

# **2006 Regulatory Blueprint for Action**

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## INTRODUCTION

The Regulatory Blueprint for Action identifies important regulatory issues for home care, hospice and home medical equipment providers. It provides a summary of each issue, including background information, recommendations, and rationale for the recommendations. This document provides a guide to the home care industry's position on the issues addressed. The National Association for Home Care & Hospice (NAHC) 2006 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 home 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 Associations' 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.

## **EXECUTIVE SUMMARY**

The 2006 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 home medical equipment issues.

Regulatory priorities were determined through a survey of NAHC members. Members were asked to score current issues from "least important" to "most important." The results were tabulated and ranked according to the highest average score. The top twenty home care regulatory priorities for 2006 appear below:

1. Reduce and refine OASIS requirements and fully reimburse for costs.
2. Improve application of wage index for Medicare home health and hospice.
3. Reimburse home health agencies for telehealth.
4. Eliminate inequities in partial prospective payment system (PPS) payment.
5. Ensure the development of appropriate pay-for-performance measures.
6. Ensure adequate cash flow under PPS.
7. Promote an adequate case-mix adjuster.
8. Ensure home care services under managed care.
9. Provide fair and targeted reimbursement for medical supplies.
10. Ensure access to Medicaid home care services.
11. Require automated correction of underpayments and overpayments.
12. Revise current significant change in condition (SCIC) payment policy.
13. Refine Medicare home health PPS outlier payment.
14. Ensure fairness in government fraud and abuse activities.
15. Promote consistent application of coverage rules.
16. Increase flexibility in aide supervision requirements.
17. Ensure application of professional auditing and accounting standards.
18. Increase flexibility in the application of the conditions of participation.
19. Ensure patient choice and equal advantage to all providers.

20. Identify federal specialists to resolve survey discrepancies

The top seven hospice regulatory priorities are:

1. Ensure access to drugs necessary for pain control.
2. Increase training for hospice surveyors.
3. Abolish payment delays caused by sequential billing policy for hospice.
4. Study hospice reimbursement for dually eligible patients residing in NFs.
5. Base survey frequency for Medicare hospice providers on performance.
6. Modify hospice regulations for inpatient respite care.
7. Reinstate presumptive status for hospice waiver of liability.

**I.**  
**REIMBURSEMENT**  
**REFORM**

## **PROMOTE USE OF AN EQUITABLE PPS WITH AN ADEQUATE CASE-MIX ADJUSTER**

**ISSUE:** CMS is in the process of reviewing home health payment data with the intention of updating the case-mix system. MedPAC, and others have raised concerns about the adequacy of the current case-mix system. CMS implemented the home health PPS on October 1, 2000. An average episode payment rate, which is updated annually, was established based on 1997 cost data. Wage index and case-mix adjustments are made to the average episode payment rate for each patient episode. The data that was used reflects the costs of service delivery and supplies at that time. It does not take into consideration additional costs resulting from such things as new regulatory requirements.

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 status and pre-admission circumstances of the patients served. The final rule implementing PPS, published on July 3, 2000, included a case-mix adjuster with 80 case-mix groupings. The reliability of the current case-mix adjuster in explaining the variations in resource use by patients has deteriorated from just over 30% prior to PPS going into effect to 20% at the present time. In the development of the case-mix adjuster, CMS made certain policy decisions such as excluding any consideration of informal caregiver services. Rehabilitation considerations were limited to the services of therapists. Furthermore, questions have been raised as to whether episodes with intensive nursing services are adequately addressed in the case-mix system and lack of sensitivity of some OASIS items (the data set that is the basis for case-mix) leads to inaccuracies in case-mix adjustment.

Home health agencies were not permitted to use certain ICD-9-CM codes because of OASIS restrictions until implementation of the Health Insurance Portability and Accountability Act required CMS to comply with coding standards. These changes in coding guidelines resulted in the need to create a new OASIS item for recording case-mix diagnoses codes when replaced by HIPAA compliant V codes. In addition, “points” for the calculation of reimbursement under PPS were determined based on historic service and coding patterns. As a result, some points that would affect payment were misallocated to ICD-9 codes that agencies were no longer permitted to use. For example, use of trauma codes for wounds was a common practice and led to the allocation of additional reimbursement for codes that were misused in the past and not allowed under PPS. Therefore, points are not given for intensive services delivered to many wound care patients (e.g. pressure ulcer) whose diagnoses were incorrectly coded as trauma wounds prior to PPS. CMS has promised to evaluate the impact of diagnosis coding changes on case-mix system reliability.

### **RECOMMENDATIONS:**

1. Provide at least 12 months notice for any adjustments to payment rates and the case-mix system.
2. Study the adequacy of the case-mix adjuster with input from providers and case-mix study contractors
3. Modify the case-mix adjuster to consider the rehabilitation services provided by other home care personnel.
4. Initiate a program of continued quality improvement to implement refinements that would extend or increase the case-mix system reliability.
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 as prior hospitalization and 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. Migrate “points” to the appropriate ICD-9 codes to reflect the severity of needs and services.
9. Analyze the level of services needed for persons receiving skilled, palliative care services and adjust the case-mix appropriately.
10. Evaluate whether intensive skilled nursing episodes are adequately compensated under the current case-mix system.

**RATIONALE:** Failure to identify added costs of doing business resulting from new regulatory requirements will result in underpayment of providers. The case-mix adjuster proposed by CMS has been subject to limited evaluation as to its effect on access to home health services. Any continued refinement will increase its explanatory power capabilities. Alignment of OASIS diagnosis coding guidelines with HIPAA required ICD-9-CM codes will eliminate the burdensome requirement of two different diagnosis codes for home health patients when PPS diagnosis codes are not HIPAA compliant. Furthermore, if case-mix “points” are not appropriately adjusted, agencies will be under-reimbursed for services. For example, a primary function of home health nurses is rehab nursing. 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. An effective crosswalk will ensure accurate payment to home health agencies under PPS.

## **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. As a result of CMS analysis of outlier payments it was determined that only a portion of the outlier budget was actually being spent. Therefore, CMS lowered the outlier threshold effective January 1, 2005 and again for 2006, with the intention of allowing more episodes to qualify for outlier payments. The 2006 outlier threshold has been set at 0.65 in order to allow more episodes to qualify for outlier payments.

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 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.

**RECOMMENDATION:** Revise the outlier payment methodology in the following manner:

1. Eliminate the shared loss ratio for excessively high cost episodes.
2. Include the cost of medical supplies as an eligibility element for outlier payment
3. Include a cost based outlier methodology along with the present “number of visit” based outlier methodology; and
4. 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.
5. Monitor the impact of the lowered outlier threshold on payment for high cost episodes.

**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 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.

## ENSURE ADEQUATE CASH FLOW UNDER PPS

**ISSUE:** The final PPS rule establishes a split payment approach to reimbursement. An initial percentage payment equal to 60 percent of the estimated case-mix adjusted episode payment is made with the initial payment request. The second, final payment, is equal to 40 percent of the actual case-mix adjusted episode payment with the initial percentage payment adjusted to reflect LUPA, PEP, SCIC, or medical review determination as applicable. Subsequent episodes are paid on a 50/50 split.

The split payment approach is a significant concern within the home health industry. The split payment methodology results in serious cash flow problems for home health agencies nationwide. These cash flow problems are due to the fact that most health care utilization occurs in the early stages of a 60-day episode. In addition, the time frames for completion of a Medicare claim and the payment processing by the intermediary result in extended delays in receipt of payment relative to the time when service costs are incurred.

### **RECOMMENDATION:**

1. Refine the split payment approach to assist providers in meeting their cash flow obligations while providing adequate, programmatic protection for Medicare by modifying split payment to 90 percent on the request for anticipated payment (RAP) and 10 percent on the final claim.
2. Eliminate the 14 day payment floor.

**RATIONALE:** Home health agencies do not have sufficient reserves or access to capital that can provide the means to bridge the period between when costs are incurred, obligations honored, and payment received from the Medicare program. There are few instances where the final payment is not based upon the original HHRG adjusted episode payment rate. A 90/10 split allows Medicare to recognize delays inherent in payment, while balancing those cases where additional payment is due where the home health agency has been overpaid. With 73 percent of visits provided in the first 30 days of an episode and the front-loaded administrative costs, a 90 percent initial payment is necessary to meet the cash flow needs of a home health agency.

## **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), in accordance with Congressional mandate, has been based upon varying wages within hospitals across the nation. This 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, one recent example being a swing of 16%. 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 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.

**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 to 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 were not required to provide 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.

The shortcomings of the medical supply component of the PPS system are many. CMS consolidated the payment for medical supplies into the episodic payment rate without considering the varying use of supplies by particular patients. In addition, the amount of money allotted for medical supplies in each episode is inadequate because large numbers of HHAs did not provide supplies pre-PPS and Part B files did not account for supplies costs of 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. Finally, CMS did not build in inflationary considerations for new, high cost supplies such as those needed for chest drainage and complex wound care. Complicating the issue of accounting for supplies further, contractors and home health agencies had to delete supply charges from claims for an extended period of time in 2002 and 2003 because of CMS system problems. As a result, Medicare claims files and PS&R reports do not reflect accurate home health costs.

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.

Congress mandated a Government Accounting Office (GAO) study on bundled medical supplies under home health PPS. The GAO concluded that excluding certain supplies and reimbursing them separately may help ensure that patients have access to care and that home health agencies are protected financially for providing them. However, GAO qualified this finding by stating that CMS needs to collect patient-specific data on costs and utilization to determine whether payment groups and adjustments properly reflect differences in supply costs. CMS has agreed to analyze current supply reimburse and consider the changes in the proposed update to the system planned for 2006.

### **RECOMMENDATION:**

1. Unbundle **non-routine** supplies from the episodic payment rate and establish a fee schedule for targeted reimbursement of supplies.

OR

2. If this policy cannot be implemented, the PPS case-mix adjustment system should be immediately revised to address varying utilization of supplies;
3. Develop an outlier payment mechanism for medical supplies
4. 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
5. Allow individuals to receive Medicare B payment for supplies that are not ordered as part of the plan of care, especially those supplies that create an access problem for patients (e.g.

colostomy supplies), from their supplier of choice with appropriate Medicare reimbursement under Medicare Part B

6. Ensure that lost supply costs resulting from CMS system problems and Part B limitations are accounted for when updating home health case-mix system.

**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. CMS has concluded that it had no authority to address supply costs in home health PPS other than through the method employed. However, the legislative authority did not restrict CMS from establishing a separate fee schedule for medical supplies or require CMS to include supplies as the responsibility of home health agencies even where those supplies are unrelated to the care provided by that agency for the patient. Unbundling supplies, particularly those used by the patient, would ensure patient choice and appropriate payment to home health agencies. Furthermore, because CMS failed to acknowledge the limit on coverage of supplies used by patients and their caretakers and project added costs of new technologies, the Medicare benefit is unfairly expanded on the backs of home health agencies. Finally, it is essential that government agencies and researchers be made aware of the inaccuracies in the home health claims data as related to medical supplies and pointed to correct data sources before drawing conclusions and making changes to the PPS system.

## **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.

Further, CMS failed to implement the PEP adjustments consistent with the PPS where a patient was discharged from one HHA and admitted to another within the original 60 day episode. This created substantial overpayment liabilities to Medicare from as far back as October 2000. CMS began a two year PEP overpayment recovery effort in the summer of 2003. Providers were assured that recovery would be spread out over the full two years. However, providers reported recovery of large sums of money at a single time point in late 2005 due to failure of CMS contractors to identify a recoup overpayments in a phased-in approach over the two year period.

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.

### **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. There should be a time limit of one year on retroactive recovery of overpayments that were caused by CMS or contractor errors and all recoveries should be evenly spread over a reasonable period of time.
5. Establish fair and equitable policies and protocols for providers to follow to avoid PEP episodes and conflicts when determining “primary agency.”

