

2009 Regulatory Blueprint for Action

National Association for Home Care & Hospice
228 Seventh Street, SE
Washington DC 20003-4306

TABLE OF CONTENTS

TABLE OF CONTENTS	i
INTRODUCTION	vi
EXECUTIVE SUMMARY	vii
I. REIMBURSEMENT REFORM	1
ESTABLISH PROCEDURES FOR TIMELY & ACCURATE ADJUSTMENTS TO THE CASE-MIX SYSTEM THAT ADDRESS CHANGES IN PATIENT CHARACTERISTICS AND HOME HEALTH RESOURCES	2
REFINE MEDICARE HOME HEALTH PPS OUTLIER PAYMENT.....	4
IMPROVE APPLICATION OF WAGE INDEX FOR MEDICARE HOME HEALTH AND HOSPICE	5
PROVIDE FAIR AND TARGETED REIMBURSEMENT FOR MEDICAL SUPPLIES	6
ELIMINATE INEQUITIES IN PARTIAL EPISODE PAYMENTS	8
REIMBURSE HOME HEALTH AGENCIES FOR TELEHEALTH AND PROVIDE FOR REGULATORY FLEXIBILITY.....	10
ENSURE USE OF STATISTICALLY VALID SAMPLING METHODOLOGY FOR POSTPAYMENT REVIEW	12
ENSURE HOME CARE SERVICES UNDER MANAGED CARE.....	13
ENSURE ACCESS TO MEDICAID HOME CARE SERVICES	15
ENSURE THAT OASIS-C IS VALID AND RELIABLE AND IMPLEMENTATION IS DONE IN A SYSTEMATIC MANNER WITH ADEQUATE CONSIDERATION GIVEN TO COST	17
ESTABLISH A FAIR AND EQUITABLE PAY FOR PERFORMANCE (P4P) SYSTEM.....	20
PROMOTE MEDICARE-MEDICAID COORDINATION	23
ENSURE FAIRNESS IN GOVERNMENT FRAUD AND ABUSE ACTIVITIES	25
ENSURE APPLICATION OF PROFESSIONAL AUDITING AND ACCOUNTING STANDARDS.....	27
REFORM MEDICARE HOME HEALTH MARKET BASKET INDEX	28
II. QUALITY	29
IDENTIFY FEDERAL SPECIALISTS TO RESOLVE SURVEY DISCREPANCIES AND ESTABLISH A FORMAL IDR PROCESS	30

INCREASE TRAINING FOR HOME HEALTH AND HOSPICE SURVEYORS.....	32
INCREASE FLEXIBILITY IN THE APPLICATION OF THE CONDITIONS OF PARTICIPATION.....	34
INCREASE FLEXIBILITY IN AIDE SUPERVISION REQUIREMENTS.....	36
IMPROVE AIDE QUALIFICATIONS TO PROTECT CONSUMERS.....	38
ENSURE FAIR APPLICATION OF IMMEDIATE JEOPARDY CITATIONS AND APPEAL RIGHTS.....	40
DEVELOP APPROPRIATE POLICIES AND REGULATIONS FOR EQUITABLE IMPLEMENTATION OF SURVEY AND CERTIFICATION PENALTIES AND SANCTIONS	42
REQUIRE REGION OFFICE REVIEW OF CHALLENGES TO DEFICIENCIES	44
REQUIRE FEDERALLY FUNDED CRIMINAL BACKGROUND CHECKS AND ESTABLISH A NATIONAL REGISTRY SYSTEM	46
SUPPORT REQUIRED QUALITY IMPROVEMENT PROGRAM.....	48
ENSURE THE USE OF APPROPRIATE QUALITY INDICATORS AND ACCURACY OF HOME HEALTH COMPARE.....	50
ALLOW HHAs AND HOSPICES TO PROVIDE UNLIMITED SERVICES UNDER ARRANGEMENTS	52
ESTABLISH BRANCH OFFICE AND SERVICE AREA REQUIREMENTS THAT REFLECT QUALITY MEASURES	54
ENSURE THE CMS S&C GROUP EMERGENCY PREPAREDNESS PLAN ADEQUATELY ADDRESSES THE NEEDS OF PROVIDERS OF SERVICES IN THE HOME.....	56
PROVIDE INFORMATION TO HOME HEALTH AGENCIES ON THE INTRODUCTION OF THE CONSUMER ASSESSMENT OF HEALTHCARE PROVIDERS AND SYSTEMS (CAHPS) PATIENT PERCEPTION OF CARE TOOL	57
ENSURE ADEQUATE FUNDING FOR MEDICARE SURVEY AND CERTIFICATION TO PROTECT QUALITY OF CARE.....	59
ESTABLISH APPROPRIATE PROCESS FOR APPROVAL OF BRANCH BY ACCREDITING BODIES.....	60
PROMOTE INCLUSION OF THE HOME HEALTH IN THE 9th SCOPE OF WORK	61
III. ADMINISTRATION	62
ENSURE FAIRNESS UNDER MEDICARE CONTRACTING REFORM	63
DEVELOP AN EFFECTIVE EMERGENCY PREPAREDNESS SYSTEM THAT INCLUDES HOME CARE AND HOSPICE AND ENSURES REGULATORY RELIEF	65

ESTABLISH REFERRAL STANDARDS AND DISCHARGE PLANNING REGULATIONS THAT ENSURE PATIENT CHOICE AND EQUAL ADVANTAGE TO ALL PROVIDERS.....	68
CONTROL PAPERWORK BY REQUIRING CMS TO FOLLOW THE PAPERWORK REDUCTION ACT.....	70
MODIFY PAYMENT TO PHYSICIANS FOR CARE PLAN OVERSIGHT AND CLARIFY RULES FOR PAYMENT FOR CERTIFICATION/RECERTIFICATION.....	71
ENSURE REASONABLE ENROLLMENT AND PARTICIPATION REQUIREMENTS FOR AGENCIES	73
SUPPORT PHYSICIANS IN ADOPTION OF E-PRESCRIBING AND E-HEALTH RECORDS RELATED TO HOME HEALTH & HOSPICE SERVICES	78
PROHIBIT PUBLICATION OF MULTIPLE PROVIDER REGULATIONS IN A SINGLE NOTICE UNLESS ADEQUATE NOTIFICATION IS PROVIDED	79
REQUIRE MEDICARE TO FULLY ASSESS AND REPORT ON THE IMPACT OF ITS NEW RULES	81
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.....	82
CLARIFY THAT THE FTIC IDENTITY THEFT (RED FLAG) RULES DO NOT APPLY TO SIMPLE SALES TRANSACTIONS	84
IV. COVERAGE & APPEALS.....	85
ENSURE HOME HEALTH ACCESS FOR HOMEBOUND BENEFICIARIES.....	86
PROMOTE CONSISTENT APPLICATION OF COVERAGE RULES AND ABANDON LOCAL COVERAGE POLICIES.....	88
REFINE CLAIMS REVIEW & ADDRESS TECHNICAL ERRORS	90
CLASSIFY CLAIMS CURRENTLY SUBJECT TO TECHNICAL DENIALS AS “INCOMPLETE CLAIMS”	92
ENSURE INDEPENDENCE OF ADMINISTRATIVE LAW JUDGES	94
PROHIBIT CMS OVERPAYMENT RECOUPMENT PRIOR TO QIC DECISIONS	95
V. OTHER.....	97
PROMOTE PROVIDER RIGHTS & OPPORTUNITIES TO COMPETE THROUGH EFFECTIVE ENFORCEMENT OF ANTITRUST LAWS	98
DEVELOP QUALITY OF CARE STANDARDS FOR CONSUMER DIRECTED CARE	99
OPPOSE CHANGES TO COMPANIONSHIP SERVICES EXEMPTION TO THE FAIR LABOR STANDARDS ACT	101

MONITOR THE HOME AND COMMUNITY-BASED CARE BENEFIT IN THE MILITARY HEALTH SYSTEM	103
MONITOR OSHA ACTIVITY ON ERGONOMICS AND ENSURE APPROPRIATE ENFORCEMENT IN HOME SETTINGS	104
ENSURE ACCEPTABLE STANDARDS FOR CULTURALLY AND LINGUISTICALLY APPROPRIATE HEALTH SERVICES	105
REVISE THE POLICY GUIDANCE FOR PROVIDERS SERVING PERSONS WITH LIMITED ENGLISH SKILLS	106
VI. DURABLE MEDICAL EQUIPMENT	107
ENSURE APPROPRIATE QUALITY STANDARDS, CLINICAL CONDITIONS COVERAGE, AND MANDATORY ACCREDITATION REQUIREMENTS FOR DME SUPPLIERS	108
REQUIRE FAIRNESS IN IMPLEMENTATION OF COMPETITIVE BIDDING FOR DURABLE MEDICAL EQUIPMENT	110
ENSURE ADEQUATE REIMBURSEMENT FOR OXYGEN EQUIPMENT AND OXYGEN SUPPLIES AND REPAIRS	112
RELAX THE “IN-HOME” RESTRICTION FOR MEDICARE PART B REIMBURSEMENT OF DME SUPPLIES	114
SUPPORT EFFORTS TO ADEQUATELY REIMBURSE HME SUPPLIERS FOR COSTS ASSOCIATED WITH IN – HOME DRUG THERAPIES	115
VII. HOSPICE	117
REINSTATE THE BUDGET NEUTRALITY ADJUSTMENT FACTOR IN THE MEDICARE HOSPICE WAGE INDEX	118
WORK WITH HOSPICE INDUSTRY TO EVALUATE REVISION OF THE MEDICARE HOSPICE BENEFIT REIMBURSEMENT SYSTEM	119
RESPOND TO NEW HOSPICE CONDITIONS OF PARTICIPATION (CoP) ISSUES	120
ENSURE ACCESS TO DRUGS NECESSARY FOR PAIN CONTROL	121
ENCOURAGE ACCOUNTABILITY FOR HOSPICE UTILIZATION	122
SUPPORT QUALITY ASSESSMENT PERFORMANCE IMPROVEMENT PROGRAM FOR HOSPICE	123
ABOLISH PAYMENT DELAYS CAUSED BY SEQUENTIAL BILLING POLICY FOR HOSPICE	124
STUDY HOSPICE REIMBURSEMENT FOR DUALY ELIGIBLE PATIENTS RESIDING IN NURSING FACILITIES	125

