Submitter : Ms. Ju-Ming Chang

Date: 09/25/2006

Organization : Healthcare Association of New York State

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Attached please find HANYS' comments.

CMS-1304-P-62-Attach-1.DOC

#62

Healthcare Association
of New York State

September 25, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–1304–P
P.O. Box 8014
Baltimore, MD 21244–8014

Re: CMS–1304–P, Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment; Proposed Rule

Dear Dr. McClellan:

The Healthcare Association of New York State (HANYS), on behalf of our more than 550 hospitals, nursing homes, home health agencies, and other health care providers, welcomes the opportunity to comment on the proposed rule related to the Medicare Home Health (HH) Prospective Payment System (PPS).

PROVISIONS OF THE PROPOSED REGULATIONS

Quality Measures:

CMS proposes that the ten publicly reported Outcome and Assessment Information Set (OASIS) quality measures be submitted by home health agencies (HHAs) to meet the reporting requirements of the Deficit Reduction Act (DRA) of 2005 to be eligible for the full HH PPS update. Use of the OASIS data to meet reporting requirements minimizes the burden on providers, as HHAs currently collect and submit OASIS data for all Medicare and Medicaid funded patients.

The proposed rule would only require reporting of OASIS measures. However, CMS states, "*We believe that at this time the noted ten quality measures are the most appropriate measure of home health quality.*" HANYS applauds CMS' efforts to improve the quality of home health care, but is concerned with the use of OASIS data for measuring quality for certain HHAs that serve patients with special needs or provide long-term care services.

New York State has a 1915(c) waiver from the federal government that enables the state to provide home health care to individuals who would otherwise be medically eligible for placement in a residential health care facility for an extended period. The waiver program is called the Long Term Home Health Care Program (LTHHCP), or "Nursing Home Without Walls." Individuals for whom the LTHHCP is considered to be the most appropriate community-based option include those who exhibit poor prognosis for full recovery and those whose health status is apt to deteriorate rapidly. **Participants in this program by definition are not expected to show improvement in activities of daily living that are**

measured by OASIS items. Stabilization in these areas may be a more desirable and realistic outcome for the majority of these individuals.

CMS' discussion of this provision in the proposed rule acknowledges, *"The MedPAC testimony recognizes that while the goal of care for many home health patients is improving health and functioning, for some patients the goal of the HHA is to simply stabilize their conditions and prevent further decline."*

This is particularly true for LTHHCP patients.

HANYS is concerned that as the reporting of quality measures in the HH setting moves towards refined measures and a pay-for-performance model, LTHHCPs would be disadvantaged because they use a community based approach to serve patients eligible for an institutional level of care.

HANYS recommends that CMS consider the differences in expected outcomes between patients receiving services within a Medicare certified episode of care and dual eligible patients in Medicaid waiver programs such as the LTHHCPs as it relates to the reporting of quality data.

HANYS urges CMS to study quality reporting specific to these special waiver programs.

Rural Add-On:

By law, the 5% add-on for home health episodes or visits performed in rural areas will expire on December 31, 2006.

Beginning in 2001, as part of the Benefits Improvement and Protection Act (BIPA) of 2000, Congress determined that there is a cost difference for providing HH services in rural areas, and provided a 10% add-on for HH services provided in rural areas. Congress has mandated continuation of this add-on, reduced to 5%, in its last two Medicare bills, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 and the DRA of 2005.

For its other PPSs, CMS has thoroughly researched and analyzed the cost differences for providing care between rural and urban service providers and currently provides rural adjustments for the following payment systems:

- Inpatient Rehabilitation Facility PPS—21.3% add-on;
- Inpatient Psychiatric Facility PPS—17% add-on; and
- Outpatient PPS—hold harmless payments for rural hospitals with fewer than 100 beds (currently being phased out), and a 7.1% add-on to rural sole community hospitals.

HANYS is concerned that CMS has not effectively analyzed and evaluated the cost differences associated with HHAs caring for Medicare patients in rural areas as compared to their urban counterparts. HANYS believes CMS should examine these differences and not simply rely on Congress to mandate a payment adjustment.

In its June 2001 *Report to the Congress: Medicare in Rural America*, the Medicare Payment Advisory Commission (MedPAC) recognized the need to study the potential cost differences between urban and

rural home health episodes of care; *"Historically, rural agencies have had significantly longer lengths of stay than urban ones (Goldberg and Schmitz 1994). But because beneficiaries may receive an unlimited number of episodes of care—as long as they remain eligible for home health care—differences in length of stay should not be a problem. Further, outlier payments are made for cases with very high costs within a 60-day episode. As PPS data become available, the volume of care within urban and rural patients' episodes should be monitored."*

Now that HH PPS data are available and the legislated rural add-on is expiring, HANYS urges CMS to follow up on MedPAC's 2001 call to study the cost differences between urban and rural episodes of home health care and to determine the need for a rural adjustment as CMS has thoroughly done for the other payment systems defined above.

Wage Index:

For calendar year 2007, CMS is proposing to continue using the most recent hospital wage index available at the time of publication of the final rule, adjusting the HH PPS episode rate by the 2007 inpatient hospital wage index. CMS has also proposed to continue application of this wage index before any rural floor or reclassification adjustments.

Although HANYS is concerned that use of the hospital wage index may not be the best proxy to account for area wage differences for HHAs, we agree that they are the most reliable data available at this time. Because these data may not reflect the cost structures of HHAs, **HANYS urges CMS to once again consider the application of the rural floor adjustment and any hospital reclassifications in applying the hospital wage index to the HH PPS.**

HEALTH CARE INFORMATION TRANSPARENCY AND INFORMATION TECHNOLOGY

HANYS supports CMS' efforts to expand the adoption of standardized health information technology (IT). Health IT is particularly critical to an HHA's ability to improve the quality and efficiency of health care services. HHAs depend upon the transfer of information from other providers and settings of care to provide quality care and to receive accurate reimbursement.

Many providers have already made significant investments in IT to meet specific needs; other providers do not have the resources to make such investments. A significant financial investment will be needed in the future. We view IT as a public good that requires a shared investment between providers and purchasers of care.

HANYS appreciates the opportunity to comment on the proposed rule. If you have any questions, please contact me at (518) 431-7704 or at jchang@hanys.org, or Stephen Harwell, Director, Economic Analyses, at (518) 431-7777 or at sharwell@hanys.org.

Sincerely,

Ju-Ming Chang
Vice President, Economics, Finance, and Information

JC:djo

Submitter :

Date: 09/25/2006

Organization :

Category : **Individual**

Issue Areas/Comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

As a low income user of home oxygen, these proposed rule changes will eliminate my ability to travel outside my home. This includes the ability to attend doctors appointments. Portable oxygen supplies are vital for oxygen dependent persons. I will not be able to afford out of pocket expenses for portable oxygen on my income.

