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APTA
American Physical Therapy Association

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CSM 2007:
Combined Sections Meeting
February 13-19, 2007
Boston, Massachusetts

PT 2007:
The Annual Conference & Exposition of the American Physical Therapy Association
June 27-30
Denver, Colorado

September 25, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1540-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Submitted electronically

RE: Comments of the American Physical Therapy Association on the 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 Center for Medicare and Medicaid Services (CMS) published a proposed rule in the Federal Register *(71 FR 44081)* on August 3, 2006, which proposes to update the prospective payment rates and revise existing policies for home health agencies for Calendar Year (CY) 2007. The purpose of this correspondence is to submit comments on behalf of the American Physical Therapy Association (APTA) in response to the proposed rule. The APTA is a professional organization representing the interests of over 66,000 physical therapists, physical therapist assistants, and students of physical therapy. APTA members furnish services to Medicare beneficiaries in the home health setting, and we are committed to ensuring that patients receive the best possible care. Therefore, we are very interested in any proposed changes to the system.

APTA commends CMS for its efforts to update the prospective payment system to accurately reflect the costs of treatment in the home health setting. Physical therapy is an integral component of care in the home health setting, and APTA would like to collaborate with CMS to enhance and improve the payment system in any way possible.

Provisions of the Proposed Regulations

Physical therapists are primary caregivers in home care and have vast experience in using the OASIS tool in their daily practice. Physical therapists are highly trained professionals that provide therapy and develop an individualized home program to restore each patient to the highest level of function and independence.

Power of Caring.

In the home health setting, physical therapists are responsible for providing physical therapy services to patients through a written plan of care. Physical therapists assess and evaluate therapeutic, rehabilitative, and functional status in order to develop the comprehensive plan of care. The physical therapist also instructs patients and caregivers in the use and care of therapeutic devices, including prosthetics and orthotics. Additionally, the physical therapist determines the priority needs and initiates the physical therapy program and instructs other personnel and caregivers in certain phases of physical therapy in which they may work with the patient.

In the proposed rule, CMS states plans to continue efforts to refine the current OASIS tool and pursue the development of patient level process measures for home health agencies. The agency announces that these process measures will refer to specific care practices that are, or are not, followed by the home heath agencies for each patient and are slated for release in 2008 and 2009.

A common example of this type of measure, as illustrated in the proposed rule, is the percentage of patients at risk of falls for whom prevention of falls was addressed in the care plan. Physical therapists provide specific examinations (tests and measures) for evaluation of physical falls risk though assessment of patient balance, strength, and endurance, along with gait, transfers, and vertigo. Physical therapists can also evaluate components of patient cognition and patient and caregiver's safety. Physical therapists modify home and living arrangements and provide adaptive equipment and assistive devices to allow individuals to function safely in their homes and communities.

Therefore, we would like to extend our expertise to CMS as it seeks to refine the OASIS tool and develop process measures for home health agencies. We believe that it is imperative that CMS understand the practice of physical therapy in the home health setting and that the professional and clinical expertise of the physical therapist be incorporated in the development process. We have a number of members that have worked in home health for a significant number of years, and we would be more than happy to provide them to the agency as it embarks on this project over the next five years.

APTA thanks CMS for the opportunity to comment on this proposed rule, and we look forward to working with the agency to craft patient-centered reimbursement policies and home health process measures that reflect quality health care. If you have any questions regarding our comments, please contact Roshunda Drummond-Dye, Associate Director of Regulatory Affairs, at (703) 706-8547 or roshundadrummond-dye@apta.org.

Sincerely,

G. David Mason
Vice President, Government Affairs

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14998 W. 6th Ave., Bldg E-700
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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

RE: CMS-1304-P

Dear Sir or Madam:

We are Denver Biomedical, Inc. (DBI). We are a Colorado corporation and currently employ about 43 workers. We manufacture clinically-proven, patented Pleurx Pleural Catheters, Drainage Kits, and Vacuum Drainage Bottles used for the drainage of symptomatic, recurrent, pleural effusions and malignant ascites. For your review, we have attached a copy of a Benefit Category Determination Memorandum by the Centers for Medicare and Medicaid Services (CMS) dated March 14, 2002, classifying our products as implanted prosthetic devices and accessories to implanted prosthetic devices. We respectfully submit our comments to the proposed rule regarding the 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 (CMS-1304-P), which was published on August 3, 2006 (71 Fed. Reg. 44082).

Specifically, we respectfully request that CMS exclude from Home Health PPS our Vacuum Drainage Bottle, which is denoted by HCPCS code A7043 (vacuum drainage bottle and tubing for use with implanted catheter). These sterile bottles are accessories to the implanted catheter/prosthesis denoted by HCPCS code A7042 (implanted pleural catheter). For your consideration, we set forth two (2) reasons for unbundling the payment for this bottle from the Home Health PPS rates.

First, the regulations authorize CMS to exclude from Home Health PPS prosthetic devices and items related to prosthetic devices that are covered under Medicare Part B. 42 C.F.R. §409.49(f). Furthermore, although "[c]atheters, catheter supplies, ostomy bags, and supplies relating to ostomy care" are not subject to this exclusion from Home Health coverage, the Pleurx Pleural Catheter and Vacuum Drainage Bottle squarely meet the definition of a prosthetic device set forth in §410.36(a)(2) because they replace the malfunctioning pleura (an internal body organ) by artificially draining the pleura. Consequently, the Pleurx Pleural Catheter and

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Vacuum Drainage Bottle are covered under Part B as a prosthetic device as set forth in the attached Benefit Category Determination Memorandum.

Second, the current and proposed Home Health PPS rates do not adequately compensate home health agencies when they care for beneficiaries requiring the Pleurx Pleural Catheter and Vacuum Drainage Bottle because the cost of these bottles was not included in the cost data base used by CMS to compute the Home Health PPS rates. In addition, prior to 2003, the Vacuum Drainage Bottle was billed using a miscellaneous HCPCS code. Consequently, the specific cost of these bottles was not considered during the development of the home health prospective payment system. Furthermore, CMS has not refined the case-mix weights used to calculate payment rates since the inception of the Home Health PPS. Thus, cost data specific to these bottles has not been included in the case-mix weights used to determine the Home Health PPS rates.

Overall, Medicare beneficiaries typically use one Vacuum Drainage Bottle per day, but some cancer patients require more than one bottle per day. Home health agencies pay approximately $34.50 per bottle. Plus, along with other medically necessary items (e.g., latex gloves, gauze), home health agencies need a catheter cap to replace each bottle, which costs $5.75. This means that, over a 60-day episode, the cost to a typical home health agency just to replace these bottles in cancer patients exceeds $2,412. Accordingly, we respectfully request that CMS unbundle the payment for the Vacuum Drainage Bottle (HCPCS Code A7043) from the Home Health PPS and permit them to bill Part B separately or otherwise adjust Medicare payments to home health agencies caring for such cancer patients so that home health agencies can continue to furnish this non-routine care.

* * * * *

On behalf of over 40 hard-working families of DBI, we thank you for the opportunity to comment on the proposed rule. We hope that CMS will consider our comments.

Sincerely,

Tom Daulton
Vice President and General Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop N2-13-16
Baltimore, Maryland 21244-1850

Center for Medicare Management/Chronic Care Policy Group

DATE: MAR 14 202

FROM: Director
Chronic Care Policy Group
Center for Medicare Management

SUBJECT: Revised Benefit Category Determination for the Pleurx Pleural Catheter and the Pleurx Pleural Drainage Kit

TO: Ms. Stephanie Gammon
Region Six - Dallas Regional Office
Centers for Medicare & Medicaid Services

Dr. Paul Metzger
Medical Director
Region C DMERC

Stephanie Gammon of the Dallas Regional Office submitted a benefit category determination request regarding the Pleurx Pleural Drainage Kit on April 4, 2000. The patient or caregiver uses the Pleurx Pleural Drainage Kit (Drainage Kit) at home to periodically drain fluid from the Pleurx Pleural Catheter (a catheter implanted in the pleural lining of the patient's lung).

Our original benefit category determination found that the Pleurx Pleural Drainage Kit may be considered as "incident to" a physician's service, and when used under a home health plan of care, is a covered supply under the home health benefit. We have further researched the "incident to" benefit category and found that the Pleurx Pleural Drainage Kit is not "incident to" a physician's service according to section 1861(s)(2)(A) of the Social Security Act (the Act). However, the Drainage Kit would continue to be covered under the home health benefit as a covered supply as long as the patient was under a home health plan of care.

Section 1861(s)(2)(A) defines medical and other health services as including "services and supplies.... furnished as an incident to a physicians professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills;". MCM 2050.1 further states "incident to a physicians professional service means that the services or supplies are furnished as an integral, although incidental, part of the physicians personal professional services..." Therefore, this provision is intended to cover incidental supplies used by the physician in providing a professional service, but not intended for ongoing use by the patient or caregiver at home.

Based on the above findings, we have reconsidered the benefit category determination for the Pleurx Pleural Catheter and Pleurx Drainage Kit. The Pleurx Pleural Catheter falls under the prosthetic device benefit category and specific components of the Pleurx Drainage Kit would then be categorized as accessories to the prosthetic device.

We have made this determination on the basis of the following findings:

- The Pleurx Pleural Catheter and drainage kit are indicated for intermittent, long term drainage of symptomatic, recurrent, pleural effusion and other recurrent effusions that do not respond to medical management of the underlying disease. The pleural and other effusions result from the malfunction of the pleura and its inability to maintain a sealed lining around the lung and prevent fluid build-up. These items are used for 1) the palliation of dyspnea due to pleural effusion and 2) for providing pleurodesis (resolution of the pleural effusion). The Pleurx Pleural Catheter is for single use only and inserted in the patient in a hospital operating room or hospital procedure room. Once the catheter is in place, fluid is evacuated from the pleural space. A sterile dressing is applied after the fluid has been evacuated and the patient can then be discharged from the hospital when the physician determines that the patient is stable. Once the patient is at home, components of the Pleurx Drainage Kit are used to collect the pleural fluid and is obtained directly from a supplier, but only when prescribed by a physician.

- Section 1861 (s)(8) of the Social Security Act defines a prosthetic as a device that replaces all or part of an internal body organ. The Medicare Carriers Manual at section 2130 further extends this definition by stating that, "Prosthetic Devices which replace all or part of an internal body organ, or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ are covered when furnished on a physician's order." Because the Pleurx Pleural Catheter replaces the malfunctioning pleura (an internal body organ) by artificially draining the pleura, it meets the definition of a prosthetic device.

- The vacuum drainage bottle and tubing, gauze, gloves and the wound clamp and cup would be considered as accessories to the prosthetic device (Pleurx Pleural Catheter). In addition, those components of the Drainage Kit may be covered as nonroutine medical supplies under the home health benefit. Under section 206.4 of the Home Health Agency Manual, non-routine medical supplies are covered to treat a patient's specific illness or injury in accordance with the physician's plan of care. The physician must specifically order non-routine supplies or the physician's order for services must require the use of the specific supplies to be effectively furnished. If the patient is in a Skilled Nursing Facility (SNF), then these supplies would be included as supplies provided by the SNF.

If you have any questions concerning the revised benefit category determination, please contact Lynn Riley at (410) 786-1286.

Thomas E. Hoyer

cc: Dr. Paul Hughes, Tricenturion
Dr. Adrian Olcik, DMERC Region B
Dr. Robert Hoover, DMERC Region D
Dr. Mike Nelson, SADMERC

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**

e. **Be evidence-based and appropriately risk-adjusted and achieve reasonable norms of reliability and validity testing as appropriate for the type of measure**

A Pay-for-Performance system should:

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

b. **Compensate providers that demonstrate improvement as well as top performers**

c. **Facilitate relief from current data collection requirements and administrative burdens and costs**

d. **Ensure that financial incentives are provided for the adoption of technology**

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**

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Coloplast

MEMORANDUM

TO: RANDY THRONDSET

FROM: JOHN ANDERSON, GLOBAL DIRECTOR OF MARKETING COLOPLAST

SUBJECT: PROSPECTIVE PAYMENT CATHETER POLICY

DATE: 9/22/2006

CC: CAROL BLACKFORD

Dear Mr. Throndset,

Thank you for the opportunity to comment on the prospective payment system and consolidated billing with regards to the specialty urological product, A 4353 code.

As a manufacturer of urological products billed under this code, our dealers have experienced significant difficulty in providing continuous supplies to their patients. We ourselves do not sell directly to end users (patients); we only sell through our distribution network that has been chosen based on size of a business, credit worthiness, time etc. These products cannot be purchased directly from Coloplast (formally Mentor Urology) a manufacturer.

We have a large network of dealers that carry our products; however, it is a smaller number that carry our full line of specialty products billed under the HCPCS A4353 code.

Moreover, these products are prescription specific. The prescription includes three different requirements. They include the length of the catheter (6, 10 or 16 inches), the diameter or French size (6-20 French), and firmness of the catheter, (soft, coated firm). Because there are so many types of patients, (young, old, male, female, etc) there are many specialty products that are in limited distribution. It would not be practical for visiting nurses to have even half of these products in stock. We rarely receive calls from Home Health Agencies to obtain the specialty items that patients require. More often, dealers complain the patient stops receiving their necessary supplies.

