the six tier severity scale.
4. Make timely adjustments to the medical supply case-mix to provide accurate payment based on findings.
5. Develop an outlier payment mechanism for medical supplies.
6. Modify the PPS standard to require that home health agencies provide only those medical supplies that are directly related to the treatment provided by the home health agency to the patient.
7. Allow individuals to receive Medicare B payment for supplies that are not ordered as part of the plan of care from their supplier of choice, with appropriate Medicare reimbursement under Medicare Part B
8. Analyze the cost of medical supplies provided and determine whether a supply add-on is appropriate in LUPA episodes
9. Include appropriate medical supply case mix adjuster revisions in any reformed service model

RATIONALE: Home health agencies have an expanded responsibility for medical supplies, the true costs of which have not been captured and reflected in the episodic payment rate. Unbundling supplies as put forth in the new policy could ensure appropriate payment to home health agencies. However, poor data resulting from home health agencies' failure to include supply charges on claims may have resulted in incorrect conclusions about supply needs, patient characteristics, and costs. The new supply case-mix system, which was developed based on incomplete data, could be seriously flawed and the payment amount inadequate. Furthermore, because CMS failed to acknowledge the limit on coverage of supplies used by patients and their caretakers and failed to project added costs of new technologies, the Medicare benefit has been unfairly expanded on the backs of home health agencies. Finally, patient choice of supplies and suppliers should be taken into consideration in CMS payment policy. Many LUPA episodes, such as those for catheter changes, require the home health clinician to use costly supplies in the course of care. Often patients in LUPA episodes have the need for other supplies that they use that must be provided by home health agencies due to the bundled supply requirements.

ELIMINATE INEQUITIES IN PARTIAL EPISODE PAYMENTS

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

Finally, current CMS policy and intermediary actions in cases where two agencies bill for services provided within a 60 day period of time are confusing. CMS policy identifies the home health agency of record as the “primary agency.” The primary agency is responsible for provision of all bundled services to the home health patient. However, in cases where a second agency bills for home health services CMS has instructed its contractors to assume that this constitutes a “beneficiary elected transfer” resulting in a PEP of the first agency’s episode. This policy also applies when Medicare beneficiaries must relocate during disasters if services are delivered by a different provider in the temporary shelter.

RECOMMENDATION:

1. CMS should eliminate the payment gaps or carve-outs under its current interpretation of PEP payments.
- 2 Full episode payments should be made when readmissions or beneficiary elected transfers occur for conditions unrelated to the initial reason for care.
3. If readmission or transfer is required for the same condition, partial episode payments should be prorated based on the total number of days out of 60 from the start of care or first day of the episode through the day prior to the date the patient was readmitted or came under the care of the second home health agency.
4. Fair and equitable policies and protocols should be established for providers to follow to avoid PEP episodes and conflicts when determining “primary agency.”
5. Eliminate the application of the PEP policy for home health patients who relocate during declared disasters.

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

PPS should not exclude portions of episodic payment where there is a gap between intervening events since the nature of homecare is the provision of part time or intermittent care. A patient is under a home health plan of care for the duration of the treatment plan, not only on those days that

visits are actually made. CMS has implemented an inconsistent manner of calculating and applying payment rates under its current interpretation of PEP adjustments. Home health agencies are faced with countless financial burdens as a result of disasters. PEP episodes when patients receive services after relocation due to a disaster compounds the agency's financial losses.

REIMBURSE HOME HEALTH AGENCIES FOR TELEHEALTH AND PROVIDE FOR REGULATORY FLEXIBILITY

ISSUE: Interest in the concept of delivering home health services via telehealth (also known as telemedicine) has grown over the last few years, especially with the implementation of the home health prospective payment system (PPS) in 2000. 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 technology.

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

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.

Currently, the cost of telehealth equipment and transmission of information can be prohibitive. Obstacles to the growth of telehealth services in home health include geographic practice limitations imposed by state professional licensure laws and liability laws. Furthermore, CMS requirements to apply the CoP 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 benefit. Nevertheless, there are steps that CMS can take to address telehealth within the Medicare home health benefit without further congressional authorization needed.

RECOMMENDATION:

1. Expand telehealth demonstration projects to include home health and hospice services to Medicare beneficiaries to identify potential cost-savings to the Medicare program; appropriate patients; and the quality and effectiveness of telehealth services.
2. Develop payment mechanisms to reimburse home health and hospice agencies 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. Consult with industry representatives and develop guidelines under the current Conditions of Participation (CoP) to allow for telehealth services delivered by home health and hospice providers.
5. Do not apply CoP requirements in instances where telehealth is used solely for monitoring stable individuals.

RATIONALE: Home health 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, especially as we are experiencing one of the greatest nursing shortages in our history. CMS and the home health industry need information that would be learned through demonstration projects to support the expansion of telehealth services for home health patients, 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 POSTPAYMENT REVIEW

ISSUE: Since July 1992, the Centers for Medicare and 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 intermediary 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 not only been questioned 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 a 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 the provider has incurred great expense/ The decision to apply sample adjudication is not subject to administrative review in an appeal.

RECOMMENDATION: 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. Ensure statistically valid sampling procedures and overpayment methodology.
3. Improve educational programs for providers and establish guidelines for minimum training of all Medicare contractor reviewers.
4. Expand contractor provider relations, services, and education to reduce claim errors.
5. Implement a time-limited prepayment review if the provider has evidence of non-covered claims before applying sampling denial rate to all claims.
6. Develop criteria and standards for the exclusion of providers from the program that have a history or pattern of submitting claims for non-covered services after education has been provided.
7. Require repayment only after all appeal rights are exhausted.

RATIONALE: Sampling imposes significant risk of bankruptcy to agencies and reduces the protection available in an appeal. Even if CMS can develop a valid sampling methodology, extrapolation of denial rates to a large percentage of claims, with recovery of funds before appeals have been exhausted, is unfair to agencies and patients. If sampling is used by CMS, safeguards as recommended are essential.

ENSURE HOME CARE SERVICES UNDER MANAGED CARE

ISSUE: The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 increased payment to Medicare Advantage plans to encourage more beneficiaries to leave traditional Medicare and join private HMO and PPO plans. The Medicare plans have an obligation to provide the same scope of home health services benefits as is available under traditional Medicare. However, these plans have often covered home health services on a "per visit" basis while traditional Medicare covers episodic care. Further, some Medicare Advantage plans impose significant cost sharing obligations on enrollees while Medicare has no coinsurance requirements for home health services. Also, many Medicare Private Fee for Service (PFFS) MA plans have advised home health agencies that they do not intend to adopt Medicare 2008 PPS fee-for-service case-mix methodology and rates. Failure of PFFS plans to pay in accord with the new case-mix system will result in the need for agencies to complete two OASIS assessments for patients, OASIS 2008 to comply with CMS regulatory requirements and OASIS 2002 to bill PFFS plans

The Part D Medicare prescription drug plan has created policies that result in the automatic enrollment of special needs Medicaid enrollees into Medicare managed care plans. This further impinges on the ability of home health agencies to deliver needed care and to be paid for care delivered.

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

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

In 2010, traditional Medicare will be required to compete against private plans in six metropolitan areas in demonstration projects. In addition, in its efforts to control costs, CMS announced establishment of multi-state Medicare Preferred Provider Organizations (PPO) and several Disease Management projects. These new plans will have greater flexibility in the delivery of services to Medicare beneficiaries. However, many of the problems inherent in managed care could arise within these new plans since they will have increased flexibility in coverage requirements, with potential for limiting home health and hospice benefits.

Some non-Medicare, federally-qualified managed care plans have restricted the home care benefit for subscribers by limiting visits to a bare minimum and applying a "part-time or intermittent" care limitation. These plans have taken the position that home care services for these patients are limited to nursing care, thereby excluding home care aide services, therapy, and medical social services and supplies. Others have used the "custodial care" exclusion to limit payment.

Managed care providers that are not Federally-qualified are also providing coverage in a restrictive manner. No Federal laws govern these providers, and the state laws that do exist are inadequate in their definition of home care and coverage of services. Also, increasing reports are being received

from home health agencies that, despite contracts and prior authorization of services, managed care plans are not paying for services provided.

RECOMMENDATION:

1. Enforce laws that mandate that Federally-qualified managed care plans to provide home care services to the non-Medicare subscriber without limit as to frequency or duration (up to 24 hours a day, 7 days a week), where delivery of home care services represents a cost-effective and reimbursable service meeting the client's needs.
2. Require managed care plans and preferred provider organizations serving Medicare beneficiaries to provide home care services consistent with the coverage guidelines. Specifically, the plans should cover episodic care.
3. Require managed care plans and preferred provider organizations to notify patients and their current providers of authorization of service requirements prior to the effective date of enrollment.
4. Require immediate notification of the CWF by managed care plans and preferred provider organizations of enrollment and disenrollment and improve the timing for updating CWF by CMS.
5. Clarify state laws regulating managed care plans and preferred provider organizations.
6. Establish an appropriate policy to encompass all disciplines of care, supplies, and HME within a definition of "home health services", and develop a reasonable definition of "custodial care".
7. "Hold harmless" providers, who in good faith, provide physician ordered, reasonable and necessary home health services to beneficiaries before notification of enrollment.
8. Ensure that preferred provider organizations and disease management programs assure access, adequacy of coverage and quality care.
9. Impose penalties on managed care organizations that fail to pay for authorized services in a timely manner.
10. Enforce PFFS statutory and regulatory requirements to implement revised provider payment schedules on the same date that such changes are required of contractors administering the Original Medicare benefit consistent with 42 CFR 422.503.

RATIONALE: Failure to require managed care plans to become Federally-qualified results in dual standards. Also, it is unfair to Medicare beneficiaries enrolled in managed care plans that limit the amount of home health service and impose co-pays because they receive a lower level of benefits than fee-for-service beneficiaries. Further, different levels of benefits will result if new insurance models, such as preferred provider organizations and disease management programs that are not held to the same standards and ensure access to home health and hospice services that fee-for-service Medicare beneficiaries receive. Finally, home health agencies unfairly suffered, and will continue to suffer, serious financial problems caused by inadequate communication of beneficiary enrollment in these plans and failure of plans to pay for service provided.

ENSURE ACCESS TO MEDICAID HOME CARE SERVICES

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

Some state Medicaid directors are inappropriately enforcing homebound requirements that are contrary to federal law. Others have removed the term “homebound” from their manuals and replaced it with a requirement that the agency document why the patient cannot go elsewhere for care, which is essentially the same as a homebound requirement. Although CMS has communicated to states that these policies are inappropriate, several continue to apply them.

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

States also have curtailed home care access through the use of so-called consumer-directed care where Individuals rather than home care agencies provide the care. This care delivery model compromises access to care as It discriminates against beneficiaries unwilling or unable to manage their own care.

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

Currently, CMS is becoming more active in managing Medicaid compliance by the states. CMS recently reminded the states that a homebound requirement is not permitted under the Medicaid home health services benefit. In addition, CMS is pushing for better rebalancing of long term care spending in favor of home care. CMS also plans to develop new Medicaid federal rules on such topics as rate setting standards.

RECOMMENDATION:

1. Establish accountability and program integrity standards in Medicaid home care.
2. Develop appropriate rate setting structures for use within the individual state Medicaid programs.
3. Enforce federal Medicaid law that requires states to set rates in a manner that secures access to necessary care and ensures quality.

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

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

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

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

PROMOTE MEDICARE-MEDICAID COORDINATION

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

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

Significant costs to providers, Medicare, and Medicaid are incurred because these projects require retrospective claims review, submission of claims to Medicare, and administrative appeals. Further, the unsupportable position that Medicare covers everything in the home for each day of the 60 day episode leaves providers with unpaid services.

Problems exist with the demand bill process, sometimes taking 3-4 months when the payer (e.g., Medicaid) requires billing in a shorter time. Agencies have to bill without the Medicare denial, get rejected, and re-bill when the Medicare denial is received. This costs agencies considerable dollars. Some programs have required billing to Medicare for services clearly not covered (e.g., personal care only, housekeeping).

At the end of 2002, CMS and several states established demonstration programs in Connecticut, Massachusetts, and New York utilizing sampling adjudication to address this cross program conflict. Although home health agencies must supply documentation for sampled claims subject to review by state Medicaid programs, any resultant recovery of funds is completed between Medicare and Medicaid. The program has been extended in Connecticut and New York. No other states are allowed to participate at this time. However, these demonstration programs are ending despite the clear cost savings that they achieve as an alternative to high volume "demand billing" approaches with massive individual claim appeals.

States have returned to individual claim submissions and appeals since the end of the sampling demonstration programs. This has led to high administrative costs and never-ending confusion. Additional states from the original ones pursuing Medicare-maximization are now instituting recovery programs or other barriers to Medicaid payment for dual-eligibles.

RECOMMENDATIONS:

1. Modify third-party liability regulations to require that states utilize the most cost effective method for recovering payment for dually eligible patients.

2. Implement of a system of claims review that does not require individual claims submissions and appeals. Medicare and Medicaid claims submission should be combined with initial billing to Medicare and a transfer billing of remaining non-covered care to the respective state Medicaid program.
3. States should be required to recoup incorrect payments from the Medicare program rather than the provider. No recovery should take place against a provider until after third party (Medicare's) liability is established.
4. Monitor the Medicaid third party liability demonstration programs.
5. Establish clear coverage standards for Medicare and Medicaid that differentiate between the Medicare responsibilities in an episode of care and the Medicaid coverage obligations for additional services.

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

ENSURE FAIRNESS IN GOVERNMENT FRAUD AND ABUSE ACTIVITIES

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

CMS has supported the concept that all parties involved in the home health benefit work together to protect both the beneficiary and 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, the continuing adoption of more stringent enrollment requirements in an attempt to identify and eliminate fraudulent providers.

The shift to PPS requires a retooling and revision of anti-fraud efforts from cost reporting and claims concerns to issues of care quality and access. Enforcement authorities are not adequately prepared to make this adjustment. CMS has developed a long-term strategy for detecting and preventing fraud and abuse in response to provisions in the Health Insurance Portability and Accountability Act. The strategy involves separating program safeguard functions from the claims processing activities carried out by intermediaries and assigning them to Program Safeguard Contractors (PSC) and Zone Program Integrity Contractors (ZPIC). There is growing concern about inappropriate PSC and ZPIC coverage interpretations, denials, and sampling applications.

In addition to PSCs and ZPICs, Medicare is using Recovery Audit Contractors (RAC) that engage in large-scale automated claims reviews and are paid on a contingency basis. While the RACs have not been authorized to undertake home health or hospice projects, their performance in other sectors indicate that the concerns with PSCs and ZPICs are warranted with RACs as well.

RECOMMENDATION:

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 PSCs, ZPICs, and RACs to ensure appropriate fraud investigation and referrals.
3. Ensure timely processing of provider applications, whether for initial enrollment, revalidation, change of information, or change of ownership.
4. Offer timely guidance and assistance to providers when innocent errors lead to incomplete or erroneous applications.
5. 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.

The Office of Inspector General should:

Establish minimum training requirements for OIG and Department of Justice investigators, as well as work with the industry to address concerns regarding fraud and abuse, particularly under the new incentives of PPS.

1. 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.
2. Provide timely responses to providers’ legal questions, as well as access to published legal opinions.

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

ENSURE APPLICATION OF PROFESSIONAL AUDITING AND ACCOUNTING STANDARDS

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

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

Medicare home health payment rates and the payment model for hospice are planned for rebasing and reform as early as 2013 for hospice and 2014 for home health. To the extent that these reforms rely on cost report data, Medicare is ill-prepared to conduct fair and accurate audits of provider costs.

RECOMMENDATION:

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

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

REFORM MEDICARE HOME HEALTH MARKET BASKET INDEX

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

Over the last several years, the Market Basket Index (MBI) has been significantly lower than the index calculated for other provider sectors. In 2009, the home health MBI is 2.9% while the hospitals and skilled nursing facilities are 3.6% and 3.4% respectively. Even though these provider sectors share the same labor pool, the index shows a lower projected inflation rate for home health services than the other sectors. In addition, despite dramatically increased costs of transportation, the index reflected a small cost impact.

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

RECOMMENDATION: CMS should thoroughly review and evaluate all aspects of the home health Market Basket Index to ensure that it reasonably forecasts annual cost increases. That review and evaluation should include the appropriateness of the BLS proxy data choices, the choice of cost components, the accuracy of the cost component weights, and the reliability of the forecasting model. The CMS review and evaluation should be made publicly available as part of the issuance of a proposed rule regarding the annual rate update. The index should incorporate a forecast of expected changes in costs resulting from new legislative and regulatory mandates.

RATIONALE: Home health agencies compete with hospitals and skilled nursing facilities for nurses, therapists, medical social workers, and aides. Further, home health care is vulnerable to the swings in gasoline pricing and other transportation costs. Further, changes in law and regulations often increase the costs of care. An accurate inflation update is crucial to secure continued access to home health care.

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

ISSUE: Section 3131 of the Patient Protection and Affordable Care Act of 2010 (PPACA) requires that payment rates for Medicare home health services be rebased beginning 2014 and that the rebased rates be phased-in over a 4 year period concluding in 2017. The legislation leaves much to Medicare to decide on the process and factors considered in the rate rebasing. The law itself provides that the rates “shall be adjusted by a percentage determined appropriate by the Secretary to reflect such factors as changes in the number of visits in an episode, the mix of services in an episode, the average cost of providing care per episode, and other factors that the Secretary considers to be relevant.” The legislation also allows the Secretary to consider differences between hospital-based and freestanding providers, for-profit and not-for-profits, and urban and rural providers.

Data demonstrates that there are wide variations between home health agencies in terms of Medicare financial outcomes. The differences may be due to both factors within and outside the control of the agencies. Further, business needs exist that require that agencies have access to capital to a greater degree than is generally assumed and that the ability to make a profit in Medicare has triggered efficiencies that have benefited Medicare as well as the provider. Finally, data shows that most of any Medicare margin is redistributed to health care through the offsetting of shortfalls from other payers such as Medicaid and Medicare Advantage plans.

In its January 2011 recommendations to Congress, the Medicare Payment Advisory Commission (MedPAC) proposed moving rebasing for home health forward to 2012, with completion by 2014.

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

1. Ensure that all existing costs of home health care are known and considered including telehealth, caregivers such as respiratory therapists and nutritionists, marketing, taxes, acquisition of capital, and new regulatory requirements.
2. Recognize that a reasonable financial margin is needed for any business, including home health agencies in order to meet cash flow needs and to incent efficiencies
3. Convene a technical expert panel of home health agency representatives to provide advice and direction to CMS in determining rate rebasing standards
4. Recognize differences in types and location of providers in setting rebased rates only to the extent that the difference relate to factors outside the control of the providers
5. Publish the standards for rate rebasing with sufficient time for all stakeholders to fully evaluate and develop comments for consideration

6. Evaluate the impact of rebased payment rates in a manner that considers short and long term impact, the impact on the viability of the existing businesses, the impact on access to care, and the impact on clinical practices.

RATIONALE: The rebasing of payment rates is the single most important reimbursement action that can be undertaken by Medicare. A well-informed and rationally developed set of rebasing standards can ensure that Medicare beneficiaries maintain access to high quality care. Conversely, poorly devised rebasing standards can be a disaster for beneficiaries and the providers that serve them. The rebasing standards must be developed with the recognition that home health care is a health care business that needs to operate within reasonably normal business principles that include the need to accumulate capital for growth and improvement and the opportunity to secure a margin to justify the investment whether from a for-profit enterprise or a nonprofit entity that needs a margin to support any mission.