Submitter : Mrs. Mary St.Pierre **Date:** 09/25/2006

Organization : National Association for Home Care & Hospice

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1304-P-64-Attach-1.DOC

CMS-1304-P-64-Attach-2.DOC

ATTACHMENT 1 TO #64

Ruth L. Constant
Chairman of the Board

HOMECARE & HOSPICE
NATIONAL ASSOCIATION FOR HOME CARE & HOSPICE
228 Seventh Street, SE, Washington, DC 20003 • 202/547-7424 • 202/547-3540 fax

Val J. Halamandaris
President

September 25, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1304-P
P.O. Box 8014
Baltimore, MD 21244-8014

Via: Electronic submission

Re: Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment: Proposed Rule

71 Fed. Reg. 44082 (August 3, 2006)

To whom it may concern:

Thank you for the opportunity to provide comment on the above referenced Proposed Rule. The National Association for Home Care and Hospice, Inc. (NAHC) is the largest trade association in the country representing the interests of home care and hospice providers and their patients. As a central part of its membership, NAHC represents over 6,000 Medicare participating Home Health Agencies (HHA). Many of these members also provide Durable Medical Equipment (DME) under Medicare. Accordingly, the Proposed Rule is of great interest to NAHC and its members.

As general comment related to the proposed rule as a whole, NAHC recommends:

1. **Future proposed rules should be confined to a single subject.**

   For the first time in recent memory, the Centers for Medicare and Medicaid Services (CMS) combined three unrelated matters into a single public notice. With the instant public notice, CMS includes: (a) a proposal relative to the 2007 Medicare home health rates of payment; (b) a significant proposal related to Medicare payment for DME; and (c) an invitation for home health agencies to comment on Health Care

Information Transparency and Health Information Technology. This style is confusing to the public and is counter to the CMS initiatives for better public communications.

The difficulties posed by this style are highlighted in the sandwiching of two home health related matters with the DME payment proposal. Sections II. A-F relate solely to home health payment. These sections are followed by Sections II. G-L, concerning the DME proposals. At the end thereof is another home health related matter, Health Care Information Transparency and Health Information Technology in Section II.M. If CMS is sincere in its efforts to maintain an "open door" policy, publication of proposed rules should not occur in such manner.

2. **Home health payment proposed rules should include more detailed information on all areas involved in the payment rate calculation.**

There are relevant information areas that are not displayed in sufficient detail in the proposed rule. For example, the proposed rule sets out the 2007 Market Basket Index at 3.1 while glaringly absent is a detailed presentation of the inflation factors that make up the calculation. While CMS officials made such available on request, the request should be unnecessary as this crucial information should be contained in every payment rate proposal.

SPECIFIC COMMENTS

Update to the Market Basket Index

The proposed CY 2007 home health market index is 3.1%. This estimate falls short of increased costs in the delivery of home health services. Labor costs have risen significantly with the continuing shortage of nursing and therapy staff. In addition, transportation costs skyrocketed in 2005-6 at a rate far greater than the estimated 2.2% that was set out in the 2006 rate setting rule. Finally, technology costs have grown as a cost segment in home health services.

The problem with the estimated MBI appears to stem from two weaknesses in the calculation formula. First, while CMS rebased the index in the 2005 rate rulemaking, the use of FY 2000 cost reports in that rebasing guaranteed that the cost weights would be inaccurate as FY 2000 cost reports contained only a portion of the operational changes that have occurred since the onset of the prospective payment system. Since FY 2000, home health services have transformed significantly with greater use of professional health services over home health aide services. In addition, the use of state-of-the-art clinical and operational technologies has grown in all areas of home health services. As such, it can be expected that the FY 2000 based cost weights are out of date.

Illustrative of this concern is the ratio of fringe benefits to wages and salaries. The inpatient hospital PPS sets out a ratio of 24.5% (11.822 to 48.171 to) as compared to the home health ratio of 16.7% (11.009 to 65.766). While the exact current ratio of fringe benefits to wages and salaries is not known, on the surface the vast difference between inpatient services and home health warrant further examination as to the validity of the current home health rating.

Second, the CY 2007 projection of cost inflation in transportation raises serious doubts about the accuracy of the projection methodology. The projection of a 0.3 percent increase given the 6.8% increase in the private transportation CPI in 2005 and 7.1% for the first six months of 2006 requires an incredible change in cost patterns to be well founded. The projection weakness is evident in the CY 2006 calculation where the inflation in cost was estimated by CMS at 2.2% when the CPI in 2006 has not fallen lower than 5.0% in any 2006 month and is as high as 9.3% in May.

Recommendations

The market basket index inputs and the weights assigned to each input should be re-examined every two years using cost report data that is no older than two years prior. The validity of the weights should be periodically tested using audited cost report data.

The inflation rate proxies and the projections of cost increase should be thoroughly evaluated and validated. If either or both are not determined to be valid, immediate reforms should be developed and implemented. NAHC is aware that CMS uses a proprietary system, Global Insights, Inc., in its projection of cost increase. This system should be examined by a CMS Technical Expert Panel in the immediate future.

Shortfalls in annual cost increase projections should be added to succeeding year inflation updates. For example, the under-projection in transportation cost increases in 2006 should be reflected in 2007 or 2008 rates.

Wage Index

For several years, NAHC has expressed serious concerns about the use of the pre-floor, pre-reclassified hospital wage index to establish area specific adjustments to the home health services payment rates. NAHC strongly believes that the continued use of this index will cause significant harm to the stability of the home health care delivery system by providing payment rates that are not reflective of the local health care economy. This can lead to inadequate rates for HHAs competing for health care staff with hospitals that are benefited by higher wage indices. It is time for CMS to commit sufficient resources and effort to transition home health services to a wage index that achieves some reasonable semblance of parity with hospitals.

Since the return of the hospital wage index to home health services in the early 1990s, many changes in the application of that index have occurred that render its continued use in the current form improper. **First**, the number of hospitals securing a geographic area reclassification has increased greatly. **Second**, there are increased bases for reclassification of hospitals that are intended to address changes in the employment patterns between geographic areas. Some of these new bases have been implemented without regard to budget neutrality. **Third**, there have been many hospitals that have been excluded from the wage index calculation because they have been classified as Critical Access Hospitals. That has weakened the depth of the wage index calculation and left some areas victim to the use of proxies for data to determine an actual relative wage status. **Fourth**, the application of the "rural floor" to hospitals seriously disadvantages home health agencies operating in the same geographic area.

CMS has the regulatory power to repair the home health wage index. Section 1895 of the Social Security Act provides CMS with wide discretion in its choice and administration of a wage index. Legislative intervention should not be necessary to correct the obvious flaws in the current and proposed wage index adjustment.

Recommendations

CMS should takes immediate steps to implement a wage index that secures a reasonable level of parity with the wage index values applicable to hospitals in the geographic area served by the home health agencies. The following steps should be taken:

1. Apply the state specific rural floor to all urban areas.
2. Implement a reclassification value proxy for home health agencies operating in areas where the hospital(s) have been awarded a wage index reclassification. The proxy can be based on the actual reclassification wage index value if the CBSA or rural area is served by a single hospital or by an average of the wage indices of the hospitals serving the area.

Rural Area Wage Index Proxy

In the proposed rule, CMS invited specific comment regarding its plan to continue using the 2005 rural wage index for geographic areas where there is no rural hospital data to compute a wage index value. CMS references Massachusetts and Puerto Rico as two areas affected by the lack of data. This lack of data highlights the inequities of continuing to use the pre-floor, pre-reclassified hospital wage index for home health services. The need to create proxies due to an absence of hospital data defines the problem referenced above in vivid detail.