I would like to thank you for the opportunity to offer my input as a manufacturer of these specialty items. I am pleased to hear that this issue is being looked at and that these "at risk" patients' status will be rectified. I offer to meet with you to further clarify and to further demonstrate the intricacy of this product, closed system catheter, A4353.

Sincerely,

John Anderson
Global Director of Marketing
Coloplast Corporation
(805) 879-6788

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LATHAM & WATKINS LLP

SEP 25 2006

September 25, 2006

BY HAND DELIVERY

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

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"—COMMENTS ON "PROVISIONS OF THE PROPOSED REGULATIONS"

Dear Administrator McClellan:

On behalf of our client, Rotech Healthcare Inc. ("Rotech" or the "Company"), we submit these comments on the proposed rule to implement certain provisions of the Deficit Reduction Act of 2005 ("DRA") regarding Medicare reimbursement for oxygen equipment and capped rental durable medical equipment ("DME").[1] Rotech is concerned about a number of the proposed revisions and appreciates the opportunity to offer its comments and recommendations.

Rotech provides a wide range of respiratory therapy equipment, including oxygen concentrators, liquid oxygen systems, portable oxygen systems, ventilator therapy systems, nebulizer equipment, and sleep disorder breathing therapy systems, for rental or sale. The Company's principal customers are older patients with breathing disorders, such as chronic obstructive pulmonary diseases, chronic bronchitis, emphysema, obstructive sleep apnea and other cardiopulmonary disorders. As such, the Company has a considerable interest in ensuring that the continued needs of its customers are met.

We recognize that the agency's proposed rule seeks to implement major changes to how the Centers for Medicare and Medicaid Services ("CMS") pays for oxygen equipment and capped rental DME supplied to Medicare beneficiaries. Specifically, CMS seeks to implement changes prescribed by section 5101 of the DRA, requiring that the beneficiary take ownership of oxygen equipment after a continuous rental period of 36 months.[2] For beneficiaries receiving

[1] *See* 71 Fed. Reg. 44082 (Aug. 3, 2006) (proposed oxygen provisions to be codified at 42 C.F.R. pt. 414).

[2] *See* Deficit Reduction Act of 2005, § 5101(b), Pub. L. No. 109-171 (Jan. 8, 2006).

oxygen equipment on December 31, 2005, the 36-month rental period began on January 1, 2006. For beneficiaries who began to rent oxygen equipment on or after January 1, 2006, the 36-month rental period commences at the time they begin to rent the equipment.[3]

What is most concerning to Rotech is that in conjunction with implementing the DRA's mandates to cap rental periods, CMS has proposed to amend reimbursement levels for oxygen and oxygen equipment and to promulgate rules regarding repair and maintenance in a manner that ignores the fact that companies like Rotech supply not only oxygen, but a whole host of other services and supplies that are required by manufacturers and accrediting bodies and are necessary for patient safety. CMS's proposed monthly payments for oxygen contents are so low that they will be insufficient to cover the cost of delivery of the oxygen, not to mention the cost of regular maintenance or the provision of necessary supplies. Because a supplier is required under the proposal to continue to furnish oxygen for the period of medical necessity at such dramatically lower payment rates, CMS has essentially required that suppliers provide beneficiaries with free goods and services for as long as they require oxygen. By requiring suppliers to provide oxygen, supplies and regular maintenance, and by not paying suppliers sufficiently in return, CMS's proposed reimbursement structure would deter suppliers from furnishing oxygen to beneficiaries and, worse, might restrict beneficiary access to oxygen.

Accordingly, Rotech offers the following comments and recommendations for CMS's consideration:

(1) **Do not implement proposed reimbursement cuts for oxygen contents that are not budget neutral.** Although CMS specifically notes in the preamble to the proposed rule that it is prohibited from creating separate classes of payment for oxygen unless any such change is "budget neutral," the agency's proposed cuts in reimbursement threaten not to be budget neutral. Rotech urges the agency to refrain from implementing the changes. In the alternative, the Company suggests that CMS (1) work with the oxygen industry to develop payment levels that attain budget neutrality and (2) upwardly adjust the monthly payment for portable oxygen equipment and contents.

(2) **Include the cost of required maintenance and supplies in the monthly reimbursement of oxygen after title transfers.** If CMS does implement its proposed changes to reimbursement, it should take into account certain implications of the oxygen industry. For instance, reimbursement amounts need to cover the costs of (1) required monthly maintenance of oxygen equipment, and (2) supplies dispensed in conjunction with oxygen therapy (*e.g.*, masks, tubes, filters and humidifier bottles) that are necessary for the oxygen equipment to properly function and for patient safety. As drafted, for as long as a beneficiary requires oxygen, suppliers would be required to provide such maintenance services and replacements of necessary supplies for free. The result for beneficiaries will be a reduction in the number of suppliers that furnish oxygen

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[3] *See* 71 Fed. Reg. at 44093.

and an overall restriction in available oxygen.

(3) **Provide more explanation for its proposed reimbursement amounts.** CMS has not provided adequate justifications for its decision to apportion 65% of the $156 payment for oxygen contents to stationary oxygen contents and 35% of the payment to portable oxygen contents. As such, it is difficult for affected entities to comment on this proposal.

(4) **Do not require suppliers to transfer title to oxygen tanks to beneficiaries.** CMS should also consider revisiting the proposed requirement that title to oxygen tanks will transfer to beneficiaries. This proposal creates an unnecessary burden on suppliers to keep track of thousands of tanks, virtually all of which are interchangeable and identical.

(5) **Revisit the 60% threshold for determining when a supplier must replace oxygen equipment.** CMS should not adopt its proposal that a supplier be required to replace equipment once accumulated repair costs exceed 60% of the cost to replace the equipment. CMS explains that the 60% threshold is based on a similar provision for artificial limbs. But, the two products are not comparable in that an artificial limb, unlike oxygen equipment, does not require regular servicing and maintenance. In addition, whereas oxygen equipment requires a host of additional supplies in order to properly function, artificial limbs do not. CMS has also not defined "replacement cost" and how such cost would be calculated.

(6) **Account for situations in which the supplier does not hold title to the oxygen equipment.** CMS should acknowledge in its policies those situations in which title is not held by a supplier that rents oxygen equipment to beneficiaries. It is common practice for a supplier to rent equipment from a manufacturer and never itself hold title to the equipment.

(7) **Take into consideration situations in which beneficiaries fail to pay required deductibles and copayments.** Under the proposal, oxygen suppliers are required to transfer the title of oxygen equipment to beneficiaries, regardless of whether they have paid required deductibles and copayments. Rotech believes that CMS should consider adopting special policies for discrete situations, including those where beneficiaries fail to make coinsurance payments under Part B.

(8) **Provide limits to a beneficiary's ability to switch suppliers.** CMS should impose restrictions on a beneficiary's ability to switch suppliers at will in order to prohibit beneficiaries from "shopping around" and delaying the start of the beneficiary ownership period. The Company suggests that CMS clarify that a new 36-month rental period begin each time a beneficiary switches suppliers or relocates. In conjunction with this rule, CMS should also impose safeguards (for instance, limits on the number of times a beneficiary can switch suppliers) that prevent beneficiaries from gaming the system.

(9) **Loosen the requirement regarding published assignment information.** CMS should not adopt its proposal to post assignment statistics for each supplier on its website. If it decides to proceed with publication, CMS should coordinate this effort with suppliers to ensure correct information is distributed to the public.

(10) **Do not implement the agency's proposed reimbursement changes at this time.** The oxygen industry has already been subjected to a variety of significant price cuts, and CMS should allow sufficient time to assess whether these cuts result in cost savings, which would eliminate the need for further payment adjustments.

Below are more detailed explanations of each of the Company's comments.

I. CMS SHOULD NOT IMPLEMENT ANY CHANGES TO PAYMENT RATES WITHOUT FURTHER ASSURANCES OF BUDGET NEUTRALITY.

Payment for Oxygen Contents for Beneficiary-Owned Oxygen Equipment; Classes of Oxygen and Oxygen Equipment

Rotech urges the agency not to implement its proposed oxygen payment rates because they do not adequately account for budget neutrality. CMS is expressly prohibited from establishing new, separate payment rates for classes of oxygen and oxygen equipment if these new payment rates result in expenditures that are more or less than the expenditures that would have been made if such actions had not been taken.[4] In fact, in the preamble to the proposed rule, the agency specifically notes its intention to be budget neutral in cutting monthly reimbursement for oxygen.[5] In the alternative, CMS should work with the oxygen industry to ensure that payment levels are budget neutral.

1. *CMS Proposal*

In the proposed rulemaking, CMS has indicated that Medicare beneficiaries generally use four categories of oxygen systems:

- 69% of beneficiaries use both a stationary concentrator and a portable system that requires delivery of oxygen;
- 5% use a stationary system that requires delivery of oxygen and a portable system that requires delivery of oxygen;
- 24% use a stationary concentrator only; and

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4 *See* 42 U.S.C. § 1395m(9)(D) (2006).

5 *See* 71 Fed. Reg. at 44104.

- 2% use only a stationary system that requires delivery of oxygen.[6]

Medicare currently makes two separate payments for beneficiaries who use both stationary and portable systems during the rental period: (1) a "stationary payment" for the rental of stationary equipment, delivery of stationary oxygen contents and delivery of portable oxygen contents and (2) a separate add-on payment for the portable equipment.[7] CMS also makes monthly payments during the period of beneficiary ownership for (1) stationary and portable oxygen contents together (for beneficiaries who use both stationary and portable equipment or stationary equipment alone) and (2) portable oxygen contents (for beneficiaries who use portable equipment alone).[8] The current average monthly payment amounts are as follows: (1) $199 for stationary equipment and contents; (2) $32 for portable add-on; (3) $156 for stationary and portable oxygen contents; and (4) $21 for portable contents only.

CMS proposes to establish a new class and monthly payment amount for oxygen-generating portable oxygen equipment (*i.e.*, portable concentrators).[9] CMS proposes a higher monthly payment amount ($64) in lieu of the regular $32 portable add-on to account for increased costs to the supplier of furnishing the more expensive portable concentrator systems.[10] CMS selects $64 as a monthly payment amount based on the agency's calculations of long-term savings stemming from the fact that portable concentrator equipment will not require the proposed $55 monthly payment for portable oxygen contents.

CMS also proposes to segregate the monthly payment amount for oxygen contents into two categories: one payment for stationary oxygen contents for beneficiary-owned equipment and one payment for portable oxygen contents for beneficiary-owned equipment.[11] Currently, the combined average monthly payment amount of $156 for furnishing oxygen contents for beneficiary-owned stationary and portable systems includes payment for both stationary contents and portable contents. This combined payment results in Medicare reimbursement of portable oxygen contents, even when the beneficiary does not use portable oxygen equipment. The CMS proposal would split the $156 payment into a $101 payment for stationary oxygen contents and a $55 payment for portable oxygen contents. CMS indicates that it proposed a higher rate ($101 or 65% of $156) for stationary oxygen contents because stationary equipment requires delivery of larger, heavier oxygen cylinders or vessels—a more difficult, time-consuming, laborious and fuel-consuming task than delivery of smaller portable oxygen cylinders. Payment for the portable oxygen would be at a lower rate ($55 or 35% of $156).[12]

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6 *See id.* at 44095.

7 *See id.*

8 *See id.*

9 *See id.* at 44096.

10 *See id.*

11 *See id.*

12 *See id.* at 44096-97.

In addition, the agency intends to reduce the current monthly payment amount for stationary oxygen equipment and content during the rental period from $199 to $177.[13] CMS indicates that this cut was planned to attain budget neutrality. CMS believes that the reduction in the stationary payment is needed to offset the increased payments for the other changes.[14]

2. *Rotech Comments and Recommendations*

Rotech believes that CMS's proposed payment classes and payment amounts will not achieve budget neutrality as mandated by Congress and contemplated by CMS. The Company's understanding of industry analyses is that Medicare expenditures under the proposed reimbursement structure would differ markedly from expenditures under the current structure.[15] Because CMS cannot establish new, separate payment rates for classes of oxygen and oxygen equipment if these payment rates result in Medicare expenditures that are more or less than the expenditures which would have been made if such actions had not been taken, the agency should proceed cautiously with this life-sustaining benefit.[16] As such, Rotech urges CMS not to implement its proposed changes to oxygen reimbursement.

In the alternative, if CMS does decide to revise classes of products and implement reduced payment levels, the agency should recalculate Medicare expenditures under the new plan and develop payment rates that are truly budget neutral. Most critically, as noted above, CMS proposes to eliminate the joint stationary and portable payment and to create one monthly payment for stationary oxygen and one monthly payment for portable oxygen. To do this, CMS intends to split the $156 joint payment into a $101 payment for stationary oxygen contents and a $55 payment for portable oxygen contents. Rotech believes that this and other adjustments should be made in consultation with industry experience and only after detailed data is obtained for costs of all services at issue are obtained.

