



Competitive Bidding Surveys - Request for Public Comments

December 20, 2019

The undersigned organizations appreciate the opportunity to submit comments to CMS on questions that should be asked of key stakeholders to strengthen the agency's ability to monitor and enforce the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program and to increase its effectiveness in contacting referral agents.

Of general concern is the need for more transparency from CMS on issues that have been reported regarding beneficiary complaints relative to competitively bid products and follow-up actions by CMS to address the issues. Often CMS will suggest that if a complaint has been handled, it is not an issue; yet, surveys conducted by patient advocate groups, the pulmonary community and even the home care industry show otherwise. Using a dedicated email address to submit comments on potential survey questions obviates the need to issue a notice in the Federal Register whereby CMS is required to address the comments and prepare a response. In the past, surveys have been announced in the Federal Register as part of Agency's Information Collection Activities. If CMS is serious about improving its ability to monitor and enforce the competitive bid program absent a Federal Register notice, we strongly urge CMS to publish the final survey instrument on its website and respond publicly to comments received in response to this request.

While we appreciate the latest report¹ from the Medicare Competitive Acquisition Ombudsman (CAO) in which selected DMEPOS access issues are discussed, e.g., liquid oxygen, that is just one aspect of understanding the significance of the problems reported. Prior to 2012, we question why reports from the CAO were issued annually and the latest one covered a period of 4 years. It is important to know from year to year the impact of the competitive bidding program; a report every 4 years is inadequate to identify the issues and to inform the public on actions taken to resolve them satisfactorily. If CMS has already established baseline data from previous surveys, it should be publicly available. We would note that the Medicare CAO's reports from 2009, 2010, and 2011, listed as downloads on CMS 'CAO webpage, are no longer accessible. Being able to compare the earlier year results in comparison to the latest available data is crucial to show whether progress has been made over the years.

Our comments and survey questions focus on oxygen and oxygen equipment and are discussed below.

Beneficiary Questions Related to Use of Oxygen Systems

Part of the survey instrument is intended to provide CMS with answers to questions that will inform the agency of the extent to which Medicare beneficiaries have problems with their equipment, costs they

¹ <https://www.cms.gov/Center/Special-Topic/Ombudsman/2012-2016-Report-to-Congress-Medicare-Competitive-Acquisition-Ombudsman-.pdf>

have incurred out-of-pocket, and satisfaction with the services provided by their home medical equipment suppliers. Our organizations are particularly concerned with beneficiary access to liquid oxygen.

Medicare claims data reveal a devastating decrease in liquid oxygen since the inception of the program through 2016, the latest data we evaluated. It is generally acknowledged that the creation of new oxygen classes for those individuals who need 4 liters or more of oxygen will not change the situation. Representatives Lewis and Stewart, Co-Chairs of the COPD Caucus, called for CMS to provide an update on policy steps the Agency is taking to ensure all Medicare beneficiaries receive access to medically necessary liquid oxygen systems during the current “gap” in competitively bid contracts and to track beneficiary access during the first six months of the gap period. The findings were to be reported before December 2019 and we are anxiously awaiting the results. New survey questions need to expand on this issue to ensure enforcement issues are addressed during the next round of competitive bidding that begins January 1, 2021.

We suggest CMS consider the following questions to use in developing its survey instrument. Some of these questions, while related to oxygen, may also apply to other items of DMEPOS.

Oxygen Prescription

- What was the amount of oxygen flow rate in liters per minute your doctor prescribed to maintain an appropriate oxygen saturation rate? 1 liter or less, 2 liters, 4 liters, 6 liters, greater than 6?
- If you first received oxygen in the hospital, did you experience a delay in being discharged because your oxygen system could not be delivered timely by a home medical equipment supplier?
- How long did you have to wait for your doctor’s prescription to be filled by a home medical equipment supplier?
- Have you had to track down an order from your supplier to find out why you didn’t receive your oxygen equipment?
- Does the oxygen equipment you received comply with your doctor’s prescription? If not, what is the discrepancy? How was the issue resolved?
- Does the oxygen system meet your needs and allow you to function as you and your doctor believe you should be functioning?
- Did the supplier who provided your equipment tell you they did not have the item prescribed in inventory, and provided you with another system they said was comparable? If yes, did it meet your oxygen and activity level needs? Your doctor’s prescription?
- If your supplier could not supply the type of oxygen system your doctor ordered, did they find another supplier who could? If so, how long did it take to get the equipment?
- Have you been asked to agree to a change in your oxygen system? If so, for what reason?
- Have you received a full listing with complete specifications of any and all equipment your supplier is offering for replacement that meets your needs and allows you to continue to have an active life?

- Have you ever been given a different oxygen system due to the prior system not meeting your clinical or activity needs?