BASE SURVEY FREQUENCY ON PERFORMANCE OF MEDICARE HOSPICE BENEFIT PROVIDERS126

REINSTATE PRESUMPTIVE STATUS FOR HOSPICE WAIVER OF LIABILITY127

OPPOSE EFFORTS TO REQUIRE PHYSICIAN CERTIFICATION FORMS TO INCLUDE A FALSE CLAIMS WARNING.....128

ENSURE TIMELY UPDATE OF LOCAL COVERAGE DECISIONS FOR HOSPICE129

CLARIFY HMO HOSPICE SERVICES TO MEDICARE BENEFICIARIES.....130

COMPENSATE PHYSICIANS FOR HOSPICE CERTIFICATION131

ASSURE SNF/NF MEDICARE BENEFICIARY RESIDENT’S RIGHT TO CHOOSE HOSPICE PROVIDER132

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) 2009 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 2009, are:

EXECUTIVE SUMMARY

The 2009 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.

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 costs of service delivery and supplies at that time.

A case-mix adjuster is used to avoid penalizing agencies that serve patients who require more care than the average and to avoid rewarding agencies that serve only low cost patients. 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, home health cost reports, and claims up to 2006. Unfortunately, CMS found that a large percentage of the cost reports on file could not be used because of errors and omissions. In addition, many 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.

RECOMMENDATIONS:

1. Conduct ongoing analysis of the adequacy of the case-mix adjuster with input from providers and case-mix study contractors.
2. Implement further refinements that would extend or increase the case-mix system reliability, in a timely manner, based on study findings.

3. Modify the case-mix adjuster to consider the rehabilitation services provided by other home care personnel.
4. Study the impact of poverty, by analyzing service utilization of dually eligible beneficiaries.
5. Analyze the impact of “no available informal caregiver” on home care resources and adjust case-mix.
6. Work to eliminate the use of surrogates for patient characteristics such the volume of therapy visits.
7. Study the impact of out-of-home time spent by home health care workers on the cost of care.
8. Evaluate whether intensive skilled nursing episodes are adequately compensated under the revised case-mix system.
9. Provide at least 4 months notice when making future adjustments to payment rates and 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. Continued refinements will increase its 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.

REFINE MEDICARE HOME HEALTH PPS OUTLIER PAYMENT

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 2006 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.

RECOMMENDATION:

Revise the outlier payment methodology in the following manner:

1. Investigate the grossly uneven distribution of outlier payments
2. Reduce the fixed dollar loss ratio to the 2007 level
3. Eliminate the shared loss ratio for excessively high cost episodes.
4. Include the cost of medical supplies as an eligibility element for outlier payment
5. Include a cost based outlier methodology along with the present “number of visit” based outlier methodology
6. In the event that the full outlier budget is not expended, issue retrospective adjustments to the outlier payments in order to fully expend the five percent budget.

RATIONALE: The original outlier payment methodology was established based upon speculation and assumptions that have not proven accurate. With outlier expenditures far below budgeted levels, it is clear that CMS established eligibility thresholds and cost sharing inappropriately high. The dramatic increase in outlier spending in a single geographic area should not be the basis for a national outlier policy. Outlier reimbursement payments still fall far short of costs of outlier episodes and many that fail to qualify for outlier payments. At the same time there is strong evidence that, on a national basis, long term and high cost home health patients are no longer being served in the home care setting, but instead are receiving care in a nursing facility, possibly as a result of underpayment. The loss of access to Medicare home health services for high cost patients requiring intensive care over the long term and individuals with uniquely high cost needs strongly demonstrates that the outlier payment methodology has failed to achieve its intended goal.

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 Factor (the BNAF will be phased out between FY2009 and 2011.) .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.

RECOMMENDATION: Allow hospices and home health agencies to obtain a geographic reclassification for wage index purposes in a manner comparable to that available to the hospitals or allow reclassifications automatically when a hospital in the geographic locale of the hospice or home health agency receives a reclassification. Establish limitations on swings in a wage index from one year to the next.

RATIONALE: 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.

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 adjustor 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

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. To 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.

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.

RECOMMENDATION: CMS should discontinue sampling and overpayment projections.

If this is not possible in light of legislative and regulatory requirements:

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.
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 DME 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.

RECOMMENDATION:

1. Develop appropriate rate setting structures for use within the individual state Medicaid programs.
2. Enforce federal Medicaid law that requires states to set rates in a manner that secures access to necessary care and ensures quality.
3. Curtail cuts in the scope of benefits.
4. Prohibit co-payment requirements.
5. Ensure that home health is included in every state Medicaid benefit package if block grants are established.
6. Address service and payment rate requirements that must be followed by managed care organizations serving Medicaid clients.

7. Ensure comprehensive reform of Medicaid home care consistent with the Olmstead decision.
8. Ensure compliance with the elimination of the homebound requirement at the state level.
9. Require that minimum standards be established for consumer directed care programs.
10. 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.

ENSURE THAT OASIS-C IS VALID AND RELIABLE AND IMPLEMENTATION IS DONE IN A SYSTEMATIC MANNER WITH ADEQUATE CONSIDERATION GIVEN TO COST

ISSUE: The Centers for Medicare and Medicaid Services (CMS) require home health agencies to collect and submit patient data using the Outcomes Assessment and Information Set (OASIS). The OASIS information is used for outcome measures, public reporting of quality indicators, and case-mix adjustment in the prospective payment system (PPS) for home health. Reimbursement for OASIS expenses incurred by home health agencies is limited to data entry and transmission costs which are built into episode rates. While there is industry-wide support for an outcome-based assessment process, OASIS imposes a substantial burden on home health agencies and their staff. OASIS is often cited as the number one reason why nurses are leaving home health care. As a result, it has exacerbated the already scarce supply of available and qualified nurses nationwide. The next version of OASIS (OASIS-C) has requires the collection of even more data items.

Assessments that are unnecessary burdens to home health agencies include significant change in condition assessments that are used for neither payment nor quality and follow-up assessments of Medicaid patients. Although OASIS data collection for Medicare patients is limited to payment items, CMS continues to require full OASIS data collection for Medicaid patients at recertification despite the fact that this information is used neither for quality measurement or payment.

CMS contracted with Abt Associates to analyze the current OASIS data set (OASIS B1) for needed refinements, and consideration of new process measures and burden reduction. In response, OASIS-C was developed and tested based on input from the industry and a technical expert panel. OASIS-C, which incorporates process measures, eliminates "prior status," adopts refinements to current items, and eliminates certain items deemed inappropriate for home health quality and payment was tested and sent to the Office of Management and Budget (OMB) for approval. CMS hopes to receive OMB approval of OASIS-C by April 30, 2009 and publish a proposed and final rule shortly thereafter, enabling them to require mandatory adoption of the new data set by January, 2010. Very limited validity and reliability testing was carried out on OASIS-C.

Despite CMS' contention that adoption of OASIS-C will not increase home health burden, the OMB package, the following comparison to OASIS-B1 appears to contradict that claim.

Data Set	SOC	ROC	Recert	Transfer	Discharge
OASIS B-1	76	61	30	11	75
OASIS-C	105	90	32	26	74

In regard to OASIS requirements to collect data on non-Medicare and non-Medicaid patients, CMS completed a study as mandated by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. MMA further required that data collection on this population be temporarily suspended until findings could be analyzed. The study has been completed and a report was submitted to Congress. In its report, CMS admitted that the researchers could not accurately predict the actual impact of a decision to either permanently suspend or require OASIS data collection on private pay patients. CMS has given no official indication of what next steps it might take relative to the pending suspension of OASIS data collection for private pay patients.

