



September 6, 2018

Seema Verma
 Office of the Administrator
 Centers for Medicare & Medicaid Services
 Department of Health and Human Services
 Attention: CMS-1691-P
 200 Independence Avenue, SW
 Washington, DC 20201

Re: RIN 0938-AT28

Dear Administrator Verma:

The national organizations listed below appreciate the opportunity to submit comments on CMS-1691-P, the proposed rule for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) for Calendar Year 2019. This group represents the nation's patients, providers, caregivers and interested stakeholders collectively focused on delivering optimal care for those with lung disease. As you are aware, chronic lung disease is the third-leading cause of disease-related death in the U.S.¹ and accounts for over \$64

¹ Centers for Disease Control and Prevention. National Center for Health Statistics. CDC WONDER On-line Database, compiled from Compressed Mortality File 1999-2016 Series 20 No. 2V, 2017.

billion in direct medical costs annually.² While more than 33.6 million Americans have been diagnosed with a chronic lung disease,³ spirometry tests showing impaired lung function suggest many more cases may be undiagnosed.^{4,5} Our organizations represent and treat the hundreds of thousands of Americans who rely on DME oxygen, and we applaud the agency for recognizing the significant issues related to the access of necessary supplemental oxygen and look forward to working with you to improve the marketplace for all stakeholders to ensure patients receive the oxygen care they need.

While most of our comments focus on Section VII of the proposal, “New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes” (83 FR 34383), we also are providing comments related to other aspects of the proposed rule that impact access to medically appropriate oxygen systems which, in general, are not functioning optimally. The current oxygen system is based on archaic statutory provisions that have the effect of pushing CMS to implement a benefit that impacts millions of Medicare beneficiaries in a framework that is no longer efficient.

Our organizations provide recommendations to CMS on ways to use its statutory authority to address the unique problems posed by providing liquid oxygen, while also ensuring that the needs of the overwhelming majority of beneficiaries who require supplemental oxygen are also met and improved. We welcome the opportunity to discuss these issues in greater detail with agency officials.

Our organizations also urge that as CMS continues its review of competitive bidding and during suspension of competitive bidding, that every necessary measure is taken to ensure that patients are never without their supply of oxygen. People who use supplemental oxygen depend on it for their survival and simply cannot afford to risk interruption during any transition. We ask CMS to develop and publicize specific mechanisms that will be put in place to monitor the transition and to respond rapidly and effectively if any losses or interruptions in providing supplemental oxygen to patients occurs during this transition period.

² U.S. Department of Health and Human Services. National Institutes of Health. National Heart Lung and Blood Institute. Fact Book Fiscal Year 2012. 2013. Page 52.

³ Centers for Disease Control and Prevention. National Center for Health Statistics. National Health Interview Survey, 2016. Analysis performed by the American Lung Association Epidemiology and Statistics Unit using SPSS software.

⁴ Tilert T, Dillon C, Paulose-Ram R, et al. Estimating the U.S. Prevalence of Chronic Obstructive Pulmonary Disease Using Pre- and Post-Bronchodilator Spirometry: The National Health and Nutrition Examination Survey (NHANES) 2007–2010. *Respiratory Research*. 2013; 14(1):103.

⁵ United States Census Bureau. Population Estimates, 2009.

Below is a list of the topics we will address in our comments.

1. Reduction in Access to Liquid Oxygen
2. Clinical Issues Associated with High-Flow Oxygen/Liquid
3. Issues Related to Service Costs and Statutory Restrictions that Impede Access to Clinically Appropriate Oxygen Systems
4. Detailed Recommendations
5. Additional Comments

Reduction in Access to Liquid Oxygen

We commend the agency for its recognition of numerous problems associated with beneficiary access to oxygen in general and particularly liquid systems. Several of our societies and organizations have met with agency officials over the past decade in an effort to remedy this specific liquid oxygen access issue (in addition to other issues), and we are encouraged by CMS' recognition of this important component of the oxygen therapy benefit.

