Submitter : Ms. Patrick Conole

Date: 09/22/2006

Organization : Home Care Association of New York State

Category : Health Care Professional or Association

Issue Areas/Comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See attachment

CMS-1304-P-28-Attach-1.DOC

ATTACHMENT TO #28

HOME CARE ASSOCIATION of New York State, Inc.

September 25, 2006

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

Re: File Code CMS-1304-P, Medicare Program, Home Health Prospective Payment System Rate Update for Calendar Year 2007

To Whom It May Concern:

The Home Care Association of New York State, Inc. (HCA), on behalf of its 254 member agencies that serve approximately 188,000 Medicare beneficiaries annually, appreciates the opportunity to provide comments on the proposed rule for the Medicare Home Health Prospective Payment System (PPS) for Calendar Year (CY) 2007. HCA members serve the majority of Medicare beneficiaries throughout the state, and HCA actively participated in the development of home health PPS.

General Comments

HCA believes it is critical that CMS establish a home health technical advisory group to regularly review and update the multitude of component parts of the PPS reimbursement methodology. For example, home health's use of technology continues to dramatically increase, first as a necessity for PPS billing and OASIS processing, and second, with the application of telehealth to extend the workforce, improve the quality of care, and decrease costs. While home health agencies continue to implement these technical advances, they lack adequate capital for these acquisitions. Additionally, workforce shortages, which can be partially addressed through the application of technology, have continued to cause problems for many agencies. Home health agencies can neither keep up nor compete with facilities that have both access to capital and the ability to gain wage index reclassifications like hospitals. Home health care, particularly with the advent of telehealth applications, is providing Medicare with substantial savings in hospitalizations and emergency room use. These cost components deserve timely attention and are essential to PPS refinements and updates.

Specific Issues

HCA offers the following comments as CMS continues to evaluate refinements and reforms to the home health PPS.

194 Washington Ave., 4th Floor, Suite 400 • Albany, NY 12210
Phone: 518.426.8764 • Fax: 518.426.8788 • E-mail: info@hcanys.org • www.hcanys.org

Market Basket Update

HCA agreed with CMS'decision to rebase and revise the home health market basket in the 2005 final rule, which resulted in a revised labor (76.775%) and non-labor share (23.225%). While CMS is not proposing to rebase the market basket for CY 2007, HCA hopes, as more current data becomes available, that CMS will consider rebasing more frequently than previous years. Ensuring that the market basket update adequately reflects the price changes of efficiently provided home health services should be a constant goal of CMS.

While HCA realizes that CMS is required to follow all legislative requirements like the Deficit Reduction Act (DRA) of 2005 or the Medicare Modernization Act (MMA) of 2003, which eliminated the 3.6% market basket update in 2006 and reduced our market basket update in 2004 and 2005, there are still many areas in which HCA urges CMS to take action. In particular, HCA encourages CMS to take the initiative and rebase the home health PPS rates on the most recent Medicare cost report data rather than relying on outdated price data from the 2000 Medicare cost reports.

Even if the proposed 3.1% market basket update is applied to the CY 2007 PPS rates, our new rates will not reflect the rapid rise in **fuel prices** that have occurred since 2005 because our PPS rates are based on price data from the 2000 Medicare cost reports. Unlike inpatient facilities, the home health care service delivery system is significantly affected by rising gasoline prices, particularly in rural and sparsely populated areas where the distance between patients can exceed 50 miles. However, even in metropolitan areas the cost of transportation has grown dramatically along with the price of gasoline. Many agencies have had to make the choice of either dramatically increasing their mileage payments to staff who make numerous home care visits every day or risk losing staff to other health care providers.

Besides our members' increased costs in technology mentioned in our general comments and the increased transportation costs due to gasoline prices, HCA is also concerned that CMS' market basket update has not considered the increased costs home health agencies face due to emergency preparedness and purchasing professional and general liability insurance. Since September 11, 2001, both the state and federal governments realized the importance of the home health industry to emergency preparedness and how it supports the surge capacity readiness of the hospital sector. However, costs for home health preparedness have not received the same reimbursement as the hospital and public health sectors, and CMS should consider this in any market basket refinements. The home health industry has also been negatively impacted by major changes in the cost of professional and general liability and workers compensation insurance. These costs should also be considered in any market basket refinements.

Market Basket Recommendation

As we mentioned in our general comments, HCA encourages CMS to establish a technical advisory group that includes economists who can review the costs going into the home health market basket. With the establishment of a technical advisory group, CMS would be able to examine all of the cost changes impacting home health and incorporate them as quickly as possible in order to most accurately reflect actual input costs.

HCA also strongly recommends that CMS institute a revision to the market basket index formula to allow for consideration of extraordinary cost increases. Specifically, with respect to transportation costs, CMS should analyze the most recent Medicare transportation cost data compared to the original Medicare data used to implement PPS in October of 2000, substantiate how much agencies' transportation costs have increased over time and make adjustments according. This cost tends to experience the greatest amount of change while the other elements of the market basket calculation experience more stable change patterns. Another option would be to move away from using the private transportation index in the Consumer Price Index (CPI) and substitute it for a more accurate reflection of home health care transportation experience.

Wage Index Update

CMS' decision last year to adopt the Office of Management and Budget's (OMB's) revised definitions of Metropolitan Statistical Areas (MSAs) to the new definition of Core-Based Statistical Areas (CBSAs) for the wage index calculation has had serious financial ramifications for home health agencies in New York. While in CY 2006, CMS' final rule incorporated a 50/50 blend of MSAs and CBSAs in the wage index calculation, CMS' CY 2007 proposed rule is based solely on the adoption of the CBSA based labor market definition and its wage index. HCA estimates that this two year wage index shift from using MSAs to CBSAs has resulted in an estimated $14 million decrease in Medicare home health reimbursement statewide and over $9 million less for home health agencies in the New York City (NYC) metropolitan area. More disconcerting for home health agencies in the NYC metropolitan area is that their home health wage index has decreased 8.4% since 2004 (1.4414 to 1.3208), which has resulted in approximately $26 million less in Medicare reimbursement to those agencies.

For example, under the 2005 MSA designation for the NYC area, an agency had a wage index of 1.3586, but under the proposed CBSA wage index in 2007 (which adds Bergen, Hudson and Passaic counties from New Jersey) the value drops to 1.3208, representing approximately a 2.8% decrease from 2005. As the provision of home health care is a local endeavor, CMS' decision to view the new CBSA area designation in the "aggregate" for a large geographic region like NYC fails to represent the actual impact of the change. For agencies in NYC, CMS' shift to the CBSA wage index designation will result in them seeing only a 0.3% reimbursement increase since 2005, due to CMS' policy change implementing the CBSA designation and the DRA legislation which eliminated the entire market basket update in 2006.

Wage Index Recommendations

HCA is greatly concerned about the continuing volatility of the home health wage index from one year to the next. In addition, HCA has consistently voiced its concern regarding the lack of parity between different health care providers, each of whom utilizes one form or the other of a hospital wage index yet experience distinct index values in their specific geographic area. CMS' decision to adopt solely the CBSA-based labor market definition serves to exacerbate that instability.

HCA believes that CMS should consider wholesale revision and reform of the home health wage index. This reform should consider the following factors:

- The impact on care access and financial stability of home health agencies must be measured at the local level;
- Significant swings in the wage index cause instability and jeopardize access to care; and,
- The use of a hospital wage index with modifications that do not include hospital wage index reclassifications or the application of the rural floor creates an uneven marketplace for healthcare employers seeking to hire and retain comparable staff.

Existing law permits CMS nearly unlimited degree of flexibility to utilize a wage index that recognizes the geographic differences in labor costs in the provision of home health services across the country. Section 1895(b)4(C) of the Social Security Act (SSA) mandates the establishment of area wage index adjustment factors, provides the CMS Secretary discretion to determine which factors are used, and permits the Secretary to utilize the same wage index adjustment factors as are utilized in composing the hospital wage index. However, despite CMS' ongoing recognition that home health agencies compete in the labor marketplace for the same health care staff utilized within inpatient hospitals, the wage index employed is comparable in name only.

Consequently, HCA recommends that CMS reform the home health wage index by instituting a proxy that allows home health agencies to receive the same reclassification as hospitals if they provide services in the same service area. HCA believes that by making this policy change an important goal of parity in the labor marketplace between hospitals and home health agencies would finally be accomplished.

Home Health Care Quality Improvement

While HCA is generally supportive of CMS implementing the new pay-for-reporting requirements mandated by the DRA of 2005 in the proposed rule, we do have one significant concern as CMS eventually considers transitioning to a pay-for-performance environment. In New York we have a 1915 waiver program called the Long Term Home Health Care Program (LTHHCP), which provides an intensive array of Medicaid home and community-based services to nursing home eligible patients. The majority of the patients in the LTHHCP are dually eligible patients (Medicare/Medicaid) but Medicaid is the appropriate payer of services approximately 90% of the time. Patients must also meet the requirements of a mandatory state assessment every 120 days, which is separate from the federal OASIS requirement.

HCA's concern is that CMS does not differentiate between NYS' LTHHCP and our traditional Medicare Certified Home Health Agency (CHHA) providers. CMS simply recognizes both as Medicare certified providers submitting Outcome and Assessment Information Set (OASIS) data. However, since the majority of patients being served by our LTHHCP members have long term, chronic needs who are unlikely to improve compared to our CHHA members who serve patients with more acute needs and are expected to improve, HCA strongly recommends that CMS remove NYS' LTHHCP from this initiative. This would ensure that in the future when CMS begins rewarding home health agencies for their OASIS performance measures, NYS' LTHHCPs would not be adversely effected.

LUPA Rates

Most recent United Government Services (UGS) data for New York (July 2005 – December 2005), shows that 13.76 % of the episodes qualify for Low Utilization Payment Adjustment (LUPA) reimbursement. UGS' data for New York in 2004 showed that over 12 % of the home health PPS episodes qualified for the LUPA reimbursement. Although CMS predicted that the proportion of LUPA episodes would drop from 15 % to 5 % once PPS was implemented, HCA has not found support in either New York or national data.

HCA has also been able to review Medicare cost report data submitted by home health agencies in New York from 2001-2004. Those cost reports clearly demonstrate that the revenue on four out of the six LUPA payment falls short of the average cost of those visits. Quite simply, average cost per visit by discipline for agencies in New York (except physical and occupational therapy) is significantly greater than the proposed LUPA rates for CY 2007. The following chart provides a comparison.

Discipline Type	Proposed CY 2007 LUPA Rate	NYS' Average Cost Per Visit (2004 Cost Report Data)
Home Health Aide	$46.15	$79.12
Skilled Nursing	$101.91	$144.30
Physical Therapy	$111.43	$108.92
Occupational Therapy	$112.18	$103.20
Speech Therapy	$121.08	$121.10
Medical Social Work	$163.36	$183.20

Because of the aforementioned information and the fact that New York's average cost per visit data is from Medicare cost reports submitted for 2004, HCA strongly recommends that there be a review and increase to the LUPA per visit rates to ensure that they cover the costs of care for these patients.

Case Mix Weight

HCA wishes to highlight a few areas with respect to case mix weight. First, we believe that the HHRG case mix classification does not recognize the added costs of the dually eligible. This population has more comorbidities and often lacks the informal supports others have. Since the existing Medicare case mix system does not recognize these complexities that add to the cost of care, we recommend that an add-on for these patients be implemented until refinements to the case mix system can be made.

In addition, we believe that the case mix system does not adequately recognize the costs of wound care given the intensity of some of these patients and the newest supplies that can facilitate rapid healing.

Finally, we urge CMS to institute ongoing analysis of the case mix weights along with a mechanism to refine the case mix adjustments. CMS has four years of data that should assist in this process and should make use of that data.

In conclusion, we thank you for this opportunity to comment and would be happy to assist CMS staff in any way going forward.

Sincerely,

Patrick Conole

Patrick Conole
Vice President, Regulatory Affairs
Home Care Association of New York State, Inc.

Submitter : Mr. Michael Tracey

Organization : Mr. Michael Tracey

Category : Other Health Care Professional

Date: 09/22/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1304-P-29-Attach-1.DOC

ATTACHMENT TO # 29

Regarding proposed rule 1304-P regarding Medicare payments for oxygen equipment.