**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 the patient received a full episode of care, the agency receives the full episodic payment, without the carve-outs. 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.

Retroactive recovery of overpayments can cause serious significant financial harm. Therefore, retroactive recovery of overpayments that were caused by CMS or its contractors should be time limited and conducted in a fair and equitable manner.

## **REVISE CURRENT SIGNIFICANT CHANGE IN CONDITION (SCIC) PAYMENT POLICY TO ENSURE APPROPRIATE PAYMENT FOR INCREASED SERVICES**

**ISSUE:** The prospective payment system (PPS) regulations included a provision for a payment adjustment to an episode of care in which a patient experienced a “significant change in condition” (SCIC) that was not envisioned in the original plan of care. The intent of the SCIC adjustment was to provide HHAs with the ability to meet the changing resource needs of their patients. CMS stated in the preamble to the final rule that the SCIC adjustment policy was to provide financial relief to HHAs that would otherwise “be locked into a case-mix adjusted payment based on a point in time of the patient’s condition at the beginning of the episode.” However, the current operation of the policy does not meet this intent.

The SCIC adjustment is based on the span of billable visit dates. The gaps between billable visits are carved out of the payment to the provider for a given episode. These gaps occur mid-episode, in between the last billable visit under the first HHRG and the first billable visit under the second HHRG. Additional gaps occur at the end of the episode if the last billable visit is made prior to the last day (day 60) of the episode. Though the payment rate may increase for that portion of the episode, the gaps in service dates more often results in a lower overall payment to the home health agency.

CMS attempted to alleviate this burden by offering home health agencies the option of not claiming the SCIC if doing so would result in a lower net payment to the agency. However, this option constrains the agency to payment for a full episode under the patient’s original HHRG. Therefore, the agency is not adequately compensated for any increased resource needs of the patient who experienced a significant change in condition. Additionally, in cases where the significant change in condition is the result of an unexpected improvement in the patient’s condition, CMS requires that a SCIC must be claimed. Complicating this issue even further, CMS responded to provider inquiries that, should the therapy threshold be reached unexpectedly during the course of a SCIC episode, the provider is prohibited from claiming therapy case-mix points for the pre-SCIC portion of the episode and for the entire episode if no SCIC is claimed.

Finally, it is difficult to determine if a change in condition is “significant” since the term is not defined by CMS other than to state that determination of SCICs should be done by the clinician and should not be based solely on changes to the HHRG. CMS advised home health providers to claim a SCIC when an unexpected change in a patient’s condition results with a higher HHRG and new orders are required. However, CMS has not defined “unexpected” change.

### **RECOMMENDATIONS:**

CMS should eliminate SCICs for payment purposes from PPS.

If this is not done, CMS should amend the current regulation at 42 CFR 484.237 as follows:

1. Eliminate SCICs for situations where there is an unexpected improvement in the patient’s condition.
2. Define a SCIC as an increase in an HHRG value accompanied by a change in orders that adds additional services or increased frequency of services into the plan of care resulting in increased payment.
3. Pay home health agencies for a full 60 day episode, prorated based on the date(s) in the episode on which the HHRG increased.
4. Pay for therapy threshold for the full episodes in all instances that 10 or more therapy visits are provided.

**RATIONALE:** The inability to develop a consistent definition of a SCIC results in confusion and inconsistent application of the policy. Home health agencies continue to be financially and administratively burdened by the current SCIC policy. As result of the current SCIC payment policy, an agency is penalized when a patient experiences a SCIC during an episode of care. But when a patient does not experience a SCIC, the agency receives payment for a full episode, regardless of gaps in days between billable visits. Eliminating the gaps in payment that occur under the current SCIC policy will more fully meet CMS' intent of providing additional payment to agencies that must utilize additional resources to meet the changing needs of the patient. Eliminating these gaps is also more consistent with the definition of an episode CMS calculated PPS costs and payment rates based on a 60-day period.

The option not to bill a SCIC when a patient's condition deteriorates, but the overall payment to the agency would be lower if the SCIC were billed, creates an administrative and financial burden on home health agencies. An agency must first determine whether it will receive a lower net payment if the SCIC is billed. In the event it does not claim the SCIC, it will still receive an episode payment that does not adequately represent the increased resource needs of the patient.

Finally, CMS interpretation of the SCIC policy as it relates to the therapy threshold is inaccurate. According to the July 3, 2000 *Federal Register* notice for home health PPS "In the SCIC situation, the therapy threshold applies to the total therapy visits provided to the beneficiary during the episode both before and after the significant change in condition occurred."

## **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. Home health providers foresee application of telehealth as a means to improve the delivery of services in the home, provide greater access to specialists, and produce cost savings for specific types of patients. 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

The Centers for Medicare and Medicaid Services (CMS) has not made plans to extend the Medicare home health and hospice benefits to specifically include telehealth services. However, 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 are to 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 as allowable expenses on the home health cost report when 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. Quality Improvement Organizations (QIO) have been charged in the 8<sup>th</sup> 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.

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 requirement 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 .
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:** 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, shortened hospital stays, and improved patient outcomes and patient satisfaction. However, regulatory burdens must be minimized and payment, when telehealth is applied in Medicare episodes of care, 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 for all intermediary reviewers.
4. Expand RHHI provider relations and services.
5. Implement a time-limited prepayment review if the provider has evidence of non-covered claims before application of a 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.
7. Require repayment only after all appeal rights are exhausted.

**RATIONALE:** Sampling imposes significant risks 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 increases payment to Medicare Advantage plans to encourage more beneficiaries to leave traditional Medicare and join private HMO and PPO plans. Federally-qualified managed care plans, known as Medicare Advantage, have restricted the home care benefit for non-Medicare subscribers by limiting visits to a bare minimum and applying a “part-time or intermittent” care limitation to non-Medicare patients. Some federally-qualified managed care 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. In addition, although not required by the legislation, Medicare Advantage plans will have the option of imposing their own co-payment structure, including home care co-payments

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.

Managed care programs enrolling Medicare beneficiaries have been known to engage in questionable marketing practices resulting 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. Some Medicare Advantage plans are also known to authorize fewer services than beneficiaries would receive under traditional Medicare and/or impose co-pays. 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 would 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 with in these new plans since they will have increased flexibility in coverage requirements, with potential for limiting home health and hospice benefits.

### **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.
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 the 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.

**RATIONALE:** Managed care plans that choose to become Federally-qualified should be required to provide home care services to all subscribers without limit as to time or cost. Medicare beneficiaries enrolled in managed care plans should not be denied home health services to which they are entitled. Imposition of co-pays limits access to home care for many Medicare beneficiaries. In addition, new insurance models, such as preferred provider organizations and disease management programs, must be held to the same standards and ensure access to home health and hospice services that fee-for-service Medicare beneficiaries receive.

## **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.

State Medicaid directors are enforcing homebound requirements that are contrary to federal law or 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 creating a care dilemma for home care providers when faced with patients who have continuing needs when their limit on benefits has been reached.

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, 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 and oppose co-payments.
4. Ensure that home health is included in every state Medicaid benefit package if block grants are established.
5. Address service and payment rate requirements that must be followed by managed care organizations serving Medicaid clients.
6. Ensure comprehensive reform of Medicaid home care consistent with the Olmstead decision.
7. Ensure compliance with the elimination of the homebound requirement at the state level.
8. Require that minimum standards be established for consumer directed care programs.

**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.

## **REDUCE AND REFINE OASIS REQUIREMENTS AND FULLY REIMBURSE HOME HEALTH AGENCIES FOR OASIS COSTS**

**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. 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.

Many of the OASIS items are not useful for payment or outcome measurement. In addition, a significant number of items offer limited descriptions and require narrative notes to describe individual patients. The timelines for completion and transmission of OASIS data are unrealistic and limitations on practitioners permitted to perform certain assessment result in added non-covered visits and costs to agencies. The usefulness of many of the OASIS data items has not been demonstrated to the home health industry and the validity of the OASIS data set for measuring outcomes for chronic long-term patients has been questioned. The value of “significant change in condition” assessments is questionable since significant change is defined by each agency. Finally, use of different forms for patient assessments at different time points is confusing to home visiting personnel and often results in duplicative paperwork when the wrong forms are completed.

In 2002 CMS took steps to reduce the OASIS burdens in response to requests from the industry and the Secretary of Health and Human Services’ Regulatory Reform Committee recommendations. Changes to OASIS requirements include elimination of several OASIS items, elimination of demographic information from subsequent assessments, streamlining follow-up assessments for Medicare patients to the 23 items needed for payment, and elimination of Reason for Assessment (RFA) 2 and 10. A technical expert panel of providers and researchers was appointed in a three-year project to determine the necessity and validity of each of the OASIS data items and requirements.

As a result of The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 requirements for collection of OASIS data on non-Medicare and non-Medicaid patients has been temporarily suspended. OASIS data collection will not be required for these patients until a regulation regarding the collection and use of OASIS for non-Medicare and non-Medicaid patients has been published. MMA also required that the Secretary reports to Congress on:

1. The benefits of these data
2. The value of the data compared to the administrative burden of data collection in small agencies
3. Use of OASIS information by large and small agencies.

CMS completed the conduct of a study to collect this information but the results are unknown and the report has not yet been sent to Congress.

CMS continues to require full OASIS data collection for Medicaid patients at recertification even though this information is not used for quality measurement or payment.

### **RECOMMENDATIONS:**

1. Support the industry's recommendations for 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. 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.
8. Allow the use of a single universal form for all OASIS collection time points.
9. Eliminate the requirement to complete OASIS for significant changes, including payment driven SCICs (See Revise Current Significant Change in Condition Policy... issue).
10. Revise the guidelines for assessment when 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 and 14 days to lock.
13. Limit OASIS items and requirements to those that are valid, reliable and necessary for payment and quality measurement.

**RATIONALE:** OASIS is a valuable tool that, over time, will greatly enhance the delivery of home health services. However, requiring OASIS data collection and submission for non-Medicare patients constitutes an unfunded mandate and is of questionable value. 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 and the SCIC payment policy is fraught with problems, hence should be eliminated.

## **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) the Medicare Payment Advisory Commission (MedPAC) recommended that Congress 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. Although not yet passed, legislation was introduced in 2005 to achieve the purpose of creating a pay for performance (P4P) system for health care providers. CMS is preparing for P4P through the conduct of P4P demonstration projects for certain providers. Hospitals are already reporting performance measures and being paid based on performance. CMS plans to expand these efforts as allowed by legislation. CMS is also considering applying a P4P system to Medicaid services.

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 proposed legislation also identifies the need for the Secretary to identify process measure and ways to reward providers to use of health information technology (HIT). This legislation also requires that the Secretary work with interested parties, including health care providers, on the identification of quality measures. Such a system must be budget neutral.

### **RECOMMENDATION:**

1. Ensure consultation with provider representatives in identification of appropriate P4P measures and the development of a fair and equitable system.
2. Require CMS to retest the validity and reliability of OASIS using current guidelines in the "real world" of home health application
3. Require that OASIS refinements be in place before outcome 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. Establish funding mechanisms for HIT, especially for small providers
6. Create a separate pool that would be used to fund the P4P system, rather than withholding a percentage of payment from all providers until the end of the year

**RATIONALE:** Identification of acceptable fair and equitable measures can be problematic, especially in light of the many variations in the needs and social and economic status of Medicare beneficiaries and Medicaid enrollees. Therefore, development of such a 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.

## **ENSURE ACCESS TO REVIEW OF MEDICARE REIMBURSEMENT DECISIONS**

**ISSUE:** CMS plans to issue a proposed rule affecting the rights of home health agencies, hospices, and other health care providers to seek review of reimbursement determinations by intermediaries. In this proposed rule, CMS intends to clarify the standards governing the administrative appeals process for payment disputes, including rules distinguishing the amending of cost reports and the re-opening of Medicare intermediary payment determinations and administrative review decisions. The onset of Medicare PPS has not eliminated home health agency interest in the arena of reimbursement appeals since there are several years of residual cost reports disputes.