Liquid oxygen is an important option for people who need high liter flows of oxygen, usually greater than 6 liters per minute. Liquid oxygen is most often prescribed for patients with advanced Chronic Obstructive Pulmonary Disease (COPD), pulmonary fibrosis or other severe lung disease. Home based systems often require ancillary humidification systems uniquely designed for high flow therapy. Without access to sufficient quantities of portable liquid oxygen, patients who require a high liter flow cannot leave their homes, which jeopardizes their physical health, mental health and quality of life, and limits or prohibits their ability to continue working.

A review of Medicare data illustrates the problem both in terms of access and expenditures. We provide two tables of Medicare data that document this issue.

Medicare LOX Stationary 2004-2016

| Liquid Stationary (E0439) | | | |
|---------------------------|-----------------|---------------|-----------------|
| YEAR | CHARGES | CLAIMS | PATIENTS |
| 2004 | \$153,508,470 | 737,321 | 61,443 |
| 2005 | \$143,814,414 | 724,639 | 60,387 |
| 2006 | \$136,594,841 | 682,936 | 56,911 |
| 2007 | \$130,285,460 | 653,005 | 54,286 |
| 2008 | \$134,480,871 | 670,925 | 55,910 |
| 2009 | Transition year | | |
| 2010 | \$67,355,848 | 386,645 | 32,220 |
| 2011 | \$59,497,447 | 349,775 | 29,148 |
| 2012 | \$46,893,878 | 271,233 | 22,603 |
| 2013 | \$31,983,339 | 199,486 | 16,624 |
| 2014 | \$19,536,044 | 136,656 | 11,388 |
| 2015 | \$10,829,115 | 99,252 | 8,271 |
| 2016 | \$7,482,476 | 71,377 | 5,948 |

Medicare LOX Portable 2004-2016

| Liquid Portable (E0434) | | | |
|-------------------------|--------------|---------|----------|
| YEAR | CHARGES | CLAIMS | PATIENTS |
| 2004 | \$33,337,087 | 966,846 | 80,571 |
| 2005 | \$32,000,258 | 990,322 | 82,527 |
| 2006 | \$30,993,007 | 977,251 | 81,438 |
| 2007 | \$29,158,453 | 917,702 | 75,933 |
| 2008 | \$28,199,074 | 887,309 | 73,942 |
| 2009 | \$15,756,604 | 547,900 | 45,658 |
| 2010 | \$14,127,684 | 491,253 | 40,938 |
| 2011 | \$12,439,576 | 442,027 | 36,836 |
| 2012 | \$9,728,130 | 337,668 | 28,139 |
| 2013 | \$6,814,689 | 250,125 | 20,844 |
| 2014 | \$4,368,905 | 173,161 | 14,430 |
| 2015 | \$2,455,215 | 128,727 | 10,727 |
| 2016 | \$2,020,306 | 97,690 | 8,141 |

While liquid systems have never been a significant expense, these data clearly demonstrate the dramatic decline in access to liquid oxygen since the implementation of the competitive bidding program. Beneficiary use of stationary liquid systems dropped from nearly 56,000 patients using stationary liquid oxygen systems in 2008 prior to competitive bidding to 16,000 in 2013. The most recent data show that fewer than 6,000 beneficiaries were able to secure stationary liquid systems in 2016, a six-fold decrease since implementation of competitive bidding. For additional context, in 2004, stationary liquid oxygen accounted for 1.2 percent of total DMEPOS and 5.8 percent of total oxygen supplies and equipment. In 2016, stationary liquid was 0.4 percent of total DMEPOS and less than 4 percent of total oxygen.

The same pattern exists for access to portable liquid systems. In 2008, prior to competitive bidding, approximately 74,000 beneficiaries had access to portable liquid systems; the first year of competitive bidding that number dropped to just under 41,000. In 2016 the number of beneficiaries with access to portable liquid systems has dropped to 8,141. For additional context, in 2004, portable liquid oxygen accounted for 0.3 percent of total DMEPOS and 1.36 percent of total oxygen supplies and equipment. By 2016, portable liquid had dropped further to constitute 0.1 percent of total DMEPOS and 0.7 percent of total oxygen supplies and equipment.