In addition, if CMS recalculates Medicare expenditures under the new plan and determines that an upward adjustment in payment levels is needed to attain true budget neutrality, Rotech contends that any such adjustment in payment levels should, at minimum, be made to the proposed payment rates for monthly portable oxygen equipment and contents (both during and subsequent to the capped rental period). The Company believes that any new payment level—even if, for example, derived by splitting the joint payment for both stationary and portable contents as has been proposed by the agency—must consider the economies

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13 *See id.* at 44097.

14 *See id.*

15 In addition, it appears that CMS's assumptions about Medicare expenditures on oxygen do not correlate with industry experience and require reassessment. For example, in its Regulatory Impact Analysis, the agency notes that current Medicare monthly payment rates for oxygen are significantly higher than the average payment made by the largest medical center operated by the U.S. Department of Veterans Affairs ("VA"). *See id.* at 44104 (noting an average per-patient Medicare payment of $7,164 over 5 years and an average VA payment of $1,435 over 5 years). As a large contractor with the VA, however, Rotech has considerable data and experience showing that VA payments for oxygen have been consistently greater than Medicare payments on a per-patient basis.

16 *See* 42 U.S.C. § 1395m(9)(D).

achieved by deliveries of both stationary and portable oxygen. Further, supporting the trend towards greater beneficiary usage of portable equipment serves to benefit beneficiaries' ability to live more independently. As described further below, the proposed rates are insufficient for continued necessary regular maintenance and servicing, replacement of supplies or the delivery of oxygen to beneficiaries. In fact, based on the proposed low rates in conjunction with the fact that suppliers are now required to furnish oxygen to beneficiaries for the period of medical necessity, CMS is essentially requiring that suppliers furnish tank after tank of free portable oxygen to beneficiaries. To avoid this inequitable result, Rotech strongly urges that any amounts to be added to attain budget neutrality should be added to the portable oxygen payment.

II. IF CMS DOES IMPLEMENT THE PROPOSED CHANGES TO PAYMENT AMOUNTS FOR OXYGEN EQUIPMENT, THE AGENCY SHOULD ADJUST ITS FINAL RULE TO ACCOUNT FOR IMPLICATIONS ON THE OXYGEN INDUSTRY.

Payment for Oxygen, Oxygen Equipment and Capped Rental DME

A. CMS payment levels should account for required maintenance of oxygen equipment and for supplies provided to beneficiaries in conjunction with oxygen therapy.

CMS's proposed monthly payment—$55 for portable oxygen contents and $101 for stationary oxygen contents—during the period of beneficiary ownership does not account for most of the costs associated with home oxygen therapy. Specifically, the agency does not account for (1) regular maintenance required by manufacturer guidelines and accreditation organizations or (2) the ongoing replacement of supplies used with oxygen equipment. As currently drafted, the proposed rule mandates that oxygen suppliers furnish free regular maintenance and replace supplies at virtually no charge. Suppliers of equipment that use oxygen concentrators will not receive any monthly payment for maintenance or supplies after title transfers; however, they will still be required to perform regular maintenance. CMS has proposed a reimbursement structure that does not reimburse suppliers for their services once beneficiaries own the equipment. Oxygen suppliers face a difficult decision—provide oxygen, maintenance and supplies for nothing or withdraw from the program altogether. Unfortunately, most suppliers will choose to withdraw rather than to go unpaid, and Medicare beneficiaries might have their ability to obtain oxygen supplies reduced substantially.

Clearly, these are unintended consequences of the proposal. CMS should provide payments sufficient to cover the costs of the mandatory services and supplies in addition to the monthly oxygen content payment. We propose that the agency either consult with the oxygen industry to assess the actual costs of maintenance and servicing of equipment or develop a study in conjunction with the industry that would provide data on maintenance and servicing costs, or both.

1. *Comments and Recommendations Regarding Maintenance*

It cannot be overstated that the total cost of providing oxygen therapy in the home includes more than the cost of equipment and the cost of oxygen contents. Suppliers also

perform patient intake, preparation and delivery, scheduled and unscheduled maintenance, patient assessment, training and education, ongoing patient support (including costs associated with oxygen fills, disposable supply items and delivery).[17] In particular, oxygen suppliers like Rotech must perform regular servicing and maintenance on oxygen equipment, such as changing filters and checking oxygen levels being dispersed to the patient. For Rotech and other oxygen suppliers, this regular maintenance takes place in the patient's home, on average, every 90 days.

This regular maintenance is required by manufacturer warranties and guidelines. Many manufacturers of products supplied by Rotech require the Company to make the following maintenance and service checks every 90 days:

- Check exterior for damage and cleanliness,
- Check hours and compare to manufacturer's recommendations for compressor preventative maintenance,
- Check flow meter for accuracy,
- Check oxygen concentration,
- Check internal and exterior filters,
- Ensure that alarms are activated with appropriate settings and are sufficiently audible with respect to distances and competing noise within the unit or home environment, and
- Perform any additional requirements.

Annually, manufacturers require Rotech to check and clean the interior of the device of dust or debris. Manufacturers also require the Company to perform maintenance every 5,000 hours, which includes replacement of filters and checking of compression in addition to interior cleaning of the device. This type of maintenance, which requires disassembly of the device, must be performed at the supplier's facility and not in the patient's home. To provide this maintenance, the supplier incurs the additional costs of picking up equipment and providing loaner equipment.

Regular maintenance is also required by industry accreditation standards. Specifically:

- The Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") requires that an oxygen supplier plan for the effective selection, delivery, setup and maintenance of equipment provided to patients. This includes: (1) selecting and acquiring equipment; (2) delivering equipment; (3) setting up equipment;

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[17] *See* Morrison Informatics, Inc., *A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy* (June 27, 2006), *available at* http://www.aahomecare.org/associations/3208/files/Morrison%20Oxygen%20Cost%20Study%20Report%20June%2027%202006.pdf.

(4) maintaining equipment; (5) providing an appropriate backup system; (6) appropriately receiving and storing equipment; (7) monitoring and acting on equipment hazard notices and recalls, including notifying patients, staff and prescribing physicians as appropriate; (8) monitoring and reporting incidents in which a medical device is connected to the death, serious injury, or serious illness of any individual, as required by the Safe Medical Devices Act of 1990; and (9) reporting within the organization and investigating equipment management problems, failures and user errors.

- JCAHO also requires that medical equipment be maintained, tested and inspected by: (1) performing routine and preventive maintenance at defined intervals and according to manufacturers' guidelines; (2) inspecting all medical equipment between patient uses; and (3) doing basic safety, operational and functional checks on equipment according to organization policy and manufacturers' guidelines.[18]

In addition, maintenance and servicing requires that the Company incur additional administrative and overhead costs. Supplying oxygen does not simply involve collecting tanks, filling them and delivering them. Rotech and other oxygen suppliers must take the following actions to be able to supply oxygen: (1) maintain all Federal, state and local licensure and permits to supply oxygen, (2) maintain a Medicare supplier number, (3) maintain the proper equipment inventory to fill orders on an expeditious basis, (4) maintain an adequate inventory of repair parts and disposable supplies for equipment, (5) incur freight and postage costs, (6) maintain appropriate physical facility space, (7) create and distribute appropriate signage and safety instructions at the facility, (8) operate telephone lines and answering services to provide after-hours accessibility, (9) maintain liability insurance, (10) purchase or lease general office equipment and supplies, (11) purchase or lease vehicles for delivery, (12) fuel delivery vehicles, (13) maintain computer systems and suppliers, (14) oversee and supervise employees in a variety of fields (e.g., management, billing, clinical, patient service technicians, customer service representatives, etc.), (15) pay for and maintain employee insurance (e.g., Group Health, Worker's Compensation, etc.), (16) make payroll taxes and pension contributions, (17) train employees and (18) pay for clinical employees' licensure fees. This extensive list of overhead costs does not address every facet of the oxygen supply business that a supplier like Rotech must take into consideration and pay for in order to keep furnishing oxygen to Medicare beneficiaries. The virtual lack of reimbursement by Medicare means that suppliers like Rotech cannot offset their administrative costs of doing business, making it even more difficult to continue supplying beneficiaries.

There is also another practical problem with CMS's proposed rule. The agency has noted that it expects beneficiaries and caregivers to perform routine maintenance, "such as testing, cleaning, regulating, changing filters and general inspection."[19] CMS states that "the beneficiary

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[18] *See generally* Joint Commission on Accreditation of Healthcare Organizations, *Patient Equipment Management Standards.*

[19] 71 Fed. Reg. at 44099.

and/or caregiver should be very knowledgeable regarding the routine maintenance required for the item."[20] The Company believes that CMS should reassess these assumptions for several reasons. First, suppliers are in a better position than beneficiaries to take care of routine maintenance—suppliers deal with this equipment on a routine basis and have the expertise and resources to provide quality maintenance in an expeditious manner. Second, maintenance frequently requires disassembling and reassembling the equipment and such procedures can only take place in the supplier's facility. This means a disruption in oxygen service for the beneficiary. It is safer for the beneficiary if the supplier—i.e., the maintenance expert—perform the necessary servicing, thereby keeping the period of disruption to a minimum.

Finally, and most importantly, it is simply unsafe to transfer the responsibility for maintenance and servicing to oxygen-dependent beneficiaries, as CMS suggests. Many of these services require moving or opening of the equipment—strenuous activities for weak, oxygen-needy patients. Rotech cannot emphasize strongly enough its patients' conditions. The Company's patients lack the capacity to take on even the smallest of tasks. Many are so vulnerable that they can barely get out of bed, let alone drive to an oxygen supplier to drop off equipment for servicing or perform the physically exerting maintenance themselves. Although some of Rotech's patients have caregivers, in many instances these caregivers are elderly spouses and are just as sick as the patients. For these reasons, CMS should recognize that it is simply unsafe to impose the responsibility for maintaining this equipment on beneficiaries.

Because suppliers must furnish regular maintenance pursuant to industry accreditation requirements and manufacturer guidelines and for the safety of its patients, Rotech urges CMS to amend the monthly payment to cover such services. As noted above, the proposed payment methodology for oxygen—$55 or $101 per month for portable and stationary oxygen contents, respectively—cannot cover regular maintenance. More troubling is that suppliers do not receive any monthly payment for oxygen concentrators, yet they are still required to provide these maintenance services.[21] The proposed oxygen reimbursement structure, therefore, simply does not sufficiently reimburse oxygen suppliers. Furthermore, by requiring suppliers to provide oxygen for the period of medical necessity, the agency's proposed rule essentially imposes a requirement for free services to be provided to Medicare beneficiaries indefinitely. Should these *de facto* requirements take effect, suppliers may choose to withdraw from the program, limiting beneficiary access to oxygen. Rotech therefore urges CMS not to reduce current reimbursement levels.

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20 *Id.*

21 The need for appropriate payments for the services was recognized in the recently-released report on home oxygen therapy by the Office of Inspector General ("OIG"). The OIG acknowledges that its study on additional cost savings if the oxygen concentrator capped rental period is 13 months has not accounted for maintenance and servicing payments. According to the OIG, accounting for these factors would "likely result in lower savings than our estimate." *See* U.S. Department of Health & Human Services, Office of Inspector General, Medicare Home Oxygen Equipment: Cost and Servicing, Report No. OEI-09-04-00420, at 15 (September 2006).

2. *Comments and Recommendations Regarding Supplies*

In addition to the ongoing maintenance of oxygen equipment, oxygen suppliers must also furnish beneficiaries with supplies necessary to make the equipment function. In particular, a supplier must provide a beneficiary with new tubing every month and new oxygen masks, if applicable, every 2-3 months. Humidifier bottles, if applicable, also require changing each month. This regular supply replacement schedule—which is above and beyond the actual furnishing of oxygen contents—is necessary for patient safety and to avoid infection.

Here as well, the proposed rule fails to account for the costs incurred for the supplies and the delivery of the supplies. The proposed rule requires the $55 or $101 monthly payment for oxygen to be stretched to cover not only the oxygen itself, but the supplies needed to deliver the oxygen to the patient. For oxygen systems with concentrators, suppliers would receive no payment for these supplies. Again, the low payment rates in conjunction with the requirement that the supplier furnish oxygen for the period of medical necessity serve to create a *de facto* mandate that suppliers furnish filters, masks, tubes, and humidifier bottles free of charge to beneficiaries for an unlimited period of time. It is inappropriate to require companies like Rotech to provide these necessary supplies to beneficiaries and not pay for them.

CMS should revisit its analysis of what is being provided to beneficiaries both during and after the capped rental periods and ensure adequate payment for these supplies. If it does not, Medicare suppliers may no longer be able to service this population, and Medicare beneficiaries will be in jeopardy of losing access to oxygen.

B. The agency's proposed payment rates for oxygen contents do not even cover the cost of gas used to fuel oxygen delivery trucks.