RECOMMENDATIONS:

1. Support the industry's recommendations for further refinement of the OASIS form and requirements, including elimination of items with no relationship to payment or quality determinations.
2. Permanently eliminate the collection of OASIS items for non-Medicare patients.
3. Reassess the frequency of assessments and eliminate unnecessary time points.
4. Until that is done, eliminate recertification OASIS data collection for Medicaid patients.
5. Limit OASIS data item collection to those items necessary for establishment of an HHRG when needed to bill maternity and pediatric services to Medicare.
6. Reimburse the full costs that agencies incur in collecting and submitting OASIS data for each assessment submitted.
7. Eliminate the SCIC assessment requirement.
8. Adjust payment rates to include costs that agencies incur when complying with regulatory and legislative requirements not in the rate calculation, including data collection requirements for payment and quality.
9. Allow the use of a single universal form for all OASIS collection time points.
10. Revise the guidelines for assessment of patients receiving inpatient care to admissions of more than 72 hours
11. Allow any practitioner to conduct a start of care assessment.
12. Amend timelines to 10 days to complete an OASIS assessment.
13. Limit OASIS items and requirements to those that are valid, reliable and necessary for payment and quality measurement.
14. Reevaluate the burden analysis related to the OASIS – C implementation to accurately reflect time and resources associated with staff training and completion of the data set.
15. Consider additional expenses and staff training associated with software modification that will be required to accommodate the OASIS-C.
16. Ensure adequate training is provided to home health providers and Medicare state surveyors before implementing the tool.
17. CMS should be prepared to delay the implementation date for OASIS-C if by Fall 2009 agencies and vendors express difficulty meeting the January 1, 2010 implementation date.

RATIONALE: OASIS requirements should impose as few administrative and financial burdens as possible upon already severely strained home health agencies. It is counterproductive to require collection of data that is not proven to be effective and essential for quality measurement and payment, particularly in light of the national nursing shortage. SCIC assessments are not used to measure quality. Home health agencies are paid by Medicare to provide health care services. Therefore, they should not be evaluated based on their ability to improve patients' performance of IADLs. Requiring OASIS data collection and submission for non-Medicare patients constitutes an unfunded mandate and is of questionable value.

When the OASIS assessment instrument was first implemented in 1999, the amount of training needed and degree of complexity involved in using the tool was not well understood. As a result of these miscalculations, clarification on how to accurately answer many of the items continues today, almost 10 years later.

The OASIS instrument serves a critical function in the operations of a home health agency. The data set determines a patient's case mix index for payment and drives quality measures used for public reporting and internal review of quality care. CMS needs to seriously consider the implications for agencies and the integrity of the Medicare program when evaluating the financial and administrative impact of the implementing the OASIS –C. The revisions to the instrument are not simple changes and additions as suggested by CMS's supportive statements and burden estimate outlined in the OMB packet.

CMS must use this opportunity to ensure that training is adequate and resources are available to providers before implementing the OASIS –C

ESTABLISH A FAIR AND EQUITABLE PAY FOR PERFORMANCE (P4P) 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. Through the Deficit Reduction Act (DRA) of 2005 Congress legislated that home health agencies be penalized with a minus 2% to their market basket update if they failed to report certain quality measures, as identified by the Secretary.

In addition, 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 taken away 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 meant 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 plans to expand P4P efforts only as allowed by legislation. However, CMS established a home health P4P demonstration project in order to prepare for eventual legislation which was very different than that proposed by MedPAC. Through the CMS P4P demo contractor, Abt Associates, home health agencies have been recruited to participate in the demonstration, which began in January 2008 and will end in December 2009. Rewards to agencies in this two year project will be based on savings in other areas of the Medicare program. Performance will be evaluated based on OASIS outcomes for Medicare patients, with rewards to those providers with highest scores on outcomes and highest levels of improvement. CMS also contract with Abt Associates to revise the OASIS data set, add new process measures. CMS hopes that this revised and expanded OASIS will improve its capability to reward providers under P4P.

RECOMMENDATION:

1. Ensure consultation with provider representatives in identification of appropriate P4P 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 using current guidelines in the "real world" of home health application
3. Require that OASIS-C refinements be in place and 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 P4P system, add funding sources for home health agencies.
6. Create a separate pool that would be used to fund P4P, rather than funding by withholding a percentage of payment from home health agencies.
7. Fund P4P 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 agencies with anomalous patient populations, such as large numbers of dually eligible patients, chronically ill long stay, or small numbers of patients served
13. Apply P4P to the Medicare Program only
14. Ensure that the risk adjustment methodology effectively adjusts for age, the number of co-morbidities, and Medicaid eligibility.
15. Consider 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 P4P in home health until completion of demonstration projects, analysis of the results, and pilot testing.

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 P4P 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 P4P.

P4P will only serve as an incentive to providers to improve the quality of care if they 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 P4P principles that the National Association for Home Care & Hospice and other organizations in the home care community have established. The MedPAC commissioners appear to be more in line with NAHC's principles for a workable and appropriate P4P 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 P4P. However, many questions exist about the validity and reliability of OASIS. In addition, the 2005 proposed legislation identifies the need for the Secretary to test new process measure and ways to reward providers to use of health information technology (HIT).

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 comparison of performance thresholds be compared separately. Therefore, geographic areas smaller than an entire state should be identified for comparisons of agency performance. CBSA's may serve as more appropriate for determining performance thresholds.

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 demonstrations 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.

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 (PCS). Twelve program safeguard contractors have been named to carry out fraud detection and prevention. There is growing concern about inappropriate PSC coverage interpretations, denials, and sampling applications.

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 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.

The Office of Inspector General should:

1. 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.
2. Streamline their enforcement procedures to minimize the investigative impact on non-fraudulent providers. They should seek assistance from NAHC/HHA in drafting "Fraud Alerts" and investigative procedures.
3. 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.

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.

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 a 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.

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.

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. An accurate inflation update is crucial to secure continued access to home health care.

II. QUALITY

IDENTIFY FEDERAL SPECIALISTS TO RESOLVE SURVEY DISCREPANCIES AND ESTABLISH A FORMAL 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.
5. Arbitration and clarification should stop the clock on immediate jeopardy citations and occur prior to the closure of an agency for all challenged deficiencies.
6. 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.

INCREASE TRAINING 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 and achieve compliance within 30 days.

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. A contractor for CMS is conducting an evaluation of project and anticipated a report to be issued in Spring 2008; however, a final report has yet to be published.

RECOMMENDATION:

1. 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.
2. Such a system should be voluntary until an efficient and accessible background check system is in place.
3. Federal and state background check requirements should not be duplicative.
4. 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.
5. Requirements should mandate that agencies be adequately reimbursed for the cost of the background checks.
6. A standard definition of abuse, neglect, or misappropriation of patient property should be used for purposes of establishing a national registry.
7. 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.
8. Congress should establish efficient, effective and economical criminal background check requirements based on the findings of the pilot.
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 outcomes of care and create adverse event reports. At the present time home health agencies must access the Outcome Based Quality Monitoring (OBQM) reports and include them as part of the agency's clinical record review and annual program evaluation. The use of Outcome Based Quality Improvement (OBQI) is voluntary at this time, but the reports are used both for survey preparation and process. In addition, outcome measures derived from OBQI reports are used for public reporting.

CMS will be re-issuing the proposed home health CoPs in the near future, OBQI activities will likely be mandatory as part of an agency's "quality assessment performance improvement" program with more specific guidelines to surveyors for incorporation of OASIS and outcome reports in the survey process. CMS will issue guidelines to surveyors for incorporation of OASIS and outcome reports in the survey process. In the meantime, Quality Improvement Organizations (QIO) were charged with helping home health agencies implement OBQI 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 outcomes 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 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 outcomes 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 adverse event and outcome 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. 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 outcome reports generated by the OASIS assessment tool in its present form. 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.

In 2004, CMS arranged with the National Quality Forum (NQF) to identify and analyze all available home health quality indicators in order to determine which ones are most appropriate for public reporting. NQF identified 28 indicators, 17 based on the outcome reports presently received by home health agencies based on OASIS data, 3 hospice indicators, and 8 ACOVE measures which are process measures for the frail elderly developed by RAND Corporation. After an internal review process, NQF made final recommendations to CMS for measures that were subsequently included in Home Health Compare. Currently, there are twelve quality indicators publicly reported on the Home Health Compare web site. These indicators are limited to outcome measures. The revised OASIS-C data set, which is scheduled for an implementation on January 1, 2010, includes process measures. Process measures could be identified for public reporting in the near future.

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.

Decisions about quality of care should not be limited to outcome measures. 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. Agencies strive to improve outcomes, the “means” are going to be ratcheted upward, and by definition, a mean has half above and half below. It is theoretically possible for agencies giving excellent care to be below the mean because all providers have enhanced their outcomes. 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, has been meeting since in October 2006.

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 causality events as it relates primarily to inpatient settings. Recommendations for action in many disaster-planning models do not consider the uniqueness of home care. 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 PROVIDERS AND SYSTEMS (CAHPS) PATIENT PERCEPTION OF CARE TOOL

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. After reviewing field test results with a technical expert panel consisting of home health industry experts, patient advocates, and researchers, the Home Health Care CAHPS Survey was finalized as a 36-item survey instrument. CMS has submitted the survey to the National Quality Forum (NQF) for consideration and approval in their consensus process. The final survey has also been submitted to the Office of Management and Budget (OMB) for their approval under the Paperwork Reduction Act (PRA) process.

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. Recruitment and training of vendors who wish to be approved to collect Home Health Care CAHPS data will begin in 2009. Initially, home health agency participation will be voluntary. However, CMS announced in the Home Health Prospective Payment System Rate Update (Calendar Year 2009), in the November 3, 2008 Federal Register, that it eventually plans to public report patient experiences with home health care agencies along with other publically reported quality measures.