The suggested alternative imputed rural wage index for Massachusetts falls far short of correcting the flaws evident in the continued use of the 2005 wage index value. CMS's

proposal to calculate a rural wage index for Massachusetts based on an average of the rural index values of the other four New England states with rural area values is not a reasonable alternate approach. The economy of Dukes and Nantucket counties are obviously different than the rural areas of these four states. The cost of living in these two counties is higher than most areas in Massachusetts or any of the contiguous states.

However given the unlikely event that CMS will reform the 2007 home health wage index in the near term, an alternative imputed rural wage index must be developed. There are options that meet the four principles set out in the proposed rule and achieve a result that should reasonably reflect the labor economy in the affected two counties.

Recommendations

The imputed rural wage index for Massachusetts can be based on the rural wage index for the states contiguous to Massachusetts. The result would be an index based on Connecticut, Vermont, and New Hampshire as Maine is not contiguous and Rhode Island does not have a rural wage index. The exclusion of Maine is based on the understanding that very few, if any, Maine residents are employed in the Massachusetts health care system as the state is insufficiently proximate to blend labor forces. The resulting calculation avoids the "cliff" affect that exists in some wage index areas where the contiguous counties (often the source of the workforce) have much higher wage index values. With a 1.0833 value, the result remains significantly lower than Barnstable County (1.2561), the county immediately neighboring Nantucket and Dukes counties. Nevertheless, this approach meets the four principles set out in the proposed rule.

Another alternative is the use a Medicare enrollee weighted average of rural index values in the contiguous states to Massachusetts. With Massachusetts rural areas more populated that rural areas of most other New England states, the use of an enrollee-based weighted average would bring a balance of impact in the calculation between the higher populated Connecticut and the sparsely populated other states.

The best alternative imputed wage index in Massachusetts is the application of the Barnstable County index value. While this alternative does not meet all of the principles set out by CMS, it does reflect the commonly understood reality that Dukes and Nantucket counties share many of the characteristics of the Barnstable labor economy in that the area economies are based on tourism, agriculture, and seafood. Further, it should be noted that workers from Barnstable County routinely travel on a daily basis by ferry and air shuttle to the off-shore islands.

OUTLIER PAYMENT

The proposed rule suggests no change in the existing outlier payment method that uses a 0.65 fixed dollar loss ratio (FDL) to achieve an expenditure of the 5% outlier episode "budget." However, the proposed rule states that a change may be implemented through the final rule if data becomes available prior to its issuance that supports a change.

Recommendation

In the event that CMS secures data that indicates a potential basis to alter the outlier FDL, NAHC recommends that CMS provide an opportunity for review and comment before implementation of any change that reduces the likely number of episodes qualifying for outlier payment.

QUALITY DATA

The proposed rule implements Section 5201(c) of the Deficit Reduction Act of 2005 establishing standards for a 2% reduction in the home health market basket increase to any home health agency that "does not submit data to the Secretary" relative to the measurement of quality. CMS proposes to establish a data submission requirement that is comparable to the existing standard under the Medicare conditions of participation regarding the submission of OASIS data. CMS proposes to use data submissions related to episodes beginning on or after July 1, 2005 and before July 1, 2006 to determine whether the market basket increase applies to a particular home health agency.

NAHC supports the CMS proposal to use the existing OASIS data submission requirements to implement Section 5201(c) of the DRA. NAHC further supports the exclusion of certain new providers from the requirement as the submission of required data during the established submission period is not reasonable or possible. However, NAHC has several concerns about CMS implementation plans for "pay for reporting" (P4R).

We are concerned about the longstanding misperception that CMS has that the Omnibus Budget Reconciliation Act of 1987 (OBRA 87) is the basis for OASIS authorization and patient standardized assessment requirements. Specifically, OBRA 87 required the development of "Assessment Instruments for Surveys." This provision required the Secretary to "Designate an assessment instrument or instruments not later than April 1, 1989, for us in conducting surveys." Further, the Secretary was required to evaluate the assessment process and make necessary modifications, and "provide training to State and Federal surveyors in the use of the assessment 'instrument' or instruments." In response to this legislation CMS developed the Home Health Functional Assessment Instrument Modules A through F for use in the survey process. The assessment instrument referenced in OBRA 87 is not a patient assessment instrument.

Secondly, NAHC is concerned about the data submission time frame identified by CMS in the proposed rule in that it can be interpreted as establishing a compliance requirement that is retroactive since it relates to episodes beginning after July 1, 2005 and before July 1, 2006. Although OASIS data submission is mandated by the home health Conditions of Participation (CoP), it was not tied to payment until passage of DRA 2005. The DRA provision expressly states "in the case of a home health agency that **does not submit** data

to the Secretary" (emphasis added), indicating a future requirement. We do not believe that Congress intended for CMS to base full market basket updates on data that agencies would have submitted both prior to this proposed rule and prior to passage of DRA. Such a requirement is unfair to agencies since they could not know of the financial penalties they would suffer if they failed to submit data. We believe that providers should be given prior warning of the impact of their failure to comply with requirements. Further, in the event that CMS interprets the proposed rule to establish a data submission compliance period prior to the date of the final rule, it is retroactive rulemaking clearly in violation of the Administrative Procedures Act and the Medicare laws.

In addition, there is no reference in the proposed rule to the degree of compliance that will be required in order for agencies to receive their full market basket update. We believe that CMS should have provided specific information about the level of compliance with OASIS data submission requirements that will be required. The proposed rule is unclear as to whether compliance will be evaluated on qualitative and/or quantitative bases, such as submission errors, reporting on all Medicare and Medicaid patients, a full 12 months of data, or in some other manner. Finally, we believe that the details of reporting requirements for payment should be addressed in the form of a regulation, rather than by way of a notice or policy.

Recommendation

CMS must establish the data submission requirement with dates of compliance subsequent to the issuance of a final rule. The current proposal is of minor consequence in that regard since the submission requirement is consistent with existing requirements relative to the conditions of participation. Changes in quality data requirements in the future should provide prospective submission obligations to qualify for the full market basket increase in a given year. While the Secretary has leeway in implementing the DRA provision, the specific language in that provision reflects a future responsibility ("does not submit data") rather than a past responsibility.

CMS should clarify the responsibility for data submission to indicate whether OASIS data must have been submitted for all episodes within the qualifying period. NAHC does not believe that Congress intended to disqualify an HHA from the full market basket index increase in the event of an isolated non-submission of OASIS data on some episodes.

Performance measures and OASIS improvement

We would also like to respond to your request for input related to payment for performance to home health agencies and outcome and process measures. NAHC, the Visiting Nurse Association of America, and the American Association for Home Care have engaged in a quality initiative, meeting with representatives of the home health community to establish principles for quality performance measures and identify outcome and process measures that reflect quality care. Attachment A spells out our recommended guidelines for quality performance measure selection and for pay-for-performance system

requirements. We wish to express our interest in establishing a reward system that is both meaningful and fair, while ensuring continued access to care for Medicare beneficiaries. We appreciate CMS' expressed desire to ensure reporting the minimum amount of data necessary to accurately reflect quality of home health services, without creating additional burden for providers.

