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CQRC | COUNCIL FOR QUALITY RESPIRATORY CARE

SEP 25 2006

September 25, 2006

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1304-P
7500 Security Blvd.
Baltimore, MD

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

Dear Dr. McClellan,

On behalf of the Council for Quality Respiratory Care (Council), I am writing to comment on the Proposed Rule on the Deficit Reduction Act (DRA) of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment (71 Fed. Reg. 44082). The Council is a coalition of the nation's eleven leading home oxygen therapy provider and manufacturing companies, representing a majority of the more than one million Medicare patients who rely upon home oxygen therapy to maintain their independence and enhance their quality of life. We appreciate the opportunity to comment on these provisions implementing the home oxygen payment changes enacted by the DRA, as well as the proposed reimbursement policy changes. We look forward to working closely with the Centers for Medicare and Medicaid Services (CMS) to develop a payment system that will ensure access to these vital services for Medicare beneficiaries.

Specifically, the Council is concerned about certain aspects of the proposal.

- First, the proposed policy does not meet the statutory requirement of being budget neutral. In fact, based upon an analysis prepared by The Lewin Group, which is attached to this letter, the proposed policy takes hundreds of millions of dollars out of the system in direct contradiction to the congressional mandate.

- Second, based upon The Lewin Group analysis, $239 million has been removed from the system annually and must be reallocated among the proposed classes of oxygen and oxygen equipment. We strongly believe these dollars should be

reallocated by directing a vast majority of the funding to the provision of portable gaseous and liquid systems.

- Third, the Agency should adopt a transition period for its proposed reimbursement policy changes, which significantly modify the reimbursement of home oxygen therapy. In other health care sectors, CMS has recognized that major shifts in reimbursement policy can destabilize a sector and threaten beneficiary access. In these cases, CMS has provided for a transition period that allows the community to adjust to the new policy so that it remains economically viable. CMS should follow a similar approach with home oxygen therapy.

- Fourth, we recommend that CMS evaluate its proposed system in light of the current reimbursement policy and safety requirements. An important benefit of the current policy is that it is "modality neutral," which means that physicians can provide their patients with the equipment that best meets the patients' needs. While we understand the existing policy may be changed, we encourage CMS to examine the clinical and operational needs of the home oxygen community and adjust its policy so that physicians may continue to prescribe the most appropriate equipment to their patients.

- Finally, to ensure appropriate implementation and uninterrupted access for patients, CMS should also clarify several provisions of the Proposed Rule.

I. The Proposed Policy Does Not Meet the Statutory Budget Neutrality Requirements.

There is no disagreement that the proposed policy must be budget neutral. As CMS notes in the Preamble, Congress mandated that any changes in payment rates for home oxygen equipment must "not result in expenditures for any year to be more or less than the expenditures which would have been made if such actions had not been taken." 42 U.S.C. § 1395m(9)(D)(ii). The Preamble states that the proposed increases and decreases are "roughly equal over the next two or three years."

Although the Proposed Rule acknowledges that the proposed policy must be budget neutral, it does not provide the data or methodology CMS used to reach this conclusion. In addition, there has been no pilot or study to evaluate the impact on patients, providers, or other members of the home oxygen community. Given the sweeping nature of the proposed changes, CMS should provide the home oxygen community with sufficient information to evaluate its work.[1] As a threshold matter, the Council urges CMS to provide greater transparency regarding the calculations used to develop the new policy, as well as the data supporting the specific proposed rates. In particular, CMS should provide the data and methodology used to establish its conclusion about budget neutrality.

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[1] *See generally*, 67 Fed. Reg. 8452, 8458 (Feb. 22, 2002); *Guidelines for Ensuring the Quality of Information Disseminated to the Public* Centers for Medicare and Medicaid Services, *available at* http://aspe.hhs.gov/infoquality/Guidelines/CMS-9-20.html.

Even without this information, however, it appears clear that the proposed changes do not meet the statutory budget neutrality requirement. In its analysis, The Lewin Group[2] estimated the migration in modality use from stationary concentrators to the portable concentrators or transfilling systems of five percent. (See Attachment 1) This percentage is consistent with the estimates of the home oxygen community, as well as the estimate CMS described in a meeting with members of the Council. When this estimate is used, however, it is clear that the proposed changes are not budget neutral. As the table below demonstrates, it results in approximately $239 million per year being pulled out of the system in 2007 alone.

Table 3: Impact of NPRM on Oxygen and Oxygen Equipment for 2007 – Assumes 5% Migration into O2 Generating

Equipment Modality	Current Per Month Payment	Proposed Payment	Proportion Users	Number of Users- Annual	Number of Users - Per Month	Total Current Annual Payment	Total Annual Proposed Payment	Proposed Difference in Annual Payment
Stationary O2 Concentrator	$199	$177	24%	2,809,616	234,135	$559,113,568	$497,302,018	-$61,811,550
Stationary Liquid/Gas System	$199	$177	2%	234,135	19,511	$46,592,797	$41,441,835	-$5,150,963
Stationary O2 Concentrator + Portable System	$231	$209	64%	7,492,309	624,359	$1,730,723,407	$1,565,892,606	-$164,830,801
Stationary O2 Concentrator + O2 Generating Portable	$231	$241	5%	585,337	48,778	$135,212,766	$141,066,133	$5,853,367
Stationary Liquid Gas System + Portable	$231	$209	5%	585,337	48,778	$135,212,766	$122,335,360	-$12,877,406
Stationary Liquid/Gas System + O2 Generating Portable	$231	$241	0%	0	0	$0	$0	$0
Beneficiaries on O2				11,706,733	975,561	$2,606,855,304	$2,368,037,951	-$238,817,353

The Lewin Group also simulated several different potential scenarios to determine what assumptions the Agency would have had to make to meet the statutory budget neutrality requirement. If there were only a two percent increase, the loss to the system would be approximately $239 million in 2007. With a 20 percent increase to self-generating portable systems, the one-year loss would be $162 million. To get close to a budget neutral system using sound methodology, the assumption would have to be that approximately 73 percent of patients would switch to such oxygen self-generating portable systems during the first year. Based upon our understanding of the market, as well as CMS's own assumptions, it is indeed more likely that the first year would see a much more modest increase.

Additionally, the Proposed Rule indicates that CMS must offset increased payments for portable oxygen contents and oxygen generating portable equipment. The preamble indicates the Agency obtains the offset by reducing the current stationary payment by $22. Assuming the calculations are correct, the offset should be $16 million. However, based upon the work of The

[2]A letter from The Lewin Group describing its analysis and findings is attached to this letter.

Lewin Group, the actual offset is approximately $223 million for one year alone, assuming a five percent assumption for new technology.

The Agency should review the attached data analysis from The Lewin Group and re-evaluate its assumptions to assure that the proposed policy is in fact budget neutral, as required by law. Once the changes are budget neutral, the Council believes The Lewin Group analysis correctly predicts that $239 million has been removed from the system inappropriately. As discussed in detail below, at a minimum, the Council urges CMS to reallocate the $223 million (the $239 million minus the $16 million for the change in payments) within the system.

II. CMS Should Reallocate the Remaining Dollars So that the Final Rule Is Budget Neutral.

After CMS has complied with the budget neutrality requirement, the Agency should reallocate the $223 million by directing the funding to portable equipment and the delivery of contents, including lightweight liquid and gaseous equipment and contents and self-generating portable equipment (collectively, portable equipment and contents). These classes remain underfunded when compared to the cost of providing them. The problem would be greater after ownership transfers and the reimbursement is capped at 36 months. CMS states that one of its goals is to ensure that patients have ongoing access to portable devices. Thus, the Agency should pay particular attention to the reimbursement rate it sets for them.

Increasing payment for portable equipment and contents would meet an important clinical and policy goal as well. One of the major goals of caring for oxygen-dependent patients is encouraging them to be more active and mobile. Limited mobility can lead to an exacerbation of the patient's clinical condition and has the potential to result in hospitalization or institutional care. In the early decades of the Part B home oxygen benefit, patients were limited in their ability to be more active and mobile because of the cumbersome nature of large tanks and home concentrator systems. In recent years, however, manufacturers have responded to the clinical goal of increasing a patient's ambulatory abilities and freedom by developing smaller, more portable oxygen tanks and systems that can serve as both stationary and portable systems. The days of patients being forced to stay close to their homes have ended.

The Council is pleased that CMS recognizes the importance of providing patients with greater freedom of movement. However, the Council is concerned that the proposed rates for portable equipment and contents are not sufficient to offset the cost of providing these systems to beneficiaries. As described below, we encourage CMS to work with the home oxygen community to develop the data necessary to establish appropriate reimbursement rates. In the meantime, however, we encourage CMS to direct the majority of the "extra" money that results from the appropriate calculation of the budget neutrality requirement to portable devices. This shift will not only assist in maintaining beneficiary access to these devices, but also provide patients with an improved quality of life and improved health, as numerous clinical studies demonstrate.

III. CMS Should Provide for an Appropriate Transition Period to Minimize the Negative Impact the Revisions Will Have on the Home Oxygen Community and To Allow for the Collection of Data that Will Support the Development of Accurate Reimbursement Rates.

A. Consistent with Its Implementation of Other Major Reimbursement Policy Changes, CMS Should Implement the Proposed Reimbursement Policy Over a Three-Year Transition Period.

In addition to the significant changes in the proposed reimbursement rates for individual modalities, the Proposed Rule implements the transfer of ownership requirements and a 36-month cap established by Congress. These changes, if implemented, together could destabilize the home oxygen community. Another important change will be the implementation of the competitive bidding program scheduled to begin in late 2007. The Proposed Rule states that it would implement the revisions to the payment system for oxygen and other capped rental equipment on January 1, 2007. If the implementation date were adopted, the home oxygen community would have only one or two months to make the adjustments necessary under these policies. Because the DRA does not mandate that the reimbursement policy changes occur by this date, we strongly urge CMS to adopt a blended rate[3] during a three-year transition policy.

In the past, when CMS has proposed significant reimbursement changes, it has provided a transition period. For example, both the payment policy changes for ambulatory surgical centers included in the Proposed Rule on the Changes to the FY 2007 Hospital Outpatient Prospective Payment System (71 Fed. Reg. 49506) and the changes to the diagnosis-related groups (DRG) rates contained in the Final Rule on Changes to the FY 2007 Hospital Inpatient Prospective Payment System (71 Fed. Reg. 47870) include transition periods in an effort to manage the economic stability of the affected providers. Similarly, CMS provided transition periods before implementing new prospective payments systems for both skilled nursing facilities (SNF) and long term care hospitals (LTCH).

At the very least, CMS should establish a "blended" payment rate to phase-in the proposed rate changes over a three-year period. Not only would this transition period allow affected parties to prepare for the forthcoming changes, but it would also provide the industry and CMS with the necessary time to develop the cost data needed to develop accurate payment rates. The Council looks forward to collaborating with CMS in this data collection process and believes it is an important step towards CMS's goal of creating an effective payment system that reimburses providers appropriately for the quality oxygen services furnished to Medicare beneficiaries.

Alternatively, CMS could establish a grandfather policy that would allow Medicare patients currently receiving oxygen services to remain under the current oxygen reimbursement system. This would eliminate the significant disruption that would otherwise occur for patients and providers. These patients have become accustomed to operating under the current oxygen delivery service, and a new reimbursement system may impede the ability of suppliers to maintain that system in the fashion to which those patients have become accustomed. Under this transition model, CMS would allow patients receiving service prior to January 1, 2007, to remain subject to the current reimbursement system, whereas new patients who begin using services after that date will be reimbursed under the new reimbursement system.

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[3]Traditionally, CMS has established blended rates by taking 75 percent of the original rate and 25 percent of the new rate during Year One; 50 percent and 50 percent in Year Two; and 25 percent and 75 percent in Year Three.

Another alternative would be for CMS to establish a "grace period" during which providers could transfer patients with their consent to other modalities. Because the Rule, as proposed, would restrict these activities (unless modified as suggested below), allowing a grace period would provide patients with a smoother transition between payment methodologies. Given the change in the flexibility of a supplier to make such transfers, it may be necessary to adjust modalities in order to best serve the patient's long-term needs. As such, CMS should consider allowing suppliers an adequate grace period in which they can assess patient needs and make adjustments where appropriate before the more restrictive policy takes effect.

B. A Transition Period Will Provide CMS with Time to Collect Appropriate Data To Ensure It Establishes Appropriate Reimbursement Rates for the Classes.

A transition is even more important to the home oxygen community because there is very little data about the total cost of providing services to beneficiaries. Implementing a phased-in reimbursement policy will provide the Agency and the community with the time needed to determine what data it needs and how to collect it. It will also allow sufficient time to develop the appropriate methodology to set reimbursement rates based upon the data it collects.

Allowing CMS time to develop the necessary information upon which it should base its payment policies is critical to achieving an appropriate payment structure and is a required component in the Agency's compliance with its responsibilities under the Information Quality Act.[4] Under the Information Quality Act, CMS must use accurate, objective data in the formulation of the policies it disseminates to the public through the Federal Register publication. Given the lack of data available to establish the payment rates, we encourage CMS to provide a transition period during which it can work with the community to ensure that the rates it believes are appropriate in fact are.

Home oxygen therapy provides beneficiaries with the freedom to remain with their families while they receive this life-saving treatment. CMS should ensure that the reimbursement rates it sets for these products and services cover the cost of providing them. If they do not, beneficiaries will suffer. Without the appropriate data, it is difficult to determine the true cost of these products and services. CMS should examine how the proposed rates relate to the cost of integrating new technology into the home oxygen therapy benefit. It may determine that higher payments are needed to encourage its adoption. The community has recently undertaken significant efforts to gather and validate industry-wide data on the costs of providing oxygen services to beneficiaries, such as the cost analysis of Medicare home oxygen therapy published by Morrison Informatics, Inc. in June 2006 (Morrison Study) (See attachment 2). The Morrison Study provides essential information on the costs of all aspects of providing oxygen to patients, beyond the costs of equipment alone, and data such as this is critical to developing a reimbursement system that pays appropriately based upon the actual costs of suppliers. For example, this study supports the Council's position that the rates proposed for providing portable oxygen are too low. Therefore, the Council encourages CMS to work with the community during the transition period to identify the appropriate data and develop the methodology necessary to establish reimbursement rates for home oxygen that are based on solid evidence.

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[4] 44 U.S.C. §3516 (2002); *see supra* note 1 for CMS guidelines implementing the Act.

The Council appreciates the difficulty in collecting appropriate data to set reimbursement rates. CMS should set an appropriate timetable to work with the community to ensure that the appropriate data is collected. The Proposed Rule, however, appears to rush the process by relying on anecdotal evidence. For example, the Proposed Rule cites an example from the Department of Veterans Affairs (VA) to justify the proposed payment system changes. The conclusion drawn from this comparison is a *non sequitur* and should not be used as the basis to form CMS policies or rates. First, according to the contract provider, American Medical Equipment, the Tampa VA contract referred to in the Proposed Rule is an unbundled contract that reimburses separately for each portable cylinder and pound of liquid oxygen provided to a beneficiary. That means if viewed in the aggregate, this VA contract may pay more than the Medicare rate. Thus, it is inappropriate for CMS to use the unbundled rates to set Medicare bundled rates. In addition to the bundling difference noted above, there are a number of other differences between the VA and Medicare that are worth noting:

- The VA currently uses competitive bidding in procurement of its oxygen service contracts, while Medicare renders payment to all qualifying providers. Thus, VA contractors may be able to provide a lower rate because they are guaranteed a specified volume of business and exclusivity, whereas Medicare providers have no such guarantee.

- Medicare providers spend a significant amount of time and resources ensuring their compliance with Medicare requirements and the associated administrative paperwork and processes related to patient intake, billing, and collections. In contrast, the VA process is relatively simple and streamlined. It requires significantly fewer resources for compliance and billing, which significantly lowers the cost of providing services.

- The VA has no patient co-payment requirements. In contrast, a Medicare provider must pursue individual patients and secondary payers to reimburse portions of the service, with additional administrative and documentation costs. These obligations are often left unfulfilled, resulting in expensive bad debt write-offs for Medicare providers.

- The VA contract referenced in the Proposed Rule also includes additional rate protections and service fees that Medicare does not provide. Among other things, VA contractors receive separate service fees for equipment maintenance, refills of oxygen, therapy visits, and supplies. VA contracts also include built-in escalation provisions to account for providers' increasing costs over time.

This example demonstrates that there is a need to engage in a more rigorous review of data regarding home oxygen therapy pricing and costs. A transition period would allow CMS to undertake this important activity.

C. The Transition Period Will Also Provide CMS with the Necessary Time To Work with the Home Oxygen Community to Develop a Fee Schedule for Equipment and Maintenance Services Provided after the Transfer of Title.

The Proposed Rule indicates that Medicare will make maintenance and service payments for capped rental oxygen equipment after title has transferred to the beneficiary using the existing policy

that covers only certain routine maintenance or periodic servicing. Because not all maintenance and services will be reimbursed, CMS should establish a specific, standardized fee schedule that all DME MACs reference and that clearly describes the specific maintenance and services that Medicare would cover. The Council looks forward to working with CMS as it develops this fee schedule. Because this will take time to establish the codes and appropriate reimbursement rates, the need to develop this fee schedule also supports the need to allow for a transition of the new reimbursement policy.

D. A Transition Period Will Allow CMS Time to Address Providing Emergency and On-Call Services to Patients after the Transfer of Ownership.

Under the current reimbursement policy, providers provide emergency and on-call services to patients as part of the rental arrangement. However, the Proposed Rule does not address the need for after-hours or emergency services for patients following the transfer of title for either their capped rental or oxygen equipment. Without such a policy and reimbursement rates that acknowledge the need for such services, patients may be at serious risk for increased levels of hospitalization, emergency room visits, or physician visits.[4] The Council would be pleased to work with CMS to develop a rational, reasonable methodology to provide for emergency services for patient-owned equipment to ensure that beneficiaries continue to have access to life sustaining services during power outages or other emergency situations.

E. A Transition Period Will Allow CMS Time to Address the Implementation of Competitive Bidding and the Impact the Proposed DRA Policy and Payment Changes Will Have on that Program and Participating Providers.

The Proposed Rule contains sweeping changes to the reimbursement policies for home oxygen equipment. The Council is concerned that these changes, along with the ownership changes mandated by Congress and the upcoming competitive bidding rules will destabilize the community and place patients at risk and may threaten their ability to access these life-saving technologies. The competitive bidding program will also introduce new supplier quality standards, restrictive contracting requirements, and market-driven pricing for the first time in the history of the home oxygen therapy benefit. The introduction of these changes significantly increases the complexity of the landscape. Yet, there has been little examination of the interaction of these new policies. Without a transition period, basic questions about implementation that may arise will not be answered until it may be too late to address them. Given the reframing of the entire home oxygen benefit, the Council strongly urges CMS to provide a transition period during which the community can resolve problems that may arise at the intersection of these different policies.

IV. Any New Reimbursement Methodology Should Ensure that Physicians May Continue to Prescribe the Equipment that Most Appropriately Meets Patients' Needs and Ensures High Quality Care.

Although we understand the Agency's goals in revising the reimbursement policy, it is important that patients continue to receive the equipment and services that most appropriately meets their needs and ensures high quality care and quality of life for patients. In general, the

[4] *See* Michael J. O'Grady, "White Paper on Medicare's Payment Policy for Oxygen" (Sept. 12, 2006) (Attachment 3).

Council recommends that CMS evaluate its proposed system in light of the current reimbursement policy. An important benefit of the current policy is that it is "modality neutral," which means that physicians can prescribe the equipment that best meets the patients' needs. We encourage CMS to examine the clinical and operational needs of the home oxygen community and adjust its policy so that physicians may continue to prescribe the most appropriate equipment to their patients and that patient compliance and safety remain a top priority.

A. CMS Should Work with the Home Oxygen Community to Develop Safety Standards to Ensure that Patients and Their Caregivers Understand the Responsibilities Associated with Owning Home Oxygen Equipment.

The Council understands that Congress requires the transfer of the title of ownership for home oxygen equipment after 36 months. Because the Council remains extremely concerned about this requirement, it encourages CMS to work with it and other members of the home oxygen community to develop safety standards that can be applied to patient-owned equipment to reduce the risk of oxygen-related accidents or improper use. The patients who receive home oxygen therapy through Medicare are often elderly and/or have disabilities. These vulnerable patients rely upon caregivers to assist them. In many cases, these caregivers are also elderly spouses. It may be extremely difficult for the patients and their caregivers to perform simple troubleshooting of their equipment despite written instructions or professional guidance via phone.