RECOMMENDATIONS:

- 1) Ensure adequate information on the development of the CAHPS tool is provided to home health providers.
- 2) Ensure the home health industry is well informed of how CMS intends to use the CAHPS survey and provide a reasonable time line for required implementation.
- 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 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. The accreditation organizations will now have to assume the role of approving branches.

RECOMMENDATIONS:

1. Require CMS to inform the accrediting organizations of their responsibility 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 a standard procedure for approving branches. In addition, the accrediting organizations have had no time to prepare for the additional responsibility. Agencies seeking branch approval will either have to wait until the State survey agency can resume this survey activity or be subjected to inconsistent and potentially inadequate approval processes for HHA branches.

PROMOTE INCLUSION OF THE HOME HEALTH IN THE 9th SCOPE OF WORK

ISSUE: CMS contracts with one organization in each state, as well as the District of Columbia, Puerto Rico, and the U.S. Virgin Islands to serve as that state/jurisdiction's Quality Improvement Organization (QIO) contractor. QIOs are private, mostly not-for-profit organizations, which are staffed by professionals, mostly doctors and other health care professionals, who are trained to review medical care and help beneficiaries with complaints about the quality of care and to implement improvements in the quality of care available throughout the spectrum of care. QIO contracts are 3 years in length, with each 3-year cycle is referenced as a Scope of Work (SOW).

In August 2008, CMS announce QIO awards for the 9th SOW. The 9th SOW will focus on quality improvement initiatives aimed at nursing homes, hospitals and physician practices, without any considerations for home health providers. During the 7th SOW, the QIOs were charged with helping home health agencies implement Outcome Based Quality Improvement, and during the 8th Scope of Work, QIOs helped agencies identify and implement best practices to improve the quality of care delivered.

Failure for CMS to include home health agencies in the 9th SOW led to a formal request from the home health providers, through the National Association for Home and Hospice, to incorporate home health providers in the 9th SOW.

RECOMMENDATIONS:

- 1) Ensure CMS includes home health care providers in the 9th SOW to continue improvements made in quality of care that were fostered during the 7th and 8th scopes of work.
- 2) Allow provider input on the development of future SOWs to ensure the home health care is provided appropriate consideration.

RATIONAL:

Many home health providers have developed good working relationship with the QIOs and have found their assistance in promoting home health quality initiatives invaluable. In addition, it is difficult to understand how the following goals identified by CMS for the 9th SOW can be achieved without including home health providers in quality initiatives.

- Working on projects that span across the entire spectrum of the health community, rather than in “silos” based on specific care settings;
- Addressing key priorities of health care quality, including the identification and reduction of health care disparities across the continuum of care and across racial/ethnic, geographic, socioeconomic, and demographic lines.

III. ADMINISTRATION

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. 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 will include home health and hospice Jurisdiction A and
- Jurisdiction 15 will include home health and hospice Jurisdiction B.

Contracts are expected to be awarded to the jurisdictions responsible for home health and hospice by the end of 2008, with workload transition in March 2009.

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. Health care providers that might 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. Health care providers that might 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. RAC payment will be based on a percentage of the funds that are recovered for the Medicare program as a result of their work.

Although four RAC contracts have been awarded, CMS is required to put an automatic stay on all RAC contract work as a result of protests filed by two unsuccessful bidders for the RAC program with the Government Accountability Office (GAO). Approximately 35% of denials during the demonstration have been successfully appealed by providers.

The criteria used in the selection of the contractors in the transition process from the RHHIs to the MACs and selection of RACs and contractors knowledge level of Medicare coverage and payment policies for home health care and hospice are all issues that require stakeholder input. CMS elicited provider input prior to implementing all phases of the MAC transition process to ensure considerations is given to providers concerns regarding the transition from RHHIs to MACs. However, the effectiveness of the safeguards and processes established will not be known until the transitions have taken place and appropriateness of RAC recoveries is in question in light of the high level of successful appeals.

RECOMMENDATIONS:

Carry out seamless transition to MACs and establishment of RACs by monitor and take correction 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.

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 syndromic 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 we prepared in response to Hurricane Katrina. The policies outlined in that document may be applied in areas designated by the Secretary as officially declared disaster areas. However, additional considerations are needed to truly ensure uninterrupted service delivery and provider viability during disasters.

RECOMMENDATION:

- 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.
- Include home care and hospice in the infrastructure as vital participants in efforts to develop state emergency preparedness plans.
- 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.
- Make Federal resources available to home care and hospice providers for disaster planning, practice, and training.
- 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
- 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. Communication systems are needed to enable clinicians to communicate with one another, patients, other providers and government entities from areas without power or phone availability.
- Promote paperless documentation software and hardware.
- 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.
- 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.

Those that provide home care and hospice services in this country are often invisible. In part this is

because they are nurses, therapists and aides who travel to patients' homes. In America's past, however, they were very visible as they traveled on foot in traditional uniforms with their medical bags. The organizations known as Visiting Nurses date back to the late 19th century and made visits to the thousands who were suffering from flu in the pandemic of 1918.

Today, home care is the only "system" that is oriented to the community in a broad enough way to provide a massive infrastructure. Through the home care and hospice agencies in this country, it is possible to put a nurse in every zip code. In fact, in many counties in this nation, the public home care agency is the sole community provider. The home care clinicians are well acquainted with their communities to the point that they can be quickly deployed. They already form the system for flu immunization, and since the average age of the nurse is now 47, many still are current in their knowledge of how to inoculate for smallpox and other deadly diseases. Epidemics occur in communities and should be treated in the community; this is what home care nurses have done for over 100 years. Furthermore, should quarantine be needed, the patient's home could be an option which could afford protection of the community at large.

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. The paperwork could further increase for home health if process measures are added to reporting requirements if OASIS is not streamlined.

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 these recommendations have been implemented to date.

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 is to be used 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. There is great concern that required use of this tool by home health agencies will be added on to already burdensome paperwork requirements.

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.

MODIFY PAYMENT TO PHYSICIANS FOR CARE PLAN OVERSIGHT AND CLARIFY RULES FOR PAYMENT FOR CERTIFICATION/RECERTIFICATION

ISSUE: Medicare reimbursement rates for physicians for time spent on care plan oversight activities for patients receiving Medicare covered home health and hospice services have increased significantly since CMS published the regulation, which became effective in 1995. In order to bill for these services, the physician must spend at least 30 minutes or more in a calendar month on oversight activities. Physicians may bill only one care plan oversight charge for a patient in a calendar month, regardless of how much time they spend in excess of the 30 minute minimum time requirement. Hospice medical directors have been excluded from payment for care plan oversight payment, even when the hospice medical director is a volunteer who is also the patient's attending physician. In addition, CMS has determined that, when a physician bills for certification and recertification, only that physician and/or a non-physician practitioner associated with that physician, is entitled to bill for care plan oversight for that period.

In 2000, CMS established two new HCPCS codes that physicians may use to bill for the services involved in certifying and recertifying home health plans of care. These codes become effective January 1, 2001. In the final rule, CMS stated that physicians may bill for certifying an initial home health plan of care where the patient "has not received Medicare-covered home health services for at least 60 days." In situations where a patient is admitted to home health, but also has received home health services within the last 60 days (e.g., where a patient is discharged from the HHA, and is later readmitted, though 60 days have not elapsed), CMS has instructed physicians to report the recertification code, even though they are certifying an initial plan of care. Under PPS, physicians will be allowed to bill for certification and recertification services in addition to care plan oversight where the patient meets all criteria.

In 2002, CMS revised the definition for codes G170 and G180 which eliminated the requirement that a physician review the OASIS assessment as part of the certification and recertification process, yet, several contractors have kept this requirement and are issuing denials for payment if there is no evidence of the assessment review.

CMS has not provided clear billing instructions on how physicians are to record the date of service for certification and recertification. Some physicians use the date they sign the plan of care rather than the episode start date for the date of service. Contractors have issued confusing instructions and built-in edits that result in payment denial if that date is outside the home health episode.

RECOMMENDATION:

Payment for care plan oversight should be enhanced as follows:

1. CMS should study the time spent by a physician in care plan oversight activities in excess of 60 minutes and establish guidelines for additional compensation to the physician.
2. Physician payment should be extended to care plan oversight services provided on behalf of patients receiving home care services outside of a Medicare covered home health plan (e.g., Medicaid services, Medicare beneficiaries receiving non-covered home care services).
3. Volunteer hospice medical directors should be paid for care plan oversight activities for those patients for whom they also serve as the attending physician.
4. The certification and recertification benefit should be extended to hospice patients' attending physicians (other than the hospice medical director).

5. Contractor edits for certification and recertification should be improved to ensure that claims are not inappropriately denied based on signature dates, specialties, incorrect coding definitions, inappropriate documentation requirements.
6. Improve billing instructions to eliminate confusion over the date of service to be documented on physicians' claim forms.
7. Eliminate the requirement that the physician who bills for care plan oversight must be the same physician that signed the plan of care.

RATIONALE: The 1995 rule was a first step in the process of encouraging physician involvement in the delivery of home health and hospice services. But, in order to accomplish this end effectively, compensation should be extended beyond beneficiaries receiving covered home health and hospice services, as well as to those volunteer hospice medical directors who are not paid by the hospice for their services. Fair compensation is needed for the management of care of those complex, unstable patients requiring more than 60 minutes a month of the physician's time to ensure that these individuals receive appropriate care and remain at home.