We thank you for the opportunity to offer our recommendations for changes to the existing OASIS data set. Under the Medicare and Medicaid benefits, home health agencies are primarily responsible for delivery of professional health care services. Medicare payment to home health agencies is limited to medically necessary services delivered by or under the direction of health care professionals. Although we believe that beneficiaries' ability to perform instrumental activities of daily living (IADL) are important to their overall well being, we do not believe that improvement in IADLS are appropriate measures of home health agency performance. Further, some OASIS items need greater specificity. Still others can be eliminated entirely.

Recommendations

NAHC recommends that data collection by home health agencies be limited to medical diagnoses, physical function, and clinical problems necessary for measurement of stabilization or improvement of an individual's health status. In light of this we are offering the following recommendations for OASIS streamlining, many of which we have made over the years.

- Eliminate OASIS items measures related to IADL including M0720 light meals, M0730 transportation, M0740 laundry, M0750 housekeeping, M0760 shopping, and M0770 telephone use.

According to Volume 4 *OASIS Chronicle and Recommendations* the following OASIS items are not used for outcome measurement, risk factor measurement, adverse event measurement, case mix measurement, case mix adjustment for payment, or for performance indicators for consumer reporting. Therefore, we recommend that these items be eliminated from the OASIS items that must be collected and reported:

- M0180 Inpatient Discharge Date
- M0474 Does this patient have at least one Stasis Ulcer that Cannot be Observed
- M0486 Does this patient have at least one Surgical Wound that cannot be observed
- M0810 Patient Management of Equipment
- M0820 Caregiver Management of Equipment
- M0880 After discharge, does the patient receive health, personal, or support Services or Assistance
- M0890 If the patient was admitted to an acute care Hospital, for what Reason
- M0895 Reason for Hospitalization
- M0903 Date of Last (Most Recent) Home Visit.

Other OASIS items lack specificity needed to adequately demonstrate the impact of home health services. In addition to lack of specificity in each item, clinicians are instructed to base their responses to activities of daily living items on whether patients can perform the activity more than 50% of the time. We recommend refinement of the following:

- M0400 Hearing and Ability to Understand Spoken Language combines multiple aspects of receptive communication in a single question
- M0484 and M0484 Surgical Wounds options are insufficient to adequately demonstrate improvement, including lack of a "healed" option and misleading conclusions that the number of wounds has increased when a single wound heals in segments.
- M0640 Grooming includes multiple activities that require different skills and safety considerations (e.g. face washing versus shaving).
- M0650 Ability to Dress Upper Body requires a variety of skills and safety considerations. For example, buttoning garments takes different skills than removing items from closets and donning shirts.
- M0660 Ability to Dress Lower Body requires a variety of skills and safety considerations. For example, donning pants requires different skills than putting on and tying shoes.
- M0700 Ambulation/Locomotion is not sensitive to improvement in ambulation when progressing from a walker to a cane.
- M0780 Management of Oral Medications fails to measure successful teaching of medication management to caregivers, which is a very common goal when caring for the high number of home health patients that lack the mental acuity to self-manage their medications.

Additional quality assessment concerns

Adverse events can serve as important measures of the adequacy of care. Two significant adverse events are re-hospitalization and urgent care. However, NAHC believes that further refinement of OASIS and the outcome measure methodology are needed to more accurately reflect the impact of home health services when using these two measures. Specifically, re-hospitalization fails to differentiate between those events that occur very early in an episode that may be due to premature hospital discharge or inappropriate placement in the home setting. Also, re-hospitalizations that occur ten to twelve months into a spell of illness are viewed as having the same negative impact as those that occur in early episodes of care.

Recommendation

CMS should institute a more robust evaluation of re-hospitalizations to ensure a clearer picture of home health quality. This can be accomplished through the use of re-hospitalization time frames that distinguish between those that closely follow the original hospital discharge and may be related to hospital quality of care rather than home health quality.

Finally, NAHC wishes to express its concerns about the shortcomings in the current OASIS outcome measures when applied to chronic long term patients. The primary goal of care with individuals receiving long term care, many of whom are very old, have multiple co-morbidities and functional limitations, is to maintain them in their homes as long as possible. The current system measures outcomes from admission to re-hospitalization or admission to discharge. Due to the nature of their age and health status, most long term patients' episodes end at the point that they are hospitalized, admitted to a nursing home, or die. If they remain on service for more than twelve months without a hospitalization or discharge they are eliminated from the data base. The current OASIS system fails to recognize the value of maintenance of individuals in their homes for long periods of time.

Recommendation

CMS should institute a separate re-hospitalization score that accounts for the re-hospitalization risks of long term, chronically ill patients. CMS should seriously consider separately scoring HHA performance with long term, chronically ill patients in all areas of the Home Care Compare evaluation. Such a system should recognize the duration of home health services. The current performance assessment disregards the length of the patient's stay at home, evaluating only the changes from start of care to discharge.

Process Measures

In our efforts to identify the most appropriate measures for home health, NAHC and the, home health quality initiative participants determined that high risk patients with the most serious health problems and who are most costly to Medicare should be the primary focus. Diabetes is a growing problem in American society. It is one of the most frequently occurring primary diagnoses in home health patients and is the underlying cause of many other conditions which home health patients are treated, such as hypertension, cardiovascular disease, and wound complications. The second most costly and frequently occurring diagnosis in home care is congestive heart failure. Patients with these conditions have frequent re-hospitalizations.

Recommendations

NAHC recommends that process measures related to these conditions be identified and tested in the home health setting. Also, although assessment is the basis for all future actions in health care delivery, we believe that the process measures selected should be limited to specific interventions that result in reduction of complications and adverse events. Specifically, we recommend the following as potential home health process measures for development since they are basic interventions that are under the control of home health agencies and have a significant impact on the well being of patients under their care:

- Teaching medication regimen, side effects, to patient/caregiver
- Reporting medication regimen errors and problems

- Implementing of pain management protocols
- Teaching blood sugar testing and sliding scale insulin administration to diabetic patients/caregivers
- Teaching weight monitoring and reporting of weight gain to heart failure patients/caregivers

Payment for Oxygen, Oxygen Equipment and Capped Rental DME Items

CMS' proposal for transition of oxygen equipment to beneficiary ownership after 36 months raises concerns and questions because it could leave vulnerable Medicare beneficiaries without the clinical resources needed to ensure appropriate oxygen administration in the home setting. Specifically, transition of oxygen equipment to beneficiaries could leave them without necessary tools and expertise to ascertain whether they are receiving the appropriate oxygen dosage. NAHC is concerned that the CMS proposal to omit "routine maintenance and periodic servicing of purchased equipment, such as testing, cleaning, regulating, changing filers, and general inspection of beneficiary owned CMS" will place Medicare beneficiaries in jeopardy. Failure to ensure that oxygen doses are not too high, or too low, could result in harm to patients and potentially costly hospital stays. Specifically:

- Oxygen delivery systems do not verify the purity of oxygen being delivered. Under the current payment system suppliers periodically check oxygen concentrators to ensure that they are dispensing the proper concentration of oxygen and flow rate. The frequency of these checks varies by manufacturer. Some require annual oxygen purity checks, others more or less often. Verification of the purity of oxygen is accomplished with a piece of equipment that costs several hundred dollars and must also be maintained.
- Routine maintenance includes changing of filters. Filter life is based upon manufacturer guidelines, but also depends upon the cleanliness of the home environment. Filter life varies from months to years depending on the product. Some filters are external to the working components of the equipment and relatively simple to change. However, other filters are placed inside the equipment and can only be accessed by removal of screws and external covers.