ESTABLISH A FAIR AND EQUITABLE VALUE BASED PURCHASING (VBP) SYSTEM

ISSUE: Medicare is the largest health care payer in the nation. Growing concerns are being voiced about the poor quality of health care and the country's lack of an adequate system for compensating providers of care based on the quality of services that they deliver. As a result of the publication of findings about unacceptable quality of care by the Institute of Medicine (IOM), Congress responded to the Medicare Payment Advisory Commission (MedPAC) recommendation to develop legislation that would require the Secretary of Health and Human Services (HHS) to identify quality measures and pay providers of Medicare services based on quality of care, rather than quantity of services. Referred to as Pay for Performance (P4) in the past, rewarding providers for quality of care is now referred to as Value Based Purchasing (VBP)

Under the DRA, Congress charged MedPAC with the responsibility of submitting a report on its recommendations for models for P4P-type home health reimbursement. In January 2007, MedPAC provided the first indications of the direction that this report may take. MedPAC proposed a P4P payment model utilizing 20 OASIS-based outcome indicators such as toileting, ambulating, and managing oral medications. Under this system, points would be given for improving or stabilizing functional levels- and deducted for each potentially avoidable adverse event, such as an unplanned hospitalization or emergency room visit. A single quality score for each agency would be calculated through this method. MedPAC staff also suggested calculating a confidence interval around each agency's score. This would be used to pad the score for agencies with small numbers of patients where results would be likely to vary from the mean due to "luck of the draw." Finally MedPAC staff made several recommendations for balancing rewards and penalties. MedPAC commissioners raised several objections to the MedPAC staff proposals and suggested consideration of measures other than OASIS outcome measures.

CMS established a home health P4P demonstration project in order to prepare for eventual legislation. The provisions of this demonstration were very different than those proposed by MedPAC, but reflected many of the recommendations made by the home health industry. Through the CMS P4P demonstration contractor, Abt Associates, home health agencies were recruited to participate in January 2008. The demonstration ended in December 2009, with awards amounting to over \$15 million to agencies for savings to Medicare spending during the first year of the project. Performance was evaluated based on OASIS outcomes for Medicare patients to agencies: 1) with highest scores on outcomes, and 2) highest levels of improvement. CMS will calculate savings and determine which HHAs are eligible for incentive payments for the second year of the demonstration in early 2011.

CMS also contracted with Abt Associates to revise the OASIS data set and add new process measures. CMS hopes that the addition of process measures, which have been reported to home health agencies since September 2010, will improve its capability to reward providers under VBP. The Affordable Care Act (ACA) of 2010, Section 3006, mandates that the Secretary of HHS develop a plan for a home health value-based purchasing (VBP) program, known in the past as P4P, and submit that plan to Congress by October 1, 2011. The plan must be developed in consultation with "relevant affected parties" and consider demonstration experience. The Secretary must consider the following issues:

1. Development, selection and modification of process measures of all dimensions of quality and efficiency
2. Reporting, collection and validation of quality data
3. Structure of value-based payment adjustments, including improvement thresholds, size of payments, and sources of funding for VBP payments
4. Methods for public disclosure of information about performance

RECOMMENDATION:

1. Ensure consultation with provider representatives in identification of appropriate VBP outcome and process measures and the development of a fair and equitable system.
2. Require CMS to thoroughly test the validity and reliability of OASIS-C using current guidelines in the “real world” of home health application.
3. Require that OASIS-C quality refinements and new process measures be proven accurate predictors of quality before these measures are used to pay home health agencies for performance.
4. Establish a system that is adequately risk adjusted and does not negatively impact Medicare beneficiaries.
5. If HIT is part of a VBP system, add funding sources for home health agencies.
6. Create a separate pool that would be used to fund VBP, rather than funding by withholding a percentage of payment from home health agencies.
7. Fund VBP incentive from savings realized by the Medicare program as a result of quality care.
8. Base the system on measures that are under the control of, or reasonably susceptible to, the influence of the home health agency while the patient is on service with the agency.
9. Base selected measures on uniform data that home health agencies have collected and reported for a sufficient period of time in order to ensure consistency and reliability.
10. Compensate providers that demonstrate improvement as well as top performers.
11. Facilitate relief from current data collection requirements and administrative burdens and costs.
12. Take into account geographic variations and agencies with anomalous patient populations, such as large numbers of dually eligible patients, chronically ill long stay, or small number of patients served.
13. Apply VBP to the Medicare patient data only.
14. Ensure that the risk adjustment methodology effectively adjusts for age, the number of comorbidities, and Medicaid eligibility.
15. Consider patient length of stay when measuring the “incidence of acute care hospitalization.”
16. Withhold support of the initial MedPAC staff P4P proposal.
17. Base the system on measures that are meaningful to patients, providers, payers, and other stakeholders and represent value and important aspects of care and services.
18. Refrain from implementing VBP in home health until completion of demonstration projects, analysis of the results, and pilot testing of any proposed plan.
19. Spread reward payments throughout the calendar year.

RATIONALE: Identification of acceptable, fair and equitable measures can be problematic, especially in light of the many variations in the needs and social and economic status of Medicare beneficiaries. Therefore, development of a VBP system must be undertaken carefully, in concert with the provider community, and only after sufficient research has been conducted in order to ensure that providers are rewarded appropriately and not unfairly penalized. Small providers do not have the reserve funds to invest in costly HIT. Furthermore, it would be unfair to providers to withhold monies needed for daily operation until in the end of the year in order to fund VBP.

VBP will only serve as an incentive to providers to improve the quality of care if the agencies that improve, as well as top performers, are rewarded. The model P4P system displayed by MedPAC staff fails on a number of fronts to meet the VBP principles that the National Association for Home Care & Hospice and other organizations in the home care community have established. The CMS P4P demonstration appears to be more in line with NAHC's principles for a workable and appropriate VBP reimbursement model in home health than does the MedPAC staff.

It is generally accepted in government circles that, because of the outcome measures already available to home health providers, home health is a step closer than most other providers in preparing for VBP. However, many questions exist about the validity and reliability of OASIS in light of new changes and additions. The testing of these new process measures has yet to be done since they were implemented beginning 1/1/2010.

In consideration of the P4P demonstration project, as well as any system adopted for implementation, variations of health status and practice patterns found in various parts of the country necessitate that performance thresholds be compared separately. Therefore, geographic areas that are smaller than entire states should be identified for comparison of agency performance. CBSA's may serve as more appropriate for determining performance thresholds.

REFINE GUIDANCE FOR SELECTION AND MAKE APPROPRIATE DECISIONS BASED ON G CODES

ISSUE: In order for CMS to collect more specific information about the sort of services provided to home health patients and the qualifications of clinicians providing the services, CMS revised the current descriptions for existing G-codes as follow:

- *G0151* Services performed by a qualified physical therapist in the home health or hospice setting, each 15 minutes.
- *G0152* Services performed by a qualified occupational therapist in the home health or hospice setting, each 15 minutes.
- *G0153* Services performed by a qualified speech-language pathologist in the home health or hospice setting, each 15 minutes.
- *G0157* Services performed by a qualified physical therapist assistant in the home health or hospice setting, each 15 minutes.
- *G0158* Services performed by a qualified occupational therapist assistant in the home health or hospice setting, each 15 minutes.

G0159 Services performed by a qualified physical therapist, in the home health setting, in the establishment or delivery of a safe and effective physical therapy maintenance program, each 15 minutes.

G0160 Services performed by a qualified occupational therapist, in the home health setting, in the establishment or delivery of a safe and effective occupational therapy maintenance program, each 15 minutes.

G0161 Services performed by a qualified speech-language pathologist, in the home health setting, in the establishment or delivery of a safe and effective speech-language pathology maintenance program, each 15 minutes.

• *G0154* Direct skilled services of a licensed nurse (LPN or RN) in the home health or hospice setting, each 15 minutes.

• *G0162* Skilled services by a licensed nurse (RN only) for management and evaluation of the plan of care, each 15 minutes (the patient's underlying condition or complication requires an RN to ensure that essential non-skilled care achieves its purpose in the home health or hospice setting).

• *G0163* Skilled services of a licensed nurse (LPN or RN) for the observation and assessment of the patient's condition, each 15 minutes (the change in the patient's condition requires skilled nursing personnel to identify and evaluate the patient's need for possible modification of treatment in the home health or hospice setting).

• *G0164* Skilled services of a licensed nurse (LPN or RN), in the training and/or education of a patient or family member, in the home health or hospice setting, each 15 minutes.

CMS issued conflicting instructions to home health agencies as to how to determine which code to report when more than one nursing or therapy service is provided during a visit. In one guidance home health agencies were told that they must report the G-code which reflects the service for which the clinician spent most of his/her time. However, in other guidance, home health agencies were told that they could report the code representing the primary reason for the visit. Although CMS issued definitions for new G codes, home health agencies continue to be confused as to code selection, especially when both non-covered and covered services are provided. Furthermore, home health agencies concerns about the cost and challenges of educating home visiting staff and implementing billing software.

RECOMMENDATIONS: Refine guidance and policies for billing G codes:

- Consider that new coding requirements always carry with them the burden of system changes and education of providers
- Develop and disseminate additional educational materials, referencing information in the Medicare Benefit Policy Manual covered services
- Clarify guidance to providers on how to determine which code(s) to report when multiple services are provided during a visit
- Continue to make coverage determinations based on medical review of clinical documentation, and not resort to decisions based on frequency of the appearance of certain codes on home health claims
- Do not use information collected to make changes in payment and medical review activities until the accuracy and value of the information has been validated

RATIONALE: Information gleaned from new billing codes will be of value only if clinicians are thoroughly educated and experienced in coding. Correct code selection can be guaranteed only after complete and consistent guidance has been disseminated by CMS. Furthermore, it would be counter-productive to make decisions about claims selection for medical review until clinicians have completed the learning curve. Failure to recognize the impact of software program decision tools on data accuracy could also result in incorrect decisions about payment policies. Finally, failure of CMS to verify the worth of G code information through clinical record review will lead to faulty payment policy decisions.

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

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

As part of the certification form itself, or as an addendum to it, the physician must document that the physician or NPP saw the patient, and document how the patient's clinical condition supports a homebound status and need for skilled services. The form may not contain standardized language or check boxes. In addition, the physician's office staff may not complete the form from the medical record even if the encounter occurred within the required time frame and supports the patient's need and eligibility for home health services. Finally, CMS has recently clarified that it is not permissible for the physician to dictate the face to face encounter findings to the home health agency staff to transcribe and send for signature. The stringent documentation guidelines are proving to be burdensome to physicians. Many physicians have expressed frustration with the additional documentation requirement, and are resisting complying with the regulation.

CMS provided some flexibility regarding institutional physicians when patients are hospitalized or in skilled nursing facilities. Medicare will allow a physician who attended to the patient but does not follow patient in the community, such as a hospitalist, to certify the need for home health care based on their face to face contact with the patient. However, the documentation requirements and restrictions are the same, and many institutional physicians are not willing to certify patients for Medicare home health services.

CMS has yet to initiate education or awareness efforts directed to physicians, non-physician practitioners, or Medicare beneficiaries; leaving the bulk of the education on the face to face requirement to the home health agency.

Furthermore, home health agencies have been informed that they may not bill a patient for uncompensated care due to noncompliance with the new requirement nor will agencies be reimbursed for care if the face to face encounter is delayed beyond 30 days. Therefore, agencies will be held financially responsible for any care provided to a patient where the face to face encounter has not occurred during the prescribed time frames or the physician's documentation does not satisfy CMS' requirements.. Agencies will have to choose whether or not to admit

patients that are referred but have not had the required face to face encounter, or to discharge patients on services that have not had a face to face encounter with the physician within 30 days of admission. Forcing agencies to choose between providing uncompensated care or not accept a patient onto service will likely result in a lack of access to home health services for certain Medicare beneficiaries. Beneficiaries without transportation, a primary care physician at the time services are required, or resources to facilitate a visit to the physician are placed at a disadvantage for receiving home care services for which they are entitled.

RECOMMENDATIONS:

1. Further delay the enforcement of the face to face requirement until such time that the full impact to health care delivery operations is understood.
2. Provide flexibility in the documentation requirements to:
 - Limit the documentation to permit the physician to sign an attestation statement that the face to face encounter had occurred or;
 - Permit a uniform certification and face to face encounter form and language.
 - Permit information from the clinical record to serve as proof that a physician face to face encounter occurred or;
 - Permit the physician to dictate the face to face encounter information to the home health staff.
3. Conduct an initial and ongoing effective education campaign for physicians and beneficiaries on the face to face requirement.
4. Apply “without fault” provisions, or permit the agency to bill the patient, when non-compliance is the fault of the physician or beneficiary.
5. For delayed face to face encounters, structure payment so that agencies are reimbursed for care provided from the date of the encounter through discharge.
6. Establish a process to re-evaluate CMS policies for the face-to-face requirement that includes input from providers, physicians and beneficiaries.
7. Modify Medicare coverage rules to cover an ambulance transport to a physician’s office for beneficiaries that require an ambulance.

RATIONALE:

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

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

In the absence of a uniform certification statement, the physician certification is confusing and overly burdensome to physicians. The majority of physicians will fail to provide a statement that meets CMS' requirements, which implies the need for an intricately thought out statement that connects encounter reasons to homebound status to Medicare coverage of medically necessary services. Medicare's own contractors have difficulty themselves with such a task as it is carried out in the appeals process. The current plan of care includes detailed information to support homebound status and the medical necessity of care by requiring medical diagnoses, functional status, medications, and detailed orders for care.

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

ENSURE THE PROVIDER ENROLLMENT, CHAIN, AND OWNERSHIP SYSTEM (PECOS) IS FULLY OPERATIONAL AND ADEQUATELY MAINTAINED PRIOR TO IMPLEMENTATION

ISSUE: Section 6405 of the Patient Protection and Affordable Care Act of 2010 conditions Medicare payment for home health services only if the physician that certifies and recertifies the patient for home health services is enrolled in Medicare. The Centers for Medicare and Medicaid Services (CMS) promulgated an Interim Final Rule on May 5, 2010 requiring that the ordering physician listed on the home health claim have an approved enrollment record or a valid opt-out record in the Provider Enrollment, Chain, and Ownership System (PECOS) as validation of Medicare enrollment. The Act required and the regulation established a July 1, 2010 effective date for the rule.

PECOS is an internet based application that allows physicians, non-physician practitioners, providers, and supplier organizations to enroll, make a change in their Medicare enrollment, view their Medicare enrollment information on file with Medicare, or check on the status of a Medicare enrollment application. Through PECOS, CMS is able to manage, track, and validate enrollment data collected in both paper form and electronically via the Internet. However, PECOS only contains information for providers who have enrolled Medicare or submitted changes to their enrollment information since 2003. There are many Medicare enrolled physicians eligible to order home health services that are not in PECOS.

A review of the PECOS database indicates that approximately 20 percent to 40 percent of physicians who order home health services are not in the records. The main reasons that they are not in PECOS include errors in PECOS; the absence of an updated enrollment record since the initiation of PECOS; and CMS inability to keep up with the backlog of enrollment applications from eligible providers. In addition, the only resource providers have to confirm if a physician has a record in PECOS is through a report that CMS posts on its web site which lists the names of enrolled physician and practitioners. Unfortunately, the list is updated only once or twice a week and reflects an inaccurate PECOS data base.

CMS has delayed claims editing for PECOS enrolled physicians until July 1, 2011 and will not be denying any claims because the ordering and referring physician is not enrolled in PECOS until such time as that the system to enroll is working properly and the backlog of applications has been processed. Since the July 1, 2010 effective date for the requirement was established in the Act, CMS has not delayed the effective date only the edits in the Medicare claims processing system. CMS has never affirmed for home health providers that they will not apply the regulation retroactively. Home health agencies could be vulnerable if program integrity contractors begin reviewing for compliance on claims with episodes that started between July 1, 2010 and July 1, 2011.

RECOMMENDATIONS

1. Delay the implementation of requiring the ordering physician have an approved record in PECOS until such time that CMS can assure the system fully operational and maintains accurate information.

2. Confirm that agencies will not be held responsible for claims where the ordering physician did not have a record in PECOS, but was otherwise eligible to order Medicare home health services, until the system edits are fully operational and public notice to that effect is given.
- 3 Provide an ongoing educational campaign to inform physicians of the requirement to enroll in PECOS in accord with the statutory requirement.
4. Allow home health agencies access to Fiscal Intermediary Standard System records to research the enrollment status of physicians updated on a daily basis.

RATIONALE: We recognize the need for CMS to establish the process for approving physicians enrolled in Medicare, and creating an official roster for listing all physicians approved by Medicare. However, numerous problems, including poor communication with and misinformation to physicians, delayed enrollment processes, problems with the PECOS system, and infrequent updates make it impossible to establish a firm implementation date at this time. It is our belief that Congress did not intend to disrupt medically necessary services to Medicare beneficiaries and would agree that CMS must ensure they are capable of maintaining the system that conditions payments to Medicare providers and supplies. In addition, physician cooperation is paramount in order to implement the PECOS enrollment requirement. CMS must ensure they have an effective education campaign with ongoing outreach to physicians and eligible practitioners.

II. QUALITY

IDENTIFY FEDERAL SPECIALISTS TO RESOLVE SURVEY DISCREPANCIES AND ESTABLISH AN INFORMAL DISPUTE RESOLUTION (IDR) PROCESS

ISSUE: Issues with Medicare certification surveys and interpretations of the Conditions of Participation for Home Health Agencies have created survey problems in many parts of the country. The resulting controversies have not been adequately addressed in current guidelines and regulations. Lacking an effective formal appeal process, agencies are often put in the position of admitting error and submitting a plan of correction even though the agency believes itself to be in compliance. The Secretary's Advisory Committee on Regulatory Reform identified the lack of alternative dispute resolutions as one of the major regulatory problems facing Medicare providers. As a result the Committee adopted a resolution to the Secretary for issuance of a notice of proposed rulemaking that would require implementation of an Informal Dispute Resolution (IDR) program. Of additional concern is CMS's position that their agreements with the state survey agencies precludes them from arbitrating differences between survey agencies and providers. Therefore, home health agencies have been required to submit plans of correction, thus admitting guilt to deficiency citations, in cases where the agency is in the right.

In view of the planned issuance of new proposed home health conditions of participation there needs to be a means of clarifying requirements under the new regulations other than training by deficiency.

RECOMMENDATION:

1. Retain final responsibility for interpretation and application of federal regulations rather than abdicate authority to states
2. Work with industry representatives to develop an effective communications process among CMS, surveyors and the industry.
3. Identify one or more persons to be available to answer questions and resolve conflicts between surveyors and providers prior to issuance of statements of deficiency.
4. Develop regulations for an arbitration process, such as an IDR by an independent body, to address issues that cannot be resolved between surveyors, agencies and the CMS interpretation experts. The IDR should:
 - a) Afford providers opportunity for a face-to-face review of contested deficiencies.
 - b) Be incorporated as a required step in all provider appeals related to survey and certification.

Arbitration and clarification should stop the clock on immediate jeopardy citations and occur prior to the closure of an agency for all challenged deficiencies.

Examine survey trends to identify states or parts of states showing aberrant deficiency patterns (e.g., where every agency is cited with one or more condition level deficiencies) and provide needed training of surveyors and/or providers.

RATIONALE:

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

By establishing an organized process for resolving disagreements that can be accessed prior to the formal appeal process, both surveyors and providers would be in a better position to appropriately fulfill their responsibilities and providers will have due process prior to closure and irreparable harm.

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

ISSUE: State surveyors for Medicare certified providers often survey all types of providers, i.e., 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 intermediaries 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, without an adequate appeals process. Although CMS required projection of costs for training, including on-site, web casts, and satellite broadcasts, there is no mechanism for enforcement or penalties for failure to participate. Surveyors have been resistant to computerized documentation of care, requiring home health agencies to print hard copies of records required for review.

RECOMMENDATION:

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 fiscal intermediary (FI);
5. Ensure consistent interpretation and application of the regulations
6. Utilize technology to reach all surveyors instead of only a small group such as, web casts, 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 on-line record review.

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 healthcare background
4. Required to compensate surveyors commensurate with area standards.

CMS should promote communication between survey agencies and intermediaries:

1. A formal procedure for sharing information between the FIs and state survey agencies (SA) should be developed.
2. SAs should report suspected coverage problems to the FIs and the FIs should report suspected quality problems to the SAs.
3. FISS 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. 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 intermediary, 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.

