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Memorandum

Advocacy: the voice of small business in government

December 17, 2008

Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 309-G
Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1403-FC
P.O. Box 8013
Baltimore, MD 21244-8013
File Code CMS-1403-FC

Re: Medicaid Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (73 Fed. Reg. 69726, November 19, 2008)

Dear Acting Administrator Weems:

As Acting Chief Counsel for Advocacy, I am submitting comments on this matter because I am concerned about the agency's compliance with the requirements of the RFA in this rulemaking. Congress established the Office of Advocacy (Advocacy) under Pub. L. 94-305 to represent the views of small business before federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such the views expressed by Advocacy do not necessarily reflect the views of the SBA or of the Administration. Section 612 of the Regulatory Flexibility Act (RFA) also requires Advocacy to monitor agency compliance with the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act.[1]

[1] Pub. L. No. 96-354, 94 Stat. 1164 (1981) (codified at 5 U.S.C. §§ 601-612) amended by Subtitle II of the Contract with America Advancement Act, Pub. L. No. 104-121, 110 Stat.857 (1996). 5 U.S.C. § 612(a).

CMS states in this final rulemaking that 85% of suppliers of durable medical equipment are considered small businesses under the SBA's size standards.[2] My office has received several verbal and written communications from small durable medical equipment suppliers, and their representatives, that are concerned with the final rule's provisions regarding the supply and payment for oxygen and oxygen equipment to Medicare beneficiaries.[3] Industry stakeholders argue that CMS has failed to take into account the effect of the new provisions regarding providing oxygen to beneficiaries and the reduced payments to suppliers of oxygen and oxygen equipment. Further, they believe that CMS failed to analyze the economically burdensome nature of this regulation on small suppliers pursuant to the requirements of the RFA. The small businesses are concerned that the net effect of this rule will be to force many small durable medical equipment (DME) suppliers out of business, especially when this regulation is viewed in conjunction with other recent rulemakings regulating the DME industry. While Advocacy appreciates that the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) may limit some of CMS' flexibility in providing regulatory relief to small oxygen providers, the statute does not obviate CMS' responsibilities to analyze the impacts of the regulation under the RFA.

I. The RFA requires CMS to perform a more detailed analysis of the economic impacts of a regulation if the agency cannot certify that it will not have a significant impact on a substantial number of small entities.

Section 605(b) of the RFA provides that if the head of the agency makes a certification that the regulation will not have a significant economic impact on a substantial number of small entities then the agency is not required to perform a Final Regulatory Flexibility Analysis. The certification must be accompanied by a statement providing the factual basis for the certification. If the agency cannot certify "no impact" in the final rule, it is required to prepare a Final Regulatory Flexibility Analysis (FRFA).[4] The law states that the FRFA shall address the reasons that an agency is considering the action; the objectives and legal basis of the rule; the type and number of small entities to which the rule will apply; the projected reporting, record keeping, and other compliance requirements of the proposed rule; and all Federal rules that may duplicate, overlap or conflict with the proposed rule.[5] The agency must also provide a description of the steps taken to minimize the significant economic impact on small entities, a statement of the reasons for selecting an alternative adopted in the final rule, and a statement about why other significant alternatives to the rule which affect small entities were rejected.

While CMS does provide some analysis in its Regulatory Impact Analysis (RIA), it is unclear whether the agency is certifying that the rule's provisions related to oxygen and oxygen equipment will not have a significant impact on a substantial number of small

[2] 73 Fed. Reg. 69918.
[3] Section 144(b) of the Medicare Improvements for Patients and Providers Act of 2008 repealed the requirement that the supplier transfer title to oxygen equipment to the beneficiary after the 36-month rental cap and amended section 1834(a)(5)(F) of the Social Security Act by adding three new payment rules and supplier requirements for furnishing oxygen and oxygen equipment after the 36-month rental period.
[4] 5 U.S.C. Section 604(a)(5).
[5] 5 U.S.C. Section 604(a)(1-4).