Other important considerations include:

Oxygen equipment failure is now handled by suppliers responsible for the rental to beneficiaries. Once equipment is owned by patients they may find it difficult to locate an oxygen supplier that is willing or able to provide them with a loaner unit on short notice.

The proposed rule does not mention plans for ensuring that emergency back-up tanks for concentrators are available during power failures and other disasters.

In addition, CMS has not offered the specific criteria that will be used for determining the "lifetime" of oxygen equipment. It is unclear whether CMS intends to base lifetime on

manufacturer warranty or some other basis. This could be problematic since "lifetime" varies widely by manufacturer and type of equipment. For example, some manufacturer warranties are limited to 2-3 years, while others are as long as 5 years.

Finally, the notice does not offer information about how equipment failures due to beneficiary neglect or abuse will be determined. This type of information is critical in order to ensure the protection of oxygen equipment suppliers.

Recommendations:

We urge CMS to reconsider its decision to exclude payment for routine maintenance. CMS should establish a payment rate for routine maintenance that would be applicable after ownership is transferred. Also, CMS should provide solutions to the problems beneficiaries may face in securing loaner equipment and repairs when faced with routine equipment breakdown, as well as for dealing with loaner or replacement equipment needs during power failures or disasters. In terms of equipment replacement, more detail is needed as to how CMS will determine oxygen equipment "lifetime" and how beneficiary neglect and abuse of equipment will be established.

Health Care Information Transparency and Health Information Technology

The proposed rule includes a separate discussion of an unrelated topic on health care information transparency and health information technology. NAHC repeats its objection to including non-germane topics in the home health payment rate rule notice. In addition, NAHC rejects CMS's implication that public comment was solicited from the home health services community on these topics in the 2006 Inpatient Prospective Payment Systems proposed rule published in the April 25, 2006 Federal Register. That publication focused entirely on hospitals without a single reference to home health agencies on these subjects.

The request for comment involves very complicated matters ranging from the Secretary's authority to make pricing information public and how CMS can promote the use of information technology in home health services. NAHC is pleased that CMS has initiated a public dialogue in this area.

Recommendations:

CMS should outline in greater detail its thoughts and potential direction on these matters. NAHC is open to detailed discussions at any time. Further, CMS should conduct a technology inventory in home health services to determine what technology is available, the extent of use, and perceived roadblocks to expanded use. NAHC believes that there is significant use of technology in many forms and performing a array of tasks beyond that commonly understood outside of the home health community. Electronic health records, point of care service planning, and internet based care communications are just some of the IT advancements in home care. Only through a comprehensive inventory can a discussion begin about "next steps" in promoting or facilitating the uses of IT.

With respect to CMS authority to mandate the use of technologies, NAHC believes that the conditions of participation do not provide sufficient authority unless the Secretary can make a strong connection between IT and the health and safety of patients. There is no other authority available under current law. Further, any mandate for the use of IT must be accompanied by adjustments to payment rates as the current PPS rates are founded on data from a point when no such costly mandate existed. NAHC recommends that CMS seek sufficient authority before proceeding from a mode of facilitation to a mandate.

In relation to pricing transparency, NAHC recommends that CMS proceed with great caution. The home health prospective payment system is a "soft" reimburse method. The payment rate has little relationship to the home health agency's pricing of services. With some patients, the payment rate falls far short of the HHA's charges for the care provided. In others, the payment far exceeds charges. Providing pricing information to the public who do understand how HHPPS works is dangerous.

Thank you for the opportunity to submit these comments.

Very truly yours,

William A. Dombi
Vice President for Law

Mary St. Pierre
Vice President for Regulatory Affairs

Attachment A

INDUSTRY RECOMMENDED GUIDELINES FOR QUALITY PERFORMANCE MEASURE SELECTION AND THE DEVELOPMENT OF A PAY FOR PERFORMANCE SYSTEM

Selected measures should:

a. **Be meaningful to patients, providers, payers, and other stakeholders**

b. **Represent value and important aspects of care and services**

c. **Represent aspects of care that are under the control or reasonably susceptible to the influence of the home health agency while the patient is on service with the agency**

d. **Be based on uniform data that home health agencies have collected and reported for a sufficient period of time in order to ensure consistency and reliability**

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A Pay-for-Performance system should:

a. **Improve quality of home care services and patient access to care**

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e. **Identify home health agencies performing well on measures, leading to reduced state survey and certification activities**

f. **Take into account agencies with anomalous patient populations, such as large numbers of dually eligible patients, chronically ill long stay, or small numbers of patients served**

g. **Be pilot tested prior to national implementation**

h. **Apply to the Medicare Program only**

i. **Require that incentive pools be funded by overall cost savings throughout the Medicare program**

ATTACHMENT 2 TO #64

Ruth L. Constant
Chairman of the Board

HOMECARE & HOSPICE
NATIONAL ASSOCIATION FOR HOME CARE & HOSPICE
228 Seventh Street, SE, Washington, DC 20003 • 202/547-7424 • 202/547-3540 fax

Val J. Halamandaris
President

September 25, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1304-P
P.O. Box 8014
Baltimore, MD 21244-8014

Via: Electronic submission

Re: Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment: Proposed Rule

71 Fed. Reg. 44082 (August 3, 2006)

To whom it may concern:

Thank you for the opportunity to provide comment on the above referenced Proposed Rule. The National Association for Home Care and Hospice, Inc. (NAHC) is the largest trade association in the country representing the interests of home care and hospice providers and their patients. As a central part of its membership, NAHC represents over 6,000 Medicare participating Home Health Agencies (HHA). Many of these members also provide Durable Medical Equipment (DME) under Medicare. Accordingly, the Proposed Rule is of great interest to NAHC and its members.

As general comment related to the proposed rule as a whole, NAHC recommends:

1. **Future proposed rules should be confined to a single subject.**

   For the first time in recent memory, the Centers for Medicare and Medicaid Services (CMS) combined three unrelated matters into a single public notice. With the instant public notice, CMS includes: (a) a proposal relative to the 2007 Medicare home health rates of payment; (b) a significant proposal related to Medicare payment for DME; and (c) an invitation for home health agencies to comment on Health Care

Information Transparency and Health Information Technology. This style is confusing to the public and is counter to the CMS initiatives for better public communications.

The difficulties posed by this style are highlighted in the sandwiching of two home health related matters with the DME payment proposal. Sections II. A-F relate solely to home health payment. These sections are followed by Sections II. G-L, concerning the DME proposals. At the end thereof is another home health related matter, Health Care Information Transparency and Health Information Technology in Section II.M. If CMS is sincere in its efforts to maintain an "open door" policy, publication of proposed rules should not occur in such manner.