Rotech is also troubled by the agency's proposal because it does not appropriately and fully account for the cost of delivering oxygen contents in creating the $55 and $101 monthly payments. Specifically, CMS has assumed that, once title transfers, a beneficiary will own two sets of tanks and that these very tanks will be refilled once every month.[22] In fact, Rotech—and other oxygen suppliers—furnish oxygen as needed by the patient and not according to a set monthly schedule. This means multiple trips to many patients' homes per week to furnish many more than two sets of oxygen tanks. The $55 and $101 payments do not cover the cost of these multiple deliveries and are so minimal that they translate to free delivery of oxygen. Unfortunately, CMS's proposed payment levels will act as a deterrent to the industry and therefore run the risk of depleting the pool of oxygen suppliers available to service Medicare beneficiaries, particularly those residing in rural areas.

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22 *See* 71 Fed. Reg. at 44095. Here CMS states, "Customary practice by suppliers for refilling oxygen contents is to deliver to the beneficiary cylinders filled with contents and take back the empty cylinders to the supplier's place of business to refill the oxygen contents. Under [the agency's] proposal, title would transfer for *both* sets of cylinders, *meaning the ones that are being used by the beneficiary for the month and the ones that the supplier refills in its business location and delivers for use during the next subsequent month.*" (emphasis added).

Although CMS indicates that it will consider the cost of delivery in calculating reimbursement levels for oxygen contents,[23] the agency has based its considerations on an underestimate of the level of oxygen consumed by patients. Beneficiaries use anywhere from 2 to 10 or more tanks of oxygen *per week*, and Rotech and other oxygen suppliers are required to maintain enough oxygen in the home as is medically necessary.[24] When a patient needs oxygen, he or she calls the Company, and the Company delivers the oxygen. This means that a Medicare beneficiary could (and, in most cases does) go through *more than* two sets of cylinders in a week. Accordingly, the Company frequently makes more than one delivery per patient per week. Not only does this go beyond CMS's contemplated two-cylinder model, but the cost of the Company's delivery—personnel wages, oxygen refilling costs, and fuel—for one week's worth of oxygen is not covered by the $55 or $101 payments, which are designed to cover the Company for the entire month for one patient.

In sum, the monthly payment—which must cover regular maintenance and servicing, overhead and supplies—must also be stretched further to cover the cost of delivery. Frankly, the payment cannot stretch this far. The effect is a CMS directive that oxygen suppliers provide free delivery of oxygen to beneficiaries. This is an inequitable result.

Rotech suggests that CMS delay setting new rates until it has gathered sufficient data to identify the costs of oxygen services—both during and after the capped rental period. This can be accomplished, for example, through a study to determine the monthly average consumption of oxygen contents among Medicare beneficiaries. A methodology may be adopted to address payments for outliers. Because the first title transfers for oxygen equipment are not slated to take place until January 1, 2009, CMS has ample time to conduct such a study.

Rotech also suggests that CMS consider establishing a delivery fee for each time a supplier delivers oxygen. As proposed and as noted above, the $55 or $101 per month payments will not even cover the cost of gas—let alone the items being delivered. The U.S. Department of Health and Human Services Office of Inspector General ("OIG") has even recently noted that the monthly payment for "contents . . . does not vary based on the amount of oxygen a beneficiary requires" and that "[t]his payment may not adequately reimburse suppliers" for refills and "related services" once a beneficiary takes title to the equipment.[25] Such low reimbursement levels act to deter suppliers from continuing operating in the oxygen industry, thereby diminishing beneficiary access to oxygen—particularly in rural areas. The ultimate unintended result is a greatly reduced supply of oxygen to Medicare beneficiaries. A delivery fee would

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23 *See id.* at 44097.

24 Rotech's experience with oxygen delivery differs significantly from the OIG's findings in its recently released report on home oxygen therapy. In particular, the Company delivers multiple tanks of oxygen each week to a substantial number of beneficiaries. Rotech believes that the OIG's findings that "[s]uppliers deliver cylinders *once every 3 months*" and that "[a]mong beneficiaries who rented concentrators for 1 year or more, 65 percent received *two or fewer cylinders from their suppliers in the first year of rental*" is off the mark and inconsistent with industry experience. *See* U.S. Department of Health & Human Services, Office of Inspector General, Medicare Home Oxygen Equipment: Cost and Servicing, Report No. OEI-09-04-00420, at 12 (emphasis added).

25 *See id.* at 14 (specifically referencing the monthly payment for portable oxygen contents).

help to offset these costs and compensate suppliers for their services.

III. THE AGENCY SHOULD PROVIDE A MORE DETAILED JUSTIFICATION FOR ITS PROPOSED REIMBURSEMENT CUTS.

In addition to the proposed monthly payment for oxygen not covering maintenance, supplies or delivery, CMS has not provided adequate notice for affected entities to comment fully on its decision to split the $156 payment for oxygen contents into two separate payments. Specifically, in splitting the $156 payment for both stationary and portable oxygen contents, CMS proposes to apportion 65% of the payment (or approximately $101) to stationary oxygen contents and 35% of the payment (or approximately $55) to portable oxygen contents. It is unclear how CMS decided to use a 65/35 split. The agency does note:

> The 65/35 split is based on our understanding that there are higher costs associated with delivering stationary tanks (cylinders of gaseous oxygen and vessels of liquid oxygen) which are approximately twice as large as the portable tanks. Such costs include supplier overhead costs, including the costs to purchase, maintain, and dispatch trucks, obtain insurance, and purchase fuel. The 65/35 split is intended to account for the difference in costs associated with the size of the tanks. Larger tanks take up more space on the trucks, take longer to fill, are harder to move, and result in increased fuel costs.[26]

CMS does not quantify, however, the higher costs of stationary tank delivery and how these higher costs warrant 65% of the $156 combined oxygen payment. Accordingly, the 65/35 split appears to be selected arbitrarily. Rotech submits that the result is an inadequate basis on which affected parties can provide comments that are useful to the agency.

IV. TITLE TO OXYGEN TANKS SHOULD NOT TRANSFER TO BENEFICIARIES.

Payment for Oxygen, Oxygen Equipment and Capped Rental DME

CMS proposes that, during the rental period, a supplier cannot provide different equipment from that which was initially furnished to the beneficiary.[27] Different equipment can be provided if one of the following exceptions applies: (1) the equipment is lost, stolen, or irreparably damaged; (2) the equipment is being repaired while loaner equipment is in use; (3) there is a change in the beneficiary's medical condition such that the equipment initially furnished is no longer appropriate or medically necessary; or (4) the carrier determines that a change in equipment is warranted.[28] The Company urges the agency to reconsider this proposal or to add an exception for oxygen cylinders and vessels.

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26 71 Fed. Reg. at 44097.

27 *See id.* at 44094.

28 *See id.*

Transferring title to oxygen tanks is impracticable and contrary to industry practice. As it currently works, when Rotech or another oxygen supplier receives a call from a patient in need of oxygen, the delivery personnel take full cylinders from inventory and deliver them to the patient's home, where they pick up the empty cylinders and return them to inventory. Indeed, these cylinders are, for the most part, completely interchangeable. Under the proposal, a supplier would be required to use the exact same cylinders for each beneficiary and to track the cylinders at a supplier's refilling warehouse, where the cylinders of hundreds or thousands of other beneficiaries' identical, completely fungible tanks are stored and awaiting refilling. This is an overly burdensome and unnecessary process. So long as a beneficiary has access to oxygen—a current supply and refills—there is no need for the beneficiary to "own" or have an interest in any particular cylinders. Consequently, we ask that the agency revise its proposal to address this issue.

V. CMS SHOULD RECONSIDER ITS PROPOSAL THAT A SUPPLIER REPLACE BENEFICIARY-OWNED EQUIPMENT IF THE COSTS OF REPAIRS EXCEED 60% OF THE REPLACEMENT COST OF THE ITEM.

Payment for Replacement of Beneficiary-Owned Oxygen Equipment, Capped Rental Items, and Associated Supplies and Accessories

CMS has proposed that a supplier of oxygen equipment or capped rental items would be required to replace beneficiary-owned equipment at no cost to the beneficiary or to the Medicare program if: (1) the total accumulated cost to repair the item after transfer of title to the beneficiary exceeds 60% of the "replacement cost" and (2) the item has been in continuous use for less than its reasonable useful lifetime.[29] CMS believes that this protects the beneficiary from receiving substandard equipment. CMS does note, however, that exceptions to this rule may be granted by the agency or the applicable carrier, citing the example of a supplier not being responsible for replacing an item in need of repair due to beneficiary neglect or abuse.[30]

To define "accumulated costs" of repairs, CMS uses the example of a capped rental item that can be replaced for $1,000 (the total fee schedule payments after 13 rental months) and for which title has transferred. If Medicare pays a total of $500 for 3 repairs necessary to make the item functional, and a fourth repair costing $200 is needed in order to make the item functional, the accumulated costs for repair in this case will equal $700, which exceeds $600 or 60% of the $1,000 cost to replace the item. In this example, the supplier would be required to furnish a replacement item.[31]

Rotech notes the following problems with CMS's approach. First, CMS assumes that an item is no longer useful after being subjected to numerous repairs. To the contrary, each time it is repaired, the repaired item can function as well as a brand new item. Second, by looking at the

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29 *See id.* at 44100. Medicare would not pay for the replacement of beneficiary-owned oxygen equipment or capped rental items covered by a manufacturer's or supplier's warranty.

30 *See id.*

31 *See id.*

accumulated costs of repairs, a supplier is motivated to keep its overall repair costs low. The result could be a string of cheap, quick fixes that slow repair costs from accumulating to the 60% replacement threshold rather than a potentially necessary and expensive overhaul of the equipment. The unintended consequence is Medicare beneficiaries being exposed to substandard repairs. Third, CMS indicates that it will look at "replacement cost" when determining when a replacement will be required. However, CMS does not define "replacement cost." It is unclear whether this means the original cost to Medicare of the equipment being replaced or the fair market value of the item. CMS must provide a definition for this term.

Finally, Rotech questions CMS's use of 60% of the replacement cost as the threshold for replacement. CMS notes that the 60% threshold is "consistent with the threshold repair costs that can result in the replacement of prosthetics (artificial limbs) in accordance with section 1834(h)(1)(G) of the Act."[32] The agency states that this threshold "should apply to oxygen equipment and capped rental items as well, because artificial limbs, like these items, are built to withstand repeated use."[33] Unlike artificial limbs, however, oxygen equipment has many associated supplies such as tubes, canulas, filters, and masks, among others. These items must also be regularly replaced. In addition, artificial limbs do not undergo regular maintenance every 90 days to 6 months, as oxygen equipment does. It is unclear whether the cost of replacing oxygen supplies or the cost of maintaining oxygen equipment will be included in the cumulative 60% threshold.

Rotech offers three suggestions:

- First, CMS should eliminate the 60% analysis altogether. Oxygen suppliers have an ethical obligation to their patients, who depend upon them for oxygen, to ensure that equipment works properly and safely.

- Second, CMS should look at the cost of each incident of repair rather than the accumulation of repairs. CMS appears to taking an approach similar to the concept of "totaling" a car—*i.e.*, the total cost to repair damage after a car accident is more than the total value of the car. When one "totals" a car, it occurs in a single event. Instead of looking at a number of repairs, CMS should determine whether the equipment is so damaged and so in need of repair that it is more reasonable and practical to pay for a new piece of equipment. Just as a car owner makes the same analysis after a car accident, the agency should do the same when a piece of equipment is in need of repair.

- Finally, CMS should define "cost of replacement" by using a definable value, such as fair market value or the original price of the equipment being replaced.

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32 *Id.*

33 *Id.*

VI. CMS SHOULD ADAPT ITS POLICIES REGARDING THE TRANSFER OF TITLE TO ACCOUNT FOR SITUATIONS IN WHICH A SUPPLIER DOES NOT OWN THE EQUIPMENT.

Payment for Oxygen, Oxygen Equipment and Capped Rental DME

The proposed changes are impracticable under one very prevalent scenario in the oxygen industry. Many suppliers of oxygen do not own the equipment. Instead, these suppliers lease the equipment from manufacturers and then furnish the equipment to patients, including Medicare beneficiaries. Consequently, once suppliers of such items are required to transfer title of the equipment to Medicare beneficiaries, they will not be legally permitted to do so. Only the manufacturer of the equipment—the actual owner—would be able to transfer title. The 36 month rental cap, however, fails to address this quite common problem, and the result is a *de facto* requirement that oxygen suppliers must own the oxygen equipment they rent to beneficiaries—suppliers cannot lease the equipment. We urge CMS to provide significant revisions to the regulations to account for this prevalent occurrence.

VII. CMS SHOULD ACCOUNT FOR SITUATIONS IN WHICH BENEFICIARIES HAVE FAILED TO MAKE COINSURANCE PAYMENTS.

Payment for Oxygen, Oxygen Equipment and Capped Rental DME

Rotech notes that another prevalent situation that CMS should consider in implementing the DRA's title transfer requirements is a common failure by beneficiaries to pay deductible and copayment amounts. (This does not include instances where deductibles and copayments are waived due to a beneficiary's bona fide financial hardship.) Suppliers—not to mention beneficiaries—are faced with a dilemma because they recognize that oxygen is life-sustaining and must be furnished. The inequitable result of the title transfer requirement is that suppliers must hand over equipment to beneficiaries who have neglected to pay their fair share.