**RECOMMENDATION:** Any changes to reimbursement appeals rules must ensure that providers have full access to the systems for review of improper reimbursement determinations.

**RATIONALE:** Home health agencies and hospices have regularly faced improper reimbursement determinations by fiscal intermediaries. The right to seek a re-opening of a payment determination and the right to appeals before the PRRB are important mechanisms designed to protect providers and the clients from improper reimbursement determinations by intermediaries. Any weakening of this system will reduce the likelihood that home health/hospice agencies receive adequate reimbursement from Medicare.

## **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. 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. 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. Significant costs to providers, Medicare, and Medicaid are incurred because these projects require retrospective claims review, submission of claims to Medicare, and administrative appeals.

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 pilot 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 will be completed between Medicare and Medicaid.

### **RECOMMENDATION:**

1. Modify third-party liability regulations to require that states utilize the most cost effective method for recovering payment for dually eligible patients.
2. Consider the development 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. Work with CMS to implement those pilot programs that incorporate the above recommendations for dually eligible beneficiaries' coverage decisions on a nationwide basis.
5. Monitor the Connecticut, Massachusetts, New York third party liability demonstrations.

**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.

## **REJECT MEDICAID WAIVERS THAT REDUCE BENEFITS FOR**

## CURRENT BENEFICIARIES

**ISSUE:** The Administration's waiver policy, the Health Insurance Flexibility and Accountability Initiative (HIFA), was touted as a way for states to expand Medicaid and State Children's Health Insurance program (SCHIP) coverage. However, it includes no new funds and gives states new tools to pay for those expansions by curbing Medicaid spending for current low-income beneficiaries, including children and their parents, disabled people, and seniors.

The policy gives states expanded power to charge current and future low-income beneficiaries fees for health care services they cannot afford and to cut many (now mandatory) critical health services for some groups of beneficiaries and not for others. It also allows states to cap the number of people who can enroll. Nothing in the new policy ensures that all dollars raised from fees or saved from cutting services will be re-invested in Medicaid or SCHIP expansions. Alternatively, it is possible that a small expansion could be used to justify significant increases in fees charged to low-income beneficiaries and significant cuts in covered health benefits.

While those in mandatory groups would continue to be entitled to mandatory services and limited cost-sharing, states would have new discretion, as well as incentives, to cut benefits and increase cost-sharing, both for optional groups and for people eligible under any new expansions. Under this new scheme, low-income seniors on Medicaid are particularly at risk because the majority of them, 56%, are optional beneficiaries. Forty-four states set Medicaid eligibility for optional beneficiaries at or below the federal poverty level. In 2002, several states initiated HIFA waivers. In these states there was no reduction in available home care benefits for the current Medicare recipients.

**RECOMMENDATION:** This new policy should be rescinded. At a minimum, state officials should be required to provide full disclosure of waiver proposals and ample opportunity for all advocates and stakeholders to have real input in the design of waivers. Unfortunately, rather than promoting public participation, the new HIFA waiver policy includes an expedited federal review process that is likely to diminish public participation.

**RATIONALE:** Under the HIFA waiver proposal, states that want to expand their programs are encouraged to cut services for currently eligible people. The HIFA waiver puts these states in a catch-22: To help new people, the state must hurt current enrollees.

Under the HIFA waivers, states could charge premiums, deductibles, copayments, and coinsurance to optional Medicaid seniors with no limits on the out-of-pocket costs. For low income seniors, who generally use more health care services, the burden of meeting repeated out of pocket copayments and coinsurance may prevent them from receiving needed care.

States that request waivers could eliminate skilled nursing care provided in the home for optional beneficiaries. For both mandatory and optional beneficiaries, the states could eliminate home and community-based care (other than skilled nursing services), prosthetic devices and medical equipment, rehabilitative and physical therapy services, hospice, and personal care services. By allowing states to cap enrollment, the new waiver policy converts Medicaid from an entitlement program, in which all eligible applicants can enroll and receive services, to a block grant that stops enrollment when a finite expenditure is reached.

## **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 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 shift to PPS requires a retooling and revision of anti-fraud efforts from cost reporting and claims concerns to issues of care quality and access. Enforcement authorities are not adequately prepared to make this adjustment. CMS has developed a long-term strategy for detecting and preventing fraud and abuse in response to provisions in the Health Insurance Portability and Accountability Act. The strategy involves separating program safeguard functions from the claims processing activities carried out by intermediaries and assigning them to Program Safeguard Contractors (PSC). 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 PSC personnel.
2. Closely monitor the work of PSCs to ensure appropriate fraud investigation and referrals.

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.

## **SIMPLIFY MEDICARE DETERMINATION PROCEDURES AND REVISE MEDICARE SECONDARY PAYER RULES**

**ISSUE:** Under current Medicare Secondary Payer (MSP) rules, home health and hospice providers are improperly denied fair and reasonable reimbursement for services that may be subject to coverage from an alternative primary health insurer. Under the old rules, home health agencies were limited in reimbursement to the aggregate amount that would have been received under Medicare for the full episode even when the primary insurer limited coverage to certain disciplines of care. The MSP plan under home health PPS perpetuates this inequity. CMS guidelines call for the limitation of PPS payment under MSP to the aggregate amount payable under episodic reimbursement regardless of the primary insurance standards.

In addition, many alternative primary health insurers require documentation or verification of Medicare non-coverage. However, there are no simple procedures for obtaining this information from Medicare. Non-coverage decisions through the demand bill process take several months. CMS has failed to identify a simple format for confirmation of primary payment responsibility of other health insurers. Home health agencies are frequently unable to bill primary payers because of timely filing limits in cases where it is not evident that Medicare is the secondary payer.

### **RECOMMENDATION:**

1. Medicare providers should receive full payment from Medicare for discipline specific services that are not covered by the primary insurance.
2. Home health agencies should be reimbursed up to the full episodic payment rate.
3. The home health LUPA per visit rates should be paid for these visits under home health PPS.
4. Demand billing procedures should be revised to ensure prompt issuance of non-coverage determinations.
5. CMS should allow submission of the demand bill as soon as the “initial assessment” has been completed as defined in the Medicare CoP or agency personnel have determined that the beneficiary does not meet qualifying criteria or services do not meet coverage criteria.
6. Statement of Medicare Secondary Payer determinations should be available upon request.

**RATIONALE:** Where home health agencies and hospices provide a combination of services, yet receive reimbursement from insurance companies for some of the services, it is only fair that the amount payable for the care by the primary payer should not be considered by Medicare in determining the Medicare payment due.

It is Medicare’s responsibility to simplify procedures and ensure access to needed health care to its beneficiaries. Without assurance of timely determinations by Medicare, home health agencies and hospices are reluctant to accept these beneficiaries since they may not receive payment for services that they have delivered for several months.

## **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.

## **REQUIRE AUTOMATED CORRECTION OF UNDERPAYMENTS OF HOME HEALTH CLAIMS, NOT JUST OVERPAYMENTS**

**ISSUE:** The Centers for Medicare and Medicaid Services (CMS) philosophy is to pay claims correctly. However, CMS has established automated edits to identify and correct potential overpayments, but has not taken similar actions to identify and correct underpayments. The home health prospective payment system is a complex payment system with multiple variables impacting the payment rate. Of major importance is the case-mix system, which is based on the Outcome and Assessment Information Set (OASIS). Twenty-three OASIS items that are collected at the start of each episode of care are used to determine case-mix payment weight for home health episodes. Response to one OASIS item, M0825, requires clinicians to project whether patients will receive 10 or more therapy visits in an episode of care. Another item, M0175, requires clinicians to identify all inpatient stays, including the type of stay billed to Medicare, during the 14 days prior to admission to home health. CMS has instituted automated edits on both of these OASIS items to identify and correct home health agencies' claims that would lead to overpayment. There exists unlimited potential for CMS to implement other edits. CMS has the capability to edit for, and correct underpayments on these same items, but has announced that it is the provider's rather than their responsibility to identify and correct underpayments.

### **RECOMMENDATION:**

1. Institute edits to identify coding errors that would lead to underpayments that are correctable by the CMS claims processing systems.
2. Pay providers at the higher rate for 10 or more therapy visits when the home health agency failed to project the therapy threshold at the start of an episode. If that is not possible, return claims to providers where the correct number of therapy visits is not reflected in the home health resource group (HHRG).
3. Retroactively adjust claims, after verification with the common working file (CWF), that were underpaid because a provider did not reflect a SNF or rehab facility stay within the previous 14 days in the OASIS assessment and HHRG.

**RATIONALE:** CMS's responsibility to pay claims correctly should apply to underpayment as well as overpayment. It is impossible for home health clinicians to accurately project the number of therapy visits a patient will need in 100% of cases. Also, physicians, patients, and caretakers are not always able to accurately identify and inform clinicians of inpatient stays that occurred during the prior 14 days. CMS and its contractors have demonstrated the ability to create and install system edits to identify fewer than 10 therapy visits and pre-home care inpatient stays that lead to recovery of overpayments. They have the capability and responsibility to identify and correct underpayments as well.

## **II. SURVEY AND CERTIFICATION**

## **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 issuance of new proposed home health conditions of participation scheduled for spring 2006 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. As of 2003 CMS will require 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, in the state agency budget call for 2003 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 to be 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. FIs 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 on-line as more home health agencies move to e-health records.

## **ABOLISH PRESCRIPTIVE AND BURDENSOME PROCEDURAL REQUIREMENTS RELATED TO VERBAL ORDERS**

**ISSUE:** The Medicare Home Health Conditions of Participation (CoP) at 42 CFR §484.18(c) and coverage rules at 42 CFR §409.43(d) require that all verbal orders be signed and dated by the registered nurse or therapist responsible for furnishing or supervising the ordered services. Although not in the regulations, CMS contends that this will ensure that verbal orders received by agency personnel, other than the professionals directly responsible for the patient's care, will be reviewed by the responsible person prior to implementation. In addition, §409.43(d) states that "verbal orders must also be countersigned and dated by the physician before the HHA bills for the care." CMS has interpreted this to mean that "all" verbal orders must be signed prior to billing regardless of whether or not the verbal orders support billed services (e.g. oral medication changes).

CMS' office of survey and certification and some Regional Home Health Intermediaries (RHHI) have interpreted this regulation to mean that the piece of paper prepared by the person receiving the verbal orders must be reviewed and signed by the nurse or therapist and countersigned by the physician.

### **RECOMMENDATION:**

1. Reinstatement of the verbal order requirements as they were prior to February 1995 as follows: "The nurse or therapist immediately records and signs verbal orders and obtains the physician's countersignature."
2. Limit required signed orders prior to billing to include only orders needed to support billed services.
3. Do not cite agencies with deficiencies when they can demonstrate that they made a good faith effort to obtain the paperwork timely from the physician to validate verbal orders.

**RATIONALE:** HHAs have not, as common practice, allowed unlicensed personnel to accept verbal orders. Home health regulations and professional practice acts in many states prohibit acceptance of verbal orders by any person other than nurses and therapists. Also, nurses and therapists have expressed concern about their legal liability for verbal orders accepted by an unlicensed employee. The legality of such documents is questionable and places liability on the nurse or therapist.

It is within the responsibility and scope of practice of a licensed professional to accept, note and communicate verbal orders. To require the nurse or therapist providing or supervising care to write and sign all orders is unnecessary if only qualified nurses or therapists receive verbal orders. The fact that the countersignature is not required prior to the provision of services contradicts the necessity to have the providing or supervising clinician also sign the verbal order.