The recently-published OIG report entitled "Medicare Home Oxygen Equipment: Cost and Servicing," issued on September 14, 2006, supports the Council's concerns that many patients will not be able to perform routine maintenance once they own their equipment. "When suppliers visit beneficiaries, they often perform services that a beneficiary has been instructed to do. The data suggests that 50 percent of the visits conducted by homecare providers included what has been described as 'routine maintenance' by CMS."[5] Under the current reimbursement policy, providers do not receive additional payments for providing routine maintenance. Therefore, it is reasonable to conclude that providers perform this routine maintenance on behalf of patients because the patients and caregivers cannot do so.

In the experience of the Council members, patients rely on the 24-hour, seven-day-a-week on-call service provided by their homecare company to answer questions related to their equipment. They call providers frequently, namely whenever there is a major or minor issue or concern. For example, one large national provider that provides services and equipment outside of the home oxygen community indicates that the number one and two product categories for which patients access its after-hours service are oxygen and home medical equipment, respectively. A large percentage of these calls result in an in-home visit after hours and on weekends.

Once the title transfers, the patient will be responsible for performing certain services that would have otherwise been covered in a monthly bundled rental and service fee (in the case of oxygen) or a semi-annual service and maintenance fee (in the case of other capped rental medical equipment). The Council is concerned that under the proposed system, ongoing beneficiary education and monitoring regarding oxygen usage and safety will no longer be tracked or performed,

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[5]Office of Inspector General Report: "Medicare Home Oxygen Equipment: Cost and Servicing," September 2006. Page 11-12.

creating the potential for unsafe use of oxygen and oxygen equipment. Oxygen cylinders must be stored properly in order to be safe and must be periodically tested hydrostatically to assure they will safely hold contents under high pressures. Liquid oxygen vessels are regularly inspected for leaks to assure the cryogenic contents are safety contained. There is also a requirement that equipment repair and maintenance be documented to provide a history for each item. Filling stations are deemed manufacturing plants and are highly regulated by the Food and Drug Administration (FDA). These stations may be reluctant to fill beneficiary-owned equipment in those cases in which the beneficiary does not label the transferred cylinder properly or its fill history is unknown. This would create a dangerous situation. Cylinder concerns include the need for hydrostatic cylinder testing, product traceability, drug product labeling with potential for misbranding, chain of custody, and control issues. Additionally, oxygen requires compliance with specific regulations developed by the respective state boards of pharmacy, Department of Transportation (DOT), FDA, as well as guidelines from the Compressed Gas Association (CGA). Refilling cylinders requires medical quality oxygen content to avoid life-threatening contamination problems. Patients may not be aware of, or comply with, these guidelines thus putting them and others at risk. We strongly urge CMS to work with the Council and other interested groups to develop safety standards that can be applied to patient-owned equipment in an effort to reduce the risk of oxygen-related accidents or improper use.

In particular, the Council remains extremely concerned about the transfer of ownership title as it relates to the ownership of cylinders, regulators, and oxygen vessels although it appreciates that CMS may have little authority to change this congressional mandate. Specifically, the transfer of title of ownership of cylinders means that patients will be more likely to try to move cylinders on their own. This can be extremely dangerous, as demonstrated by the tragic bus fire that occurred during the evacuation of nursing home residents during Hurricane Katrina. A single spark that resulted from the bus having a flat tire led to the volatile oxygen accelerating the resulting fire and killing the evacuees. If ownership remained with the provider, the provider would be responsible for moving this dangerous equipment and be able to provide trained personnel to ensure its safe transport.

The Council is also concerned about the effect of the transfer of title on the current practice of exchanging cylinders. Today, when a cylinder empties, the provider is responsible for picking it up and providing the patient with a full cylinder. The provider retains ownership of the cylinder, while the beneficiary rents it. This allows for the provider to use different cylinders with the same patient. The current process is efficient. The Proposed Rule implies that patients would own two or more cylinders. This would be unnecessarily costly and inefficient because providers would have to develop tracking systems that would ensure that each patient's cylinder could be identified. In addition, cylinders must be disposed of safely. The more efficient and safer approach is for the provider to retain ownership of all cylinders and for the current rental process to continue. This is also the practice in other countries and other non-medical industries.

B. CMS Should Work with the Food and Drug Administration (FDA) and the Home Oxygen Community To Ensure the Safety of Used Home Oxygen Equipment Sold by Patients or Their Families.

With the title of ownership transferring to beneficiaries, it is likely that more home oxygen equipment will become part of the marketplace for used goods. Therefore, the Council strongly urges CMS to coordinate with the FDA to develop national guidelines that apply specifically to the public resale of used medical devices.

Even before the transfer of title, used medical devices (either discarded inappropriately, stolen, or in limited circumstances patient-owned) are already finding their way into flea markets and classified ads, as well as on-line marketplaces for sale. The sellers advertise oxygen cylinders "as-is" without evidence or guarantees that the devices are functioning properly. Some online marketplaces require a seller to check a box that the seller is licensed to distribute the equipment. However, there is no check to confirm the truth of the assertion. There is virtually no safeguard for the average patient or interested party to know whether or not the medical device purchased, such as an oxygen concentrator, is appropriate for their condition, if that device is in proper working order providing therapeutic oxygen levels, needs preventive maintenance, minor or major repairs, or other service and maintenance. In addition, the potential for the spread of infection is highly likely. The general public does not have the knowledge or expertise to properly disinfect this equipment prior to selling to other members of the public. Transmission of respiratory pathogens is highly likely if the device is not properly disinfected in between patient uses as it is by accredited providers who comply with the infection control requirements of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or other accreditors.[6] These "new" patients would lack the necessary training and knowledge for safe use and operation of these devices, creating potentially dangerous situations.

In addition to providing equipment with questionable quality, sellers are transporting used oxygen cylinders through United Parcel Service (UPS), FedEx, and other air carriers without providing sufficient information to Transportation Safety Administration (TSA), Homeland Security Department, or the Federal Aviation Administration (FAA). With the legal transfer of ownership to patients, these practices are likely to increase.

Because the Safe Medical Device Act (SMDA) never technically contemplated the concept of broad-based medical device ownership among the American public, we strongly believe CMS should confer with the FDA to review the impact of the changes in the ownership requirement. For example, the transfer of ownership will mean that current FDA requirements that mandate that providers trace equipment so that they can provide notices of recalls will be next to impossible to meet if a patient sells his/her equipment. In addition, CMS and the FDA should discuss the ability for medical oxygen fillers to comply with 21 C.F.R. §§ 210 and 211 once the patients own their own devices and equipment. If necessary, the Federal Trade Commission (FTC) should be consulted to stop on-line marketplaces from selling medical equipment that may only be sold or dispensed to a specific patient based on a licensed physician's prescription.

We would welcome the opportunity to work through these important safety issues with CMS and FDA.

V. CMS Should Clarify Several Provisions in the Final Rule to Ensure the Appropriate Implementation of the New Reimbursement Methodology and Transfer of Ownership Requirements.

[6]Joint Commission on Accreditation of Healthcare Organizations Standards Manual for Home Medical Equipment Providers, 2006. Sections on Infection Control, Quarantine of Clean/Dirty Equipment and Patient Safety Goals.

In addition to addressing the budget neutrality concerns and providing for a transition period, CMS should also clarify several provisions of the Proposed Rule. These clarifications will ensure the appropriate implementation of the changes and ensure that patients continue to receive high quality care.

A. In the Final Rule, CMS Should Clarify Reimbursement for Exchanges or Changes of Equipment.

The Proposed Rule, while appearing to address the issue of changing clinical needs of patients, does not adequately account for the expense associated with servicing this vulnerable population. For example, a subset of oxygen patients will progress to the point of requiring higher flow rates. An informal survey of six large home oxygen providers indicated that one-to-two percent of oxygen patients require a liter flow of four liters per minute (LPM) or greater, inferring that the patients are in the later stages of their illnesses and perhaps even approaching the terminal stage.[7] While there is an increase in payment for flow rates greater than four liters per minute, the higher reimbursement does not offset the increased cost of changing the equipment (*i.e.*, to a ten LPM concentrator) or the modality (*i.e.*, to liquid oxygen, which can accommodate higher liter flow requirements). This disparity in payment versus equipment cost increases throughout the first 36 months of rental; however, it becomes even more critical after 36 months. The need for higher flow rates typically comes late in the progression of their disease and is most likely to occur after the 36-month transfer of title and cessation of payments to the provider.

The Council suggests that CMS develop a mechanism to increase payments to providers who, for medically necessary reasons, are required to provide additional equipment to support the patient as he/she progresses through his/her illness. This would include a mechanism to increase payments when a change to a more expensive modality is required during the time period in which they are providing services to a patient.

B. CMS Should Clarify Its Restrictions on Equipment Exchange or Change Options.

The Council appreciates the Agency's attempt to ensure that providers do not substitute substandard equipment to patients just before the required transfer of title. However, we are concerned that as drafted the Proposed Rule is too restrictive. Therefore, we encourage CMS to clarify that in certain circumstances it is appropriate to exchange or change equipment as long as the exchange or change is sufficiently documented and the provider certifies that the equipment is not a lesser-quality device.

In some cases, it may be appropriate for a provider to exchange or change a patient's home oxygen equipment. For example, if a patient who refuses to stop smoking in the home, the provider should be allowed to adjust the equipment to lessen the danger associated with this non-compliant behavior. Providers should also be permitted to exchange or change equipment when a more appropriate item is available. Additionally, patients may learn about new equipment through friends, their doctors, or their support groups, such as The American Lung Association's Better Breathers

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[7]Survey of CQRC members Air Products Homecare, American HomePatient, Apria Healthcare, Lincare, Pacific Pulmonary Services and Praxair Healthcare Services.

Clubs. Traditionally, providers have accommodated these requests when appropriate. However, home oxygen providers would be placed in a difficult situation if a patient who has had one type of equipment for 33 months were to learn about a new device and were to request it. The provider would have to tell the patient that Medicare would not permit the change. As drafted, the Proposed Rule would restrict the ability of providers to provide patients with new equipment that represents important technological advances or has demonstrated improved clinical outcomes of patients.

The most important reason to exchange or change patient equipment is because of a change in the patient's clinical needs. The Propose Rule acknowledges that equipment may be exchanged or changed if the patient's medical condition changes, but limits the exception to situations when the equipment is no longer appropriate or medically necessary. An exchange or change may also be appropriate if the equipment is still appropriate and/or medically necessary, but a different piece of equipment would better meet the patient's changing needs. For example, a different piece of equipment may allow a patient to perform more activities of daily living. When the equipment is first provided, a patient's movement may be limited as she recovers from a recent hospitalization. Yet, once the patient's strength increases, she may be able to engage in more daily life activities. A different piece of equipment could help speed her recovery and her independence. The Proposed Rule would not permit an exchange of equipment that would clearly benefit the patient.

The proposed carrier determination exception is not sufficient to address this concern because it does not outline the process for the carrier to make these determinations. To be effective, an exception must provide clear guidance to the community. Without such guidance, providers are unlikely to make exchanges or changes in equipment that are warranted, which will only hurt patients. Therefore, we recommend that CMS allow providers to judiciously exchange or change a patient's equipment during the period of medical need provided that this exchange or change is sufficiently documented and that the provider certifies that the new equipment is not a lesser-quality device. CMS should also develop medical necessity requirements for modality changes that take into account the medical benefit that a change in equipment might provide in terms of ambulatory ability and participating in activities of daily living.

C. CMS Should Clarify the Responsibility of Providers To Repair or Replace Equipment After Patients Receive the Title of Ownership.

The Council is concerned that the Proposed Rule would require providers to replace equipment for which ownership has already transferred to the patient if the repair cost is greater than 60 percent of the replacement cost. The proposed requirement is inconsistent with the intent of Congress to make patients more responsible for their home oxygen equipment. It also inappropriately holds providers responsible for equipment over which they no longer have control or ownership. CMS should specify that once ownership shifts to the patient, it becomes the patient's responsibility to maintain and repair the equipment. The patient is also protected from any concerns about substandard equipment through the restrictions on the exchange or change of equipment requirements.

The Rule proposes that, if equipment replacement is not covered by a manufacturer's or provider's warranty, the provider must still replace patient-owned oxygen equipment or patient-owned capped rental items at no cost to the patient or to the Medicare program if (1) the total accumulated costs to repair the equipment are greater than 60 percent of the replacement cost and (2) the item has been in continuous use for less than its reasonable useful lifetime. First, the 60

percent repair versus replacement comparison does not equitably apply to a capped rental item. For capped rental home medical equipment or devices, the item will convert to sale at 13 months, or at 21.7 percent of the item's "useful life" (currently defined as 5 years by CMS). For example, if a wheelchair that converts to sale to a beneficiary at 13 months breaks down in the 14th month, the Proposed Rule would require the provider to be responsible for replacing this wheelchair if the total accumulated cost to repair the wheelchair was greater than 60 percent of the replacement cost. This places an unreasonable economic burden on providers because it shifts the responsibility for the equipment in years four and five from the manufacturers to the providers. This is clearly not an economically equitable proposal because providers will have no control over the maintenance and servicing of the equipment by the patient, but will still be responsible for the equipment.

Second, for oxygen equipment, the beneficiary would own the equipment after 36 months. However, the provider would be responsible for replacing the currently owned equipment if the repair cost is greater than 60 percent of the replacement cost. Again, CMS is proposing that the provider continue to be responsible for equipment for which it has no control over how it is maintained.

We recommend that CMS specify that once equipment converts to sale, the responsibility for repairing or replacing the equipment should become the responsibility of the beneficiary. Although the proposed exchange and change of equipment restrictions should address any concerns about substandard equipment, CMS could establish a separate toll free number could be established for Medicare beneficiary complaints to determine if the problem really exists. CMS could also establish a provider responsibility period of 30 days that would require replacement if the repair costs were 60 percent of the replacement cost if the equipment failed during the first 30 days after the transfer of title. This would allow a patient to examine the equipment to ensure they have received the equipment in good working order, similar to a "free look" period or "lemon law" provided to consumers by some states now. Additionally, the 60 percent rule should be viewed as a one-time repair cost and not be viewed cumulatively.

The Council is also concerned that the Proposed Rule does not define the term "replacement cost" for purposes of calculating the 60 percent threshold. The Council assumes that the replacement cost would equal the total of the monthly payments or purchase price. However, because these payments differ on a state-by-state basis, CMS should clarify how the replacement cost would be established. CMS should also clarify and provide additional guidance about how it expects providers to account for the replacement cost or to track accumulated repair costs per beneficiary.

Finally, as noted earlier in this letter we encourage CMS to work with the home oxygen community to develop the appropriate data to support the provisions. For example, there is only anecdotal data that supports that 60 months is the useful life of equipment. In the experience of members of the Council, however, we have found that many lightweight portable systems break before 36 months. Most of their warranties are only 36 months as well. Therefore, CMS should work with the community to address the data issues before implementing policies that are not evidence based.

D. CMS Should Clarify the Requirements for In-Home Clinical Patient Assessments after the Transfer of Ownership/36 month cap.

CMS should clarify whether or not in-home clinical assessments will be part of patient care after they have received home oxygen therapy for 36 months. In-home clinical patient assessments are extremely important to ensuring high quality care for patients. It is not uncommon for a physician to ask a home oxygen provider to conduct an in-home clinical patient assessment on a long-term oxygen patient so that the licensed homecare clinician can listen to breath sounds, discuss the patient's level of compliance to the physician's prescribed regimen, and document other findings in a summary to be provided to the physician. In fact, he/she may write an order for a homecare provider to conduct such a visit every three or six months depending on the patient's individual needs. In addition, certain oxygen modalities have built-in oxygen conserving devices (OCDs), such as the transfilling systems and portable oxygen concentrators (POCs). A patient must be tested and titrated on an OCD before he/she can use that oxygen modality. Most state respiratory therapist licensing laws require these therapists to perform that testing and titration. In the case in which a patient exceeds the 36th month and an equipment exchange is warranted, the Council is concerned that there would be no requirement for the in-home testing/titration to be provided.

The Council strongly encourages CMS to allow patients to continue to receive these assessments pursuant to physician orders. However, this activity is sustainable only if CMS establishes a new code and an appropriate reimbursement rate. The rate should take into account the value of the therapists' time, mileage reimbursement expense, and related costs. Patient assessment, training, education and monitoring currently comprise nine percent of providers' total costs of caring for patients.[8] Providers cannot provide these assessments without fair reimbursement rates because they could constitute an illegal inducement and raise other fraud and abuse concerns. The Council welcomes the opportunity to work with CMS to provide accurate, fully-loaded cost data that would facilitate the Agency's ability to establish not only a fair reimbursement rate, but also a process that would inhibit any potential for fraud or abuse.

E. CMS Should Clarify the Definitions of Routine and Non-Routine Maintenance.

The Council encourages CMS to clarify the definitions of "routine maintenance" and "non-routine maintenance" so providers have a better understanding of what services would be covered. The Proposed Rule contains conflicting guidance as to what services would be reimbursed once the title transfers to the patient. For example, the Proposed Rule suggests that patients should perform routine maintenance, while also indicating that if special tools were required to perform such maintenance (tools which patients would not typically own, such as an oxygen analyzer), Medicare would reimburse providers for the services.

The Council encourages the Agency to establish definitions of routine and non-routine maintenance to take into account the differing needs of patients. Many of the tasks required in performing ongoing medical equipment and oxygen concentrator maintenance require hand-to-eye coordination, strength, depth perception, and tactile ability. Although some patients or their caregivers may possess the necessary physical skills, others may not. Many patients who require

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[8] "A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy - A Study for the American Association for Homecare," June 27, 2006, Morrison Informatics, Inc. The report collected data from 74 home oxygen providers nationwide who collectively serve over 600,000, or approximately 60 percent, of the total Medicare oxygen-dependent beneficiaries in the United States.

home oxygen therapy are vulnerable, elderly individuals who have difficulties performing certain basic activities of daily living and simply may not be able to perform repair or maintenance tasks.[9]

For example, the simple removal of the cover of an oxygen concentrator requires the proper use of a screwdriver and adequate strength to loosen and remove the screws. The changing of the internal filters requires the ability to loosen the tubing attached to both ends of the in-line regulator filter and then to reattach the tubing to the new filter. This requires hand strength and dexterity, both of which are compromised in most COPD patients, as well as those with arthritis. While these may seem like simple tasks to most individuals, experience shows that they are complex for many elderly patients. The Council encourages the Agency to take a second look at the definition of routine maintenance so that it avoids the problems encountered when CMS required beneficiaries to change their own power wheelchair batteries. This policy was ultimately changed when it became apparent that beneficiaries often reversed polarity on the batteries and ruined the electronics on the chair.

To provide more clarity on this issue, we suggest that CMS develop specific definitions as to what should be considered routine or non-routine equipment maintenance for both oxygen and capped rental home medical equipment. Based upon surveys of oxygen equipment manufacturers and oxygen equipment technicians who repair and service the same, we suggest the following tasks should be considered "routine" oxygen concentrator maintenance:

1. Wiping down external surfaces;
2. Removing, cleaning and replacing the external cabinet filter;
3. Changing oxygen tubing; and
4. Cleaning, disinfecting and replacing O_2 humidifiers if used.

Of course, there should also be an exception to permit providers to engage in reimbursable maintenance when patients do not have the physical ability to undertake such activities. We also recommend the following tasks be considered "non-routine" maintenance performed by trained professionals and reimbursed via a fair and equitable payment structure by CMS:

1. Inspection of internal components for dust, debris, evidence of wear;
2. Changing of internal mail flow and regulator flow bacteria filters;
3. Using any specialized device to test oxygen purity output of equipment;
4. Cleaning of internal heat dissipation coils; and
5. Any maintenance that requires breaking of internal seals such as sieve bed repair, compressor rebuilds electric motor repair, etc.

We look forward to working with CMS to help develop the appropriate definitions for all product and service categories subject to this Rule.