As provider and patient organizations, we can state with confidence that there has not been a change in respiratory disease patterns that would explain the sharp decrease in utilization of liquid oxygen systems. No differences or advancements in treatment of respiratory disease can explain the decrease; nor has there been a new “disruptive” innovation or technology that has pushed liquid oxygen systems aside for a more novel technology.

We believe there are several reasons for this dramatic decline in liquid modalities:

- 1) Insufficient payments. CMS acknowledges that the difference in payment between stationary oxygen (both compressed and stationary concentrators) and liquid stationary and portable equipment has led to a substantial difference in use. CMS states: “The higher payments and incentives for furnishing OGPE [oxygen generating portable equipment] have in essence created a disincentive to furnish portable liquid equipment.” As early as 1997, the then-General Accounting Office (GAO) examined payment reductions for supplemental oxygen therapy and stated, “The upcoming reduction in Medicare payment rates, however, could lead some suppliers to shore up their profits by offering only oxygen concentrators for stationary systems, which would also reduce access to liquid portable refills from stationary units.”⁶ In its 2011 report, GAO further documented beneficiary access challenges and the effect of decreased payments to liquid oxygen systems.⁷
- 2) Aspects of the competitive bidding program. While competitive bidding contracts stipulate that a winning bidder must provide liquid systems when ordered by a physician who provides documentation of medical necessity, suppliers fail to comply in many instances⁸. In those instances, it is unclear what enforcement policies CMS has in place to address the issue. For instance, when a beneficiary shifts from a liquid system to another modality, does CMS surmise that this is an integral part of the standard of care?
- 3) Innovative technologies. New oxygen generating technologies have re-shaped the industry into a “non-delivery model” of services. As new technologies such as portable oxygen concentrators and transfill systems came to the marketplace, suppliers quickly learned that compressed cylinders and liquid reservoirs/portable systems did not align with the new “non-delivery model.” The notable expense of a driver and DOT approved delivery vehicle (truck/van) was no longer a necessity, and the industry was able to re-invent the way oxygen systems are now provided to beneficiaries.

Delivery models, especially those providing liquid oxygen, require far higher capital costs, more frequent deliveries, and more sophisticated operations that understandably increase service costs. Simply stated, liquid systems for Medicare beneficiaries who have been prescribed such systems have undoubtedly become challenging to suppliers because of the need for ongoing visits to the beneficiary’s home. It is virtually impossible to enjoy “the economy of scale” in the provision of liquid systems, a reality well recognized by physicians, patients and suppliers alike.⁹ In the aforementioned report to Congress,

⁶ GAO Report to Congress. Home Oxygen Program Warrants Continued HCFA Attention. November 1997.

⁷ GAO Report to Congress. Refining Payment Methodology Has Potential to Lower Program and Beneficiary Spending. January 2011.

⁸ GAO Report. Information on the First Year of Nationwide Reduced Payment Rates for Durable Medical Equipment. July 2018.

⁹ *Ut supra, at 1*

GAO noted even in 1997 that the vast majority of oxygen suppliers received less than 5 percent of their Medicare revenue from liquid systems.¹⁰

While we acknowledge that pricing of oxygen was problematic for numerous reasons, not the least of which is a statutorily mandated payment methodology that does not account for evolving technologies, the competitive bidding program has failed to ensure appropriate access to liquid oxygen systems for patients whose providers have prescribed this therapy. This access failure was documented recently in a study conducted by the American Thoracic Society’s Nursing Assembly (ATS Survey). While not designed to measure the impact of competitive bidding on beneficiaries, the study found not only a lack of access to portable oxygen systems but also lack of education, instruction and support that led to poor patient outcomes.¹¹ Thus, while we appreciate CMS has proposed positive changes to the pricing of liquid oxygen systems, we believe challenges in the oxygen market extend beyond just the liquid oxygen market, as demonstrated by the chart below, excerpted from the ATS study.