2. **Home health payment proposed rules should include more detailed information on all areas involved in the payment rate calculation.**

There are relevant information areas that are not displayed in sufficient detail in the proposed rule. For example, the proposed rule sets out the 2007 Market Basket Index at 3.1 while glaringly absent is a detailed presentation of the inflation factors that make up the calculation. While CMS officials made such available on request, the request should be unnecessary as this crucial information should be contained in every payment rate proposal.

SPECIFIC COMMENTS

Update to the Market Basket Index

The proposed CY 2007 home health market index is 3.1%. This estimate falls short of increased costs in the delivery of home health services. Labor costs have risen significantly with the continuing shortage of nursing and therapy staff. In addition, transportation costs skyrocketed in 2005-6 at a rate far greater than the estimated 2.2% that was set out in the 2006 rate setting rule. Finally, technology costs have grown as a cost segment in home health services.

The problem with the estimated MBI appears to stem from two weaknesses in the calculation formula. First, while CMS rebased the index in the 2005 rate rulemaking, the use of FY 2000 cost reports in that rebasing guaranteed that the cost weights would be inaccurate as FY 2000 cost reports contained only a portion of the operational changes that have occurred since the onset of the prospective payment system. Since FY 2000, home health services have transformed significantly with greater use of professional health services over home health aide services. In addition, the use of state-of-the-art clinical and operational technologies has grown in all areas of home health services. As such, it can be expected that the FY 2000 based cost weights are out of date.

Illustrative of this concern is the ratio of fringe benefits to wages and salaries. The inpatient hospital PPS sets out a ratio of 24.5% (11.822 to 48.171 to) as compared to the home health ratio of 16.7% (11.009 to 65.766). While the exact current ratio of fringe benefits to wages and salaries is not known, on the surface the vast difference between inpatient services and home health warrant further examination as to the validity of the current home health rating.

Second, the CY 2007 projection of cost inflation in transportation raises serious doubts about the accuracy of the projection methodology. The projection of a 0.3 percent increase given the 6.8% increase in the private transportation CPI in 2005 and 7.1% for the first six months of 2006 requires an incredible change in cost patterns to be well founded. The projection weakness is evident in the CY 2006 calculation where the inflation in cost was estimated by CMS at 2.2% when the CPI in 2006 has not fallen lower than 5.0% in any 2006 month and is as high as 9.3% in May.

Recommendations

The market basket index inputs and the weights assigned to each input should be re-examined every two years using cost report data that is no older than two years prior. The validity of the weights should be periodically tested using audited cost report data.

The inflation rate proxies and the projections of cost increase should be thoroughly evaluated and validated. If either or both are not determined to be valid, immediate reforms should be developed and implemented. NAHC is aware that CMS uses a proprietary system, Global Insights, Inc., in its projection of cost increase. This system should be examined by a CMS Technical Expert Panel in the immediate future.

Shortfalls in annual cost increase projections should be added to succeeding year inflation updates. For example, the under-projection in transportation cost increases in 2006 should be reflected in 2007 or 2008 rates.

Wage Index

For several years, NAHC has expressed serious concerns about the use of the pre-floor, pre-reclassified hospital wage index to establish area specific adjustments to the home health services payment rates. NAHC strongly believes that the continued use of this index will cause significant harm to the stability of the home health care delivery system by providing payment rates that are not reflective of the local health care economy. This can lead to inadequate rates for HHAs competing for health care staff with hospitals that are benefited by higher wage indices. It is time for CMS to commit sufficient resources and effort to transition home health services to a wage index that achieves some reasonable semblance of parity with hospitals.

Since the return of the hospital wage index to home health services in the early 1990s, many changes in the application of that index have occurred that render its continued use in the current form improper. **First**, the number of hospitals securing a geographic area reclassification has increased greatly. **Second**, there are increased bases for reclassification of hospitals that are intended to address changes in the employment patterns between geographic areas. Some of these new bases have been implemented without regard to budget neutrality. **Third**, there have been many hospitals that have been excluded from the wage index calculation because they have been classified as Critical Access Hospitals. That has weakened the depth of the wage index calculation and left some areas victim to the use of proxies for data to determine an actual relative wage status. **Fourth**, the application of the "rural floor" to hospitals seriously disadvantages home health agencies operating in the same geographic area.

CMS has the regulatory power to repair the home health wage index. Section 1895 of the Social Security Act provides CMS with wide discretion in its choice and administration of a wage index. Legislative intervention should not be necessary to correct the obvious flaws in the current and proposed wage index adjustment.

Recommendations

CMS should takes immediate steps to implement a wage index that secures a reasonable level of parity with the wage index values applicable to hospitals in the geographic area served by the home health agencies. The following steps should be taken:

1. Apply the state specific rural floor to all urban areas.
2. Implement a reclassification value proxy for home health agencies operating in areas where the hospital(s) have been awarded a wage index reclassification. The proxy can be based on the actual reclassification wage index value if the CBSA or rural area is served by a single hospital or by an average of the wage indices of the hospitals serving the area.

Rural Area Wage Index Proxy

In the proposed rule, CMS invited specific comment regarding its plan to continue using the 2005 rural wage index for geographic areas where there is no rural hospital data to compute a wage index value. CMS references Massachusetts and Puerto Rico as two areas affected by the lack of data. This lack of data highlights the inequities of continuing to use the pre-floor, pre-reclassified hospital wage index for home health services. The need to create proxies due to an absence of hospital data defines the problem referenced above in vivid detail.

The suggested alternative imputed rural wage index for Massachusetts falls far short of correcting the flaws evident in the continued use of the 2005 wage index value. CMS's

proposal to calculate a rural wage index for Massachusetts based on an average of the rural index values of the other four New England states with rural area values is not a reasonable alternate approach. The economy of Dukes and Nantucket counties are obviously different than the rural areas of these four states. The cost of living in these two counties is higher than most areas in Massachusetts or any of the contiguous states.

However given the unlikely event that CMS will reform the 2007 home health wage index in the near term, an alternative imputed rural wage index must be developed. There are options that meet the four principles set out in the proposed rule and achieve a result that should reasonably reflect the labor economy in the affected two counties.

Recommendations

The imputed rural wage index for Massachusetts can be based on the rural wage index for the states contiguous to Massachusetts. The result would be an index based on Connecticut, Vermont, and New Hampshire as Maine is not contiguous and Rhode Island does not have a rural wage index. The exclusion of Maine is based on the understanding that very few, if any, Maine residents are employed in the Massachusetts health care system as the state is insufficiently proximate to blend labor forces. The resulting calculation avoids the "cliff" affect that exists in some wage index areas where the contiguous counties (often the source of the workforce) have much higher wage index values. With a 1.0833 value, the result remains significantly lower than Barnstable County (1.2561), the county immediately neighboring Nantucket and Dukes counties. Nevertheless, this approach meets the four principles set out in the proposed rule.

Another alternative is the use a Medicare enrollee weighted average of rural index values in the contiguous states to Massachusetts. With Massachusetts rural areas more populated that rural areas of most other New England states, the use of an enrollee-based weighted average would bring a balance of impact in the calculation between the higher populated Connecticut and the sparsely populated other states.