CMS cannot expect physicians to avail themselves of these new payment options if burdensome billing requirements and inappropriate contractor edits result in denials of their claims. It is not unusual for patients receiving home health care to have a change in physician, particularly if these patients are on service for extended periods. Physician certification for home health services and care plan oversight are two separate and distinct services. These activities are conducted and billed at separate time points. Although these activities are designed to work in concert with another, it is not always necessary or practical to have a single physician carry out both activities.

ENSURE REASONABLE ENROLLMENT AND PARTICIPATION REQUIREMENTS FOR AGENCIES

ISSUE: CMS has expressed growing concerns about the entry of fraudulent providers into the Medicare program. CMS published a final regulation and manual instructions that change the Medicare enrollment process and outline specific requirements that must be maintained in order for providers and suppliers to maintain billing privileges in the Medicare program. The new enrollment regulation requires verification and periodic re-validation of enrollment information, or Medicare certified providers could face revocation of their billing numbers and termination of Medicare certification. As a result of the efforts of NAHC and others, CMS eased the requirement for revalidation of enrollment information from every 3 to every 5 years. In the meantime, changes in provider and management status, ownership and control, and demographic information require submission of that part of the form containing the updated information within 30 days of change of ownership information and 90 days for all other changes.

Although CMS adopted timeframes in which intermediaries must process enrollment forms for Medicare changes of ownership and for new entrants, these forms must also pass through the state agency and then to the Regional Office (RO) for final approval. There are no timeframes for the state or the RO to act. This results in an open-ended process, and adds to the delays in obtaining final approval. CMS has recently added to these delays by giving contractors 21 days to process the approval after receipt of the tie-in notice from the RO. CMS started significant revalidation activities in 2007, however, only limited guidance was subsequently issued regarding exactly what information and documentation a provider needs to submit.

CMS commenced a provider enrollment fraud demonstration project for all home health agencies in Harris County, Texas and in Los Angeles, Orange, Riverside, and San Bernardino Counties, California in October 2007. Agencies had 60 days from the date of the revalidation request to submit a complete 855A enrollment form and all necessary supporting documentation, or be terminated from the program. CMS issued no comprehensive guidance regarding the information and documentation a provider needed to submit for revalidation. Providers were merely directed to submit complete 855A forms and supporting documentation. Numerous questions were posed to the intermediaries regarding what needed to be filed, resulting in both different answers among the intermediaries, as well as answers that changed over the sixty-day response period. The fraud demonstration actions were extremely harsh, threatening termination for failure to timely notify CMS of an 855A of changes occurring prior to the start of the demonstration period. In addition, the demonstration waived the 90-day notification period in the regulations for reporting a change of address and required such notification within 30 days of the change during the demonstration period. Non-timely notification will result in termination. CMS gave no indication that discretion would be exercised in many cases prior to a determination to terminate for non-compliance with technical filing requirements. Although CMS assured NAHC that terminated agencies would have appeal rights, it was unclear what those rights would be because the enrollment appeal rules were not finalized until 8 months after the fraud demonstration project began.

CMS has advised State Survey Agencies that they are not to conduct home health start-up surveys until they have met their contractual obligations to carry out re-surveys of existing agencies in accord with the prescribed frequency. This has caused significant delays for new entrants, and required them to incur significant expense to pay for private accreditation in lieu of state start-up surveys. Other providers and suppliers often must wait long periods of time before they are surveyed and receive their notification of

approval or disapproval of their enrollment applications. No consideration is given to new providers that are being added to a chain or multi-site organization who may be better situated to comply with requirements and for whom the extent of investigation could be streamlined.

Certification of new home health agencies is based upon compliance with the Conditions of Participation (CoP) but there is no test for knowledge of Medicare coverage, billing procedures, or business acumen or compliance with Medicare fraud and abuse requirements. There is concern that some new agencies are ill-prepared to operate a Medicare business. According to CMS, many fail within the first three years of operation. New requirements for Medicare-certified HHAs continue to add to the burden for start-up agencies. For example, in 1998, CMS published initial capitalization regulations for new providers requiring three months of operating capital at the time a provider number is issued. Prospective providers can obtain a copy of the Conditions of Participation (CoP) from the state survey agency prior to their certification survey. However, they must access information about coverage, billing, and cost reporting guidelines and the OIG compliance guidance and fraud alerts online.

CMS adopted final enrollment regulations which give providers hearing rights in the case of denial or non-renewal. However, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 also directed the Secretary to consult with providers and suppliers before changing enrollment forms. Despite the consultation requirement, CMS did not consult with NAHC prior to implementing the new enrollment form which was approved in 2006. Section 12(b) of this form contains a requirement for information regarding nurse registries and requires that this information be updated. NAHC takes the position that this information must only be updated during the capitalization period, and that other agencies do not have to complete this subsection. CMS has flip-flopped several times on its policy, first agreeing with NAHC and later determining that agencies filing an 855A for revalidation purposes must answer this section (Section 12(b)).

CMS issued a new enrollment form in 2008. In a recent manual provision, CMS has advised that if such a provider requests reactivation of its Medicare billing privileges, it must submit a copy of a claim it plans to submit or the beneficiary name, HIC number, date of service and phone number for a Medicare beneficiary for whom it furnished services.

CMS has also issued conflicting guidance in enrollment instructions regarding the need for a National Provider Identifier (NPI) for a home health agency branch. Although the Survey and Certification and Claims Processing divisions of CMS stated that a branch offices do not need NPIs, CMS stated in its enrollment instructions that a branch should obtain an NPI for Medicare purposes. This language was not changed even after CMS revised a different section of the enrollment guidance stating that a branch bills under its parent's agency or its subunit's number.

In recent Manual changes, CMS announced that if an intermediary determines that a provider seeking Medicare enrollment is doing so only to become a Medicaid provider, the intermediary will deny the enrollment. Many states require Medicare certification for an entity to become a Medicaid provider. NAHC has contacted CMS to determine what coordination CMS has done with State Medicaid Agencies to address this issue and to find out whether State Survey offices have been directed to take action from such a determination. However, no response has been received.

CMS has adopted new appeal rules which address denial of enrollment and revocation of billing

privileges, and termination of a Part A provider's Medicare certification. The new rules prohibit direct appeal to an administrative law judge (ALJ), and instead require a prior appeal to the intermediary that revoked the enrollment. This changes the prior appeal route for terminated providers and unnecessarily delays the appeal process. CMS also proposed that a revoked provider wait three years before re-enrolling in the program. This changes the current process by which a Part A provider that is terminated from the program may reapply at any time, but must operate without the deficiencies that caused the termination for a reasonable assurance period before reinstatement. Although these proposed changes have not been finalized, CMS changed the Manual to require an initial reconsideration before the intermediary.

CMS adopted its proposal to reduce in the time in which a provider can respond to a request for additional information or for supporting documentation regarding its enrollment application from 60 to 30 days. CMS stated that this change was necessary due to so many applications filed with missing information. However, NAHC submitted evidence that provider problems with the enrollment process were due to multiple form changes in a short time period and inconsistent demands by the intermediaries regarding its completion and accompanying documents. CMS ignored this evidence.

RECOMMENDATION:

1. Make available training and materials on requirements for Medicare-certified HHAs and hospices, including CoP, coverage, billing, cost report and audit/reimbursement and OIG compliance guidance and fraud alerts in advance of applying for certification in an easy to access format.
2. Charge a fee for pre-certification materials and training.
3. Require prospective agencies to demonstrate compliance with the CoP, knowledge of coverage guidelines, ability to implement billing and accounting procedures, and understanding of fraud and abuse compliance before certification is granted.
4. Require administrators to have a bachelor's degree, and training and experience in health care administration, supervision, or management. Apply any new regulation prospectively, allowing grandfathering of current home health agency administrators.
5. Establish a:
 - a) 14 day time limit for state agency review of Medicare changes of ownership
 - b) 30 days for review of new providers
 - c) 14 day time limit for Regional Office review of all applications.
 - d) 3 day time limit for contractor implementation after receipt of the tie-in notice.
6. Publish clear guidance in the Program Integrity Manual regarding each section of the enrollment form and each supporting document that must be submitted with revalidation by provider type.
7. Exercise discretion, rather than termination, for non-compliance with technical enrollment requirements in the fraud demonstration.
8. Clarify in the Program Integrity Manual that a home health agency branch does not need an NPI.
9. Consult with providers before changing enrollment forms.
10. Clarify Program Integrity Manual regarding section 12(b) by applying the nursing registries requirement to new home health agencies and subunits and those undergoing a CHOW that do not accept assignment of the provider agreement.
11. Consider a streamlined approach to survey of new providers who are part of a chain or multi-site organization.
12. Ensure coordination between CMS and State Medicaid Agencies to address procedures to certify

Medicaid-only providers.

13. Establish timeframes for this coordination process and publish this guidance as a proposed rule so that providers and States can comment upon the process before it is imposed upon them.
14. Reinstate the direct appeal to an ALJ for Part A providers whose billing privileges have been revoked and whose Medicare certification has been terminated.
15. Reinstate the 60-day timeframe for providers to submit additional information or documentation.
16. Refrain from adopting manual changes that implement rule changes while the rulemaking is still pending.