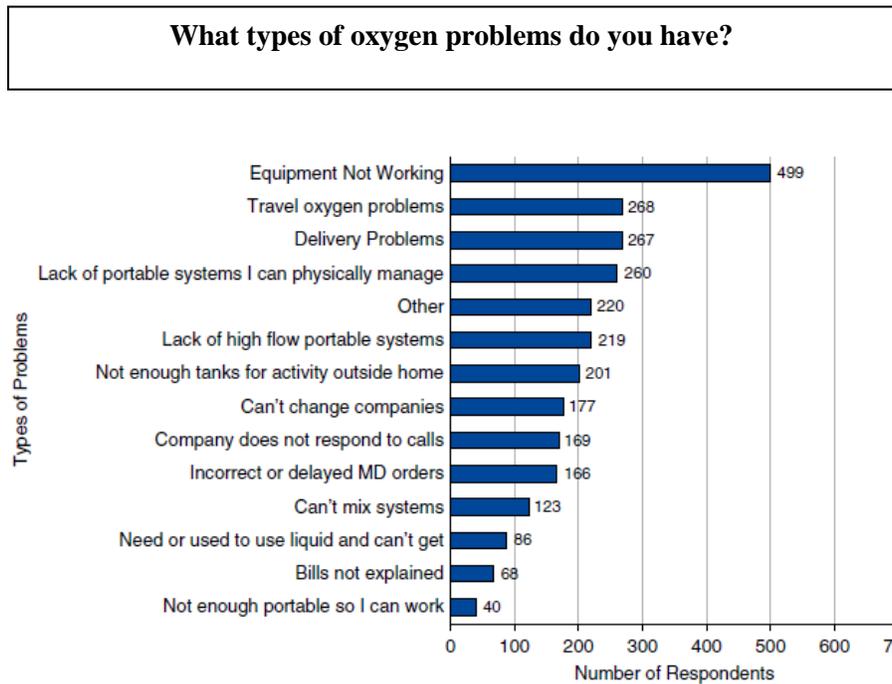


Figure 2. Frequency of types of oxygen problems reported by respondents who replied “yes” to having oxygen problems (n = 899; able to check more than one response).

CMS recognizes the current disincentives and lack of requirements in certain cases deter competitive bidding contract suppliers from providing liquid oxygen systems. In the proposed rule, CMS believes the increase in payments to mirror OGPE would

¹⁰ Jacobs SS, et al. Patient Perceptions of the Adequacy of Supplemental Oxygen Therapy: Results of the American Thoracic Society Nursing Assembly Oxygen Working Group Survey. *Ann Am Thorac Soc.* 2018;15(1):24-32.

¹¹ *Ut supra*, at 3.

“eliminate” such access issues vis a vis OGPE. While we agree that financial disincentives deter providing appropriate oxygen modalities, we disagree that increasing payments to match OGPE would eliminate or even substantially modify the disincentive. In this situation, and under the principles of budget neutrality, it is inconceivable to properly reimbursement suppliers without forcing significant harm to other oxygen modalities (i.e., it is not possible to rob Peter enough to sufficiently pay Paul) and therefore other oxygen patients.

- 4) Lack of enforcement: We believe there is a huge disconnect between statutory requirements, contractual requirements, and the actual delivery of supplemental oxygen therapy in general, and more specifically as it relates to liquid oxygen. Competitive bidding contracts stipulate that suppliers MUST provide liquid when ordered by a physician and is clinically justified by that physician.