Comments:

CMS is not understanding nor recognizing the amount of service that goes into providing oxygen in the home for people that are disabled, elderly, and medically comprised by a severe pulmonary disease. These people have limited function due to their severe shortness of breath and lack of oxygen. Many cannot remember well or think clearly because of the everyday severe hypoxemia that they suffer from. You are expecting these disabled and medically comprised individuals to take care of their own equipment after 36 months. Many of our patients cannot keep their external filter clean on a regular basis, non-the-less change internal filters that are required to be checked and changed. Our patients are visited by a Respiratory Therapist every 50-70 days and a follow-up is done. During the usually 90 minute follow-up the following is done:

- the equipment is checked over for proper function
- the tubing's are all changed
- the filters checked and cleaned or replaced when needed
- the concentrator analyzed for proper oxygen output
- the flow meter checked for accurate flow
- the back-up system checked
- the portable system checked for proper function
- a review of all of the procedures is done with feedback demonstration from the patient or caregiver
- a check of the patients medical condition is done along with a review of their medications
- blood pressure is checked
- pulse is checked
- oximetry is checked
- lungs are listened to

Under the proposed rule this will go away for all Medicare patients beginning month one. Suppliers like ourselves will not be able to afford to provide this service if we are will not get paid for it. This service has been an important aspect to providing quality care and keeping the patient healthy and out of the hospital. There is no question that by eliminating the supplier to patient interaction that the amount of physician visits, emergency room visits and hospitalizations will increase dramatically. Dose this represent a cost savings? I think not. One avoidable hospitalization of acute exasperation of COPD because they were not getting their oxygen because of improper use will cost CMS about $4500. Did the Medicare program really save money in this case?

Regarding transfer of ownership of equipment. First of all the FDA classifies oxygen as a legend drug and a concentrator as a legend device. These devices are not to be dispensed without a prescription and are to be tracked by manufacturer serial number for recall purposes. By allowing the transfer of ownership to the beneficiary and removing the supplier from the responsibility of assuring compliance to the law, the public will be at serious risk. For example, the beneficiary dies and therefore no longer needs the

equipment. The family decides to sell the concentrator at an estate sale or auction. A buyer comes along and purchases the unit (direct violation of FDA rules). The first problem is that the machine may not have been inspected for a year or more because the previous owner did not want to pay to have it done. Someone may be purchasing a unit that is putting out less than therapeutically pure oxygen and not even know it. In most cases this would be a good thing because in the wrong hands, high levels of oxygen could cause death. If someone with COPD were to obtain a concentrator illegally from a private party and treat themselves with the maximum flow of oxygen (6 liters per minute) they would die. People with COPD retain carbon dioxide. Normally our brain tells us to take a breath when our carbon dioxide level rises. With COPD and chronically high carbon dioxides this drive is taken away. This person now is told to breathe when their oxygen level decreases to a certain point. If they over oxygenate themselves they will stop breathing, go into a comatose state and ultimately die. Most COPD patients can only handle 2 liters per minute as a maximum flow rate. The equipment is designed to go to 6 to 10 liters per minute. Again, we as suppliers assure that the equipment is properly dispensed, used and cared for. We can't do that if we are removed from the loop.

To transfer the ownership of the cylinder, including the empties that are circulated is unrealistic at best. Our empties are picked up and brought back to the store. Twice weekly they are picked up by another company, transported about 200 miles, cleaned, depressurized, refilled, and transported back. There is no way that these cylinders will be able to be kept track of by who they go to. There are several hundred at a time that go back and forth. Mot always to we get them all back as some develop leaks and others require their every five year hydrostatic test. It may be weeks before they would get back to us. In this case the customer would be without. Who pays for the repaired valve or for the hydro test?

Regarding the proposed fees. The payment of $64 per month for 36 months on a transfilling system covers about half to two thirds of our cost to purchase the unit by the time you buy the transfilling unit, the special cylinders and gauges and conserving devices. We will not be providing these to Medicare patients if this rule goes through as is. As far as the $55 for the portable contents delivery. Is this per delivery or per month? Currently we deliver weekly to all of our ambulatory patients. They get anywhere from 2 to 10 tanks per week. We have been able to do this under the current structure because we have always been told that the "contents" for the portable refills is included in the payment for the stationary system. How soon we forget. This was changed not that many years ago. Were not any of you around then? By eliminating our payment after 36 months you are eliminating portable contents refills unless you plan to pay the $55 for each delivery. Currently we provide the patients with as many tanks and refill as they need. In many cases we provide an electronic conserving device at no charge (retail value of $500-$750). These units reduce the usage of the oxygen therefore requiring the patient to use fewer tanks. Under the proposed rule, we will not provide these either. Please set a limit on how many tanks and refills the supplier is required to provide. It is extremely unfair for you to mandate fixed and reduced payments and then require that we provide an "unlimited" supply of portable contents. If your plan is to pay $55 per month for contents then limit the number of deliveries that we have to make in a month as well

as the number of cylinders they are allowed to have and the number of refills they get. For $55, I can deliver three tanks once per month. Does the $55 portable contents fee start from month one or does it only kick in after the 36 months?

Other key items missed in proposed rule:

If you are not willing to pay for routine maintenance then who will pay for the internal filters that requires replacement and who will pay for the technician to do it? The filters can range in price from $30 to $80 and will require replacement as early as every 6 months and no later than every 12 months. Who will pay to have the machine rebuilt when it wears out? Currently we average spending about $150 per year per concentrator in parts and labor to keep them properly maintained. A total rebuild of a compressor, sieve beds, and valves will cost somewhere in the $800 to $1000 range. Who will pay for the cost of the replacement unit while the other one is getting serviced?

Currently under the existing reimbursement structure, we provide 24 hour emergency service 7 days a week for all of our oxygen customers. Who will pay for this service when the reimbursement halts? We will not provide these services to people that are not paying for it. It costs our company about $25 per month per oxygen patient to provide this service. This includes the on-call pay for our technicians and professionals. The answering service, the pagers and cell phones, the overtime incurred because of after hours calls and the mileage paid out for the emergency calls. Without our availability the beneficiary in need will have to call an ambulance and be transported to the emergency room. What if there is a natural disaster and they require replacement tanks or equipment? Currently our disaster plan for our oxygen patients assures that they will all have access to our serves, replacement tanks, etc. This will go away under the proposed rule.

Currently we provide a back-up system to the concentrator in case of a power outage or equipment failure. This system is a cylinder holding 3450 liters of oxygen (24 hour supply at 2 liters per minute), a special regulator, a stand, and extra tubing and connectors. Cost of this system is $350-$500. This is provided free of charge. Under the proposed rule, this system is not recognized and therefore will not be provided. The patient will be required to go to the hospital ($4500) if their electricity goes out.

Currently we supply an unlimited quantity of oxygen tubing, connectors, cannula's, humidifiers, swivels, etc. on a monthly basis and do not charge for this. The cost of this is about $20 per month on average. There is no provision in the rule to allow for payment for the supplies. Currently the supplies are built into the rental payment that we currently receive.

All in all, Congress has made a huge mistake through the guidance and leadership of a small group of very ill informed individuals. The 36 month cap on oxygen will severely limit beneficiary access to oxygen equipment. CMS will not save money, but rather shift the cost over to the other sectors of health care previously mentioned. Under the current reimbursement structure, CMS is getting a bargain. Think about it, for less than $7.50

per day they are getting all of the above listed equipment, services and supplies. The proposed rule is an attempt to comply with the legislation but does not meet the test in assuring that the beneficiary is not negatively affected or harmed.

Respectfully submitted,

Michael R. Tracey
HME Manager
Bay Pharmacy
1300 Egg Harbor Rd, Suite 112
Sturgeon Bay, WI 54235
(920) 746-2158

Submitter : Ms. Sharon Fowler

Date: 09/22/2006

Organization : Inspire Medical Equipment & Services, Inc.

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1304-P-30-Attach-1.DOC

#30

September 22, 2006

Department of Health and Human Services
Centers for Medicare & Medicaid Services

RE: [CMS-1304-P] Comments

To Whom It May Concern,

I am writing to you first as a Registered Respiratory Therapist who has been serving patients in their homes since 1982 and second as a founding partner of Inspire Medical Equipment & Services, Inc. I am commenting because I believe the NPRM proposals are poorly conceived and if enacted as currently written will create hardships to both beneficiaries and home oxygen providers.

Let me start by stating that acquisition costs for oxygen equipment and supplies are only a fraction of our overall costs and that the financial assumptions of the Deficit Reduction Act do not account for our costs of labor, facilities, utilities, vehicles, fuel, and administration of services. While it is true that the acquisition costs for oxygen concentrators have declined in recent years, all of our overhead expenditures have increased significantly.

Regardless of these increases, we have made the sacrifices necessary to continue to provide service to home patients 24 hours/day, 7 days/week. The proposed rule makes no provision for back-up/emergency oxygen supplies that are currently provided to our patients and are a requirement of accreditation. We are required to provide "3 times the response time" for use in the event of equipment malfunction and power failures. It appears to me that at the time of transfer of title of the concentrator the back-up oxygen supply (we use M-60 cylinders which provide 14 hours of oxygen @ 2 L/M) would have to be removed OR the beneficiary would have to pay for the cylinder, regulator, and stand on a rental basis and/or agree to a Service Contract to ensure an emergency oxygen supply and after hours services as needed. If home oxygen patients do not have back up oxygen supplies, they may call ambulances to go to emergency rooms for oxygen during extended power outages or when the concentrator fails. I do not believe that this is a desired outcome of this proposal, and thus an amendment should be made to ensure that back-up oxygen supplies are provided.

Furthermore, if title transfer of cylinders is to be included with transfer of a concentrator I have numerous concerns. First, we are required to track hydrostatic test dates for cylinders by the DOT. Aluminum cylinders must be tested every 5 years. Second, if cylinders are to be tracked by patient name it will create labeling issues currently not covered by the FDA, nor software programs by which serial and lot numbers are tracked. And what is the expected "after-market" life of these cylinders. Once the beneficiary no longer needs them, where will they go? eBay? Waste disposal? Garage sales? What happens to the tracking then. Oxygen cylinders are deemed "hazardous material" but DOT and FDA enforcement will be hampered once these items are in the public domain and no longer controlled by a gas supplier. It is conceivable that cylinders may be transferred amongst family members and filled by non-medical gas sources.

It is also unclear how many cylinders will be allotted to each beneficiary and of what size? If they need more or less portable cylinders post title transfer, how will that be addressed?

Apparently, beneficiaries are expected to clean, test, and maintain the concentrator. Does this mean that CMS plans to provide liter meters and oxygen analyzers to beneficiaries after the title of ownership is transferred?

If the concentrator is not maintained properly, or if the beneficiary attempts to repair the device or have it serviced by an unauthorized dealer the warranty will be voided.

Also, it seems that there is an assumption that concentrators have a five year warranty. That is no longer true. Every concentrator we own has a three year warranty, and now the manufactures have begun issuing notices that these warranties will be non-transferable. Thus, even if the beneficiary ends service with a new unit, the warranty will expire at the time of title transfer.

If concentrator servicing and repairs exceed 60% of the equipment's value the item is to be replaced. This is unreasonable because the CMS service fees have not been increased in approximately 10-15 years - even though our costs for parts and labor have increased. Thus, we will be unable to provide service or repair at the current rates, forcing beneficiaries to find a repair service on their own. And if another company provides service and repair, and does not have a Medicare Supplier Number, we should not be expected to replace the unit at the 60% threshold since we will have no way of verifying that the work performed was necessary or properly done. CMS is asking us to provide another unit without further compensation through no fault of our own. In the current system, we are held responsible for all maintenance and service and are required by accreditation to keep detailed records of the service history. But once the title transfers to the beneficiary we will loose control of the device service history and should not be expected to replace devices at no charge.

Respiratory Therapists are required to perform an initial assessment and patient/client instruction for home oxygen patients by the state of Massachusetts. It is also part of our service to provide follow-up visits by Respiratory Therapists based on the identified needs of a Care Plan or upon the written order of a physician. This is currently provided without charge to the beneficiary; however professional hourly fees based at a fair market value will be charged to the beneficiary for any visits needed post title transfer. Given the fixed income of the majority of our clients, we expect the level of care and monitoring in the home to decline because of this.