Rotech believes that CMS needs to find a solution to this situation. We recommend three options. First, CMS could provide an exception to the title transfer requirement if a beneficiary has failed to pay his or her coinsurance for a significant period (such as more than 6 months) across the course of the 36-month rental period. Second, once title transfers, CMS could take responsibility for attempting to collect the amount of missed copayments from the beneficiary. Third, CMS can pay the supplier's bad debt (as is currently done for other provider types) for the amount of missed deductibles and copayments. Any of these potential solutions will alleviate the inequity of providing valuable equipment to a beneficiary when the beneficiary has not paid his or her deductible and/or coinsurance.

VIII. CMS SHOULD IMPOSE RESTRICTIONS ON BENEFICIARIES' ABILITY TO SWITCH SUPPLIERS.

Payment for Oxygen, Oxygen Equipment and Capped Rental DME

CMS has proposed a handful of exceptions to the requirement that title to oxygen equipment transfer to the beneficiary after 36 months of continuous use. These exceptions

include (1) cases where a beneficiary relocates on either a temporary or permanent basis to an area outside the normal service area of the initial supplier and (2) cases where the beneficiary chooses to obtain equipment from a different supplier, among others. In other words, if the beneficiary moves, he or she can switch suppliers. More importantly, if the beneficiary simply chooses to do so, he or she can switch suppliers. No reason is required to be provided.[34]

Rotech believes that this proposal has created a dilemma for suppliers. CMS does not indicate (1) whether a new rental agreement with a new supplier restarts a full 36-month rental period, thereby delaying the transfer of title to the beneficiary, or (2) whether the new supplier will be required to take over the rental period where the previous supplier ended. If the rental period is restarted, beneficiaries could take advantage of the exceptions to "shop around" and to perpetually delay the transfer of title from taking effect. It cannot be overlooked that many beneficiaries may not want to hold title to the equipment, which might mean responsibility for regular maintenance and service, among other obligations.

If the proposed changes require the new supplier (after the beneficiary has moved or chosen to switch suppliers) to take over the rental period where the previous supplier ended, the result is inequitable. Specifically, a supplier might be required to provide a brand new piece of equipment to a beneficiary for 10 months of the 36 months, for instance. This *de facto* diminished reimbursement could deter suppliers from offering services to Medicare beneficiaries and diminish beneficiary access to oxygen supplies.

Consequently, Rotech urges CMS to specify that a new 36-month period begin. In conjunction with this provision, CMS should also include safeguards—such as limits on the number of times a patient can switch providers—to prevent beneficiaries from gaming the system and delaying the transfer of title.

IX. CMS SHOULD NOT FINALIZE ITS PROPOSAL TO POST ASSIGNMENT STATISTICS FOR EACH SUPPLIER ON ITS WEBSITE.

Payment for Oxygen, Oxygen Equipment and Capped Rental DME Items

In its proposed rule, CMS notes that intends to post information on a CMS website indicating supplier-specific information on oxygen equipment and capped rental items. This information could include (1) the percentage of beneficiaries for whom each supplier accepted assignment during a prior period of time and (2) the percentage of cases in which the supplier accepted assignment during the beneficiary's entire rental period.[35] Although we understand that CMS wants to require disclosure of assignment information to inform the beneficiary about potential out-of-pocket payments, we would urge CMS to refrain from posting assignment information on a public website. First, CMS does not indicate how often it will make such postings and how it will verify the accuracy of its postings. Second, the result might be an inaccurate picture of a supplier's assignment history—suppliers could choose not to accept

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34 *See id.* at 44094.

35 *See id.* at 44094-95.

assignment for a variety of reasons, which a basic percentage will not demonstrate. Rotech recommends that, if CMS does intend to post such information, the agency should give suppliers 30 days notice as well as an opportunity to review information prior to posting and to correct erroneous information or identify the risks posed by erroneous information.

X. CMS SHOULD NOT IMPLEMENT FURTHER DECREASES IN REIMBURSEMENT LEVELS FOR OXYGEN AND OXYGEN EQUIPMENT WITHOUT ASSESSMENT OF THE IMPACT OF RECENT REDUCTIONS.

Payment for Oxygen Contents for Beneficiary-Owned Oxygen Equipment; Classes of Oxygen and Oxygen Equipment.

In recent years, the oxygen industry has been made subject to a variety of pricing cuts, and the agency has not allowed sufficient time to pass for the impact of these cuts to ripen. As such, it is impossible to tell what effect each of the price changes will have on the oxygen industry or on CMS's cost savings. CMS should therefore not implement its proposed changes to the oxygen reimbursement methodology.

At the outset, Rotech is concerned that CMS is proposing payment reductions without allowing sufficient time to pass after prior cuts—taken only recently—may be evaluated to determine whether such prior cuts have resulted in sufficient cost savings. The Company notes that if the proposed pricing changes for oxygen take effect, the Federal government will have sought to cut reimbursement levels for oxygen three times in as many years. Specifically, as detailed above, section 5101(b) of the DRA establishes the 36-month limit on monthly payments for stationary and portable oxygen equipment furnished on or after January 1, 2006. Monthly rental payments for affected items terminate after a period of continuous use of 36 months, at which point the supplier transfers title for the stationary and/or portable oxygen equipment to the beneficiary.[36] The cap on the rental period for oxygen alone should result in significant cost savings. Only nine months have passed since the effective date (January 1, 2006) of these caps. Because the cost savings of these caps will not be felt until January 2009 (at the earliest) for oxygen equipment, it is simply premature to subject the industry to further reimbursement decreases at this time.

In addition, section 302(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") reduces the fee schedule amounts of certain items of DME, including oxygen and oxygen equipment.[37] Under the MMA price reduction, Medicare payment amounts for oxygen are decreased by the percentage difference between the amount of payment otherwise determined for 2002 and the median amount of payment under the Federal Employee Health Benefits Program ("FEHBP"), as determined by the OIG.[38] According to an OIG report, in 2002, FEHBP median payments were approximately 12.4% less than Medicare

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36 *See* Deficit Reduction Act of 2005, § 5101(b).

37 *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-73, Section 302(c) (2003).

38 *See id.*

payments for stationary home oxygen equipment and approximately 10.8% less than Medicare payments for portable home oxygen equipment.[39] In other words, oxygen suppliers have already been subject to substantial reimbursement cuts. CMS has also noted that significant savings have been achieved through these reductions.[40]

Moreover, CMS only recently proposed the competitive acquisition program for DMEPOS, which will most likely include oxygen and oxygen equipment. This will, once more, reduce reimbursement to oxygen suppliers. Again, however, it is difficult to determine the effect of the competitive acquisition plan, which is not expected to be implemented until late 2007, on cost savings to Medicare.

Importantly, CMS does not need to take the position that it must further reduce oxygen payments at this juncture. First, the future relevance of the agency's proposed monthly payments is uncertain at best. Identical bills introduced in the U.S. House of Representatives in May and the U.S. Senate in August—both entitled the Home Oxygen Patient Protection Act of 2006[41]—seek to amend Medicare Part B to restore the pre-DRA treatment of ownership of oxygen equipment. If passed, these bills would require CMS to withdraw its proposed monthly payments for oxygen contents after title transfers, as these payments would become irrelevant if title does not transfer. Second, CMS has approximately three years to determine whether further price cuts are necessary, because the diminished monthly payments for oxygen contents will not go into effect until 2009 at the earliest. As such, there is no reason to rush the process—CMS should make a careful study of the issue over the course of the next three years before deciding to further reduce oxygen payments.

Simply put, the full impact of the 36-month cap and other recent reimbursement changes remains unknown. CMS should allow sufficient time to pass after the implementation of the DRA's 36-month rental cap, the MMA's FEHBP price reduction and the proposed competitive acquisition program to determine whether these initiatives will achieve significant savings for the Federal government without compromising beneficiary access to oxygen. Suppliers, in turn, should be afforded sufficient time to determine the full impact of these changes on their ability to continue to provide oxygen services to beneficiaries.

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39 *See* U.S. Department of Health & Human Services, Office of Inspector General, Medicare and FEHB Payment Rates for Home Oxygen Equipment, Report No. OEI-09-03-00160, at i (March 2005).

40 In the Regulatory Impact Analysis section of the proposed competitive acquisition rule, CMS recognizes that prices have fallen for certain DMEPOS suppliers, specifically pointing out the 2005 reductions in oxygen supplies. *See* 71 Fed. Reg. 25654, 25693 (May 1, 2006).

41 *See* Home Oxygen Patient Protection Act of 2006, H.R. 5513, 109th Cong. (2006); *see also* Home Oxygen Patient Protection Act of 2006, S. 3814, 109th Cong. (2006).

LATHAM&WATKINS LLP

Thank you for considering Rotech's comments regarding the agency's proposed changes to oxygen reimbursement regulations. Should you have any questions or comments, I can be reached at (202) 637-2200.

Sincerely,

Stuart S. Kurlander /MEW

Stuart S. Kurlander
Of LATHAM & WATKINS LLP

Cc: Rotech Healthcare Inc.

16M

Supporting Quality Health Care Services at Home

Via Hand Delivery and Electronic Submission

September 25, 2006

Mark McClellan, M.D., Ph.D.
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Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
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Re: Medicare Program; Home Health prospective Payment Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 (DRA)[1] Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment; Proposed Rule [CMS-1304-P] RIN 0938-AN76[2]

Dear Dr. McClellan:

The American Association for Homecare (AAHomecare) submits the following comments in response to the Centers for Medicare and Medicaid Services' (CMS') request for comments on the above captioned proposed rule. AAHomecare is the only national association representing every line of service within the homecare community. AAHomecare members include providers of oxygen equipment and therapy, providers and manufacturers of durable medical equipment (DME), prosthetics, orthotics, and supplies (collectively "DMEPOS") including rehab and assistive technologies, home health agencies, and pharmacies that provide home infusion and inhalation drug therapies to patients in their homes. Our membership reflects a cross-section of the homecare community, including national, regional, and local providers and suppliers. With approximately 800 member companies at 3,000 locations nationwide, AAHomecare and its members are committed to advancing the value of quality health care services at home.

Section 5101 of the Deficit Reduction Act of 2005 (DRA) amends the provisions of the Social Security Act (Act) governing Medicare payment for home oxygen therapy and capped rental DME. Beneficiaries who use home oxygen or rent DME now bear a

[1] Pub. L. 109 -171 (2006).
[2] 71 Fed. Reg. 44082 (August 3, 2006).

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greater burden to manage their care and coordinate service and maintenance for their medical equipment. These comments primarily address CMS' implementation of the DRA's transfer of ownership requirement for oxygen equipment.[3] The proposed rule would establish new payment amounts for different classes of oxygen equipment and specify new billing and other requirements that would apply to suppliers furnishing oxygen or capped rental equipment.

We understand the need to examine the current payment methodology for oxygen. The fee schedules result in one payment amount (plus an add-on for portable equipment) for all oxygen equipment regardless of the beneficiary's clinical needs. We remain concerned, however, that the approach in the NPRM compounds the flawed policy codified under the DRA which does not recognize the full array of professional and administrative costs of furnishing oxygen to Medicare beneficiaries. Importantly, our analysis indicates that CMS' proposal to revise payment for oxygen is not budget neutral, contrary to the controlling statute. CMS' goals in implementing the DRA should be to preserve beneficiary choice of oxygen equipment and modality, promote high quality care, and support the continuing development of new oxygen technologies. The proposal in the NPRM does not promote these goals.

We recommend that CMS refine payments for oxygen in a manner that supports increased mobility for patients and continuing innovation in product development. We look forward to working with CMS and other oxygen stakeholders to ensure that these refinements are based on accurate data that reflects the current product and service costs of furnishing oxygen to Medicare beneficiaries. We also strongly urge CMS to "grandfather" beneficiaries currently on oxygen from the implementation of the new policies. This will promote a smooth transition to the new policies for all stakeholders. We address these issues and our concerns about operational impact of the new policy in greater detail below.

I. BACKGROUND

1. Chronic Obstructive Pulmonary Disease is a Chronic, Progressive and Debilitating Disease

Home oxygen is critical to approximately one million Medicare beneficiaries who suffer from respiratory illnesses such as chronic obstructive pulmonary disease (COPD). These beneficiaries require oxygen therapy for their long-term survival and well-being. COPD includes chronic bronchitis and emphysema and has been defined as the physiologic finding of nonreversible impairment of pulmonary function.[4] COPD is the fourth leading cause of death in the world and the only leading cause of death for which both prevalence

[3] Although the main focus of these comments is on the implementation of the new payment policies for home oxygen, we have a number of concerns about the application of the proposed rule to capped rental DME. We discuss these issues in later sections of these comments.