INCREASE FLEXIBILITY IN THE APPLICATION OF THE CONDITIONS OF PARTICIPATION

ISSUE: CMS requires the application of all of the Medicare Conditions of Participation (CoP) to all patients served by the Medicare-certified agency regardless of payer source or services. These requirements increase the cost of services to all payers. Yet, one CoP, supervision of home health aides, has been written to provide flexibility in application based on service needs. Another, OASIS, varies depending on payer, but CMS plans to apply OASIS requirements to all patients in the future. The Secretary's Advisory Committee on Regulatory Reform adopted a recommendation apply certain Medicare Home Health CoP to Medicare patients only.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003, Section 953 calls for the GAO to report to Congress on flexibility in applying home health conditions of participation to patients who are not Medicare beneficiaries. This report was suspended pending CMS' completion of their Suspension of OASIS Data Collection on Non-Medicare and Non-Medicaid Patients study. The results of the study, which were not made public until December 2007, do not provide any conclusive recommendations.

RECOMMENDATIONS:

1. Allow HHAs flexibility in application of the CoP to payers other than Medicare.
2. Limit application of the following requirements to medically unstable patients and patients receiving medical interventions for treatment of diseases only:
 - a) Plan of care (42 CFR §§484.18(a) and 484.18)
 - b) Advance directive (42 CFR §484.10(c)(2)(ii))
 - c) Comprehensive assessment (42 CFR §484.55) at specific time points
3. Limit the application of medication monitoring (§484.18(c)) requirements to those patients receiving nursing services, regardless of the payer.
4. Apply OASIS requirements to Medicare patients only.
5. Ensure input from home health providers and associations in the GAO analysis of the impact of flexibility of application of the CoP.

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

Advance directives are not indicated for medically stable persons and persons not receiving medical intervention for treatment of diseases, such as maternity and newborn patients.

It is not necessary for physicians to review and sign the plan of care for medically stable persons receiving health promotion and personal care services according to state nurse practice acts. Physician order requirements were designed for legal authority to provide care and control of utilization. Nursing and therapy practice acts now recognize all but invasive procedures as independent aspects of practice, so orders are not usually required for legal coverage. Physicians'

orders, with the intent of controlling utilization, are a payer issue rather than an operations or practice issue. If a payer wants to require this and assume the costs thereof, it should be a condition of payment.

Patients' medication monitoring should be the responsibility of physicians and pharmacists when home health patients require only therapy, medical social work or aide services.

OASIS data collection and reporting is not covered by most payers. Medicaid payments do not cover the cost of care in most states before the added burden of OASIS.

Home health providers and associations have expertise and in-depth knowledge needed by the GAO to thoroughly investigate the impact of flexibility in of application of the CoP to non-Medicare patients.

INCREASE FLEXIBILITY IN AIDE SUPERVISION REQUIREMENTS

ISSUE: The current Conditions of Participation (CoP) for home health and hospice require one aide supervision visit to every home health/hospice patient receiving skilled services every two weeks by an RN, with or without the aide present (42 CFR §484.36(d)). Therapists are permitted to perform aide supervision in therapy only cases. For home health patients not receiving skilled services, the aide supervisory visit must occur at least every sixty days with the aide present. The purpose of the supervisory visit is to assess relationships with the patient and the need for services. The CoP also require HHAs to complete a performance review for each home health aide at least every 12 months (§484.36(b) (2)). These requirements do not promote the most efficient or effective aide supervision. CMS requested recommendations for changes to supervisory requirements when the proposed CoPs were published. If CMS changes the aide supervision regulations, there is a concern that states will not update their requirements to match changes promulgated by CMS.

In addition, CMS has expanded the bathing competency requirements for hospice aides in the revised hospice CoPs to include competence in sponge, shower, *and* tub bathing. CMS has expressed its intent to require the same for home care aides (HCAs). Under the current CoPs for home care agencies, HCAs are only required to demonstrate competency in performing a sponge, shower, *or* tub bath. Requiring HCAs to demonstrate competency in all bathing methods is burdensome, and depending on the patient assignment, may not be appropriate. Furthermore, HHAs have been functioning under this CoP since 1994 without compromising patient safety or quality of care.

RECOMMENDATION:

1. Eliminate the current supervisory requirements.
2. Focus aide supervisory requirements on the aide, not the patient.
3. Allow HHAs to establish their own policies for frequency of aide supervision based on the aide's skills, experience, and past performance.
4. At a minimum, require supervision of every aide every sixty days in at least one home while the aide is performing patient care.
5. Allow LPNs/LVNs to supervise home health aides.
6. Allow therapist to perform aide supervision as appropriate, regardless of whether nursing services are being provided.
7. Urge states to adopt rules for aide supervision that mirror federal requirements.
8. Only require competency in tub bathing if the aide assignment requires the skill.

RATIONALE: Assessing patient needs, developing a plan of care, and care coordination (including aide services) are already the home care professional's responsibility. The current regulation does not ensure that every aide is observed performing the job functions on a regular basis. Skills and knowledge of home health aides vary widely depending on training and experience. Therefore, frequency of supervisory visits should reflect these variations. Supervisory visits to observe the aide's performance of skills and interaction with patients provide opportunities for ongoing performance review, corrective action, and teaching. Additionally, consistent federal and state requirements will eliminate conflicting and burdensome rules. Supervision of every aide every two weeks creates an unnecessary strain on limited nursing resources. Since therapists are deemed capable of supervising home health aides in therapy-only cases, they should not be prohibited from doing so in nurse/therapy cases. Furthermore, licensed practical/vocational nurses have sufficient training in personal care to effectively evaluate and supervise aide services.

IMPROVE AIDE QUALIFICATIONS TO PROTECT CONSUMERS

ISSUE: Regulations require training and/or competency evaluation for home health aides working in home health agencies and hospices (42 CFR §484.36). Therefore, some aides may not receive training. This may be appropriate for workers with experience, but could be insufficient for new workers. Home health aide training and testing is provided primarily by the hospice or home health agency.

In the proposed CoP, CMS suggested that nurse aides in good standing with State registries for nursing homes be considered qualified home health aides. Nursing home regulations include training requirements, approved training programs, and a registry for nurse aides. CMS has suggested that there should be more consistency between home health/hospice and nursing home regulations for aides.

CMS has included a criminal background check requirement for home health aides in the revised hospice CoPs. However, currently there is no national system for conducting background checks and many local systems are too narrow in scope and lack timely responses.

There are home care workers who function at a less complex level than the home health aide (e.g., homemakers, personal care aides). However, because of the CMS policy to apply the CoP to all clients and services the agency offers, all home health aides must meet the qualifications cited in 42 CFR §484.36. The only exceptions are state Medicaid personal care aides.

RECOMMENDATIONS:

1. CMS' core requirements should be consistent for home health aides working in all settings. Aide training and certification programs should address core content applicable to all aides as well as site-of-practice specific requirements and certification. These requirements should apply to Medicare as well as all Medicaid programs (e.g., PCA, waiver programs).
2. CMS should include in the HHA-approved training program the Home Care Aide Code of Ethics (developed by the Home Care Aide Association of America in 1999), which focuses on the basic principles of quality care and contains guidelines for client's rights and home care aide's rights.
3. There should be three levels of certification with specific training and testing requirements for each level as proposed by the Home Care Aide Association of America's position paper entitled "National Uniformity for Paraprofessional Title, Qualifications, and Supervision." The nurse aide and home health aide should be required to meet the level III requirements described in this paper.
4. If training is required, certified aides presently working in home care should be grandfathered.
5. Training programs should be approved by the state or by an approved accrediting organization.
6. Additional orientation hours should be provided to aides to assist the aide to adjust to home care.
7. Educational institutions and community organizations, as well as providers, may be approved by these accrediting organizations to offer training and competency evaluation programs
8. A national registry for aides practicing in all settings (home care, nursing homes and hospitals) should be established to maintain an up-to-date list of aides who are in good standing.
9. A system for criminal checks should be developed that is organized, reasonable in cost and will provide up to date information in a timely manner. (See Make Personnel Qualifications Consistent and Require Criminal Background Checks)

RATIONALE: The basic job functions for home health aides and aides in other settings are the same with the differences being in application to a particular setting. A consistent training and certification program would prevent unnecessary duplication and allow easier mobility of home health/hospice workers. Aides would only have to complete the site-specific requirements when changing settings. Home health agencies/hospices would be able to accept with confidence a previous certification from an approved program.

There are different levels of home health/hospice workers with some only performing homemaker functions, so different levels of training and competency evaluation are indicated. Consistency in training programs will also better prepare hospice aides to provide personal care services to nursing home residents enrolled in a hospice program.

Home health aides and nursing home aides should be tracked through the same registry since workers may move in and out of these settings. Although criminal checks are indicated, there is no systematic and effective way to accomplish them in a timely manner.

ENSURE FAIR APPLICATION OF IMMEDIATE JEOPARDY CITATIONS AND APPEAL RIGHTS

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

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

RECOMMENDATIONS:

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

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

necessary to avoid citations and termination proceedings based on risky situations that result from patient's choice.

Home health agencies lack a true right of appeal since appeals cannot be filed until after the agency has been terminated. Beneficiaries often choose to remain in unsafe, non-therapeutic situations, and protective service agencies frequently fail to intervene in response to home health referrals.

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

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

ISSUE: The Omnibus Budget Reconciliation Act of 1987 (OBRA-87) authorized administrative and civil money sanctions against agencies that are not in compliance with the Conditions of Participation. The "intermediate sanctions" could be imposed in addition to or in lieu of termination from the Medicare program. With implementation of the Medicare reforms contained in the Budget Reconciliation Act of 1987, P.L. 100-203, the impact of deficiencies became increasingly serious whether or not they lead to program termination recommendations. Agencies with conditional deficiencies are barred from performing home health aide training; surveyor reports of deficiencies are available to the public through inquiries to home health hotlines; and intermediate sanctions, including civil monetary penalties, may be levied against agencies for certain deficiencies.

CMS developed a range of sanctions, specific procedures and conditions for imposing sanctions and the severity of each sanction as proposed rules published in the Federal Register notice of August 2, 1991. The proposed rule does not identify which conditions or standards of participation are more serious than others. In addition, the guidelines are vague regarding temporary management and civil money penalties. Final regulations were expected in 1995, but have not yet been published. Since the Medicare Prescription Drug, Improvement and Modernization Act of 2003 required final rules must be published within 3 years of the proposed rule, it is anticipated that a new proposed rule will follow.

Current appeal procedures do not adequately protect providers from inaccurately issued deficiencies. An agency may receive deficiencies that lead to the agency being terminated from program participation. The agency has a right to appeal this determination through a hearing before an administrative law judge (ALJ) and appeal to the Departmental Appeals Board. However, the appeal of a termination notice does not suspend the termination process. An agency may be subjected to public notice of termination and may be required to transfer all Medicare patients before the ALJ finds that the deficiencies cited are unsupported by statute and regulation. For example, a home health agency successfully appealed its termination only to be reinstated nearly two years later by which time the agency's operation had virtually ceased and could not be restarted.

More commonly, the agency receives deficiencies that do not result in a recommendation for termination. But the surveyor demands that the deficiencies be corrected. No formal appeal mechanism exists for agencies that disagree with the findings or interpretations of a surveyor. Lacking a recommendation for termination, the Centers for Medicare and Medicaid Services (CMS) Regional Office is not involved. The agency's only recourse is to informally appeal to the state survey agency and/or regional CMS office to discuss the deficiencies in question, even though the state or regional office may not be receptive to resolving the issues. The agency may be subject to significant costs and operational changes in correcting nonexistent deficiencies.

The 2003 Medicare reform legislation allows for expedited judicial review of provider agreement terminations in circumstances where facts are not in dispute. However, this change would be of limited value since it would be usable only in rare circumstances. In addition, the legislation requires the Secretary to develop a "process to expedite proceedings" in termination cases. This change will not affect the timing of appeal rights that begin only after termination. CMS was considering the

establishment of an alternative dispute resolution process to address survey deficiencies but no progress has been made.

RECOMMENDATION: CMS should include the following points in the regulations implementing OBRA-87 Sanctions:

1. Home health agencies should be allowed access to a formal appeals process that can be implemented prior to termination.
2. Agencies should be able to continue to provide services, and public notices of deficiencies and issuance of information regarding deficiencies subject to appeal should be suspended until the issuance of a final ruling
3. Only condition level deficiencies that impact quality of care should warrant sanctions.
4. Condition level deficiencies should be differentiated from standard level deficiencies and those that pose a threat to patients.
5. Complaint surveys should be based on "significant" complaints that affect patient health, safety, and rights (42 CFR §§484.10, 484.18, 484.30, 484.32, 484.34, and 484.36).
6. Personnel responsible for imposing sanctions should be trained and tested on the CoP.
7. An objective structured system for imposing civil money penalties should be developed.
8. All surveys should conclude with an exit interview to permit the provider to clarify issues.
9. The time frame should be amended to allow for fourteen days between the last survey and imposition of sanctions.
10. All recommendations for sanctions should be subject to region office review prior to imposition.
11. Sanctions should not be imposed for deficiencies that have been self-corrected by the provider prior to determination of noncompliance by the Secretary.
12. Further study should be undertaken to determine how to relate payment for services and sanctions to quality of care.
13. The trade associations must be permitted to review and work with CMS prior to development of regulations to assure that intended regulations are clearly explained.
14. Interpretive guidelines should be made available with those regulations.
15. Development of an alternate dispute resolution process should be undertaken with input from the industry (See "Identify Federal Specialists to Resolve Survey Discrepancies...").

RATIONALE: It is unfair to require agencies to write plans of correction for deficiencies that do not actually exist. There already are processes in place that provide expedited termination authority for situations where patients are potentially placed in life-threatening situations. Establishment of an alternate dispute resolution process will provide an avenue for appealing potentially inappropriate survey findings before a plan of correction is required.

It is important that the sanctions and appeals process assure equitable application of the Omnibus Budget Reconciliation Act of 1987 (OBRA-87, P.L. 100-203) provisions and they protect agencies from unwarranted penalties. The type of sanctions, levels of civil money penalties, and the correlation between the sanctions and specific deficiencies is critical in assuring that the provisions are implemented appropriately and equitably. Therefore, any intermediate sanction should be subject to objective standards for application and review. Furthermore, specific guidelines for surveyors are essential to ensure equitable imposition of sanctions.

REQUIRE REGION OFFICE REVIEW OF CHALLENGES TO 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 resulting in arbitrary classifications by state survey agencies. States are citing agencies with more condition level deficiencies, stating that the CMS region office expects them to do so. Often state surveyors 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 side 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.

Regional offices 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.

RECOMMENDATION:

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 Region Office and a response given to the HHA/hospice within 30 days.
3. Challenges to a deficiency should stop the clock until the Region Office 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

Region Office 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 Region Office reverses the determination, then the HHA/hospice can abandon the corrective action plan.
6. Region Office determinations need to be included in the file for public disclosure. If an HHA 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. 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.

In 1998, Congress authorized the U.S. Department of Justice and the Federal Bureau of Investigation to create a system whereby home health agencies could access a criminal background check from a national database relative to existing or prospective home care personnel. The background check system developed by the FBI is not widely available to home health agencies as a result of the reluctance of state entities to implement coordinating systems. Further, expeditious access to the criminal background check is relying upon technology that is not readily available in an efficient manner to home health agencies. Alternative criminal background check systems are expensive, cumbersome and often do not reflect the overall background of the individual screened.

The Centers for Medicare and 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 who are 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.

RECOMMENDATION:

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 requirement 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 care 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 over burdensome.

SUPPORT REQUIRED QUALITY IMPROVEMENT PROGRAM

ISSUE: The current Conditions of Participation (CoP) require quarterly clinical record reviews and an annual agency evaluation but not an overall patient-centered quality management program. The current evaluation of home health agencies (HHAs), although improved with home visits by surveyors, does not adequately assess the quality of care delivered.

CMS requires home health agencies to use standard patient assessment items to identify and report quality measures of care. At the present time home health agencies must access the quality monitoring reports for outcome and process measures and include them as part of the agency's clinical record review and annual program evaluation. The use of these quality measure reports for agency quality improvement activities is voluntary at this time, but the reports are used both for survey preparation and process. In addition, select outcome and process measures derived from the quality reports are used for public reporting.

CMS will be re-issuing the proposed home health CoPs in the near future, the use of these quality measure reports will likely be mandatory as part of an agency's quality assessment performance improvement program with more specific guidelines to surveyors for incorporation of Outcome and Assessment Information Set (OASIS) and quality measure reports in the survey process. CMS will issue guidelines to surveyors for incorporation of OASIS and quality measure reports in the survey process. In the meantime, Quality Improvement Organizations (QIO) were charged with helping home health agencies implement quality improvement based on outcome measures on a voluntary basis under their 7th Scope of Work. In the 8th Scope of Work, QIOs help agencies identify and implement best practices to improve the quality of care delivered.

RECOMMENDATION: Requirements for quality improvement based on patient outcome and process measures should allow flexibility in design of the quality management program.

1. Evaluation of agency "quality assessment performance improvement" programs should be based on their effectiveness, not prescribed design and content.
2. Broad parameters of quality improvement requirements should be specified but providers should be allowed to design their own quality management program.
3. The following conditions must be met in implementing an outcome measurement system:
 - a. Indicators must be reliable and valid.
 - b. Outcome and process measures should be limited to those that most accurately predict quality.
 - c. An accurate method for risk adjustment must be available.
 - d. Standard assessment items must be limited to those items needed for quality measurement and risk adjustment.
 - e. The system must be simple, reports easily accessible and have clinical utility.
 - f. A mechanism must be available for CMS to validate agency data.
 - g. Ongoing evaluation and refinement of the entire system must take place so that changes can be made as needed.
4. Reimbursement methodology should ensure appropriate compensation to agencies for the cost of collecting and analyzing data needed for an effective quality improvement program.
5. Outcome reports must be timely, readily available, and in easily manageable format.

6. Surveyors must be trained on appropriate use of potentially avoidable events, outcome measure and process measure reports as resources for care investigation rather than the basis for issuance of citations.
7. Alternate systems that are appropriate, simple, and easy to implement should be investigated for measuring quality for non-Medicare patient.
8. Continue to provide prompt and useful assistance from Quality Improvement Organizations to home health agencies seeking to improve their quality of care.

RATIONALE: The ideal quality management system is based on what happens to the patients served. Several items on the OASIS assessment tool, from which the OBQI and OBQM reports are derived, have been challenged on their validity and reliability. PBQI reports from the recently added process measures are too new to be challenged on their validity and reliability. Until a quality performance program is designed that is evidenced based using a variety of measure types, every effort must be made to ensure surveyors realize the limits of assessing quality of care using quality reports generated by the OASIS assessment tool. Additionally, CMS should continue their support of QIOs to assist home health agencies in quality improvement efforts.

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

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

CMS, in conjunction with the National Quality Forum (NQF), identify and analyze all available home health quality indicators in order to determine which ones are most appropriate for public reporting. Public reporting of home health quality measures began in 2002 and was limited to outcome based measures. CMS added 13 process measures to Home Health Compare in October 2010. All of the process measures received a time limited endorsement by NQF through March 2011. Currently, there are twenty-three quality indicators publicly reported. The indicators consists of 10 outcome measures and 13 process measures.

Home Health Compare provides a listing of Medicare participating home health agencies and the geographic area that they serve along with information regarding the performance of the agencies in terms of certain patient outcomes. Actual use of this tool as a guide to provider selection is unknown. Further, there have been some questions raised regarding the accuracy and relevance of the information contained in Home Health Compare.

RECOMMENDATIONS:

1. Continue to work with the home care industry, including providers, to ensure the use of valid, reliable quality indicators.
2. Avoid adding unnecessary and burdensome requirements to collect data on quality indicators that have not been researched and proven to be necessary for public awareness and quality assessment.
3. Present measures in ways that are useful and understandable to the public.
4. Continuously evaluate and update measures.
5. Establish thresholds or trigger points for quality reporting instead of averages.
6. Provide assistance to home health agencies in identification and implementation of best practices for improved care.
7. Conduct research into home health appropriate structure and process measures

RATIONALE: The usefulness of quality reporting hinges on the accuracy of the quality measures selected as well as the ability of consumers to relate to them. Measures should not be static, but rather need to change with advances in health care. A system of reporting that does not provide opportunities for improvement does little to help consumers in the long run.