Oxygen accessory supplies such as regulators, carts/stands, nasal cannulas, tubing, adapters, connectors, humidifiers, and filters are all supplied as part of the rental agreement. Our patients are instructed to change their nasal cannula weekly. What quantity of supplies will be allowed to the patient and in what time frame? Will delivery or shipping charges be included or charged to the beneficiary?

If you require any further information please contact me directly at 978-372-2290.

Respectfully yours,

Sharon E. Fowler, RRT, RCP
General Manager

Submitter : Mr. Glenn Hackbarth **Date:** 09/22/2006

Organization : MedPAC

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1304-P-31-Attach-1.PDF

#31

MEDPAC Medicare Payment Advisory Commission

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Glenn M. Hackbarth, J.D., Chairman
Robert D. Reischauer, Ph.D., Vice Chairman
Mark E. Miller, Ph.D., Executive Director

September 22, 2006

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: File Codes CMS-1304-P.
Sections D. and F.

Dear Dr. McClellan:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit these comments on CMS's proposed rule entitled *Medicare program: Home Health Prospective Payment System Rate Update for Calendar Year 2007*, Federal Register Vol. 71, No. 149, pages 44085-44092 (August 3, 2006). In this letter our comments are on measuring quality and the wage index in home health. We appreciate your staff's ongoing efforts to administer and improve the home health payment system, particularly considering the agency's competing demands.

Reporting on Quality

MedPAC supports CMS's plans to expand the quality measure set to include process measures. We have published work that discusses process measures in home health, focusing on fall prevention and wound care practices. (http://www.medpac.gov/publications/congressional_reports/Jun06_Ch05.pdf.) The discussion concludes that the practices listed in Tables 1 and 2 should be considered for development into process measures for the care of falls and wounds.

Table 1. Pressure wound practices

Improve assessment	○ Assess skin from head to toe ○ Assess wound at each visit ○ Photograph wound as part of the record
Improve treatment	○ Offload pressure ulcers ○ Maintain moist wound bed as appropriate ○ Develop a turning schedule or increase mobility as appropriate ○ Use infection control techniques ○ Educate caregivers regarding infection control
Develop physician contact protocols	○ Contact physician at first sign of infection ○ Contact physician if wound does not respond to treatment within 2 weeks

Table 2. Fall prevention practices

Use a standard, multifactor tool	○ Include patients' fall history ○ Include a medication inventory
Use validated techniques to measure fall risk	○ Measure postual hypotension ○ Measure balance deficits by asking patient to stand on one foot for 10 seconds
Link assessment tool to appropriate follow-up activities	Follow-up could include: ○ Contacting physician about medications that increase fall risk ○ Referring patient to a physical or occupational therapist ○ Initiating gait training, balance training or strength training

These measures could complement the process measures being developed by CMS and elsewhere for other important health conditions, such as chronic disease or other functions such as medication management.

Home Health Wage Index

The rule proposes to use the pre-floor pre-reclassification hospital wage index for home health as has been done in the past and solicits comments about new methods to establish wage index values for areas without hospitals.

For rural Massachusetts, for example, the rule proposes using last year's value of 1.0216. It also discusses an alternative: the average of the rural wage indexes for the New England Census Division.

However, these indexes range from .8410 in Maine to 1.1753 in Connecticut. Because this range is so broad, the Census region average does not seem to be a reasonable approximation of the wages in any of the constituent rural areas.

An alternative that CMS could consider is using BLS wage data to derive a ratio of rural Massachusetts' wages to wages in an urban MSA in Massachusetts (Boston, for example) for the mix of workers hospitals employ. That ratio could then be multiplied by the current Boston MSA wage index to derive an estimated wage index for rural Massachusetts.

MedPAC appreciates your consideration of these comments. If you have any questions, or require clarification of our comments, please feel free to contact Mark Miller, MedPAC's Executive Director, at (202) 220-3700.

Sincerely,

Glenn M. Hackbarth
Chairman

Submitter : **sharon bradley** **Date: 09/22/2006**

Organization : **Nursing & Home Care Inc**

Category : **Home Health Facility**

Issue Areas/Comments

GENERAL

GENERAL

Provisions of the proposed regulations -
A market basket update of 3.1% is critical to Nursing & Home Care's ability to continue to provide services to the frail, elderly & disabled.
We strongly support the 15% adjustment to standardized rates for patients eligible for both Medicare & Medicaid. 'Dually eligible' patients with chronic care needs overlaid with acute care needs require additional care and longer care.
Hospitalization and emergent care clinical outcomes, as currently measured, do not consider the long term care patients on the skilled care services of many home health agency programs. Payment schemes should not be based upon these measures until these considerations are addressed.
Health information technology -
Telehealth services should be directly funded. The cost savings to the Medicare and Medicaid programs in terms of decreased hospitalization rates and overall decrease use of multiple medical services has been documented. Funding to be able to continue and to expand these offerings is essential.

Thank you.

Submitter : **Ms. Ann Howard** **Date: 09/22/2006**

Organization : **American Association for Homecare**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1304-P-33-Attach-1.DOC

#33

Via Electronic Submission

September 22, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445-G Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1304-P

Dear Dr. McClellan:

The American Association for Homecare (AAHomecare) appreciates the opportunity to submit comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule entitled "Home Health Prospective Payment System Rate Update for Calendar Year 2007," published in the Federal Register on August 3, 2006.

The American Association for Homecare is the only national association that represents every line of service within the homecare community. Our members include providers and suppliers of home health services, durable medical equipment services and supplies, infusion and respiratory care services, telehealth, and rehabilitative and assistive technologies, as well as manufacturers and state associations. With more than 700 member companies at 3,000 locations nationwide, AAHomecare and its members are committed to advancing the value and practice of quality health care services at home.

Our comments will focus on two areas: home health outcome and process measures and Health Information Technology (HIT). Our responses follow questions posed by CMS in the August 3 proposed rule, which we have paraphrased in italics.

How can CMS make home health outcome measures more useful?

AAHomecare has long advocated that the Outcome and Assessment Information Set (OASIS) be streamlined to include only those elements that are necessary for case mix assignment and payment under the home health prospective payment system (PPS). For outcome measures to reach the level of maximum usefulness, OASIS elements must be further refined. The wording of some problematic questions, from which home health agency outcomes are derived, has led to subjective responses and distorted publicly reported measures, for example, in the areas of

emergent care, medication management, dyspnea, and improvement in bathing. The national home health associations (AAHomecare, the National Association for Homecare, and the Visiting Nurse Associations of America) made a number of recommendations to the CMS Administrator in 2003 for refinement of OASIS. We are aware that an OASIS Technical Expert Panel (TEP) has a number of additional recommendations pending at CMS though we are not privy to the specifics. CMS should enter into a dialogue with the home health industry to evaluate these recommendations and determine how they could lead to the development of process measures that are evidence-based, reliable, validated, clinically significant, and risk-adjusted.

The hospitalization and emergent care measures seem to be the most useful of the possible measures available through OASIS. It would be worthwhile for CMS to put resources into refining these measurements, for example, changing the wording of the questions if necessary, refining the risk adjustment methodology, and eliminating factors outside of a home health agency's influence and control. In particular, the emergent care measure should focus on emergency room utilization, which is how most payors nationwide evaluate emergent care. We note that another outcome is being skewed -- "Discharged to Community." If a home health agency appropriately transfers a patient to a hospice program, this is not scored as a Discharge to Community. Also, it would not be difficult to develop a measure related to healing of chronic wounds, including consideration of the length of stay adjusted for severity of wound.

AAHomecare agrees with the Medicare Payment Advisory Commission's recommendation that measures should be developed for patients whose conditions and disease processes are such that they will not improve. Such measures might apply to patients who can be maintained but will not improve, e.g., some who have multiple complex chronic conditions, or to beneficiaries whose conditions will inevitably deteriorate, e.g., hospice-eligible patients who decline the hospice benefit.

Are there measures of home health care processes for which there is evidence of improved care to beneficiaries?

AAHomecare formed a task force of home health clinicians in 2004 to develop principles, measures, and a framework for Medicare home health Pay-for-Performance (P4P), and in 2005 joined with the other national home health associations to further refine an approach to P4P. We are aware that CMS has a contractor exploring best practices in a number of disease areas. Also, MedPAC convened a TEP to consider existing wound care and falls prevention protocols in search of validated evidence based best practices, and we support this initiative.

AAHomecare's Pay-for-Performance workgroup has recommended a number of prime areas for development of evidence based best practices: in particular, **wound care, falls prevention, congestive heart failure, diabetes, and chronic obstructive pulmonary disease.** Workgroup participants have themselves implemented protocols in these disease areas. Based on their agencies' outcomes, they have determined that their best practices are effective. There is, however, no consistent set of protocols employed across these agencies. In light of the desire of Congress, MedPAC, and CMS to move expeditiously to a home health pay-for-performance system, there is a compelling need for CMS to work with the industry to identify and validate

best practices in these and other promising areas. (For example, one area of promise would be research on congestive heart failure guidelines relating to nursing implementation of standard guidelines, such as daily weights on CHF patients, teaching patients about wellness activities, and taking action when a patient is outside of established parameters.)

The national home health associations, working in collaboration, have developed principles for P4P that depend in significant part upon identification and validation of evidence-based best practices. These principles are as follows:

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, payors, 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 homecare 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

Are you aware of any home care patient "experience of care" measures?

We are not aware of any standardized experience of care measures at this time, but in the late 1990's the Picker Institute in Boston did work with consumer groups on homecare standardized experience questions. The use of patient satisfaction surveys is widespread among home health agencies, with some utilizing instruments such as Press Ganey or conducting their own surveys. Again, this is an area where CMS should invest in research to develop a uniform survey, an initiative in which the home health associations would be pleased to participate but no doubt do not have the resources to develop on their own.

Are you aware of any home health efficiency measures?

There is a copious amount of utilization information available. CMS should focus on measures that reflect care producing the best outcomes adjusted for case weight with the fewest visits. In this regard, we recommend that CMS look at Outcome Concept System's bubble graph approach which profiles utilization and risk adjusted outcomes per individual agency quarterly and annually.

Do you believe CMS has the statutory authority to require adoption of Health Information Technology (HIT) as a "normal cost of doing business" for home health agencies?

This query raises many questions for which we need answers from CMS before we can comment further. Before considering such a requirement, CMS should first address the scope of Health Information Technology it may be considering. Which of the following would HIT encompass: point of care devices; telemonitoring and the central station to oversee the results from multiple patients; electronic access to physicians so they may review the home health Plan of Care and sign it electronically, and also review the results of monitoring and assessment; electronic interfacing with pharmacies to efficiently support a current patient medication profile and screen for interactions; access to laboratory results which are appropriate to the scope of the Plan of Care; the use of cameras for reviewing patient conditions such as wounds; and so on? Would CMS envision home health agencies integrating all of the above technologies into their operations or just those of their own choosing based on what best suits their programs and their financial resources?

Does CMS anticipate enforcement of mandated consistent technical requirements for HIT across the whole health care spectrum? This is the sine qua non for HIT to improve transparency in reporting and sharing of health information across providers and settings. CMS must ensure that home health representatives are participants on task forces developing the HIT and Electronic Health Record platform standards and common measures across settings.

CMS should first define the scope of HIT needed for efficient and effective care and then consider the cost of such technology to home health agencies. In an era when Medicare home care providers have sustained seven reimbursement reductions in the last nine years, including a freeze in the current calendar year, funding of such technology would be problematic for many

providers. Maintenance of the 3.1 percent market update for 2007 is vital for HHAs trying to integrate technology into their programs, but that may not be enough to fund investment in HIT at a time when truncated inflation updates have failed to keep pace with rising costs in other areas for HHAs, such as transportation costs and the cost of recruiting and retaining nurses and therapists. A major issue is whether CMS anticipates subsidizing such a HIT mandate and if so, how. As it considers financial incentives for home health agencies to move towards HIT, CMS must provide for consideration of providers who have already undertaken research, piloting, and redesign of their information technology systems.