The best alternative imputed wage index in Massachusetts is the application of the Barnstable County index value. While this alternative does not meet all of the principles set out by CMS, it does reflect the commonly understood reality that Dukes and Nantucket counties share many of the characteristics of the Barnstable labor economy in that the area economies are based on tourism, agriculture, and seafood. Further, it should be noted that workers from Barnstable County routinely travel on a daily basis by ferry and air shuttle to the off-shore islands.

OUTLIER PAYMENT

The proposed rule suggests no change in the existing outlier payment method that uses a 0.65 fixed dollar loss ratio (FDL) to achieve an expenditure of the 5% outlier episode "budget." However, the proposed rule states that a change may be implemented through the final rule if data becomes available prior to its issuance that supports a change.

Recommendation

In the event that CMS secures data that indicates a potential basis to alter the outlier FDL, NAHC recommends that CMS provide an opportunity for review and comment before implementation of any change that reduces the likely number of episodes qualifying for outlier payment.

QUALITY DATA

The proposed rule implements Section 5201(c) of the Deficit Reduction Act of 2005 establishing standards for a 2% reduction in the home health market basket increase to any home health agency that "does not submit data to the Secretary" relative to the measurement of quality. CMS proposes to establish a data submission requirement that is comparable to the existing standard under the Medicare conditions of participation regarding the submission of OASIS data. CMS proposes to use data submissions related to episodes beginning on or after July 1, 2005 and before July 1, 2006 to determine whether the market basket increase applies to a particular home health agency.

NAHC supports the CMS proposal to use the existing OASIS data submission requirements to implement Section 5201(c) of the DRA. NAHC further supports the exclusion of certain new providers from the requirement as the submission of required data during the established submission period is not reasonable or possible. However, NAHC has several concerns about CMS implementation plans for "pay for reporting" (P4R).

We are concerned about the longstanding misperception that CMS has that the Omnibus Budget Reconciliation Act of 1987 (OBRA 87) is the basis for OASIS authorization and patient standardized assessment requirements. Specifically, OBRA 87 required the development of "Assessment Instruments for Surveys." This provision required the Secretary to "Designate an assessment instrument or instruments not later than April 1, 1989, for us in conducting surveys." Further, the Secretary was required to evaluate the assessment process and make necessary modifications, and "provide training to State and Federal surveyors in the use of the assessment 'instrument' or instruments." In response to this legislation CMS developed the Home Health Functional Assessment Instrument Modules A through F for use in the survey process. The assessment instrument referenced in OBRA 87 is not a patient assessment instrument.

Secondly, NAHC is concerned about the data submission time frame identified by CMS in the proposed rule in that it can be interpreted as establishing a compliance requirement that is retroactive since it relates to episodes beginning after July 1, 2005 and before July 1, 2006. Although OASIS data submission is mandated by the home health Conditions of Participation (CoP), it was not tied to payment until passage of DRA 2005. The DRA provision expressly states "in the case of a home health agency that **does not submit** data

to the Secretary" (emphasis added), indicating a future requirement. We do not believe that Congress intended for CMS to base full market basket updates on data that agencies would have submitted both prior to this proposed rule and prior to passage of DRA. Such a requirement is unfair to agencies since they could not know of the financial penalties they would suffer if they failed to submit data. We believe that providers should be given prior warning of the impact of their failure to comply with requirements. Further, in the event that CMS interprets the proposed rule to establish a data submission compliance period prior to the date of the final rule, it is retroactive rulemaking clearly in violation of the Administrative Procedures Act and the Medicare laws.

In addition, there is no reference in the proposed rule to the degree of compliance that will be required in order for agencies to receive their full market basket update. We believe that CMS should have provided specific information about the level of compliance with OASIS data submission requirements that will be required. The proposed rule is unclear as to whether compliance will be evaluated on qualitative and/or quantitative bases, such as submission errors, reporting on all Medicare and Medicaid patients, a full 12 months of data, or in some other manner. Finally, we believe that the details of reporting requirements for payment should be addressed in the form of a regulation, rather than by way of a notice or policy.

Recommendation

CMS must establish the data submission requirement with dates of compliance subsequent to the issuance of a final rule. The current proposal is of minor consequence in that regard since the submission requirement is consistent with existing requirements relative to the conditions of participation. Changes in quality data requirements in the future should provide prospective submission obligations to qualify for the full market basket increase in a given year. While the Secretary has leeway in implementing the DRA provision, the specific language in that provision reflects a future responsibility ("does not submit data") rather than a past responsibility.

CMS should clarify the responsibility for data submission to indicate whether OASIS data must have been submitted for all episodes within the qualifying period. NAHC does not believe that Congress intended to disqualify an HHA from the full market basket index increase in the event of an isolated non-submission of OASIS data on some episodes.

Performance measures and OASIS improvement

We would also like to respond to your request for input related to payment for performance to home health agencies and outcome and process measures. NAHC, the Visiting Nurse Association of America, and the American Association for Home Care have engaged in a quality initiative, meeting with representatives of the home health community to establish principles for quality performance measures and identify outcome and process measures that reflect quality care. Attachment A spells out our recommended guidelines for quality performance measure selection and for pay-for-performance system

requirements. We wish to express our interest in establishing a reward system that is both meaningful and fair, while ensuring continued access to care for Medicare beneficiaries. We appreciate CMS' expressed desire to ensure reporting the minimum amount of data necessary to accurately reflect quality of home health services, without creating additional burden for providers.

We thank you for the opportunity to offer our recommendations for changes to the existing OASIS data set. Under the Medicare and Medicaid benefits, home health agencies are primarily responsible for delivery of professional health care services. Medicare payment to home health agencies is limited to medically necessary services delivered by or under the direction of health care professionals. Although we believe that beneficiaries' ability to perform instrumental activities of daily living (IADL) are important to their overall well being, we do not believe that improvement in IADLS are appropriate measures of home health agency performance. Further, some OASIS items need greater specificity. Still others can be eliminated entirely.

Recommendations

NAHC recommends that data collection by home health agencies be limited to medical diagnoses, physical function, and clinical problems necessary for measurement of stabilization or improvement of an individual's health status. In light of this we are offering the following recommendations for OASIS streamlining, many of which we have made over the years.

- Eliminate OASIS items measures related to IADL including M0720 light meals, M0730 transportation, M0740 laundry, M0750 housekeeping, M0760 shopping, and M0770 telephone use.

According to Volume 4 *OASIS Chronicle and Recommendations* the following OASIS items are not used for outcome measurement, risk factor measurement, adverse event measurement, case mix measurement, case mix adjustment for payment, or for performance indicators for consumer reporting. Therefore, we recommend that these items be eliminated from the OASIS items that must be collected and reported:

- M0180 Inpatient Discharge Date
- M0474 Does this patient have at least one Stasis Ulcer that Cannot be Observed
- M0486 Does this patient have at least one Surgical Wound that cannot be observed
- M0810 Patient Management of Equipment
- M0820 Caregiver Management of Equipment
- M0880 After discharge, does the patient receive health, personal, or support Services or Assistance
- M0890 If the patient was admitted to an acute care Hospital, for what Reason
- M0895 Reason for Hospitalization
- M0903 Date of Last (Most Recent) Home Visit.

