

### MEMORANDUM

Date: November 1, 2018

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Subject: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS (CMS-1691-F)

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On November 1, 2018, the [End-Stage Renal Disease \(ESRD\) final rule](#) was announced on the federal register. This rule finalizes all the major changes proposed in the [proposed rule](#) that was published on July 19, 2018.<sup>1</sup> CMS will put a hold on the Competitive Bidding Program (CBP) beginning January 1, 2019 and moving the bidding methodology to lead item pricing. CMS also finalizes changes to the oxygen benefit, introduces a new fee schedule methodology for multi-functioning ventilators beginning January 1, 2019, and will add Northern Mariana Islands to the national mail order CBP.

#### CHANGES TO THE COMPETITIVE BIDDING PROGRAM

CMS will implement lead item bidding, a bidding methodology that will require suppliers to submit a bid on one item in a product category. This one item referred to as the “lead item” is determined based on national allowed charges preceding each competition. The bid submitted by the supplier on the lead item will be known as the “composite bid.” The composite bid cannot be higher than the rate used in the 2015 DMEPOS fee schedule.

The single payment amount (SPA) for the non-lead items will be based on their respective ratios to the lead item from the 2015 fee schedule. CMS will later announce changes to the product categories to ensure discrete categories of like items are grouped together to prevent price inversion.

CMS changed the definition of ‘bid’ to: “an offer to furnish an item or items for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item or items.” CMS also changed the definition of ‘composite bid’ to: “the bid submitted by the supplier for the lead item in the product category.”

CMS will project demand and supplier capacity for future rounds of bidding based on lead item within each product category. The range of winning suppliers will be based on their cumulative capacity to furnish the lead item. CMS is assuming that the group of suppliers’ abilities to service the lead item is also a reflection of their ability to supply the non-lead items. This logic however does not work for CPAP devices; CMS projects there could be a drop in the number of winning CPAP suppliers, but does not believe this would have any negative impact on access.

CMS will use the maximum winning bid to establish the SPAs.

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<sup>1</sup> The proposed rule is published in the July 19, 2018 *Federal Register*.



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CMS expects expenditures for the lead item will increase, but this increase will have an off-set by decreases in expenditures for the non-lead items.

Small suppliers that are awarded contracts due to CMS' requirement to meet small supplier target will not have their bids be considered in maximum winning bid. Small suppliers who refuse a contract will not be forced to accept the contract.

In the proposed rule, CMS requested feedback on splitting large CBAs into smaller CBAs in order to establish a more manageable service area. There are currently nine large CBAs that have a range of 7,000-9,000 square miles. The CBAs being considered for this change include: Phoenix-Mesa-Scottsdale, AZ; Boise City, ID; Dallas-Fort Worth-Arlington, TX; Riverside-San Bernardino-Ontario, CA; Houston-The Woodlands-Sugar Land, TX; Bakersfield, CA; Salt Lake City, UT; San Antonio-New Braunfels, TX; and Atlanta-Sandy Springs-Roswell, GA. CMS will consider the comments received in future policy making.

CMS will educate suppliers on the new bidding process.

Lead item pricing is projected to cost Medicare \$10 million between January 1, 2019-September 30, 2023, and \$3 million to beneficiaries.

### NEW DMEPOS PRICING BEGINNING JANUARY 1, 2019

CMS will place a hold on the new round of bidding that was slated to begin on January 1, 2019. The current contracts in place in Round 1 2017 and Round 2 Recompete will end on December 31, 2018 as scheduled and beginning January 1, 2019, any willing provider may supply equipment in competitive bidding areas (CBAs). The following is the new reimbursement rates beginning January 1, 2019 until December 31, 2020:

- CBAs: current single payment amounts (SPAs) + inflation (CPI) increase
- Non-Rural: current fully adjusted fee schedules
- Rural and non-contiguous: Extends the IFR relief of 50/50 blended rate through 2020 or when the new bid program begins
- National Diabetic Supplies: SPA that is applied to current national mail-order program will also be applied to non-mail order supplies, but no inflation (CPI) increase

CMS is monitoring outcomes related to access before implementing the next round of bidding. CMS will address fee schedules beginning January 1, 2021 in a separate rule.