A recent GAO report found that some oxygen suppliers no longer provided liquid oxygen to beneficiaries, and also noted that four of the DME trade associations admitted that patients have been delayed in leaving the hospital because DME suppliers could not provide the DME needed by the patient.¹²

Medicare claims data document the total failure to ensure that access and while our organizations are very pleased that CMS has taken note, we are troubled about the delay in this acknowledgement. It is simply not possible that the drop in the number of patients receiving stationary liquid systems went from nearly 56,000 in 2008 to under 6,000 in 2016 due to changes in the standards of care for advanced COPD, pulmonary fibrosis and related diseases that could have changed so dramatically that would explain such a precipitous drop. It is equally as implausible that the drop in the number of patients receiving portable liquid systems from nearly 74,000 in 2008 to 8,000 in 2016 reflects some sort of change in the standards of care for advanced COPD, pulmonary fibrosis and related diseases that would explain such a precipitous drop. The evidence is irrefutable that these drops in access correlate to pricing driven by competitive bidding.

Clinical Issues Associated with Various Aspects of the Home Oxygen Benefit

From its comments, CMS clearly appreciates the uniqueness of liquid oxygen systems, which have revolutionized oxygen delivery; in the case of portable liquid devices, these new systems have provided the opportunity for critically important ambulation outside the home for a distinct set of Medicare beneficiaries.¹³ Liquid systems are singularly able to provide continuous oxygen

¹² GAO Report. Information on the First Year of Nationwide Reduced Payment Rates for Durable Medical Equipment. July 2018

¹³ Emter M. et al. Benefits of Supplemental Oxygen in Exercise Training in Nonhypoxemic COPD Patients. *Am J Respir Crit Care Med.* 2003;168(9):1034-42; Rabe KF, Hurd S, Anzueto A et al. Global initiative for chronic obstructive lung disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: GOLD executive summary. *Am J Respir Crit Care Med.* 2007;176:532-555; Nici L, ZuWallack R. American Thoracic Society Subcommittee on Integrated Care of the COPD Patient. An Official American Thoracic Society Workshop Report: the integrated care of the COPD patient. *Proc Am Thorac Soc.* 2012 Mar;9(1):9-18.

at high-flow rates, a feature that neither portable oxygen concentrators nor transfill systems are able to provide. The distinction between “continuous” flow rate and “intermittent” or “pulse” dosing is not a nuance; rather, it is a distinction that is critical for certain beneficiaries who cannot adequately saturate with intermittent/pulse dosing. These narrow and select patient populations, particularly those experiencing advanced COPD, pulmonary fibrosis and other interstitial lung diseases, require continuous high-flow oxygen to meet their clinical needs. Continuous flow/liquid oxygen is these patients’ **singular** treatment option. It is also important to emphasize that for many of these patients, the standard of care includes appropriate levels of exercise, and it is clear that if a portable liquid system is unavailable, the Medicare beneficiary experiences **substandard care**.

Of significant concern is the continued statutory policy linking liter flow to payment. Historically, prior to the advent of current technologies, it was understandable that oxygen, as a commodity, had its payment based upon quantity delivered. But that payment structure is antiquated and has become problematic in today’s oxygen technologies. As a concept, there is no clinical justification for this mandate. Moreover, the business justification ended decades ago. The unequivocal standard of care today, as it has been for two decades, is “titrate to saturate.” In its simplest description, a Medicare patient should be titrated on the specific type of device he/she is going to use to determine what flow achieves appropriate saturation. A setting of “2” on a stationary concentrator, or any device for that matter, does not necessarily translate to a 2 liter per minute flow rate. The statutory concept that 2 liters per minute is a baseline does not correlate to any clinical justification and has the impact of arbitrary flow rates because of statutorily mandated payment formulas, a reality that has the effect of patients receiving the appropriate flow rate almost by accident rather than clinical intent.

Researchers have submitted a grant proposal to the National Heart, Lung and Blood Institute to more closely examine the relationship between hospitalizations and COPD exacerbations. A preliminary snapshot review of Medicare data (one year) for 200,000 beneficiaries hospitalized for a COPD exacerbation indicate about one-third of those beneficiaries received supplemental oxygen in the preceding 30 days. Moreover, this group has a 24 percent greater likelihood of re-hospitalization or death within 30 days, compared to those who were not receiving supplementary oxygen. For the two thirds who did not receive oxygen, the percentage of risk of re-hospitalization or death dropped to 20 percent.