CMS should consider adoption of HIT/telehealth as a component of evidence based process measures for certain diseases or conditions, such as congestive heart failure (CHF), with the choice of technology left to the judgment of the home health agency.

If CMS has such authority, should it require HHAs to integrate HIT into their operations?

It would be appropriate for CMS to set systems standards for organizations that choose to adopt HIT. CMS must, however, take into consideration that small home health agencies, including many in rural and underserved areas, would find it too much of a financial burden to comply with a mandate in the next several years.

Finally, with regard to the Core Based Statistical Areas (CBSA) wage index, although some of our members are satisfied with the new 100 percent CBSA formula, one of our large multi-state companies reports that its experience has been that that the 2006 blended rate has had a serious negative impact on a number of its agencies. The company expects the proposed 2007 CBSA rates to also have a further serious negative effect on a number of their offices. These types of abrupt reimbursement adjustments are better tolerated when a home health company has time to adjust to reduced reimbursement rates. The changes in 2006 were layered on top of the denial of the annual update. We recommend a period of stabilization for home health agencies impacted by the new CBSA wage formula.

AAHomecare looks forward to working with CMS to address the questions posed in the August 3 proposed rule, as well as during the coming months as CMS further refines the home health Prospective Payment System.

Sincerely yours,

Ann Howard

Ann B. Howard
Director of Federal Policy

Submitter : Brian Ellsworth **Date:** 09/25/2006

Organization : CT Association for Home Care

Category : Home Health Facility

Issue Areas/Comments

Health Care Information Transparency and Health Information Technology

Health Care Information Transparency and Health Information Technology

The CT Association for Home Care provides the following comment on health information technology:

CMS should create a direct funding mechanism for the provision of telemonitors by HHAs to patients with certain chronic illnesses and it should provide grants and other direct economic incentives to develop electronic health records.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

The CT Association for Home Care submits the follwing comments on behalf of 82 Home Health Agencies (HHAs)serving over 50,000 Medicare beneficiaries using home health services:

1) HHAs in CT absolutely need the proposed market basket update of 3.1 percent. Based on the most recent Medicare cost report data available, CT HHA total operating margins are minus 2.73 percent, due to chronic under-funding of Medicaid home health rates and the unrecognized costs of patients dually eligible for Medicare & Medicaid.

2) CT HHAs strongly support a 15 percent adjustment to the standardized rate for patients that are eligible for Medicare & Medicaid. Data from a national benchmarking firm (Outcome Concept Systems) indicates a persistent 15 percent higher per episode cost for dual eligible patients compared to Medicare-only patients in the same case mix category. This is due to the unmeasured effects of multiple chronic illnesses, tendency to lack informal supports and lack of patient compliance with care plans.

3) CT HHAs strongly support the implementation of the rural floor policy, wherein no urban wage index is lower than the rural wage index for that state. We believe that CMS has ample statutory authority to effectuate this policy. This adjustment would counteract an unjust 5 percent decline in the Hartford region s wage index due to changes hospital cost reporting of pension costs. Implementation of this policy would also be a down payment on moving the system towards greater parity in Medicare payments for labor costs since HHAs compete with hospitals for the same scarce labor.

4) The hospitalization and emergent care outcome measures are fatally flawed because of upward biases resulting from the effects of the inclusion of long stay, chronic care Medicaid patients in the calculation. Generally, these patients only appear in the calculation when an adverse event occurs necessitating hospitalization and the length of stay is less than 12 months. The average length of stay for patients in CT s Medicaid waiver program is four years. Those patients with no hospitalizations during that time are never measured in the outcome calculation. CT HHAs have approximately twice the national average proportion of Medicaid patients and are thus disproportionately impacted by the bias from inclusion of long stay, chronic care patients. Pay for performance cannot be implemented until this bias is eliminated.

Submitter : Kathy De Almo **Date:** 09/25/2006

Organization : Connecticut VNA

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

HHAs in CT need the proposed market basket update of 3.1 percent. Based on the most recent Medicare cost report data available, CT HHA total operating margins are minus 2.73 percent, due to chronic under-funding of Medicaid home health rates and the unrecognized costs of patients dually eligible for Medicare & Medicaid.

Connecticut VNA is having difficulty attracting nurses and therapists because we don't have the money to provide competitive salary and benefits.

CTVNA strongly supports a 15 percent adjustment to the standardized rate for patients that are eligible for Medicare & Medicaid. Data from a national benchmarking firm (Outcome Concept Systems) indicates a persistent 15 percent higher per episode cost for dual eligible patients compared to Medicare-only patients in the same case mix category. This is due to the unmeasured effects of multiple chronic illnesses, tendency to lack informal supports and lack of patient compliance with care plans.

The hospitalization and emergent care outcome measures do not reflect that Connecticut has a large number of dually eligible patients in Connecticut..... proportionately it's twice the number of Medicaid patients as some other states. The average length of stay for patients in CT s Medicaid waiver program is four years. Connecticut is disproportionately impacted by the bias from inclusion of long stay, chronic care patients. Pay for performance cannot be implemented until this bias is eliminated.

Please create a direct funding mechanism for the provision of telemonitors by HHAs to patients with certain chronic illnesses. This could improve care and reduce cost.

Thanks you for considering this input.

Submitter : **Ms. Rosemary Mastrobattisto** **Date: 09/25/2006**

Organization : **VNA Community Healthcare**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

HHAs in CT absolutely need the proposed market basket update of 3.1 percent. Based on the most recent Medicare cost report data available, CT HHA total operating margins are minus 2.73 percent, due to chronic under-funding of Medicaid home health rates and the unrecognized costs of patients dually eligible for Medicare & Medicaid.

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Health Care Information Transparency and Health Information Technology

? CMS should create a direct funding mechanism for the provision of telemonitors by HHAs to patients with certain chronic illnesses and it should provide grants and other direct economic incentives to develop electronic health records.

Submitter : Dr. Leanne M. Chrisman **Date:** 09/25/2006

Organization : Case Western Reserve University

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

University Hospitals
Department of Family Medicine
11100 Euclid Avenue Mailstop 5036
Cleveland, OH 44106-5036
25 September, 2006
Re: HHA PPS/Consolidated Billing; A-4353

Dear Mr. Herb Kuhn:

As a family physician practicing in a tertiary care setting, I care for many patients primary care needs within the scope of their high-risk conditions. Such patients usually have a great number of problems, and secondary prevention, or the prevention of health consequences from their underlying conditions becomes as paramount as their primary prevention.

One such group is patients with spinal cord injury. Because of neurogenic bladder, these patients are prone to life-threatening infections and kidney failure. Because of the incomplete emptying of the bladder, bacteria tend to colonize and eventually cause catastrophic illness. Often because of the chronic and recurrent nature of the infections and use of antibiotics the bacteria present escalate in their virulence and resistance to antibiotics. Hence, we try to prevent this situation by prescribing sterile technique with catheters that best suit their individual needs.

Unfortunately, when other problems arise, such as stasis ulcers, these patients enter into home care, with a home health agency. When this occurs, my secondary prevention of their bladder care ends. These patients do not receive sterile technique supplies; and, when they do, they are the wrong type and number. This practice of having the home health agency provide other such supplies is untenable. They do not have an intimate knowledge of the breadth of urological supply; and, when they do have the knowledge, they do not have access.

These patients have already had problems by the time they get this sterile technique as we must document recurrent urine culture positive, symptoms of more severe disease and underlying risks before the patient is approved to receive the A-4353 supplies. These patients have already had problems by the time they get this sterile technique as we must document recurrent urine culture positive, symptoms of more severe disease and underlying risks before the patient is approved to receive the A-4353 supplies. Once documented, the patient receives this supply to continue their bladder management without interruption.

An analogy to this situation would be to take a cardiac patient who requires medication to prevent further complications by controlling their risk factors of high blood pressure, high cholesterol, and diabetes. The analogy to the loss of supplies is when that heart patient goes to for instance need wound care for their Coronary artery bypass incision, and then is denied their heart medications because the home health agency doesn t stock them. Thereby, allowing this heart patient s blood pressure to run amuck simply because they now need home health care.

I look to hear from you on this important matter: lmc17@case.edu; or address above.
Respectfully submitted,
Leanne M. Chrisman, MD, MEd

Submitter : Patti Hoffman **Date:** 09/25/2006

Organization : American HomePatient, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See attached comments re: Payment for Oxygen, Oxygen Equipment and Capped Rental DME Items.

CMS-1304-P-38-Attach-1.RTF

Attachment to #38

FILE CODE CMS-1304-P
COMMENTS FROM AMERICAN HOMEPATIENT, INC.
Re: Payment for Oxygen, Oxygen Equipment and Capped Rental DME Items

On August 3, 2006, the Centers for Medicare & Medicaid Services ("CMS") published a proposed rule in the *Federal Register* entitled "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," **file code CMS-1304-P.**

American HomePatient, Inc. (OTC: AHOM), one of the nation's largest home health care providers, has chosen to provide comments to CMS related to the section on Payment for Oxygen, Oxygen Equipment and Capped Rental DME Items. In 2004, there were approximately 1.3 million Medicare beneficiaries on oxygen therapy. We are concerned that some of the provisions of CMS-1304-P will have unintended consequences for beneficiaries who depend on home oxygen not only to help them breathe but also to maintain some level of quality of life.

American HomePatient would like thank CMS for its expressed willingness to work with the industry to ensure that the Medicare beneficiary continues to have access to their much needed oxygen therapy.

We are committed to working with CMS and with legislators to make certain that oxygen therapy is available for every Medicare beneficiary needing this vital treatment. Toward that end, we are submitting comments on several provisions of the DRA that are of concern to us and we believe are of concern to the Medicare beneficiary.

Specifically, we plan to comment on the following provisions of the NPRM:

- We are concerned that the proposed changes to the regulatory payment rates for oxygen and oxygen equipment are not "budget neutral" as statutorily required, but rather the changes will result in a significant reduction in the current oxygen reimbursement.

- We are concerned that certain of the beneficiary's protection and access provisions will result in access being limited or denied instead of access being safeguarded. In addition, certain beneficiary protection and access provisions disadvantage the supplier and in some cases provide no remedy for the inequities.

New Payment Rate—Budget Neutrality

CMS states in the NPRM that the new payment rate is budget neutral. However, the agency did not provide adequate information to determine if the data or methodology used actually support their assertion. An industry commissioned review of the proposed rule conducted by the Lewin Group, raises concern that the new payment rate is not budget neutral, but will result in an estimated $256 million being taken out of the system. The Lewin Group report was submitted to CMS by the industry's association.

CMS asserts that the need for the new payment rate, in part, is to ensure that the beneficiary has access to portable oxygen contents and to newer portable oxygen technology. While we appreciate CMS' acknowledgement that portable oxygen is currently inadequately reimbursed, we are concerned that the new payment rate is insufficient and does not lessen earlier concerns voiced relative to the creation of a potential access issue for the beneficiary.

We encourage CMS to continue to work with the industry to achieve appropriate payment for each modality of oxygen therapy provided. We also request that CMS provide clarification relative to the data and methodology used in their assertion that the new payment rate is budget neutral.

Beneficiary Protection and Access Provisions

To safeguard the beneficiary's access to equipment during the capped rental period, the proposed rule would require the supplier providing the equipment in the first month of the rental period to continue to do so until the capped rental period ends. The proposed rule allows for certain exceptions but none of the exceptions allows a new supplier to receive a new continuous rental period. Two of the exceptions seek to ensure the patient's right to his/her choice of suppliers by allowing the patient to "switch" suppliers at any time. We agree that the patient's right to choice should be protected. However, by failing to provide a new continuous rental period for the new supplier, CMS will severely limit or more likely eliminate any options the patient has in exercising his/her right to choose a different supplier.

Another provision proposes to safeguard the beneficiary's access to quality equipment by prohibiting the supplier from exchanging the patient's equipment during the continuous rental period. The proposed rule does allow for certain exceptions such as the equipment being lost, stolen or irreparably damaged by the beneficiary. We agree this is a valid exception. However, if the equipment is not yet patient-owned, the proposed rule does not allow the supplier to receive a new continuous rental period for the replacement equipment. We believe that

such an inequity was inadvertent and we ask that CMS provide a remedy for making whole the supplier for losses (assets) resulting directly from the acts of the beneficiary.