This portion of the proposal is estimated to cost Medicare \$1.05 billion and \$260 million for beneficiaries between January 1, 2019-December 31, 2020. For dual eligible, the federal and state cost sharing are expected to be \$5 million and \$30 million, respectively.

### CHANGES TO OXYGEN PAYMENT

Due to the low reimbursement rate of servicing portable liquid oxygen, CMS will split the portable oxygen into two separate classes (gas and liquid) and increase the portable liquid oxygen rate to the

OPGE rate. CMS' goal is to decrease incentives to prescribe OPGE.

**TABLE 36: Current and Proposed Oxygen and Oxygen Equipment Classes**

Current Oxygen and Oxygen Equipment: 5 Classes Described in 414.226	Proposed Oxygen and Oxygen Equipment, for years after 2018: 7 Classes Described in 414.226
Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable)	Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable)
Portable equipment only (gaseous or liquid tanks)	Portable gaseous equipment only
	Portable liquid equipment only
Oxygen generating portable equipment only	Oxygen generating portable equipment only
Stationary oxygen contents only	Stationary oxygen contents only
Portable oxygen contents only	Portable gaseous and liquid oxygen contents only with the exception of portable liquid contents greater than four liters per minute
	Portable liquid contents only greater than four liters per minute

CMS will add a new class for “portable liquid oxygen contents only for prescribed flow rates of more than 4 liters per minute.” The initial reimbursement amount for this item will be 50% more than the portable oxygen contents fee schedule. Moving forward, the price would be adjusted based on CBP.

Starting January 1, 2019, CMS will apply budget neutrality offset to all oxygen contents and equipment. Table 37 is an example of rates under current budget neutrality method and the proposed method.

**TABLE 37: January 1, 2018 Fees for Current and Proposed Budget Neutrality Methods**

Current Method	2018 Rate	Proposed Method	2018 Rate
Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable)	\$70.23	Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable)	\$72.59
Portable equipment only (gaseous or liquid tanks)	\$17.29	Portable gaseous equipment only	\$16.04
		Portable liquid equipment only	\$34.73
Oxygen generating portable equipment only	\$37.44	Oxygen generating portable equipment only	\$34.73
Stationary oxygen contents only	\$53.32	Stationary oxygen contents only	\$49.46
Portable oxygen contents only	\$53.32	Portable gaseous and liquid oxygen contents only with the exception of portable liquid contents greater than four liters per minute	\$49.46
		Portable liquid contents only greater than four liters per minute	\$74.19

**MULTI-FUNCTION VENTILATOR**

A multi-function ventilator is classified as a ventilator by the Food and Drug Administration (FDA), but it



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has four other functions: oxygen concentrator, nebulizer, suction pump, and cough stimulators. CMS will create a new fee schedule amount for multi-function ventilators by using the current ventilator rate plus an additional amount of the average cost of oxygen concentrator, nebulizer, respiratory airway suction, and cough stimulator. The add-on rate is not affected based on the patient's utilization of the other features, whether patients uses just one feature or all the features, the add-on amount will stay constant. However, if the patient only qualifies under the ventilator criteria, Medicare will only cover the ventilator cost. Beneficiaries who receives a multOfunction ventilator will not qualify for a separate oxygen and oxygen equipment, nebulizers and related accessories, suction pumps and related accessories, and cough stimulators and any related accessories.

Multi-function ventilator will be classified as in the frequent and substantial servicing payment category. This new payment methodology is effective January 1, 2019. CMS will publish further guidance in a separate rule.

Payment for Multi-Function Ventilators are expected to cost Medicare \$15 million and \$0 million for beneficiaries between January 1, 2019-September 30, 2023.

### **INCLUDING NORTHERN MARINA ISLANDS IN FUTURE NATIONAL MAIL ORDER CBP**

CMS will include Northern Marina Islands to the national mail order program for diabetic supplies.

Adding Northern Mariana Islands in future rounds of national mail order CBP has no fiscal impact.