F. CMS Should Clarify the Definition of Modality.

The Council encourages CMS to establish a definition of "modality" so that there is no confusion between the clinical meaning of this term and the regulatory use of it. Clinicians have

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[9] *See* O'Grady, "White Paper on Medicare's Payment Policy for Oxygen."

established three oxygen modality categories: (1) liquid oxygen; (2) compressed gas; and (3) oxygen extraction from room air (*i.e.*, concentrator). These categories are then divided into subcategories based upon the level of ambulation afforded to patients: (1) stationary (which might include stationary concentrators, large compressed gas cylinders, and liquid reservoirs); (2) portable; and (3) ambulatory (which include high-tech "lightweight" portable systems that dispense oxygen in various ways depending on the patient's breathing strength and rate). The Proposed Rule appears to use a different definition of "modality."

The Council believes it is important to provide a clear definition of modality to ensure that when it is appropriate to switch a patient, there is no confusion as to what constitutes medical necessity. For example, if the clinical viewpoint is taken, there would be no medical necessity justification necessary to change a patient from compressed gas cylinders delivered to the patient's home from a transfilling unit since there is no change in modality (both are compressed gas). However, that would not be the case under the Proposed Rule's use of the term.

CMS should clarify its definition and interpretation of the term "modality" in the Final Rule. If CMS does not adopt the clinical community's definition, the Agency should also define the specific circumstances when patients may be changed from one type of equipment to another. For example, if CMS seeks to encourage home oxygen providers to adopt newer, more operationally efficient equipment, the Final Rule should also set out: (1) the medical policy that clearly defines the criteria allowing patients to switch from one category to another (*i.e.*, gaseous or liquid cylinders that are delivered to the home vs. cylinders that are self-filled in the home); and (2) a payment policy that allows for full reimbursement when the patient changes from one equipment type to another, even if the change occurs during the first 36 months of rental. The Council encourages CMS to work with the home oxygen community to develop these policies.

G. CMS Should Clarify the Transfer of Ownership Provisions.

The Council is concerned that the Proposed Rule does not provide sufficient guidance about how the transfer of ownership requirement will be implemented. Although we have serious concerns about the appropriateness of the transfer of title to patients, we appreciate that CMS is bound by the DRA mandate. However, we urge CMS to provide additional guidance about the actual implementation of this requirement.

The Proposed Rule states that the title for oxygen equipment will transfer to a Medicare beneficiary after 36 months of continuous rental and after payments have been made for these months, consistent with the DRA requirement. For capped rental home medical equipment products and services, the title will transfer after 13 months. However, the Proposed Rule does not address how this timeframe would be affected by a break-in-service or whether the title of the equipment will transfer to the beneficiary if their rental period includes such a break. For example, a patient who receives eight tanks of oxygen per month, but is then hospitalized during flu season, may require 14 tanks per month upon discharge. Let us assume that the patient is in the 20th rental month of service. Because the patient's volume requirement for oxygen has increased, there is clearly a change in medical necessity. The Proposed Rule is not clear how those additional six tanks per month would be reimbursed and whether the "36-month" clock starts over on the new equipment that the home oxygen provider must place in the home.

The DRA specifically states that the transfer must occur "after the 36th continuous month during which payment is made." 42 U.S.C. § 1395m(a)(5)(F)(ii)(I). If there is a break or change in service, there is not continuous payment. Therefore, CMS should clarify in the Final Rule that if there is a break in service or rental period, the clock is reset.

Additionally, the Proposed Rule does not address how the beneficiary copayments or secondary payer payments are accounted for in the determination of the 36th continuous month calculation. Because the DRA uses the generic term "payment," CMS should clarify that payments must include not only Medicare payments, but also beneficiary copayments and secondary copayments. If these payments have not been made continuously during the 36th months, the title should not transfer.

To address these potential problems, we recommend that CMS: (1) establish a mechanism to indicate a "non-transfer of title to the beneficiary" so that CMS can distinguish an ongoing rental decision related to a pre-existing capped rental beneficiary from the above-described situation; (2) allow providers to have access to the Common Working File to verify break-in-service or previous equipment from another provider; and (3) address the impact of a break-in-service on the calculation of the 13 or 36 month period for purposes of capped rental home medical equipment and oxygen equipment ownership, respectively; and (4) implement a policy that specifies that title to capped rental home medical equipment and oxygen equipment will not transfer to a beneficiary if there remains any unpaid portion of the Medicare allowable charge, whether the unpaid portion is from Medicare, a secondary payer or the beneficiary themselves.

H. CMS should clarify its notice requirements about Medicare Assignment

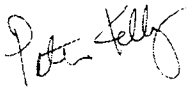
The Propose Rule requires all providers to "disclose to the beneficiary [their] intention regarding whether [they] will accept assignment of all monthly rental claims for the duration of the rental period." 71 Fed. Reg. at 44107. The rental period may be as long as three years. Participating providers must accept assignment on all claims for a period of a single calendar year. The decision to become a participating provider is voluntary.

The Council urges CMS to clarify this language to ensure that it is consistent with the general rule that participating providers are bound to accept assignment on an annual basis and can modify their status as a participating provider annually as well. If this clarification is not made, beneficiaries could be confused and make incorrect assumptions about their financial liability, which is inconsistent with CMS's intent in establishing the notice requirement. We recommend that the Agency clarify that providers disclose to beneficiaries their intent to accept assignment on all claims for the duration of the rental period (as defined in the disclosure). In addition, the provider should be able to clarify under what circumstances assignment would no longer be appropriate, such as if the beneficiary is no longer eligible for coverage. The Council agrees that beneficiaries must understand their financial obligations and strongly encourages CMS to clarify that providers have the flexibility to provide clear explanations of these obligations.

VI. Conclusion

The Council members sincerely appreciate your review of our concerns and look forward to working with the Agency on these issues. Please do not hesitate to contact Peter Kelly at 800-572-7522 ext. 206 if you have questions regarding these comments.

Sincerely,



Peter Kelly
Chief Executive Officer of Pacific Pulmonary Services and
Chairman of the Council for Quality Respiratory Care

Council Members

American HomePatient

Pacific Pulmonary Services

Apria Healthcare

Respironics Inc.

AirSep Corporation

Rotech Healthcare Inc.

Invacare Corporation

Air Products Global Healthcare

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September 22, 2006

Tyler J. Wilson
President & CEO
American Association for Homecare
625 Slaters Lane, Suite 200
Alexandria, VA 22314

Dear Mr. Wilson:

The Lewin Group is pleased to provide you and the association with an independent assessment of: 1) the likely impact of the Notice for Proposed Rulemaking (NPRM) on Medicare payment for home oxygen therapy and oxygen equipment; and, 2) the extent to which the proposed rule meets the budget neutrality requirement.

After careful assessment of the proposed rule and a financial analysis using CMS' utilization figures, The Lewin Group has concluded that the proposed payments are not budget neutral for oxygen and oxygen equipment in 2007. The proposed regulations would result in a reduction of approximately 10 percent ($257M) in the amount paid for oxygen and equipment in 2007 alone, with additional payment reductions from the capped rental provision in the Deficit Reduction Act that requires providers to transfer title of oxygen equipment to the beneficiary after 36 months of rental. Table 1 summarizes our findings.

Table 1: Impact of NPRM on Medicare Payment for Oxygen and Oxygen Equipment in 2007

	In Millions
Total Calculated Payment - Current	$2,607
Proposed Payment - NPRM	$2,349
Calculated Loss to Industry	$ 257

Source: Lewin Group analysis.

Under the proposed rule, CMS changes the oxygen classification system, dividing stationary and portable oxygen contents into two separate payment classes. The proposal also calls for a third payment class for new technologies, such as portable concentrators and home transfilling systems, that eliminate the need for refilling and delivery of oxygen contents.

According to the NPRM, payment for portable oxygen contents would increase to $55 compared to the current average payments of $21, but the monthly payment amounts for stationary oxygen equipment and contents would drop from an average of $199 to $177.

The proposed payment rates take effect January 1, 2007 and are as follows:

- Stationary payment: $177
- Portable add-on: $32
- Oxygen-generating portable equipment add-on (portable concentrators or transfilling systems): $64
- Stationary contents delivery: $101
- Portable contents delivery: $55

Lewin Group Analysis

Our analysis involved several steps, beginning with identifying utilization and payment data supplied by CMS in the NPRM, as outlined below. We first calculated the current payment for oxygen and oxygen equipment provided to 975,561 Medicare beneficiaries per month (11,706,733 per year using 2004 claims). We then calculated payment using the proposed rates, assuming no migration into portable concentrators or transfilling equipment. See Table 2, where the rule results in a reduction in payment of $257,548,126.

Utilization data provided in the proposed rule were based on Medicare beneficiary claims for 2004. Unfortunately, these claims do not provide specific utilization rates for portable concentrators or transfilling systems, since separate HCPC codes did not exist for these services at that time. In order to determine the potential impact of the multiple changes in payments across modalities, The Lewin Group estimated a migration in modality use from stationary concentrators to the portable concentrators or transfilling systems of five percent, consistent with industry estimates. See Table 3, where the rule results in a reduction in payment of $238, 817,353.

Table 2: Impact of NPRM on Oxygen and Oxygen Equipment for 2007 – Assumes No Migration into O2 Generating

Payment Analysis- Impact of NPRM	***Current Per Month Payment***	***Proposed Payment***	***Proportion Users***	***Number of Users- Annual***	***Number of Users - Per Month***	***Total Current Annual Payment***	***Total Annual Proposed Payment***	***Proposed Difference in Annual Payment***
Stationary Concentrator	$199	$177	24%	2,809,616	234,135	$559,113,568	$497,302,018	-$61,811,550
Stationary Liquid/Gas System	$199	$177	2%	234,135	19,511	$46,592,797	$41,441,835	-$5,150,963
Stationary Concentrator + Portable System	$231	$209	69%	8,077,646	673,137	$1,865,936,173	$1,688,227,966	-$177,708,207
Stationary Concentrator + O2 Generating Portable	$231	$241	0%	0	0	$0	$0	$0
Stationary Liquid Gas System + Portable	$231	$209	5%	585,337	48,778	$135,212,766	$122,335,360	-$12,877,406
Stationary L/G + O2 Generating Portable	$231	$241	0%	0	0	$0	$0	$0
Beneficiaries on O2				11,706,733	975,561	$2,606,855,304	$2,349,307,178	-$257,548,126

Table 3: Impact of NPRM on Oxygen and Oxygen Equipment for 2007 – Assumes 5% Migration into O2 Generating

Equipment Modality	Current Per Month Payment	Proposed Payment	Proportion Users	Number of Users- Annual	Number of Users - Per Month	Total Current Annual Payment	Total Annual Proposed Payment	Proposed Difference in Annual Payment
Stationary O2 Concentrator	$199	$177	24%	2,809,616	234,135	$559,113,568	$497,302,018	-$61,811,550
Stationary Liquid/Gas System	$199	$177	2%	234,135	19,511	$46,592,797	$41,441,835	-$5,150,963
Stationary O2 Concentrator + Portable System	$231	$209	64%	7,492,309	624,359	$1,730,723,407	$1,565,892,606	-$164,830,801
Stationary O2 Concentrator + O2 Generating Portable	$231	$241	5%	585,337	48,778	$135,212,766	$141,066,133	$5,853,367
Stationary Liquid Gas System + Portable	$231	$209	5%	585,337	48,778	$135,212,766	$122,335,360	-$12,877,406
Stationary Liquid/Gas System + O2 Generating Portable	$231	$241	0%	0	0	$0	$0	$0
Beneficiaries on O2				11,706,733	975,561	$2,606,855,304	$2,368,037,951	-$238,817,353

In addition to the straightforward analysis described in the preceding table, we simulated several different potential scenarios to determine what it would take to result in the proposed payment rates being budget neutral in the first year of implementation. The proposed payment for oxygen and oxygen equipment based on the newly proposed rates (2004 utilization) vary depending on the assumptions related to migration from stationary concentrators to portable equipment. With a two percent migration in 2007, the payment would be $2,415,840,000, with a loss to industry of $256,320,000. The negative impact on the industry decreases as migration assumptions increase. With a 20 percent migration, the loss to industry would be $162,120,000. In order for the proposed payments to be budget neutral, one would have to assume a 73% migration from stationary to O2 generating portable equipment in the first year. It is our understanding that this kind of shift in the first year of the new payment rates is not possible.

In the event that we can be of further help in your work, please do not hesitate to call.

Sincerely,

Joan E. DaVanzo, PhD
Vice President

STRATEGIC DIRECTION THROUGH INFORMATION MANAGEMENT

A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy

A Study for the American Association for Homecare

June 27, 2006

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1150 Lancaster Blvd., Suite 101
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A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy
A Study for the American Association for Homecare

Executive Summary

A national study of the costs and resources required for providing home oxygen therapy for Medicare beneficiaries was conducted for the American Association for Homecare. Seventy-four (74) oxygen services providers delivering services to more than 1.7 million Medicare beneficiaries and more than 600,000 beneficiaries receiving medical oxygen at home, completed a detailed survey, which identified the costs and resources used in providing oxygen services. Survey findings demonstrated that oxygen systems (equipment) alone represent only 28 percent of the cost of providing medically necessary oxygen to Medicare beneficiaries. Oxygen therapy in the home also requires preparing and delivering equipment, delivering supplies and maintenance of oxygen equipment, assessing, training and educating patients, obtaining required medical documentation and providing customer service for beneficiaries, other related services, and operating and overhead costs, which taken together represent 72 percent of the cost of home oxygen therapy for Medicare beneficiaries. These services are essential components of providing oxygen therapy to the more than 1 million Medicare beneficiaries who rely on this treatment.

Introduction

The total costs of services for providing medical oxygen therapy in the home have not been well documented; however, it is known that multiple items contribute to these costs. In addition to the cost of equipment, the cost of providing oxygen therapy to homecare patients includes costs such as patient intake, preparation and delivery, scheduled and unscheduled maintenance, patient

assessment, training and education, ongoing patient support, including costs associated with oxygen fills, disposable supply items and delivery, related services and compliance with Federal and State regulations, including Food and Drug Administration (FDA) and Department of Transportation (DOT) requirements. Limited documentation of these components and their costs has led to misunderstanding by policymakers about the resources required to provide home oxygen equipment and services for Medicare beneficiaries.

A clear understanding of the costs for home oxygen therapy is particularly important because of policy changes made by the Deficit Reduction Act of 2005 (DRA), which changed the method of reimbursement for home oxygen under the Medicare program. The DRA requires that patients take ownership of home oxygen equipment after 36 months of rental. The changes assume that the ongoing costs of services required for home oxygen therapy are low and can be essentially disregarded in determining Medicare reimbursement. The DRA changes also assume that the overseeing of key services required for home oxygen therapy can in some manner become the responsibility of home oxygen patients, who require oxygen therapy for such illnesses as chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), respiratory failure, ALS and other serious diseases.

In order to more completely document the costs for providing home oxygen to Medicare beneficiaries, the American Association for Homecare (AAHomecare) commissioned a study by Morrison Informatics, Inc. (MII), to determine the costs of providing oxygen to Medicare homecare patients. MII conducted a national survey of provider members of AAHomecare to collect comprehensive financial and resource use data associated with providing home oxygen to Medicare beneficiaries. The survey captured detailed activity-based cost data from providers

representing more than 600,000 Medicare home oxygen beneficiaries, or approximately 60% of the estimated 1 million total Medicare population receiving such services.

Methods

The *Homecare Oxygen Service Provision Survey* was developed and sent in March 2006 to members of AAHomecare, an organization that includes homecare providers of all sizes operating in all 50 states. The survey contains detailed questions on the costs and resources for providing oxygen to Medicare homecare patients for the most current year-to-date time period available (Appendix A). Major cost categories contained in the survey include: total oxygen system cost; patient intake, obtaining required medical documentation and providing customer service for beneficiaries; preparation and return processing of equipment; equipment delivery, set-up and instructions for the patient; scheduled and unscheduled delivery and equipment maintenance; maintenance supplies and disposables; patient assessment and compliance monitoring; and other operating and overhead costs. The survey collected data on the average time, materials and cost for each survey item within a category for providing home oxygen and oxygen equipment to home oxygen patients for each homecare provider. Detailed explanations of each survey question are contained in the survey (Appendix A).

Home Oxygen Provision Survey Results

1. Survey Participants

A total of 78 provider organizations completed the survey; 74 usable surveys were obtained (four surveys were not usable because of missing data). The 74 completed surveys represent results from providers serving 1.7 million Medicare beneficiaries, of whom 600,000 receive oxygen equipment. This represents a substantial proportion of all Medicare beneficiaries receiving home

oxygen equipment. Providers responding to the survey provide services to an average of 24,000 Medicare beneficiaries per year and an average of 8,000 oxygen equipment Medicare beneficiaries per year (Table 1).

Table 1: Organizations Responding to the Oxygen Service Provision Survey

Total number of provider organizations responding to survey	74
Total number of Medicare beneficiaries YTD serviced by providers	1,750,723
Total number of oxygen equipment Medicare beneficiaries YTD by providers	607,484
Average number of Medicare beneficiaries YTD per company	23,982
Average number of oxygen equipment Medicare beneficiaries YTD per company	8,209

2. Survey Results

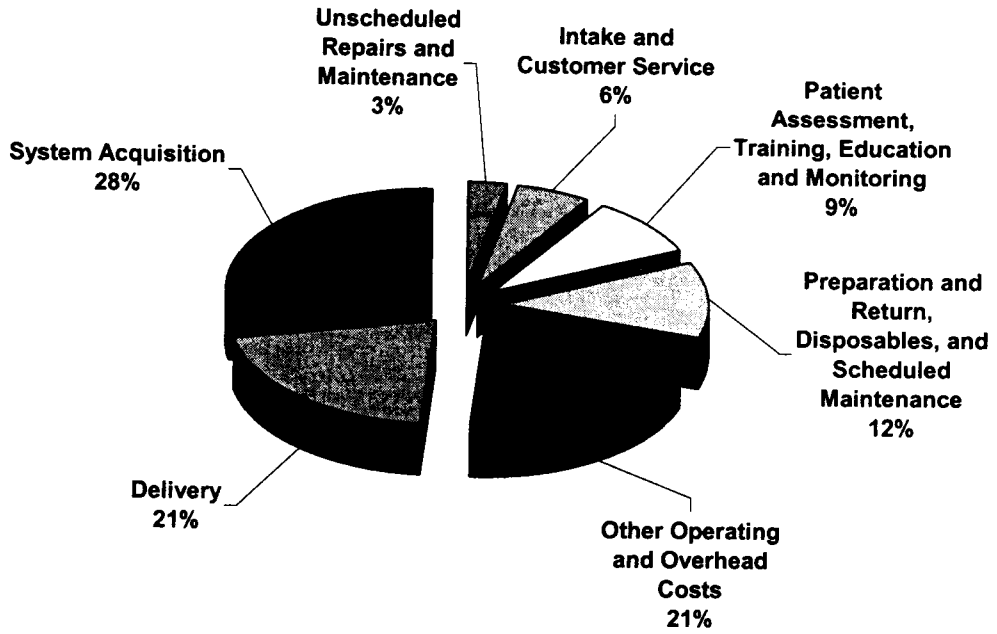
The overall average per-patient, per-month cost and resource use data from each survey item can be found in Appendix B. In addition to total oxygen equipment costs, including stationary, portable and backup unit costs, the major cost components of providing oxygen to patients at home include: the cost of obtaining patient information and related medical documentation necessary for patient intake; labor related to initial preparation of equipment; equipment delivery and set-up time; costs associated with scheduled and unscheduled maintenance and repair; ongoing patient support, including costs associated with oxygen fills, disposable supply items and delivery; vehicle costs associated with deliveries, maintenance and other in-home patient support services; costs of ongoing patient assessment, training, education and compliance monitoring; and other necessary operating and overhead costs. The average provider cost of each major cost component is shown in Table 2 and the relative proportional contribution of each major cost component to the total direct cost is shown in Figure 1.

Table 2: Overall per-Patient per-Month Costs for Major Cost Components of Home Oxygen Provision

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

[1] The amount includes acquisition costs for stationary, portable and backup units, conserving devices, ancillary equipment and accessories, and oxygen system contents (liquid and gaseous oxygen).
[2] The amount includes labor associated with patient intake functions, ongoing customer service (patient inquiries, scheduling of deliveries/maintenance/clinical visits, accommodating patient travel plans), and initial and renewal prescription processing.
[3] The amount includes labor associated with equipment preparation (testing, cleaning, and repair), equipment set-up and maintenance upon return, initial patient instruction, cost of disposable and maintenance supplies, and labor costs associated with scheduled preventive equipment maintenance.
[4] The amount includes labor and vehicle costs associated with unscheduled equipment repair and maintenance.
[5] The amount includes labor and travel costs associated with clinical visits by respiratory care practitioner, in-home patient assessments (including home environment safety assessment and oxygen therapy plan of care), training, education and compliance monitoring.
[6] The amount includes delivery costs associated with oxygen fills (liquid and gaseous oxygen), preparation, return, disposables and scheduled maintenance.
[7] The amount includes rent and other facility costs, administration, insurance, legal, regulatory compliance, MIS systems/controls, communications systems, employee training, accreditation, supplies, billing and compliance functions.