A combination of structure, process and outcome measures are needed to adequately determine whether care is provided in accord with currently acceptable standards.

However, ongoing scrutiny of publicly reported measures is essential. Large numbers of quality indicators are not necessarily helpful to the public, and can be confusing when trying to identify an

appropriate provider of care. In addition, unless proven essential to quality, collection of data is unnecessarily costly and burdensome.

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 that HHAs 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 be published within 3 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-routing 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. There is a growing shortage of health care workers, particularly nurses, that is impacting all providers. 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 the opportunity 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, PPS 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."

RECOMMENDATION: 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.

ESTABLISH BRANCH OFFICE AND SERVICE AREA REQUIREMENTS THAT REFLECT QUALITY MEASURES

ISSUE: In response to the Medicare, Medicaid, and SCHIP Benefits Improvement Act of 2000 (BIPA) prohibiting consideration of time or distance from the parent site as the sole determinant of branch status, CMS revised its guidance to surveyors in the State Operations Manual (SOM) to resolve problems related to previous interpretations of branch office requirements as meaning branches must be within 50 miles or one hour driving time. However, other problematic requirements are included that fail to take longstanding home health structures and practices into consideration.

According to SOM instructions, home health agencies may not provide services across state lines unless the states involved have entered into formal reciprocity agreements. However, many home health agencies have a long history of providing services in multiple states, either directly from the parent or through branch offices located in the other states, where no reciprocity agreements are in place. In addition, language was added to the manual that requires home health service areas to be contiguous. Yet, many state approved home health services areas are noncontiguous. Some noncontiguous areas are served by field staff sent by a parent agency, while others are served by staff from a noncontiguous branch.

The GAO report in 2002 identified concerns that the quality of branch office services is not being evaluated when only the parent is surveyed. The issuance of branch office numbers to enable the creation of reports for branches helps to address this issue. In addition, there is no prohibition against reviewing services to patients served from branches, even if in another state.

RECOMMENDATION:

1. Allow flexibility to home health agencies in the establishment of organizational structures as long as they meet state requirements.
2. Enforce current regulations related to quality, administrative control and supervision.
3. Monitor states and Region Offices to make certain that branch office disapprovals are not based on mileage/travel time as well as distances between office and patients' homes.
4. Require all state agencies to enter into reciprocity agreements as a condition of their contract with CMS.
5. Until agreements are in place, allow all home health agencies currently providing services across state lines where there is no reciprocity agreement to continue to do so through a "grandfather" provision.
6. Eliminate contiguous area requirement.
7. Survey quality of care provided by home health agency branch offices.
8. Establish appeal rights for branch office denials.

RATIONALE: One of the goals of the CMS regulatory initiative was administrative simplification. This will not be achieved merely by re-interpreting old regulations that do not address the current environment. In this age of rapid contact via telephone, fax machines, and pagers, communication between various service sites is instantaneous. Modern transportation and mail services in addition to telecommunication promote effective sharing of administration, supervision, and services between sites. Current site definitions and rules have not kept pace with changes in the health care environment.

HHAs that serve either large geographic rural areas or densely populated metropolitan areas operate branch offices and subunits in order to: 1) provide a home base for personnel that is close to the patients that the agency serves 2) where supervision is available, 3) where patient records will be accessible, 4) where supplies are available, and 5) where personnel can meet to coordinate care with others who are serving the patient. Establishment of branch offices is a very efficient, cost-effective means of providing high quality service while avoiding duplication of administrative positions and functions.

Enforcement of reciprocal agreements and contiguous area requirements will seriously impact access to home health services for many patients in need. Medicare is a national program with uniform conditions of participation throughout all states. The failure to require reciprocity agreements can deprive residents of one state the availability of home health services centered in a neighboring state, many of which are centered in a metropolitan region that borders another state. Records can be taken to the parent. Since surveyors' authority to survey certified agencies comes from federal rather than state authority there should not be a restriction on a surveyor crossing a state line to conduct visits to branch office patients in another state.

ENSURE THE CMS S&C GROUP EMERGENCY PREPAREDNESS PLAN ADEQUATELY ADDRESSES THE NEEDS OF PROVIDERS OF SERVICES IN THE HOME

ISSUE: In response to the 2005 hurricane season and concerns over an avian influenza pandemic, several federal agencies, including the Department of Health and Human Services (HHS) have developed emergency planning guides and recommendations specifically for health care providers. Adding to list of emergency planning initiatives is Centers for Medicare and Medicaid Services (CMS) Survey and Certification Group.

The CMS Survey and Certification Emergency Preparedness Stakeholders Workgroup, which includes representatives from federal and state public health organizations, health care trade associations and public interest groups, held meetings from October 2006 through 2009.

Similar to other federal emergency preparedness plans already developed, the initial S&C group plan was primarily aimed towards preparations and actions for in-patient facilities that did not adequately address the unique needs of the home health care industry.

Participation of home care representatives on the workgroup has provided an opportunity to present the unique needs of home health care providers in emergency planning to federal regulators. However, the role of home health care in emergency preparedness and response is still misunderstood by many federal and state officials involved in disaster planning.

RECOMMENDATIONS:

1. Ensure home health is adequately represented when developing emergency preparedness guidelines.
2. Ensure requirements in emergency preparedness plans such as patient evacuation plans, shelter-in place plans and patient supply provisions are presented in context appropriate for home health agencies to implement.
3. Ensure any Emergency Preparedness Plan addresses both plans for home care patients and the agency office setting.
4. Ensure an emergency preparedness plan as part of a Medicare Condition of Participation is not implemented unless the above conditions have been met.

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 Survey and Certification "Emergency Preparedness Plan" address mass casualty events as it relates primarily to inpatient settings. Recommendations for action in many disaster-planning models do not consider the uniqueness of home care.

The Survey and Certification Emergency Preparedness plan and any emergency preparedness plan as a Condition of Participation for home health care must be tailored appropriately for home health care and hospice providers to avoid unrealistic expectations that will ultimately subject an agency to unfair deficiency citations.

PROVIDE INFORMATION TO HOME HEALTH AGENCIES ON THE INTRODUCTION OF THE COMSUMER ASSESSMENT OF HEALTHCARE PROVIDERSAND SYSTEMS (CAHPS) PATEINT PERCEPTION OF CARE TOOL

ISSUE: The Home Health Care CAHPS survey is part of a family of CAHPS surveys that ask patients about their health care experiences and creates a standardized survey for home health patients to assess their home health care providers and the quality of their home health care. Prior to this survey, there was no national standard for collecting such information that would allow comparisons across all home health agencies.

The survey captures topics such as patients' interactions with the agency, access to care, interactions with home health staff, provider care and communication, and patient characteristics. The survey allows the patient to give an overall rating of the agency, and asks if the patient would recommend the agency to family and friends

Field testing of the tool was conducted to determine the length and content and to test the reliability and validity of the survey items.

Administration of the survey will be conducted by multiple, independent survey vendors working under contract with home health agencies to facilitate data collection and reporting.. Initially, home health agency participation was voluntary. However, CMS announced in the Home Health Prospective Payment System Rate Update (Calendar Year 2010), that agencies must continuously collect Home Health Care CAHPS beginning 4th quarter 2010 to be eligible for the full annual payment update for CY 2012. In addition, the Home Health CAHPS data will be included on Home Health Compare to public report patient experiences with home health care agencies along with other publically reported quality measures. CMS anticipates public reporting of the Home Health Care CAHPS data by Spring/Summer 2011.

RECOMMENDATIONS:

- 1) Ensure the home health industry is well informed of how CMS intents to use the CAHPS survey and provide a reasonable time line for required implementation.
- 2) Ensure home health industry involvement in measure selection for public reporting of the Home Health Care CAHPS data
- 3) Ensure additional costs incurred by agencies associated with implementing the CAHPS survey are considered when updating annual payment rates for home health providers.

RATIONAL

A standardized survey to measure patients experience with their home health care will be a valuable tool for providers, patients, and payers of home health care services. However, administering the home health CAHPS tool will place additional financial burdens on providers since they will be required to contract with a CMS approved vendor to conduct the monthly surveys. In addition, certain survey items will ultimately be required for quality reporting. Therefore, agencies need to be fully informed on how the tool was developed, tested, and finalized. The home health community should also be involved in the decision making process for quality measure selections derived from the Home Health Care CAHPS survey.

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

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

In recent years, Medicare has been under-funded for many of its administrative responsibilities. With respect to survey and certification, Medicare has found that the contracted state agencies have not been able to handle all of the complaints, periodic surveys, and initial certifications on a timely and comprehensive basis. The main reason for that shortcoming is inadequate administrative funding. As a result, Medicare has curtailed initial certifications in many states and backlogs on complaint response and the periodic surveys continue to grow. While initial certification applicants can use the alternative of a private “deemed status” entity, that alternative is costly and can require administrative changes in a provider’s operation that are unnecessary under federal standards.

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

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

ESTABLISH APPROPRIATE PROCESS FOR APPROVAL OF BRANCH BY ACCREDITING BODIES

ISSUE: In 2007, The Centers for Medicare and Medicaid Services (CMS) instructed state Medicare survey agencies to prioritize federal survey functions into four priority “Tiers.” Tier 1 consists of statutory mandates, such as surveys of existing home health agencies and surveys related to complaints. State Survey agencies must complete the work in tier 1 before conducting initial surveys of new home health care providers or approving new branches.

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

RECOMMENDATIONS:

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

RATIONAL:

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

III. ADMINISTRATION

MAKE CERTAIN THAT HOME HEALTH AGENCIES HAVE A ROLE IN NEW HEALTH CARE DELIVERY MODELS

ISSUE: The Patient Protection and Affordable Care Act (ACA) calls for sweeping health reform. New health delivery models to be tested under the health reform bill includes: (a) chronic care coordination services to high cost Medicare beneficiaries, (b) better transitions, (c) paying for performance, (d) increased involvement of primary care physicians. Home health providers will have many opportunities in models, projects and programs established in the ACA, including the following:

Accountable Care Organizations (Sec. 3022)

ACO allows hospitals and physician groups and other groups providers identified by the Secretary to enter into agreements with HHS to be held accountable for quality, costs and overall care of Medicare beneficiaries.

Independence at Home (Sec. 3024)

The IAH program provides a new chronic care coordination benefit under Medicare for high cost beneficiaries with multiple specific chronic conditions. Physician/nurse practitioner directed teams provide care to beneficiaries in their homes and coordinate their care across all treatment settings.

Health Homes for Chronically Ill Patients (Sec. 2703)

Planning grants to states to develop a new state plan option to permit Medicaid enrollees with at least two chronic conditions, one condition and risk of developing another, or at least a serious and persistent mental health condition to select a designated provider or health team operating with such a provider to serve as the individual's health home for purposes of providing the individual with health home services.

Providing services to individuals with a postpartum condition and their families (Sec. 2952)

Award grants to states, local government and/or non-profits to support education and services that diagnose and manage post-partum conditions. Projects may deliver or enhance out-patient home-based supports, inpatient supports, quality of available supports, and education about these issues.

Community Transformation Grants (Sec. 4201)

The Secretary of Health and Human Services shall award competitive grants to State and local governmental agencies and community based organizations for the implementation, evaluation, and dissemination of evidence-based community preventive health activities in order to reduce chronic disease rates, prevent the development of secondary conditions, address health disparities, and develop a stronger evidence-base of effective prevention programming.

National Diabetes Prevention Program (Sec.10501)

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a national diabetes prevention program targeted at adults at high risk for diabetes in order to eliminate the preventable burden of diabetes. The program shall include a grant program for community-based diabetes prevention program model sites.

Healthy Aging, Living Well; Evaluation Of Community-Based Prevention And Wellness Programs For Medicare Beneficiaries. (Sec. 4202)

The Secretary of Health and Human acting through the Director of the Centers for Disease Control and Prevention, shall award grants to State or local health departments and Indian tribes

to carry out 5-year pilot programs to provide public health community interventions, screenings, and where necessary, clinical referrals for individuals who are between 55 and 64 years of age.

Grants or Contracts to Establish Community Health Teams to Support the Patient-Centered Medical Home. Sec. 3502

Creates a program to establish and fund the development of community health teams to support the development of medical homes by increasing access to comprehensive, community based, coordinated care. The health team is to collaborate with local primary care providers and existing State and community based resources to coordinate disease prevention, chronic disease management, transitioning between health care providers and settings and case management for patients.

Community Based Transitions Program (Sec. 3026)

Funding will be provided to hospitals with high admission rates and certain community-based organizations that improve care transition services for “high-risk Medicare beneficiaries” A community based entity means an appropriate community-based organization that provides care transition services under this section across a continuum of care through arrangements with hospitals. These funds might provide opportunities for home health agencies.

Center For Medicare and Medicaid Innovation

Establish a Center for Medicare and Medicaid Innovation(CMI) in CMS; The purpose of the CMI is to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to individuals. Creates opportunities for chronic care and other initiatives -Funding home health providers who offer chronic care management services to applicable individuals in cooperation with interdisciplinary

Medicaid Money Follows the Person (MFP) Long Term Care Demonstration (Sec. 2403)

Extends the MFP Demonstration Program through September 30, 2016, and appropriates an additional \$450 million for each FY 2012-2016, totaling an additional \$2.25 billion.

Medicaid Waiver Demonstration Projects for Dual Eligibles (Sec. 2601)

Extends these demonstrations for five years, and, upon requests from a state, they can be extended for additional five year periods.

Bundled Payments Medicaid (Sec. 2704)

Demonstration project in Medicaid to pay bundled payments for episodes of care that include hospitalizations, including physician services provided within the hospital. Home health agencies might have an opportunity to partner with the hospital.

Demonstration Program to Improve Immunization Coverage (Sec.4204)

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a demonstration program to award grants to States to improve the provision of recommended immunizations for children, adolescents, and adults through the use of evidence based, population-based interventions for high-risk populations.

Demonstration Based on Study of Home Health Agencies (sec. 10315)

HHS Study and Report: By March 1, 2014, HHS must report results of a study with recommendations for legislative and administrative action, regarding home health agency costs for care provided to low-income beneficiaries or those in medically underserved areas, and those with varying levels of severity.

Home Health Medicare Demonstration Project: HHS Secretary may provide for a four-year (beginning no later than January 1, 2015) \$500M demonstration project to test whether making

payment adjustments based on the study substantially improve access to care for patients with high severity levels of illness or for low-income or underserved Medicare beneficiaries.

National Medicare Pilot Program on Medicare Payment (Sec. 3023)

A national Medicare pilot program to develop and evaluate paying a bundled payment for acute, inpatient hospital services, physician services, outpatient hospital services, and post-acute care services for an episode of care that begins three days prior to a hospitalization and spans 30 days following discharge.

RECOMMENDATION: Make certain that home health agencies are included in planning and opportunities to be leaders and active participants in ACA models, projects and programs.

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

ENSURE FAIRNESS UNDER MEDICARE CONTRACTING REFORM

ISSUE: Section 911 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) established Medicare Contracting Reform (MCR) which brought standard contracting principles to Medicare, such as competition and performance incentives that the government has long applied to other federal programs under the Federal Acquisition Regulation. Medicare Administrative Contractors (MACs) will perform the work now being handled by fiscal intermediaries and carriers in administering the Medicare fee-for-service program. MMA requires that CMS transition all work to MACs by 2011. Durable Medical Equipment (DME) MAC contracts were awarded in 2006 in the first MAC cycle.

Medicare Administrative Contractors (MAC): In March 2007, CMS announced that the home health and hospice workloads would be consolidated into four of the A/B MAC contracts. CMS will integrate the four home health and hospice jurisdictional claims workloads into the following four A/B MAC competitions:

- Jurisdiction 6 will include home health and hospice Jurisdiction D,
- Jurisdiction 11 will include home health and hospice Jurisdiction C,
- Jurisdiction 14 now in place and includes home health and hospice Jurisdiction A and
- Jurisdiction 15 will include home health and hospice Jurisdiction B.

Contracts were expected to be awarded to all jurisdictions responsible for home health and hospice by the end of 2008, with workload transition in March 2009. However, as of January, 2011 transition has taken place in only one jurisdiction due to protests lodged against CMS to contract awards. Transition in Jurisdiction A was seamless because the contract winner subcontracted with an existing RHHI to continue home health and hospice work for the New England area, thus eliminating the potential for transition problems. A final decision was made to award Palmetto GBA the home health Jurisdiction B contract and transition, which will be seamless since Palmetto is the current RHHI for that region, will also be seamless.

However, the transition in the two remaining home health and hospice Jurisdictions may be problematic. The current Cahaba GBA workload will be taken over by CIGNA, winner of the Jurisdiction 15, Home Health C contract. CIGNA expects to become operational for home health work effective June 13, 2011. Concerns lie in the fact that CIGNA has no experience in home health and there is no evidence that they plan to subcontract with a company currently processing claims and conducting review. The home health and hospice Jurisdiction D contract for the region now served by National Government Services (NGS) was awarded to Noridian, but remains under protest. Noridian also has no experience in home health and hospice claim processing or medical review.

Recovery Audit Contractors (RAC): In the Tax Relief and Health Care Act of 2006, Congress required a permanent and national Recovery Audit Contractor (RAC) program to be in place by January 1, 2010. The national RAC program is the outgrowth of a demonstration program that used RACs to identify Medicare overpayments and underpayments to health care providers and suppliers in California, Florida, New York, Massachusetts, South Carolina and Arizona. Home health and hospice providers were not included in the demonstration. Under the now formal nationwide RAC program, health care providers that will be reviewed include hospitals, physician practices, nursing homes, home health agencies, durable medical equipment suppliers and any other provider or

supplier that bills Medicare Parts A and B. Payment by CMS to RACs will be based on a percentage of the funds that are recovered for the Medicare program as a result of their work.

All four RAC contracts have been awarded and RAC work is underway. The impact of RAC work on home health and hospice claims will not be known until CMS approves of any home health and hospice RAC work plans for review targets and strategies, as required by RAC contracts. Accuracy of RAC determinations will need to be followed closely.

RECOMMENDATIONS:

Carry out seamless transition to MACs and the establishment of RACs by monitoring and taking corrective action to ensure:

1. Successful transfer of electronic records and back-up systems for timely payment on claims
2. Adequate level of MAC knowledge regarding the Medicare home health prospective payment system and their ability to process home health care claims
3. Ability of MACs to incorporate system updates issued by CMS with the minimum of errors and delays
4. Ability of MACs and RACs to interpret Medicare coverage rules to prevent inappropriate coverage denials during medical review
5. Timely conduct of medical review activities
6. Timely conduct of appeals
7. Close working relationship with providers and the establishment and communication of clear transition steps throughout the transition process and problem resolution
8. Appropriate edits for identification of improper billing practices
9. Education of providers of their rights of appeal

RATIONALE:

The transition from the current RHHIs to the new MACs has potential to cause tremendous hardship for home health providers if these new contractors do not have the ability to process claims seamlessly. Providers are at risk for experiencing significant cash flow problems while contractors “iron out glitches”. Inappropriate denials stemming from medical reviews will occur if these contractors are not well versed in the complexities of the Medicare coverage guidelines. Because of poor understanding of coverage rules, denials during the demonstration project were successful appealed in approximately 35% of all cases.

DEVELOP AN EFFECTIVE EMERGENCY PREPAREDNESS SYSTEM THAT INCLUDES HOME CARE AND HOSPICE AND ENSURES REGULATORY RELIEF

ISSUE: The terrorist attacks on New York City and Washington, DC, on September 11, 2001, and subsequent release of active anthrax spores through the U.S. Postal Service and the hurricanes of 2005 have dramatically underscored the vital role of all aspects of the health care delivery system, including home care, in addressing emergency situations. While the response to these unprecedented occurrences was exemplary, had there been large numbers of injured survivors to the terrorist attacks, the entire health care system would have been taxed beyond capacity. Home care and hospice agencies can be a fundamental foundation that can support the traditional hospital health care system during a time of disaster, since hospitals have very little surge capacity.