A similar provision that proposes to safeguard the beneficiary's right to quality equipment requires the supplier, under certain circumstances, to replace free of charge beneficiary-owned equipment. We agree that equipment for which ownership has transferred should be in good working condition. However, it is inequitable to require the supplier to replace free of charge patient-owned equipment that prematurely fails because the patient did not maintain it in accordance with the manufacturer's guidelines. Again, we believe that this inequity was inadvertent and we ask CMS to remedy same by providing for a new continuous rental should the beneficiary's action during the ownership useful lifetime period result in the premature failure of the equipment.

Summary

In summary, we believe that lacking CMS remedy, certain provisions of the NPRM will result in unintended consequences that could directly and indirectly lead to 1.3 million beneficiaries being limited in their choice of supplier and access to much-needed oxygen therapy.

Submitter : Gary Morse **Date:** 09/25/2006

Organization : DME MAC Jurisdiction A Council

Category : Health Care Provider/Association

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Mr. Phillip Porte **Date:** 09/25/2006

Organization : National Home Oxygen Patients Association

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1304-P-40-Attach-1.DOC

CMS-1304-P-40-Attach-2.DOC

NHOPA
National Home Oxygen Patients Association

September 25, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1304-P
Room 445-G
Hubert M. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Reference: File Code CMS-1304-P - Comments Related to Proposed Rule re: 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 (July 28, 2006)

Dear Dr. McClellan:

The National Home Oxygen Patients Association (NHOPA) welcomes the opportunity to comment on the CMS proposed regulation revising the entire methodology for payment of home oxygen therapy. NHOPA is a ten year old non profit organization whose sole purpose is to improve the lives of people who require supplementary oxygen. This proposal moves the Medicare payment system in that direction.

We believe our perspective is unique in that, for the most part, we are able to remove ourselves from the heated discussions regarding costs and payments and we can focus on our primary concern – access to appropriate oxygen systems as prescribed by physicians. To that end, we have reviewed the comments of the key pulmonary medicine societies, the American College of Chest Physicians, the American Thoracic Society and the National Association for Medical Direction of Respiratory Care and echo and support their comments and recommendations.

For several years NHOPA has supported the concept of modality (class) specific oxygen payment. We believe this issue was dramatically highlighted by the review of the Polk County pilot study for competitive bidding which clearly signaled a reduction in the use of lightweight portable oxygen systems once the competitive bidding process took hold. We had long surmised that oxygen patients received an oxygen system based on the provider's determination of appropriateness rather than the physician's recommendations.

The continuing presence of e-cylinders rather than the lightweight technologies that have arrived on the market further verify the Polk County findings.

As mentioned above, we do support the methodology recommended by the pulmonary physician societies to assign beneficiaries to classes of devices based on clinical need rather than primarily on the particular characteristics of the device. The creation of three classes of oxygen systems, stationary, portable and ambulatory is logical, clinically sound, and would go a long way to ensure that patients receive clinically appropriate devices rather than devices that might provide the supplier with attractive profit margins. While truly homebound patients would certainly enjoy a lightweight (more expensive) system, it is difficult to justify the placement of such a device with a patient who rarely leaves the home.

We believe, however, that CMS must move aggressively with an important, even critical, campaign to educate beneficiaries regarding not only the creation of classes but there must be a focus on the specific devices within each class. We are told that most prescriptions for oxygen therapy are understandably written by primary care/family practice physicians. In candor, most of these physicians are completely unaware of the existing technologies for oxygen delivery, and our own survey of NHOPA members verifies that. Beneficiaries who are using cumbersome systems are frequently totally unaware that there are optional systems, lightweight in nature, that would not only meet their clinical needs but also provide dramatically greater opportunities for ambulation, involvement in activities of daily living, etc. We genuinely believe that the vast majority of oxygen users simply do not know what device options exist. The information is not forthcoming from the prescribing physician, often because of his/her own lack of information, and the provider understandably wants to provide a cost effective device, whether or not it is clinically appropriate for the patient's specific needs. We strongly recommend that CMS undertake an extensive educational program to eliminate this ongoing barrier to portable and ambulatory devices.

In terms of the specific proposal, we support the recommendations of the pulmonary medicine societies for creation of 3 specific classes:

- Stationary class: Patient is moribund, bed bound, or limited to nocturnal oxygen need only. Limited need/ability to leave home. Stationary system (traditional oxygen concentrator) is exclusive of appropriate back-up

- Portable class: Patient requires oxygen at night and for limited mobility (or a single system that meets both needs). E cylinders and other bulky non ambulatory systems fit into this class.

- Ambulatory class: Oxygen needs include support for high ambulation (device for exercise and/or exertion only; also for oxygen at rest or nocturnally (stationary device plus high ambulation device or one device that meets both needs.

More specifically, traditional stationary concentrators would be categorized into the stationary class; e-cylinders and other bulky (over 10 pounds) systems that can be placed in carts, on wheels, etc. would be in the portable class. Systems under 10 pounds, according to manufacturer specifications, would be placed in the ambulatory class.

Beneficiary ownership of oxygen devices: A significant portion of the proposed regulation addresses many of the complicated issues that arise in the context of the transfer of ownership that is mandated by the Deficit Reduction Act (DRA). We do recognize that CMS must implement that provision of DRA but we must state in no uncertain terms **the National Home Oxygen Patients Association strongly opposes mandated beneficiary ownership of oxygen systems. Our members do not want the responsibility associated with maintenance and servicing of this life sustaining device, and we repeatedly hear from family members their concern about keeping the equipment once the need no longer exists. We do understand the physician concern regarding creation of a gray market for these devices if this DRA provision is actually implemented, and see virtually no benefit whatsoever in this legislative mandate.** We do recognize that some devices, particularly stationary concentrators, may lend themselves to relatively uncomplicated servicing and maintenance, but to leap to the conclusion that the newer technologies also fall into that category is, to the best of our understanding, not a valid presumption.

If we can assist CMS in clarifying any of these matters, please feel free to contact me directly at Jon.M.Tiger@spiritaero.com.

Sincerely,

Jon Tiger
NHOPA President

Submitter : Mr. Phillip Porte

Organization : National Home Oxygen Patients Association

Category : Consumer Group

Date: 09/25/2006

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1304-P-41-Attach-1.DOC

#41

NHOPA
National Home Oxygen Patients Association

September 25, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1304-P
Room 445-G
Hubert M. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Reference: File Code CMS-1304-P - Comments Related to Proposed Rule re: 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 (July 28, 2006)

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We believe our perspective is unique in that, for the most part, we are able to remove ourselves from the heated discussions regarding costs and payments and we can focus on our primary concern – access to appropriate oxygen systems as prescribed by physicians. To that end, we have reviewed the comments of the key pulmonary medicine societies, the American College of Chest Physicians, the American Thoracic Society and the National Association for Medical Direction of Respiratory Care and echo and support their comments and recommendations.

For several years NHOPA has supported the concept of modality (class) specific oxygen payment. We believe this issue was dramatically highlighted by the review of the Polk County pilot study for competitive bidding which clearly signaled a reduction in the use of lightweight portable oxygen systems once the competitive bidding process took hold. We had long surmised that oxygen patients received an oxygen system based on the provider's determination of appropriateness rather than the physician's recommendations.

The continuing presence of e-cylinders rather than the lightweight technologies that have arrived on the market further verify the Polk County findings.

As mentioned above, we do support the methodology recommended by the pulmonary physician societies to assign beneficiaries to classes of devices based on clinical need rather than primarily on the particular characteristics of the device. The creation of three classes of oxygen systems, stationary, portable and ambulatory is logical, clinically sound, and would go a long way to ensure that patients receive clinically appropriate devices rather than devices that might provide the supplier with attractive profit margins. While truly homebound patients would certainly enjoy a lightweight (more expensive) system, it is difficult to justify the placement of such a device with a patient who rarely leaves the home.

We believe, however, that CMS must move aggressively with an important, even critical, campaign to educate beneficiaries regarding not only the creation of classes but there must be a focus on the specific devices within each class. We are told that most prescriptions for oxygen therapy are understandably written by primary care/family practice physicians. In candor, most of these physicians are completely unaware of the existing technologies for oxygen delivery, and our own survey of NHOPA members verifies that. Beneficiaries who are using cumbersome systems are frequently totally unaware that there are optional systems, lightweight in nature, that would not only meet their clinical needs but also provide dramatically greater opportunities for ambulation, involvement in activities of daily living, etc. We genuinely believe that the vast majority of oxygen users simply do not know what device options exist. The information is not forthcoming from the prescribing physician, often because of his/her own lack of information, and the provider understandably wants to provide a cost effective device, whether or not it is clinically appropriate for the patient's specific needs. We strongly recommend that CMS undertake an extensive educational program to eliminate this ongoing barrier to portable and ambulatory devices.

In terms of the specific proposal, we support the recommendations of the pulmonary medicine societies for creation of 3 specific classes:

- Stationary class: Patient is moribund, bed bound, or limited to nocturnal oxygen need only. Limited need/ability to leave home. Stationary system (traditional oxygen concentrator) is exclusive of appropriate back-up

- Portable class: Patient requires oxygen at night and for limited mobility (or a single system that meets both needs). E cylinders and other bulky non ambulatory systems fit into this class.

- Ambulatory class: Oxygen needs include support for high ambulation (device for exercise and/or exertion only; also for oxygen at rest or nocturnally (stationary device plus high ambulation device or one device that meets both needs.

More specifically, traditional stationary concentrators would be categorized into the stationary class; e-cylinders and other bulky (over 10 pounds) systems that can be placed in carts, on wheels, etc. would be in the portable class. Systems under 10 pounds, according to manufacturer specifications, would be placed in the ambulatory class.

Beneficiary ownership of oxygen devices: A significant portion of the proposed regulation addresses many of the complicated issues that arise in the context of the transfer of ownership that is mandated by the Deficit Reduction Act (DRA). We do recognize that CMS must implement that provision of DRA but we must state in no uncertain terms **the National Home Oxygen Patients Association strongly opposes mandated beneficiary ownership of oxygen systems. Our members do not want the responsibility associated with maintenance and servicing of this life sustaining device, and we repeatedly hear from family members their concern about keeping the equipment once the need no longer exists. We do understand the physician concern regarding creation of a gray market for these devices if this DRA provision is actually implemented, and see virtually no benefit whatsoever in this legislative mandate.** We do recognize that some devices, particularly stationary concentrators, may lend themselves to relatively uncomplicated servicing and maintenance, but to leap to the conclusion that the newer technologies also fall into that category is, to the best of our understanding, not a valid presumption.

If we can assist CMS in clarifying any of these matters, please feel free to contact me directly at Jon.M.Tiger@spiritaero.com.

Sincerely,

Jon Tiger
NHOPA President

Submitter : Mr. Phillip Porte
Organization : ACCP, ATS, NAMDRC
Category : Physician
Date: 09/25/2006

Issue Areas/Comments

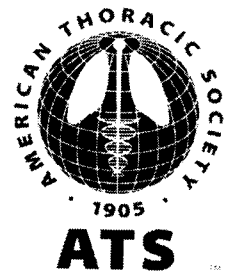
GENERAL

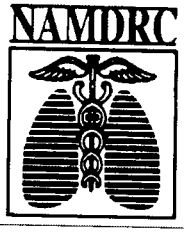
GENERAL

see attachment

CMS-1304-P-44-Attach-1.DOC

#44





September 22, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1304-P
Room 445-G
Hubert M. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Reference: File Code CMS-1304-P - Comments Related to Proposed Rule re: 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 (July 28, 2006)

Dear Dr. McClellan:

The American College of Chest Physicians, the American Thoracic Society and the National Association for Medical Direction of Respiratory Care welcome the opportunity to comment on CMS' proposal to base payment for home oxygen therapy and related equipment on classes. We believe this shift from a "modality neutral" model to a "class specific" model is sound and the three pulmonary medicine societies support CMS' movement of payment policy in this new direction.

We do believe, however, that the CMS proposal includes some inherent flaws that can be remedied relatively easily:

Problem #1: The proposal clearly recognizes problems that exist in the current modality neutral environment that can create financial incentives that inhibit access to lightweight portable/ambulatory oxygen systems. While a reduction in payment for stationary oxygen systems may be warranted, we are concerned that any reduction in reimbursement for stationary oxygen systems without corresponding upward adjustments for portable and ambulatory systems would affect access to those classes and would be counter to Medicare beneficiaries' best interests. The statutory requirement for budget neutrality must be respected.