In regard to physician signatures on all verbal orders, HHAs cannot control the actions of physicians. Since HHAs cannot ensure that physicians will sign for the verbal orders that they have issued, penalties should be limited. Therefore, HHAs that have, in good faith, accepted and carried out physicians' verbal orders should only be required to demonstrate that they have taken appropriate steps to obtain the physician's signature on verbal orders. Since the intent of the law is to ensure that services paid for by the Medicare program are ordered by a physician, denial of payment should not occur when agencies have been unable to obtain the physician's signature for minor changes in the plan of care. Payment should be withheld only when the provider has not obtained signatures on those verbal orders needed to support the services billed.

## **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. As of December, 2005 the CMS study has not been made public.

### **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 CoP 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.

### **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.

**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 proposed CoP. 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 the new CoPs scheduled for release in 2004 are 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 has selected states and initiated the MMA provision to establish pilot projects in no more than 10 states for the purpose of expanding background checks for workers with direct patient access who are employed by Medicare and Medicaid long term care providers. 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). The pilot will run from 2004-2007. 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.

### **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 posting on the CMS national Quality Initiative web site. CMS issued guidelines to surveyors for incorporation of OASIS and outcome reports in the survey process effective July 1, 2003.

CMS plans to publish the final home health CoP in 2004, making OBQI activities mandatory. CMS will issue guidelines to surveyors for incorporation of OASIS and outcome reports in the survey process, some of which will be implemented prior to publication of the final CoP. In the meantime, Quality Improvement Organizations (QIO) were charged with helping home health agencies implement OBQI on a voluntary basis under their 7<sup>th</sup> Scope of Work. In the 8<sup>th</sup> Scope of Work, QIOs will help agencies identify and implement best practices to improve the quality of care delivered.

**RECOMMENDATION:** Support requirements for quality improvement based on patient outcomes. Such a requirement 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. CMS has funded research to develop outcome indicators for home health care. Such a quality system will have the tendency to involve massive data collection unless controlled. Even minimum data collection will result in added costs for agencies. Every effort must be made to keep data collection and paperwork burden to a minimum so that resources can be used for patient care rather than paperwork. Furthermore, outcome information produced by such a system must be viewed and used appropriately in order to prevent inappropriate consequences. Funding of QIOs to assist home health agencies in quality improvement efforts ensures access to objective quality expertise at no cost to providers.

## **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. These indicators have been limited to outcome measures since there has been no research on process and structure measures in the home care arena.

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.

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 Medicare Prescription Drug, Improvement, and Modernization Act 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.

**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.

# **III.**

# **ADMINISTRATION**

## **MEDICARE CONTRACTING REFORM**

**ISSUE:** Section 911 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) established Medicare Contracting Reform (MCR). MCR brings 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. MCR mandates changes to original Medicare's administrative structures directing CMS to conduct full and open competitions for new Medicare Administrative Contractors (MACs), which 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.

A/B MACs will administer both the Part A and Part B work currently being handled by Fiscal Intermediaries (FI) and carriers in 15 designated geographical jurisdictions. Home health/hospice MACs will perform work currently performed by Regional Home Health Intermediaries (RHHIs) in four designated geographical jurisdictions, while Durable Medical Equipment (DME) MACs will perform the work of the current Durable Medical Equipment Regional Carriers (DMERCs) in four designated geographical jurisdictions that correspond to the jurisdictions of the home health/hospice MACs. Contracts will be awarded to home health /hospice MACs in September, 2008.

The criteria used in the selection of the contractors, the transition process from the RHHIs to the MACs, and contractors knowledge level of Medicare coverage and payment policies for home health care are all issues that require stakeholder input. CMS must elicit provider input prior to implementing all phases of the transition process to ensure considerations is given to providers concerns regarding the transition from RHHIs to MACs.

### **RECOMMENDATIONS:**

1. Establish specific criteria for evaluating prospective contractors prior to rewarding contracts. The criteria should include, but not be limited to:
  - Contractor's ability to successful transfer electronic records and be equipped with back-up systems to ensure timely payment on claims;
  - Contractor's knowledge regarding the Medicare home health prospective payment system and their ability to process home health care claims;
  - Contractor's ability to interpret Medicare coverage rules to prevent inappropriate coverage denials during medical review and;
  - Require contactors permit new and existing CMS-certified chain providers to have the option to choose the FI that serves the chain home office, as currently exists.
2. Clearly define for providers what performance incentives will be used when contracting with the MACs, and allow provider input if these incentives have potential for conflicts of interest.
3. Work closely with the providers to establish clear transition steps and be required to communicate these steps at regular intervals.

### **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. Having one contractor for chain providers has enabled both the contractors and providers

perform administrative functions more efficiently than if several contractors were processing claims.

## **REQUIRE RESEARCH ON THE VALIDITY AND RELIABILITY OF OASIS**

**ISSUE:** Decisions about the use of home health outcome measures for such considerations as public reporting and pay for performance are based on OASIS validity and reliability studies that were conducted by the University of Colorado prior to the roll-out of OASIS. As such, these studies were limited to a small number of home health agencies, many of whom participated in the development of the OASIS data set and the item definitions and guidance. Since the national roll-out of OASIS in 1999, CMS has issued new guidance on how to interpret and respond to many of the OASIS questions. However, very little research has been conducted since that time. The most recent was an in-depth study of AOSIS validity and reliability conducted by the Visiting Nurse Service of New York's Center for Home Care Policy & Research.

The Center for Home Care Policy & Research found that, in the real-world application of OASIS, many of the data items scored low in reliability tests. Of particular concern were their findings of low reliability for the instrumental activities of daily living (IADS), functional status in the 14 days prior to the episode, and prognosis.

### **RECOMMENATION:**

1. Require consideration of the findings of the Center for Home Care Policy & Research
2. Conduct additional research on the validity and reliability of OASIS application to the real-world.
3. Refrain from using outcome measures derived from OASIS data for pay for performance (P4P) until further studies have been completed and necessary changes made to the data set.

**RATIONALE:** Research on the validity and reliability of OASIS conducted during its development cannot be relied upon outside of the study environment. Furthermore, the many changes to the guidance that were issued by CMS after its national roll-out raises serious concerns as to whether OASIS retains the level of validity and reliability levels found prior to the changes. The Centers for Health Policy and Research findings support this. It is unfair to providers to base pay for performance on a tool that lacks adequate levels of validity and reliability.

## **DEVELOP A SYSTEM THAT INCLUDES THE NATIONAL HOME CARE NETWORK TO PROMOTE EFFECTIVE PREPAREDNESS FOR AND RESPONSE TO NATURAL AND MANMADE DISASTERS**

**ISSUE:** The terrorist attacks on New York City and Washington, DC, on September 11, 2001, and subsequent release through the U.S. Postal Service of active anthrax spores 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, the entire health care system would have been taxed beyond capacity. Home care 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. Home care's role and inclusion in emergency preparedness is crucial especially in an environment of syndromic surveillance, home isolation and home quarantine.

The recent hurricanes that struck the Gulf States, 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 health care is just beginning to be included in planning proposals for handling large scale disasters. During hurricanes Katrina and Rita home health care 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 health care providers can play a vital role in implementing pandemic influenza plans. Home health agencies 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, \$26.6 billion has 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.

### **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 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 Medicare-certified home care 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 Medicare home health agencies, e.g. communications systems and paperless documentation software and hardware. Communication systems are needed to enable clinicians to communicate from patients' homes and from areas without power or phone availability. Paperless documentation software and hardware would enable clinicians to have access to a patient's medical record.
- 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.
- Provide immediate regulatory relief to home care providers by announcing regulatory concessions at the same time 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 is 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 agencies frequently has performed important functions that protect and serve communities.

Those that provide home care 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 19<sup>th</sup> 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 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 discharge planning regulation in order to implement one of the BBA requirements in August, 2004. According to the final rule, 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.

### **RECOMMENDATION:**

1. Educate surveyors about this 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 based upon intensive service and supply needs.
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 but similar regulations are needed for hospice. Similar regulations are needed to govern referrals made by all providers and suppliers. 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 requirements could further increase for home health if additional outcome measures are required if CMS adopts the National Quality Forum's recommendations for 28 publicly reportable outcome measures, 11 of which will require data collection beyond OASIS.

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.

**RECOMMENDATION:** Promote paperwork reduction by eliminating duplicative information and establishing efficient procedures. 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. Providers should be appropriately compensated for added costs.

**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 benefit and promote more efficient use of limited financial resources. Any increased paperwork requirements should have benefits that outweigh the costs. The reimbursement system must be adjusted for any new requirements imposed on home health providers.

## **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 can 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.

CMS billing instructions require physicians to record the date of service as the date they sign the plan of care. However, 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' development of two new codes for certification and recertification of home health plans of care is a positive step toward recognizing these are separate and distinct services from care plan oversight, and that physicians should receive appropriate compensation for performing these necessary services.

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. In 2002, CMS revise 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.

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 proposed regulation that will 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 will require verification and periodic re-validation of enrollment information, or Medicare-certified providers could face termination of their billing numbers. If finalized in its present form, the regulation will require reapplication every 3 years. In the meantime, changes in provider and management status, ownership, and demographic information require completion of a enrollment form in order to register updated information.

Presently 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. In addition, they do not have appeal rights if disapproved and some providers have reported lifting of provider rights when they failed to continue to serve patients during the post-survey waiting period. Further delays are experienced when intermediaries fail to give providers timely access to billing numbers.

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. 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 on-line.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 directed the Secretary to establish a regulation whereby providers will have hearing rights in the case of denial or non-renewal. In addition, CMS will be required to consult with providers and suppliers before changing enrollment forms. However, regulations to implement this provision have not been published.

### **RECOMMENDATION:**

1. Make available training and materials on requirements for Medicare-certified HHAs and hospices, including CoP, coverage, billing, cost report and audit/reimbursement 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, and ability to implement billing and accounting procedures before certification is granted.
4. New course designs must take into consideration that certain agency functions may be carried out effectively outside of the local agency by a parent organization.

5. 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.
7. Refrain from establishing an “every 3 year reapplication” requirement and limit submission of updated information to changes in significant information such as address, management and administrative personnel.
8. Establish a 60 day time line for decisions on applications, and 30 days on reapplication.
9. Establish a provider enrollment process with hearing rights in the case of a denial or non-renewal.
10. Require CMS contractors to initiate billing privileges within 5 days of notification of assignment of a provider number.
11. Consult with providers before changing enrollment forms.
12. Allow long-term providers with no 855 on file to simply submit updated information rather than complete an entire 855.
13. Consider a streamlined approach to survey of new providers who are part of a chain or multi-site organization.

**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.

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.

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. 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. 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 perform functions are executed by the parent organization which has the expertise and may be conducting its own training. Information about existing, related organizations should be recognized when new applications or changes are received. Further survey or new sites for the organizations should be streamlined in order to reduce unnecessary government expenditures.



# **IV. COVERAGE & APPEALS**

## **REVISE EXPEDITED DETERMINATION PROCESS**

**ISSUE:** As of July 1, 2005, Home Health Agencies (HHAs), with beneficiaries in Fee-For-Service Medicare are required to notify beneficiaries of their right to a new expedited review process when these providers anticipate that Medicare coverage of their services will end.

HHA are required to provide a Generic Notice to beneficiaries to alert them that Medicare covered item(s) and/or service(s) are ending and give beneficiaries the opportunity to request an expedited determination from a Quality Improvement Organization (QIO). Once a Generic notice is given, the beneficiary has until noon the following day to contact the QIO and request an expedited appeal. The agency must provide both the beneficiary and the QIO with a detailed notice by the end of the day the QIO informs the agency of the beneficiary's appeal request. The agency will also be required to provide any additional information the QIO requests by the end of the day. The QIO then has 72 hours from the time of the beneficiary appeal request is known to render a decision.