Figure 1: Home Oxygen Services Cost Component Proportions



3. Discussion

The purpose of this study was to determine, for homecare providers, the relative cost of the components of providing home oxygen to Medicare beneficiaries. The *Homecare Oxygen Service Provision Survey* did not collect data on specific components of *other operating and overhead* costs, which contributed a large proportion (21%) of the total cost of providing home oxygen. The components of *other operating and overhead* costs include costs associated with rent and other facility costs, administration, insurance, legal, regulatory compliance, MIS systems/controls, communications systems, employee training, accreditation, supplies, and billing and compliance functions. Because the values for other operating and overhead costs reported by the survey respondents were collected on an aggregate basis, further study of these

components will be necessary to better understand the nature of these expenses. The reported provider average total cost of providing oxygen, oxygen equipment and services, per patient is $201.20 per month.

The costs of providing oxygen and oxygen equipment for Medicare beneficiaries consist of multiple components, including ***total oxygen equipment costs, patient intake and obtaining required medical documentation and providing customer service for beneficiaries, preparation and return processing of equipment, equipment delivery, set-up and instruction of the patient, scheduled and unscheduled delivery and equipment maintenance, maintenance supplies, disposables and deliveries, patient assessment and compliance monitoring, and other operating and overhead costs***. The cost of oxygen equipment represents only 28 percent of the total cost of providing oxygen to Medicare beneficiaries. Many, if not most, of the other costs of providing home oxygen have not been carefully documented and recognized by policymakers, and have been assumed to be low and easily obtained when providing home oxygen services. Data from the *Homecare Oxygen Service Provision Survey* demonstrate that providing homecare oxygen requires multiple interdependent tasks which are essential to assure continuous and consistent oxygen services for Medicare beneficiaries. These required tasks are performed by providers to assure adequate oxygen services for Medicare beneficiaries. It is not clear how these services would be performed for beneficiaries if Medicare coverage of the required services were not provided.

Conclusions

A national study of the costs and resources required for providing home oxygen therapy for Medicare beneficiaries was conducted for the American Association for Homecare. Seventy-

four (74) oxygen services providers delivering services to more than 1.7 million Medicare beneficiaries and more than 600,000 beneficiaries receiving medical oxygen at home, completed a detailed survey, which identified the costs and resources used in providing oxygen services. Survey findings demonstrated that oxygen systems (equipment) alone represented only 28 percent of the cost of providing medically necessary oxygen to Medicare beneficiaries. Oxygen therapy in the home also requires preparing and delivering equipment, delivering supplies and maintenance of oxygen equipment, assessing, training and educating patients, obtaining required medical documentation and providing customer service for beneficiaries, other related services, and operating and overhead costs, which taken together represent 72 percent of the cost of home oxygen therapy for Medicare beneficiaries. These services are essential components of providing oxygen therapy to the more than 1 million Medicare beneficiaries who rely on this treatment. Further reductions in Medicare reimbursement for home oxygen as a result of the 36-month cap, the CPI freeze and the effects of competitive bidding will be problematic for home care providers and may jeopardize the quality of home care oxygen services given to Medicare beneficiaries.

Appendix A: Oxygen Service Provision Survey Items

1. The total number of Medicare beneficiaries served during the most recent one-year period
2. The total number of Medicare oxygen equipment beneficiaries during the most recent one-year period

A. EQUIPMENT ACQUISITION (Stationary, Back-up and Portable Equipment)

1. Stationary system average acquisition cost
2. Home back-up unit average cost (cylinder, stand, regulator, flow meter)
3. Portable system average acquisition cost, including conserving devices
4. Equipment salvage / trade-in average value for stationary and portable
5. Total equipment average acquisition cost
   ***** A1 + A2 + A3 - A4 *****
6. Average useful equipment life in months
7. Average monthly equipment acquisition cost
   ***** A5 / A6 *****
8. Total oxygen contents average cost per month, all systems
9. Average cost of debt %
10. Average monthly financing charge - equipment acquisition
    ***** (A1+A2+A3-A4) x A9 / 12 *****
11. Average monthly acquisition cost of system
    ***** A7 + A8 + A10 *****
12. Average number of stationary systems required in stock
    to support every 10 units in the field
13. *TOTAL SYSTEM AVERAGE COST PER MONTH*
    ***** *A11+ (A7 + A10) x (A12 / 10)* *****

B. CUSTOMER SERVICE AND PATIENT INTAKE

1. Estimated annual intake time per patient, in minutes (Complete ***Patient Intake Worksheet***)
2. Ongoing customer service time, in minutes, per patient per month
   (patient inquiries, scheduling of deliveries/maintenance/
   clinical visits, accommodating patient travel plans, etc.)
3. Annual prescription renewal preparation and processing time, in minutes per patient
4. Labor cost per hour - Customer Service Representative
   a. Average hourly wage rate
   b. Fringe benefits as a % of wage rate
   c. *Labor cost per hour*
      ***** B4a x (1+ B4b) *****
5. *AVERAGE TOTAL MONTHLY COST OF INTAKE AND CUSTOMER SERVICE PER PATIENT*
   ***** ((B2 + (B1 + B3)/12) / 60) x B4c *****

C. PREPARATION BEFORE DELIVERY

1. Average labor amount per unit (teardown, testing, cleaning, reassembly, bagging, boxing, loading), in minutes
2. Repair labor necessary as a result of problems encountered during pre-delivery preparation:
   a. Percentage of units requiring repair
   b. Average labor amount per unit (diagnosis and repair), in minutes
   c. Average repeat preparation labor amount per unit (testing, cleaning, etc,), in minutes
   d. Total weighted average repair labor per unit, in minutes

   ***** (C2b + C2c) x C2a *****
3. *Total weighted average preparation and repair labor per unit, in minutes*

   ***** C1 + C2d *****
4. Labor cost per hour - Equipment Technician
   a. Average wage rate
   b. Fringe benefits as a % of wage rate
   c. *Average labor cost per hour*

   ***** C4a x (1+ C4b) *****
5. *AVERAGE TOTAL COST OF PREPARATION PER UNIT*

   ***** (C4c / 60) x C3 *****

D. VEHICLE COST PER MILE

1. Acquisition and repair cost:
   a. Average vehicle acquisition cost per month (fully outfitted) - lease
   b. Average maintenance & repair cost per vehicle per year
   c. Average insurance & registration cost per vehicle per year
   d. Average odometer miles per vehicle per year
   e. Average vehicle acquisition, maintenance & repair cost per mile

   ***** ((D1a x 12) + (D1b + D1c)) / D1d *****
2. Gasoline cost per mile:
   a. Average miles per gallon
   b. Average gasoline cost per gallon
   c. Average gasoline cost per mile

   ***** D2b / D2a *****
3. *TOTAL VEHICLE COST PER MILE*

   ***** D1f + D2c *****

E. DELIVERY / SETUP / PICKUP COST

1. Average round trip travel time, in minutes
2. Average in-home setup time, in minutes
3. Average in-home client instruction time (Complete Patient Education Worksheet)
4. Average in-home pickup time, in minutes
5. a. Average service technician wage rate per hour
   b. Fringe benefits as a % of wage rate
6. Labor cost - delivery, setup, pickup

   ***** (E1 x 2 + E2 + E3 + E4) x (E5a x (1+E5b)) / 60
7. Average round trip miles
8. Average vehicle cost - delivery, setup, pickup

   ***** E7 x D3 *****
9. TOTAL AVERAGE DELIVERY / SETUP / PICKUP COST PER PATIENT

   ***** E6 + E8 *****

F. EQUIPMENT MAINTENANCE UPON RETURN

1. Average labor amount (preparation plus filter change), in minutes
2. Repair labor necessary as a result of problems encountered during pre-delivery preparation:
   a. Percentage of units requiring repair upon return
   b. Average labor amount per unit (diagnosis, repair), in minutes
   c. Average repeat preparation labor amount per unit (testing, cleaning, etc,), in minutes
   d. Total weighted average repair labor per unit, in minutes

      ***** (F2b + F2c) x F2a *****
   e. Total weighted average preparation and repair labor per unit, in minutes

      ***** F1 + F2d *****
3. Average wage rate, including fringe benefits
4. AVERAGE TOTAL COST OF MAINTENANCE PER UNIT UPON RETURN

   ***** F3 / 60 x F2e *****

G. AVERAGE MONTHLY COST TO PREPARE, DELIVER AND RETURN

1. Average total cost for delivery and return

   ***** C5 + E9 + F4 *****
2. Average number of months in service, per patient
3. AVERAGE MONTHLY COST TO PREPARE, DELIVER AND RETURN

   ***** G1 / G2 *****

H. ROUTINE, IN-HOME DELIVERY, DISPOSABLE AND SCHEDULED MAINTENANCE COSTS

1. Maintenance Supplies:
   - a. Gross particle filters
     - Quantity used per year
     - Price, each
   - b. Pre-felt filters
     - Quantity used per year
     - Price, each
   - c. Hepa filters
     - Quantity used per year
     - Price, each
   - d. Intake filters
     - Quantity used per year
     - Price, each
   - e. *Average monthly maintenance supplies cost*
     ***** (Sum 1a thru 1d) / 12 *****
2. Disposable Supplies:
   - a. Humidifier bottles
     - Quantity used per month
     - Price, each
   - b. Tubing
     - Quantity used per month
     - Price, each
   - c. Tubing Connectors
     - Quantity used per month
     - Price, each
   - d. Nasal Cannulas
     - Quantity used per month
     - Price, each
   - e. *Average monthly disposable supplies cost*
     ***** (Sum 1a thru 1d Totals) *****
3. Routine, in-home delivery and scheduled maintenance labor and vehicle costs:
   - a. Average vehicle cost per mile ***** D3 *****
   - b. Average round trip miles ***** E7 *****
   - c. Average round trip travel time, in minutes ***** E1 *****
   - d. Average time to perform scheduled/preventive equipment maintenance, in minutes ***** C2c *****
     {including filter cleaning/replacement, oxygen purity testing, alarm battery testing, PSI check on back-up unit, liter flow compliance with Rx, and in-home repair of unit}
   - e. Average time to perform gaseous and/or liquid fills, in minutes ***** C2c *****
   - f. Service Technician wage rate per hour plus fringes ***** E5a x (1+E5b) *****
   - g. Number of scheduled/preventive equipment maintenance visits per year
   - h. Number of oxygen contents delivery visits per year (including gaseous and/or liquid fills)
   - *i.* *Average monthly routine maintenance labor and vehicle cost*
     ** (H3a x H3b + (H3c/60 x H3f) x ((H3g + H3h) - H3g) / 12 + ((H3d / 60) x H3f x H3g) / 12 + ((H3e / 60) x H3f x H3h) / 12 **
     Note: Formula assumes that preventive maintenance visit occurs simultaneously with a delivery of oxygen fills
4. *AVERAGE TOTAL MONTHLY ROUTINE DISP AND SCHEDULED MAINT COSTS PER PATIENT*
   ***** H1 + H2 + H3 *****

I. **COST OF UNSCHEDULED MAINTENANCE**

1. Average vehicle cost, round trip ***** D3 x E6 *****
2. Service Technician labor cost per hour ***** E1 x H3e *****
3. Repair / Maintenance labor cost ***** F2b x F4 / 60 *****
4. Average # of calls per month per 10 units in service
5. Vehicle and delivery cost per unit per month
   ***** (I1 + I2 + I3) x (I4 /10) *****

J. **COST OF PATIENT ASSESSMENT**

1. Average number of clinical visits per year by RCP
2. Average round trip travel time, in minutes
3. Average in-home patient assessment time per visit, in minutes
   - Include time for home environment safety assessment - storage and maintenance
   - Include time for home environment safety assessment - administration
   - Include time for development of oxygen and equipment in-home care plan
4. Average in-home follow up and compliance monitoring time per visit, in minutes
   - Include weekly calls to patients to determine requirement for portable oxygen
   - Include compliance monitoring conducted in the home at least once per month
   - Include time for contacting physician whenever there is a question about the oxygen order or a change in patient status or care plan
5. a. Average RCP wage rate per hour, excluding benefits
   b. Fringe benefits as a % of wage rate
6. Average vehicle reimbursement per visit for RCP (at federal rate per mile of $0.445)
7. AVERAGE TOTAL COST OF PATIENT ASSESSMENT PER PATIENT PER MONTH
   ***** ((J2 + J3 + J4) x ((J5a x (1 + J5b)) / 60) +J6) x (J1 / 12) *****

K. **TOTAL MONTHLY DIRECT COST BEFORE OVERHEAD AND PROFIT**
   ***** A13 + B5 + G3 + H5 + I5 + J7 *****

L. **OVERHEAD COSTS**

1. Overhead Factor - Overhead costs as a % of Direct Costs
   {Rent, Facility, Administration, Insurance, Legal, MIS Systems/Controls, Regulatory Compliance, Communications Systems, Training, Accreditation, Supplies, Billing and Reimbursement Functions}
2. Estimated average monthly overhead cost per patient

M. **TOTAL MONTHLY COST**
   ***** K + L2 *****

N. **PROFIT SUMMARY**

1 Average Medicare Reimbursement per patient - Stationary and Portable Oxygen
2. Less: Write-offs, Hardships, etc. (%)
3. Net Reimbursement per patient per month **** N1 + N2 ****
4. Less: Average Total Costs to Supplier Per Patient
5. Average Net Profit Per Patient Before Taxes **** N3 + N4 ****

O. **Net Profit Margin Before Taxes**
   ***** N5 / N1 *****

PATIENT INTAKE (Minutes per-patient per year)

A. Verification of beneficiary eligibility, claims management, and claims submission

B. Collect and record physician information

C. Receive, document and process order for oxygen and oxygen equipment

D. Verification of the following:

1 Patient demographic information

2. Patient possession of a valid Medicare number

3. Patient emergency contact information

4. Caregiver and/or conservator information

5. Secondary insurance information

6. Qualifying diagnosis

7. Estimated total time for verification per year per patient

**** D1 + D2 + D3 + D4 + D5 + D6 ****

E. Input patient data in computer at service center

F. Schedule delivery

G. Contact physician to verify order, demographic information and license number

H. Verify physician UPIN with independent database

I. Coordinate or verify the existence of independent blood oxygen saturation study or ABG test

J. Obtain physician-signed certificate of medical necessity (CMN)

K. *Average estimated annual total intake time per patient*

**** *A + B + C + D7 + E + F + G + H + I + J + K* ****

PATIENT EDUCATION (Minutes per-patient per episode)

A. Supplier required training of patient and caregiver

B. Contracted interpreter services, if applicable

C. Patient and/or caregiver instruction in assembly and operation of oxygen and equipment

D. Oxygen safety training

E. Patient and/or caregiver training on "troubleshooting" possible equipment problems

F. Patient and/or caregiver instruction on proper infection control in the home

G. Patient and/or caregiver instruction on safe handling and storage of medications

H. *Average total intake time per patient*

**** *A + B + C + D + E + F + G* ****

Appendix B: Overall per Patient per Month Costs for Home Oxygen Providers

Survey Item	Average
A1.Stationary system average acquisition cost	$706.23
A2.Home back-up unit average cost (cylinder, stand, regulator, flow meter)	$152.32
A3.Portable system average acquisition cost, including conserving devices	$471.09
A4.Equipment salvage / trade-in average value for stationary and portable	$40.11
A5.Total equipment average acquisition cost	$1,288.63
A6.Average useful equipment life in months	60.44
A7.Average monthly equipment acquisition cost	$23.23
A8.Total oxygen contents average cost per month, all systems	$17.77
A9.Average cost of debt %	0.07
A10.Average monthly financing charge - equipment acquisition	$7.76
A11.Average monthly acquisition cost of system	$48.76
A12.Average number of stationary systems required in stock to support every 10 units in the field	2.53
A13.TOTAL SYSTEM AVERAGE COST PER MONTH	$55.81
B1. Estimated annual intake time per patient, in minutes (From the Patient Intake Worksheet)	166.36
B2. Ongoing customer service time, in minutes, per patient per month (patient inquiries, scheduling of deliveries/maintenance/ clinical visits, accommodating patient travel plans, etc.)	28.73
B3. Annual prescription renewal preparation and processing time, in minutes	43.07
B4a. Labor cost per hour - Customer Service Representative Average wage rate	$13.52
B4a. Labor cost per hour - Customer Service Representative Fringe benefits as a % of wage rate	0.22
B4a. Labor cost per hour - Customer Service Representative Labor cost per hour	$16.55
B5. AVERAGE TOTAL MONTHLY COST OF INTAKE AND CUSTOMER SERVICE PER PATIENT	$12.66
C1. Average labor amount per unit (teardown, testing, cleaning, reassembly, bagging, boxing, loading), in minutes	36.70
C2a. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Percentage of units requiring repair	0.10
C2b. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Average labor amount per unit (diagnosis and repair), in minutes	37.09
C2c. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Average repeat preparation labor amount per unit (testing, cleaning, etc,), in minutes	30.54
C2d. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Total weighted average repair labor per unit, in minutes	6.70

C3. Total weighted average preparation and repair labor per unit, in minutes	43.40
C4a. Labor cost per hour - Equipment Technician Average wage rate	$13.82
C4b. Labor cost per hour - Equipment Technician Fringe benefits as a % of wage rate	0.22
C4c. Labor cost per hour - Equipment Technician Average labor cost per hour	$16.92
C5. AVERAGE TOTAL COST OF PREPARATION PER UNIT	$11.93
D1a. VEHICLE COST PER MILE Acquisition and repair cost: Average vehicle acquisition cost per month (fully outfitted) – lease	$599.19
D1b. VEHICLE COST PER MILE Acquisition and repair cost: Average maintenance & repair cost per vehicle per year	$1,844.74
D1c. VEHICLE COST PER MILE Acquisition and repair cost: Average insurance & registration cost per vehicle per year	$1,427.62
D1d. VEHICLE COST PER MILE Acquisition and repair cost: Average odometer miles per vehicle per year	28,764
D1e. VEHICLE COST PER MILE Acquisition and repair cost: Average vehicle acquisition, maintenance & repair cost per mile	$0.40
D2a. Gasoline cost per mile: Average miles per gallon	13.45
D2b. Gasoline cost per mile: Average gasoline cost per gallon	$2.46
D2c. Gasoline cost per mile: Average gasoline cost per mile	$0.19
D3. TOTAL VEHICLE COST PER MILE	$0.60
E1. Average round trip travel time, in minutes	46.22
E2. Average in-home setup time, in minutes	33.35
E3. Average in-home client instruction time, in minutes	60.22
E4. Average in-home pickup time, in minutes	18.36
E5a. Average service technician wage rate per hour	14.01
E5b. Fringe benefits as a % of wage rate	0.22
E6. Labor cost - delivery, setup, pickup	$59.33
E7. Average round trip miles	23.43
E8. Average vehicle cost - delivery, setup, pickup	$13.73
E9. TOTAL AVERAGE DELIVERY / SETUP / PICKUP COST PER PATIENT	$73.06
F1. Average labor amount (preparation plus filter change), in minutes	35.81
F2a. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Percentage of units requiring repair upon return	0.21
F2b. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Average labor amount per unit (diagnosis, repair), in minutes	37.64
F2c. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Average repeat preparation labor amount per unit (testing, cleaning, etc,), in minutes	30.95