Education and Training

- When your oxygen equipment was delivered to your home, did you and/or your caregiver receive education and training on how to use it properly? If yes, did a medical person such as a nurse or respiratory therapist (e.g., a specially trained visit you in your home to check on your oxygen needs?
- If you have more than one oxygen tank, were you educated regarding safe and secure storage of tanks at home and while traveling in automobiles, and other conveyances?
- If multiple oxygen tanks were delivered, did the supplier secure them safely by using a rack or stands to make sure they cannot fall over?
- Were you educated by the supplier on conforming to local fire marshal, National Fire Protection Association, or the Compressed Gas Association's rules for safe use and storage of oxygen tanks?
- Did you understand the information you were given about your equipment?
- If you had questions, were all of them addressed to your satisfaction?

Liquid Oxygen

- Do you have a need for continuous or high-flow oxygen that requires use of a liquid oxygen system? If yes, what is the liter flow required to maintain your oxygen saturation rate?
- Do you use both portable and stationary liquid oxygen? If so, how often is it delivered by your supplier?
- Were you educated by your supplier on safe storage and use of liquid oxygen systems both at home and when traveling ?
- Have you been told by your supplier that they will no longer furnish liquid oxygen? If yes, what was the reason given for not providing the liquid?
- If you have been prescribed a liquid oxygen system that best meets your clinical and activity needs and the supplier will not provide it, has your supplier found one who will furnish it?
- If your doctor writes a prescription that requires liquid oxygen and the supplier cannot provide it, have you been asked by the supplier to go back to your doctor to get another prescription?
- If you use or were using a liquid oxygen system, have you been asked to request a change in your prescription in order to switch to a less expensive non-liquid system? Has your doctor been asked to do so?
- If you have been provided with an oxygen system in lieu of liquid oxygen, have you experienced breathing problems or limitations in your typical activities of daily life as a result?

Supplier Issues

- What is the name of the home medical equipment supplier (e.g., company) you use to get oxygen?
- Were you given a choice of suppliers when first prescribed oxygen ? If so by whom?
- Did your home medical equipment supplier provide you with enough contact information for you to reach someone if you have a problem?
- Are you satisfied with the amount of time your supplier spends with you or answers your questions?
- If you had questions about your equipment after it was delivered, did you get a satisfactory response from your supplier? How long does it typically take to get your question answered to your satisfaction?
- Have you received from your supplier, or been asked to purchase, any items you did not want or need? What items? How was the issue resolved?
- Are you aware there is a 1-800-MEDICARE number you can call to register complaints about the service you receive? If so, have you used it to file a complaint? If not, why not? Did the person who handled your complaint resolve it to your satisfaction? If not, please explain.

Equipment Problems

- If you've experienced problems with your oxygen equipment, list the types of problems you have encountered.(i.e., oxygen tank storage, too many oxygen tanks to load and transport, equipment too heavy, limits my activities, etc.).
- If you received faulty equipment and filed a complaint, how soon was the equipment replaced or repaired? If delayed what reason was given?
- How many times in the past 3 months have you had to contact your supplier because of problems with the equipment?
- If you have contacted someone to report the issue, if so who? What occurred during these interactions?
- If you reported problems with your oxygen equipment, did the issue get resolved to your satisfaction? If yes, how long did it take to resolve the issue to your satisfaction? If you do not feel your issues were resolved to your satisfaction, please explain.
- Have the issues related to oxygen you have experienced, or are still experiencing, affected your health, activity level and/or quality of life? If so, please explain.
- Have you experienced problems with your oxygen equipment that caused you to stop using it? Please explain. Did you request a different oxygen system in order to solve the problem(s)? Were you required by the supplier to purchase additional pieces of equipment?

Out-of-Pocket Expenses

- Have you purchased a portable oxygen system online or one that you've seen advertised on TV? If so, how much did you spend? How long did it take to receive it?
- If you purchased your own portable oxygen system, what is the reason you did so as opposed to getting it through Medicare if you are eligible ?
- Before using your online purchase, did you consult with your doctor regarding any setting changes, since portable systems may have different outputs depending on brand and type?
- Have you had to dispute your copay or had copays that you believe exceeded the 20% Medicare coinsurance rate?

Maintenance and Servicing

- In the first 3 months after you got the oxygen equipment you now use, how often did a nurse or respiratory therapist come to your home to check on how you are doing and if you getting enough oxygen?
- In the first 3 months after you got the equipment you use now, how often did your supplier send someone to check on the equipment?
- Did your supplier send someone to do routine maintenance on the equipment after the first 3 months?
- If your oxygen system needs maintenance or repair, how long have you usually had to wait for it to be fixed or replaced? If delayed, what reason was provided to you?
- Are you required to pick up equipment, such as oxygen tanks, sieve bed replacements, batteries etc.?
- For the equipment you have now, do you get your equipment, supplies, maintenance and repairs from more than one equipment supplier? Are they supplied in a timely manner? Are you being asked to pick up replace parts, or supplies?