A key element to the expedited appeal process is a physician certification stating the beneficiary will be harmed if home care services were to be discontinued. Without the physician statement the QIO can not precede with the appeal. Neither the Generic Notice nor Detailed Notice contains this information. The beneficiary is not aware of the requirement until after they have contacted the QIO with an appeal request. In addition, CMS allows a beneficiary 60 days to obtain a physician certification. During this time the QIO must keep the appeal pending.

The QIO's decision on appeal requests are binding for intermediaries. If the QIO rules in favor of the beneficiary, regardless if whether or not a correct coverage decision was made, Medicare payment will continue for care. A QIO ruling favorable to the beneficiary requires the provider continue Medicare covered services until which time the provider believes the Medicare covered services should be discontinued. The notice of Medicare non-coverage and possible appeal request will continue until both the provider and the QIO reach an agreement that discontinuing Medicare covered services is appropriate.

### **RECOMMENDATIONS:**

- 1) Include in the Generic Notice that a physician certification must be obtained before a decision can be made.
- 2) Limit the time frame a beneficiary has for obtaining the physician certification to the 72 hours with which the QIO has to render a decision.
- 3) Require QIO personnel reviewing home health appeal requests receive adequate training in Medicare coverage guidelines for home health care.

### **RATIONALE:**

Informing the beneficiary of the necessity to obtain a physician certification early in the expedited appeals process will facilitate a timely review. Both the provider and the QIO have potential to spend hours retrieving and review clinical records for appeal requests that may never go forward since a physician certification was not obtained. In addition, the 60 day time frame a beneficiary has to obtain the physician certification is contrary to the intent of an "expedited" appeal decision. After 60 days a beneficiary's care needs, if any, would likely be significantly different than at the time of the initial appeal request; rendering any decision meaningless.

Inappropriate appeal decisions to continue care often result from the QIO's lack of knowledge regarding Medicare home health coverage guidelines. The decision to continue care is often based entirely on the clinical condition of a patient without regard as to whether the care

required would be considered Medicare covered services under the home health benefit. For example, patients with chronic conditions who may require some level of assistance but do not meet the coverage criteria for skilled services. Incorrect interpretations of the homebound definition could cause patients to remain under a home health plan of care for periods of time far beyond what the benefit intended. As a result, Medicare expenditures for home health services will ultimately be higher than expected. When conflicting Medicare coverage information is communicated to the beneficiary providers are placed in a position of appearing unknowledgeable, or worse, unscrupulous to the beneficiary. This also confuses beneficiaries as to what items and services the benefit truly provides.

## **IMPLEMENT CLEAR AND REASONABLE STANDARDS FOR HHABNs AND DEMAND BILLS**

**ISSUE:** Over the past two years, CMS has struggled to resolve a long-standing weakness in the Medicare coverage-determinations process. That process requires home health agencies to determine whether there is reason to believe that services required by an individual are outside the scope of the Medicare home health benefit. In such cases, home health agencies must tender written notice to the affected individual who has a right to demand that the home health agency submit a bill to Medicare for a formal determination as to ineligibility for coverage. A uniform and mandatory beneficiary notice was developed (the home health advance beneficiary notice, or HHABN) in the context of ongoing litigation and the transition to a new and entirely different reimbursement system under home health PPS. This notice was revised into a one-page HHABN has been approved by OMB that became effective on January 1, 2004.

When a home health agency suspects that physician ordered services ordered might not be covered by Medicare, the agency notifies the beneficiary in writing using the HHABN. If the beneficiary wants to continue to receive the services, he or she must accept financial liability for services or must pay out of pocket until Medicare makes that determination. If the beneficiary wants a formal determination, the home health agency may submit a demand bill, but under PPS, that bill cannot be submitted until the end of an episode of care. Once the demand bill is sent, the intermediary asks for the clinical record. Thus, 3-4 months elapses before an official determination can be obtained, leaving agencies with significant outstanding receivables. If that determination favors the beneficiary, the HHA must then refund any previously collected funds. A beneficiary may be forced to pay for up to four months of care before a formal coverage decision is rendered. Beneficiaries without the resources to continue care are left without other options.

Delayed Medicare determinations often result in the inability of agencies to submit claims to other payers in a timely manner, resulting in loss of payment for services not covered by Medicare but covered by third parties.

CMS states that it is necessary to wait until the end of the episode for the FI to make a determination since they cannot make a decision based on 1 visit at the beginning of care.

### **RECOMMENDATION:**

1. Modify the recently approved mandatory home health advance beneficiary notice (HHABN) to reflect the consequences to a patient dually entitled under Medicare and Medicaid and the extent of financial liability that may be involved in waiting several months for the Medicare determination
2. Clarify and streamline demand billing procedures.
3. Correct system problems that result in inability of intermediaries to issue demand bill determinations in a prompt manner.
4. Limit the demand billing process to those circumstances where a Medicare non-coverage decision is issued by the home health agency.
5. Streamline the process whereby beneficiaries who cannot afford to pay out of pocket to continue services may obtain a timely coverage decision, ideally within one visit of the determination.
6. Apply streamlined solutions to all other insurance situations.

NAHC should work cooperatively with beneficiary groups to promote an improved and streamlined demand billing process.

**RATIONALE:** Home health agencies have no authority to make final determinations regarding Medicare coverage. However, as a result of an intentional shift of liability under Medicare law, home health agencies must render informal determinations regarding the coverage status of a particular individual. These affected individuals should have informed and ready access to a process to obtain a timely formal determination regarding Medicare coverage and to access available rights of appeal.

Since home health agencies are expected to make immediate decisions about eligibility for home health services based on the assessment visit, intermediaries should also be able to make such decisions in most cases.

The home care community believes that all potential Medicare patients deserve clear and comprehensive notice regarding their Medicare coverage standards and ready access to a claim determination process that affords appropriate appeal rights.

## **ENSURE HOME HEALTH ACCESS FOR HOMEBOUND BENEFICIARIES**

**ISSUE:** The Balanced Budget Act of 1997 (PL105-33) replaced an earlier legislative proposal to impose strict numerical limitations on how often a home health beneficiary could leave home for non-medical reasons (no more than approximately 5 times a month and no more than about 3 hours each time) and recognized persons absent from home for adult day care and religious services as homebound if certain criteria are met. CMS revised homebound requirements to reflect absences to attend adult day care but many states do not license or certify such programs.

There has been much interest in expanding the homebound definition to include individual with chronic conditions who may leave home frequently but require assistance to do so. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 requires 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 will continue through the Spring 2006. The problem appears to lie in the stringent eligibility requirements, such as daily attendant service and lifelong skilled nursing need.

### **RECOMMENDATION:**

1. Work with the industry to establish homebound definition and guidelines that:
  - a) Ensure access to home health services as intended by the Social Security Act are based on functional limitations and the clinical condition of the patient as documented in the patient record rather than arbitrary number and duration of absences.
  - b) Do not impose burdensome documentation requirements such as detailed information about reasons, frequency, and duration of non-medical absences from the home.
  - c) Expand definitions of “licensed” and “certified” adult day programs.
  - d) Support a definition of homebound that focuses on clinical and functional status.
  - e) Ensure that analysis of the impact of expansion of the homebound definition addresses the financial impact on providers as well as the Medicare program.
2. Monitor progress of the homebound demonstration project and identify barriers to home health admission under this project.

**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.

Failure to expand the definition of “licensed” or “certified” creates access barriers to beneficiaries living in states without these processes.

Since beneficiaries included in the 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 RHHIs 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 RHHIs 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 100-2) coverage and payment rules, rather than new and potentially more restrictive policy.
2. Until LCDs are abandoned, require RHHIs 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 RHHIs are not local due to the extensive geographic areas that they serve. In fact, one RHHI is responsible for chain home health agencies that operate throughout the country. RHHIs 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.

## **ENSURE PROVIDER RIGHTS THROUGH JUDICIAL REVIEW OF MEDICARE REIMBURSEMENT POLICY DISPUTES**

**ISSUE:** In the administration of the Medicare program, issues arise concerning the validity of policy that has been implemented by the Centers for Medicare and Medicaid Services (CMS) and its contractors. Those policies have significant impact on the rights of home health agencies and beneficiaries if their validity can only be challenged after providers incur costs and have completed the administrative appeals process. Due to current backlogs, challenge to the validity of the CMS policy is delayed until as many as five years later. Judicial review is not available until exhaustion of this process.

In addition, the Balanced Budget Act of 1997 (BBA) prohibited judicial review of any decisions by CMS relative to the creation and implementation of the home health prospective payment system (PPS). This leaves CMS with unfettered discretion.

The Centers for Medicare and Medicaid Services (CMS) and the Office of Inspector General (OIG) have subjected home health and hospice providers to survey activities or targeted medical review using sampling and overpayment projections. Some agencies have been required to pay back as much as \$250,000 or more based on overpayment projections from a single claim denial. These overpayments must be repaid before agencies have had the opportunity to exercise their appeal rights. In many cases, agencies have been forced to close, only to have these adverse determinations overturned at a later date.

### **RECOMMENDATION:**

1. Providers should be allowed to exercise their appeal rights prior to repayment.
2. CMS and its contractors should adhere to rules and published manual instructions for all activities.
3. Judicial review should be available where the claim is collateral to a direct claim for payment and the provider of services faces irreparable harm without judicial intervention.

**RATIONALE:** Home health agencies and hospices may be unfairly and irreparably harmed by oversight efforts that result in large financial repayment when based on incorrect determinations. Overpayment can be financially disastrous to a provider when sampling is applied and repayment required prior to completion of appeals. CMS' own data supports the need to allow providers to exhaust appeal rights prior to repayment. On average, CMS reports that approximately 40% of coverage denials appealed at the intermediary level and 80% of the denials appealed to the Administrative Law Judge (ALJ) are reversed for home health and hospice providers. Furthermore, the sampling methodology used in some activities does not employ statistically valid sampling procedures. In light of the high percentage of coverage reversals on appeal, it is unfair to require home health and hospice providers to repay projected overpayments prior to completion of appeals.

## **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 RHHIs. 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 RHHIs 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 are 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, including the RHHIs. 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 plan of care data elements that can be submitted electronically in response to a request for medical review such as from the electronic plan of care.
2. Require RHHIs 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 RHHI 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 RHHI 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 RHHIs 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 Regional Home Health Intermediaries (RHHI) to issue Medicare denials to home health agencies and hospices when claims were reviewed and fail 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, RHHIs 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.

## **ELIMINATE PLAN OF CARE DOCUMENTATION OF THE END POINT FOR DAILY SERVICE**

**ISSUE:** In order to qualify for the home health benefit, the need for skilled nursing services must be intermittent. CMS has defined this to mean less than 7 days per week. However, daily care is covered if the need for daily skilled nursing care is finite and predictable. To determine if daily service meets this requirement, RHHIs require physicians to predict and HHAs to record an "end point" to the need for daily care on home health plan of care.

**RECOMMENDATION:** Discontinue the practice of requiring that home health agencies specify an "end point" for daily service on the plan of care. Establish a screen to cue intermediaries to review services when a patient has received daily nursing visits for an extended period of time to determine if the care provided continues to meet the finite and predictable requirement for daily nursing services. Additional clinical information needed to make a determination can be obtained from the patient's record or from the physician, if necessary.

**RATIONALE:** The requirement for documenting an end point tends to be confusing and burdensome, and may result in denial of care for beneficiaries who are qualified to receive care under the intermittent definition. Because the information required to determine whether daily nursing services will end is contained in parts of the patient's clinical record other than the plan of care form, it is inappropriate to make denials based solely on the lack of a predicted end point on the plan of care. In addition, documentation of the end point of daily services is redundant in many instances since this information is frequently reflected in the frequency and duration in the orders section of the plan of care. Because most daily care ends, it can be presumed to have met the finite and predictable requirement. It is time consuming and resource-intensive for both HHAs and FIs to conduct focused review on all daily skilled nursing cases. Therefore, if the types of cases and average time frames are identified, medical review can be limited to those cases where it appears there may be a question as to an end to daily care.