oxygen suppliers, or whether the RIA is supposed to satisfy the required elements of a FRFA.[6] Advocacy appreciates that CMS does provide some limited RFA analysis. However, CMS admits in its analysis that it is difficult to estimate the impact of the regulation on small entities and oxygen and oxygen equipment suppliers in general.[7] Of further concern is CMS' suggestion that this rule will have a minimal impact on oxygen suppliers because the MIPPA repealed the requirement that the supplier transfer title to oxygen equipment to the beneficiary after the 36-month rental cap. Because of this change CMS surmises that the net impact on small entities will be positive rather than negative as oxygen suppliers can furnish the equipment to other patients.[8] Advocacy submits that the analysis provided on the rule's likely impacts on oxygen suppliers does not rise to the level required by the RFA. CMS' inability to estimate the impact of this rule on oxygen suppliers merely highlights the need for a FRFA as required under the RFA. CMS does not adequately analyze and balance the potential benefit of retaining ownership of the oxygen equipment with the other provisions of the rule that serve to reduce payment to the industry for providing oxygen and oxygen suppliers to Medicare beneficiaries. Advocacy's belief that a FRFA is required in this rulemaking is supported by data provided by suppliers of oxygen and oxygen equipment as to the impact that this rulemaking will have on their industry.

II. DMEPOS industry sources are concerned with the rule's impact on their industry, compliance with the RFA, and their ability to service Medicare beneficiaries.

Industry representatives have told Advocacy that they are concerned the rulemaking will have a significant economic impact on their industry, which runs counter to the conclusion reached by the CMS in its Regulatory Impact Analysis. These industry concerns primarily involve their view of the rule's regulatory requirements versus what the regulated entities experience daily in the marketplace. The small businesses believe that the rule's economic impact has been underestimated because the incremental costs and value of suppliers' services are significantly higher than those estimated by CMS. The industry stakeholders submit that if CMS had adequately analyzed the impacts of this regulation as is required by the RFA, then the true costs to oxygen and oxygen suppliers would become more apparent.

The industry has three primary problems with the new oxygen provisions contained in the rule and they are as follows:

1) Oxygen providers disagree with CMS' contention that the retention of ownership of the oxygen equipment by the provider after the 36-month cap has been reached is a benefit to the provider.[9]

[6] 73 Fed. Reg. 69918 (November 19, 2008).
[7] Id.
[8] Id.
[9] MIPPA section 144(b)(1).

The rule states CMS' belief that retention of the ownership of the oxygen equipment is a benefit to oxygen suppliers.[10] CMS suggests that the oxygen equipment is very dependable and requires very little maintenance and servicing.[11] However, there is no data or discussion in either the Regulatory Impact Analysis or RFA section of the rule in which CMS attempts to quantify the value of three-year-old oxygen equipment to the supplier, nor is there a discussion of the cost of maintenance or servicing the equipment after three years of use.

Representatives from the Accredited Medical Equipment Providers of America (AMEPA)[12] provided Advocacy with information that suggests that the cost of a new standard oxygen concentrator ranges from $450 to $650. The cost of a Liquid Oxygen System, a Home-fill or portable battery system ranges from $2,000 to $3,000. They suggest that despite the cost of the system, Medicare reimburses providers $200 per month or less for any system. AMEPA representatives submit that after three years of continuous usage each oxygen system has lost substantial value (estimated at between zero and $100). After five years the equipment has no value and actually costs the supplier for disposal. Based on a weighted average, AMEPA calculates that the three-year-old oxygen equipment is worth $40. Also, before the equipment can be provided to another patient there is a cost incurred by the supplier to ensure that the equipment is operating within applicable industry accreditation standards. These costs may include the $144 cost of replacing a sieve bed if the oxygen concentrator is not producing 100% oxygen; the cost of replacing a compressor, PC board or solenoid is approximately $90 each. AMEPA representatives estimate that the value of a refurbished three-year-old oxygen concentrator with 10,000 hours of use ranges from $150 to $200 and comes with a warranty of six to twelve months.

Small oxygen suppliers attempted to highlight the negative effect of this rule on their industry by trying to quantify how they would be affected under the provisions of this final rule. They told Advocacy that based on current Medicare reimbursement rates, oxygen providers can receive up to $200 per month for providing oxygen to beneficiaries.[13] Suppliers calculate that for each beneficiary that receives oxygen they bill Medicare a maximum of $200/month or $2,400 per year based on the current fee schedule. Suppliers also bill Medicare for maintenance of the oxygen equipment and under this rule they are allowed to bill for a maximum of one 30-minute maintenance call every six months at a fee of $15 to $30 per visit for a maximum of $60 per year.[14] Industry representatives believe that CMS has miscalculated the value of used oxygen equipment and they suggest that the value of the equipment after the 36-month cap has been exceeded is approximately $50. Therefore, the industry representatives calculate that at minimum they lose $2,290 per patient per year ($2,400 per patient per year