F2d. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Total weighted average repair labor per unit, in minutes	13.17
F2e. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Total weighted average preparation and repair labor per unit, in minutes	48.98
F3. Average wage rate, including fringe benefits	$16.92
F4. AVERAGE TOTAL COST OF MAINTENANCE PER UNIT UPON RETURN	$13.65
G1. Average total cost for delivery and return	$98.63
G2. Average number of months in service, per patient	22.13
G3. AVERAGE MONTHLY COST TO PREPARE, DELIVER AND RETURN	$5.34
H1a. Maintenance Supplies: Gross particle filters quantity used per year	2.32
H1a. Maintenance Supplies: Gross particle filters Price each	$2.98
H1b. Maintenance Supplies: Pre-felt filters, quantity used per year	1.77
H1b. Maintenance Supplies: Pre-felt filters, price each	$2.01
H1c. Maintenance Supplies: Hepa filters quantity used per year	1.54
H1c. Maintenance Supplies: Hepa filters Price each	$7.00
H1d. Maintenance Supplies: Intake filters Quantity used per year	3.19
H1d. Maintenance Supplies: Intake filters Price each	$3.89
H1e. Maintenance Supplies: Average monthly maintenance supplies cost	$2.34
H2a. Disposable Supplies: Humidifier bottles Quantity used per month	1.38
H2a. Disposable Supplies: Humidifier bottles Price each	$1.46
H2b. Disposable Supplies: Tubing Quantity used per month	1.73
H2b. Disposable Supplies: Tubing Price each	$1.83
H2c. Disposable Supplies: Tubing Connectors Quantity used per month	1.43
H2c. Disposable Supplies: Tubing Connectors Price each	$0.84
H2d. Disposable Supplies: Nasal Cannula Quantity used per month	3.19
H2d. Disposable Supplies: Nasal Cannula Price each	$0.69
H2e. Disposable Supplies: Average monthly disposable supplies cost	$7.53
H3a. Average vehicle cost per mile	$0.59
H3b. Average round trip miles	23.43

H3c. Average round trip travel time, in minutes	46.26
H3d. Average time to perform scheduled/preventive equipment maintenance, in minutes {including filter cleaning/replacement, oxygen purity testing, alarm battery testing, PSI check on back-up unit, liter flow compliance with Rx, and in-home	26.69
H3e. Average time to perform gaseous and/or liquid fills, in minutes	20.16
H3f. Service Technician wage rate per hour plus fringes	$17.09
H3g. Number of scheduled/preventive equipment maintenance visits per year	4.90
H3h. Number of oxygen contents delivery visits per year (including gaseous and/or liquid fills)	19.01
H3i. Average monthly routine maintenance labor and vehicle cost	$53.40
H4. AVERAGE TOTAL MONTHLY ROUTINE DISP AND SCHEDULED MAINT COSTS PER PATIENT	$62.16
I1. COST OF UNSCHEDULED MAINTENANCE Average vehicle cost, round trip	$13.54
I2. COST OF UNSCHEDULED MAINTENANCE Service Technician labor cost per hour	$13.20
I3. COST OF UNSCHEDULED MAINTENANCE Repair / Maintenance labor cost	$10.31
I4. COST OF UNSCHEDULED MAINTENANCE Average # of calls per month per 10 units in service	$1.60
I5. COST OF UNSCHEDULED MAINTENANCE Vehicle and delivery cost per unit per month	$6.10
J1. COST OF PATIENT ASSESSMENT Average number of clinical visits per year by RCP	10.82
J2. COST OF PATIENT ASSESSMENT Average round trip travel time, in minutes	46.02
J3. COST OF PATIENT ASSESSMENT Average in-home patient assessment time per visit, in minutes; Include time for home environment safety assessment - storage and maintenance; Include time for home environment safety assessment - administration; Include time	45.72
J4. COST OF PATIENT ASSESSMENT Average in-home follow up and compliance monitoring time per visit, in minutes; Include weekly calls to patients to determine requirement for portable oxygen; Include compliance monitoring conducted in the home at least once	45.89
J5a. COST OF PATIENT ASSESSMENT Average RCP wage rate per hour, excluding benefits	$21.74
J5b. COST OF PATIENT ASSESSMENT Fringe benefits as a % of wage rate	0.22
J6. COST OF PATIENT ASSESSMENT Average vehicle reimbursement per visit for RCP (at a federal rate per mile of $0.445)	$10.13
J7. COST OF PATIENT ASSESSMENT AVERAGE TOTAL COST OF PATIENT ASSESSMENT PER PATIENT PER MONTH	$17.54
K. TOTAL MONTHLY DIRECT COST BEFORE OVERHEAD AND PROFIT	$159.61
L2. OVERHEAD COSTS Estimated average monthly overhead cost per patient {Rent, Facility, Administration, Insurance, Legal, MIS Systems/Controls, Regulatory Compliance, Communications Systems, Training, Accreditation, Supplies, Billing and Reimbursement}	$41.59
M. TOTAL MONTHLY COST PER PATIENT	$201.20

PATIENT INTAKE	Average Minutes
A. Verification of beneficiary eligibility, claims management, and claims submission	43
B. Collect and record physician information	8
C. Receive, document and process order for oxygen and oxygen equipment	12
D1. Verification of Patient demographic information	4
D2. Verification of Patient possession of a valid Medicare number	3
D3. Verification of Patient emergency contact information	3
D4. Verification of Caregiver and/or conservator information	2
D5. Verification of Secondary insurance information	4
D6. Verification of Qualifying diagnosis	5
D7. Estimated total time for verification per year per patient	21
E. Input patient data in computer at service center	7
F. Schedule delivery	7
G. Contact physician to verify order, demographic information and license number	7
H. Verify physician UPIN with independent database	3
I. Coordinate or verify the existence of independent blood oxygen saturation study or ABG test	11
J. Obtain physician-signed certificate of medical necessity (CMN)	38
K. Total intake time per patient	157
PATIENT EDUCATION	Average Minutes
A. Supplier required training of patient and caregiver	16
B. Contracted interpreter services, if applicable	5
C. Patient and/or caregiver instruction in assembly and operation of oxygen and equipment	14
D. Oxygen safety training	7
E. Patient and/or caregiver training on "troubleshooting" possible equipment problems	7
F. Patient and/or caregiver instruction on proper infection control in the home	6
G. Patient and/or caregiver instruction on safe handling and storage of medications	4
H. Average total intake time per patient	60

White Paper on Medicare's Payment Policy for Oxygen

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Executive Summary:

Medicare's oxygen payment policy has a long history. This analysis examines the characteristics of the oxygen beneficiaries using oxygen; what equipment, supplies and services they receive; the market dynamics of the providers and payers involved; and the essential characteristics of a well designed payment policy.

Background:

Physicians prescribe oxygen therapy for Medicare beneficiaries for a number of reasons. Chronic Obstructive Pulmonary Disease (COPD) is responsible for more than half (66%) of all patients requiring oxygen therapy. The next three most common diagnoses are Congestive Heart Failure (11%), Asphyxia (5%) and Sleep Apnea (3%).

Oxygen beneficiaries are more likely to be poor; in 2004, 26 percent of oxygen beneficiaries were dually eligible for both Medicare and Medicaid compared to 19 percent of non-oxygen beneficiaries. Oxygen beneficiaries are also more likely to have other serious diseases. They are more than twice as likely to have anemia (24.3% compared to 11.2%). They are almost twice as likely to have diabetes (41.8% compared to 24.7%).

Among Medicare beneficiaries, oxygen concentrators are the most commonly used method of receiving oxygen at home. Concentrators are electrically operated machines that extract oxygen from room air. While concentrators represented about half the claims, they accounted for the vast majority of the spending. Meanwhile, portable oxygen required for doctor visits, grocery shopping, etc., represented nearly half the claims, but only one tenth of the spending.

The Federal government is the dominant, if not close to monopsonistic, purchaser of home oxygen products with Medicare representing about half of the home oxygen market and Medicaid representing almost another 20 percent of the market. In contrast to the purchasers' side of the market, home oxygen has no single dominant provider. The most recent data indicates that the largest supplier represents 23 percent of the market.

Payment Concerns:

In 1987, the Congress and HCFA (now CMS) began moving the Medicare program away from paying based on individual providers' charges to fee schedules for medical equipment and supplies. The net effect of all these changes was a disconnect between the costs that providers faced and the fees they were paid. The result was a de facto global payment. As long as overpayments balanced underpayments, the system worked.

While payments for equipment were sufficient to also cover underpayments for services and supplies, significant problems either with access or quality were avoided. However, the history of Medicare payment policy has shown that this type of situation cannot continue forever. The government began to focus on the items that were overpaid without considering those areas in which underpayments were made. Not surprisingly, neither the HHS Inspector General nor the General Accounting Office focused on identifying areas in which the taxpayer should be paying more. Further complicating matters, a provision of the Deficit Reduction Act of 2005 shifted ownership of the oxygen equipment from the provider to the Medicare beneficiary after 36 months.

At the same time, results from the CMS competitive bidding demonstrations from 1999-2003 for durable medical equipment, including oxygen, showed that prices were lower and that quality of services were essentially unchanged. As a result, Congress included competitive bidding as a major change in oxygen payment policy in the Medicare Modernization Act (MMA) in 2003. Section 302 of the MMA requires competitive bidding to begin in 10 of the largest MSAs in 2007; in 80 of the largest MSAs in 2009; and in additional areas after 2009. Given this timetable, CMS may ultimately choose not to spend scarce resources to refine a payment methodology that they intend to phase-out.

For the Medicare beneficiaries, there is the potential that all of these changes in recent years will leave them facing significant access and quality problems. The combined effect of a number of factors leads to the following concerns:

- A particularly vulnerable population in a poor position to navigate a new system for oxygen supplies and services.
- A payment methodology for specific supplies and services that has not gone through a serious recalculation since the 1980s.
- The small likelihood that CMS will be able or willing to invest significant scarce resources into developing a workable payment methodology so close to the transition to competitive bidding,
- Medicare's balance billing prohibitions that would block any ability to offset underpayment.
- A new generation of legal questions involving liability for equipment no longer owned by the provider.

For the taxpayers, projected savings may never appear. A study for HHS's Agency for Healthcare Quality and Research (AHRQ) indicates that restrictions on access to Long-Term Oxygen Therapy may actually cost taxpayers more than it saves them due to increased hospitalizations and other health care spending.

A second major concern is the interaction between taxpayer savings that have been scored or associated with the introduction of the new competitive bidding program and savings associated with the 36-month cap.

For the providers, significant new policy changes to an industry attempting a smooth transition to the new competitive bidding system presents yet another concern. Major changes now may risk the success of competitive bidding. It may drive players out of the market that might not be efficient in the current fixed-priced system, but that would be very efficient in a competitive bidding system.

The Medicare Payment Advisory Commission (MedPAC) defined the essential characteristics of an effective/efficient payment methodology for a well designed Medicare payment. Each of these characteristics are listed and then examined in this paper.

Given the vulnerability of the population involved and the imminent implementation of a new, very different payment methodology, it is hard to see the wisdom of additional short-term shocks to the system that would be triggered by policy changes designed to lower the 36-month cap or make any other major changes prior to implementation of the new system.

White Paper on Medicare's Payment Policy for Oxygen

This paper presents an analysis and discussion of Medicare's oxygen payment policy. Specifically it examines: 1) the effect of current policy on beneficiaries, taxpayers and providers; and 2) the importance of a well-designed, robust payment policy that meets the needs of beneficiaries, taxpayers, and providers and overcomes the negative aspects and disruptions of the current policy.

Background

For those Medicare beneficiaries unable to meet their bodies' oxygen needs through normal breathing, oxygen therapy is often the only alternative. The most recent data (2004) indicates that about 1.4 million, or 4 percent, of Medicare beneficiaries find themselves in this situation. They suffer from advanced chronic obstructive pulmonary disease (COPD) and other respiratory and cardiac conditions. Long-term oxygen therapy has been clinically shown to assist many of these patients.[1]

Physicians prescribe oxygen therapy for Medicare beneficiaries for a number of reasons. Chart 1 indicates the most common diagnoses. Chronic Obstructive Pulmonary Disease (COPD) is responsible for more than half (66%) of all patients requiring oxygen therapy. As a result, smokers (or former smokers) diagnosed with COPD are the most common Medicare beneficiaries of oxygen therapy. The next three most common diagnoses are Congestive Heart Failure (11%), Asphyxia (5%) and Sleep Apnea (3%).[2]

The demographic profile of oxygen beneficiaries reveals a subpopulation considerably more vulnerable than the average Medicare beneficiary:

- Oxygen beneficiaries are closer to death – in 2004, 16 percent of oxygen beneficiaries died during the year, compared to 4 percent of non-oxygen beneficiaries.[3]

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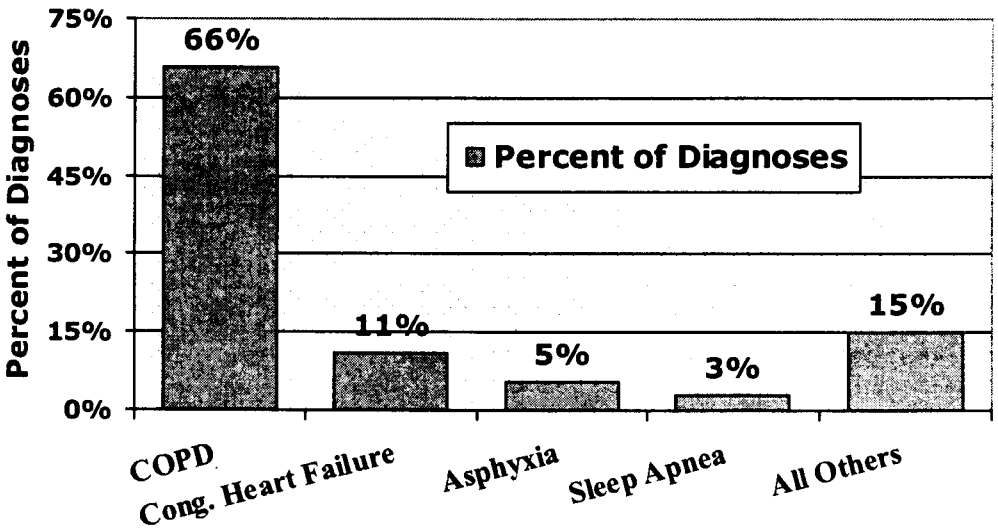
[1] Long-Term Oxygen Therapy for Severe COPD, FINAL REPORT, June 11, 2004, Lau, et al. Tufts-New England Medical Center Evidence based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD.

[2] Chronic obstructive pulmonary disease (COPD) is comprised primarily of two related diseases - chronic bronchitis and emphysema. In both diseases, there is chronic obstruction of the flow of air through the airways and out of the lungs, and the obstruction generally is permanent and progressive over time. http://www.medicinenet.com/chronic_obstructive_pulmonary_disease_copd/page4.htm.

[3] Medicare Fee-For-Service Beneficiaries, By Presence of Oxygen DME Claims, 2004. For more details see the "Methodological note for the overall analysis:" on the last page on this paper.

Chart 1- Most Common Diagnoses Among Medicare Beneficiaries on Oxygen Therapy



Source: 2004 claims for All Oxygen Codes, most common line diagnoses, 5% sample file.

- Oxygen beneficiaries are more likely to be poor or made poor enough by their catastrophic medical expenses to trigger Medicaid, as well as Medicare eligibility – in 2004, 26 percent of oxygen beneficiaries were dually eligible for both programs, compared to 19 percent of non-oxygen beneficiaries.[4]

- Oxygen beneficiaries are more likely to have other serious diseases, other than the range of respiratory disease they suffer from –
  - More than twice as many are likely to have anemia, 24.3% compared to 11.2%.[4]
  - Almost twice as many are likely to have diabetes, 41.8% compared to 24.7%.[4]

- Oxygen beneficiaries are older than average – 50 percent of oxygen beneficiaries are older than 75, compared to 39 percent of non-oxygen beneficiaries.

Oxygen Therapy and Medicare Coverage

Medicare beneficiaries can obtain supplemental oxygen three different ways:

[4] Ibid.

- Oxygen concentrators, electrically operated machines about the size of a dehumidifier that extract oxygen from room air;
- Portable oxygen, available in both compressed and liquid form; and
- Stationary oxygen, also available in both compressed and liquid forms.

Oxygen concentrators are the most commonly used method of receiving oxygen while in the home. While concentrators represented about half the claims, they accounted for the vast majority of the spending (see Table 1). Meanwhile, portable oxygen required for doctor visits, grocery shopping, etc., represented a little less than half the claims, but only about a tenth of spending. Finally, stationary oxygen represented only 4% of the claims and 6% of the spending.[5]

Table 1 – Medicare Beneficiaries Major Methods/Modalities of Receiving Oxygen Therapy – 2004

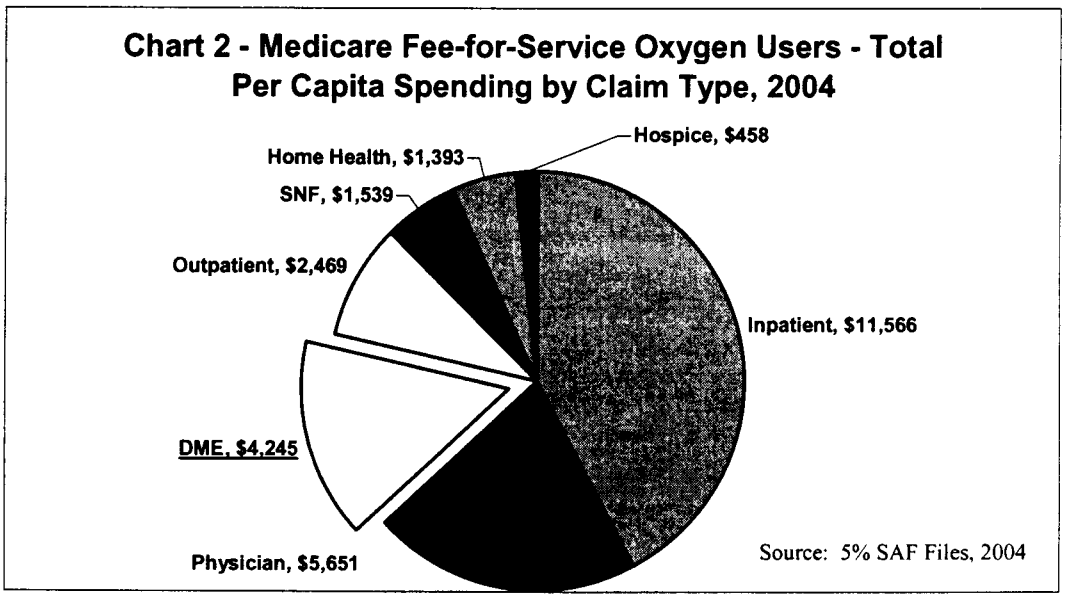
Method/Modality	Percent of Claims	Percent of Spending
Oxygen Concentrators	50.2%	83.8%
Portable oxygen (liquid and gaseous)	45.4%	10.4%
Stationary oxygen (liquid and gaseous)	4.3%	5.8%
All other oxygen claims	0.1%	0.02%
Total oxygen claims	100.0%	100.0%

Source: For the purpose of these calculations oxygen claims are defined as all HCPCS codes in 2004 BETOS D1C category, 2004 units and volume are from physician/supplier procedure summary master file.

For Medicare coverage, patients must have the following: (1) an appropriate diagnosis, such as COPD; (2) third party clinical tests documenting reduced levels of oxygen in the blood; and (3) a certificate of medical necessity, partially completed and signed by a physician, prescribing the volume of supplemental oxygen required and documenting whether the patient needs a portable unit in addition to a home-based stationary unit.

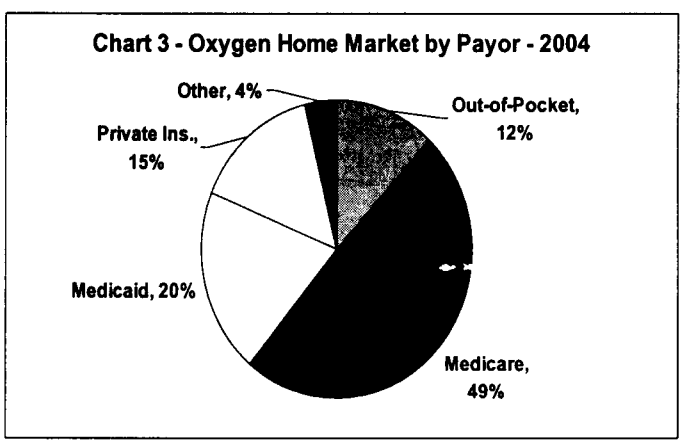
Analysis of the claims file for 2004 reveals that oxygen spending is only one component of Medicare spending and far from the largest component. Chart 2 displays the average spending for Medicare beneficiaries with oxygen claims in 2004. While durable medical equipment (DME) spending, which includes oxygen, averaged over $4,200 in 2004, this was less than these same beneficiaries spent on physician services, $5,651, and close to a third as much as they spent on hospitals, $11,566. In addition, these beneficiaries had substantial other Medicare spending, on outpatient, home health and nursing home services. Beneficiaries receiving oxygen services had average total spending of $27,323, indicating that these are seriously ill patients. All of DME, of which oxygen is a percentage, accounted for only 16 percent of their total Medicare spending.