# **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.

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 as worker's compensation responsibility and liability for clinical errors, has resulted.

The Medicare consumer-directed care demonstration project is still in development. Many concerns have arisen surrounding this project including beneficiary selection, home health agencies' roles and responsibilities, and payment methodology to name a few. Therefore, the successful implementation of this project is questionable.

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. Participation in Medicare and Medicaid 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 bloodborne 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. The Medicare 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 not 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 proposed changes would eliminate 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, the history of DOL on this issue indicates it is likely to resurface.

However, in Spring 2004 the federal Second Circuit Court of Appeals issued an important 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.

The National Association for Home Care & Hospice has filed a "friend of the court" legal brief 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.

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

**RATIONALE:** Most home care providers are small business with limited resources. The companionship exemption result would be to reduce the availability of care to the elderly and the infirm and to increase the costs of service delivery with no corresponding increase from third party payers, such as Medicaid. Direct care providers will be deprived of the opportunity to voluntarily work beyond 40 hours in order to supplement their income. The Department of Labor and the court failed to analyze the impact of the rule on both small businesses and consumers of the services. Both providers and recipients of services are adversely affected by the proposed rule change. No action should occur unless the interests of all affected parties can be protected.

## **IMPLEMENT A COMPREHENSIVE 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."

**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), bloodborne 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 bloodborne 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 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. HOME MEDICAL EQUIPMENT**

## **MONITOR DEVELOPMENT OF QUALITY STANDARDS, CLINICAL CONDITIONS OF COVERAGE, AND MANDATORY ACCREDITATION FOR HME SUPPLIERS**

**ISSUE:** The Medicare Prescription Drug, Improvement and Modernization Act (P.L. 108- 173) requires the Centers for Medicare & Medicaid Services (CMS) to establish and implement quality procedures for home medical equipment (HME) suppliers. Standards are to be set out in program memorandum on a prospective basis after consultation with relative parties. In addition, CMS is to designate one or more independent accreditation organizations no later than one year after the new quality standards are implemented. The legislation also requires CMS to establish clinical conditions, a face-to-face examination, and a written prescription in order to receive payment for a HME claim.

CMS published proposed DMEPOS Quality Standards and allowed for acceptance of comments through November 28, 2005. These standards mirror requirements found in most recently published provider conditions of participation with an emphasis on data collection and quality assessment performance improvement. However, they also include specific, overly prescriptive requirements related to such topics as personnel issues including criminal background checks, inventory control, physician notification of problems and prescribed services via “visit” frequency recommendations for certain supplies and pieces of equipment. Supplier procurement of proof of manufacturer testing of equipment is implied. Prohibition of all mail order services for initial delivery is required. Several of the standards are contradictory and others fail to reflect the latest in clinical practice in the home.

### **RECOMMENDATION**

1. Consider comments submitted by the HME provider community to the proposed standards.
2. Ensure flexibility in clinical conditions so that coverage is based on medical necessity and not linked to any specific diagnosis.
3. Ensure that the latest clinical practices are reflected in the standards
4. Allow exceptions or alternatives to the accreditation process for very small suppliers who may not have the resources to become accredited.
5. Consider cost of compliance in the finalization of standards and testing procedures.

**RATIONALE:** Given recent concerns regarding fraudulent activity in the HME benefit, there should be increased standards and accountability to ensure that HME suppliers are playing by the rules. Standards and accreditation requirements, however, must strike a balance between the need to curtail fraudulent activities and HME suppliers’ ability comply in a cost effective manner.

These standards may create access problems for patients, especially those in rural areas. Moreover, there is concern that linking particular HME products to specific clinical conditions could severely restrict access to beneficiaries with legitimate needs who may not fall into a qualified category. Eligibility for HME must be predicated on medical necessity and functionality and not linked to any specific condition or diagnosis.

Burdensome personnel and inventory requirements will be costly for all suppliers and will result in small providers being unable to remain in business. Procurement of manufacturer testing information is an unnecessary burden to impose on suppliers who are ill equipped to evaluate the appropriateness of such documentation. Imposition of “visit” requirements adds the burden of

service delivery for which suppliers are not compensated.

Accreditation will place considerable financial burdens on suppliers at a time when Medicare reimbursement for equipment is being reduced. Also, accrediting organizations may not have the surge capacity to accredit the large numbers of suppliers not currently accredited.

## **OPPOSE RECERTIFICATION RULE FOR OXYGEN PATIENTS**

**ISSUE:** Oxygen coverage is determined by the results of an arterial blood gas or oximetry test. A certificate of medical necessity for oxygen equipment must include results of specific testing before coverage can be determined. The policy for home oxygen and oxygen equipment limits the initial coverage period for home oxygen to three months for all Group II patients, regardless of diagnosis, disease severity and baseline laboratory results. Group II patients are those whose arterial PO<sub>2</sub> is 56 to 59 mm Hg or whose arterial blood oxygen saturation is 89%. Since the policy requires that all Group II oxygen patients be recertified, a new arterial blood gas or oxygen saturation study is required for coverage beyond the initial three-month period in a 29-day window between the 61st and 90th days after the start of the home oxygen therapy.

Homebound HME patients may be unable to get laboratories to come to their homes to draw blood specimens needed for recertification oxygen saturation testing. Medicare has historically prohibited home oxygen suppliers from performing any laboratory testing related to the determination of medical necessity. This policy is based on an administrative requirement designed to prevent a theoretical conflict of interest. Failure, for any reason, to achieve recertification during this brief time frame will result in stopped payment for a patient's legally prescribed home oxygen on the basis of a "lack of medical necessity."

CMS contractors also have the discretion to require recertification of Group I patients (those with an arterial PO<sub>2</sub> at or below 55 mm HG, or arterial oxygen saturation at or below 88%), the sickest category of patients who often need access to home oxygen services for their lifetime. Currently, practice is to require Group I patients to be recertified every 12 months.

### **RECOMMENDATION:**

1. Eliminate the policy requiring regular oxygen saturation testing requirement for individuals with chronic, long-term respiratory conditions.
2. Permit suppliers providing oxygen in areas that are documented to have limited access to home laboratory services to participate in the conduct of laboratory tests.
3. Conduct a study to evaluate the need for a change to the current policy to ensure that beneficiary access to necessary oxygen therapy services is not compromised as a result of the limitation and recertification rule

**RATIONALE:** The restrictions on oxygen coverage and the recertification mandate is based on limited and conflicting scientific evidence and fails to adequately address the medical complexities and testing logistics associated with retesting those with oxygen needs. While some patients may improve clinically after the start of home oxygen therapy, there is like to be merely false short-term improvement as a result of the reparative effect of oxygen therapy. If left untreated, however, the patient could return to their baseline hypoxemia.

The policy requiring oxygen saturation testing is outdated and not in keeping with current standards of practice. Many private insurance carriers and state Medicaid programs have eliminated the need for retesting. Of those that still require retesting, many authorize the home medical equipment (HME) providers to perform the test. Additionally, many state Medicaid programs have no initial or recertification requirements and instead prefer to treat oxygen like other legend drugs, requiring only a valid physician prescription. Moreover, in most states, a prescription for oxygen is valid for one year. Medicare medical necessity guidelines are designed to control utilization and often conflict with prescription dispensing law and medical practice.

## **ENSURE FAIRNESS IN USE OF INHERENT REASONABLENESS AUTHORITY**

**ISSUE:** In the mid-1980s, the Health Care Financing Administration (HCFA), now the Centers for Medicare and Medicaid Services (CMS), was given the authority to change Medicare reimbursements for home medical equipment (HME). This authority, known as inherent reasonableness (IR), permits CMS to adjust, up or down, reimbursement levels for individual items if the payment levels are found to be grossly deficient or excessive. Under CMS's original IR authority, if an adjustment to reimbursement was made, CMS was required to publish the new rate in the *Federal Register*, consult the parties affected, and allow 60 days for public comment.

The Balanced Budget Act of 1997 (BBA) expanded CMS's IR authority, allowing CMS to make reimbursement adjustments of 15 percent in one year without public notice and comment and without input from affected parties. Moreover, CMS believes it may transfer IR authority to the Durable Medical Equipment Regional Carriers (DMERCs), the CMS contractors who process HME claims, at its discretion

In December of 2002, CMS issued an interim final rule on implementation of IR authority that became effective February 11, 2003. Under the interim rule, CMS is required to alert the public and allow a 60-day comment period on any price changes. In addition, CMS has added a new methodology to ensure that the IR adjustment is based on "valid and reliable data." These steps include:

- Developing written guidelines for data collection and analysis;
- Ensuring consistency in any survey to collect and analyze pricing data;
- Developing a consistent set of survey questions to use when requesting retail prices;
- Ensuring that sampled prices fully represent the range of prices nationally;
- Considering the geographic distribution of Medicare beneficiaries;
- Considering relative prices in the various localities to ensure that an appropriate mix of areas with high, medium, and low consumer prices was included;
- Considering criteria to define populous state, less populous state, urban area, and rural area;
- Considering a consistent approach in selecting retail outlets within selected cities;
- Considering whether the distribution of sampled prices from localities surveyed is fully representative of the distribution of the U.S. population;
- Considering the products generally used by beneficiaries and collecting prices of these products; and
- When using wholesale costs, considering the cost of the services necessary to furnish a product to beneficiaries.

While the interim final rule requires notice and comment prior to any IR determination and establishes a new methodology to determine whether payment for certain items are "grossly deficient or excessive," there are still concerns that DMERCs or CMS could abuse IR authority, cutting reimbursement rates so as to sacrifice quality, limit access, and curtail patient choice.

Moreover, Congress recognized the "double-dipping" potential of competitive bidding, which lowers reimbursement through market competition, and IR, which lowers reimbursement through automatic cuts. To protect HME items from being subject to cuts under both competitive bidding and IR, the "Medicare Prescription Drug, Improvement and Modernization Act" (P.L. 108-173) restricts the use of IR for HME items that have been subject to competitive bidding.

**RECOMMENDATION:**

1. Use of their IR authority to ensure that it is being utilized in an appropriate context.
2. Comply with the standards specified in the interim final rule for identifying IR adjustments.
3. Limit IR authority on competitively-bid items and make good policy given that the competitively-bid prices will be, in most cases, the lowest reimbursement level that could be offered by a supplier.
4. Involve HME suppliers and beneficiaries in implementation of reimbursement policies.
5. Monitor and oversee the DMERC's use of their IR authority to ensure that it is being utilized in an appropriate context.

**RATIONALE:** Under CMS's expanded IR authority, drastic cuts in HME reimbursement could result through unilateral action by either CMS or the DMERCs, with little or no input by either beneficiaries or HME suppliers. Moreover, CMS could expand its IR authority to cuts in reimbursement of over 15 percent by spreading the cuts over more than one year. While the interim final rule requires notice and comment prior to any IR determination and establishes a new methodology to determine whether payment for certain items are "grossly deficient or excessive," there are still concerns that DMERCs or CMS could abuse IR authority, cutting reimbursement rates so as to sacrifice quality, limit access, and curtail patient choice.

## **REQUIRE FAIRNESS IN IMPLEMENTATION OF COMPETITIVE BIDDING FOR HOME MEDICAL EQUIPMENT**

**ISSUE:** The Medicare Prescription Drug, Improvement and Modernization Act (MMA) contains a provision that would phase-in the implementation of a national competitive bidding program for home medical equipment (HME). Upon implementation of competitive bidding, the Medicare program will no longer reimburse HME suppliers through a specified fee schedule, but instead award suppliers who submit the lowest bid with the contract to supply the region with the particular product.

Specifically, the legislation phases-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.

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. To participate in the bidding program, HME suppliers are required to waive their right to administrative or judicial review of the competitive bidding process.