Solution #1: As the review of the pilot study in Polk County signaled, payment rates of stationary systems in a competitive bidding environment can affect access to lightweight systems. The drop in access by one third is not, we believe, an aberration. Rather, it is a clear indication that the relatively higher margins associated with stationary concentrators are not enough to balance the increased costs associated with lightweight systems. The experience in Polk county shows that home oxygen suppliers will restrict access to more expensive portable and ambulatory modalities. This reduced access is not in the best interest of the Medicare beneficiary.

We also note that a recent Office of Inspector General report recommends further reductions in Medicare reimbursement for oxygen concentrators. While further reductions in reimbursement for oxygen concentrators may be warranted, the pulmonary community strongly urges CMS to offset any future cuts in home oxygen concentrator payments with appropriate increases in other classes of oxygen systems. By offsetting further reductions in stationary oxygen equipment with increases in portable and ambulatory oxygen systems, CMS will help avoid the access problems experienced in Polk County. We further believe offsetting future reduction in stationary equipment with increases in portable and ambulatory equipment is consistent with Congressional intent for budget neutrality.

Problem #2: The proposal creates, we believe, an environment for suppliers to direct patients towards a device that may be the most profitable rather than the device that is clinically appropriate. For example, we envision a scenario where a terminally ill patient who requires supplementary oxygen in a hospice for 8 months might receive a portable oxygen concentrator or transfilling system despite the fact that virtually all stationary concentrators would meet the beneficiary's clinical need for oxygen.

A second scenario we envision is a supplier selectively recommending an oxygen system based on their estimate of the patient's prognosis. If the supplier genuinely believes the beneficiary may be part of the estimated 35% of Medicare beneficiaries living longer than 36 months, they may be very hesitant to commit to the provision of a portable concentrator or transfilling system, knowing that the title of the system transfers to the beneficiary after 36 months. Likewise, if the supplier anticipates the Medicare beneficiary will have a short life expectancy, they may install the system with the highest payment, regardless of the beneficiary's ability to ambulate, leave home, etc.

Solution #2: Classes should be based on the clinical characteristics of the beneficiary rather than the physical characteristics of the device.

- Stationary class: Patient is moribund, bed bound, or limited to nocturnal oxygen need only. Limited need/ability to leave home. Stationary system (traditional oxygen concentrator) is exclusive of appropriate back-up

- Portable class: Patient requires oxygen at night and for limited mobility (or a single system that meets both needs). E cylinders and other bulky non ambulatory systems fit into this class.

- Ambulatory class: Oxygen needs include support for ~~high~~ frequent ambulation (device for exercise and/or exertion only; also for oxygen at rest or nocturnally (stationary device plus high ambulation device or one device that meets both needs.

  More specifically, traditional stationary concentrators would be categorized into the stationary class; e-cylinders and other bulky (over 10 pounds) systems that can be placed in carts, on wheels, etc. would be in the portable class. Systems under 10 pounds, according to manufacturer specifications, would be placed in the ambulatory class.

Problem #3: The proposed rule is relatively silent on the issue of retesting/recertifying oxygen beneficiaries. Oxygen is a prescription drug for treatment of a chronic disease, similar to insulin as a drug treatment for diabetes or ~~xxx~~ hydrochlorothiazide is a drug treatment for high blood pressure. Physicians are not permitted to write open ended prescriptions for those drugs for several reasons, most notably the importance to monitor the patient's condition and, when appropriate, adjust the treatment plan/medications.

Solution #3: Similarly, patients who receive their initial prescription for supplementary oxygen as a result of an acute event (pneumonia, for example), the patient should be retested in the 60-120 day window after initial certification to determine the need for ongoing therapy. We believe this retest is not necessary for patients with a diagnosis of COPD or other related chronic diagnosis where there is medical evidence that the patient will need supplementary oxygen on an ongoing basis.

While implementation issues of a retesting requirement must be considered, current technologies exist to make retesting a reasonable requirement.

Additional considerations: Clearly, the coding of oxygen devices should be modified to ensure that devices in each respective class can be appropriately identified. There are several possible approaches to this matter and we re confident that CMS and the SADMERC can implement timely coding clarifications to ensure proper processing of claims.

Secondly, we believe that suppliers must be permitted leeway to select devices within a class prescribed by the physician. It is understandable that suppliers should not be obligated to carry every available device within each class and should be afforded a certain level of flexibility once the physician has clinically determined the appropriate class for the beneficiary.

Thirdly, there are important changes that must be made in the Certificate of Medical Necessity for home oxygen therapy. Specifically, a revised CMN should –

- Guide the physician through a relatively simple clinical algorithm that leads to device selection within a particular class;
- Specify the flow rate (liters per minute) or the intermittent flow device setting;
- Require the physician to test the patient on the actual type of system within a class that is intended for beneficiary use;
- Indicate the need for retesting in the event that the primary diagnosis leading to the oxygen prescription is acute in nature.

The pulmonary physician community is crafting its specific suggestions for reformatting of the CMN and our recommendations will be provided separately to this formal comment.

Title Transfer Provision

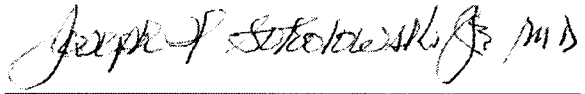
Finally, while the professional societies recognize that it is beyond the scope of this rule making, however, we do want to state our strong opposition to the title transfer provision of the Deficit Reduction Act. Requiring patients to take ownership of the oxygen system after 36 months, as mandated by Congress, offers no clinical benefit to Medicare beneficiaries. We believe that the title transfer provision could create a perverse incentive that will induce oxygen suppliers to attempt to game the system and will weaken the essential service links between oxygen suppliers and the services they provide, and Medicare beneficiaries.

While we appreciate CMS's effort, in drafting the proposal rule, to limit the Medicare beneficiaries financial risk for repairs and replacement of oxygen equipment after title transfer, we still believe that title transfer is not in the best interests of patient care.

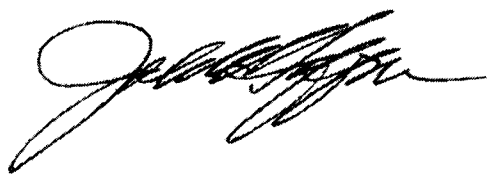
We will b e glad to clarify these matters upon request, and feel free to contact either Phillip Porte at 703-752-4359 (Phil@namdrc.org) or Gary Ewart at 202-785-3355 (gewart@lungusadc.org).

Sincerely,

W. Michael Alberts, MD, FCCP
President, American College of Chest Physicians



Joseph W. Sokolowski, Jr., MD, FCCP
President, National Association for Medical Direction of Respiratory Care



John E. Heffner, MD, FCCP
President, American Thoracic Society

Submitter : Cynthia Istvan **Date:** 09/25/2006

Organization : Bayada Nurses, Inc.

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

Bayada Nurses strongly supports the market basket update of 3.1 percent. The most recent Medicare cost report data indicates that home health agencies in Connecticut have total operating margins that are minus 2.73 percent due to chronic underfunding of Medicaid home health rates and the unrecognized costs of patients dually eligilbe for Medicare & Medicaid.
We strongly support a 15 percent adjustment to the standardized rate for patients that are eligible for Medicare and Medicaid. We believe that the hospitalization and emergent care outcome measures are fatally flawed because of upward biasis resulting from the effects of the inclusion of long stay,chronic care Medicaid patients in the calculation. Pay for performance cannto be implemented untild this bias is eliminated.

Submitter : **Mr. Larry Thacker** **Date: 09/25/2006**

Organization : **A-Med Health Care**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

Herb B. Kuhn
Director of Management Policy
Centers for Medicare & Medicaid Services
MS C5-01-14
7500 Security Boulevard
Baltimore, MD 21244-1849

September 21, 2006

Dear Mr. Kuhn:

My name is Larry Thacker, and I am the owner of A-Med Health Care, A-Med specializes in serving the urological supply need of the catastrophically disabled (spinal cord injury, traumatic brain injury, etc&). I am writing this letter today to request your help in resolving a problem that has impacted the lives of thousands of individuals. The problem I am referring to is with the Prospective Payment System (PPS) and its impact on a catastrophically injured Medicare Beneficiary. PPS is used to calculate the reimbursement for Home Nursing when a Medicare Beneficiary requires nursing services in their home. The PPS rule requires that the Home Health Agency provide all medical supplies that a beneficiary requires each day as part of their per diem reimbursement.

For most Medicare Beneficiaries this rule has little or no impact. For certain catastrophically injured individuals this rule is creating tremendous hardship and a lack of access to the same product(s) that they have been using to achieve their current quality of life. The problem seems to revolve around one code in the HCPCS system, A4353; this code describes the urinary product that is required to take over the function of the bladder in a catastrophically disabled individual. For this type of beneficiary, these products are life sustaining and are required for life. Due to the complications of the Urinary Tract, these beneficiaries require these products to keep them infection and hospitalization free. In many instances the products that this population uses cost more than the nursing services themselves and according to the PPS rules the Home Health Agency is required to provide these products as part of their nursing reimbursement.

After 4 years I can tell you that the Beneficiaries are not being provided the product that their physicians prescribe for their special needs to prevent catastrophic illnesses. They are typically provided a less effective product or in many instances, the beneficiary is denied the products altogether.

We as the supplier also deal with the impact of PPS. PPS requires that the Home Health Agency file a paper called a Plan of Care, which tells Medicare that they have the beneficiary under their care. This Plan of Care may take up to two months to reach

Medicare. Until the time that Medicare receives the Oasis their system continues to report to the provider community that the beneficiary can receive services. What we are unable to know is that once the Oasis is loaded into Medicare s system the claims for my services that I provided will be denied or if they have already been paid to me will be refunded.

As a provider, my only awareness of PPS comes from the beneficiary community. The beneficiaries who are dealing with a catastrophic injury know that if they tell me they have nursing then will not receive their supplies and subsequently deny that nursing is being provided through and HHA. The other problem is that the Home Health Agency does not educate the catastrophically disabled beneficiary and in many instances the first the beneficiary knows about PPS is when I call them telling them that their claim was denied and they cannot receive their product.

We are proposing for your consideration a solution since the majority of the problem is located around the code A4353: let s remove this specialty product from the PPS requirements so that these beneficiaries can continue access to the products that they need including during periods of home health agency services.

Thank you for your consideration of this letter.

Sincerely,

Larry N Thacker, Jr.
Chief Executive Officer
A-Med Health Care

cc: Carol Blackford

Submitter : Mr. Phillip Porte **Date:** 09/25/2006

Organization : ACCP, ATS, NAMDRC

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1304-P-44-Attach-1.DOC

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Mr. Joseph Lewarski** **Date: 09/25/2006**

Organization : **Inogen, Inc.**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attached comments

CMS-1304-P-45-Attach-1.DOC

#45

inogen

Sent Via Electronic Transmission

September 25, 2006

Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1304-P
PO Box 8014
Baltimore, MD 21244-8013

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

Dear Dr. McClellan,

Inogen, Inc. an oxygen technology research, development and manufacturing organization respectfully submits the following comments on the Centers for Medicare and Medicaid Services (CMS) notice for a proposed rule rulemaking (NPRM) identified as CMS-1304-P: Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 Changes to the Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment; Proposed Rule.

Changes to the CMS home oxygen therapy coverage rules and payment methodologies directly impact the home medical device and technology industry. As a manufacturer of new and innovative home oxygen technologies, we have a number of concerns with the NPRM, which we believe must be corrected before any final changes are made to the existing oxygen rule.

I. BACKGROUND

For over 30 years, long term oxygen therapy (LTOT) in the home has been a standard and accepted treatment for patients with severe chronic obstructive pulmonary disease (COPD) demonstrating stable, chronic hypoxemia. Oxygen is the only non-invasive therapy shown to prolong the life of COPD patients with severe hypoxemia, as was evidenced in the two major randomized, controlled studies in this area. The well known and frequently referenced *Nocturnal Oxygen Therapy Trial*

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Phone 805-562-0500

(NOTT)[1] and the *British Medical Research Council* (BMRC) report on domiciliary oxygen use[2] set the scientific basis for the use of LTOT in the treatment of chronic hypoxemia. Both of these studies demonstrated significant morality improvement with prolonged oxygen therapy.