[4] Centers for Disease Control and Prevention – MMWR Surveillance Summaries, August 2, 2002/Vol. 51/ no. SS-6

and mortality are rising.[5] The clinical course of COPD is characterized by chronic disability with intermittent acute exacerbations that occur more often during the winter months. The World Health Organization has projected that COPD will rank fifth in 2020 as a global burden of disease.[6]

Approximately 15 million Americans have been diagnosed with COPD, and an estimated 15 million more have undiagnosed COPD. COPD costs the U.S. economy over $18 billion a year in direct medical costs and an estimated $11 billion in indirect costs.[7] Although oxygen represents a substantial expenditure for Medicare under the DME benefit, beneficiaries on home oxygen also incur significant expenses for other health care services. COPD is responsible for a significant part of all physician office visits and emergency room (ER) visits and ranks number three (3) in acute hospital admissions among Medicare aged persons. Based on 2001 data from Medicare, over 397,000 patients were discharged from acute care hospitals with a diagnosis of COPD. The average length of stay for a COPD admission is 5.1 days at the rate of $4,000 per day. Medicare payments to hospitals for routine COPD admissions alone exceed $1.5 billion.

The profile of the patient who uses oxygen suggests that these individuals comprise what has been called the "frail elderly." AAHomecare members who serve oxygen patients report that these beneficiaries are likely to live alone and are highly circumscribed in their activities of daily living (ADLs). Recent clinical studies have examined the correlation between the ADLs and patients with severe COPD who are on long-term oxygen therapy. A study last year in *Chest* examined the impact on the ADLs for individuals suffering from one of three long-term chronic conditions, including COPD. [8] The study concluded that, for all the patients in the sample, COPD was associated with a distinctive pattern of disability expressed by loss of selected ADLs. Other studies have shown that of individuals with COPD, those who required long-term oxygen therapy, were less independent in their ADLs than those who did not require oxygen therapy. [9] Earlier studies also confirm that individuals with COPD decline in their cognitive function as their disease progresses. These studies find that: "cognitive decline is faster in the presence of severe bronchial obstruction and parallels the worsening of the affective status in COPD patients on oxygen therapy." [10] [11]

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[5] Global Initiative for Chronic Obstructive Lung Disease (GOLD) of the U.S. National Heart, Lung, and Blood Institute and the World Health Organization, Am J Respir Crit Care Med Vol 163. pp 1256- 1276, 2001.

[6] Murray CJ, Lopez AD. Evidence-Based Health Policy—Lessons from the Global Burden of Disease Study. Science. 1 996; 274: 740-743.

[7] Data derived from Moran & Associates estimates from the 2001 MEPS full year consolidated file.

[8] Incalzi RA, et al. Construct Validity of Activities of Daily Living Scale: A Clue to Distinguish the Disabling Effects of COPD and Congestive Heart Failure. *Chest* 2005; 127:830-838

[9] Okubadejo AA, et al. Home assessment of activities of daily living in patients with severe chronic obstructive pulmonary disease on long-term oxygen therapy. *Eur Respir J* 1997;10:1572-1595

[10] Incalzi RA, et al. Predicting cognitive decline in patients with hypoxemic chronic obstructive pulmonary disease. *Respir Med* 198; 92:527-533.

[11] Incalzi RA, et al. Verbal memory impairment in COPD: Its mechanisms and clinical relevance. *Chest* 1997; 112:1506-1513.

Clearly, Medicare payment policies for oxygen will impact a large number of very vulnerable patients. Consequently, we urge CMS to proceed cautiously in establishing new payment methodologies for oxygen. Payment for oxygen must be adequate to support on an ongoing basis the array of professional and administrative services that are necessary to safely furnish oxygen to beneficiaries in their homes. Payment policies also need to preserve beneficiary and physician access to their choice of oxygen modality and technology both before and after title to the oxygen equipment transfers to the beneficiary. Moreover, while spending for home oxygen may be a sizeable portion of overall Medicare spending for DMEPOS, spending for oxygen should not be viewed in isolation. CMS must consider the other health care services and resources that beneficiaries on oxygen consume. Maintaining these patients at home on oxygen is by far more cost effective for the Medicare program than institutional care.

2. Medicare Reimbursement for Home Oxygen Has Declined Sharply Since 1997

Prior to February 8, 2006, Medicare reimbursed for oxygen and oxygen equipment on the basis of a continuous rental. In other words, Medicare would pay for home oxygen therapy as long as a beneficiary met Medicare's coverage criteria. Medicare reimburses home oxygen under fee schedules established by Congress in 1989. The first fee schedule payments were based on supplier charges from 1986. The fee schedules bundled the payment for the oxygen and stationary oxygen equipment and included and add-on fee for portable equipment only (because contents payments were bundled into the payment for the stationary equipment). Consequently, the monthly rental payment for oxygen is a "modality neutral" bundled payment that covers ongoing service and maintenance for the equipment. Fee schedule updates were based on the Consumer Price Index (CPI).

Payment rates for oxygen have been subject to numerous freezes and reductions since the inception of the fee schedules. The largest reduction occurred under the Balanced Budget Act of 1997 (BBA). The BBA cut Medicare reimbursement for oxygen by 25% in 1998 and an additional 5% for 1999. The BBA also permanently froze all CPI updates for home oxygen. With the exception of modest, temporary updates that occurred in 2000 and 2001, the BBA statutory provisions for oxygen preclude any further CPI updates to oxygen payments unless Congress expressly approves them. Congress applied further reductions to oxygen payments under the Medicare Modernization Act of 2003 (MMA). The MMA reduced oxygen payment by an amount equal to the percentage difference in the median reimbursement for oxygen between the Federal Employee Health Benefit (FEHB) program plans and Medicare. The FEHB reductions, which averaged 10% across each durable medical equipment regional carrier (DMERC) region, were effective in 2005.

Congress did not change the fee schedule methodology or explicitly reduce payment for oxygen under the DRA. Instead, §5101 of the DRA limits rental payments for oxygen equipment to a 36 month period of "continuous use," after which ownership of the equipment transfers to the beneficiary. After the conclusion of the period of continuous use, Medicare will pay only for "oxygen" and service and maintenance of oxygen equipment that the Secretary deems "reasonable and necessary." This payment

methodology became effective January 1, 2006 for all Medicare beneficiaries on home oxygen as of December 31, 2005.

Under the NPRM, CMS proposes to establish separate classes and payment for oxygen equipment based on its authority under §1834 (a) (9)(D) which permits the Secretary to depart from the modality neutral methodology so long as the result is "budget neutral."[12] The proposed rule would create separate classes and monthly payment amounts for oxygen generating technologies and separate classes and monthly payment amounts for stationary gaseous and liquid systems that require refills of oxygen contents. To obtain budget neutrality, CMS would offset payment increases for these classes with a reduction in the monthly payment for concentrators.

II. COMMENTS

A. CMS Has Not Established Budget Neutrality for the Proposal in the NPRM or Met Minimum Requirements for Notice and Comment Under the Administrative Procedure Act (APA)

1. The Proposed Policy is Not Budget Neutral

As CMS acknowledges, the proposal to tie the monthly payment for oxygen to the equipment technology must be budget neutral.[13] While we understand the need to revisit the current methodology, we are concerned by the lack of data to establish that this proposal is budget neutral. The preamble vaguely asserts that the proposed payments result in increases and offsets that are "roughly equal," but there is no data or analysis to support that conclusion. The lack of verifiable data on this threshold issue falls short of the requirement that CMS give stakeholders reasonable notice of a proposed action. CMS has an obligation to publish the factual basis for its determination in sufficient detail so that all stakeholders can confirm its analysis.[14] Without this data, stakeholders cannot fully evaluate a proposed rule and assess its impact. CMS has not satisfied the notice and comment requirement under the APA.[15] The lack of adequate data to support CMS' analysis also falls short of the agency's commitment to ensure the quality, utility, objectivity, and integrity of the information it disseminates contrary to the requirements of the Data Quality Act (DQA).[16]

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[12] 42 U.S.C. §1395m (a)(9)(D)(ii), (2006).

[13] The statute limits the Secretary's authority as follows:

> [T]he secretary may take actions under clause (i) only to the extent such actions do not result in expenditures *for any year* to be more or less than the expenditures which would have been made if such action had not been taken.

42 U.S.C. §1395m (a) (9)(D)(ii) (emphasis added).

The statutory requirement for budget neutrality is not satisfied if payments in any year are more of less than would have otherwise been made.

[14] Motor Vehicle Mfrs. Ass'n. v. State Farm Mutual Insurance Co. 463 U. S. 29 (1983).

[15] Association of Data Processing Serv. Orgs. V. Board of Governors, 745 F.2d 677 (D. C. Cir. 1984); Air Transp. Assn. of Am. V. FAA, 169 F. 3d. 1 (D. C. Cir. 1999).

[16] CMS has an obligation under the DQA to ensure the quality, utility, objectivity, and integrity of the information it disseminates. Under CMS' guidelines, the DQA standards apply to the information in the

Our own shows analysis that the reimbursement methodology announced in the policy is not budget neutral. The Lewin Group examined the proposal on behalf of AAHomecare using different assumptions about the migration of beneficiaries to portable concentrators and transfilling systems. For 2007 alone, Lewin concluded that the policy would result in a ten percent (10%) reduction in payments for oxygen with additional reductions in later years. According to Lewin, if no migration is assumed, the CMS proposal includes an additional $257 million payment reduction over what would otherwise be necessary to achieve budget neutrality. When Lewin assumed a 5% migration, the difference between the CMS proposal and what would be necessary for budget neutrality was approximately $239 million.[17] Lewin concluded that CMS would have to assume that approximately 73 percent of patients would switch to portable concentrators and transfilling systems to achieve budget neutrality.

Clearly, CMS cannot implement the new policy unless it demonstrates that the policy is budget neutral. We encourage CMS to review Lewin's analysis and reevaluate its assumptions to assure that the proposed policy is in fact budget neutral as required under the statute. We believe that Lewin correctly concludes that the CMS proposal includes $239 million more than what would otherwise be necessary to establish budget neutrality. We also request that CMS articulate the factual basis for its conclusions and allow all stakeholders an opportunity to comment on the data.

2. Medicare Payment for Home Oxygen Must Support Beneficiary Access to Portable Oxygen Contents and the Development of New Technologies

Once CMS has revised the new policy to make it budget neutral, we recommend that CMS reallocate the monthly payment amounts for oxygen equipment using the $239 million identified by Lewin. This reallocation should occur in a manner that supports portable oxygen contents as well as the continuing development of new oxygen technologies. AAHomecare has worked collaboratively with the physician and respiratory practitioner community over the past several years. We understand their concerns that patients on oxygen be assured access to the portable equipment of their choice. Promoting increased mobility for oxygen patients is an important clinical objective because active COPD patients have better overall health status and greater ability to participate in ADLs. Beneficiaries and their physicians have numerous choices for portable oxygen equipment today, and Medicare payment policy should preserve those choices.

Current reimbursement is inadequate to support these goals, especially after ownership of the equipment transfers to the beneficiary. The new payment policy is likewise inadequate. The inaccurate reimbursement occurs because CMS has not acknowledged that providers will continue to incur professional and administrative costs after title to the

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proposed rule. We believe that the analysis in the NPRM fails to meet DQA standards. *See* Treasury and General Government Appropriations Act of 2001, Pub. L. No. 106-544, 114 Stat. 2763A-150, 153-154).

[17] Letter from Joan E. DaVanzo, Ph.D, The Lewin Group, to Mr. Tyler Wilson, President and CEO, American Association for Homecare, September 22, 2006 (Lewin study), attached.

equipment transfers. Moreover, CMS lacks the data to evaluate those costs in light of the proposed payment policies. In fact, until CMS has accurate data, all attempts to establish payment policies based on the relative cost of one type of equipment over another will be arbitrary. As we discuss below, the study by Morrison Informatics published by AAHomecare earlier this year, is the only source of current data on the equipment and service costs of furnishing oxygen to Medicare beneficiaries.[18] We encourage CMS to consider the Morrison study when it reconsiders the policy in the NPRM.

3. Equipment Acquisition Costs Constitute less than One-Third of the Total Cost of Furnishing Oxygen to Medicare Beneficiaries

We understand that the DRA dictates the transfer of ownership of oxygen equipment and that CMS' role is to implement the DRA requirements. Nonetheless, we want to emphasize that the policies underlying the DRA are fundamentally flawed and based on a misapprehension of the full range of administrative and support services that are necessary to ensure that Medicare beneficiaries receive safe and effective oxygen therapy in their homes. This misunderstanding is evident in the CMS longstanding position that the oxygen benefit is an equipment benefit only. As a result of this "equipment only" stance, Medicare has never fully acknowledged the array of professional and administrative services, including delivery, education, oversight, and monitoring that are necessary to ensure that that oxygen therapy is administered safely and effectively in the home. Moreover, oxygen is a prescription drug that is regulated by multiple Federal and State agencies, including the Food and Drug Administration (FDA), other Federal agencies such as the Department of Transportation (DOT), and State pharmacy boards. A payment policy that fails to explicitly recognize the professional and administrative costs inherent in furnishing home oxygen results in inaccurate reimbursement and can seriously erode the quality of care that beneficiaries receive.