RATIONALE: Provider enrollment and reapplication procedures should be uncomplicated and efficient in order to minimize the cost. Responses should be timely in order to ensure beneficiary access to needed services and supplies. Information to be updated should not be burdensome to providers.

Initial capitalization is a sound program requirement for new home health agencies provided the agencies may use that capital to maintain cash flow in the early months of operation. However, while initial capitalization ensures availability of operating funds during the home health agency start-up phase, it does not address the issue of provider knowledge of Medicare rules. Imposition of the subsection of the enrollment process related to reporting contracts with registries, with a requirement for continual update, would be extremely burdensome upon home health agencies. Since this request for information is part of Section 12 of the enrollment form, which only applies to new providers subject to the capitalization requirements, it should not be imposed on existing agencies.

Branch offices of home health agencies are not providers and do not have independent billing privileges. The conflicting manual privileges should be changed so that there is no recommendation that a branch have a separate NPI from its parent or subunit. This would be consistent with the other manual provisions that state that a branch bills through its parent or subunit. Having manual language that recommends that a branch office secure an NPI will lead to serious confusion on the part of surveyors, intermediaries, and providers who may be under the false impression that they should bill for services delivered from a branch office using a branch NPI.

Making detailed information available to prospective providers to educate them on the complexity of Medicare requirements and procedures, and requiring demonstration of compliance, will act as a deterrent for those who are not prepared to meet the requirements and better protect the Medicare program from loss. CMS resources should be allocated to make sure new agencies can perform successfully to prevent significant and costly problems that develop if the agency is not proficient in the complex coverage, billing and cost accounting procedures and fraud and abuse compliance. Qualified administrators are essential to ensure quality HHAs.

Hospital-based, chain and other multi-provider structured agencies have accounting and billing departments outside of the home health agency. Information about existing, related organizations should be recognized when new applications or changes are received. Further survey or new sites for multi-provider organizations should be streamlined in order to reduce unnecessary government expenditures.

Terminating providers for non-compliance with technical provider enrollment requirements is unduly harsh and will not address the fraud that CMS has alleged exists in the program. If HHAs are billing for services that they have not rendered CMS can determine this through inexpensive site visits and can

terminate those agencies with no locations. In contrast, terminating an existing provider that failed to timely report a change of address prior to the fraud demonstration, or that fails to timely report an address change during the fraud demonstration, bears no reasonable relationship to the fraud alleged by CMS, and unfairly penalizes a provider for technical noncompliance. CMS should exercise discretion in the fraud demonstration, rather than terminate providers for non-technical compliance with provider enrollment requirements.

Existing providers whose billing privileges have been revoked, resulting in the termination of their Medicare provider agreements, should have the same direct appeal rights to an ALJ as they would have if the sole action CMS took was to terminate their provider agreements. Furthermore, there is no basis for not allowing providers to immediately seek re-enrollment and be re-enrolled once they can establish that they are in compliance with all requirements during a reasonable reassurance period. The existing process contains sufficient safeguards to protect the program from non-compliant providers, or those terminated for technical non-compliance. Requiring providers to wait 3 years before re-applying imposes an unnecessary hardship on Part A providers.

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. NAHC addressed issues regarding care plan oversight, but did not address other issues that appeared to relate solely to physicians. 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.

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 the notice heading 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 on notice 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. Often, NAHC's comments 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. As a result, rules are adopted that affect the home care industry without any input from NAHC, or with

inadequate input from NAHC. Although giving meaningful notice and comment will 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 business 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 multiyear rule fails to display the true impact of the rule.

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.

CLARIFY THAT THE FTC IDENTITY THEFT (RED FLAG) RULES DO NOT APPLY TO SIMPLE SALES TRANSACTIONS

ISSUE: In 2007, the Federal Trade Commission issued its so-called Red Flags Rule pursuant to the Fair and Accurate Credit Transactions (FACT) Act of 2003. Under the Rule, financial institutions and creditors with covered accounts must have identity theft prevention programs to identify, detect, and respond to patterns, practices, or specific activities that could indicate identity theft. The Rule is scheduled to take effect on May 1, 2009 after the FTC postponed the original effective date.

The Rule applies to creditors and financial institutions. Federal law defines a creditor to be: any entity that regularly extends, renews, or continues credit; any entity that regularly arranges for the extension, renewal, or continuation of credit; or any assignee of an original creditor who is involved in the decision to extend, renew, or continue credit. Accepting credit cards as a form of payment does not, in and of itself, make an entity a creditor. Some examples of creditors are finance companies, automobile dealers, mortgage brokers, utility companies, telecommunications companies, and non-profit and government entities that defer payment for goods or services. Financial institutions include entities that offer accounts that enable consumers to write checks or to make payments to third parties through other means, such as other negotiable instruments or telephone transfers.

Questions have been raised as to whether home care companies that bill for services after those services have been rendered and impose a finance or late fee charge for bills unpaid after a certain date are considered “creditors” under the Red Flag Rule.

RECOMMENDATION: The FTC should clarify that the billing for services after those services have been provided and the imposition of additional charges for late payment does not result in that business being considered a creditor under the Red Flag Rule.

RATIONALE: The purpose of the rule is to protect against identity theft of customers doing business with financial institutions and credit advancing businesses. That is a meritorious goal. However, small business with limited customer accounts where the only form of “credit” is the timing of billing should not render that business a creditor under the Red Flag Rules. Further, small businesses are unlikely targets for identity theft.

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 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, leaving Medicare beneficiaries as potential prisoners in their homes in order to qualify for home health services. In addition, adult day programs must be licensed, accredited or certified in order to meet CMS criteria. However, many states do not license or certify adult day programs, leaving beneficiaries who attend adult day care in those states without the ability to access the home health benefit. The adult day care demonstration project began in September, with selection of home health agencies that will deliver adult day care services at adult day centers, assuming the cost of both day care and home care. The project is going smoothly with the exception minor claims processing problems.

There has been much interest in expanding the homebound definition to include individuals with chronic conditions who may leave home frequently but require assistance to do so. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 required the Secretary to conduct a two-year demonstration project under which up to 15,000 beneficiaries enrolled in Medicare B with specified chronic conditions would be deemed to be homebound in order to receive home health services. The demonstration project began in Spring of 2004 and continued through the Spring 2006. A major concern was that no consideration was given to increased home health costs if large numbers of beneficiaries previously barred would qualify for home health services under the demonstration. However, very few individuals were enrolled in the project, most likely as a result of the stringent eligibility requirements, such as daily attendant service and lifelong skilled nursing needs. As a result, the only information that was gleaned from the project was pure conjecture.

Medical review staff at the current Regional Home Health Intermediaries have an acceptable understanding of homebound criteria. However, other contractor staff, such as the Medicare Program Safeguard Contractor, have been known to issue inappropriate denials because of their lack of knowledge of Medicare "confined to home" policies. The 2009 introduction of MACs could result in more denials.

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. Does not impose burdensome documentation requirements, such as detailed information about reasons, frequency, and duration of non-medical absences from the home.
3. Expands the definitions of “licensed” and “certified” adult day programs.
4. Ensures that analysis of the impact of 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 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. Counting frequency and hours of absences from the home will be burdensome and frequently inaccurate. Functional status and medical condition are appropriate criteria for determining whether a person can leave home, without undue hardship or negative health consequences.

Inappropriate denials and subsequent appeals based on homebound status are costly to providers and the Medicare program. Further, 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.

Since beneficiaries included in the adult day demonstration were not eligible for home health services at the time that PPS rates were established, the cost of their care was not considered when formulating prospective payment rates for home health agencies. It is essential that these costs, and their impact on agencies, be identified and included in future payment rates.

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). Interpretation of the coverage rules and explanations varies among Medicare contractors and managed care organizations. As a result, utilization and coverage may vary dramatically among regions and among Medicare-risk enrollees. In many instances new or revised policies are created.

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. CMS instructed its contractors to ensure that all 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 in the last 10 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 there are only four Regional Home Health Intermediaries serving the entire country, LCDs are applied to large geographic areas. 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. 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.

Local policies are reviewed by CMS regional offices only upon request. 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 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.

Managed care organizations have reinterpreted coverage rules. 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, require Medicare contractors to receive CMS approval for new local coverage decisions.
 - a) Establish formal procedures that allow providers to seek CMS review of questionable contractor interpretation of coverage policies.

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

RATIONALE: Policies developed and implemented by Medicare contractors are not local due to the extensive geographic areas that they serve. In fact, one Medicare contractor is responsible for chain home health agencies that operate throughout the country. 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. 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. 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 required 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 implement 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 suspicions of billing errors by first conducting probe reviews of small number 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 know 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 duplication of OASIS information. Furthermore, OASIS assessments capture information about a patient’s condition at a particular point in time, rather than the need for home health services related to that condition. Therefore, it is not unreasonable when no documentation of services is found in the record.

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. The 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.
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.

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. 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 four years 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.

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.

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.