- **COPD is a major health concern in the United States and within the Medicare program**

  - Approximately 15 million Americans have been diagnosed with COPD and there are an estimated 15 million more with undiagnosed COPD.
  - COPD is the fourth leading cause of death in the US and is projected to be the third leading cause of death for both males and females by the year 2020.[3]
  - COPD costs the U.S. economy over $18 billion a year in direct medical costs and an estimated $11 billion in indirect costs.
  - 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 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.[4]
  - The average length of stay for a Medicare short-stay hospital admission is 5.9 days at the rate of over $4,000 per day.[5] At the current Medicare oxygen payment rates, one hospital admission costs Medicare more than 10 times the cost of one full year of home oxygen therapy.

Home oxygen is a critical and life sustaining prescription drug therapy administered to approximately 1.3 million Medicare beneficiaries. These beneficiaries require oxygen therapy for their long-term survival and well-being. Although not measured as part of the NOTT and BMRC studies, quality of life, reduced cost of care and the ability to remain in the home are important and often overlook outcomes associated with the use of LTOT. In a recent cohort study of over 246 patients, home oxygen therapy was demonstrated to be associated with a significant decrease in the frequency of hospitalization, length of stay and decreased cost of care for patients with COPD.[6]

Medicare payment policies for oxygen will impact a large number of very vulnerable patients. Spending for home oxygen cannot be viewed as a single line item on a spreadsheet and must be considered in the context of the overall cost of care for patients with COPD. Maintaining these patients at home on oxygen is by far more cost effective than institutional care.

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[1] Continuous or nocturnal oxygen therapy in hypoxemic chronic obstructive lung disease: a clinical trial. Nocturnal Oxygen Therapy Trial Group. *Ann Intern Med* 1980;93(3):391-398

[2] Report of the Medical Research Council Working Party. Long-term domiciliary oxygen therapy in chronic hypoxic cor pulmonale complicating chronic bronchitis and emphysema. *Lancet* 1981; 1: 681-685.

[3] http://www.copd-international.com/library/statistics.htm

[4] Data retrieved from the SADMERC website

[5] CMS Statistics 2005. US Department of Health & Human Services 80146-23597

[6] Ringbaek TJ, Viskum K, Lange P. "Does long-term oxygen therapy reduce hospitalization in hypoxemic chronic obstructive pulmonary disease? Eur Respir J. 2002 Jul;20(1):38-42

II. PROVISIONS OF THE PROPOSED REGULATIONS

The DRA of 2005 imposes unprecedented changes to long-standing Medicare policies covering payment for home oxygen therapy. CMS is now challenged with developing policy around inherently flawed and problematic legislation that inappropriately imposes a forced transfer of ownership burden of prescription oxygen and oxygen related technologies on its elderly beneficiaries. While we recognize that CMS does not have within its authority the ability to eliminate the 36-month purchase and transfer of title for home oxygen therapy equipment, the irrationality of this requirement cannot be understated.

The Medicare payment rates for home oxygen therapy have been subject to myriad freezes and reductions since the introduction 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 addition 5% for 1999. The BBA also permanently froze all CPI updates for home oxygen. 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 averaged 10% across each durable medical equipment regional carrier (DMERC) region. When compounded and adjusted for inflation, since 1989 the cuts to the Medicare oxygen payments have exceeded 60%, despite the rising cost and complexity of providing home oxygen therapy.

For the first time in the brief history of home oxygen therapy, Medicare beneficiaries, who have always rented their oxygen equipment and had their routine maintenance, service and emergency support provided by a home medical provider (HME) will be faced with new challenges and responsibilities in understanding the myriad safety warnings and instructions on how to manage and care for the equipment themselves.

Section G. Payment for Oxygen, Oxygen Equipment and Capped Rental DME Items

- **Beneficiary choice of home oxygen technology must be considered**

CMS states that it believes there may be incentives under the current rules for suppliers to avoid transferring the title of oxygen equipment as required by the DRA and cite an example of a supplier choosing not to accept Medicare assignment and shifting the financial liability for the oxygen equipment purchase to the beneficiary at the full retail value. CMS proposed to several rules intended to protect the patient from such practices.

The first of the proposed rules is a requirement that any oxygen item(s) the supplier provides in the first month of rental must be provided throughout the entire period of rental up to the point when the title(s) transfer to the beneficiary. CMS proposes only limited exceptions to this requirement.

CMS states there might be potential for a supplier to replace newer or more valuable equipment with older or less valuable equipment at some point before the transfer of title to the beneficiary. In this area, CMS adds additional exceptions for the replacement of the originally placed equipment, including a change in medical condition that must be validated with physician documentation. We believe an important exception to the change in equipment requirement is needed to insure beneficiaries maintain access to a variety of home oxygen therapy technologies. Patient choice and

the authority for the beneficiary to make a personal decision to change their equipment must be considered as part of the exceptions to allow for a patient to change home oxygen therapy equipment during the 36-month rental period. As the Medicare beneficiary and a consumer of the health care products prescribed for their use, the beneficiary should be afforded freedom to make a conscious decision to change equipment that is clinically appropriate and within the prescription based on their individual lifestyle needs.

Beneficiary choice of physician prescribed and medically appropriate oxygen technologies, and the ability to change their oxygen equipment based on changes in needs and lifestyle, should be incorporated into the exceptions in the rule.[7] In the event a supplier elects not to provide the patient's preferred oxygen therapy device, the patient can exercise their right to change to an oxygen supplier that will accommodate their lifestyle and oxygen technology needs. We believe this freedom of patient choice will impose additional free-market forces that will encourage improved patient access to new and innovative oxygen therapy technologies and should be included in the rule.

- **CMS should not change the terms of participation for oxygen suppliers**

CMS is proposing both an unprecedented and unfair change to the supplier participation agreement that would require suppliers to make a highly prospective, three year advanced decision and commitment to accept or not accept Medicare assignment. In addition, CMS is proposing that suppliers confirm this decision in writing to the beneficiary at the initiation of treatment with oxygen. The need for this provision is not based on any data or factual evidence and is purely hypothetical and prejudicial. In a business climate and health care economy subject to frequent and often sweeping policy and payment change, this requirement places the supplier at a serious disadvantage. It creates a potential financial exposure in the event unfavorable changes occur in their business or through future policy. We suggest his requirement be eliminated and the standard annual participation agreements be maintained.

Section I. Classes of Oxygen and Oxygen Equipment

- **Appropriate coding and payment for innovative and portable oxygen technologies is essential and must be incorporated into any rules and payment methodologies**

As part of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87), a modality neutral oxygen payment system was established, meaning that in any given state there is one fee schedule that applies to all stationary systems (i.e., concentrator, liquid stationary) and one fee schedule that applies to all portable systems (i.e., gaseous cylinder, portable oxygen concentrator). CMS proposes to change this method by developing new classes of oxygen equipment and assigning new class specific fee schedules based on series of financial and utilization assumptions and the statutory requirement to remain budget neutral.

We believe that a better defined and more patient-centric approach toward home oxygen therapy is necessary for safe and appropriate patient care. We support the concept of modality neutral classes of oxygen technology, when such a payment and classification methodology recognizes the different cost and clinical applications for the various technologies within the defined class. In particular, we

[7] Changes in equipment based on the beneficiary's request for different oxygen technology should only be made after consultation with and at the discretion of the home oxygen supplier. Home oxygen suppliers carry various brands and models of oxygen equipment and may elect not to provide a patient with a specific brand or model.

believe attention must be given to the portable and ambulatory aspect of home oxygen therapy, which is now considered a critical component of modern home oxygen therapy and supported in the scientific literature.

In a re-analysis of the data from the NOTT study, Petty and Bliss demonstrated that the group oxygen users that ambulated frequently while on their oxygen therapy had statistically and clinically improved survival rates over both low and non ambulating oxygen patients.[8] At the *Sixth Consensus Conference on Long-Term Oxygen Therapy*, an expert group of oxygen thought leaders and stakeholders devoted significant discussion and time to the importance of mobility and activity for long term oxygen users and the critical need to ensure patient access to the technologies that promote such. As a result, a specific recommendation in the published proceedings from the conference states "CMS and other payer organizations should be encouraged to support appropriate reimbursement that will ensure access to innovative technologies that are appropriate for the individual patient's clinical and daily lifestyle needs."[9]

Within the NPRM CMS acknowledges the concern that the current Medicare payment for oxygen (approximately $231 per month) may not be sufficient to facilitate the use of these new and innovative technologies and proposes a higher monthly payment amount for these systems to allow for the increased up front cost associated with the acquisition and provision of this class of technologies. However, the newly proposed fee schedule ($241 per month) amounts to a very modest increase of approximately $10 or 4% per month over the current Medicare combined stationary and portable oxygen payment. Many of the new oxygen generating portable oxygen devices cost suppliers four to five times the initial acquisition cost of an older and more traditional stationary and portable oxygen combination system.

As a research and develop company specializing in oxygen generating portable oxygen equipment (as defined in the proposed rule), we believe the proposed monthly payment rate for this new class of oxygen system is inadequate to fully support the cost of innovation. As a result, we fear the proposed fee schedules may limit supplier adoption and therefore limit beneficiary access to such important new oxygen technologies. We believe these data must be considered and incorporated into any new oxygen payment methodology and fee schedule to ensure fair and adequate payment for this very important new class of oxygen technology.

- **Coding and payment needs to be establish to ensure safe and appropriate management of beneficiaries and their equipment following the 36 month transfer of ownership**

We also have strong concerns about the lack of additional payments for on-going maintenance and service following the payment cap and forced ownership at 36 months. The proposed rule makes an inaccurate assumption that following the transfer of ownership there is no service, maintenance or on-going support of beneficiaries receiving oxygen generating portable oxygen equipment. While we appreciate that the oxygen generating portable oxygen equipment class of oxygen technology does not require scheduled deliveries, there is periodic maintenance and service, along with patient instruction, re-training and emergency support that must be considered an integral part of the ongoing care of patients prescribed home oxygen therapy.

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[8] 1Petty TL, Bliss PL: Ambulatory oxygen therapy, exercise and survival with advanced chronic obstructive pulmonary disease. (The Nocturnal Oxygen Therapy Trial Revisited) Resp Care 2000; 45:204-213.

[9] Doherty DE, Petty TL. "Recommendations of the 6th Consensus Conference on Long-Term Oxygen Therapy." *Respir Care* May 2006:51(5): 519-525

We recommend that an oxygen technology service and maintenance HCPCS codes be developed with a corresponding fee schedule to be used by suppliers to ensure safe and consistent oxygen therapy for patients prescribed and dispensed oxygen generating portable oxygen equipment. As an example, following the 36 month title transfer the home oxygen supplier would perform a service visit to a oxygen generating portable oxygen equipment patient once per quarter. Coding and payment policy should also be developed to ensure access to respiratory therapists and/or other appropriately licensed health care professional to perform clinical assessments and interventions as prescribed by the attending physician. This too was a recommendation of the oxygen therapy experts at the 6th LTOT Consensus Conference.[10]

Section J. Payment for Maintenance and Servicing of Oxygen and Oxygen Equipment and Capped Rental Items

- **Medicare beneficiaries are receiving home oxygen therapy cannot be expected to service and maintain their home oxygen equipment**

CMS acknowledges in the proposed rule that concerns have been raised regarding the ability of beneficiaries to obtain maintenance and servicing of their equipment once they own it. In fact, CMS states that the concerns are unfounded because Medicare has traditionally paid for reasonable and necessary maintenance and servicing and will continue to do so, and the beneficiary will not be "on his or her own" to secure these services and to submit payment claims for them. We believe that CMS has over-simplified the situation and that the health and safety of the beneficiary could be at risk.