Immediately following the terrorist attacks on New York City, home care agencies and home care clinicians provided services to 5000 patients at ground zero. They rode bicycles to access their patients and paid for needed food, medicine, supplies and water out of their own funds. The inclusion of home care and hospice in emergency preparedness is crucial especially in an environment of surveillance, home isolation and home quarantine.

The hurricanes that struck the Gulf States in recent years, along with preparations for an impending influenza pandemic has brought to light that meeting the health care needs of individuals in times of crisis will require more efficient use of our nations' health care resources than currently exists. Home care and hospice are just beginning to be included in planning proposals for handling large scale disasters. During hurricanes Katrina and Rita home care and hospice professionals were instrumental in caring for patients housed in shelters and non-traditional health care facilities. Their ability to deliver health services to individual in non-structured environments without additional training makes them ideal as key responders in times of crisis. Home care and hospice providers can play a vital role in implementing pandemic influenza plans. Home care agencies and hospices already assist hospitals manage surge capacity, administer vaccines and antiviral medications and are in a position to participate in community outreach programs to disseminate necessary information to the public during an emergency. Yet, there is much that needs to be done to improve and ensure the readiness of Medicare-certified home care professionals in the event of a national emergency.

On November 25, 2002, President Bush signed into law the "Homeland Security Act of 2002" (Public Law 107-296). The Department of Homeland Security's primary mission is to help prevent, protect against, and respond to acts of terrorism within our nation's communities. Title V of the law - Emergency Preparedness and Response, directs the Secretary of Homeland Security (Secretary) to carry out and fund public health-related activities to establish preparedness and response programs. The Secretary is directed to assist state and local government personnel, agencies, or authorities, non-federal public and private health care facilities and providers, and public and non-profit health and educational facilities, to plan, prepare for, prevent, identify, and respond to biological, chemical, radiological, nuclear event and public health emergencies. Since September 11, 2001, tens of billions of dollars have been provided for first responders, including terrorism prevention and preparedness, general law enforcement, firefighter assistance, airport security, seaport security and public health preparedness. As such, Medicare home care providers should be included in the Secretary's emergency and preparedness response programs since they can be found within the private as well as public and non-profit health care centers.

CMS announced in a November 2008 letter to State Agencies that regulatory relief may be initiated in accord with a Q&A document that was prepared in response to Hurricane Katrina. CMS has a dedicated webpage where policies and procedures related to emergency response are posted and where all Medicare providers should go for up to date information during a local or national emergency. CMS has adopted this method of communicating relief from certain regulations during declared emergencies as standard operating procedure. However, additional considerations are needed to truly ensure uninterrupted service delivery and provider viability during disasters.

RECOMMENDATION:

1. Provide the leadership and resources to ensure fail-safe communication, collaboration, and coordination between the Department of Homeland Security, Health and Human Services, and state and local entities involved in protection of the public's health.
2. Include home care and hospice in the infrastructure as vital participants in efforts to develop state emergency preparedness plans.
3. Provide resources to ensure that home care agencies throughout the country have a better-prepared workforce to deal with biological, chemical, and radiological events as well as mass admissions and public health emergencies.
4. Make Federal resources available to home care and hospice providers for disaster planning, practice, and training.
5. Make Federal funds available to home care providers to educate and prepare them for nuclear, chemical and/or biological terrorism or a pandemic influenza outbreak
6. Make Federal resources available to support the development of public health outreach as well as fund a technology pass-through for needed technology infrastructure within home care and hospice agencies, e.g. communications systems and paperless documentation software and hardware.
7. Make Federal resources available to ensure coordinated disaster planning between hospitals and the home care system, as the maximization of surge capacity in hospitals is dependent on the surge capacity of home care to provide services to those discharged.
8. Establish additional regulatory relief measures for home care providers that can be activated at the time that disaster areas are designated.

RATIONALE: With respect to preparedness and response to disasters affecting the public health, it is critical that home care agencies' infrastructure be strengthened, and that the special qualities and abilities of health care providers of all types be utilized. As a discipline performed primarily in individual homes and the community, home care and hospice are essential to disaster preparedness and response efforts.

Home care has its foundation in and continues to act as an important element in our nation's public health system. In fact, as federal funding for an effective public health infrastructure has failed to keep pace with need, the nationwide network of home care and hospice agencies frequently have performed important functions that protect and serve communities.

Today, home care is the only "system" that is oriented to the community in a broad enough way to provide a massive infrastructure. The home care clinician of today is trained in public health service. They are able to assess the patient's symptoms as well as the environment in which they reside. They conduct patient and safety assessments, skilled care and treatment, educate patient and family, and assist with medical and social supports that are critical to the process of healing the sick and protecting the well. Today, these skills are essential to serve and protect our communities' health.

Because of medical advances in recent years, we often focus on hospitals. We have made significant investments in inpatient facilities and technologies, sometimes at the expense of our public health system. Today, we find ourselves facing the need to put back in place a network of providers that is trained and able to serve the public in a mobile flexible manner. We need the health care equivalent of the armed forces reserves, and we have that in home care. Integrating and connecting home health providers to other health care systems as well as to state and local governments can go a long way toward securing and establishing a preparedness and response program for the nation.

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 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 those entities to which the patient is referred in which the hospital has a disclosable financial interest. Some hospitals have misinterpreted HIPAA regulations, using them as the basis for restricting access of outside home health agencies to hospital patients.

CMS issued a final hospital discharge planning regulation in order to implement one of the BBA requirements in August, 2004. According to the final rule, for patients needing post-hospital hospice, home health or nursing home care, the patient must be given the choices of available Medicare participating post-hospital care providers such as Hospice Agencies, Home Health Agencies or Nursing Homes.

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 and the number referred to home health agencies or other entities in which the hospital had financial interest, or 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. As a result, CMS announced at a home health Open Door Forum that they intend to go back to Congress and request a change in this legislative requirement before publishing a new proposed rule.

RECOMMENDATION:

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 that 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 encounter and physical therapy assessment requirements further increase home health agency paperwork.

In January 2002, Health and Human Services Secretary Tommy Thompson established an advisory committee on regulatory reform to identify excessive and inefficient regulatory requirements and revise or eliminate those that are unnecessarily burdensome or that interfere with the delivery of quality health care. Although many recommendations were made by the advisory committee, only a small fraction of these recommendations have been implemented by CMS. For example, a number of recommendations were made for streamlining OASIS requirements. However, only a few of the OASIS streamlining recommendations have been implemented to date, and, in fact, the number of

OASIS items soared to over 130 with the addition of process measures.

The Deficit Reduction Act of 2005 required CMS to establish payment groups that reflect patient severity and related cost and resource use across post acute settings. In response, CMS awarded a contract for development of The Medicare Continuity Assessment Record and Evaluation (CARE) tool. This tool may replace OASIS to collect and transfer information about patients moving from acute to post-acute care and between post-acute care settings and to serve as a uniform assessment instrument that includes items measuring case mix at hospital discharge and explain expected resource use and outcomes in each level of post-acute care.

RECOMMENDATION:

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 the 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 & 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 provider 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.

In 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.

RECOMMENDATION

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 2-step approach:
 - 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.
 - Step 2 – Assistance for fuller interoperability and electronic prescribing capability as defined under the current safe harbor/exception.

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

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

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

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

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

The 1,700 page 2009 Hospital Inpatient Prospective Payment System Final Rule (Aug. 18, 2008) contained changes to the Stark physician self-referral rules that are not limited to hospitals or hospital issues. NAHC found one change regarding the timing of a physician's signature on contracts that affects compliance with an exception to the Stark provisions that applies to home health agencies and hospices, as well as to hospitals. In 2010, hospice rules were published in the Home Health PPS Update for 2011 and clinical laboratory rules were published in the 2010 Physician Fee Schedule. CMS has expressed concerns regarding the long amount of time it takes for a proposed rule to become a final rule. CMS has justified its practices on the ground of expediency.

RECOMMENDATION

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

RATIONALE

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

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

ISSUE: Most home health agencies and hospices are considered small business 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 meet its responsibilities of providing care to Medicare beneficiaries.

Two recent rulemaking proceedings highlight the actions of Medicare. In the rule that imposes a rate reduction on home health services payments because of an alleged improper claim coding, Medicare's impact analysis offered nothing more than aggregated regional data on the overall percentage change in payment rates. Further, its analysis was confined to a first year impact of a rule that imposes three years of rate cuts. At no time did Medicare offer analysis as to the number and location of providers that would end up with Medicare payments lower than costs even though such impact is likely to result in the closure of that provider. Medicare followed a virtually identical process in its impact analysis of its rulemaking regarding the elimination of the hospice wage index Budget Neutrality Factor.

RECOMMENDATION: 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. Medicare 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.

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.

ESTABLISH PROVIDER SAFEGUARDS FOR ONE YEAR TIMELY FILING REQUIREMENTS

ISSUE:: Section 6404 of the Patient Protection and Affordable Care Act (PPACA) amended the timely filing requirements for submission of all home health and hospice billing transactions, (Requests for Anticipated Payments (RAPs), claims, and adjustments) to one calendar year after the date of service. In addition, all billing transactions for services furnished prior to January 1, 2010, must have been filed no later than December 31, 2010.

Providers have been advised to take steps to ensure that their billing transactions are submitted and received by CMS contractors in advance of the one year deadline because of “clean claim” requirements. This recommendation is based on the fact that RAPs, claims, and adjustments that have errors and are sent to the Return to Provider (RTP) file will receive a new receipt date when corrected. The new receipt date must also adhere to timely filing

Although CMS initially announced that the one year deadline would be based on the “From” date of claims, they subsequently changed to the “Through” date as the start of the count for institutional claims that cover a span of time. As a result, home health and hospice claim “Through” dates will be used to determine whether the timely filing requirements have been met. For hospice providers, add-on bills (type of bill 815 or 825) are also subject to the timely filing requirements. However, notices of election (NOEs) are not subject to timely filing.

Currently, there is one exception found in the timely filing regulations at 42 CFR section 424.44(b)(1), for “error or misrepresentation” of an employee, Medicare contractor, or agent of the Department that was performing Medicare functions and acting within the scope of its authority.

RECOMMENDATION:

- Continue provider education on the one year timely filing requirement
- Ensure that contractors honor CMS policy for determining the through date on the claim as the start of the one year clock, rather than the date of discharge or final visit date
- Establish a process for expedited resolution of contractor “error or misrepresentations resulting in provider late filing.
- Identify exceptions that address Medicare/Medicaid coordination issues

RATIONALE: It would be unfair to deny payment to providers who deliver covered services based to a technicality or contractor error.

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 provisions requiring screening of new providers; the assessment of application fees to cover this expense; temporary moratoria; and, compliance plans. CMS issued a proposed rule governing these provisions. While NAHC has long been a supporter of the need for stronger requirements to keep fraudulent providers out of the Medicare program, NAHC has recommended revisions to the proposals to make them more practical and effective.

CMS has proposed to strengthen 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 proposal, home health agencies are assigned to all three risk levels depending on whether they are part of a publicly held company (Limited), an existing home health agency (Moderate), or a new applicant for participation in Medicare (High). Hospice is assigned the Moderate risk level except for publicly-held companies.

Each risk level is subject to three screening elements: verification of provider/supplier specific Medicare requirements: license verifications, and 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 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. While NAHC is aware that there have been instances where certain “phantom” suppliers have been uncovered through surprise site visits, it is unaware of that abusive, fraudulent phenomenon occurring in home health services or hospices. Both such providers are subject to initial on-site surveys in their offices and the homes of patients. Medicare standards also require on-site resurveys at least every several years. As such, while NAHC supports CMS’s intent with this proposal, we raise 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. Care is not provided in the home health agency or hospice office.

Such home visits are part and parcel of all home health agency and hospice surveys. CMS could easily address the concern of focus in the on-site screening by performing the already required surveys. NAHC wishes to convey that it does not oppose the on-site survey screening. Instead, NAHC believes that it would not be productive when applied as proposed to home health

agencies and hospices. CMS proposes to include publicly-held home health agencies and hospices in the “limited” risk category given the additional oversight that it placed by government agencies on publicly-held corporations. NAHC agrees that these companies are subject to additional oversight that may warrant a lower risk category provided the oversight includes elements that are adequate substitutes for CMS screenings.

CMS proposes to deny or revoke billing privileges if a provider fails to include the application fee or a request for hardship exception with its application. Both denial and revocation contain re-enrollment bars for a period of time. In addition, CMS proposes to reject an application without first giving the provider the opportunity to submit the missing fee or exception request.

CMS proposes to establish criteria for the triggering of a moratorium on enrollment of new providers that may be provider and geographic-specific. Medicare moratoria authority rests with CMS while Medicaid moratoria authority lies with both the State agency and the Secretary. The moratoria trigger focuses on risk of fraud, waste, and abuse. As proposed, the moratorium would be temporary, for a period of 6 months but with the potential for unlimited extensions in 6 month increments.

NAHC has strongly supported 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.

As with the moratoria authority, NAHC advocated with Congress that providers of services participating in Medicare be required to maintain a comprehensive compliance plan as part of their Medicare enrollment requirements. NAHC believes that a proper compliance plan along with proper use of the plan goes a long way to reducing fraud, waste and abuse. In particular, the plan is very effective in preventing errors and omissions as well as detecting employee abusive conduct.

RECOMMENDATION:

1. NAHC supports expanded screenings of new home health agencies and hospices in the form of a competency credentialing. NAHC advanced this concept during the development of the Affordable Care Act program integrity provisions and we believe that CMS has been given the authority to include competency credentialing in the provider screening model.

NAHC submits that most of the concerns raised by the OIG and other oversight bodies focus on errors and omissions rather than the type of fraud that might be uncovered through on-site visits, criminal background checks, and fingerprinting. Accordingly, NAHC recommends that CMS 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 antikickback laws and the Stark law provisions.

2. The proposed rule should clarify that the categorization of a home health agency into the “High” risk level does not occur when it modifies its delivery model to include a CMS-approved branch office. The addition of a branch office to a home health agency is not the equivalent of “establishing a new practice location” as referenced in the proposed 42 CFR 424.518(c)(1)(B). Instead, it is the establishment of a sort of satellite office that cannot function as a full home health agency. It is part and parcel of the parent home health agency and is fully subordinate to the parent. It cannot bill on its own for services nor does it have clinical authority over the patient. It cannot even operate until it has CMS Regional office approval so site visits are not even possible until that approval is given.
3. CMS must coordinate its screening standards with other rules regarding Medicare program participation. 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.
4. CMS must ensure that its enrollment requirements are consistent with its conditions of participation (COP). NAHC has already received a report from a home health agency that had a contractor site visit to a branch. The contractor revoked the agency’s billing privileges on the ground that the branch was not “operational” because the branch had no sign; there was no one in the office; and, no one answered the telephone at the branch. None of these are COP requirements for a branch office, which does not furnish services to patients at the branch. The agency served patients from that branch and supervised and administered branch services from the parent agency in compliance with the COPs.
5. Prospective provider applicants and existing Medicare home health and hospice providers who submit an application to establish a home health agency branch or a hospice multiple location should be given 30 days, following notice from Medicare, to submit the missing fee or exception request, with the potential for an extension of this time period under current subsection 424.525(b), or face rejection of the application.. For existing Medicare providers who submit a revalidation application, the contractor should furnish written notice that the application fee or hardship exception request is missing and that the provider has 30 days to furnish it, with the potential for an extension of this time period.
6. The moratoria authority must address the issues involved with providers that have initiated action to secure Medicare/Medicaid participation. A new provider of home health services or hospice care does not come about overnight. There is

significant investment of time and capital prior to finalizing a Medicare participation agreement and securing billing privileges. For example, a home health agency must undergo an extensive survey including the review of care provided to at least 10 patients prior to achieving certification and enrollment in Medicare. It would be completely unfair for CMS to block the enrollment of a provider with a last minute moratorium after that provider invested so significantly to get to that point.

NAHC recommends that a moratorium not apply to any provider applicant that has submitted the appropriate CMS Form 855A prior to the public notice of the moratorium.

7. Advance public notice of a moratorium should be issued in the Federal Register/State Register with the specific reasons for the moratorium provided in the notice. While NAHC recognizes that an advance notice may lead to a rush to apply prior to the effective date, such concern can be addressed by limiting the length of time for the advance notice to 30-60 days. Such advance notice would help potential providers from initiating a provider development that can not reach Medicare participation because of the moratorium.
8. Similarly, advance public notice should be given when CMS/Medicaid extends a moratorium beyond the 6 month period.
9. Certain standard exceptions to a moratorium should apply. These include:
 - The state has a Certificate of Need program and the state determines that there is a need for additional providers
 - The provider is establishing a branch office or multiple locations within its geographic service area
10. The proposed rule should be amended to specifically include a statement that a moratorium does not apply to instances where the new provider is a result of a merger, change of ownership, or a provider consolidation. Also, the moratorium would not apply where there is a change in practice location. These exceptions are stated at 75 Fed. Reg. 58221, but should be included directly in the rule.
11. NAHC believes that the 7 core elements of a compliance plan as set forth in the Sentencing Guidelines provide a useful framework and should be part of the CMS standard.
12. NAHC believes that the key to an effective compliance plan is to begin with the core elements and then to tailor the plan to address the provider-specific risk areas. The plan must also be subject to periodic re-evaluation to determine if it is working appropriately for the risk areas existing at a particular time. Changes in reimbursement and care delivery models necessitate adaptation of the plan to risk areas surfacing as a result of those changes. Accordingly, NAHC recommends an 8th core element that requires the plan to include periodic evaluation of changing

risk areas and adaptation of the plan to such changes. This may be incorporated in the 7th element of the Sentencing Guidelines standards, but needs more detail and specificity than is currently within that element.

13. The costs of compliance programs in home health agencies and hospices vary widely depending on the size of the organization and the depth of its plan. There is no common benchmark on compliance plan spending relative to the provider's revenue size. NAHC notes that Medicare home health services and hospices have significant reimbursement system changes over the next few years. The cost of the plans must be part of the factors considered when developing the payment rates under the new reimbursement models if it can be expected that a compliance plan requirement can be reasonably met.
14. NAHC believes that all provider/supplier types should have comparable comprehensive compliance plan requirements. Less stringent requirements in any category of provider/supplier would then necessitate a reactive response when risks increase rather than gaining the benefit of preventive controls in all provider sectors.
15. NAHC would recommend that CMS provide 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. Also, the proposals are not consistent with current CMS practice in 42 C.F.R. § 424.525(a) and (b) when a provider fails to include missing information or documentation with its application.

ENSURE REASONABLE ENROLLMENT AND PARTICIPATION REQUIREMENTS FOR HOME HEALTH AGENCIES

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

In regard to capitalization, CMS has adopted a burdensome approach which requires the agency to have the IROF available at the time the 855A is filed; when the contractor recommends approval to the Regional Office (R.O.); before the R.O. approves the application; and before the contractor conveys Medicare billing privileges and issues the billing number. Due to the lengthy time for processing the enrollment application, this is burdensome on agencies, and contractor enforcement of this provision may impose additional burdens and delays in processing new HHA enrollments. Further, none of the contractors has posted an IROF calculator on its website, although CMS promised that information would be made available to HHAs prior to applying to Medicare so that they could make appropriate business decisions about whether to apply for an initial enrollment prior to expending significant time and money.

CMS has adopted various versions of the 36-month rule effective in 2010 and in 2011 to address concerns about the new owner of a home health agency. In 2010, CMS adopted multiple versions of its interpretation of the rule, causing a freezing of the financial markets. These interpretations included versions which made the rule effective upon a 5% or more change in ownership; a 100% change of ownership; indirect ownership changes; stock sales; and, required the termination of an agency and the filing of an initial enrollment if one of the owners died.

NAHC and others worked with CMS throughout the year to bring to the attention of CMS the numerous problems caused by their various interpretations of the rule.

Effective January 1, 2011, CMS retained the so-called 36-month rule, with significant exceptions. If there is a change in majority ownership of an HHA by sale (including asset sale or sale of stock, mergers, and consolidations) within 36 months after the effective date of the HHA's initial enrollment in Medicare or within 36 months of the HHA's most recent change in majority ownership, the HHA's provider agreement does not convey to the new owner. The new owner must enroll in Medicare as a new (initial) agency and obtain state survey or accreditation.