There is an important subset of this group that the researchers are still studying, analyzing data. For the third of the 200,000 who were hospitalized due to a COPD exacerbation AND received oxygen, 6 percent experienced an interruption of oxygen services post-discharge. This group experienced an increased risk of 47 percent for readmission/death, compared with those who did not have such an interruption of access to oxygen. For this group, the risk was 22 percent.

RECOMMENDATIONS

We have several recommendations related to specific policies raised in the proposed rule and we also provide recommendations in matters indirectly tied to policies related to oxygen therapy that are not directly raised in the proposed rule.

Recommendation 1: Payment of Liquid Oxygen

As noted in detail above, the proposed increase in payment for liquid oxygen and creation of a separate class does not provide a sufficient response to the degradation of this important provision of patient care. While we appreciate CMS' acknowledgment of a serious problem with the differences in payments, a mere equity in payments for OGPE and liquid systems fails to provide adequate compensation necessary to attract sufficient numbers of suppliers to return to the business of liquid oxygen. As noted above, the "non-delivery business model" simply cannot apply to liquid oxygen, and to force these two business models into the same payment methodology would continue to present a logical challenge.

There is a relatively narrow group of patients who must receive high flow oxygen because of their specific medical condition. In the home, that need can often, but not unilaterally, be met by some stationary concentrators. Outside the home, the only viable clinical option is a liquid system. Secondly, there are some patients where the ordering physician has determined that liquid is best suited for the patient, and that medical determination, accompanied by documentation of medical necessity, needs to be acknowledged by providing the patient liquid oxygen. In addition, patients at relatively high altitude, Denver for example, may experience notable desaturation that can only be addressed by liquid systems.

According to Medicare 2016 data, the total number of stationary concentrator users was 686,000, resulting in \$840 million in allowed charges. Given these limited and relatively narrow populations (and documented by Medicare data) compared to the much larger universe of Medicare beneficiaries utilizing supplemental oxygen, **we recommend that CMS entirely remove liquid oxygen systems from the competitive bidding program and return it to the fee schedule payment methodology under durable medical equipment.** This recommendation is supported by statute, clinical evidence, and should be accompanied by certain coverage rules to preclude any "gaming" of the payment system:

There is a statutory basis for this recommendation:

- *Sec. 1847(3)(B) of the statute establishing the competitive bidding program provides that "In carrying out the programs under this section, the Secretary may exempt... (B) items and services for which the application of competitive acquisition is not likely to result in significant savings¹⁴."*

As demonstrated in the above charts, liquid oxygen systems indeed represent a financially insignificant part of the overall supplemental oxygen benefit. As shown above, in 2016, stationary and portable liquid systems constituted a small percentage of all DMEPOS as well as a

¹⁴ SEC. 1847. [42 U.S.C. 1395w-3]

small percentage of all oxygen systems. Those percentages are reflected in outlays that do not warrant inclusion because there is no potential for *significant savings*. CMS in fact recognizes this in its proposal to increase payments for portable liquid systems in stating, “[W]e do not expect this change to result in a dramatic increase in the use of portable liquid oxygen equipment, and so we do not believe the budget neutrality offset would be significant.” In addition, in proposing a new ‘Liquid High Flow’ class, CMS states that it “expect[s] that this change will have a very minimal impact on expenditures due to the limited number of beneficiaries who require a high flow rate for oxygen and can still ambulate.”

Given this acknowledgement by CMS that neither liquid oxygen nor high flow liquid meets the statutory requirement for “significant savings,” a total carve out of this segment of the oxygen benefit is within current law and, conversely, we argue keeping these narrowly focused systems within competitive bidding is a violation of Section 1847(3)(B).