[10] 73 Fed. Reg. 69918.
[11] Id. CMS based this conclusion on a September 2006 Department of Health and Human Services Office of Inspector General Report entitled: "Medicare Home Oxygen Equipment: Cost and Servicing" (OEI-09-04-00420).
[12] AMEPA is an organization representing the interests of businesses affected by the DME competitive bidding process.
[13] Per industry sources, after January 1, 2009 the reimbursement rate has been reduced to $180 per month.
[14] See the Deficit Reduction Act of 2005 (Pub. L. 109-171), Section 414.210(e)(2).

reimbursement - $60 per year Medicare reimbursement + $50 for the equipment). According to industry sources this amounts to a reimbursement reduction of 97.5% to the industry.

Small oxygen suppliers suggest that irrespective of how one calculates the value of used equipment, the residual value of the equipment cannot fairly compensate oxygen providers for the loss of the regular Medicare reimbursement rate. Those suppliers believe that the flaw in CMS' reasoning is that the regular fee payment over the first 36 months of beneficiary service is primarily related to the cost of the equipment. Small business representatives argue that the equipment cost is only a small fraction of the total cost to the oxygen provider. The main provider costs include the ongoing cost of service to the beneficiary 24 hours a day, 7 days a week.

While CMS has accounted for some of these costs in the regulation, the industry data does bring into question the validity of CMS' assertion that many of these costs are offset because the providers are now allowed to retain ownership of the oxygen equipment. The small suppliers believe that under the requirements of the RFA, CMS has the obligation to analyze these matters in greater detail. Advocacy emphasizes that CMS' lack of specificity as to the benefit stream accruing to DME providers in this rule puts it at odds with the industry as the oxygen suppliers have provided Advocacy with documentation delineating their cost structure. The transparency of this rule would be dramatically increased if CMS better analyzed the impacts of this rule on the suppliers.

2) Providers cannot afford to provide beneficiaries with the same level of service and maintain the oxygen equipment under the reduced reimbursement provisions of the regulation.

While the rule does provide for continued reimbursement for oxygen provided after the end of the 36-month cap under certain situations, CMS will no longer pay for non-routine maintenance and servicing (including repair) of supplier-owned equipment.[15] CMS believes that the provider now owns the equipment, and the provider should be responsible for maintaining it in working order after the 36-month cap is exceeded. CMS does provide payment for a routine maintenance and servicing visit following each period of continuous use of six months after the 36-month rental period ends for fiscal year 2009 only.[16] CMS appropriately seeks public comment on whether to continue providing payment for routine maintenance and servicing after 2009. If this flexibility exists under the statute, then CMS should discuss these and other possible alternatives in the FRFA.

Small oxygen suppliers believe that CMS is significantly reducing their reimbursement rates and at the same time markedly increasing their obligations to Medicare beneficiaries. They submit that the regulation will have an effect on the level of service that they render to beneficiaries because the rule either minimizes or eliminates reimbursement to the providers for care that they have rendered to beneficiaries under the

[15] 73 Fed. Reg. 69878.
[16] Id.

prior regulation. For example, providers have heretofore provided beneficiaries with non-routine after-hours service calls if the oxygen equipment fails to operate properly. The majority of these situations involve patient error and the providers attempt to take corrective measures over the phone, but in some instances an employee must travel to the beneficiary's home. Suppliers also make maintenance calls for things other than repairs to the equipment. They supply the beneficiaries with new tubing, multiple filters, cannulas, humidifier bottles, etc. Also, from time to time suppliers must retrain patients and/or caregivers on how to use the equipment.

In its argument in support of the benefits to suppliers by retaining ownership of the oxygen equipment, CMS offsets the elimination of payments to suppliers for non-routine maintenance and servicing/repair by suggesting that five-year warranties are available for the equipment during its useful lifetime.[17] AMEPA disagrees with this assertion and informed Advocacy that most manufacturers of oxygen concentrators do not have warranties that go beyond three years, and more sophisticated equipment carries a one year warranty.