CLASSIFY CLAIMS CURRENTLY SUBJECT TO TECHNICAL DENIALS AS “INCOMPLETE CLAIMS”

ISSUE: Until passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 the Centers for Medicare and Medicaid Services (CMS) required its contractors to issue Medicare denials to home health agencies and hospices when claims were reviewed and failed to meet technical requirements. Examples of claims that result in issuance of technical denials include: failure to record the date of the 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 provider's receipt of signed orders in cases where physicians have not dated their signatures. These denials were often appealed and overturned, a process that is time-consuming and costly for providers, contractors and ultimately, the Medicare program.

Section 937 of the legislation requires CMS to establish a process so providers and suppliers can correct minor errors in claims that were submitted for payment without pursuing the appeals process. The new legislation does not define “minor errors.” In a 2004 instruction to contractors and providers, CMS limited application of the MMA provision to: claims submission errors, re-openings, and correcting HIPAA compliance issues. Further intermediary instructions were issued related to re-openings under medical review whereby CMS limited technical corrections to denied claims. Although Congress did not define “minor errors,” based on the committee reports, CMS misinterpreted the intent of the legislation.

RECOMMENDATION:

1. Correct the instructions to contractors and providers to accurately reflect the intent of Congress related to correction of minor errors and omissions.
2. Do not limit reopening of claims for the purpose of correcting technical errors to denied claims.
3. Involve the provider community in defining “minor errors.”
4. Treat claims that are presently issued as “technical denials” because they are missing information as "incomplete claims."
5. Notify providers of the reason their claims cannot be processed and require resubmission.
6. In cases where the problem is discovered on post-payment review, require repayment and allow providers to resubmit these claims for payment once the incorrect or incomplete information has been received.

RATIONALE: Treating claims with missing information as "incomplete claims" is more efficient than issuing a denial. The "incomplete claims" procedure should significantly reduce the number of costly appeals filed by providers in cases where services have been delivered according to Medicare program regulations but where paperwork requirements were missing. The Medicare appeal regulation identifies the reopening for a four year period as applicable to provider technical errors and does not limit access to denied claims.

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 did not intend to pass new legislation simply to legislate a right that already exists, i.e. the right to correct billing errors. Rather, Congress intended to expand provider rights to include correction of technical errors or omissions related to coverage criteria. This is supported by the example included in the committee report: “For example, if in the case of a home health claims, the physician has signed the plan of care and/or

physician's order but has not dated it, the claim shall be returned to the home health agency and may be resubmitted by the home health agency with any incomplete or missing information without having to appeal the claim."

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.

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.

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. 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 FOR CONSUMER DIRECTED CARE

ISSUE: CMS has encouraged states to give Medicaid beneficiaries more control over the long-term care services they receive through self-directed care. 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.

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 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. 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. A fair and equitable payment mechanism that does not impact current episodic payment rates should be developed for payment of consumer-directed care under the Medicare demonstration project.
10. Any demonstration project results should be carefully reviewed for violations of patient and provider safety and rights and its financial impact.

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. All models of care should require compliance with applicable state and federal labor laws and health and safety regulations. It is unfair to require agencies to be responsible for services over which they have no control.

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.

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. 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.

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 increased 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 THE HOME AND COMMUNITY-BASED CARE BENEFIT IN THE MILITARY HEALTH SYSTEM

ISSUE: With the passage of the National Defense Authorization Act For Fiscal Year 2002, Congress has, for the first time, established a statutory scheme to deliver home health services in the TRICARE program. Additionally, the bill provides the dependants of active duty personnel with a community-based alternative to institutional care.

Through the Authorization Act Congress removed much of DOD's discretionary authority to define the terms "custodial care" and "domiciliary care." Further, the legislation established a statutory entitlement to a "Medicare-like" part-time or intermittent home health benefit, reimbursed through the use of OASIS data at the same rates as Medicare services. For the first time ever the statute allows for the provision of home health aide services as a basic TRICARE benefit. A corner stone of the legislation is a community-based care alternative to hospital and skilled nursing facility care for the dependants of active duty personnel. The legislation provided for all medically necessary care in a hospital and SNF and alternatively allows for extensive in-home care so long as that care is medically appropriate and cost effective.

On June 13, 2002, the Department of Defense issued an interim final rule to enact implementation of the TRICARE home health benefit of the National Defense Authorization Act. Implementation began on a geographic area basis beginning in July 2004, with completion in November, 2004. In light of the new statutory structure, many of the administrative burdens home health agencies have experienced with TRICARE were expected to be eliminated through the implementing regulation, including the need to register each individual nurse providing care to TRICARE participants. However, implementation continues to be fraught with problems including: inability of home health agencies to be recognized as TRICARE providers, lack of information and responses from TRICARE contractors about billing and payment procedures, and inappropriate payment for services to individuals in need of extensive in-home care.

RECOMMENDATION: The Department of Defense should:

1. Provide education and resources to contractors to ensure implementation of home health coverage and payment as required by the National Defense Authorization Act for Fiscal Year 2002.
2. Identify individuals at each contractor site to serve as the point persons for questions and problems related to provider enrollment, interpretation of the benefit, billing procedures.
3. Create educational tools and outreach programs to disseminate information to eligible individuals and potential providers about the benefit, provider enrollment procedures and billing procedures.
4. Implement an alternative payment methodology for individuals in need of extensive in-home care who do not fit the Medicare model for "intermittent nursing."
5. Ensure payments are aligned with statutorily required Medicare home health prospective payment rates.

RATIONALE: The Department should follow the direction it has received from Congress and utilize all of its administrative authority to insure that participants in need of home health services have access to a program that provides meaningful home and community based services.

MONITOR OSHA ACTIVITY ON ERGONOMICS AND ENSURE APPROPRIATE ENFORCEMENT IN HOME SETTINGS

ISSUE: Under OSHA's general duty clause, employers must ensure the safety of their employees in the work setting. In the past few years, OSHA has published a number of voluntary guidelines, compliance directives, and proposed and final regulations affecting home care agencies and hospices, covering workplace violence, occupational exposure to tuberculosis (TB), blood-borne pathogens and needle stick injuries. In November, 2000, OSHA published a final standard regarding ergonomics in the workplace that was later overturned by an Act of Congress. However, OSHA is still determined to develop an approach to ergonomic safety that will protect workers from musculoskeletal disorders (MSDs). The regulation published in 2000 met with great resistance from the business community throughout the rulemaking process. During the summer of 2001, OSHA held public forums in Washington, DC, Illinois and California in order to hear public testimony as a starting point to creating a new ergonomics approach. The Department of Labor announced in January 2002 that this new approach will not include a new rulemaking, but rather a wide variety of non-regulatory programs, including grants, web outreach, best practices and a Voluntary Protection Programs mentorship program.

NAHC has commented time and again that home health workers cannot always control the environment in the private homes of those they serve. OSHA recognized this unique characteristic of home health care when, in 1999, it restricted the application of the blood-borne pathogen standard in the home setting where the employer cannot control the conditions in a client's private residence.

In the preamble to the final ergonomics standard that was rescinded, OSHA recognized that an employers' "obligations will be limited by the control they have over their employees' actual working conditions." However, in practice, even without a specific ergonomics regulation, there are real concerns that OSHA inspectors will fine agencies that do not implement controls such as lifting aids or other mechanical devices, even in situations where use of such devices is not feasible, would be ineffective, or not desired by the patient. Of particular concern is the potential for application of OSHA Ergonomic Guidelines for Nursing Homes to the home care setting. These guidelines include recommendations for use of expensive equipment and multiple caregivers when lifting or moving patients.

RECOMMENDATIONS:

1. OSHA should include NAHC in stakeholders meetings.
2. OSHA must ensure that any proposal for enforcing its general duty clause, must be feasible and cost-effective in the home setting.
3. Home care employers should not be held responsible for offsite compliance by the employee, nor should they be cited for noncompliance in a patient's private residence, over which they have no control.
4. Guidelines developed for other settings should not be applied to the home care setting.

RATIONALE: OSHA must consider the potential financial burden of any new requirements on home health agencies, many of which are small business. It is critical that OSHA and enforcement inspectors recognize the limitations of imposing restrictions and equipment requirements in a patient's home. Furthermore, employers cannot control an employees' failure to conform to certain safety regulations in a patient's private residence. Application of cost prohibitive guidelines that require expensive equipment and multiple caregivers are not appropriate for the home setting.

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.

VI. DURABLE MEDICAL EQUIPMENT

ENSURE APPROPRIATE QUALITY STANDARDS, CLINICAL CONDITIONS COVERAGE, AND MANDATORY ACCREDITATION REQUIREMENTS FOR DME 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 durable medical equipment (DME) suppliers. CMS published a set of general quality standards, along with item specific standards for DME 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 DME quality standards under Medicare Part B.

Initially it was announced that, in order to participate in competitive bidding, suppliers must be accredited before being awarded a contract, and that all other suppliers must be accredited by September 30, 2009 in order to continue to bill the Medicare program. However, the Medicare Improvements for Patients and Providers Act of 2008, which was enacted on July 15, 2008, delayed the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program. As a result of this delay, the special accreditation deadlines previously established for competitive bidding was cancelled.

Specifically, prior to enactment of this new law, suppliers would have had to be accredited for a first round contract and would have had to have applied for accreditation by July 21, 2008 to be eligible to submit a bid for the second round of competitive bidding and have obtained accreditation by January 14, 2009 to be eligible for a second round contract. Both of these deadlines have been cancelled and no longer apply. The deadline of September 30, 2009 that was previously established by which all DMEPOS suppliers must be accredited is still in effect. CMS also announced that suppliers that enrolled with the National Supplier Clearinghouse between Jan. 1 and Feb. 29, 2008 have until Oct. 2009 to become accredited.