According to recent survey data, the profile of the average Medicare beneficiary receiving oxygen therapy at home is the following: [11]

- Average age: 73: Thirty percent are 80 or older. Fifty-eight percent female.
- Approximately 1 in 4 patients on home oxygen use it for more than 36 months.[12]
- About 1 in 4 patients qualify for both Medicare and Medicaid.
- Three out of 4 oxygen patients use a combination of oxygen systems such as a concentrator and a portable gas system.
- Fifty-six percent suffer from Chronic Obstructive Pulmonary Disease – a progressive, debilitating disease and the fourth leading cause of death in the United States.
- Nine percent suffer from congestive heart failure; 7 percent suffer from hypoxemia; 3 percent suffer from emphysema; 1 percent suffers from asthma.
- Patients experience a reduced capacity to cope with Activities of Daily Living (ADLs).[13]

Many home oxygen therapy patients live alone, are unable to drive, have poor eyesight, hearing impairments and other health complications such as arthritis. The primary caregivers are frequently similar aged spouses who are also challenged with physical and mental issues of age.

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[10] Doherty DE, Petty TL. "Recommendations of the 6th Consensus Conference on Long-Term Oxygen Therapy." *Respir Care* May 2006:51(5): 519-525

[11] American Association for Homecare 2006 survey of oxygen providers

[12] Office of the Inspector General Report: Medicare Home Oxygen Equipment. OEI 09-04-00420. September 2006

[13] Bestall JC, et al. Usefulness of the Medical Research Council dyspnoea scale as a measure of disability in patients with chronic obstructive pulmonary disease. *Thorax*. 1999;54:581-586

COPD is a very progressive disease, which becomes more debilitating with time. There have been numerous clinical studies that have studied the correlation between Activities of Daily Living (ADLs) and patients with severe COPD who are on long-term oxygen therapy.

A 2005 study published in *Chest* sought to distinguish the disabling effects of COPD, congestive heart failure (CHF) and diabetes mellitus using a scale of basic activities of daily living (BADL) and instrumental activities of daily living (IADL), which refer to higher levels of performance such as managing money and taking medicine. [14] The study concluded that COPD was associated with a distinctive pattern of disability expressed by loss of selected BADL-IADL.

Another study published in *Chest* in 1997 found that the decline of verbal memory parallels that of the overall cognitive function in COPD patients and is due to the impairment of both active recall and passive recognition of learned material. [15]

As oxygen technology continues to evolve it is likely that patients will have greater difficulty servicing and maintaining the technology and will require on-going clinical and technical support. As we stated earlier, while we appreciate that the oxygen generating portable oxygen equipment class of oxygen technology does not require scheduled deliveries, there is periodic maintenance and service, along with patient instruction and re-training that must be considered an integral part of the ongoing care of patients prescribed home oxygen therapy and strongly urge CMS to develop coding and coverage for periodic service following the 36 month payment cap and transfer of ownership.

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

- **The proposed repair and replacement requirements are unfair and place unrealistic cost and operational responsibilities on the home oxygen supplier**

The proposed rule would require suppliers to replace, at no, cost patient owned equipment if the cumulative total repairs during the useful life of the equipment exceed 60% of the equipment's value. This proposed rule essentially imposes on the supplier a mandatory 60-month equipment indemnification requirement for any and all oxygen equipment following the 36 month transfer of title regardless of the age or warranty status of the equipment.

For patient owned equipment there also will be no record of routine ongoing service and maintenance, placing the supplier in the unfair position of having to replace equipment that may not have been properly maintained. The supplier cannot guarantee that the equipment will function as it should if it is not properly maintained, which may also void the manufacturer's warranty. Similarly, the supplier that originally furnished the equipment would have no control over the repairs that may be performed by another supplier. Again, the original supplier would be placed in the situation of having to guarantee the work of another supplier who may have lacked the appropriate credentials to repair the specific equipment involved.

We believe the proposed rule imposes an inappropriate and unfair burden for the replacement and repair of purchased equipment for which title has transferred and is outside of the control of the

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[14] 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

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

supplier. We suggest CMS work with oxygen stakeholders and other regulatory agencies to develop a reasonable and effective method before imposing such policy.

IV. SUMMARY

Since its inception, Inogen has been dedicated to the design, development and manufacture of clinically efficacious oxygen technologies intended to enhance the lives of oxygen therapy patients. As an oxygen device manufacturer and stakeholder we believe we have a responsibility to support the clinicians, providers and patients we serve through our science and technology. We are very grateful for the opportunity to submit comments on this important rulemaking process and would welcome the chance to discuss our comments and concerns in greater detail at your convenience.

Respectfully,

Joseph Lewarski, BS, RRT, FAARC
Vice President of Clinical
& Governmental Affairs

Submitter : **Mr. Ron Billingsley** **Date: 09/25/2006**

Organization : **Respironics, Inc**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1304-P-46-Attach-1.DOC

#46

September 25, 2006

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments to CMS-1304-P, Deficit Reduction Act (DRA) of 2005, Changes to Medicare Payments for Oxygen Equipment and Capped Rental Durable Medical Equipment Proposed Rule

Dear Dr. McClellan,

The following comments on the Proposed Rule on the Deficit Reduction Act (DRA) of 2005, Changes to Medicare Payments for Oxygen Equipment and Capped rental Durable Medical Equipment, are submitted on behalf of Respironics, Inc. Respironics, Inc is a manufacturer of oxygen producing medical devices and a developer of advanced technologies that are used in the treatment of Medicare beneficiaries who are afflicted with respiratory disease and illnesses. Thank you for the opportunity to comment on the proposed reimbursement policy changes.

Although we are concerned that the proposed rule contains many provisions that could be disruptive to the long term oxygen services provided to Medicare beneficiaries, we will limit our comments to the provisions that concern us most as a manufacturer of medical devices. Specifically, Respironics is concerned with the following sections of the proposed rule;

1. Transfer of ownership of medical devices to Medicare beneficiaries
    - FDA regulations, and tracking of medical devices
    - Patient and public safety risks

2. Medicare payment for patient owned-equipment
    - Repair and maintenance-payment , policies and HCPCS
    - Oxygen payment- Stationary, portable, ambulatory, new technology

I- CMS proposed rules should specify policies to assure compliance with FDA regulations concerning testing, maintenance, tracking and resale of medical devices.

Respironics acknowledges that in the DRA of 2005 Congress mandated the transfer of ownership of oxygen and other medical devices to Medicare beneficiaries after a specified number of continuous rentals have been paid by Medicare, and that CMS has written Proposed Rule 1304-P to implement the law. As a manufacturer of medical devices we are concerned that the transfer of ownership to Medicare beneficiaries could result in a substantial risk to patient safety and public health. The Food and Drug Administration (FDA) has established extensive regulations regarding the sale and resale, tracking, and performance requirements of Class II medical devices. Respironics is concerned that the proposed rule is mostly silent on these important issues of patient safety.

Oxygen equipment and other medical device used to treatment of patients with respiratory illnesses often require ongoing assessment and maintenance to assure that the performance of the device is efficient, and maximizes therapeutic value to the patient. Manufacturers often provide training for authorized service technicians who perform the required maintenance and service. We are concerned that by transferring ownership to Medicare beneficiaries, the necessary maintenance will not be performed as required. Even routine maintenance can be challenging to Medicare beneficiaries. In addition to minimizing risk to the oxygen user, routine and non-routine maintenance performed by authorized service technicians are important elements of equipment warranties and product liability. We recommend that CMS work with manufacturers, oxygen and medical device providers, and Medicare beneficiaries to better define reimbursement policies for maintenance, and manufacturer and supplier warranties.

Also, Respironics is deeply concerned about the resale of patient-owned medical devices. FDA regulations require a prescription from a licensed physician for the dispensing of oxygen, oxygen equipment, and other Class II medical devices. Transfer of ownership of medical devices will inevitably result in the resale of FDA controlled devices at flea markets, e-bay, and auctions, thereby circumventing the public safety protections inherent in existing regulations. The proposed rule is silent on this important issue. We believe that the proposed rule should explain how CMS intends to work with FDA, manufacturers, suppliers, and Medicare beneficiaries to protect Medicare beneficiaries and the public from the illegal resale of FDA regulated devices.

In addition, the FDA requires the tracking of oxygen and certain medical devices. Transfer of ownership of medical devices will present significant obstacles to locating and executing a recall of defective products. The chain of custody and tracking process currently practiced by manufacturers and suppliers of oxygen and oxygen equipment will be compromised after ownership has shifted to Medicare beneficiaries. Resale of the devices by families and caregivers will make it virtually impossible to remove defective products from the market. We recognize that the proposed rule is providing instructions for implementation of DRA 2005, but we believe that CMS should acknowledge the patient and public safety risk associated with the inability to track and recall potentially life-sustaining medical devices. As previously stated, we recommend that CMS explain ways that it will work with FDA, manufacturers, equipment providers, and Medicare beneficiaries to lessen the risk to patients and the public. We recommend that CMS consult with FDA and manufacturers to understand then provisions Safe Medical Device Act, and the impact of changes in ownership of medical devices.

II- CMS proposed rules on the implementation of DRA 2005 should consider revising HCPCS code, and policies about coverage and payment of patient owned equipment

We are concerned that the proposed rule does not adequately propose alternative CMS policies that explore the market needs and specific policies regarding patient owned equipment. DRA 2005 mandates transfer of ownership for oxygen equipment that has been rented for 36 continuous months, and capped rental equipment that has been rented for 13 continuous months. We don't believe that CMS has ever contemplated the effect of broad-scale patient ownership of medical devices. We do not believe that existing HCPCS codes or Medicare policy adequately address the marketplace challenges this change will present for either Medicare beneficiaries who receive oxygen equipment, or suppliers who service them.

The proposed rule lacks specificity regarding about Medicare policies that will be implemented to pay for both routine and non-routine services after ownership transfers maintenance responsibility to Medicare beneficiaries. We believe that CMS should address the inadequacy of HCPCS coding, the changing market dynamics, and safety and service challenges that will likely occur when ownership transfer to Medicare beneficiaries. The proposed rule is silent on issues like payment for emergency service, after-hour service, and specific policies and payments for parts and labor. Current policies are inadequate and do not clearly define coverage and payment policies for repair and maintenance of specific equipment or classes of equipment. Class II medical devices are potentially life-sustaining. The proposed rule, and current Medicare policy, does not define coverage for emergency service of life-sustaining equipment. We believe that this is an inadequacy and CMS must expand the HCPCS codes to more accurately reflect coverage policies and payment amounts payable for emergency service of life sustaining medical devices. Respironics recommends that CMS initiate a comprehensive assessment repair and maintenance policies of potentially life-sustaining medical devices.

We also believe that available HCPCS codes and Medicare policies on repairs and maintenance of patient-owned equipment are inadequate. We believe that HCPCS should be established for equipment parts and components. We are concerned that if CMS does not clearly define coverage policies and payment amounts a potentially serious safety risk will exist. Furthermore, we believe that CMS must establish defined policies and payment amounts for emergency services, after-hours emergencies, back-up oxygen, and respiratory interventions. CMS should recognize that patient ownership of DME will require HCPCS and payment amounts that are appropriate for the products and services provided.

We are encouraged by CMS' recognition that oxygen patients should have freedom to be mobile. We are also encouraged that CMS recognizes that reimbursement for portable oxygen is often inadequate. We believe that the proposed rule acknowledges that CMS should reassess HCPCS codes available for billing oxygen, oxygen equipment and service, as well as to reevaluate payment policies relative to emerging oxygen-delivery technology. We recommend that CMS establish payment policies that consider the clinical needs of a patient rather that the physical characteristics of the device. Proposed rules regarding the transfer of ownership and equipment exchange are flawed because of they emphasize the characteristics of the device(s) rather than the clinical needs of the beneficiary. We are concerned that the proposed policy may create impediments for Medicare beneficiaries to access clinically appropriate equipment and therapy. We encourage CMS to establish guidelines for various oxygen modalities. Additionally, CMS should evaluate policies on coverage and payment for portable and ambulatory oxygen, and potential access issues associated with modality specific oxygen delivery systems.

Conclusion: We thank CMS for the opportunity to comment on CMS-1304-P. We look forward to working with CMS to resolve concerns and issues on implementation of DRA 2005. Please contact me if you have any questions on these comments.

Sincerely,

Ron Billingsley
Director, Government Relations
Respironics, Inc
(724) 387-4475