Other OASIS items lack specificity needed to adequately demonstrate the impact of home health services. In addition to lack of specificity in each item, clinicians are instructed to base their responses to activities of daily living items on whether patients can perform the activity more than 50% of the time. We recommend refinement of the following:

- M0400 Hearing and Ability to Understand Spoken Language combines multiple aspects of receptive communication in a single question
- M0484 and M0484 Surgical Wounds options are insufficient to adequately demonstrate improvement, including lack of a "healed" option and misleading conclusions that the number of wounds has increased when a single wound heals in segments.
- M0640 Grooming includes multiple activities that require different skills and safety considerations (e.g. face washing versus shaving).
- M0650 Ability to Dress Upper Body requires a variety of skills and safety considerations. For example, buttoning garments takes different skills than removing items from closets and donning shirts.
- M0660 Ability to Dress Lower Body requires a variety of skills and safety considerations. For example, donning pants requires different skills than putting on and tying shoes.
- M0700 Ambulation/Locomotion is not sensitive to improvement in ambulation when progressing from a walker to a cane.
- M0780 Management of Oral Medications fails to measure successful teaching of medication management to caregivers, which is a very common goal when caring for the high number of home health patients that lack the mental acuity to self-manage their medications.

Additional quality assessment concerns

Adverse events can serve as important measures of the adequacy of care. Two significant adverse events are re-hospitalization and urgent care. However, NAHC believes that further refinement of OASIS and the outcome measure methodology are needed to more accurately reflect the impact of home health services when using these two measures. Specifically, re-hospitalization fails to differentiate between those events that occur very early in an episode that may be due to premature hospital discharge or inappropriate placement in the home setting. Also, re-hospitalizations that occur ten to twelve months into a spell of illness are viewed as having the same negative impact as those that occur in early episodes of care.

Recommendation

CMS should institute a more robust evaluation of re-hospitalizations to ensure a clearer picture of home health quality. This can be accomplished through the use of re-hospitalization time frames that distinguish between those that closely follow the original hospital discharge and may be related to hospital quality of care rather than home health quality.

Finally, NAHC wishes to express its concerns about the shortcomings in the current OASIS outcome measures when applied to chronic long term patients. The primary goal of care with individuals receiving long term care, many of whom are very old, have multiple co-morbidities and functional limitations, is to maintain them in their homes as long as possible. The current system measures outcomes from admission to re-hospitalization or admission to discharge. Due to the nature of their age and health status, most long term patients' episodes end at the point that they are hospitalized, admitted to a nursing home, or die. If they remain on service for more than twelve months without a hospitalization or discharge they are eliminated from the data base. The current OASIS system fails to recognize the value of maintenance of individuals in their homes for long periods of time.

Recommendation

CMS should institute a separate re-hospitalization score that accounts for the re-hospitalization risks of long term, chronically ill patients. CMS should seriously consider separately scoring HHA performance with long term, chronically ill patients in all areas of the Home Care Compare evaluation. Such a system should recognize the duration of home health services. The current performance assessment disregards the length of the patient's stay at home, evaluating only the changes from start of care to discharge.

Process Measures

In our efforts to identify the most appropriate measures for home health, NAHC and the, home health quality initiative participants determined that high risk patients with the most serious health problems and who are most costly to Medicare should be the primary focus. Diabetes is a growing problem in American society. It is one of the most frequently occurring primary diagnoses in home health patients and is the underlying cause of many other conditions which home health patients are treated, such as hypertension, cardiovascular disease, and wound complications. The second most costly and frequently occurring diagnosis in home care is congestive heart failure. Patients with these conditions have frequent re-hospitalizations.

Recommendations

NAHC recommends that process measures related to these conditions be identified and tested in the home health setting. Also, although assessment is the basis for all future actions in health care delivery, we believe that the process measures selected should be limited to specific interventions that result in reduction of complications and adverse events. Specifically, we recommend the following as potential home health process measures for development since they are basic interventions that are under the control of home health agencies and have a significant impact on the well being of patients under their care:

- Teaching medication regimen, side effects, to patient/caregiver
- Reporting medication regimen errors and problems

- Implementing of pain management protocols
- Teaching blood sugar testing and sliding scale insulin administration to diabetic patients/caregivers
- Teaching weight monitoring and reporting of weight gain to heart failure patients/caregivers

Payment for Oxygen, Oxygen Equipment and Capped Rental DME Items

CMS' proposal for transition of oxygen equipment to beneficiary ownership after 36 months raises concerns and questions because it could leave vulnerable Medicare beneficiaries without the clinical resources needed to ensure appropriate oxygen administration in the home setting. Specifically, transition of oxygen equipment to beneficiaries could leave them without necessary tools and expertise to ascertain whether they are receiving the appropriate oxygen dosage. NAHC is concerned that the CMS proposal to omit "routine maintenance and periodic servicing of purchased equipment, such as testing, cleaning, regulating, changing filers, and general inspection of beneficiary owned CMS" will place Medicare beneficiaries in jeopardy. Failure to ensure that oxygen doses are not too high, or too low, could result in harm to patients and potentially costly hospital stays. Specifically:

- Oxygen delivery systems do not verify the purity of oxygen being delivered. Under the current payment system suppliers periodically check oxygen concentrators to ensure that they are dispensing the proper concentration of oxygen and flow rate. The frequency of these checks varies by manufacturer. Some require annual oxygen purity checks, others more or less often. Verification of the purity of oxygen is accomplished with a piece of equipment that costs several hundred dollars and must also be maintained.
- Routine maintenance includes changing of filters. Filter life is based upon manufacturer guidelines, but also depends upon the cleanliness of the home environment. Filter life varies from months to years depending on the product. Some filters are external to the working components of the equipment and relatively simple to change. However, other filters are placed inside the equipment and can only be accessed by removal of screws and external covers.

Other important considerations include:

Oxygen equipment failure is now handled by suppliers responsible for the rental to beneficiaries. Once equipment is owned by patients they may find it difficult to locate an oxygen supplier that is willing or able to provide them with a loaner unit on short notice.

The proposed rule does not mention plans for ensuring that emergency back-up tanks for concentrators are available during power failures and other disasters.

In addition, CMS has not offered the specific criteria that will be used for determining the "lifetime" of oxygen equipment. It is unclear whether CMS intends to base lifetime on

manufacturer warranty or some other basis. This could be problematic since "lifetime" varies widely by manufacturer and type of equipment. For example, some manufacturer warranties are limited to 2-3 years, while others are as long as 5 years.

Finally, the notice does not offer information about how equipment failures due to beneficiary neglect or abuse will be determined. This type of information is critical in order to ensure the protection of oxygen equipment suppliers.

Recommendations:

We urge CMS to reconsider its decision to exclude payment for routine maintenance. CMS should establish a payment rate for routine maintenance that would be applicable after ownership is transferred. Also, CMS should provide solutions to the problems beneficiaries may face in securing loaner equipment and repairs when faced with routine equipment breakdown, as well as for dealing with loaner or replacement equipment needs during power failures or disasters. In terms of equipment replacement, more detail is needed as to how CMS will determine oxygen equipment "lifetime" and how beneficiary neglect and abuse of equipment will be established.

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Thank you for the opportunity to submit these comments.

Very truly yours,

William A. Dombi
Vice President for Law

Mary St. Pierre
Vice President for Regulatory Affairs

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