[5] For the purpose of these calculations oxygen claims are defined as all HCPCS codes in 2004 BETOS D1C category, 2004 units and volume are from physician/supplier procedure summary master file



Characteristics of the Home Oxygen marketplace:

The Federal government is the dominant if not close to monopsonistic[6], purchaser of home oxygen products with Medicare representing about half of the home oxygen market from the purchaser's side and Medicaid representing almost another 20% of the market as shown in Chart 3. As a result, policy decisions made by the government, especially Medicare, will have market-wide consequences.

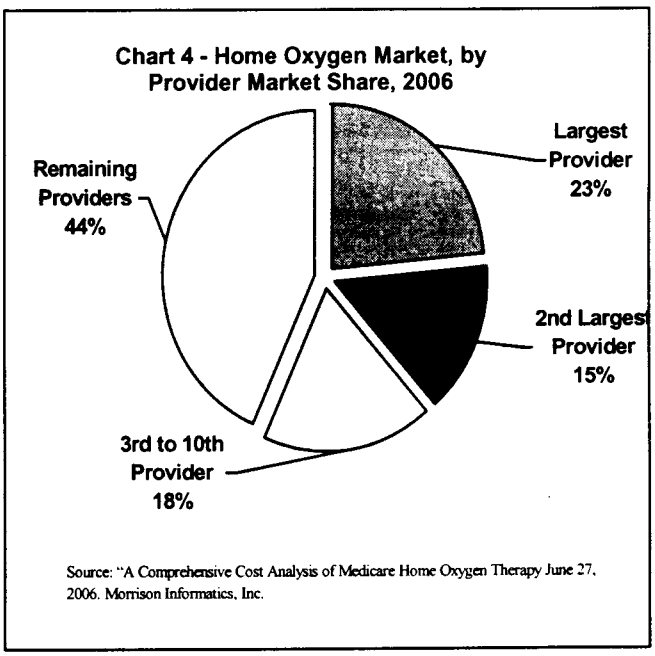


Source: CMS Home Healthcare Magazine and CIBC World.

In contrast to the purchasers' side of the industry, home oxygen has no single dominant provider. The most recent data, shown in Chart 4, indicates that the largest supplier represents 23 percent of the market. The next largest supplier has 15 percent of

[6] Monopsony is a market similar to a monopoly except that a large buyer not seller controls a large proportion of the market and drives the prices down. Sometimes referred to as the buyer's monopoly.

the market. The other bigger firms, the third through 10 largest, combined represent only 18 percent of the market.[7]



Medicare's dominant position as a purchaser, without a counter-balancing dominant supplier has a number of implications. First, it is evident why the Congress thought competitive bidding for Medicare's business was a logical policy to pursue. Second, it also means that a poorly designed Medicare payment policy could have ramifications well beyond the Medicare program and a serious flaw in Medicare payments could seriously damage the industry and significantly affect beneficiaries' access to oxygen equipment, supplies and services.

Effects of Medicare Payment Policy on Beneficiaries, Taxpayers and Providers:

Brief History of payment for oxygen:

Medicare's payments for oxygen have undergone multiple revisions during the last few decades. Prior to 1987, Medicare payments for medical equipment and supplies were based on supplier charges. Individual Medicare carriers changed payments in their areas to align them with market prices. When carriers sought to adjust payments, they gathered pricing data from local markets; determined new payment levels based on the price information obtained; and notified area suppliers of the changes. Although HCFA

[7] The most serious recent survey of the industry was done by Morrison Informatics: "A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy - A Study for the American Association for Homecare June 27, 2006. Morrison Informatics, Inc. At the same time the oxygen advisory group* estimates that the Morrison study captured only about 60 percent of the provider market, given low response rates among smaller providers. Using the 5 percent claims file yield no better information. The summary by supplier number yields no supplier bigger than about 0.3% of the file, implying the numbers are the individual retail outlets.

* The oxygen advisory group is made up of eight experts from eight different oxygen providers who were willing to provide a "consensus of the industry" on issues where there were no claims, survey or other data. They include Paul Gabos, Lincare; Cleaster Ewing, American Home Patient; Lisa Getson, Apria Healthcare; Joey Ryan, Air Products Healthcare; Chris Kane, Pacific Pulmonary Services; Dr. Robert Hoover, Sunrise Medical and Valerie King, Praxair.

monitored carriers' performance in carrying out these steps, it did not evaluate the appropriateness of the new payment levels established.[8]

In 1987, the Congress and HCFA began moving the Medicare program from paying based on individual providers' charges to fee schedules for medical equipment and supplies.[9] State-level fees were determined based on average supplier Medicare charges in the state during 1986 and 1987.

Prior to 1998, these fees were adjusted each year using formulas correlated with the Consumer Price Index (CPI). No update was provided from 1998 through 2000 or in 2002, although updates were provided in 2001. The 2002 payment amounts later were revised downward by Section 302 of the MMA to median state level 2002 FEHBP rates.

The net effect of all these changes was a disconnect between the costs that providers faced and the fees they were paid. Using the CPI to index payments for a range of goods and services is a crude instrument even under the best of circumstances. In the past, The Medicare Payment Advisory Commission (MedPAC) has warned the Congress about the negative effects of using more general indices such as the CPI to adjust payments for specific medical goods and services.[10]

In a field as significantly affected by technological advancements as oxygen therapy, correlating payments to the CPI for a decade is virtually guaranteed to overpay for some items and underpay for others. Indexing for one decade by the CPI and then making incremental adjustments without rebasing for another decade means the last serious attempt to rigorously determine a "fair" price for individual components of equipment, supplies and services was undertaken in the 1980's – 20 years ago.

The result was a de facto global payment. As long as overpayments balanced underpayments, the system worked. While payments for equipment were sufficient to also cover underpayments for services and supplies, significant problems either with access or quality were avoided. However, the history of Medicare payment policy has shown that this type of situation cannot continue forever. This became clear in other areas of Medicare payment policy, most notably oncology drugs paid under Part B. The government, through either the Inspector General's Office or the Government Accountability Office (GAO), began to focus on the items that were overpaid without considering those areas in which underpayments were made. Not surprisingly, neither the HHS Inspector General nor the GAO focuses on identifying areas in which the taxpayer should be paying more.

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[8] Testimony Before the Subcommittee on Labor, Health and Human Services, Education and Related Agencies, Committee on Appropriations, U.S. Senate United States General Accounting Office GAO Wednesday, June 12, 2002 "MEDICARE Challenges Remain in Setting Payments for Medical Equipment and Supplies and Covered Drugs," Statement of Leslie G. Aronovitz , GAO-02-833T page 5.

[9] Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 4062, 101 Stat. 1330, 1330-101 (codified at 42 U.S.C. § 1395m (1988)).

[10] Report to the Congress, "Blood Safety in Hospitals and Medicare Inpatient Payment," Medicare Payment Advisory Commission, December 21, 2001.

Further complicating matters, a provision of the Deficit Reduction Act of 2005 shifted ownership of the oxygen equipment from the provider to the Medicare beneficiary after 36 months. We estimate that 26.4 percent of Medicare oxygen patients use oxygen for more than 36-months (see Chart 6 below).[11, 12] The full implications of this transfer of ownership are not yet apparent. The CMS Proposed Rule would have suppliers still responsible for maintenance services after the 36-month cap has been reached.[13] However, this may be difficult given questions surrounding the legal liability of suppliers for equipment they no longer own, and the possible voiding of manufacturer warrantees by the transfer of title. Another complication involves the advanced stage of the beneficiary's illness at the time of transfer. There is a high probability that the beneficiary may be close to the end of life. With the transfer of title, presumably the beneficiary's heirs would take possession of the oxygen equipment after the beneficiary's death. The specter of taxpayer-purchased oxygen equipment being sold on e-Bay by the heirs seems far from Congress' policy intention of a more efficient, effective Medicare oxygen payment policy.

At a minimum, a movement away from a de facto global payment covering all equipment, supplies and services requires a re-estimation of appropriate payment levels for each of the components rather than a selective review of only those items the government feels may be overpaid. CMS realized as much in its latest work in this area, the new proposed rule for oxygen payments. It stated: "The current fee schedule amounts for oxygen contents are based on calendar year data from 1986 for the combined average Medicare monthly payment for both stationary and portable contents divided by number of rental months for stationary liquid and gaseous oxygen equipment."[14] While this represents an effort by CMS to offer a more reasonable and rational approach, they are still left having to rely on 20-year-old data.

What is the likelihood that a rigorous re-estimation of component payments will actually occur? The results of the CMS competitive bidding demonstration projects from 1999-2003 for durable medical equipment, including oxygen showed that prices were lower and that quality of services were essentially unchanged".[15] As a result, Congress included competitive bidding as a major change in oxygen payment policy in the MMA in 2003. The Section 302 of the (MMA) requires competitive bidding to begin in 10 of the largest MSAs in 2007; in 80 of the largest MSAs in 2009; and in additional

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[11] An analysis of the combined 2002, 2003 and 2004 5 percent Medicare claims files shows 26.4% of December 2004 users had at least 36 months of oxygen. Providers with a growing market share may tend to have a smaller percentage over 36 months, while providers with a stable or shrinking market share tend to have more over the 36-month threshold.

[12] CMS published results estimating the 36 percent of beneficiaries will exceed the 36 month cap. CMS Proposed Rule, "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" p.73. Attempts to resolve the difference are ongoing. http://www.cms.hhs.gov/HomeHealthPPS/downloads/CMS1304Pdisplay.pdf.

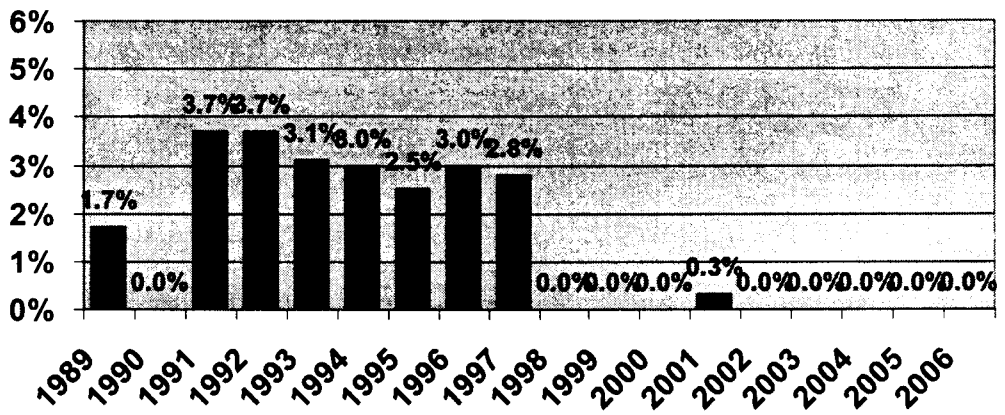
[13] Ibid.

[14] Ibid.

[15] http://www3.cms.hhs.gov/DemoProjectsEvalRpts/downloads/CMS_rtc.pdf. page two, Final Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration For Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Tommy G. Thompson, Secretary of Health and Human Services 2004.

areas after 2009. Given this timetable, CMS may ultimately choose not to spend scarce resources to refine a payment methodology that they intend to phase-out. Chart 5 below displays a summary of the changes over the last few years.

Chart 5 -- Medicare Oxygen Updates, 1989-2006



Source: Robert Hoover, MD, SVP Global Clinical Services, Sunrise Medical.

Effects of Recent Payment Policy Changes

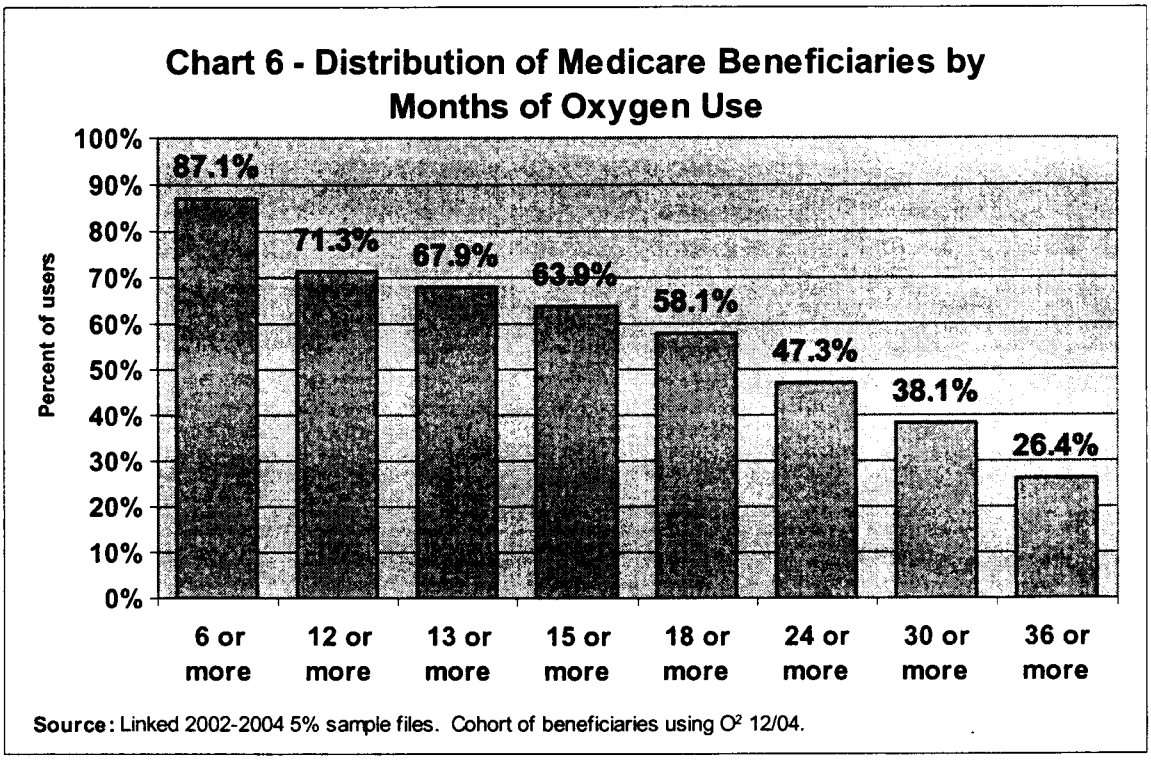
This section examines the effect of the 36-month cap on three key populations – beneficiaries, taxpayers and providers.

Effects of policy changes on patients:

Chart 6 shows the distribution of oxygen patients by the number of months they used oxygen in 2004. The vast majority use oxygen for more than six months, 87.1 percent, with 26.4 percent using oxygen for 36 months or more.

The subpopulation with more than 36 months of oxygen use does not appear significantly different from other oxygen patients across a range of measures, e.g., average age, percent dually eligible for Medicare and Medicaid, or percent disabled.[16] As stated earlier, Medicare patients requiring oxygen therapy tend to be older, more likely to also be on Medicaid and closer to end-of-life, than other Medicare patients. The 36-month subpopulation may not look much different for the rest of oxygen users, but we know that oxygen users are significantly more at risk than the Medicare population in general.

[16] Medicare Oxygen Users 2002-2004, Persons with any Oxygen Concentrator Use in December 2004. Mean age all oxygen users 73.4. Mean age 36-month oxygen users 72.7. Percent dually eligible all oxygen users 29%. Percent dually eligible 36-month oxygen users 28%. Percent disabled (non-aged) all oxygen users 14%. Percent disabled (non-aged) 36-month oxygen users 16%.



It is this subpopulation that will be affected by a 36-month cap, and it is this subpopulation that probably is in a weak position to effectively navigate this new market. As so starkly demonstrated by the implementation of the new Medicare drug benefit, the older and sicker the beneficiary, the greater the level of difficulty associated with choosing among different plans, balancing benefits and premiums, and making the other decisions needed in a more open market. Moreover, the greater the difficulty in navigating this new system, the more likely that significant problems will occur, both with access and quality of services and supplies.

Compounding this problem is the lack of an accurate rebasing of the component payment rates for the last 20 years. Without this rebasing, it is unclear why there would be an effective market for supplies and support services. Inaccurate payments at or above market rates should be available, as long as significant issues like legal liability can be resolved. However, if the inaccurate payments are lower than market rates, and certainly if they are lower than cost, other provisions of Medicare payment policy make it almost impossible for the market to work. Given Medicare provisions barring balanced billing beyond Medicare cost-sharing provisions, providers are unable to offer the supplies or services without losing money. In the private sector if an insurer pays less than market rates and the patient still wants the goods or services, the patient pays the difference and still has access to the desired goods and services. In Medicare that is illegal.

Medicare has seen this pattern in the past. The most significant example in recent Medicare history is withdrawal of Medicare+Choice HMOs during the late 1990s and early 2000s. The Medicare+Choice HMOs withdrew from markets where the Medicare contribution no longer covered the cost of providing benefits. Between 1999 and 2003 enrollments in these plans dropped almost a third – from 6.4 million to 4.6 million, as plans withdrew from market after market.[17] Undoubtedly plans were overpaid in 1997 when the payments methodology was changed, but the overpayments of the 1990 were more than compensated for by capping payments to no more than two percent a year during a time period when underlying costs were growing by at least five or six percent. As a result, the program underwent a near death experience.

The same negative potential exists for the oxygen program and the vulnerable beneficiaries it serves. Oxygen providers may follow the same pattern with geographic variation being the key determinant of access problems. However, given the methodology for updating oxygen payments over the years, it may be that the key determinant of access and quality problems is the particular supply or service. For example, underpaying for portable oxygen could leave beneficiaries stranded in their homes and is in direct contradiction to the President's "New Freedom Initiative" to assist the disabled in rejoining the community.

There is the potential for significant access and quality problems. The combined effect of a number of factors leads to these serious concerns:

- A particularly vulnerable population in a poor position to navigate a new system for oxygen supplies and services.
- A payment methodology for specific supplies and services that has not gone through a serious recalculation since the 1980s.
- The small likelihood that CMS will be able or willing to invest significant scarce resources into developing a workable payment methodology so close to the transition to competitive bidding,
- Medicare's balance billing prohibitions that would block any ability to offset underpayment.
- A new generation of legal questions involving liability for equipment no longer owned by the provider.

All these factors point to the likelihood that 26 percent of vulnerable oxygen patients will face significant problems of access and possibly lesser quality of the services and supplies they need most.

[17] "A Data Book: Healthcare Spending and the Medicare Program" (MedPAC June 2006), http://www.medpac.gov/publications/congressional_reports/Jun06DataBookSec10.pdf

Effects of policy changes on taxpayers

As stewards of the taxpayers' dollars, the government has a responsibility to spend the taxpayers' dollars prudently. This is a key objective for changing Medicare payment policy and so the question is whether or not savings will materialize in light of the changes.

To estimate Medicare savings or costs from a change in one part of the program requires also estimating the possible savings or costs in other parts of the Medicare program. For years the HMO industry justified the additional spending on prevention and education as cost effective because of the resulting reduced hospitalizations. A similar dynamic occurs with oxygen therapy.

The best empirical estimate is that about 26 percent of beneficiaries will exceed the 36-month cap (see footnote 12 for a more complete discussion). Spending for these beneficiaries will shift from equipment to supplies and services. However, other Medicare spending may result.

The Agency for Healthcare Quality and Research (AHRQ), the Department of Health and Human Service in-house experts on patient quality, access and evidence-based medicine, released a comprehensive study in 2004 of the effect of Long-Term Oxygen Therapy (LTOT) on patients' health and related health care utilizations. "In a retrospective cohort study of 246 patients that focused on the effect of LTOT on hospitalization, Ringbaek et al. (2002) reported that the average number of hospital admissions per patient per year decreased from 2.1 to 1.6 and the average number of days hospitalized decreased from 23.7 to 13.4 after LTOT."[18]

Results like these indicate that any change in payment policy that restricts access to LTOT may actually cost taxpayers more than it saves them. The cost of an average day in the hospital is above $1,600[19] and those Medicare beneficiaries requiring oxygen therapy are likely to have higher than average hospital stays. Therefore, restricting access to needed oxygen therapy may well turn estimated taxpayer savings into added taxpayer expenditures with the additional risk of significant negative health outcomes for this already very vulnerable population.