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

- The HHA has submitted two consecutive years of full cost reports (low utilization cost reports or no utilization cost reports do not qualify). This is a reduction from five years of cost reports to two years of cost reports;
- An HHA's parent company is undergoing an internal corporate restructuring such as a merger or consolidation;

- The owners of an existing HHA are changing its business structure such as from a corporation to a partnership; from an LLC to a corporation; from a partnership to an LLC, and the owners remain the same; or
- An individual owner of an HHA dies.

In the preamble, CMS further clarified that:

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

RECOMMENDATION:

In regard to capitalization:

1) CMS should require each contractor to post an IROF calculator on its website so that HHAs can determine the capitalization amount as part of their business analysis regarding whether to open a new HHA.

2) CMS should monitor its 4-time contractor review of IROF. NAHC believes that this quadruple review of IROF is unnecessary, unduly burdensome, and will further delay the processing of new HHAs. NAHC recommends that CMS have contractors check the IROF twice: when the application is filed and prior to conveying billing privileges.

In regard to the 36-month rule:

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

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. NAHC strongly recommends that CMS withdraw its proposal and revise the existing and proposed rules to provide:

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

ISSUE: Recent claims denials by intermediaries, program safeguard contractors, zone program integrity contractors, and review of claims denials by qualified integrity contractors and administrative law judges are inconsistent and are not in compliance with Medicare coverage requirements as stated in the statute, regulations and manuals.

RECOMMENDATION:

CMS should:

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 sample 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.

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.

IV. COVERAGE & APPEALS

ENSURE HOME HEALTH ACCESS FOR HOMEBOUND BENEFICIARIES

ISSUE: In order to qualify for home health services, Medicare beneficiaries must be confined to their home. Homebound is defined as having “a condition due to an illness or injury that restricts their ability to leave their place of residence except with the aid of: supportive devices...or the assistance of another person.” According to the longstanding Medicare policy, if a person leaves their home, “absences must be infrequent or for periods of relatively short duration,” unless for medical purposes. Congress attempted, but failed, to impose strict numerical limitations on how often a home health beneficiary could leave home for non-medical reasons at “no more than approximately 5 times a month and no more than about 3 hours each time.”

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

Face-to-Face encounter requirements legislated by the Affordable Care Act became effective 1/1/2011. According to CMS regulations to implement the statute, physicians must not only certify that patients are homebound, but must also write a narrative description of clinical findings that support a patient’s homebound status. However, most physicians are ill equipped to do so in light of the complexity of homebound rules and lack of education on the homebound policy. For the most part, medical review staff at the new CMS contractors (MAC, RAC, and ZPIC) does not have an acceptable understanding of homebound criteria. These contractors have been known to issue inappropriate denials because of their lack of understanding of Medicare "confined to home" policies.

RECOMMENDATION:

A. Work with the industry to establish homebound definition and guidelines that:

1. Ensure access to home health services, as intended by the Social Security Act, based on functional limitations and the clinical condition of the patient as documented in the patient record rather than arbitrary number and duration of absences.
2. Do not impose burdensome documentation requirements, such as detailed information about reasons, frequency, and duration of non-medical absences from the home.
3. Expand the definitions of “licensed” and “certified” adult day programs.
4. Ensure that analysis of the impact of any expansion of the homebound definition addresses the financial impact on providers as well as the Medicare program.

B. Require CMS to provide educational information to physicians and all of its contractors, and oversee their application of the homebound policy.

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

PROMOTE CONSISTENT APPLICATION OF COVERAGE RULES AND ABANDON LOCAL COVERAGE POLICIES

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

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

According to CMS, more than 8000 LCDs have been developed over the last 11 years. There are numerous examples where LCDs have resulted in more stringent interpretations of coverage than is spelled out in the Medicare Benefit Policy Manual (Pub 100-2). These LCDs are intended to apply in a particular contractor’s jurisdiction. In the case of home health, where three Regional Home Health Intermediaries and one Medicare Administrative Contractor serve the entire country, LCDs are applied to large geographic areas.

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

Furthermore, managed care organizations have reinterpreted coverage rules, resulting in enrollees in MA plans being deprived of entitled services. Some require unwilling patients/caregivers to learn to perform skilled procedures. In addition, many define aide services as custodial, uncovered care.

RECOMMENDATION:

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

- c. Ensure compliance with procedures that enable providers to review and comment on proposed local medical review policies.
 - d. Establish procedures that enable providers to challenge inappropriate local policies.
3. Require MCOs to provide home care services consistent with Medicare guidelines.

RATIONALE: Policies developed and implemented by Medicare contractors are not local due to the extensive geographic areas that they serve. Medicare contractors do not have the legal resources that are available to CMS and essential to ensuring appropriate interpretation of the Medicare benefit and establishment of coverage policy. Federal law requires adherence to formal processes for the establishment of national coverage decisions. Coverage policies that are applied to large areas of the country, and in some cases the entire country should be established only through this process. Medicare coverage is a complex issue. Although treatment standards and practices vary from one part of the country to another, Medicare is a national program and beneficiaries should receive all services to which they are entitled. When contractors do not adopt LCDs from other intermediaries, inconsistency in coverage results within geographic areas since provider assignment to Medicare contractors is not on a strictly geographic basis.

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

REFINE CLAIMS REVIEW & ADDRESS TECHNICAL ERRORS

ISSUE: Currently, less than 4% of all Medicare home health claims and 1% of hospice claims are reviewed. It is cost prohibitive to perform a claim-by-claim review. 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 both providers and Medicare contractors. Payment is often delayed when intermediaries fail to review records in a timely manner.

Top billing errors in home health care have consistently included: 1) failure to submit requested records and 2) lack of physician signature prior to billing. 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), and lack of a date of the providers' receipt of signed orders in cases where physicians have not dated their signature. 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 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 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 "Progressive Corrective Action" or PCA, intermediaries are to use smaller corrective actions for smaller problems and bigger corrective actions for bigger problems identified within an agency. Under the principles of PCA, data analysis should be used to identify aberrancies in an agency's billing patterns, and intermediaries should then validate suspicion of billing errors by first conducting probe reviews of small numbers of claims (between 20-40). Although probe edit instructions to CMS contractors advise a maximum of 20-40 claims per topic, they do not prescribe a minimum number of claims, resulting in increasing instances of focused review of providers based on high percentage of denials when only a handful of claims are reviewed. Individual providers that appear to have billed inappropriately are notified and remain on focused medical review (FMR) for a minimum of three to four months.

Finally, intermediaries have been known to down-code 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 not 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. 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 percent. Data from CMS found the percentage of reversals for home health and hospice denials at both the reconsideration and ALJ levels far exceeded 5 percent.

RECOMMENDATIONS:

1. Identify home health data elements that can be submitted electronically in response to a request for medical review.
2. Require Medicare contractors to review a minimum of 10 records before targeting and maintaining a provider for focused medical review due to high denial rate.
3. Direct focused medical review efforts at non-technical issues and allow providers to correct minor technical errors without denials, including dating of physician signatures.
4. 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.
5. Commit resources to educational activities and timely dissemination of information
6. Establish minimum standards for Medicare contractor medical review staff.
7. Develop a procedure for providers to explain utilization variations prior to making decisions to place them on FMR.
8. Limit medical review to 4% of claims except in cases of demonstrated cause.
9. 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.
10. Complete prepayment reviews within 30 days of receipt of records.
11. Correct the instructions to contractors and providers to accurately reflect the intent of Congress.
12. Involve the provider community in defining “minor errors.”
13. Treat claims that are presently issued as technical denials because they are missing information as “incomplete claims.”
14. Notify providers of the reason their claims cannot be processed and require resubmission, rather than issue denials.
15. 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. Home health claims may not be submitted until the close of an episode, which in many cases is 60 days. Therefore, pre-pay review can result in a minimum of a 120 day delay in payment even when Medicare contractors comply with a 60 day turn-around time.

Agencies are under severe financial hardships when payments are delayed inappropriately for weeks and, in some cases months, while under the intermediary 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.

ENSURE INDEPENDENCE OF ADMINISTRATIVE LAW JUDGES

ISSUE: The Medicare Prescription Drug, Improvement and Modernization Act of 2003, Sections 931-940 includes a number of provisions related to appeals, recovery and contractor reform. One of these shifts control of Administrative Law Judges (ALJs) and their decisions from the Social Security Administration to the Department of Health and Human Services (DHHS). The Secretary is required to place the ALJs in an office that is organizationally and functionally separate from CMS. HHS created a separate department for ALJ activities in the summer of 2005. However, it is too early to tell how well it is functioning.

RECOMMENDATION: Maintain the independence of Administrative Law Judges from CMS authority and oversight.

RATIONALE: The independence of ALJs and keeping decision-making away from the control of CMS maintains the credibility of their determinations and protects providers and beneficiaries. Finally, medical reviewers must fully understand all purposes of the OASIS assessment.

PROHIBIT CMS OVERPAYMENT RECOUPMENT PRIOR TO QIC DECISIONS

ISSUE: Congress adopted a limitation on CMS' recoupment of overpayments in Section 935 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003(MMA). This provision added subsection (f) to section 1893 of the Social Security Act, which prohibits CMS or its contractors from recouping an overpayment from a provider who has filed an appeal of the overpayment until the Qualified Independent Contractor (QIC) issues a decision on reconsideration.

Although more than four years have passed since the enactment of this provision, CMS has still not implemented it. In direct contravention of this provision, CMS immediately recoups overpayments resulting from denied claims. A provider sees that the claim has been denied on the electronic version of the Remittance Advice (RA) at the same time that the provider sees that the payment has been recouped by Medicare.

On September 22, 2006, CMS proposed rules to implement this provision in a manner that conflicts with Congressional intent. The proposed regulations do not state that if the provider submits a request for redetermination, recoupment will not be put into effect. Nor do the proposed regulations state that a provider has a certain amount of time to submit the request for redetermination to stop the recoupment. Instead, the proposed rules permit recoupment until the intermediary receives a "valid" request for redetermination, which may commence again 30 days after the date of the redetermination decision, and may continue until the QIC determines that a "valid" request for reconsideration has been filed. Recoupment can commence again upon the transmission of an unfavorable QIC decision.

CMS has made changes to the manual while the rulemaking is pending. These changes require a provider to submit a request for redetermination within 30 days of the date of the overpayment demand letter or recoupment will begin 41 days from the date of the overpayment demand letter. This will limit the timeframe in which a provider may appeal to less than 30 days from the receipt of the demand letter, if the provider wants to avail itself of the statutory limitation of recoupment. CMS also effectively shortened the period in which a provider may seek reconsideration from 180 to 160 days, as well. To stop recoupment, a provider must file a request for reconsideration within 60 days of the date of the revised overpayment determination. CMS is still taking the position that the limitation on recoupment does not apply to "certain claims adjustments at the contractors' discretion..."

In addition to the limitation on recoupment, providers have the right to file a rebuttal to show why the recoupment should not go into effect. CMS agrees that providers have the right to file a rebuttal in addition to filing an appeal to automatically stop the recoupment and have directed contractors to include information in their overpayment demand letters regarding the limitation on recoupment and the right to file a rebuttal. However, some contractors are not including information about the right to file a rebuttal in their overpayment demand letters.

RECOMMENDATION:

Immediately implement section 1893(f) of the Social Security Act by:

1. Directing its contractors to apply the limitation on recoupment to all denied claims

2. Directing contractors to refrain from recouping during the 120-day period in which a provider may submit a request for redetermination
3. Directing contractors to refrain from recouping monies during the 180-day period in which a provider may submit a request for reconsideration
4. Directing contractors to make any of these changes manually if they are unable to automate these changes at this time.
5. Oversee its contractors' compliance with rebuttal and limitation on recoupment requirements.

RATIONALE: Home health agencies have been harmed by having to repay denied claims and overpayments before they have appealed these decisions. Congress has determined that such repayment is inappropriate, but CMS has flagrantly refused to comply with the statute. CMS has failed to direct its contractors to take immediate action to implement this provision, and has proposed regulations that do not comply with the statute.

ESTABLISH REASONBLE THERAPY SERVICE REQUIREMENTS

ISSUE: In the 2011 Home Health Prospective Payment System (HHPPS) update for calendar year 2011, CMS wrote about concerns described in the notice as "current ill-defined therapy criteria." To address these concerns, CMS made extensive modifications to 42 CFR 409.44 with the goal of "slowing the rate of nominal case-mix growth." The regulatory changes include:

- New functional assessment and reassessment requirements
- Additional therapy goal and clinical documentation requirements;
- Establishment of timelines for reassessment visits by a "qualified therapist" on the 13th and 19th visit of an episode and every 30 days;
- Required physician collaboration about therapy needs based on patient progress and restoration potential;
- New physician signature requirements when goals change during the course of an episode
- Clarification of maintenance therapy coverage criteria
- Addition of non-coverage of therapy for conditions that are transient or reversible (e.g., post surgical debility) criteria; and
- Limitation of billing of a therapy visit to provide wound care to those instances where the skills of a therapist are required to provide the ordered wound care.

The therapy profession supports assessment and goal requirements imposed by CMS in the 2011 PPS Update. The regulation requiring patient assessment, physician collaboration, plan of care, goal establishment, evaluation of progress toward goals through objective measures, and documentation, are all reflective of professional standards of practice for therapy services that are in line with practice guidelines established by professional therapy associations, including the American Physical Therapy Association (APTA), the Occupational Therapy Association (OTA) and the American Speech and Language Association (ASHA) and promoted by NAHC. However, CMS has not issued clear guidelines as to the how extensive reassessments must be, other than to say that it must be reassessment of function. This could result in subjective interpretation and additional requirements by its contractors.

The scheduling of reassessment visits by qualified therapists on the 13th and 19th visits and every 30 days could prove difficult, especially if the 30th day of service occurs just prior to the 13th or 19th therapy visit in an episode, necessitating multiple therapy reassessments in a short period of time.

Although CMS allowed for flexibility in scheduling, (10th to 13th and 16th to 19th therapy visit in rural areas and circumstances outside the control of the therapist), CMS did not elaborate on what those circumstances might be, and compliance would required knowing about circumstances outside the control of the therapist prior to them occurring. Furthermore, conduct of patient assessments on visits 13 and 19 may not coincide with therapy assistant supervision requirements. For example, some states require the qualified therapist to conduct a supervisory visit every 6th visit when therapy assistant services are employed. Therefore, the 13th visit and 19th visits by a qualified therapist would be required to visit on the 6th, 12th, 13th, 18th, and 19th visits.

New regulation at 42 CFR 409.44(c)(2)(iii)(B) details maintenance therapy coverage requirements. This regulation reflects current policy. However, concern remains about whether CMS contractors will correctly interpret the policy and regulation.

A new requirements related to therapy in cases where patients have what is called a “transient condition” at 42 CFR 409.44(c)(2)(iii)(A)(3) were also promulgated. According to this regulation: "Where a patient suffers a transient and easily reversible loss or reduction of function which could reasonably be expected to improve spontaneously as the patient gradually resumes normal activities, because therapy services do not require the performance or supervision of a qualified therapist, therapy would not be considered reasonable and necessary." This regulation could result in inappropriate denial of care to patients with medical conditions or post surgery, under the assumption that they are transient conditions and full recovery will take place without therapy services. A variety of illnesses, such as pneumonia, thrombophlebitis, and post operative conditions are easily reversible when treated with medications and rest. However, these conditions often leave patients temporarily de-conditioned and incapable of carrying out routine functional activities during the recovery period. Therapy services may be needed to teach safe transfer, promote mobility, make environmental accommodations and identify equipment needs in order to prevent falls and meet activities of daily living needs during the recovery period.

RECOMMENDATIONS

- Work with the home health industry to identify quantifiable patient measures
- Issue clear guidance on timing of therapy reassessment requirements
- Consider the following policies for scheduling therapy reassessments prior to the 14th and 20th visit threshold
 - Timing of the 30th day of therapy reassessment
 - State therapy assistant supervision requirements
- Limit reassessment requirements to assessment of function, not a comprehensive assessment, using tools and measures deemed appropriate by professional therapy standards of practice
- Address coverage for conditions that may not directly impact functional status, such as pain and fall potential.
- List diseases, injuries, or condition categories and when they would be considered to be transient, rather than relying on the subjective judgment of claims reviewers disabled by 20-20 hindsight when determining coverage of therapy for transient conditions.
- Expand on policies that address the role of therapists in wound care, including coverage of electrical stimulation of pressure ulcers, sharp debridement, and whirlpool therapy for wounds that do not inappropriately limit therapy practice.
- Ensure that maintenance therapy policies are written to reflect the full scope of the benefit, not limit it.

RATIONALE: Reassessment of patients at prescribed timelines fails to take into consideration unique conditions and circumstances of home health therapy patients. Scheduling of visits by a qualified therapist in consideration of three different set of criteria (30 days of service, 14th and 20th visit threshold, and State therapy assistant supervision requirements) will cause scheduling problems that even home health software vendors may not be able to resolve through software programs. In addition, the compounding nature of 30th day and therapy visit threshold

requirements will result in duplicative reassessments at a frequency unnecessary for many patients and be costly to agencies.

CMS is required to ensure access to reasonable and necessary therapy services based on the individual's unique condition. Maintenance and restorative therapy, as well as therapy to prevent injuries and further deterioration all require the skills of a therapist. Coverage of maintenance therapy and maintenance plan development was a significant component of the nationwide class action lawsuit settled by predecessor HCFA, *Duggan v. Bowen*. This type of therapy is provided to beneficiaries with deteriorating or chronic conditions to ensure their safety and ability to maintain current function. According to this proposed rule, maintenance therapy may not be provided as the sole skilled service, and will be covered only if ancillary to another skilled qualifying service.

Exclusions of therapy for transient conditions assumes that recovery will take place fully and within the same timeframe without provision of therapy. It establishes a rule based upon the unfounded assumption that the patient's recovery does not benefit in any way from the provision of therapy. Many reversible illnesses require therapy interventions to ensure full recovery and prevent further complications or injuries.

Wound care has been provided by therapists since the start of PPS and case-mix weights have been developed based on the cost of these therapy services. Wound care is within a physical therapist's scope of practice, and for which many therapists have special training and certification. Any changes in policy on wound care that is within the scope of a therapist's scope of practice will impact case-mix budget neutrality.

Home health agency quality measures now address processes of care. Agencies are required to report whether they assess patients for pain and fall potential and provide care when needs are identified. Services to address problems identified should be paid.

V. OTHER

PROMOTE PROVIDER RIGHTS & 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 (PPACA) 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.

RECOMMENDATION: The FTC and the DOJ should promote rights and opportunities to compete through effective antitrust laws by issuing additional guidance and further "safety zones" which directly focus on the changing relationship between home health and hospice 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 PPACA. Further, individual home care providers are at a disadvantage in the market in comparison to vertically integrated health care systems that can offer a managed care plan and a range of services that fit the managed care plan's overall design. Collaborative activities among home care providers can bring about efficiencies and economies of scale that are pro-competition. However, continued and vigorous enforcement of antitrust laws is necessary to insure continued survival of competition in home care services.

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

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

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

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

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

RECOMMENDATIONS:

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

that task) and willing to assume the required employer responsibilities, such as payment of overtime.

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

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

OPPOSE CHANGES TO COMPANIONSHIP SERVICES EXEMPTION TO THE FAIR LABOR STANDARDS ACT

ISSUE: In 1974, Congress established an exemption for companionship services from the Minimum Wage and Overtime Requirements of the Fair Labor Standards Act. Congress made a societal choice in balancing the interests of the worker relative to the needs for care to the elderly and the infirm. The U.S. Department of Labor, on January 19, 2001, published a notice of proposed rulemaking suggesting a modification of the companionship services exemption. “Companionship services” can be defined as providing care and comfort, including personal care, (1) to the elderly or (2) to the infirm or disabled. Home care providers have long relied on this exemption to provide compensation to home care aides and personal care workers with the expectation that there is no obligation for overtime pay.

