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March 28, 2014

Comments on CMS-1460-ANPRM

Methodology for Adjusting Payment Amounts for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Using Information from Competitive Bidding Programs

"Have you ever watched someone dying of lung disease? Have you ever sat on the edge of a bed, your chest filled with mucus, your only emotion panic, every fiber of your being straining for your next breath? I have. Prior to a double lung transplant, I was on ridiculously high oxygen flows, the fight for air always at the front of my mind." Jim Nelson, COPD patient, Double Lung Transplant recipient, December, 2011.

The COPD Foundation is a 501(c)(3) not-for-profit organization established to undertake initiatives that result in expanded services for COPD and improve the lives of individuals affected by COPD. The Foundation's activities focus on achieving these results through research, education and advocacy programs that will lead to prevention, and someday, a cure for this disease. The COPD Foundation is the leading voice for individuals who suffer from this common and under-diagnosed multifactorial disease that share the feature of progressive airflow obstruction leaving them breathless, debilitated and in need of supplemental oxygen therapy.

COPD is currently the third leading cause of death and the second leading cause of disability. The COPD Foundation fights on behalf of individuals to ensure that they receive the treatment they need so that their COPD is well managed and they do not have repeated exacerbations. COPD is a common and neglected problem that is often well managed with long term oxygen therapy. Quite simply supplemental oxygenation prolongs life and is the standard of care in COPD.

The COPD Foundation has contended for sometime that CMS should exempt oxygen from the DME competitive bidding program. The Competitive Bidding program from the beginning has caused market place changes that have brought hardship to the patient community. Many oxygen providers have discontinued the practice of providing liquid oxygen which may significantly restrict a patients mobility by requiring them to transport multiple tanks when attempting regular day-to-day activities such as grocery shopping or going to a doctor's appointment.

The COPD Foundation appreciates the goals stated in the ANPRN of "enhancing beneficiary access to items and services under the competitive bidding program...". We also note that the comments that "CMS employs a wide range of resources to monitor the program, including beneficiary surveys, active claims surveillance and analysis, contract supplier reporting and tracking and analysis of complaints and inquiries." The CMS description of the monitoring of the program seems to be robust however, we recommend that the program should offer a special contract to an outside third party to specifically monitor oxygen delivery and devices. Our concern is for oxygen patients and the disruption and limited access that they will experience as a result of any changes CMS proposes.

CMS is requesting comments on testing or phasing in bundled payments where suppliers would submit one bid for the delivery of all equipment needed on a monthly basis; that would include supplies, accessories, maintenance and servicing. Currently, respiratory equipment covered under the competitive bidding program includes oxygen, oxygen equipment, supplies and accessories. Oxygen reimbursement is subject to a 36-month rental cap which the COPD Foundation opposed from the time it was proposed. The COPD Foundation believes that elimination of the 36-month rental cap we would be in the best interest of the oxygen patient.

Oxygen is already bundled as supplies and accessories are on a monthly rental payment and are not separately billed. Refills for oxygen contents are reimbursed with a monthly allowance and are not limited to supply allowances. Further bundling payment would simplify payments for CMS but would probably further restrict oxygen patient access if CMS does not provide for sufficient safeguards, documentation, oversight, and enforcement.

The COPD Foundation's mission is to prevent and cure Chronic Obstructive Pulmonary Disease and to improve the lives of all people affected by COPD. Currently some oxygen suppliers have discontinued and do not provide liquid oxygen which may be a necessity for a number of beneficiaries within their service area.

What the beneficiary needs:

- Patients with chronic lung disease require higher oxygen flows as their disease progresses.
- Lung disease patients find it difficult to exercise, to stay active, to keep the rest of their body strong, due to breathing difficulties.
- As the lung disease patient grows weaker, they become more susceptible to exacerbations, infections, pneumonia.
- Each exacerbation weakens the patient, thus increasing the oxygen demands, and often results in ER visits, hospital stays, and eventually, nursing home care.
- If the patient becomes homebound due to the unavailability of adequate supplies of oxygen or equipment that will deliver the necessary flow rate, the quality of their life and that of their caregivers will deteriorate, both physically and mentally.
- In order to remain socially active and maintain a decent quality of life, advanced lung disease patients must have access to high flow rates from a device that is small enough for them to carry.
- An oxygen-dependent patient should never venture away from home without some manner of backup oxygen supply.
- If a patient is using oxygen tanks, they must take enough tanks on any outing to last for the duration, plus a safety margin.
- Portable oxygen concentrators are available. However, they are expensive, and none of them will deliver a continuous oxygen flow over 3 liters per minute. Many advanced patients require a higher flow rate to ambulate.
- Under the present Medicare pricing program, the DME Competitive Bidding Program which has advanced to most major metropolitan areas and which is planned to encompass the entire country by 2016, the reimbursement rates to DME suppliers has been cut by almost half.
- In order to stay in business, DME suppliers must make a profit.
- In order to make a profit, DME suppliers are limiting the availability of liquid oxygen systems. It has been stated by suppliers that they are able to bill \$150 for services that cost them \$400.
- Suppliers are also switching customers from a supply of several tanks to a "home-fill" system, to avoid the costs of filling and delivery of the old tanks. Most patients given the new home-fill system are limited to two tanks.
- Durable Medical Equipment represents 1.4 % of Medicare expenditures.
- It is likely that 42% of these providers will go out of business, leaving all their employees without jobs.
- The program is designed to be more competitive, but it actually makes the market less competitive by putting local firms out of business and dramatically decreasing the number of providers competing for contracts.
- When local providers go out of business, patients will be forced to rely on providers located hundreds of miles away
- Patients will lose the sense of security that comes from their long-term relationships with their local caretakers, and from knowing that these local providers are available 24 hours a day.
- Patients will face delays in their services, and are at risk of having to wait long periods of time for services or equipment in case of a malfunction or other emergency.
- Patients are forced to go through multiple vendors for their services and equipment, a process that can be complicated and confusing for them
- Complaints to the COPD Foundation Info line show:
  - Many providers chose to discontinue liquid oxygen ranging from national durable medical equipment companies to smaller, more local providers.
  - 76% of complaints were specifically prescribed liquid oxygen by their doctors.
  - 83% of cases were not resolved and the patient was still unable to access liquid oxygen.
  - $\circ$  ~~ 28% of cases had reported the problem to the CMS Ombudsmen.