Small oxygen suppliers argue that even if a machine is warranted there are other provider costs that are not subject to Medicare reimbursement. Machines may need to be picked up by the provider, incurring travel time and labor. The machine must be shipped to the manufacturer, and due to the machine's weight, the cost of shipping is high. Typically a replacement machine must be furnished to the patient; that also includes costs and possible training on its use by a respiratory therapist.

Providers are concerned that by limiting their reimbursement for these types of visits to beneficiaries, CMS is significantly impacting their ability to survive and provide care to beneficiaries. While Advocacy commends CMS for seeking comment the provisions regarding reimbursement for routine maintenance and service of the oxygen equipment, Advocacy again suggests that had CMS fully analyzed these impacts under the RFA, the transparency of the rule would have been improved.

3) This regulation mandates that oxygen suppliers that furnish oxygen equipment during the 36-month rental period must continue to furnish the oxygen equipment after the 36-month rental period for the remainder of the useful life of the equipment, even if the beneficiary relocates from the area of service into a new place of residence.[18]

The aforementioned provisions are particularly onerous to small oxygen suppliers who are very concerned with the prospect and cost of having to provide capped Medicare beneficiaries who relocate with ongoing oxygen and oxygen supplies without reimbursement for two years. While large providers can simply assign the relocated beneficiary to one of their local offices, small providers will have to subcontract with another oxygen supplier located in the area where the beneficiary now resides. The

[17] Id.
[18] MIPPA section 144(b)(1). CMS assumes that the useful life of the oxygen concentrating equipment is 5-years based on information obtained from the Department of Veterans Affairs. See 73 Fed. Reg. 69878 and 69876.

provider will then have to pay the local supplier for the oxygen equipment, supplies accessories and other related services for up to two years. AMEPA estimates that this could cost the original supplier as much as $4,800 per patient over the remaining two years after the 36-month cap has been reached. These provisions are particularly onerous on oxygen suppliers located in areas where beneficiaries travel in the winter months, so called "snow-birds."

Small business oxygen suppliers are also concerned about patients that relocate close to the 36-month cap. The providers described an example using a hypothetical patient that requires the use of oxygen and relocates from Massachusetts to Florida beginning in October 2008, intending to stay in Florida until May 2009. The patient has been receiving oxygen under the provisions of the old Medicare oxygen reimbursement provisions while in Massachusetts. Under the new regulatory provisions, any Florida supplier that agrees to provide the patient with oxygen and oxygen equipment may only get reimbursed from October to December 2008. After that period the patient may reach the 36-month cap and the supplier may not receive reimbursement from January through May 2009 and would be required to provide the oxygen and oxygen equipment for the remaining two years of the equipment's life expectancy.

The costs of having to equip and supply oxygen to Medicare beneficiaries that relocate should be better analyzed by CMS as those costs will outweigh any benefit of retaining ownership of the oxygen concentrators.

III. Advocacy is concerned about the public policy implications of the rule on DMEPOS oxygen suppliers and on Medicare beneficiary access to oxygen and supplies.

This regulation, taken together with other recent CMS rulemakings impacting the DMEPOS industry, raises questions about Medicare beneficiary choice and access to care. Advocacy believes that CMS should better analyze how this rule will impact the DMEPOS industry and the Medicare beneficiaries as the rule has the potential to affect how oxygen is dispensed to patients across the United States. If the rule disproportionately impacts the viability of the DMEPOS industry, Medicare beneficiaries will increasingly seek care in emergency rooms, leading to increased hospital stays and increasing overall health care costs in this country.

Conclusion

In summary, Advocacy requests that CMS give consideration to the issues raised herein. Advocacy believes there is value bringing these industry concerns to CMS' attention in an attempt to balance industry concerns with the agency's regulatory policy. Advocacy

encourages CMS to better analyze the possible effects of this regulation on the DMEPOS oxygen supplier industry and Medicare beneficiary access to care. Advocacy appreciates being given a chance to provide CMS with these comments. If you have any questions or concerns, please do not hesitate to contact me or Assistant Chief Counsel, Linwood Rayford at (202) 205-6533.

Sincerely yours,

/s/

Shawne Carter McGibbon
Acting Chief Counsel Advocacy

/s/

Linwood L. Rayford, III
Assistant Chief Counsel for Food, Drug
and Health Affairs

cc: The Honorable Susan Dudley, Administrator, Office of Information and Regulatory Affairs