CMS established a Program Advisory and Oversight Committee according to MMA, holding two meetings in 2004. The goal of the committee is to implement the competitive acquisition program, establish financial standards, establish requirements for data collection for efficient management of the program, develop proposals for efficient interaction among manufacturers, providers, suppliers and individuals, and establish quality standards. In addition, the General Accounting Office (GAO) is required to report to Congress on a study examining competitive bidding by January 1, 2009.

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

1. Ensure fair and adequate representation of manufacturers and suppliers on the Program Advisory and Oversight Committee.
2. Carefully analyze and implement “lessons learned” from the competitive bidding demonstrations.
3. Ensure small supplier participation in the Medicare HME benefit.
4. Closely monitor the implementation of the competitive bidding program to guard against unintended negative consequences to Medicare beneficiaries or suppliers.
5. Conduct research on alternatives to competitive bidding

**RATIONALE:** Competitive bidding raises significant concerns, including loss of quality and service and the potential negative impact on beneficiary access and choice. Specifically, competitive bidding for HME supplies fosters monopolistic markets that could: a) reduce beneficiary choice by allowing only those suppliers with winning bids to serve Medicare 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 HOME MEDICAL EQUIPMENT, PARENTERAL AND ENTERAL NUTRITION, AND OXYGEN SUPPLIES**

**ISSUE:** Home medical equipment (HME), parental and enteral nutrition (PEN), and oxygen supplies help individuals remain in the comfort of their own homes while receiving needed health care services. HME, PEN, and oxygen services in the home also help avoid costly hospital and nursing home stays. The Medicare Prescription Drug, Improvement and Modernization Act (P.L. 108-173), however, freezes the consumer price index (CPI) updates for the HME, PEN, and oxygen fee schedules for 2004-2008. Moreover, in 2005, payment for certain items will be reduced by a specific amount.

For motorized wheelchairs, diabetic test strips, hospital beds/air mattresses and other items, payments will be reduced by the percentage difference between the Medicare payment and reimbursement under the Federal Employee Health Benefit Program (FEHBP) Plan. In September 2004 the Department of Health and Human Services' Office of the Inspector General (OIG) reported that Medicare payments for oxygen items are higher than those under FEHBP and Medicare managed care by 10 to 23 percent. Effective October 25, CMS imposed new rules governing coverage of power mobility devices that eliminate the certificate of medical necessity but do not provide an acceptable alternative; provide insufficient time for providers to adopt a new set of billing codes; likely will impose considerable new administrative burdens on physicians and suppliers; and provide insufficient oversight to ensure consistency relative to new local coverage determinations. In response to concerns from Congress and advocacy groups, CMS delayed imposition of the requirement to use new codes.

Relative to oxygen, in late March 2005 CMS issued new rates that became effective in April. Payment reductions vary by state; average reduction for stationary oxygen is 8.6 percent and for portable units the average reduction is 8.1 percent.

In 2005 Rep. David Hobson (R-OH) introduced legislation related to DME; HR 3559 is designed to modify current law on competitive bidding to benefit beneficiaries and small providers. In essence, the bill would allow any provider that submits a bid under the existing allowable to participate as a Medicare supplier at the winning bidder's price. The bill has several other provisions, including one that would have CMS implement DME quality standards at the same time as the competitive bidding program begins.

**RECOMMENDATION:** Congress should rescind the freeze in the HME fee schedule and amend the Medicare program to automatically adjust and update HME, PEN, and oxygen payment levels by the change in prior year's CPI. Congress should closely scrutinize OIG analysis of HME payments to ensure accuracy and thoroughness.

**RATIONALE:** Keeping reimbursement rates for HME, PEN, and oxygen services below CPI threatens patient access to care because the reimbursement for these services will not keep pace with medical inflation.

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

**ISSUE:** Current law (42 U.S.C. § 1861 (n)) requires that home medical equipment (HME) be used “in the patients home,” rather than a hospital or skilled nursing facility, to qualify for Medicare Part B reimbursement. Congressional intent was to exclude Part B coverage of HME in an institutional setting. Congress did not otherwise impose a geographical limit on the use of HME. For example, there is no requirement that the actual use of the HME be confined to the four walls of a home.

Nevertheless, the Centers for Medicare and Medicaid Services (CMS) and the Durable Medical Equipment Regional Carriers (DMERCs) have interpreted and applied the “in the patient's home” clause in an overly restrictive manner. Specifically, Medicare HME coverage has been limited to those items an individual demonstrates is needed within the home, rather than the HME needed to allow the individual to meet his or her daily responsibilities. As a result, persons with disabilities, young and old, have been denied Medicare coverage of the types of medical equipment that will enable them to attend school; go to work; meet their obligations as parents and heads of households e.g., to shop, attend meetings and activities at their children's schools; participate in religious services; and to otherwise be fully involved in their local communities and in American society.

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

**RATIONALE:** Earlier this year President Bush announced a “New Freedom Initiative” for persons with disabilities. Part of this initiative includes helping individuals with disabilities by “increasing access to assistive technologies, expanding educational opportunities, increasing the ability of Americans with disabilities to integrate into the workforce, and promoting increased access into daily community life.”

Without access to appropriate HME in the community, persons with disabilities will not be able to fulfill their potential in the work place, to get to school to develop new job skills, or to meet their family responsibilities of performing many of activities of daily living. Congressional pressure on CMS and DMERCs to ease the “in-home” restriction will allow disabled persons to be more independent and take advantage of federal government programs like the New Freedom Initiative, the Ticket to Work and Work Incentives Improvement Act, and the Americans with Disabilities Act.

## **SUPPORT EFFORTS TO ADEQUATELY REIMBURSE HME SUPPLIERS FOR COSTS ASSOCIATED WITH DRUG THERAPIES**

**ISSUE:** Prior to the implementation of the Medicare and prescription Drug, Improvement and Modernization Act, Medicare Part B paid 95% of average wholesale price (AWP) for drugs used in home infusion and home inhalation therapies that are administered through home medical equipment. A recent report by the General Accounting Office (GAO), however, characterizes the current reimbursement for drugs reimbursed 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 GAO report, the Act reduces payments for most in-home drug therapies. Drug and drug therapies furnished in 2004 will now be reimburse at 85% 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, will be paid using either the average sales price (ASP) methodology or thorough competitive bidding.

Infusion drugs furnished through covered home medical equipment starting January 1, 2004 will be paid 95% of the AWP in effect on October 1, 2003. Those infusion drugs which may be furnished in a competitive acquisition area starting January 1, 2007 will be paid on the competitive price. Intravenous immune globulin will be paid at 95% of the AWP in 2004 and paid according to the average sales price method beginning in 2005. While the Centers for Medicare and Medicaid Services (CMS) was been authorized to substitute a different percent of the April 1, 2003 AWP, this percentage cannot be less than 80%. Also, CMS may adjust the price based on data submitted by the manufacturer of the drug or biological by October 15, 2003.

**RECOMMENDATION:** Ensure fair and adequate payment for drugs by

1. Closely monitor actual costs and payments to identify underpayment as well as overpayment for covered drugs.
2. Addressing problems with the new payment methodology with Congress.
3. Supporting a new intravenous and inhalation benefit that would cover the costs of drugs and services.
4. Dropping recommendations for competitive bidding.

**RATIONALE:** The HME community is concerned that competitive bidding will lead to monopolistic practices by suppliers that hamper beneficiary choice, increase costs in the long run, and lowers quality.

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). Often times, 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. Medicare beneficiaries will be denied access to needed drugs if HME suppliers refrain from supplying those drugs where there is inadequate reimbursement.



# **VII. HOSPICE**

## **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:

1. Develop guidelines and educational material that promote effective use of drugs to control pain.
2. 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.

## **INCREASE TRAINING FOR HOME HEALTH & 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. As of 2003, CMS will require 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, webcasts, and satellite broadcasts, in the state agency budget call for 2003, there is no mechanism for enforcement or penalties for failure to participate.

### **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. Include information on Medicare coverage of services, adequate to identify possible problems to be referred to the fiscal intermediary (FI);
4. Ensure consistent interpretation and application of the regulations
5. Utilize technology to reach all surveyors instead of only a small group, i.e., webcasts, etc
6. Be available to providers.

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. Develop a formal procedure to share information between the FIs and state survey agencies.
2. Survey agencies (SAs) should report suspected coverage problems to FIs and FIs should report suspected quality problems to SAs.
3. FIs 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.

## **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 for months. Some providers have been facing severe financial hardships, and some have been unable to pay their nurses, aides and social workers.

**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, results 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 from the Hospice cost report 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 a six-year cycle for surveys but that sometimes extends to 10 years in some parts of the country. CMS' 2006 work plan will extend the time frame to every eight years.

**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.

## **MODIFY HOSPICE REGULATIONS FOR INPATIENT RESPITE CARE**

**ISSUE:** The Centers for Medicare and Medicaid Services (CMS) regulations under the Medicare Hospice Benefit (MHB) requirements for both inpatient acute care and inpatient respite care are that a registered nurse (RN) be available 24-hours a day. This stipulation is understandable for inpatient acute care (e.g., hospitals) because of inherent and implied patient need. However, institutional respite care is provided as a means of relieving the family caregiver, not because a patient's condition requires skilled care in an institution. The "24-hour RN" hospice requirement constitutes a higher standard than that required for routine skilled nursing facility (SNF) (42 CFR §483.28) or nursing facility (NF) care, which allows some SNFs and NFs to seek a waiver from the 24-hour RN requirement and allows an RN for the eight-hour day shift only, with licensed practical nurses for the balance of the shifts. The proposed Hospice conditions of participation (CoPs) made the needed change but they will not be published in final possibly until 2008.

**RECOMMENDATION:** Change the requirement in the MHB for nursing care under the inpatient respite care provision to mirror the less stringent requirements for skilled nursing facilities and nursing facilities in the Omnibus Budget Reconciliation Act of 1987 (OBRA-87). The 24-hour RN staffing requirement should be removed from the hospice Conditions of Participation now for NF and SNF in-patient respite care rather than waiting for the proposed change to take place through the new CoPs.

**RATIONALE:** Hospices generally contract with SNFs and NFs for in-patient respite care. However, with the implementation of the new SNF/NF regulation under OBRA-87, which allows application for a waiver of the 24-hour RN staffing requirement for some SNFs/NFs, hospices that continue to contract with a facility that has such a waiver will automatically be out of compliance with the Medicare Hospice Benefit regulations. Under the current regulations, the only in-patient respite option hospices often have is to place the patient in a hospital which results in unnecessary utilization of a hospital bed and increased costs. Hospice caregivers require respite; hospice patients receiving the respite level of care do not necessarily require skilled care in an institution.

## **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.

## **MAKE PUBLICATION OF FINAL HOSPICE CONDITIONS OF PARTICIPATION (CoP) A PRIORITY**

**ISSUE:** The hospice conditions of participation (CoP) have not been updated since the inception of the hospice benefit in 1983. The current hospice CoP are dated, cumbersome, and inadequate for today's health care delivery system. In 1995, CMS began the process of drafting new language that would streamline the CoP, focus on outcomes, and require quality assessment and performance improvement programs. The proposed CoP were published in May of 2005 and comments were accepted until the end of July. CMS now has up to three years to publish the final regulations. It should be a regulatory priority to release the final regulations as soon as possible – hopefully before the three year period has elapsed.

**RECOMMENDATION:** CMS should make publishing the final hospice CoP a priority.

**RATIONALE:** At the time the CoP were written, little was known about efficient and effective management of hospice agencies. While the current CoP define a philosophy of care and describe the patient and family as the center of that care, they do not provide the guidance for hospice providers to be more accountable or the mechanisms for them to be more efficient. Moreover, the quality assurance requirements are dated and inadequate, and there are no requirements for the collection of outcome data. Hospices are currently burdened with costly inefficiencies such as requirements to provide 24-hour registered nursing services in an inpatient respite setting and include cumbersome requirements for all contracted services. It is inappropriate at a time when other Medicare providers are able to update their operations consistent with current practices that hospice providers must now wait up to three years for the final new CoPs to be released.