The 2001 proposed changes would have eliminated the application of the exemption when companionship services are provided by an individual employed by a party other than the person receiving the care. In addition, the proposed changes would modify the definition of the proposed changes in a manner that would require that the bulk of services rendered are fellowship and minimize the amount of personal care services that are available to the recipient. The Department of Labor withdrew its proposed rulemaking after a review of the public comments. However, given the politicized nature of the rule, it is likely to resurface with a change in Administration.

In Spring 2004 the federal Second Circuit Court of Appeals issued an ruling concerning the Fair Labor Standards Act on the validity of the “companionship services” exemption from minimum wage and overtime payment requirements. The decision holds that the U.S. Department of Labor (DoL) regulation applying the “companionship services” exemption from overtime to an individual under the employ of someone other than the care recipient or his/her family is invalid and unenforceable. If this decision stands, it will mean that home care agencies and hospices will be required to pay overtime compensation whenever their home care aides and personal care workers exceed 40 hours of work in any week. An appeal was filed in the U.S. Supreme Court.

The National Association for Home Care & Hospice filed a "friend of the court" legal brief with the Supreme Court in September, 2004 that warned of the potential negative impact of a recent decision in a lawsuit challenging the validity of the "companionship services" exemption from minimum wage and overtime payment requirements.

The U.S. Supreme Court reversed the appeals court’s ruling and sent the case back to the Second Circuit Court of Appeals to reconsider their decision. The Second Circuit Court of Appeals maintained their original position to invalidate the ““companionship services” exemption from minimum wage and overtime payment requirements. The case returned to the U.S Supreme Court in December 2006. NAHC participated in the funding of the Supreme Court appeal as well as submitted another “friend of the court” brief.

In June 2007, the US Supreme Court ruled that the DOL regulation was valid thereby reversing the Court of Appeals in a final decision. However, the ruling leaves open the possibility that Congress could change the law or DOL could modify its interpretation of that law.

Since the Supreme Court ruling, there has been a re-focusing of efforts by the unions and other opposed to the DOL rule. Currently, they are attempting to get Congress to change the law while also seeking legislative and/or regulatory remedies at the state level. In 2010, a letter was conveyed from a number of U.S. Senators to the Secretary of Labor urging her to significantly revise the exception to eliminate application to employed home care aides. Some states already have passed laws that eliminated the companionship services exemption. In others, there are efforts to interpret the regulations in a manner different than the federal rules.

The U.S. Department of Labor includes a change to the companionship services rule in its 2011 regulatory agenda. DOL plans to issue a proposed rule in October 2011. While the nature of the changes is not known, it is expected that the proposal will eliminate the application of the exception to third-party employed personal care attendants and narrow the scope of work defined as “companionship services.”

RECOMMENDATION: A companionship services exemption should apply to all employers and should continue to apply to services that are predominately personal care. The US Department of Labor and its state counterparts should not modify the application and definition of companionship services

RATIONALE: Most home care providers are small business with limited resources. Any change in the companionship services exemption would result in reduced availability of care to the elderly and the infirm and increase the costs of service delivery with no corresponding increase from third party payers, such as Medicaid. Direct care providers will be deprived of the opportunity to voluntarily work beyond 40 hours in order to supplement their income.

MONITOR EFFORTS TO AUDIT IMPROPER EMPLOYEE CLASSIFICATIONS AS INDEPENDENT CONTRACTORS

ISSUE: The US Department of Labor (DoL) initiated an education, oversight and audit project in 2010 that will continue throughout 2011 related to the misclassification of employees as independent contractors. Among the employment areas targeted by the DoL is home health care.

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

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

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

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

RECOMMENDATIONS: The US Department of Labor should issue comprehensive standards specific to home care that allow for consistent application of worker classifications. The DoL should recognize the variations in homecare programs when proceeding with its education, oversight and auditing efforts.

RATIONALE: Misclassification of workers as independent contractors harms the worker and the employers that comply with classification standards. At the same time, Do L needs to be careful to avoid an overbroad approach to home care worker classification to recognize that certain skilled, professional caregivers can correctly operate as independent contractors.

ENSURE ACCEPTABLE STANDARDS FOR CULTURALLY AND LINGUISTICALLY APPROPRIATE HEALTH SERVICES

ISSUE: The Department of Health and Human Services (DHHS) Office of Minority Health has prepared draft standards for Culturally and Linguistically Appropriate Health Services. These standards require providers to have a comprehensive management strategy to address culturally and linguistically appropriate services including goals, plans, policies, procedures, and designated staff. Providers must establish a formal mechanism for community and consumer involvement in the design and execution of service delivery, planning, policy making, operations, evaluation, training and treatment planning. In addition, providers must recruit qualified, diverse and culturally competent staff trained to address the needs of the racial and ethnic community they serve and provide all clients with limited English proficiency access to bilingual staff or interpretation services. Use of family members and friends is not an acceptable solution to the need for interpreters.

RECOMMENDATION:

1. Abandon the draft cultural and linguistics standards in favor of already existing global standards and requirements as found in the Medicare Conditions of Participation, national accrediting body standards, and professional practice standards.
2. Develop and make available to providers translated materials to inform Medicare and Medicaid beneficiaries of their rights in all languages (i.e. patient rights, advance directives, notice of non-coverage, OASIS data set).
3. Allow the use of family members and friends to interpret.
4. Require CMS to produce beneficiary notices, OASIS Privacy notices, and other required, federally developed forms in multiple languages.

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

REVISE THE POLICY GUIDANCE FOR PROVIDERS SERVING PERSONS WITH LIMITED ENGLISH SKILLS

ISSUE: The Department of Health and Human Services (HHS), Office of Civil Rights issued policy guidance to providers of health and social services discussing methods by which entities that receive Federal financial assistance from HHS can meet their obligation to provide oral interpretation to limited English proficiency persons (LEP). The guidance also outlines obligations to provide translation of written materials. Providers must establish policies and procedures for identifying and assessing the language needs of their client populations, include oral assistance options in their plans, provide notices to those with limited English proficiency of their right to free language assistance and provide staff training and program monitoring. When providers have a significant percentage of their population with information needs in a language other than English, a provider is required to offer written materials in that language. Also, providers are required to determine the proficiency of interpreters that they use and ensure that the interpreter is familiar with medical terminology.

RECOMMENDATION:

1. Estimate provider's cost to implement the published guidelines.
2. Establish guidelines based on provider size.
3. Translate commonly used documents into languages where there are 100 or more persons residing in the country and make these translated documents available to providers.
4. Allow providers to use family members and friends as interpreters.
5. Develop resources for providers including telephone translation services, computer driven voice and written translator programs.
6. Develop and disseminate training programs and materials for training of medical personnel.
7. Eliminate the requirement for translators to have training in medical terminology.

RATIONALE: The LEP guidelines place new financial hardships on already overburdened home health and hospice providers. They create new administrative and paperwork burdens and costs for interpreters. Home health agencies do not have the financial and staffing resources to meet the recommended guideline to make available bilingual, medically oriented interpreters, limitation of use of friends and family members as interpreters creates a barrier to patient care. Finally, national standards against which to measure linguistic proficiency in medical terminology are not available. Training in medical terminology is not important for translators as information should be provided to interpreters by health care personnel in lay language that would be easily understood by patients if given directly.

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

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

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

The public authority model of care delivery often is promoted as a means to give consumers greater control in caregiver selection and supervision. However, this model does not fit for all the disabled or elderly in need of home care as it is a model that can deter individuals from seeking care, limit options for continuity of care, and weaken quality of care standards. By providing consumers with a public authority model, choice is limited to the public authority as the provider.

The public authority model raises additional concerns related to accountability and quality of services. Some of these programs operate without appropriate standards for client eligibility, service verification, and the employee's entitlement to wages earned. They fail to provide workers with basic protections related to workers compensation, collective bargaining choices, and other rights afforded most other workers. Finally, the programs operate without quality of service standards that are comparable to an agency model of care delivery.

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

RATIONALE: Workers are not well served by mandating participation in a public authority, which is at heart a monopoly composed of a union combined with an employer with the authority of government. There is no compelling evidence that imposing a public authority is the best way to achieve increased wages and benefits for employees; there are other means for attaining this goal. Under the public authority system home care aides are stripped of their right to choose their employer and the protection of working under professional supervision. Home care agencies are better equipped than public authorities to provide worker training and oversight of the home care

aide. Many agencies also provide career ladders. Home care agencies assume liability for services and can be held accountable, unlike large government-sponsored monopolies.

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

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

Given the myriad problems that have arisen where the public authority model has been tried, it would be particularly inappropriate for the federal government to impose this model on any federal long term care program. A federal Medicaid approval of the public authority model would run counter to ongoing efforts by the federal government to expand access to home care in a flexible manner that meets the needs of all the disabled and elderly.

VI. HOME MEDICAL EQUIPMENT

ENSURE APPROPRIATE QUALITY STANDARDS, CLINICAL CONDITIONS COVERAGE, AND MANDATORY ACCREDITATION REQUIREMENTS FOR HME SUPPLIERS

ISSUE: The Medicare Prescription Drug, Improvement and Modernization Act (P.L. 108- 173) required the Centers for Medicare & Medicaid Services (CMS) to establish and implement quality procedures and accreditation requirements for Home medical equipment (HME) suppliers. CMS published a set of general quality standards, along with item specific standards for HME suppliers in 2006. These were much more appropriate than the earlier proposed standards which were overly prescriptive. In addition, CMS published a final rule for enforcing accreditation requirements and identified 11 independent accreditation organizations that will accredit suppliers as meeting the HME quality standards under Medicare Part B. The final deadline for accreditation of all HME Suppliers was set at September 30, 2009.

RECOMMENDATION

1. Ensure flexibility in clinical conditions so that coverage is based on medical necessity and not linked to any specific diagnosis
2. Ensure that the latest clinical practices are reflected in application of the standards
3. Consider cost of compliance in the application of standards, with particular attention to the impact of accreditation costs on small and rural suppliers.
4. Monitor the impact of accreditation requirements on beneficiary access.

RATIONALE: HME standards and accreditation requirements must strike a balance between the need to curtail fraudulent activities and HME suppliers' ability to comply in a cost effective manner. Overly strict interpretation of the standards may create access problems for patients, especially those in rural areas. Accreditation places considerable financial burdens on suppliers at a time when Medicare reimbursement for equipment is being reduced.

REQUIRE FAIRNESS IN IMPLEMENTATION OF COMPETITIVE BIDDING FOR HOME MEDICAL EQUIPMENT

ISSUE: Competitive bidding was enacted in the Medicare Prescription Drug, Improvement and Modernization Act (MMA) which included a provision that would phase-in the implementation of a national competitive bidding program for Home medical equipment (HME). Upon implementation, the Medicare program will no longer reimburse HME suppliers through a specified fee schedule. Instead, Medicare will award suppliers who submit the lowest bid with the contract to supply the region with the particular product. To participate in the bidding program, HME suppliers are required to waive their right to administrative or judicial review of the competitive bidding process.

Specifically, the MMA required a phase-in implementation of competitive bidding starting with 10 of the largest Metropolitan Statistical Areas (MSAs) in 2007; 80 of the largest MSAs in 2009; and additional areas after 2009. In developing the competitive bidding program, the Centers for Medicare and Medicaid Services (CMS) will be allowed to exempt rural areas and areas with low population density. According to the competitive bidding legislation, CMS is prohibited from awarding a contract unless the supplier meets quality standards and financial standards (with special consideration to small suppliers), and unless there are assurances that real savings will be achieved and that beneficiaries will have a choice of suppliers.

In order to ensure budget neutrality, the legislation required that there be no increase in the scheduled amount and a reduction of 9.5% in 2009 payments for all items and services selected for competitive bidding. Budget neutral offsets are required for the years 2010 through 2014, based on the consumer price index.

As a result of protests files, the first round of competitive bidding did not go into effect until January 2011. The first round was limited to 9, rather than 10, MSAs.

RECOMMENDATION:

In establishment of national competitive bidding for HME, CMS should:

1. Carefully analyze and implement “lessons learned” after implementation of the first round of competitive bidding before embarking on expansion beyond the 9 geographic areas.
2. Offer extensive provider and beneficiary education in competitive bidding MSAs.
3. Ensure small supplier participation in the Medicare HME benefit and avoid monopolies.
4. Continue to offer assistance to small providers in the bidding process.
5. Closely monitor the implementation of the competitive bidding program to guard against unintended negative consequences to Medicare beneficiaries or supplier.
6. Consider limiting competitive bidding to geographic areas with populations of over 1 million.
7. Conduct research on alternatives to competitive bidding.
8. Announce new competitive bidding MSAs as soon as possible, ensuring adequate notice to providers as new areas are added and limit transparency by publicizing information about bid winners immediately upon selection
9. Review the results of competitive bidding with special consideration of quality and the impact on beneficiary choice.

RATIONALE: Competitive bidding raises significant concerns, including loss of quality and service and the potential negative impact on beneficiary access and choice. Specifically, competitive bidding for HME supplies fosters monopolistic markets that could: a) reduce beneficiary choice by allowing

only those suppliers with winning bids to serve beneficiaries; b) reduce quality since, under competitive bidding, price becomes the main buying criteria; c) raise costs by promoting supplier monopolies that reduce competition; and d) create beneficiary confusion for those already receiving supplies and service from a supplier who can no longer serve in the area as a result of competitive bidding. Adequate notice of competitive bidding expansion enables suppliers in these areas to prepare.

ENSURE ADEQUATE REIMBURSEMENT FOR OXYGEN EQUIPMENT AND OXYGEN SUPPLIES AND REPAIRS

ISSUE: Oxygen and oxygen supplies help extend life and maintain maximum functioning despite the presence of serious chronic illness. Payments for oxygen and related supplies have been seriously curtailed in recent years, including freezes on the annual inflation updates for the 2004 – 2008 period of time. New oxygen provisions were added in Section 144(b) of the MIPPA which repeals a provision mandated by the Deficit Reduction Act of 2005 (DRA) requiring a supplier of oxygen equipment to transfer title of the equipment to the beneficiary at the end of a 36-month rental period. MIPPA repealed the transfer of title provision, although Medicare payment for oxygen equipment will continue to be capped at 36 months. MIPPA imposed other requirements related to oxygen equipment, contents and servicing which were put into regulation by Centers for Medicare & Medicaid Services (CMS) in a November 19th, 2008 Federal Register notice. Cuts of 9.5% resulting from the MIPAA provision calling for the delay of competitive bidding, and a 2.53% budget neutrality adjustment established in 2006. The oxygen regulation imposes new responsibilities on suppliers as follows:

- Any supplier that furnishes oxygen equipment during the 36-month rental period must continue to furnish and maintain the oxygen equipment after the 36-month rental period for useful lifetime of the equipment, including resumption after a break in service occurs or by arranging for another supplier if a beneficiary moves.
- The supplier is responsible for furnishing the item for no additional rental payments between the 36th month and the useful lifetime of the equipment
- A supplier may not replace equipment unless one of the following exceptions exists:
 - The item initially furnished was lost, stolen, irreparably damaged, is being repaired, or no longer functions;
 - A physician orders different equipment for the beneficiary based on medical necessity;
 - The beneficiary chooses to obtain a newer technology item or upgraded; or
 - CMS or the carrier determines that a change in equipment is warranted.
- Payment will be made for oxygen contents for use with liquid or gaseous oxygen equipment furnished throughout, including after the 36-month rental period.
- The provider that furnished oxygen equipment during the 36 months must continue to furnish both the oxygen equipment and contents for the remainder of the useful lifetime of the equipment, or arrange for receipt of oxygen contents from another supplier if the beneficiary moves.
- Payments will be made for routine maintenance and servicing visits for certain oxygen equipment (concentrators and transfilling equipment, but not liquid or gaseous oxygen equipment) after each continuous 6 month period of use, including beyond the 36-month rental period.
- Payment will not be made for parts replaced during a routine maintenance and servicing visit
- Payment will not be made for non-routine maintenance and service during the 5 year lifetime
- Payments will not be made for supplies and accessories furnished after the 36-month rental period.

The regulation allows for oxygen equipment maintenance checks twice a year but will allot only a small payment per visit to conduct these checks, which is inadequate to cover the cost of these services. In addition, CMS does not recognize costs associated with visiting patients who require

unscheduled emergency services or have unusual needs as a result of disasters. Other concerns include the fact that CMS has not identified the specific criteria that will be used for determining the “lifetime” of oxygen equipment. It appears that CMS assumes that lifetime is 5 years in all instances. This could be problematic since “lifetime” varies widely by manufacturer and type of equipment. For example, some manufacturer warranties are limited to 2-3 years, while others are for as long as 5 years. Finally, information is not offered about how oxygen equipment failures due to beneficiary neglect or abuse will be determined. This type of information is critical in order to ensure the protection of oxygen equipment suppliers.

RECOMMENDATIONS:

1. Provide timely information and encourage Congress to conduct swift review of the combined impact of the payment cuts and capped rental on oxygen equipment that are effective in 2009, with particular focus on their impact on access to care and the financial stability of small suppliers.
2. Modify existing payments to ensure appropriate access to equipment, supplies and services.
3. Establish criteria as to how oxygen equipment “lifetime” will be defined that is commensurate with manufacturer warranties (3 years versus 5 years).
4. Eliminate requirements to provide services to individuals who move outside of a supplier’s area.
5. Ensure adequate reimbursement for routine maintenance and service of the oxygen system.
6. Recognize costs associated with visiting patients who require episodes of unscheduled emergency services.
7. Ensure adequate quality and payment policies for oxygen equipment in times of emergencies and disasters.
8. Provide clear guidance for identifying and ameliorating situations when there is beneficiary abuse or neglect of equipment.

RATIONALE: Inadequate reimbursement rates for oxygen, oxygen equipment and services threatens patient access to care and the financial stability of suppliers, especially small businesses. The new regulations requiring suppliers to arrange servicing and refills when individuals move are unenforceable and will leave vulnerable Medicare beneficiaries without the clinical resources needed to ensure appropriate oxygen administration in the home setting. Regulations should ensure that suppliers are not penalized for beneficiary actions, or equipment failures and natural disasters which are beyond their control.

RELAX THE “IN-HOME” RESTRICTION FOR MEDICARE PART B REIMBURSEMENT OF HME SUPPLIES

ISSUE: Current law (42 U.S.C. § 1861 (n)) requires that Home medical equipment (HME) be used “in the patients home,” rather than a hospital or skilled nursing facility, to qualify for Medicare Part B reimbursement. Congressional intent was to exclude Part B coverage of HME in an institutional setting. Congress did not otherwise impose a geographical limit on the use of HME. For example, there is no requirement that the actual use of the HME be confined to the four walls of a home. Nevertheless, the Centers for Medicare and Medicaid Services (CMS) and the Home Medical Equipment Regional Carriers (HMERCs) have interpreted and applied the “in the patient's home” clause in an overly restrictive manner. Specifically, Medicare HME coverage has been limited to those items an individual demonstrates are needed within the home, rather than the HME needed to allow the individual to meet his or her daily responsibilities. As a result, persons with disabilities, young and old, have been denied Medicare coverage of the types of medical equipment that will enable them to attend school; go to work; meet their obligations as parents and heads of households (e.g., to shop, attend meetings and activities at their children's schools); participate in religious services; and to otherwise be fully involved in their local communities and in American society. During 2007 the Medicare Independent Living Act of 2007 was introduced by Sen. Jeff Bingaman (D-NM) and others in the Senate (S. 2103), and by Rep. James R. Langevin (D-RI) and others in the House (H.R. 5983); the legislation would eliminate the “in the home” restriction on reimbursement of medical equipment.

RECOMMENDATION: CMS must support changes to legislation, definitions, policies and practices that will ensure that HME supplies, along with rehabilitative and assistive technologies, are a covered Medicare benefit.

RATIONALE: The “New Freedom Initiative” for persons with disabilities includes helping individuals with disabilities by “increasing access to assistive technologies, expanding educational opportunities, increasing the ability of Americans with disabilities to integrate into the workforce, and promoting increased access into daily community life.” Without access to appropriate HME in the community, persons with disabilities will not be able to fulfill their potential in the work place, to get to school to develop new job skills, or to meet their family responsibilities of performing many of activities of daily living. More over 65 Medicare beneficiaries continue to be employed. These beneficiaries should not be deprived of coverage for HME they may need to remain mobile in the community and access their employment site.