A second major concern is the interaction between taxpayer savings that have been scored or associated with the introduction of the new competitive bidding program and savings associated with the 36-month cap. In scoring the Deficit Reduction Act of 2005 (DRA), the Congressional Budget Office (CBO) estimated savings associated with the durable medical equipment (DME) provisions included in the bill. "CBO estimates those changes to Medicare's payment rules for oxygen and other durable medical equipment would reduce Medicare spending by $0.7 billion over the 2006-2010 period

[18] AHRQ op. cit., footnote #1, page 23.
[19] CMS Office of the Actuary, Medicare Cost Reports for Hospitals – updated with cost reports submitted as of March 31, 2006.

and by $1.9 billion over the 2006-2015 period." [20] Since this estimate included all the DME provisions, these estimates should not be interpreted as savings associated with the 36-month cap.

However, Section 302 of the MMA requires competitive bidding to be implemented in ten of the largest MSAs in 2007, in 80 of the largest MSAs in 2009, and in additional areas after 2009. In 2003, CBO estimated Section 302 savings of $9.2 billion over ten years.[21] As with the earlier estimate, other DME costs were also included in these calculations. Therefore, care would need to be taken to ensure that any potential savings were not already accounted for in CBO's earlier estimates. Counting them again as generating savings for the 36-month cap or lower month cap would result in double-counting.

Effects of policy changes on providers

The goals of the Medicare program have no provision to protect providers from financial hardship. However, an active market with multiple providers, especially under competitive systems, results in more choices for beneficiaries and more competitive pricing for the government. Precipitous or dramatic changes to market fundamentals can prompt economic chaos and market disruptions as a result of overregulation or overplaying a government's monopsonistic[22] powers. The California state employees' health insurance program, CalPERS, is one such example. During the peak of the HMO era, CalPERS enjoyed negative premium growth for three straight years, 1995-1997, but premiums grew by 25 percent a few years later. By contrast, the designers of the federal employees' health insurance program, FEHBP, the other major multi-plan employer-based system, made a conscious decision to keep more plans in the market rather than to push for deeper short-term premium discounts.[23]

Overly aggressive government regulation and price controls also have been shown to have a chilling effect on innovation and eventually on the industry itself.[24] This was the outcome in the European pharmaceutical industry, which has seen its strength wane significantly due to government controls.

Significant new policy changes to an industry attempting a smooth transition to the new competitive bidding system presents yet another concern. Major changes now may risk the success of competitive bidding. It may drive players out of the market that

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[20] Congressional Budget Office Cost Estimate, January 27, 2006, S. 1932, Deficit Reduction Act of 2005. Page 30.

[21] Congressional Budget Office Cost Estimate July 22, 2003, H.R. 1, Medicare Prescription Drug and Modernization Act of 2003 - As passed by the House of Representatives on June 27, 2003 and S. 1, Prescription Drug and Medicare Improvement Act of 2003 - As passed by the Senate on June 27, 2003, with a modification requested by Senate conferees. Table 13.

[22] Monopsony is a market similar to a monopoly except that a large buyer not seller controls a large proportion of the market and drives the prices down. Sometimes referred to as the buyer's monopoly.

[23] *Health Insurance Spending Growth – How Does Medicare Compare?* Joint Economic Committee June 10, 2003 and personal discussions with the Chief Actuary FEHBP

[24] *"What price competitiveness in the drugs industry?,"* THE LANCET • Vol 362 • July 26, 2003.

might not be efficient in the current fixed-priced system, but that would be very efficient in a competitive bidding system.

Towards a better designed oxygen payment policy

A well-designed oxygen payment policy is one that allows for a successful transition to a new competitive bidding process. Major changes in payment policy now may well prove highly disruptive to the implementation of competitive bidding already under way.

However, in the event that a new payment methodology must be implemented in the interim to replace the current methodology, certain steps can be taken to minimize the disruption. For example, ensuring the proper incentives; balancing price, quality and access; and collecting the best data available (not data from 1987).

The Medicare Payment Advisory Commission (MedPAC, chartered and appointed by Congress) defined the essential characteristics of an effective/efficient payment methodology for a well designed Medicare payment. [25] Each of these characteristics will be listed and then examined.

Is the product or service that Medicare is buying well defined and does HCFA have sufficient ability to monitor product attributes so that fixed-price contracting is desirable?

In considering the current payment policy with the 36-month cap, the answer is no. The mix of equipment, services and supplies has not been effectively monitored during the last twenty years. In addition, the CMS competitive bidding demonstrations have already shown that a more effective means of purchasing is available and indeed is being implemented.

If so, does the overall design—unit of payment, product or service classification system, and so forth— establish an appropriate basis for fixed-price contracting?

By not keeping up with changes occurring in the field and by allowing payments to be indexed by the general inflation rate in the economy rather than one of the range of indices better designed to measure technological change, the match between costs and reimbursements is almost guaranteed to diverge. In fact, this is the type of concern that attracted support for competitive bidding as an alternative to a formula-based price set by the government. An effective formula-based pricing methodology requires better data, better evaluation of the effects of technological change, better measures of input prices and geographic variation.

[25] "Chapter 1: Evaluating Medicare's Payment Policies," MedPAC Report to the Congress: Medicare Payment Policy | March 2001 page 7.

Is the distribution of payments consistent with expected variation in efficient providers' costs resulting from differences in product mix or market conditions beyond providers' control?

As discussed above, the current payment methodology is conveniently based on equipment cost (which is relatively easy to determine); with very little consideration given to more difficult to measure cost elements such as service levels and supplies. The 36-month cap is an attempt to move payments away from equipment. The DRA[26] provides for increased payments for services and supplies. Although the recently released HHS proposed rule adjusted upward payments for oxygen supplies, two independent teams of Wall Street analysts concluded that CMS had not raised supply reimbursements enough to meet budget neutrality.[27] In the proposed rule, payment levels for oxygen services were delegated to CMS contractors (DMERCs) to determine at a later date.

Is the current level of the payment rates consistent with the costs efficient providers (or health care organizations) would incur in furnishing covered services to beneficiaries?

The current methodology, with the addition of the 36-month cap, is a blunt instrument to adjust payments over time. The decade of indexing to general inflation in the economy, the Consumer Price Index, rather than a measure that captured the changes actually relevant to oxygen created an extremely weak empirical base for making payments. CMS' recent efforts to rationalize payments are a real step in the right direction, yet they are still based on a foundation of questionable relevance.

How are providers' costs expected to change in the forthcoming year as a result of anticipated changes in legitimate factors, such as market input prices or the introduction of new technologies?

To properly address MedPAC's questions, the options are either a rigorous data collection effort to establish a sound empirical base for a formula-based payment or to allow the market to do what it does best and reflect the actual changes in the cost of doing business in a variety of different markets around the country. This concern/consideration feeds directly into the sixth criteria: what data is needed to ensure accurate payments are being made? The answer is the same – either use the market to adjust prices for oxygen, as is done with the vast majority of all other prices in the economy, or make the substantial investment in data collection and analysis to construct a formula-based payment system that works without risking reduced access, reduced quality or both.

What payment tools and data may need improvement and how might improvements be accomplished?

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[26] The Deficit Reduction Act of 2005, Section 5101(b)(1)(B).

[27] "AHG, LNCR: Proposed Rule Looks Bad," Wachovia Securities, Wachovia Capital Markets, Llc Equity Research Department, July 17, 2006. "Lincare Holdings Inc. CMS Proposed Rule Leads Us to Downgrade to Neutral, Lower Target," Bank of America, Equity Research, July 28, 2006.

This sixth criteria for an effective payment policy focuses on the site of care. Do the payment rates established for a particular setting create financial incentives for inappropriate shifts of services to or from potential substitute settings? In the case of oxygen the concern is more between modalities rather than sites of care. A serious miscalculation in payments for certain modalities, e.g., portable oxygen, can do significant damage to important policy achievements, such as the President's New Freedom Initiative and leave oxygen patients effectively trapped in their homes.

Conclusions

Medicare's oxygen payment policy has a long history, not all of it prime examples of a well-designed payment methodologies. For beneficiaries, we look for a payment policy that protects quality, access and innovation. For taxpayers, we look for a payment policy that shows careful stewardship of the taxpayers' money. For providers, we look for a payment methodology that accurately pays for providing the best quality at the most competitive price.

The good news is that oxygen payment policy is an example of the right way for policy to evolve over time. CMS experimented with competitive bidding in selected sites; learned from that experience and developed a more adaptable, efficient, accurate design for payments in the future. CMS demonstrations are not always heralded as prime examples of efficient, evidence-based policy development, but the competitive bidding demonstration is generally recognized as a good effort. Congress concurred and the system was made law.

This analysis has explored who these oxygen beneficiaries are; what equipment, supplies and services they receive; the market dynamics of the provider and payers involved; and what the essential characteristics of a well designed payment policy are. Given the vulnerability of the population involved and the imminent implementation of a new, very different payment methodology, it is hard to see the wisdom of additional short-term shocks to the system that would be triggered by policy changes designed to lower the 36-month cap to any duration.

Methodological note for the overall analysis:

The analysis of Medicare use and cost was based on 2002 to 2004 claims and enrollment information for a 5 percent sample of Medicare beneficiaries, using Medicare standard analytic file (SAF) and denominator file data. These files allow all services and payment information for a single beneficiary to be linked across all claims files and all years, using a CMS-supplied encrypted identifier.

Oxygen services were identified by the Healthcare Common Procedure Coding System (HCPCS) codes on CMS carrier claims. All HCPCS in the oxygen category in CMS's Berenson-Eggers type of service (BETOS) system were flagged as oxygen services. This included both monthly rental of oxygen concentrators and other associated items and services (portable oxygen, supplies, refills).

Throughout the analysis, measures of cost and spending are based on total allowed charges and total payments. These figures include both Medicare program outlays and beneficiary-paid coinsurance and deductible amounts. When determining prevalence of disease, the Agency for Healthcare Research and Quality Clinical Classification System (CCS) categories were used to combine diagnoses reported on claims into disease categories. Quantitative analysis of Medicare claims performed by Christopher Hogan, PhD, Direct Research LLC.

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September 25, 2006

Administrator Mark McClellan
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1304-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Proposed Rule on 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

Dear Administrator McClellan:

Innovatix, LLC is pleased to offer comments on the proposed rule on Home Health Prospective Payment System Rate Updates and the Deficit Reduction Act of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment. Innovatix provides high quality group purchasing and consultative services to a national membership base of alternate care and non acute care institutional providers. Innovatix members provide services to patients in: Home Infusion, Extended Care, Long Term Care (dispensing pharmacy), Retail and Mail Order Pharmacy, and select medical oncologist segments.

Innovatix and its members are directly impacted by this proposed regulation. We have a number of concerns and comments regarding the proposed rule, and specifically on the oxygen and capped rental portion of the proposal. Our specific comments and concerns are provided below.

I. General Comments

The proposed rule clarifies Medicare payment for oxygen equipment and capped rental Durable Medical Equipment (DME) regarding number of rental months, maintenance and servicing, oxygen contents, replacements and oxygen supplies and accessories. In addition, CMS is proposing additional supplier requirements to safeguard beneficiaries, and modifying payment for oxygen classes to reflect new technology and compensation for delivery and refilling of portable contents. CMS proposes to implement the new home oxygen payment methodology January 2007.

Innovatix is concerned about the implementation schedule of this proposed regulation. There has been a recent influx of regulations impacting the DMEPOS industry, particularly oxygen, and we feel that suppliers will need time to understand and adapt to these changes, including the new quality standards, mandatory accreditation, and competitive bidding. Adding a new payment system and stricter requirements to the mix could make many suppliers leave the market, thus reducing patient access to this life-saving therapy.

Innovatix recommends that the implementation of the proposed rule be delayed until CMS assesses the impact of the competitive bidding and accreditation processes on suppliers and beneficiaries. In addition, we also strongly urge CMS to "grandfather" beneficiaries already on home oxygen under Medicare on December 31, 2006 from the provisions of this proposed rule. We discuss these issues and our concerns about the operational impact of the proposed rule in greater detail below.

In addition, we would recommend CMS to consult with the oxygen industry and professional associations and work together to address patient safety concerns, prior to releasing the final rule. The impact of this proposal on beneficiaries should be fully assessed. The overhaul of the payment system for home oxygen therapy may have a negative impact on providers' ability to assure access to the level of care and services beneficiaries expect and deserve.

Home oxygen therapy is the delivery of a life-sustaining prescription drug to people with chronic, often debilitating medical conditions. Under this proposed rule, beneficiaries will become responsible for the management of their oxygen equipment and therapy. This places an unrealistic burden on the patient that most beneficiaries do not want or are not ready to manage. These frail, elderly patients should not have to be concerned with maintenance and servicing of their oxygen equipment to ensure the appropriate functioning of an increasingly sophisticated technology. Oxygen suppliers already have the technical knowledge and capability to safely and effectively service and maintain this equipment. We believe that transferring the burden of maintenance and repair of oxygen technologies to the patient presents a serious risk to patient safety and care.

II. Provisions of the Proposed Rule (specifically, the Oxygen Provisions)

Concern for Patients

The home oxygen patients that our members serve have multiple and changing therapy needs. Many patients become increasingly ill over time, and high-quality home oxygen therapy keeps many of these patients stable and living independently in the home setting. As such, we are concerned that some of the provisions included in the proposed rule will adversely impact beneficiaries' access to oxygen, jeopardize the health and safety of these patients, and create additional costs to the Medicare program through an increase in the number of hospitalizations and urgent care visits.

First, with respect to access, we fear that the new payment system coupled with the anticipated competitive acquisition for durable medical equipment will change the way oxygen services are delivered to beneficiaries. Providers will not be able to offer the same quality services that beneficiaries have come to expect and rely upon, because their cost exceeds Medicare reimbursement. Some providers will be forced to leave the market and the beneficiary's access will be impacted.

Second, many of the patients receiving home oxygen are elderly and ill. Their hand eye coordination is not what it used to be and therefore they will not be able to use, change or service the equipment as well and as safely as a trained technician. Not to mention that most will not understand the workings of a concentrator's regulator or filter to know whether it is producing the correct flow. Limiting the payment for maintenance and servicing to those situations when an "authorized technician's" services are required assumes that frail seniors on home oxygen and/or

their caregivers will be able to handle routine maintenance. We believe that, for safety reasons, the burden for these operations should not be on the beneficiary.

Furthermore, from time to time, the FDA has issued recalls on certain items of oxygen equipment, or has issued advisories. Beneficiaries are not aware of these recalls or advisories as they are not tracking them (nor should they be required to). Providers however are tracking FDA recalls and advisories to ensure beneficiary safety. When the FDA issues a recall, providers will and do make necessary adjustments as to not interrupt the patient's service.

Thus, we recommend **that routine maintenance and servicing should be reimbursed by Medicare – including testing, cleaning, regulating, changing filters, and general inspection of beneficiary-owned DME – and not just when an authorized technician's services are required.**

Grandfathering of beneficiaries

CMS states that the payment and other policies announced in the NPRM will not be effective prior to January 1, 2007. With respect to patients receiving oxygen therapy under Medicare in 2006, this statement is ambiguous because the period of "continuous use" mandated under the DRA is in effect for any patient receiving home oxygen under Medicare on or after December 31, 2005. **The new payment policies and additional supplier requirements announced in the NPRM should not apply to any beneficiary currently under a period of "continuous use" to which the DRA transfer of ownership provisions apply. Consequently, the policies announced in the NPRM should not apply to any beneficiary receiving Medicare covered oxygen on December 31, 2006, although the DRA transfer of ownership will apply to these beneficiaries.**

<u>Operational Issues for Providers of Oxygen</u>

Ownership Issues for Oxygen and DME

The NPRM prohibits changing the equipment that is provided to a beneficiary on the first day of continuous use unless an exception applies. There are a number of significant operational issues that arise under this proposal:

a) Providers would have to track equipment by serial number in order to make sure that the beneficiary receives title to the equipment that was delivered on the first day of continuous use. This will be very difficult for providers to track internally if the concentrator or another type of equipment is brought into the facility for repairs. Importantly, larger providers may have regional or even national distribution centers which stock and service equipment. Other providers may use contractors to service equipment.
b) It is not clear how the "break in service" rules will apply to oxygen equipment. Will CMS simply apply the existing break in service rules to oxygen? There are a number of situations in which a beneficiary may have a short term need for oxygen that should not be included in the period of continuous use.
c) We have questions regarding which provider's equipment transfers to the beneficiary if the beneficiary has two residences with a local provider in each area. Beneficiaries who are "snow birds," or who may move or relocate during the period of continuous need will face hurdles in maintaining access to equipment. Because the propose rule states that a change in supplier would not begin a new period of continuous use, Medicare beneficiaries who move

after the conclusion of the 36 month rental period for oxygen, will have a very difficult time transferring to a new provider.

d) Title to medical equipment cannot transfer unless the beneficiary has paid all outstanding copays and deductibles.

e) The requirement that providers notify beneficiaries of their "intent" with respect to accepting assignment is unworkable and conflicts with longstanding Medicare program rules that allow suppliers to accept assignment on a claim by claim basis.

Reimbursement

The proposed rule revamps the oxygen classification system by splitting stationary and portable oxygen contents into two separate payment classes and calls for a third payment class for new technologies, such as portable concentrators and home transfilling systems. However, a majority of providers provide traditional oxygen technology and thus this new system will mainly result in reducing reimbursement to most providers. We are concerned that a further reduction in payment will cause access problems for beneficiaries.

In addition, we believe that the proposed payment structure should move beyond payment for the equipment itself and incorporate all necessary services that suppliers of oxygen and oxygen equipment provide.

For example, oxygen providers now work to:

- Make sure that beneficiaries manage their oxygen therapy in natural disasters or emergency, including 24-hour emergency support of all home oxygen patients.
- Check the purity and the 'flow' (dose) of the oxygen delivered and administered to the patient; verification is conducted periodically by specially trained technicians or therapists using calibrated oxygen analyzing technologies. This verification is key to ensuring the oxygen therapy the beneficiary receives is safe and effective.
- Check the alarm functions of the oxygen concentrator to ensure the beneficiary or caregiver has sufficient time to switch to back-up systems.
- Periodic verification and replacement of filter systems. Currently, the clean-up or replacement of filters is performed by respiratory therapists or trained technicians in accordance with the manufacturer's specifications, often a requirement to retain the equipment warranty. While beneficiaries and caregivers could be trained to conduct some of these checks and maintenance operations, many do not feel they could safely rely on their own ability to do so.

Without proper payment for these services, providers may not be able to continue to provide these much needed – sometimes life-saving services. **Our recommendation is to develop a payment structure that accurately and adequately captures all necessary services supplied by oxygen provider.**

Supplier Requirements

The proposed rule includes additional supplier requirements to safeguard beneficiaries. While Innovatix and its members do applaud CMS for trying to safeguard beneficiaries, we are concerned that these additional requirements are imposed at the same time with reduced reimbursement, which will threaten the viability of many oxygen providers, thus affecting patient access.

The additional supplier requirements include requiring a supplier who furnishes rented oxygen equipment or a capped rental item in the first month to continue furnishing the same item

throughout the entire rental period, not allowing suppliers to switch out equipment except under specified circumstances, and requiring a supplier to disclose its intentions regarding assignment for the entire rental period.

We recommend that the implementation of these additional supplier requirements should be delayed until the potential impact on beneficiary is assessed, in consultation with the industry.

III. Conclusion

Home oxygen therapy is the delivery of a life-sustaining prescription therapy to people with chronic, often debilitating medical conditions. We understand the need to control cost and safeguard beneficiaries, and applaud CMS for trying to do so. However, we are very concerned that transferring the burden of managing maintenance and repair of sophisticated oxygen technologies to the patient presents a serious risk to patient safety and care. Moreover, the reduced reimbursement coupled with additional requirements and the multitude of regulatory changes affecting the oxygen industry could lead to many oxygen providers leaving the market or drastically reducing the range of services offered, thus impacting patient access to this life-saving therapy.

Innovatix appreciates the opportunity to provide our comments on this proposed regulation. We look forward to working with CMS on this issue and would be happy to provide additional information.