Supplier Questions Related to Oxygen Systems

Enforcement of competitive bidding contracts is of interest to our organizations. Medicare's DME Supplier Standards and DME Quality Standards lay out requirements that home medical equipment companies must meet in order to be a licensed and accredited supplier. When it comes to enforcing these standards, as well as other issues that may relate to competitive bidding, the public is rarely provided insight as to what actions CMS takes to resolve the issues when a supplier is out-of-compliance. If CMS is interested in strengthening its enforcement mechanisms, it would benefit the public to know how they have enforced rules in the past relative to how they plan to do better in the future as a result of this new survey instrument.

Before the gap period began, it was reported that a couple of suppliers required to furnish liquid oxygen were not doing so as required by their contract. According to the latest CAO report, the CAO worked to bring the issue to the attention of CMS staff who in turn reminded the suppliers of their contractual obligations to supply all products under the oxygen product category as prescribed, including liquid oxygen. Subsequent to this action, CMS staff confirmed that affected beneficiaries were able to obtain the products they needed. Did CMS follow-up later within a reasonable timeframe to ensure that other beneficiaries within the suppliers competitive bid area were receiving liquid oxygen if medically necessary? Does CMS only act to enforce a violation if it is reported to them? What, if any, repercussion does a supplier face if they violate the rules. Could a contactor continue to be in violation of certain DME rules if no one reports them? There needs to be a validation process during a contract year to ensure compliance. Survey results should specify the specific situations and types of actions CMS plans to take to improve enforcement.

We suggest CMS consider the following questions for suppliers to use in developing its survey instrument.

Contractual Obligations

- Prior to the suspension of competitive bidding, if your competitive bid contract requires you to provide liquid oxygen, have you refused to do so? If so, why.
- Have you sent letters to your oxygen customers telling them you will no longer furnish liquid oxygen? If yes, what was the reason?
- Do you follow the AARC Clinical Practice Guidelines listed in the DME Quality Standards? If not, please explain.
- Does the law in your state require the clinical services of a respiratory therapist in the home?
- How many times have you had to find another supplier for your clients because you do not offer the oxygen system prescribed by their physicians?

Education and Training

- How often do you go into the home to check on your oxygen clients to ensure they are using the device(s) properly? Who provides the service?
- Who in the company provides education and training to beneficiaries regarding safe use of oxygen tanks including storage and transport? Do they follow up to assure compliance?
- Do you employ respiratory therapists to provide training and education on oxygen systems?
- What standards or education do you use to ensure that an individual's use of equipment will be safe and not cause potential risks, such as falls? Example: Putting an oxygen tank on the front of a walker that is unstable and could tip over.
- Do you provide safe and secure storage racks or stands when delivering more than one oxygen tank?

- Does your safety education conform with local fire marshal policy?
- Do you provide instruction on the safe transport of oxygen tanks in automobiles and other conveyances?
- Do you make beneficiaries aware of the risks associated with transport of oxygen tanks?

Prescription Requirements

- How long does it take for you to fill a doctor's prescription for oxygen from the time of receiving it?
- If fulfillment is delayed, is the beneficiary and the doctor notified? If so, what process do you follow?
- What are typical reasons for delay? (i.e. forms not completed, equipment not in inventory, etc.)
- Do you require beneficiaries to pick up extra oxygen tanks, replace batteries, sieve beds, nasal cannulae and other supplies?
- Do you supply the extra battery and extra charger at the time of the original drop off? If not, why? How long does it take you to get these items to the patient?
- Do you require patients/caregivers to pick up tanks?
- Do you limit the number and/or type of tanks that patients can have? How is it determined?
- Do you limit the number of batteries patients can have? How is it determined?
- Do you require patients/caregivers to pick up other oxygen equipment, such as batteries and chargers?
- If an individual's oxygen equipment needs to be replaced, do you provide a written list with full specifications of all the available oxygen systems you have to offer?
- If a medical provider and patient determine that the patient should NOT switch systems, will you comply with said determination?

Complaints

- How do you resolve disputes and complaints from patients/caregivers about provision of oxygen systems, equipment and accessories?
- What is the most common complaint you receive from patients?
- On average, how long does it take you to resolve a complaint?
- How many complaints did you receive about the provision of oxygen and oxygen equipment prior to the implementation of competitive bidding versus complaints received up to and including 2019?

Our organizations appreciate the opportunity to provide input for CMS 'proposed survey. Access to appropriate oxygen and oxygen equipment that meets the needs of the beneficiary is important to all of us. We encourage CMS to enhance its transparency with respect to forms of information it collects

regarding the competitive bidding program. It is vital that the public be made aware of the issues that come before the agency and the methods it uses to address and resolve them.

American Association for Respiratory Care

American Lung Association

American Thoracic Society

COPD Foundation

National Association for Medical Direction of Respiratory Care

U.S. COPD Coalition