We recognize the possibility that other interested parties could make their own arguments for such a carve out. To preclude the possibility of arbitrary decision-making, we urge CMS to define “significant savings,” perhaps with a specifically defined threshold, to ensure competitively bid items actually generate such savings **without** negative impact to access and quality of care.

If CMS chooses not to pursue this approach, an alternative that would afford the agency the opportunity to not only set the payment rates for these modalities AND frame this approach within time constraints, CMS has the authority to establish a demonstration project with a 24- or 36-month duration. This would give the agency ample time to develop important data and also join the broad pulmonary community in shaping updates to current law. However, we recognize that such an approach would likely take the agency 6-9 months to develop, a lag time that would have the effect of continuing to inhibit access to clinically needed supplemental oxygen.

There is strong clinical evidence supporting these recommendations. The number of Medicare beneficiaries requiring liquid oxygen for the clinical reasons cited above is quite small; our data suggests 40,000-50,000.¹⁵ This estimate is reflective of discussions with pharmaceutical companies that have extensive research on these narrow populations (pulmonary fibrosis, advanced COPD, etc.) as well as data provided by some of the societies referenced in our introduction and our analysis of Medicare data. Clearly, the percentage of claims at the 4+ liter flow is a very small percentage of all claims, a verification of the size of this population (QF modifier).

Coverage rules are needed to support these recommendations. Fundamentally, we believe it is virtually impossible for CMS to enforce its competitive bidding requirement that suppliers provide liquid systems when ordered and medical necessity is documented.

On the presumption that payment for liquid would increase substantially, it is important that CMS establish formal inclusionary/exclusionary criteria to ensure that only beneficiaries with a

¹⁵ Esposito DB, Lanes S, et al. Idiopathic pulmonary fibrosis in United States automated claims. Incidence, prevalence, and algorithm validation. *Am J Respir Crit Care Med.* 2015;192(10):1200–7.

documented need for liquid and/or high flow systems are eligible for this benefit. Objective clinical parameters including the principle of “titrate to saturate” along with a specific recommendation from the ordering physician, should ensure that the benefit stays within projected financial parameters.

Recommendation 2: Modify CMS Form 484 – Certificate of Medical Necessity (CMN)/Oxygen

Integral to any change regarding access to liquid oxygen systems, it is necessary to ensure that CMS Form 484 is modified to address those changes. The original CMS-484 provided physicians the opportunity to specify particular oxygen systems, but at the urging of the Office of the Inspector General, it was modified to accommodate the physician attestation. It is critical that the CMS-484 be modified again to ensure that physicians who are prescribing liquid, in particular, provide medical documentation that would signal the clinical need for liquid oxygen systems as well as high flow oxygen needs. We recommend that CMS amend this form to require attesting physicians signal this modality specificity along with other medical necessity requirements.

ADDITIONAL COMMENTS

Quality Measures Related to Oxygen Therapy

Payment policies tied to distinctive quality measures are now pervasive throughout many segments of the Medicare program. Conspicuously absent across the broad DME benefit is any consideration of quality in the services provided by suppliers related to oxygen therapy. The absence of such quality measures incentivizes some suppliers to provide services at such a bare minimum level that patient care is adversely affected. This could result in added cost to the Medicare program through increased ER visits, hospitalizations, etc., much of which can be addressed by ensuring a certain level of quality assurance to a multi-billion-dollar program. The broad clinical community is poised to develop such measures when there is a signal from CMS that it is moving in this important direction.

In the ATS Survey, patients who reported problems with their oxygen were more likely to be admitted to the hospital than those who did not (57 to 43 percent) or visit an emergency department (56 to 44 percent). The ATS Survey also found that receiving education from a healthcare professional (and not the delivery person) resulted in a significant difference in not experiencing problems with their oxygen system.¹⁶

We urge CMS to consider promulgation of quality measures directly tied to the broad oxygen benefit. These can be developed in a relatively timely manner if CMS was receptive to adoption of such measures. The physician community and other stakeholders are committed to working with the agency to create such standards.