Sincerely,

John P. Sganga
President and Chief Executive Officer

September 25, 2006

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

Dear Sir or Madame:

Thank you for this opportunity to comment on the proposed regulation 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 Medicare Equipment" published in the Federal Register on August 3, 2006 (Vol. 71, No 149, page 44081). The Illinois HomeCare Council (IHCC) is a trade association representing approximately 200 home health providers and suppliers serving Illinois' most vulnerable citizens. These comments were developed by IHCC's Regulatory and Reimbursement Committee.

II. PROVISIONS OF THE PROPOSED REGULATIONS

C. Rural Add-On

While IHCC members recognize that Congressional action would be required to extend the 5% add-on for rural providers, IHCC would like to go on record supporting its retention. Staffing shortages in the home health industry have not improved since the home health prospective payment system was introduced. In fact, they have worsened, spreading beyond rural areas in to more heavily populated areas. Chicago metro-area provider organizations are struggling to find therapists to work in home care, and finding clinicians of any kind who are experienced and knowledgeable about home care is difficult statewide.

Needless to say, staffing shortages are much worse in rural areas, and gasoline prices have placed considerable pressure on rural home health provider organizations whose employees must often drive 100 miles or more round trip to

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meet the needs of an individual patient. This is not a good time to discontinue the extra boost that the rural add-on has given rural providers and their patients.

D. OASIS and Pay for Reporting

CMS is proposing to implement Section 5201(c)(2) of the Deficit Reduction Act of 2005 (DRA) by examining OASIS data submission records during the time period from July 1, 2005 to July 1, 2006. Page 44088 or the preamble to the proposed regulation states that "HHAs that meet the reporting requirement would be eligible for the full home health market basket percentage increase" available for the 2007 calendar year.

IHCC members are concerned about the vague nature of the above statement. Will CMS expect that providers will have submitted every OASIS data set they are required to submit within the established time frame in order to avoid the two percentage point penalty being applied to the market basket increase? Will failure to submit a single required data set invoke the penalty? CMS' preamble is unclear on the manner in which the performance of agencies will be evaluated.

IHCC members believe that any agency making a clear, good faith effort to submit the required data should be able to avoid the penalty, and that CMS' final rule should make this policy clear.

IHCC has a number of suggestions for CMS to consider as they work in the next several years to modify the current OASIS tool and to develop process measures to evaluate agency quality.

First, IHCC strongly advocates the elimination of M0280 which asks for a prognosis of life expectancy. This item is quite subjective and adds nothing to the assessment of the home health patient that is not addressed by other OASIS items. There is no evidence-based method for estimating life expectancy that is appropriate for the use of the professionals who are completing comprehensive assessments of home health patients.

In addition, this item is used to generate a quite inappropriate and potentially inflammatory adverse event outcome referred to as "Unexpected Death." The unwarranted public relations nightmare that could arise if this score should become available to consumers and their families is of grave concern to IHCC members. CMS should eliminate both this item and the adverse event outcome measure generated from it as soon as possible. It has no potential to help home health agencies or their patients, and every potential to harm them.

IHCC also recommends reworking the OASIS items related to integumentary status, particularly the manner in which improvement is evaluated. First, M0440 provides virtually no meaningful information given how broadly the CMS instructions define a lesion. It is clear from the subsequent questions that CMS

is only interested in detailed information about three types of lesions: pressure ulcers, stasis ulcers and surgical wounds. Given that OASIS alone is not a comprehensive assessment, including M0440 without linking it to payment is meaningless. IHCC recommends eliminating this item and revising the skip patterns throughout the subsequent integumentary status items.

Consideration of the integumentary status items and the manner in which improvement and stabilization are evaluated reveals that CMS is only evaluating one aspect of improvement in wounds and their care—wound healing. Though we have seen great strides in wound care technology during recent years that have improved healing rates significantly, some wounds still do not heal. Also, the inclusion of data from managed care patients potentially skews improvement rates when only wound healing is being measured. Healing is often not the goal of a home health intervention paid for by a managed care company participating in Medicare—teaching the patient or his caregiver to be independent in wound care is frequently the goal of these time-limited interventions.

IHCC recommends that CMS re-examine and revise the manner in which they measure improvement and stabilization in wounds, and incorporate measures more like those used in the medication and equipment management items (M0780-M0820). These items reflect the acquisition of knowledge and independence in managing the patient's condition, not just improvement in the patient's health status. In this manner, the measurement of improvement and stabilization of wounds would be more fully evaluated.

IHCC members believe that M0550 should be revised to include urinary ostomies which require service delivery that is as costly and demanding as care for ostomies for bowel elimination.

While IHCC recognizes and supports the purpose of the development of patient-level process measures, members have considerable concerns about how this will be done. IHCC members believe that any process measures that CMS develops to evaluate home health agencies or for use in a performance-based system of payment adjustments must be: 1) evidence-based, objective and measurable; 2) risk adjusted to decrease subjectivity; and, 3) present no additional data submission burden to providers without adequate compensation for these activities. Process measures must also take into account the patient's ability to refuse services and to refuse to comply with the care plan.

IHCC also has concerns about the use of patient satisfaction measures in efforts to evaluate home heath agencies or to adjust their payments. IHCC believes that measuring patients' perception(s) of the care they are receiving is worthwhile, but experience shows that it is a very subjective and imprecise process. Few scientifically-developed, standardized tools are available for agencies to use. And, even when a good tool is used, it is very difficult to insure that patient's responses truly reflect the experiences about which they are being questioned.

IHCC member agencies using these tools find that they are often completed by caregivers, rather than patients, that respondents are confused about which staff members were nurses and which were home health aides, and that they often respond to the questions taking the entire constellation of service delivery personnel with whom they come into contact—the Medicare agency staff, the homemaker who provides them with services under a Medicaid-funded community support program, the folks who deliver their meals, etc. As a result, the information collected is not a reliable reflection of the patient's experience with the home health agency alone.

Finally, the few patient satisfaction tools available that are statistically tested are very expensive. The cost limits their implementation in the industry.

F. Hospital Wage Index—Revised OMB Definition for Geographical Statistical Areas

IHCC members remain concerned about the impact of implementation of the Core-Based Statistical Areas (CBSA) for wage area designation. Adoption of CBSAs alone will have a significant negative impact on several areas in Illinois, including Lake County, the northernmost part of the Chicago metropolitan area. Implementation of the CBSAs will include Lake County in the wage index area with Racine, WI, rather than with Chicago. This is an inaccurate representation of reality, and should be corrected.

In fact, Lake County draws from the same employment pool as does the Chicago metro area. Few of the professionals working in home health agencies maintain licensure in more than one state, and dual licensure would be needed in order for agencies in Lake County, Illinois to hire nurses from the Racine, Wisconsin area. This single change will cost one of IHCC's larger member agencies $70,000 in the coming year.

Sections G – L Regarding Payment for and Transfer of Ownership of Oxygen Equipment

While IHCC recognizes that CMS is faced with DRA requirements imposed by Congress, our members find it impossible to support CMS' proposed regulations related to the transfer of ownership of oxygen equipment and payment for the equipment and its contents. IHCC members believe that Congressional action and these proposals arise from an inaccurate and potentially dangerous view of oxygen and the equipment required to make it available to the Medicare beneficiaries who need it, many of whom are frail and unable to survive without this critical medication.

As has been noted by the American Association for Homecare (AA Homecare) and numerous others writing and speaking on this topic, neither Congress nor CMS seems to recognize that oxygen is a life-preserving medication. As long as

Congress and CMS continue to consider the provision of home and portable oxygen supplies and equipment to be just supplies and equipment, proposals such as this will continue to come forward, Instead, Congress and CMS should recognize that safe and effective provision of oxygen to those living in the community is a service that includes the delivery of equipment and supplies, insuring that the equipment is properly maintained and operating safely, and that the users of this medication are receiving the maximum available benefit from the medication.

It seems that CMS and Congress believe that suppliers of oxygen and related equipment are making too much money from Medicare. Even if this were the case, these proposals will hurt consumers much more than they will benefit Medicare. Unfortunately, it seems that the manner in which CMS has historically viewed the oxygen benefit contributes to this view. Because suppliers have been paid for equipment and supplies, instead of for providing an oxygen service that includes equipment, supplies, equipment maintenance, and evaluation of the patient's ability to gain the available benefits, suppliers have had to find ways to support these activities from the amounts paid for the equipment. If CMS were to update its view, a more rational payment system could be developed that would safeguard against over-paying for the equipment while at the same time providing support for the service delivery aspects of the provision of oxygen in the home. IHCC recommends a comprehensive re-thinking and revision of the oxygen benefit under Medicare.

IHCC wishes to go on record supporting the comments made by AA Homecare in their letter on this proposed regulation. Many of the proposals are unworkable and show a real lack of understanding of how the provision of oxygen services works in the real world. Similarly, CMS' expectations of the role frail, elderly Medicare beneficiaries will be able to play in the maintenance of oxygen equipment are unrealistic. Not only will many of these individuals be physically unable to perform the tasks required, many will also fail to understand why they are important. Finally, CMS suggestion that Medicare beneficiaries will be able to rely on the internet to secure needed maintenance manuals and other technical documentation is unrealistic for many of the patients IHCC members serve, particularly in rural areas where the closest computer with internet capability may be miles and miles away.

Health Care Information Transparency and Health Information Technology

While IHCC recognizes the critical role that the Certification Commission for Health Information Technology (CCHIT) potentially plays in advancing the adoption and usefulness of computerized information, our members are concerned about the potential impact of these proposals on agency costs. In the preamble, CMS quotes the 2007 Budget as stating that "the Administration supports the adoption of health information technology (IT) as a normal cost of doing business...." IHCC members recognize that IT is a critical piece of both

patient care and agency operations, but do not feel that CMS has sufficiently supported the significant investments agencies have had to make in the past several years to establish and maintain capabilities.

IHCC supports proposals that will facilitate the development and adoption of software that will communicate with other software, and is aware of CCHIT's role in this movement. IHCC's reservation about the proposal focuses on the potential financial impact on providers who have invested significantly in IT. IHCC wants CMS to pay its fair share of IT costs. IHCC also wants to be sure that CMS will not take actions that will negate the investments of agencies to date by suddenly rendering their software obsolete. Information technology transitions must be made in a measured and realistic manner, not overnight via the adoption of a new regulation.

Sincerely,

Linda Leone
IHCC President

Denver® BIOMEDICAL

14998 W. 6th Ave., Bldg E-700
Golden, CO 80401

OCT - 6 2006

September 25, 2006

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

RE: CMS-1304-P

Dear Sir or Madam:

We are Denver Biomedical, Inc. (DBI). We are a Colorado corporation and currently employ about 43 workers. We manufacture clinically-proven, patented Pleurx Pleural Catheters, Drainage Kits, and Vacuum Drainage Bottles used for the drainage of symptomatic, recurrent, pleural effusions and malignant ascites. For your review, we have attached a copy of a Benefit Category Determination Memorandum by the Centers for Medicare and Medicaid Services (CMS) dated March 14, 2002, classifying our products as implanted prosthetic devices and accessories to implanted prosthetic devices. We respectfully submit our comments to the proposed rule regarding the Home Health Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment (CMS-1304-P), which was published on August 3, 2006 (71 Fed. Reg. 44082).

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

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

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

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

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

* * * * *

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

Sincerely,

Tom Daulton
Vice President and General Manager

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

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicare Management/Chronic Care Policy Group

DATE: MAR 14 2002

FROM: Director
Chronic Care Policy Group
Center for Medicare Management

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

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

Dr. Paul Metzger
Medical Director
Region C DMERC

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

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

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

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

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

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

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

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

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

Thomas E. Hoyer

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

HOME CARE ALLIANCE
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OCT - 6 2006

September 15, 2006

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

Re: File Code CMS-1304-P

Dear Sirs:

The Home Care Alliance of Massachusetts (HCA), on behalf of our member home health care agencies, appreciates this opportunity to submit the following comments on the proposed rule for the FY 2007 Home Health Prospective Payment System Rate Update.

PROVISIONS OF THE PROPOSED REGULATIONS

A. National Standardized 60-Day Episode Rate

We are concerned that, after five years under the prospective payment system for home health, CMS has proposed no adjustments to the case mix weights upon which the 60-day episodic payments are based. We believe that CMS has by this time accumulated enough utilization data that some fine-tuning of the case mix weights is possible. **We urge CMS to undertake such a review and make appropriate adjustments to the case mix weights prior to 2008**, to ensure that agencies are reimbursed appropriately for patients across the case mix spectrum.

D. Outcomes Data Submission

We are encouraged that CMS has proposed an initial step toward incorporating a "Pay for Performance" component into the Medicare home health reimbursement system. However, we find it disconcerting that CMS has proposed a 2% payment penalty for agencies that do not submit OASIS Outcomes data, without any incentives on the other side of the equation. Our

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understanding is that "Pay for Performance" includes both incentives and penalties. Your proposal has a stick, but no carrot! CMS estimates that less than one percent of agencies and claims will be affected by this rate reduction. If one percent of all claims are reduced by two percent, the total net reduction to the Medicare home health system will be approximately $1.8 million. **We strongly recommend that the national standard episode amount be increased to make this penalty budget neutral and provide a small reward for the majority of agencies that already comply with the data submission requirement.**

F. (3) Hospital Wage Index – Labor Market Areas

We have serious concerns about CMS's proposed wage index for Rural Massachusetts. In the proposed rule, CMS states that Rural Massachusetts was one of three "geographic areas where there were no hospitals, and thus no hospital wage data on which to base the calculation of the ... home health wage index." That assertion is not accurate. There are, in fact, two hospitals in rural Massachusetts (Martha's Vineyard Hospital and Nantucket Cottage Hospital), but they are Critical Access hospitals (CAHs). In August, 2003, CMS announced a policy decision to eliminate CAHs from the wage index calculation for inpatient PPS hospitals, and, as a consequence, all other Medicare provider types whose wage index is calculated from inpatient hospital wage data.

CMS proposes to "freeze" the wage index for Rural Massachusetts at 1.0216 – the same level it has been at since 2005, the year after CMS decided to remove CAHs from the wage index calculation. This proposed wage index is based on 2004 wage data from Franklin Medical Center in Franklin County in Western Massachusetts. With the transition from MSAs to CBSAs as the basis for Medicare wage index, Franklin County is now part of the Springfield, MA, CBSA. In other words, CMS's proposed wage index for rural MA is based on OLD data from a single hospital that is no longer even considered Rural. Furthermore, the average hourly wage data from Franklin Medical Center has consistently been far lower than the average hourly wage data for Martha's Vineyard and Nantucket Cottage hospitals. For example, the Inpatient Hospital PPS update published by CMS in the *Federal Register* on August 11, 2004, reported the following average hourly wages for FY 2003:

Franklin Medical Center	$24.62
Nantucket Cottage Hospital	$31.13
Martha's Vineyard Hospital	$29.61

(This is the most recent comparative data available because CMS removed Critical Access Hospitals from the wage index calculation after 2004.) This data indicates that the average hourly wages for Nantucket Cottage Hospital and Martha's Vineyard Hospital are 26.4% and 20.3% higher, respectively, than the average hourly wage for Franklin Medical Center.

For 2005, the three home health agencies in Nantucket and Dukes Counties received combined Medicare reimbursements of $1,637,382. The cost to provide those Medicare services was $2,037,580, for a net loss from Medicare services of $400,198 (19.64%). If the wage index for Rural MA is frozen at 1.0216 for 2007, we estimate that the losses for these agencies will increase to $507,880 (23.34%).

Clearly, there is no statistical justification for continuing to use the wage data from Franklin Medical Center to set a wage index for Nantucket and Duke's Counties.

In the proposed rule, CMS recognizes that the 1.0216 wage index is an imperfect solution, and has solicited alternative methodologies. CMS identifies four "basic policy criteria" that alternatives should adhere to: 1. based on "pre-floor, pre-reclassified hospital wage data;" 2. based on rural wage data; 3. easy to evaluate; and 4. updatable from year to year. **To these four criteria, we would add a fifth, which we believe is the underlying principal behind the entire wage index, and should take precedence over all other criteria: 5. the wage index should be based on the most locally applicable data available.** We agree that an ideal solution would meet all five of these criteria, but if no such solution is possible, criterion 5 must be given extra weight in evaluation the available options.

The wage index that CMS has proposed for Rural MA meets only 2 of these 5 criteria, and should be rejected.

CMS has described one alternative in the proposed rule which would calculate an "imputed" wage index for rural MA based on the average wage index of the rural areas in four other states in the New England Census Division. **We strongly object to this alternative, as it is based on regional rather than local data that have no more applicability to Dukes and Nantucket Counties than the current practice of using two-year-old data from Franklin County.**

A review of wage data from the Bureau of Labor Statistics demonstrates that the economy in rural MA (Dukes and Nantucket Counties) is significantly different from the economy in rural areas of other New England states. For example, the following BLS data show average annual salaries in the Health care and social assistance sector for representative rural counties in the various New England states in 2005:

Windham County, CT	$34,211
Aroostook County, ME	$27,032
Dukes County, MA	**$42,281**
Nantucket County, MA	**$45,482**
Cheshire County, NH	$33,261
Lamoille County, VT	$32,723

(We are using wage data from the entire health care and social assistance sector as a proxy for this comparison because hospital-specific data is not available from BLS for many of these areas.) This BLS data shows that the average wage in the health care and social assistance sector in the two rural MA counties is $43,882 – **38.0% higher** than the $31,807 average of the representative rural counties in the other New England states. **It is clear from this data that the rural areas of Connecticut, Vermont, New Hampshire and Maine are not appropriate proxies for setting a wage index for rural Massachusetts.** ***We strongly recommend that CMS not adopt this alternative methodology.***

We believe that CMS's decision in 2003 to exclude wage data from Critical Access Hospitals in calculating the wage index for home health agencies and other non-hospital Medicare providers will come to be a major problem for CMS in coming years. For 2007, there are only three areas of the country that do not have wage data from local PPS hospitals to be used in calculating a wage index: Rural Massachusetts, Rural Puerto Rico, and the Hinesville, Georgia CBSA. However, given the extremely rapid growth in the number of hospitals around the country that have critical access status (there are now over 1,200 CAHs nationally) there will surely be additional CBSAs and rural areas in this situation in coming years.

We have attached to our comments a spreadsheet outlining the financial impact of each of these various options, along with a summary of how well each of them complies with the five policy criteria. From this analysis, it is clear that **the option that most closely complies with the five policy criteria – and that could establish a simple policy precedent going forward to prevent this situation from occurring in additional areas in the future – is for CMS to return to its previous policy of including wage data from Critical Access Hospitals in calculating the wage index for home health and other non-PPS hospital providers.**

Thank you for this opportunity to comment. We would be happy to discuss our recommendations further.

Sincerely,

Timothy Burgers
Associate Director

MA Rural Wage Index

	2005	**2007	2007 CMS Regional Alt.	***2007 Critical Access	2007 Barnstable	2007 CT rural	2007 Hospital Rural Floor
Wage index	1.0216	1.0216	1.0227	1.3361	1.2561	1.1753	1.0664
*Medicare Reimbursement	$1,637,382	$1,668,492	$1,669,827	$2,064,759	$1,963,982	$1,862,204	$1,724,887
*Medicare Costs	$2,037,580	$2,176,372	$2,176,372	$2,176,372	$2,176,372	$2,176,372	$2,176,372
*Medicare Loss	-$400,198	-$507,880	-$506,545	-$111,613	-$212,390	-$314,168	-$451,485
Percent loss	-19.64%	-23.34%	-23.27%	-5.13%	-9.76%	-14.44%	-20.74%
$ impact Medicare Expense			$1,335	$396,267	$295,490	$193,712	$56,395
****CMS criteria		A,C	A,B,C,D	A,B,C,D,E	A,C,D,E	A,B,C,D	A,C,D

*Data on Medicare Reimbursement, Costs, and Loss are based on combined 2005 data from the three home health agencies in Dukes and Nantucket Counties.
**2007 Costs are estimates based on 2005 costs updated by CMS's home health market basked inflati onadjustments for 2006 and 2007.
***Estimate based on analysis by Besler Consulting.
****In the 8/3/06 proposed rule, CMS lists four policy criteria to evaluate methodologies:

A: use pre-floor, pre-reclassifed hospital wage data;
B: use rural wage data;
C: easy to evaluate;
D: updatable from year to year.
E: to those criteria, we propose a fifth: local