At least one rationale underlying the DRA is that Medicare rental payments for oxygen equipment are many times over homecare providers' acquisition costs. This reasoning incorrectly assumes that equipment acquisition cost is the only cost inherent in serving these beneficiaries. Morrison Informatics recently completed the most comprehensive analysis to date of the services and costs of furnishing home oxygen to Medicare beneficiaries. Morrison examined the costs of 74 providers who collectively serve more than 600,000 beneficiaries who use oxygen. Morrison concluded that equipment acquisition costs represent only 28% of the total cost of servicing Medicare beneficiaries using home oxygen. Other administrative and support functions necessary to safely deliver oxygen to beneficiaries in their home account for the remaining 72% of providers' costs. These administrative and support costs include obtaining patient information and related documentation, labor related to the initial preparation of the equipment, equipment delivery and set-up, scheduled and unscheduled maintenance and repair, ongoing patient support, delivery costs, and ongoing patient assessment, training, education, and compliance monitoring as well as other necessary operating and overhead

[18] *A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy*, Morrison Informatics, Inc, prepared for the American Association for Homecare, June 27, 2006.

costs.[19] On average, the direct costs of furnishing home oxygen to Medicare beneficiaries breakdown as follows:

Cost Component	Average Cost Per-Patient Per-Month
1. SYSTEM ACQUISITION[20]	$55.81
2. INTAKE AND CUSTOMER SERVICE[21]	$12.66
3. PREPARATION, RETURN, DISPOSABLES, AND SCHEDULED MAINTENANCE[22]	$25.24
4. UNSCHEDULED REPAIRS AND MAINTENANCE[23]	$6.10
5. PATIENT ASSESSMENT, TRAINING, EDUCATION AND MONITORING[24]	$17.54
6. DELIVERY ASSOCIATED WITH PREPARATION, RETURN, DISPOSABLES, AND SCHEDULED MAINTENANCE[25]	$42.26
7. OTHER MONTHLY OPERATING AND OVERHEAD[26]	$41.59
8. TOTAL DIRECT COST BEFORE TAXES	$201.20

In the past there may have been concerns that the cost categories identified by Morrison were not representative of costs incurred by all suppliers serving Medicare beneficiaries. In other words, CMS may have been reluctant to acknowledge the non-equipment professional and administrative services furnished to oxygen beneficiaries out of a concern that not all suppliers adhered to the same standards. This issue was resolved

[19] Overhead and operating costs accounted for 21% of supplier's total costs. This data were reported to Morrison in the aggregate, so data on specific cost components for this category are not available.
[20] The amount includes acquisition costs for stationary, portable and backup units, conserving devices, ancillary equipment and accessories, and oxygen system contents (liquid and gaseous oxygen).
[21] The amount includes labor associated with patient intake functions, ongoing customer service (patient inquiries, scheduling of deliveries/maintenance/clinical visits, accommodating patient travel plans), and initial and renewal prescription processing.
[22] The amount includes labor associated with equipment preparation (testing, cleaning, and repair), equipment set-up and maintenance upon return, initial patient instruction, cost of disposable and maintenance supplies, and labor costs associated with scheduled preventive equipment maintenance.
[23] The amount includes labor and vehicle costs associated with unscheduled equipment repair and maintenance.
[24] The amount includes labor and travel costs associated with clinical visits by respiratory care practitioner, in-home patient assessments (including home environment safety assessment and oxygen therapy plan of care), training, education and compliance monitoring.
[25] The amount includes delivery costs associated with oxygen fills (liquid and gaseous oxygen), preparation, return, disposables and scheduled maintenance.
[26] The amount includes rent and other facility costs, administration, insurance, legal, regulatory compliance, MIS systems/controls, communications systems, employee training, accreditation, supplies, billing and compliance functions.

when CMS published quality standards for DME providers this year.[27] In addition to business standards that apply to all DMEPOS providers, the new standards contain detailed requirements for patient intake and assessment, equipment selection and maintenance, delivery, patient education, monitoring and follow-up that apply specifically to oxygen suppliers.

Providers who furnish oxygen to Medicare beneficiaries will be required to demonstrate that they comply with these standards in order to bill the Medicare program. For the first time all providers of home oxygen to Medicare beneficiaries will be required to meet the same standards and receive accreditation to document their compliance with the standards. Importantly, the new quality standards confirm that the cost categories reported in the Morrison study are legitimate costs that should be recognized in the Medicare payment for home oxygen. The Medicare program recognizes the cost of complying with quality standards and accreditation for providers and suppliers in other settings. Failing to acknowledge these costs for providers who furnish oxygen would be a disservice to Medicare beneficiaries who rely on this important therapy.

4. CMS Should Delay Implementation of the Payment and Policy Changes Proposed in the NPRM

CMS states that the policies announced in the NPRM will not be effective prior to January 1, 2007. This statement is ambiguous because the DRA period of "continuous use" is already in effect. The proposal in the NPRM should apply prospectively only. The proposed policy should not apply to patients on oxygen in 2006. By "grandfathering" these beneficiaries, CMS would promote a smooth transition to the new payment policies, avoid disruptions in the care of beneficiaries currently on oxygen, and minimize the impact on providers of a pronounced change from current reimbursement levels. This transition would also permit CMS to work with stakeholders to refine the new methodology in a way that accomplishes the goals we identified above. The DRA requires only that title to oxygen equipment transfer to the beneficiary after 36 months of continuous use. It does not require CMS to make any changes to reimbursement for home oxygen. Consequently, it unnecessary for CMS to rush to implement this policy by January 1, 2007. Given the interests that are at stake, all stakeholders would be well served by a delay the payment changes until CMS has current data to adjust the policy.

B. CMS Cannot Require Suppliers to Enter Into Private Supplier Agreements

CMS proposes to require suppliers to notify beneficiaries of their "intentions" regarding whether they will accept assignment for all monthly rental claims for the duration of the rental period before furnishing oxygen or capped rental equipment to the beneficiary. For oxygen equipment, this provision would require the supplier to notify the beneficiary whether it will accept assignment for all rental claims for the entire 36-month period of continuous use. The proposed regulation would permit suppliers to express their intentions in a written agreement between the supplier and the beneficiary.

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[27] Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, available at: http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/04_new_quality_standards.asp

Medicare contractors are authorized to pay certain Part B claims on the basis of an itemized bill or on an assignment related basis.[28] This requirement is widely understood to permit physicians and suppliers to accept assignment on a claim by claim basis. This understanding of the statute is longstanding and not open to further interpretation. Indeed, CMS acknowledges in the preamble that suppliers may determine whether to accept assignment on a claim by claim basis. There is an exception to this rule for participating physicians and suppliers who determine *on annual basis* whether they will accept assignment of all Medicare claims. Although the participating provider program includes a number of incentives to promote participation, the decision to become a participating provider is voluntary. However, once a supplier agrees to be a participating supplier, the supplier *must* accept assignment of all Medicare claims for that calendar year. Nonparticipating physicians and suppliers may continue to make the assignment decision on a claim by claim basis.

Although CMS has great latitude in implementing regulations to administer the program, those regulations must be consistent with the statutory framework established by Congress.[29] CMS clearly cannot require suppliers to accept assignment of all monthly rental claims throughout the period of continuous use. Such a requirement would contradict the provision of the Act that directs contractors to pay claims on the basis of an itemized bill or on an assignment-related basis. CMS also cannot require suppliers to enter into private assignment agreements such as the ones contemplated by the regulation. The law requires participating supplier agreements to be effective for one year, after which the supplier can elect not to participate. Because the statute permits suppliers to decide *annually* whether they will accept assignment of all Medicare claims, CMS could not require suppliers to make that decision effective for the entire rental period of 13 or 36 months. Otherwise, CMS would effectively change the terms of the participating supplier program established by Congress. CMS has no authority under the Act to require suppliers to enter into agreements that conflict with the statutory framework for the participating provider program. Consequently, we recommend that CMS withdraw this proposal.

C. CMS Must Work with the FDA to Address Compliance Issues for Patient-Owned Equipment

CMS proposes that beneficiaries receive title to both the oxygen cylinder or vessel currently in use by the beneficiary as well as the one being refilled by the supplier. This proposal is unworkable. As a practical matter, the provider cannot keep track of the cylinders or vessels in the manner that the NPRM contemplates so that the beneficiary retains ownership to the same set of cylinders/vessels. Many suppliers do not own the cylinders. As we describe below, they lease them from a commercial gas company that is responsible for filling them. Additionally, some suppliers may process a large volume of containers themselves while others rely on a contractor to perform this function. In either case, tracking the containers by serial number would be unmanageable from an

[28] 42 U.S.C. §1395u(b)(B)(i)(ii) (2006).
[29] 42 U. S. C. §1395hh (2006).

operations perspective. Suppliers also must comply with specific labeling requirements for oxygen containers under FDA and DOT rules. Under the current regulatory framework for oxygen as a medical gas, suppliers are not permitted to label this equipment with the beneficiary's name.

Importantly, the containers and their components are an integral part of the drug delivery system under FDA regulations and guidance.[30] As such, they are subject to detailed cleaning, maintenance and calibration requirements, a number of pre-fill and post-fill inspections and testing, and specific transportation and labeling requirements. These activities must be carried out by qualified individuals and documented in comprehensive records. As a highly regulated medical gas, oxygen has a unique status among drugs, because its container is re-usable.

FDA guidance defines the custody, control, and management of filling liquid containers to be in compliance when the filling company owns the liquid containers and the containers are filled at the company's location or curbside at the patient's home. When the patient owns the liquid containers after 36 months, the company would no longer be able to fill the container without extensive testing prior to filling because the containers would be considered by FDA to be out of the filler's control. In addition, the filling company would no longer be assured the container was maintained in accordance with the manufacturer's specification. Under these circumstances, the medical oxygen provider would be reluctant to assume responsibility for a cylinder or liquid oxygen container that is not under its control.[31]

Similarly, in accordance with DOT regulations,[32] a cylinder filled with a hazardous material may not be offered for transportation unless it was filled by the owner of the cylinder or with the owner's consent. This requires the manufacturer of the medical oxygen, *i.e.*, the company that fills the oxygen container under FDA regulations, to have the equipment owner's permission prior to refilling the container. After the patient owns the oxygen equipment, compliance with this regulation will be very difficult for the provider of medical oxygen in the home, especially if the transfilling is done by a third-party.

Medical oxygen cylinders must also be inspected for the hydrostatic test date as part of the pre-fill inspection requirements. If the cylinder test date has expired, the cylinder can not be filled. The "out-of-test" cylinder must be sent to a company that is certified by the

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[30] See 42 CFR § 210 Subpart E, Control of Components and Drug Product Closures and Containers; Specifically, the FDA defines the container and its components, including the closure, as follows:

> A *container closure system* refers to the sum of packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection to the drug product. A *packaging system* is equivalent to a container closure system.

[31] See Fresh Air 2000 testing and filling requirements for cryogenic home units.

[32] 49 CFR Part 107 173.301 (e), "*Ownership of cylinder.*"

DOT and be retested. Currently, the company filling the cylinder would quarantine the cylinder and the cylinder would be sent out for retest/requalification.[33]

DOT also provides very specific regulations for the proper handling and disposal of compressed cylinders that all companies that fill and transport cylinders must follow. The filler of liquid oxygen containers must also have access to service and maintenance records in order to determine which inspections and tests to perform and at what frequency. In this context, establishing the chain of custody for the equipment is an important step in determining what testing or servicing the equipment requires before it is filled and distributed to patients. If this information is not available to the filler, then the FDA mandates additional testing. These additional tests require more sophisticated testing equipment than the typical provider of home medical oxygen has available.

CMS' proposal to transfer title to both the cylinder/vessel that is being filled and the one in the beneficiary's home is unworkable given its impact on supplier's operations and regulatory framework for oxygen as a medical gas. Earlier this year we urged CMS to confer with the FDA about the application of FDA regulations to patient owned cylinders/vessels and we renew that request now.

D. The Proposed Rule Creates Significant Operational Hurdles for Providers

1. CMS Must Clarify the Equipment Repair and Replacement Policies Outlined in the Proposed Rule

a) Prohibition on Replacing Equipment during the Period of Continuous Use

The proposed rule specifies that a provider may not replace oxygen equipment prior to the expiration of the 13- or 36-month rental period unless one of the exceptions enumerated in the rule applies. CMS interprets the DRA to literally require that the beneficiary receive title to the same equipment that the provider delivered to him on the first day of the rental period. To comply with this new regulation, providers would have to track equipment by serial number in order to make sure the beneficiary receives title to the equipment that the provider furnished originally. This will be very difficult for providers to accomplish if the concentrator or other equipment is brought into the facility for repairs. Larger providers may have regional or even national distribution centers to stock and service equipment. Other providers may use contractors to service equipment. For both large and small providers, a requirement to track equipment in this manner would be unmanageable.