¹⁶ Jacobs SS, et al. Patient Perceptions of the Adequacy of Supplemental Oxygen Therapy: Results of the American Thoracic Society Nursing Assembly Oxygen Working Group Survey. *Ann Am Thorac Soc.* 2018;15(1):24-32.

Oxygen and CPAP

While we can understand the desire of CMS to make the competitive bidding program more efficient, we are unable to discern any clinical or marketplace rationale that requires bidders in the oxygen space to provide continuous positive airway pressure (CPAP) related services and supplies as well. Likewise, the corollary is also true: we see no rationale in a presumption that qualified CPAP suppliers are therefore qualified oxygen suppliers.

CPAP devices are used to treat patients with obstructive sleep apnea (OSA), and the requirements for appropriate servicing of devices for patients diagnosed with OSA has no correlation to the service requirements related to supplemental oxygen. Any such correlation is driven by considerations other than clinical need, and therefore we urge CMS to de-couple and eliminate the requirement that suppliers of oxygen also be required to provide CPAP equipment as part of the competitive bidding program.

Recognition of Service Component of Supplemental Oxygen

We appreciate CMS recognition of the service element associated with providing quality supplemental oxygen services. As noted, in the proposed rule, CMS identifies several components of quality supplemental oxygen that are not recognized in statute or regulation nor accounted for in CMS's payment methodology. For example, the Morrison study discussed in the proposed rule concluded that "services such as preparing and delivering equipment, driving to the home to repair and maintain equipment, training and educating patients, obtaining required medical necessity documentation, customer service, and operating and overhead costs accounted for 72 percent of overall costs."¹⁷ This is in stark contrast to the study's conclusion that "equipment acquisition only accounted for 28 percent of the costs of providing medically necessary oxygen to Medicare beneficiaries." While we are disappointed CMS did not take the next logical step and propose policy that would recognize, measure and reimburse for these essential service elements, we believe CMS's recognition is an opportunity for continued dialogue on how to account for and reimburse these service elements. We look forward to expanding this conversation with CMS.

Competitive Bidding Ombudsman

We have grave concerns that even short-term suspension of the competitive bidding program might result in the elimination of the competitive bidding ombudsman during that suspension. This position provides important pathways for Medicare beneficiaries who encounter service problems unique to DME. A pathway for patient protections and the patient voice must be maintained.

Lead Price Competitive Bidding

We support the proposal to transition to a "lead item pricing" approach to competitive bidding. As practitioners and patient organizations, we have seen the adverse consequences of the

¹⁷ Morrison Informatics, Inc. A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy. June 27, 2006.

previous bid model that forced businesses to bid on products and services for which they had little or no capacity to provide. Many experienced suppliers were forced out of the market by sustainably low bids of businesses who were naïve to the oxygen market. Too often, this resulted in inexperienced suppliers providing substandard service to supplemental oxygen users.

We expect that the lead price bidding approach will allow more experienced business with existing capacity to more effectively compete for the oxygen market. However, we do not believe that liquid oxygen should become its own lead category and remain under budget neutrality provisions. This scenario would not improve the current access situation—patients requiring liquid oxygen would still remain in a position without recourse.

Conclusion

Our organizations welcome the opportunity to discuss these issues in greater detail if the Agency wishes to explore any/all of these recommendations. Thank you for your consideration of these comments.

Sincerely,

Allergy & Asthma Network
Alliance for Patient Access
Alpha-1 Foundation
American Association for Respiratory Care
American Lung Association
American Sleep Apnea Association
American Thoracic Society
CHEST/American College of Chest Physicians
Children's Interstitial Lung Disease (chILD) Foundation
COPD Foundation
Foundation for Sarcoidosis Research
Hermansky-Pudlak Syndrome Network
LAM Foundation
Lung Transplant Foundation
LUNgevity
National Association for Medical Direction of Respiratory Care
Pulmonary Fibrosis Foundation
Pulmonary Hypertension Association
Tuberous Sclerosis Alliance
U.S. COPD Coalition