SUPPORT EFFORTS TO ADEQUATELY REIMBURSE HME SUPPLIERS FOR COSTS ASSOCIATED WITH IN – HOME DRUG THERAPIES

ISSUE: Prior to the implementation of the Medicare and Prescription Drug, Improvement and Modernization Act (MMA) (PL 108-173), Medicare Part B paid 95 percent of average wholesale price (AWP) for drugs used in home infusion and home inhalation therapies administered through home medical equipment. A report by the Government Accountability Office (GAO), however, characterized the reimbursement for drugs under Medicare Part B as flawed and called on Congress to explore new ways to pay for drugs under the home medical equipment (HME) benefit.

Partly in response to this report, the MMA reduced payments for most in-home drug therapies. Drug and drug therapies furnished in 2004 were reimbursed at 85 percent of the AWP (determined as of April 1, 2003). Beginning in 2005, drugs and biologicals, except for pneumococcal, influenza, and hepatitis B vaccines and those associated with certain renal dialysis services, were paid using either the average sales price (ASP) methodology or through competitive bidding.

Infusion drugs furnished through covered home medical equipment starting January 1, 2004, were paid 95 percent of the AWP in effect on October 1, 2003; those infusion drugs that may be furnished in a competitive acquisition area are to be paid at the competitive price. HME suppliers do not dispute that, under the old law, Medicare Part B payments for drugs were higher than the costs of the actual drugs. What CMS and GAO failed to take into consideration is that the reimbursement also paid for the high level of service that accompanies the administration of such drugs in the home. A report developed by consultants at Lewin and Associates demonstrates that actual cost of the drugs represents only a small fraction of the overall costs of caring for patients with inhalation or IV therapy. According to the Lewin report, the cost of the drugs to treat these patients represents only 26 percent of total costs, while direct patient care costs average 46 percent and indirect costs such as accreditation, information systems, and Medicare/Medicaid compliance amount to another 25 percent.

The Medicare Home Infusion Therapy Consolidated Coverage Act of 2006 (H.R. 5791) was introduced during the 109th Congress by Rep. Kay Granger (R-TX) and others to remove coverage of home infusion therapy from the HME benefit and establish a new benefit under Part B of Medicare that more accurately reflects the cost of both the drugs and the services needed to administer such drugs. No action was taken on H.R. 5791 during the 109th Congress.

RECOMMENDATION:

- Urge Congress to take action for reform of reimbursement for home infusion and inhalation therapies and discourage recommendations to subject the HME drug benefit to competitive bidding.
- Conduct new studies of the comparison of cost of infusion therapy provided in the home, versus in outpatient departments and hospitals.

RATIONALE: Current Medicare reimbursement fails to recognize such services as the need to compound certain drugs in a sterile setting, responding to emergencies and questions concerning therapies, and participating in the training and education of the patient and the patient's family. Oftentimes, the therapies require services of a nurse or respiratory therapist to perform a variety of

functions. If the patient does not qualify as “homebound” under the home health benefit, nursing services are not covered since services are not part of the HME drug benefit.

Failure to pay suppliers adequately for drugs that require provision of services to ensure appropriate drug therapy could negatively impact beneficiary access and choice and lower quality.

VII. HOSPICE

REINSTATE THE BUDGET NEUTRALITY ADJUSTMENT FACTOR IN THE MEDICARE HOSPICE WAGE INDEX

ISSUE: President Bush's proposed 2009 budget included a regulatory proposal that would permanently eliminate the budget neutrality adjustment factor for the hospice wage index resulting in about a 4 percent cut in the hospice reimbursement rates each year. The anticipated savings would be \$2.29 billion over five years. The Centers for Medicare & Medicaid Services (CMS) issued a Notice of Proposed Rulemaking (NPRM) calling for comments followed by issuance of a final rule. CMS essentially ignored the comments and began a three-year phase out of the BNAF, effective November 1, 2008. As a result of passage of the American Recovery and Reinvestment Act of 2009 which postponed elimination of the BNAF until October 1, 2009, CMS reinstated the BNAF back to October 1, 2008. In subsequent 2009 rulemaking, CMS modified the schedule for eliminating the BNAF to phase it out over a seven year period beginning in FY2010. That phase out started with a 10 percent reduction in FY2010 followed by six years of consecutive 15 percent reductions.

The House proposal for health care reform included a one year delay (until October 1, 2010) in the start of elimination of the BNAF (H.R.3962, Section 1113). This was not included in the final health reform legislation.

RECOMMENDATION: CMS should reinstate the budget neutrality adjustment factor in the Medicare Hospice Benefit wage index annual update.

RATIONALE: In 1994, as a result of disparity in wages from one geographical location to another, CMS established a committee to negotiate a wage index methodology that could be accepted by the industry and the government. The National Association for Home Care & Hospice participated in the Hospice Wage Index Negotiated Rulemaking Committee along with representatives of CMS and other hospice stakeholders. On April 13, 1995, the Hospice Wage Index Negotiated Rulemaking Committee signed an agreement for the methodology to be used for updating the hospice wage index which is now in place. At that time, CMS agreed to continue the same budget neutrality adjustment factor that was put into place when the benefit was created in 1983. Given that the agreement was entered into in good faith by all parties, action in this area should only be considered as part of a broader effort to refashion the hospice benefit.

The elimination of the BNAF creates a serious risk of loss of access to hospice care. MedPAC reports that the average hospice margin for 2011 will be approximately 4.2 percent; full elimination of the BNAF decreases hospice reimbursement annually by 4 percent. There is no reliable data available to indicate whether the majority of hospices would be able to sustain such an overwhelming cut in reimbursement rates. There is a very real danger that such deep reductions will put community hospices out of business, resulting in a lack of access to the hospice benefit, particularly in rural areas. The BNAF elimination, on top of additional hospice market basket and productivity adjustment reductions mandated by the Patient Protection and Affordable Care Act of 2010 (Public Law 111-148) will all but guarantee this result.

A June 2004 report by the Government Accountability Office (GAO) determined that 34 percent of hospices in 2000 and 32 percent in 2001 had higher costs than reimbursement. The GAO recommended that CMS collect comprehensive, patient-specific data on the utilization and cost of hospice visits and services to determine whether the hospice payment categories and methodology require modification. CMS is in the process of collecting such data. However, the existing data indicates that hospices can not sustain a 4 percent cut in Medicare payment rates.

The Medicare budget also will suffer through the loss of hospice care. A Duke University study showed that patients who died under the care of hospice cost the Medicare program an average of about \$2,300 less compared with those that did not.

WORK WITH HOSPICE INDUSTRY TO EVALUATE REVISION OF THE MEDICARE HOSPICE BENEFIT REIMBURSEMENT SYSTEM

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 32 percent of those being served by hospices. The median length of stay remains at about 17 days. There is growth in the number of long stay patients such as those with neurodegenerative conditions such as dementia, end-stage Alzheimer's disease, Parkinson's disease and cardiovascular disease. Although costs for pharmaceutical and pharmacotherapy for symptom control and pain management have increased dramatically, the reimbursement system has not changed since its inception. The Centers for Medicare & Medicaid Services (CMS) is in the process of gathering hospice data to assist in development of revisions to the MHB payment system, which were recommended by the Medicare Payment Advisory Commission (MedPAC) in 2009 and again in 2010. The Patient Protection and Affordable Care Act of 2010 (Public Law 111-148) requires that CMS revise the hospice payment system and implement these payment changes no earlier than October 1, 2013.

RECOMMENDATION: CMS should work with the National Association for Home Care & Hospice and the hospice industry to determine the most effective data to collect, the most efficient means of collecting it and what analysis of the data means when considering revision of the hospice payment system.

RATIONALE: To ensure that an accurate and rich data bank is created, it is imperative that CMS collect the necessary data to accurately reflect the full scope of services currently provided by hospices. It is critical that all stakeholders be included in the process of developing a revised hospice payment system to ensure that thorough consideration of the impact of the changes is fully considered.

ENSURE ACCESS TO DRUGS NECESSARY FOR PAIN CONTROL

ISSUE: Inadequate pain management has been identified by experts in the field as a national public health issue. Terminally ill patients may require very high doses of pain medication to achieve effective pain control. Physicians and other health professionals often do not have adequate knowledge about pain control, and/or have fears of laws related to controlled substances. Exacerbating the problem is the Drug Enforcement Agency's (DEA) reaction to Oregon's assisted-suicide law. The FDA has warned that physicians who prescribe lethal doses of narcotics under Oregon's Death with Dignity Act would be in violation of federal drug laws. The Institute of Medicine (IoM) has convened a committee at the request of the Department of Health and Human Services (HHS) to address the current state of the science with respect to pain research, care, and education and to explore approaches to advance the field.

RECOMMENDATION: HHS should closely monitor the work of the IoM related to pain research, treatment and education, and make every effort to implement IoM's findings relative to pain. HHS should also work with the Food and Drug Administration to:

--Develop guidelines and educational material that promote effective use of drugs to control pain.

--Avoid DEA actions that would discourage or prohibit physicians from prescribing adequate and appropriate controlled substances for the management of pain related to terminal illnesses.

RATIONALE: Pain and symptom management is the cornerstone of good hospice care, which rests on the belief that terminally ill patients should not have to suffer because of inadequate pain management and lack of access to appropriate medications. Creating laws and policies that impose arbitrary limitations on physicians who prescribe controlled substances could very well have the unintended consequences of discouraging or limiting them from adequately treating terminally ill patients.

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. Currently, the Centers for Medicare & Medicaid Services (CMS) has begun collecting 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 fiscal intermediaries (FI) and payments are being withheld based on the fiscal intermediaries' determination of prognosis.

RECOMMENDATION:

1. CMS should work with NAHC and the hospice industry to analyze the utilization data and identify problem areas.
2. 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.
3. Direct equal attention toward under-utilization as well as over-utilization.
4. Require fiscal intermediaries to offer provider training at least twice a year, open to all providers who wish to attend.

RATIONALE: Variation in utilization points not 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.

SUPPORT QUALITY ASSESSMENT PERFORMANCE IMPROVEMENT PROGRAM FOR HOSPICE

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 provides a strong start towards the development and implementation of a quality reporting program by 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 that hospices begin reporting these measures in FY2014. Failure to submit quality measures by a hospice would result in a 2 point reduction in the annual market basket index update (Section 3004).

RECOMMENDATION: CMS should ensure that the quality measures currently under development for hospice incorporate: a) reliable and valid indicators, b) outcome measures limited to those that most accurately predict quality, c) a method for risk adjustment, d) a standard assessment, e) a simple system with clinical utility, f) a mechanism enabling CMS to validate agency data, and g) an ongoing evaluation of the entire system.

CMS should include the National Association for Home Care & Hospice's (NAHC) adapted Edmonton System Assessment System (ESAS) as one of the data collection tools to be tested. CMS should also recommend use of NAHC's Patient Satisfaction Survey and Family Satisfaction Survey for hospice use as part of their ongoing QAPI programs based on patient outcomes.

RATIONALE: The ideal hospice quality assessment program must be based on what happens to the patients; however, there are currently no standard outcome measures for hospice care. 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.

ABOLISH PAYMENT DELAYS 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 fiscal intermediary (FI) claims processing problems and pending claims from other providers, etc. Hospices have continued to serve patients even though Medicare payments have been delayed.

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. Pay interest on claims that are not processed timely.

RATIONALE: Most hospice programs are small businesses with little financial reserve, dependent on uninterrupted payment for services delivered. Interruption of payment for weeks or months, while requiring agencies to continue services to patients, can result in severe financial hardships.

STUDY HOSPICE REIMBURSEMENT FOR DUALY 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% of the nursing home charge for room and board services. The hospice then reimburses the nursing home for: 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 the scrutiny of Health and Human Services Office of the Inspector General (OIG). In its report "Hospice Patients in Nursing Homes," the OIG made recommendations to eliminate or reduce the Medicare or Medicaid payments for hospice patients living in nursing homes.

RECOMMENDATION: CMS should not reduce payment to the hospice unless data collected and analyzed 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.

BASE SURVEY FREQUENCY ON PERFORMANCE OF MEDICARE HOSPICE BENEFIT PROVIDERS

ISSUE: Approximately 16.5 percent of Medicare-certified hospices are surveyed each year. There is no legislative requirement for the frequency of surveys for providers of the Medicare hospice benefit (MHB). CMS' 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. CMS currently has hospice providers on a six-year cycle for surveys but that sometimes extends to 10 years in some parts of the country.

RECOMMENDATION: Limited resources available for hospice surveys should be used to target quality issues by adopting the following survey frequency guidelines:

1. New Medicare hospice agencies should be surveyed annually for at least the first two years of certification.
2. Agencies with condition-level deficiencies should be surveyed at least annually until they are deficiency free.
3. Complaint surveys should be conducted following significant complaints. If deficiencies are found, annual surveys should be conducted until the hospice is deficiency free.
4. All hospices should be surveyed, at a minimum, every three years.

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.

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 an agency to be compensated under the waiver presumption, when their overall denial of claims rate was less than 2.5 percent of Medicare services provided. Any agency that exceeded this 2.5 percent 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 fiscal intermediary (FI) is to apply the usual procedures (not presumptive status) of the limitation on liability provision contained in the Medicare Intermediary 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.

RECOMMENDATION: 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 FI. Certifying terminal illness is an inexact science and extremely difficult for the physician, patient and family. An FI determination that a patient is not terminally ill is also devastating.

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.”

RECOMMENDATION: 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 CoP 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 recertifications. 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 fiscal intermediaries, 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 17 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.

ENSURE TIMELY UPDATE OF LOCAL COVERAGE DECISIONS FOR HOSPICE

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. Claims reviewers using the LCDs are given no instructions or guidance to take into account the physician's clinical judgment and the psychosocial dimensions of the illness for determination of coverage decisions.

RECOMMENDATIONS:

CMS should perform annual reviews of all LCDs and revise the policies based on available research and other pertinent findings relevant to the determination of a prognosis of six months or less. Additionally, CMS should ensure that the ICD-9-CM codes are current. Additional steps that should be taken relative to LCDs include the following:

1. Add the following criteria to LCDs to provide additional guidance to medical reviewers in determining the appropriateness of hospice admissions or recertifications:
 - a) Encourage the use of multiple LCDs to document co-morbidities so that all conditions, and not just the primary diagnosis, are being reviewed;
 - b) Require review of documentation of the clinical judgment and psychosocial dimensions of the terminal illness by medical reviewers; and
 - c) Require documentation by the reviewer of the date of patient's death, as appropriate, while enrolled in the hospice benefit or after discharge.
 - d) CMS should conduct research to validate the accuracy of the LCDs, including an analysis of their specificity and sensitivity.
2. 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.
3. Require that when making Medicare claims determinations, greater weight be given to the opinion of the treating physician.
4. Require review or additional documentation prior to issuing denials.

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

CLARIFY HOSPICE SERVICES TO MEDICARE BENEFICIARIES IN PRIVATE MA PLANS

ISSUE: Hospice providers and terminally-ill Medicare beneficiaries receive confusing and misleading information from private Medicare plans regarding the Medicare hospice benefit. Often the plans themselves are not fully informed about their role vis-à-vis Medicare-certified hospices and plan enrollees who wish to access hospice care. One of the problems is that information about hospice is scattered throughout the Medicare Advantage manual. Another problem is that hospice providers and Medicare beneficiaries are ill-informed about the interface between Medicare, its private plans, and hospices.

For example, a Medicare Advantage (MA) beneficiary can enroll in any Medicare-certified hospice, not just one that participates in the plan. The hospice, not the MA plan, is responsible for managing the patient's hospice plan of care across all levels and sites of care. The Medicare-certified hospice bills Medicare, not the private plan, for the Medicare patient's hospice care. Medicare pays the private plan for services not related to the terminal illness.

RECOMMENDATION: CMS should issue clarified policy guidelines regarding the Medicare hospice benefit and MA enrollment. CMS should also issue an explanation of rights to the hospice benefit for Medicare beneficiaries and require MA plans to disseminate it to all enrollees.

RATIONALE: Accurate information disseminated by CMS would help to educate beneficiaries, hospices, and MA plans about their rights and responsibilities and would increase access to the Medicare hospice benefit.

COMPENSATE PHYSICIANS FOR HOSPICE CERTIFICATION AND ADVANCE CARE PLANNING CONSULTATIONS

ISSUE: One of the primary requirements for Medicare beneficiaries to access the Medicare hospice benefit (MHB) 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. 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.” The most recent Centers for Medicare & Medicaid Services (CMS) data shows that the median length of stay remains at about 17 days.

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).

We applaud CMS’ creation of HCPCS codes GO179 and GO180 for physician certification and recertification of Medicare-covered home health services. The new codes will help home health agencies get physicians more involved in home health care. A similar code needs to be developed for hospice care.

RECOMMENDATION: CMS should create a new HCPCS code to compensate physicians for patient certification of eligibility for the Medicare hospice benefit. CMS should also authorize volunteer advance care planning consultations under Medicare to educate beneficiaries on issues related to end-of-life care and end-of-life care planning.

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 to 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.

PROVIDE FULL DISCLOSURE AND ENSURE SNF/NF MEDICARE BENEFICIARY RESIDENTS' RIGHT TO CHOOSE HOSPICE PROVIDER

ISSUE: In 1989, Public Law 101-239 mandated the ability of terminally ill Medicare beneficiaries residing in skilled nursing facilities/nursing facilities (SNF/NFs) to access services under the Medicare hospice benefit (MHB). As SNF/NF residents become aware of the MHB, more of them are seeking hospice services. However, the SNF/NF 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.

RECOMMENDATION: Congress should require that SNF/NFs disclose upon admission whether or not hospice services are available at the facility, and the name(s) of the hospice(s) with which the facility has contracted to provide hospice services on site. Additionally, Congress should mandate that eligible Medicare beneficiaries residing in SNF/NFs have the right to receive hospice services from the Medicare-certified hospice of their choice.

RATIONALE: SNF/NFs should provide full disclosure regarding the availability of hospice services through 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 resident may only access the Medicare hospice benefit if the SNF/NF has a formal arrangement with a hospice program to provide services in the facility.

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.

RECOMMENDATION: 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 care givers. Therefore, demonstration programs, grants, and other forms of reimbursement for telehospice 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.

REVISE REQUIREMENTS FOR HOSPICE

FACE-TO-FACE ENCOUNTERS

Issue: Section 3131(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. The provision applies to recertifications on and after January 1, 2011.

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 which 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.

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 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 scheduled the encounter.

- The face-to-face requirement is applicable to a patient's full time on hospice regardless of when the previous hospice service was provided. A patient may have been off hospice service for a lengthy period of time then begin rapid deterioration and need admission very quickly. In such cases the face-to-face requirement may delay admission.

- Centers for Medicare & Medicaid Services (CMS) data systems are not all available 24 hours, seven days a week to access patient information and most do not have full information related to a patient's history on hospice care to establish with absolute certainty whether a face-to-face encounter is required.

- 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 staffing limitations 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.

On Dec. 23, 2010, CMS announced a three-month delay in enforcement of the face-to-face requirements due to concerns that some hospice organizations may need additional time to establish operational protocols necessary to comply with the new law. CMS indicated that it expects hospices to use the first calendar quarter of 2011 establish internal processes to ensure

compliance. Beginning with the second quarter of CY 2011, hospices are expected to have fully established such internal processes and CMS will expect appropriate documentation of the encounter.

Recommendation: CMS should work with the hospice industry to ensure that:

1. Regulations and guidance governing the hospice face-to-face provide sufficient flexibility that hospice programs are able to comply with the requirements without threatening delayed access to care for beneficiaries in need of hospice services.
2. Enforcement of the hospice face-to-face requirements takes place only after CMS has assurance that hospices have sufficient guidance and understanding, as well as access to needed patient information through CMS' data systems, to reasonably be able to comply with the requirements. In no case should enforcement actions affect payment for hospice services that were provided prior to the enforcement date.

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.