Currently providers simply replace equipment in need of service or repair with equipment of the same type that is in good working order. We suggest that during the period of continuous use, providers be permitted to continue this practice. This will allow providers to streamline their operations and serve beneficiaries more efficiently in the event

[33] See Department of Transportation 49 CFR Part 107 § 180.205 General requirements for requalification of cylinders thru §180.213, Requalification markings.

equipment must be repaired or serviced at the provider's facility. Because repairs can take upwards of 30 days, the proposed rule would build in added costs of administration and delivery if the original piece of equipment must be delivered to the patient.

CMS believes this new requirement is necessary to prevent unscrupulous providers from replacing newer equipment with older used equipment before the end of the rental period. CMS can address this issue simply by requiring that the beneficiary receive title to equipment that is of comparable quality to the equipment delivered at the beginning of the period of continuous use. Moreover, with respect to oxygen equipment, the preamble acknowledges that the vast majority of beneficiaries will not require oxygen for the full 36-month period of continuous use. Consequently, for oxygen beneficiaries, there is less concern that providers will use the "bait and switch" practices CMS describes.

b) Replacement of Beneficiary-Owned Equipment

The proposed rule would require providers to replace, at no cost to the patient or the Medicare program, patient-owned equipment if the cumulative total repairs during the useful life of the equipment exceed 60% of the equipment's value and the manufacturer's warranty has expired. Given the five-year useful life of the equipment, the circumstances that would require equipment to be replaced may be so far removed from the date that title transferred that there would be no plausible connection between the provider's actions and a conclusion that the provider delivered substandard equipment. Moreover, the provider will have no control over patient-owned equipment. For example, there will be no record of routine, ongoing service and maintenance, placing the provider in the untenable position of having to replace equipment that may not have been properly maintained. We recommend that responsibility for the equipment shift to the patient once he receives the title.

We also question the rationale underlying this proposal. CMS states that the policy is necessary to prevent providers from offsetting lost revenue from rentals with revenue for repairs. Our members report that reimbursement for repairs is inadequate and requires extensive documentation. Guidelines for processing repair claims also inconsistent. Consequently, we doubt that the providers will adopt a business strategy to offset lost rental income with increased revenue from repairs. We do agree with CMS, however, that there is likely to be an up-tick in the volume of Medicare claims for repairs. As we describe more fully below, CMS can expect the increased volume because most beneficiaries chose to continue renting their equipment in the past.

It is also unclear from the regulatory language, or the preamble, how CMS would determine that the cumulative costs of repairs are 60% of the value of the equipment. We request that CMS explain the methodology it will use to make this determination.

c) Billing for Equipment Repairs

CMS must require the DME Medicare Administrative Contractors (MACs) to issue specific and comprehensive guidance for submitting claims for repairs. Specifically, we

request guidance on the type of documentation that CMS expects providers to obtain to support repair claims. As we discussed above, there is not a high volume of claims for repairs because most beneficiaries have chosen to continue to rent capped rental equipment. For oxygen, equipment repairs have been covered under the monthly fee schedule. As a result, it is reasonable to expect an increase in the volume of claims for repairs for patient owned equipment; however, the increase in volume for repair claims will be the logical consequence of the new policy, not evidence of program abuse. The MAC jurisdictions and CMS must have clear policies outlining when Medicare will pay for repairs and the documentation it will require to support those claims.

Additionally, the HCPCS codes must be revised to include codes for equipment parts. Because we anticipate that the number of repair claims will increase, it is important that the billing process be efficient. This will not be possible if there are a large number of uncoded products. For example, the following chart includes a partial list of parts that are not identified by HCPCS codes:

Hospital Beds	**Nebulizers**	**Patients Lifts**	**Concentrator**	**Liquid Oxygen Reservoirs**
Pendant control	Tubing adapter	Hydraulic cylinder	Filter, inlet	Regulator
Motor assembly	Case	Seal kit	Filter, cabinet	Primary relief valve
Drive shaft	Power cord	Hydraulic fluid	Filter, bacterial	Secondary relief valve
Junction box		Base spreader kit	Outlet nipple	Condensing coils
Frame with spring, head and foot sections		Caster wheels	Sieve bed	Flow control valve
Power cord			Regulator	Contents indicator
			Flow meter	Cryogenic vessel
			Compressor	Vent valve
			Valve , 4 way	Economizer valve
			Control board	Cover Assembly
			Product tank	
			Power cord	

d) Payment for Routine and Non-Routine Maintenance

CMS is proposing to pay for maintenance and service for beneficiary-owned capped rental DME and oxygen equipment. However, CMS has also proposed to "apply our existing policy of not covering certain routine maintenance or periodic servicing of purchased equipment, such as testing, cleaning, regulating, changing filters, and general inspection of beneficiary-owned oxygen equipment and to continue that policy for beneficiary-owned capped rental equipment."

CMS should not assume that all beneficiaries will be able to perform routine maintenance and service on their equipment. There are beneficiaries, especially the frail elderly, who will be unable to perform these tasks. As a result, CMS must ensure that beneficiary-owned can be maintained in good working order. We recommend that CMS establish codes to describe the parts and repair services that will be covered and reimbursed for beneficiary-owned oxygen equipment. We encourage CMS to work with manufacturers and providers to ensure that fee schedules are established that appropriately account for all parts and services incurred in providing the maintenance and service for patient owned capped rental and oxygen equipment.

e) Payment for Ongoing Services

It is very important for CMS to include an ongoing service and maintenance fee to cover emergency services, respiratory practitioner evaluations, on-call availability, and after hours troubleshooting for patient-owned oxygen equipment. Providers currently furnish these services under the monthly payment amount for oxygen. These services were documented in the Morrison study and are a critical component of safely furnishing oxygen in the home. When the monthly rental payments end, there will be no additional payment for these important support services.

We urge CMS to not take the position that these are noncovered services therefore placing the burden of paying for them on beneficiaries. Some, if not most, beneficiaries will elect not to pay for the services, placing these beneficiaries at risk and creating a two tiered system of care. Moreover, to the extent that the new supplier standards recognize that these services should be the standard of care for Medicare beneficiaries, Medicare payment policies should recognize them for patient owned equipment as well.

2. CMS Must Clarify How It will Determine the Period of Continuous Use

a) Application of Break-In-Service Rules

Consistent with the requirements of the DRA, the NPRM designates a 36-month period of continuous use for oxygen equipment and a 13-month period for capped rental equipment. We have numerous concerns with respect to how CMS would determine the period of continuous use for oxygen equipment. These concerns relate to the application of the break-in-service rules, replacement of equipment that is lost stolen or irreparably damaged, and the impact of these new rules on beneficiaries who move or travel. Specifically, with respect to the break-in-service rules, the proposed rule is silent on how a break-in-service affects the calculation of the period of continuous use.

There are a number of situations where a beneficiary may have a short term need for oxygen. CMS coverage policy identifies these patients as falling within the Group II coverage criteria. These patients may not be sufficiently hypoxemic to require ongoing oxygen therapy, although eventually they will need oxygen on a continuous basis. Their short-term oxygen use should not be included in the 36-month rental period when they subsequently resume oxygen therapy. Similarly, there are other breaks-in-service that

should not count towards the period of continuous use. These include skilled nursing facility (SNF) stays or acute care admissions any longer than a month. Because suppliers do not have access to the common working file (CWF), they do not know in advance of these admissions. Often, providers learn of these admissions a year or more after the fact when the DME MAC identifies an overpayment. Current Medicare program rules identify that a break-in-service of 60 days or more supported by appropriate documentation, will not count toward the capped-rental period. We believe that there is no basis for CMS to apply different break-in-service rules to oxygen. We recommend that CMS explicitly clarify this issue in the final rule.

These scenarios also underscore important related issues. The first is that CMS must move towards an audit process that is reasonably contemporaneous with the period of continuous use so that suppliers are not subject to overpayments long after title to the equipment transferred. The second is that suppliers should have access to the CWF in order to effectively administer their obligations under the DRA.

b) Equipment that is Lost, Stolen, or Irreparably Damaged

Under the proposed regulations, a new period of continuous use would begin when beneficiary-owned equipment is lost, stolen, or irreparably damaged. While we agree that this provision is necessary to ensure that beneficiaries have access to medically needed equipment, we question CMS' decision to apply this exception only to beneficiary-owned equipment. When equipment is lost, stolen, or irreparably damaged during the period of continuous use and a provider furnishes replacement equipment, a new period of continuous should begin. Otherwise, the regulation would impose a patently unfair result when rented equipment is lost or damaged through no fault of the supplier.

For example, if an expensive item like a portable concentrator is lost or stolen in the 30th rental month and the provider replaces it, the provider would in effect have to transfer title to two devices, but receive payment only for one. Under the former continuous-rental methodology for oxygen equipment, providers typically replaced lost, stolen, or irreparably damaged equipment because the provider retained title to the asset which could be used for future rentals. There is no similar rationale that would support requiring the provider to provide a beneficiary with replacement equipment during the rental period under circumstances where the provider is not responsible for the events that precipitated the need to replace the equipment.

CMS may have limited this provision to beneficiary-owned equipment out of a misplaced concern that providers would submit claims for lost, stolen, or irreparably damaged equipment simply to circumvent the DRA requirements. If this is the case, CMS should at least allow the DME MACs to make the determination whether to initiate a new period of continuous use on a case-by-case basis. This would ensure a more balanced application of the requirement to transfer equipment ownership to beneficiaries.

c) Beneficiaries Who Travel or Move Outside the Provider's Service Area

We also have questions on how the transfer of title provisions would apply to oxygen patients who travel for extended periods and beneficiaries who move out of the provider's area during the period of continuous use. The proposed regulations state that a new period of continuous use does not begin when the beneficiary changes providers. The impact of this provision will be to limit access for beneficiaries who relocate during the rental period. We recommend that CMS address this issue by permitting a new period of continuous use to begin.

Similarly, CMS should clarify which provider's equipment transfers to the beneficiary if the beneficiary has two residences with a local provider in each area. Beneficiaries who are "snow birds," or who may move or relocate during the period of continuous need will face hurdles in maintaining access to equipment, unless a new period of continuous begins when they change suppliers. Extended travel outside of the provider's service area should not be counted toward the period of continuous use to the extent the provider is not paid for oxygen during that period.

3. Backup Oxygen Equipment

The NPRM does not address backup oxygen equipment. Many beneficiaries have backup equipment solely for use in an emergency such as a power outage. AAHomecare believes that title to backup equipment does not transfer under the coverage rules established by the oxygen LCD. The LCD states that backup equipment is noncovered because it is provided solely for the convenience of the beneficiary. To the extent that CMS has not made any rental payments for the backup equipment, title to the equipment should not transfer to the beneficiary. We request that the final rule explicitly clarify this issue.

4. Title to Equipment Should not Transfer Unless all Beneficiary Copays and Deductibles have Been Paid

The DRA requires that title to oxygen and capped rental equipment transfer to the beneficiary at the conclusion of the period of continuous use. Title to equipment should not transfer to the beneficiary unless all outstanding copay and deductible amounts have been paid. Under the framework established by Congress, Medicare beneficiaries share in the cost of their care under Part B. The Medicare program pays for 80% of the fee schedule amount for oxygen and capped rental equipment and the beneficiary pays the remaining 20% co-payment plus a deductible.[34] The application of the DRA transfer of title provisions to this statutory reimbursement framework suggest that the beneficiary must pay any outstanding copay and deductible amounts before receiving title to equipment. Any other conclusion would clearly be contrary to common sense and the payment scheme devised by Congress. Moreover, transferring title of equipment to beneficiaries before they have met their financial obligations under Medicare program

[34] 42 U.S.C. §1395m(a)(1) (2006).

rules amounts to a de facto waiver of copays and deductibles in violation of the beneficiary inducement statute.[35] Once a beneficiary receives title to equipment, he will have little incentive to pay any outstanding balance. Consequently, we request that the final rule state that the beneficiary must have paid all outstanding copay and deductible amounts before receiving title to equipment.

III. CONCLUSION

We very much appreciate the opportunity to submit these comments. As we stated above, CMS must address the lack of budget neutrality in its methodology and publish all the data and assumptions it uses in this analysis. We strongly recommend that CMS apply any additional monies available after it has accounted for budget neutrality to increase monthly payment amounts for portable oxygen contents and support the continuing development of new technologies. CMS should delay the implementation of the new payment policies by grandfathering beneficiaries already receiving oxygen. This allows a smooth transition to the new policies as we described above. We also request that CMS clarify the operational issues in the manner we recommended above.

AAHomecare remains available to meet with you to discuss our recommendations in further detail. Please feel free to contact me if you have questions or if I can be of assistance in any way.

Sincerely,

Tyler J. Wilson
President and CEO

CC: Herb Kuhn
Joel Kaiser
Laurence Wilson

Enclosures: 1. Morrison Informatics study
2. Lewin letter

[35] 42 U. S. C. §1320a -7b (2006). ___.