The DME Quality Standards under the Consumer Services section states:

"If the supplier cannot or will not provide the equipment, item(s), or service(s) that are prescribed for a beneficiary, the supplier shall notify the prescribing physician...or other health care team member(s) promptly within 5 calendar days."

## What Patients tell us:

"When these changes were proposed, my O2 company began to grumble. First they were short of M6 tanks and I could only have 6 at any given time. Then it was E tanks. It didn't help that I moved from one county to another during this time and from a building with an elevator to one without. Nobody likes toting 15 E tanks to 2 flights of stairs every 2 weeks so I am not sure if it's due to the changes in Medicare billing or just delivery problems that are ultimately responsible. The latest word is that I may not have more than 20 E tanks in any 30 day period. I am making this work for now by trying to ignore my bleeding nose but I know that it is unworkable when summer returns because I simply cannot run the concentrator in my very small un-air-conditioned apt during the summer."

"My DME has quit all service calls except 2 a year to change the internal filters on my concentrator. I was very rudely told that I could stop by the office to pick up any other supplies that I might need such as cannulas or whatever else. I have Lincare & they have all ways been less than satisfactory. Humana finally pushed them hard enough that they got me a concentrator on wheels instead of the tanks. I couldn't change from an empty to a full one without help."

"I had been an Apria customer for about 5 years. Used liquid O2 for mobility, gym exercise and all outdoor activities. I used a concentrator in the house. My O2 requirements are just 2-3 LPM most of the time indoors but they go up considerably with activity. This past summer, Apria informed me that they were exiting the liquid O2 business - at least for the customers served out of their South Bend office (I do not know if they have stopped supplying liquid O2 everywhere). After some discussions and arm-twisting, they agreed to fill my two 40 liter tanks one last time while I searched for an alternative supplier."

"I did find that Lincare, out of their Benton Harbor, MI office, would take me on as a liquid O2 customer so I switched in late summer. They have been very accommodating and told me that they did not expect to go out of the liquid O2 business, at least in Benton Harbor. It would be helpful to me to know if all the areas of the Country are going to be in the competitive bidding nonsense and if anybody has that data, I would appreciate getting it.

"We are "snowbirds" and go to Florida for the winter so one of my concerns has been "Would Lincare take care of my liquid O2 in Florida?" We arrived here last week and the next day they did fill my 21 liter tank but I am on a wait list for a larger 40 liter tank as well. So far, the switch to Lincare has been a plus but I have to say that Apria had been a great supplier up until they stopped the liquid."

"Hi! I'm in Boston. I've been attempting to switch from cylinders to liquid. So far, Apria has refused even though my doctor called them. I am on Medicare and unicare (a govt insurance plan)."

Obviously, this does not meet the oxygen suppliers' responsibility to furnish "what the beneficiary needs" and results in an extra burden and additional time to find one that does. If bundled payments are expanded to include all or a select number of DME items currently covered under competitive bidding, this problem will be exacerbated and put the patient at risk while a supplier who can furnish the necessary equipment and/or accessories and supplies is located. It can also cause additional confusion for the beneficiary as to who is responsible for locating the equipment that meets their needs. This becomes an even more critical when the accessories and supplies that are currently identifiable and separately paid become part of a bundled monthly payment. We request CMS address supplier accountability regarding this issue in future proposed rulemaking.

Bundled payment methodology will provide an incentive for oxygen suppliers to limit needed accessories and supplies, and reduce their scheduled service putting the patient in harms way. The current program is not straightforward enough to hold the supplies accountable for appropriate and necessary service to equipment.

Further we assume that bundled payment will discourage oxygen supply companies from obtaining new equipment. The result will be equipment that will be aging and require more maintenance while less is paid for service.

We are concerned that beneficiaries could be adversely impacted if there are no quality measures or standards to require suppliers to make contact with them regarding refills or replacement of non-consumable items under a bundled payment system.

The COPD Foundation recommends that CMS not move forward with a bundled payment system that would be applied nationwide. If CMS does move forward the primary concern should be that patient care is not disadvantaged or harmed in any way.

We appreciate the opportunity to comment on this advance notice and look forward to future proposed rulemaking on the subject in which more details are provided.

Sincerely,

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John W. Walsh President