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.
4. Establish a clear timeline for meeting accreditation requirements that reflects the need for quality assurance.
5. Take into consideration the potential surge of suppliers seeking accreditation and adjust timelines as appropriate.
6. Continue to clearly and effectively publicize accreditation timelines in a timely manner to all suppliers.

RATIONALE: HME standards and accreditation requirements must strike a balance between the need to curtail fraudulent activities and DME 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 will place considerable financial burdens on suppliers at a time when

Medicare reimbursement for equipment is being reduced. Accrediting organizations may not have the surge capacity to accredit the large numbers of suppliers not currently accredited.

REQUIRE FAIRNESS IN IMPLEMENTATION OF COMPETITIVE BIDDING FOR DURABLE 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 durable medical equipment (DME). Upon implementation, the Medicare program will no longer reimburse DME 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, DME suppliers are required to waive their right to administrative or judicial review of the competitive bidding process.

Specifically, the MMA requires 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.

However, Section 154 of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008, which was signed into law in December, delays the DMEPOS Competitive Bidding Program for eighteen months. Items that were in contracts that were awarded in the first round of the DMEPOS Competitive Bidding Program are now being furnished by any enrolled DMEPOS supplier in accordance with existing Medicare. Medicare has adjusted payments to suppliers who won round one bids using the standard DMEPOS fee schedule amounts, retroactive to June 30, 2008.

Based on MIPPA requirements, the first round of competitive bidding will occur in 2009, exclude the San Juan MSA and exclude negative pressure wound therapy items. The second round will occur in 2011 in the MSAs CMS has already chosen. However, a new provision gives CMS the authority to subdivide MSAs with populations that exceed eight million. Competition for diabetic supplies will occur in 2010 and competition in additional areas will occur after 2011.

In order to ensure budget neutrality, the legislation requires 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 will also be required for the years 2010 through 2014, based on the consumer price index.

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

1. Carefully analyze and implement “lessons learned” from the competitive bidding demonstrations
2. Offer extensive provider and beneficiary education in competitive bidding MSAs
3. Ensure small supplier participation in the Medicare DME 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

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 DME 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.

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, are set to go into effect on the same date as the regulation.

The oxygen regulation imposes new responsibilities on suppliers as follows:

- Any oxygen provider 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 a 36-month rental period 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 visit 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 between \$15-\$30 per visit to conduct these checks. 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.

RECOMMENDATION:

1. 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.
4. Eliminate requirements to provide services for 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 evaluating and ameliorating situations where beneficiary abuse or neglect of equipment does not negatively impact suppliers.

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 DME SUPPLIES

ISSUE: Current law (42 U.S.C. § 1861 (n)) requires that durable medical equipment (DME) 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 DME in an institutional setting. Congress did not otherwise impose a geographical limit on the use of DME. For example, there is no requirement that the actual use of the DME be confined to the four walls of a home.

Nevertheless, the Centers for Medicare and Medicaid Services (CMS) and the Durable Medical Equipment Regional Carriers (DMERCs) have interpreted and applied the "in the patient's home" clause in an overly restrictive manner. Specifically, Medicare DME coverage has been limited to those items an individual demonstrates is needed within the home, rather than the DME 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 DME supplies, along with rehabilitative and assistive technologies, are a covered Medicare benefit.

RATIONALE: President Bush’ "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 DME 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.

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 starting January 1, 2007, were 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: CMS should 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.

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 often 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," nursing services are not covered by the HME drug benefit.

The HME community is concerned that competitive bidding will lead to monopolistic practices by suppliers that would hamper beneficiary choice, increase costs in the long run, and lower quality. For these reasons, the HME community supports efforts to enact legislation that establishes a separate HME infusion and inhalation drug benefit that accurately reflects the cost of both drugs and the appropriate services necessary to administer such drug therapies.

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.

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 was 3.4 percent in 2005. Elimination of the BNAF decreases hospice reimbursement 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 of putting community hospices out of business resulting in a lack of access to the hospice benefit, particularly in rural areas.

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% cut in Medicare payment rates.

The Medicare budget also will suffer through the loss of hospice care. A recent 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 43 percent of those being served by hospices. The median length of stay remains at about two weeks and about 30 percent of hospice patients are on the benefit for less than a week. 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 with the intent of determining whether the MHB reimbursement system should be changed. The Medicare Payment Advisory Commission (MedPAC) has recommended that the hospice benefit reimbursement system be revised to reflect the services being provided based on data collected and analyzed by CMS by 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 benefit payment system.

RATIONALE: CMS is currently working on what they call Phase III of collecting hospice services data in an effort to make hospices more accountable for providing required services and meeting all the patient's needs related to the terminal illness. 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. This is critical to subsequent data analysis to determine whether a revised hospice reimbursement system is appropriate and what it should be.

RESPOND TO NEW HOSPICE CONDITIONS OF PARTICIPATION (CoP) ISSUES

ISSUE: The new hospice conditions of participation (CoP) were released in June of 2008 with an effective date of December 2, 2008. They had not been updated since the inception of the hospice benefit in 1983. The new CoPs are outcome oriented and require surveyors to make more judgment calls than the prior CoPs. Surveyors were trained on the new CoPs in November and future training is planned. The final new Interpretive Guidelines were released on January 2, 2009 and included changes made as a result of questions asked in the November surveyor training. The Centers for Medicare & Medicaid Services (CMS) has agreed to work with the National Association for Home Care & Hospice (NAHC) to resolve any problems that may arise under new CoP interpretations.

RECOMMENDATION: CMS should work with NAHC and the hospice industry to resolve any problems that hospices experience under the new CoPs.

RATIONALE: At the time the original CoP were written, little was known about efficient and effective management of hospice agencies. Hospices have been operating under the original CoPs for 25 years. Hospices have adapted their care provided to meet the needs of patients and families served. Hospices are now required to meet the new CoPs which contain specific new requirements for needs assessments and hospice wide quality of care initiatives. Hospices must adapt to many new demands at the same time that surveyors are working with new regulatory requirements.

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.

RECOMMENDATION: CMS and the FDA should declare inadequate pain management a national public health issue with goals 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 some hospice visits and charges data as a first step in creating a data base 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 new 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.

RECOMMENDATION: CMS should develop a quality assessment performance improvement (QAPI) program that has: 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. Further, CMS should reinstate its second quality initiative to establish standards of care for providers of the Medicare Hospice Benefit and authorize necessary funding.

RATIONALE: The ideal QAPI program is based on what happens to the patients. In addition, research and demonstration projects are not factored into the current per diem reimbursement structure. The proposed quality system will have a tendency to involve massive data collection unless purposely controlled. Every effort must be made to keep data collection and the paperwork burden 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 durable 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 a recent report, Hospice Patients in Nursing Homes, 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.

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: Only 1% of Medicare hospice providers 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 an eight-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% 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 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 fiscal intermediary (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: Refrain from including a warning statement concerning penalties for false claims on physician certification and recertification forms for terminal prognosis. Develop educational information about the requirement of a six month prognosis and make resources available to determine a prognosis. 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, about 30 percent of patients are on the benefit for a week or less and the median length of stay remains at about two weeks. 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. Assure the ICD-9-CM codes are current.

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, great 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 HMO HOSPICE SERVICES TO MEDICARE BENEFICIARIES

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

For example, an HMO/Medicare beneficiary can enroll in any Medicare-certified hospice, not just one that participates in the HMO plan. The hospice, not the HMO, 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 HMO, for the Medicare patient's hospice care. Medicare pays the HMO on a fee-for-service or reduced capitation basis for services not related to the terminal illness.

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

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

COMPENSATE PHYSICIANS FOR HOSPICE CERTIFICATION

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 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." They 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 CMS data shows that the median length of stay remains at about two weeks and 30 percent of hospice patients were on the benefit for less than a week.

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.

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 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.

ASSURE SNF/NF MEDICARE BENEFICIARY RESIDENT'S 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. As SNF/NF residents become aware of the MHB, more of them are seeking hospice services. However, the SNF/NF has the right to deny hospice services to their residents or at a minimum choose the hospice the SNF/NF will allow to provide the services.

Currently, a terminally ill SNF/NF resident may only access the Medicare Hospice Benefit if the SNF/NF will allow this to occur. If the facility agrees to permit a hospice to provide services for the SNF/NF resident, the Hospice and SNF/NF must have a written agreement that specifies the coordinated services each provider will perform.

RECOMMENDATION: CMS should require that eligible Medicare beneficiaries residing in SNF/NFs have the right to receive hospice services from a Medicare-certified hospice of their choice.

RATIONALE: A Brown University Medical School study funded by the Agency of Healthcare Research and Quality, US Department of Health and Human Services, was released in August 2006. The study, "Hospice Enrollment and Evaluation of its Causal Effect on Hospitalization of Dying Nursing Home Patients" showed that nursing-home residents in hospice care have about half the chance of being admitted to a hospital in their last 30 days of life compared to peers who don't receive hospice care, such hospitalizations can result in large and unwarranted Medicare expenditures.