## **REQUIRE HOSPITAL DISCHARGE PLANNERS TO SUPPLY A LISTING OF HOSPICE PROVIDERS**

**ISSUE:** In 1994, Congress passed legislation that would require hospital discharge planners to inform appropriate patients about the availability of the Medicare Hospice Benefit. Section 146(b)(5) of the Social Security Act Amendments of 1994 (Public Law 103-432) mandated that “the hospital conditions of participation with respect to discharge planning be modified to require an evaluation of a patient’s likely need for appropriate post-hospitalization services, including hospice services and the availability of those services.”

The Centers for Medicare & Medicaid Services (CMS) has stated they are currently in the process of rewriting the hospital conditions of participation and would look at expanding the discharge planning section to reflect this legislative mandate. However, CMS has stated they do not believe the legislative language requires the hospital to supply a listing of qualified agencies available to provide hospice services.

**RECOMMENDATION:** CMS should change the new hospital conditions of participation (CoP) to ensure the legislative mandate with regard to hospice is reflected, including the provision of a list of available, qualified providers. As the CoPs are likely to take some time to develop, CMS should require hospitals to notify appropriate patients about the option of Medicare Hospice Benefit services now.

**RATIONALE:** If the hospital discharge planner conducts an evaluation of a patient’s likely need for hospice services but does not give a list of available, qualified providers, the patient and their family will then have to search out the hospices in their community. It is then less likely the patient will receive needed services in a timely manner. When a patient is at their most critical time of life, every day has added intensity of meaning. Our nation’s health care system should provide appropriate information to ensure the most vulnerable in our society spend their final days in the peace, comfort and dignity they deserve.

## **CLARIFY THE "95% RULE" FOR HOSPICE PATIENTS IN NURSING FACILITIES**

**ISSUE:** The Omnibus Budget Reconciliation Act of 1989 (OBRA 89, P.L. 101-239) contained a provision requiring states to pay hospices at least 95% of the room and board rate they would normally pay to a nursing facility (NF) or skilled nursing facility (SNF) for the same Medicaid patient who elects hospice care, effective for services furnished on or after April 1, 1990. Federal statute requires the hospice and facility to have a written agreement under which the nursing home resident becomes a hospice patient, the hospice takes full responsibility for the professional management of the individual's hospice care, and the facility agrees to provide room and board to the individual. The State Medicaid Agency pays the hospice at least 95% of the room and board payment while the patient is receiving hospice care, and the hospice pays the facility according to the terms of their agreement.

It is appropriate for hospices to purchase additional services (beyond room and board) from the nursing facility such as collecting co-payments. There is concern that if the hospice agrees to pay the SNF/NF more than the 95% of the room and board rate, regardless of the services the hospice chooses to purchase from the SNF/NF, the agreement will be construed as fraudulent activity and the hospice will be subject to investigation by the Office of the Inspector General (OIG) or other state or federal agencies.

**RECOMMENDATION:** CMS and the OIG should clarify that hospices can contract with SNF/NFs to purchase items such as medical supplies and equipment, medications, and other non-core hospice services at fair market value without violating federal anti-kickback laws and regulations. In addition, hospices should be allowed to purchase, at fair market value, non-core services related to the terminal illness that are available from SNF/NF such as: medical supplies and equipment and nursing aide services. These services should be included in the written agreement under the supervision of the hospice, with a fair market value attached to each. This should apply to only those items and services that are not part of the Medicaid room and board payment.

**RATIONALE:** Terminally ill SNF/NF residents should not be denied access to their hospice benefit and hospices should be able to negotiate and enter into legal agreements with SNF/NFs without the fear of unnecessary, costly investigations.

## **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 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. Institute a CMS/HAA project to study 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 proposed 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) has indicated its intent to require hospices to either develop their own or use currently available systems of measures to track patient outcomes in such areas as pain management, quality of life, skin integrity, and patient satisfaction. The requirement will include retaining the information in a database that permits analysis over time. CMS has also indicated that it will not be initiating any research and demonstration projects to develop systems of measures for the hospice industry, but in the future it may require that hospices report performance data into a national database.

**RECOMMENDATION:** CMS should establish standards of care for providers of the Medicare Hospice Benefit and authorize necessary funding. Agencies should be responsible for ongoing quality assessment performance improvement (QA PI) programs based on patient outcomes. There does not yet exist a valid and reliable data set of performance measures for use in hospice care QA PI programs.

1. Broad parameters of quality improvement requirements should be specific but providers should be allowed to identify, prioritize, and phase in specific systems of measures to capture outcomes they believe are essential to their provision of optimal hospice care.
2. The following conditions must be met in implementing any outcome measurement system for hospices:
  - a. Reliable and valid indicators.
  - b. Number of outcome measures limited to those that most accurately predict quality.
  - c. Method for risk adjustment.
  - d. Standard assessment limited to those items needed for outcomes measurement and risk adjustment (agencies may develop their own assessment tool and will use additional assessment items for care planning purposes).
  - e. A simple system with clinical utility.
  - f. A mechanism enabling CMS to validate agency data.
  - g. Ongoing evaluation of the entire system.

**RATIONALE:** The ideal QA PI program is based on what happens to the patients. However, currently there are no standard, valid, and reliable outcome measures for hospice. In addition, research and demonstration projects are not factored into the current per diem reimbursement structure. Therefore, hospices should be surveyed for initiating QA PI programs based on currently available tools until such time as the industry has been able to develop hospice-specific systems of measures. Also, quality assessment should not rely solely on outcome measures; limited structure and process measures are appropriate.

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.

## **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 have become extremely cautious about certifying terminally ill patients for hospice care because of the intense scrutiny of the OIG, CMS and the fiscal intermediaries. 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 HOSPICE LOCAL COVERAGE DECISIONS**

**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) Create an additional LCD similar to the "General Guidelines" section of the *Guidelines*, to allow for appropriate supplemental documentation;
  - (b) Encourage the use of multiple LCDs to document co-morbidities so that all conditions, and not just the primary diagnosis, are being reviewed;
  - (c) Require review of documentation of the clinical judgment and psychosocial dimensions of the terminal illness by medical reviewers; and
  - (d) Require documentation by the reviewer of the date of patient's death, as appropriate, while enrolled in the hospice benefit or after discharge from the benefit. Include additional instructions.
  - (e) 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-a-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. 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 has declined from 19 days in 1998 to 16 days in 2003 and 25 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, it is important to encourage physicians to refer patients sooner by compensating them for hospice certification. Increasing the hospice length of stay 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:** In March, 2000, the Office of Disability, Aging and Long-Term Care Policy, Department of Health and Human Services, and the Urban Institute released a study, "Outcomes and Utilization for Hospice and Non-Hospice Nursing Facility Decedents." This study resulted in six reports: 1) Synthesis and Analysis of Medicare's Hospice Benefit: Executive Summary and Recommendations; 2) Important Questions for Hospice in the Next Century; 3) Medicare's Hospice Benefit: Use and Expenditures; 4) Use of Medicare's Hospice Benefit by Nursing Facility Residents; 5) Outcome and Utilization for Hospice and Non-Hospice Nursing Facility Decedents; 6) Hospice Benefits and Utilization in the Large Employer Market.

The study showed that:

- Hospice patients in daily pain are twice as likely to receive level 3 analgesics as are non-hospice patients in daily pain.
- Hospice patients are less likely to be restrained, to receive tube or parenteral/IV feedings and to be given medications via intramuscular or intravenous routes.
- Hospice patients receive less occupational, speech and physical therapy.
- Hospice patients consistently have fewer hospitalizations, with the greatest differences observed 30 days prior to death (9.8 percent vs 31.7 percent).
- A nursing facility's hospice concentration appears to have a strong influence on the hospitalization patterns of non-hospice patients. Non-hospice patients in a nursing facility with no hospice involvement had a 30 percent probability of dying in a hospital. Where there was a .01 to 5 percent hospice concentration, non-hospice patients had a 24 percent probability of dying in a hospital. Nursing facilities with a 5+ percent hospice concentration had a 21 percent probability of dying in a hospital.

## **REQUIRE HOSPITAL DISCHARGE PLANNERS TO DISCUSS THE HOSPICE OPTION**

**ISSUE:** In 1994, Congress passed legislation that would require hospital discharge planners to inform appropriate patients about the availability of the Medicare Hospice Benefit. Section 146(b)(5) of the Social Security Act Amendments of 1994 (Public Law 103-432) mandated that “the hospital conditions of participation with respect to discharge planning be modified to require an evaluation of a patient’s likely need for appropriate post-hospitalization services, including hospice services and the availability of those services.”

The Centers for Medicare & Medicaid Services (CMS) has stated they are currently in the process of rewriting the hospital conditions of participation and would look at expanding the discharge planning section to reflect this legislative mandate. However, CMS has stated they do not believe the legislative language requires the hospital to supply a listing of qualified agencies available to provide hospice services.

**RECOMMENDATION:** CMS should change the new hospital conditions of participation (CoP) to ensure the legislative mandate with regard to hospice is reflected, including the provision of a list of available, qualified providers. As the CoPs are likely to take some time to develop, CMS should require hospitals to notify appropriate patients about the option of Medicare Hospice Benefit services now.

**RATIONALE:** If the hospital discharge planner conducts an evaluation of a patient’s likely need for hospice services but does not give a list of available, qualified providers, the patient and their family will then have to search out the hospices in their community. It is then less likely the patient will receive needed services in a timely manner. When a patient is at their most critical time of life, every day has added intensity of meaning. Our nation’s health care system should provide appropriate information to ensure the most vulnerable in our society spend their final days in the peace, comfort and dignity they deserve.

## **SUPPORT PROPOSED QUALITY ASSESSMENT/PERFORMANCE IMPROVEMENT PROGRAM FOR HOSPICE**

**ISSUE:** The proposed new hospice conditions of participation are expected to require hospices to develop, implement, maintain, and evaluate an effective, data driven quality assessment and performance improvement program. CMS has indicated its intent to require hospices to either develop their own or use currently available systems of measures to track patient outcomes in such areas as pain management, quality of life, skin integrity, and patient satisfaction. The requirement will include retaining the information in a database that permits analysis over time. CMS has also indicated that it will not be initiating any research and demonstration projects to develop systems of measures for the hospice industry, but is forming a work group to look at setting standards of care for hospice for use in establishing a national database.

**RECOMMENDATION:** Agencies should be responsible for ongoing quality assessment/performance improvement (QA/PI) programs based on patient outcomes. Such requirements should recognize that there is not yet a valid and reliable data set of performance measures for use in hospice care and allow flexibility in design of individual hospice QA/PI programs.

1. Broad parameters of quality improvement requirements should be specific but providers should be allowed to identify, prioritize, and phase in specific systems of measures to capture outcomes they believe are essential to their provision of optimal hospice care.
2. The following conditions must be met in implementing any outcome measurement system for hospices:
  - a. Reliable and valid indicators.
  - b. Number of outcome measures limited to those that most accurately predict quality.
  - c. Method for risk adjustment.
  - d. Standard assessment limited to those items needed for outcomes measurement and risk adjustment (agencies may develop their own assessment tool and will use additional assessment items for care planning purposes).
  - e. A simple system with clinical utility.
  - f. A mechanism enabling CMS to validate agency data.
  - g. Ongoing evaluation of the entire system.

**RATIONALE:** The ideal QA/PI program is based on what happens to the patients. However, currently there are no standard, valid, and reliable outcome measures for hospice. Research and demonstration projects are not factored into the current per diem reimbursement structure. Quality assessment should not rely solely on outcome measures; limited structure and process measures are appropriate.

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.