Comment on Proposed Rule to the DMEPOS Competitive Bidding Program and Fee Schedule Amounts

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS- 1691-P

To Whom It May Concern,

I am writing today in order to provide comments on the "CMS Proposed Updates to Policies and Payment Rates for the End-Stage Renal Disease Prospective Payment System, the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program CMS-1691-P". Specifically, this comment is in regards to section, "Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)."

As a supplier of durable medical equipment (DME), while some of the proposed changes make incremental improvements to the DMEPOS program, the current proposed rule falls short in protecting access to DME for Medicare beneficiaries. Without a progression plan of the DMEPOS competitive bidding program, suppliers have little indication of long term stability for their businesses. CMS must issue polices which to bring sustainability in the marketplace in order to strengthen beneficiary access to cost saving durable medical equipment that we provide.

Lead Item Bidding Proposal

Overall, the implementation of lead item bidding as it improves and simplifies the bidding process. This change must come with clear transparency and rational for all items and product categories. Additionally, as the proposed rule outlined, CMS must split certain product categories into multiple, smaller product categories to ensure that Medicare beneficiaries have quality access to the latest technology. This is also crucial in setting proper reimbursement levels for contracted suppliers, and by extension the suppliers who are in non-CBAs who are subject to the pricing methodology of the competitive bidding program.

However, as expressed by industry stakeholders, not all product categories are conducive to a single, lead-item approach. To protect beneficiary access CMS should consider a bidding product category for items associated with a specific medical need. For example, any mobility product category is likely to include wheelchair bases, options, accessories, and complementary seating systems. While this makes sense from a beneficiary access standpoint to construct a bidding product category this way, it also illustrates potential problems with a lead-item bidding approach. With such a diverse group of items, delivery times, billing costs and service needs in these cases would not serve beneficiaries well to utilize lead-item bidding.

In order to protect beneficiaries with complex needs, some bidding product categories must be further divided into subcategories and a specific lead-item be identified, and bid, for each subcategory. The single payment amount determined for each subcategory lead item would then be used to adjust the payment rate for all other items within the subcategory.

Further, for bidding product categories that contain subcategories, the method to determine a bidder's composite bid would be to establish the total historic expenditures for the product category and percentage each subcategory represents of the total. Subcategory percentages would be used to establish a weighted value for the lead-item bid of each sub-category and the sum of the weighted subcategory lead items would become the composite bid. It is important to note that this is consistent with the methodology currently used by CMS in determining a composite bid. Further, as with the initial lead-item proposal, it will greatly simplify the current composite bid methodology as the composite bid calculation will be derived from a small handful of items.

Conclusion

These are the major provisions within the ESRD, which contains proposals for modifying the competitive bidding program. While CMS is calling this "modernizing" the DMEPOS program, disguising it as an overhaul, this proposed rule, as currently written is a missed opportunity for major regulatory reform to strengthen access to DME in urban, non-rural, and rural areas across the country. In reality, while the competitive bidding program is inevitably delayed until CMS conducts another round of bidding, CMS has effectively extended the current program, with no indication of when the next program will be. The status of the industry right now is not acceptable, as suppliers are at the mercy of CMS to make these crucial changes.

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As a supplier of durable medical equipment (DME), while some of the proposed changes make incremental improvements to the DMEPOS program, the current proposed rule falls short in protecting access to DME for Medicare beneficiaries. Without a progression plan of the DMEPOS competitive bidding program, suppliers have little indication of long term stability for their businesses. CMS must issue polices which to bring sustainability in the marketplace in order to strengthen beneficiary access to cost saving durable medical equipment that we provide.

Adjustments to the DMEPOS Fee Schedule Amounts Based on Information from the CBP

The proposed payment methodology within this rule for CBAs and non-rural areas is concerning and contradictory to the apparent intent of this proposed rule of strengthening access DME for Medicare beneficiaries.

- <u>Within a competitive bidding area</u>
    - The premise of the competitive bidding program was to offer lower pricing on equipment and supplies with the idea that lost revenue would be made up in a volume of patients. While it can be argued that previous median bid pricing methodology and lacking safeguards were missing to discourage unsubstantiated low bids, opening up the bid areas to any willing provider without any adjustment to the single payment amount (SPA) threatens patient access even greater than the flawed pricing methodology.

      Prior to a final rule being issued, CMS must revise this to a minimum of the 50/50 blended reimbursement rate until another round of bidding is conducted with suggested policy changes from the industry. CMS is required by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 to conduct a bidding program every three years. In the extremely likely even that

CMS does not conduct a round of bidding prior to July 2019, which is the extent of their legal authority, CMS should fall back to the 50/50 blended rate. This would allow suppliers to confidently provide equipment and slow the amount of massive supplier closures occurring across the United States.

- Within a non-rural, non-bid area
    - Suppliers in non-rural and non-bid areas, similarly to the interim final rule released in May 2018, excludes a large portion of the Medicare population living in communities which require suppliers to travel significant distances on artificially low reimbursement which does not reflect their costs to provide this vital equipment. By maintaining the current adjusted fee schedule, supplier locations serving vulnerable patients in both a rural and non-rural setting see little to no relief and are equally as vulnerable to closing their doors due to the unsustainable reimbursement.

      These areas are in significant need of the relief immediately which contain a substantial amount of beneficiaries. The current proposed rule's timeline of possible reform not being until 2021 is unacceptable and does not protect patient accessibility in the interim period. The intent of the 21st Century Cures Act passed into law has clearly outlined reimbursement relief for all non-CBAs, not just rural areas. CMS is responsible for implementing policy based on the intent of Congress. If no change is made to this proposed rule to include all non-bid areas, CMS will have largely ignored the complete intent of Congress.

- Rural and non-contiguous areas
    - CMS has now acknowledged a great concern of patient accessibility in some of the most remote areas of the country. With rates moving to the "blended rate" (January 2016 levels), suppliers have some more room to breathe and prevent many from closing their doors and going out of business. CMS must take steps to strengthen the long term stability by reforming the competitive bidding program to ensure that patient choice of supplier and network adequacy remain a top priority rather than reducing reimbursements for the future of the program.

Conclusion

These are the major provisions within the ESRD, which contains proposals for modifying the competitive bidding program. While CMS is calling this "modernizing" the DMEPOS program, disguising it as an overhaul, this proposed rule, as currently written is a missed opportunity for major regulatory reform to strengthen access to DME in urban, non-rural, and rural areas across the country. In reality, while the competitive bidding program is inevitably delayed until CMS conducts another round of bidding, CMS has effectively extended the current program,

with no indication of when the next program will be. The status of the industry right now is not acceptable, as suppliers are at the mercy of CMS to make these crucial changes.

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As a supplier of durable medical equipment (DME), while some of the proposed changes make incremental improvements to the DMEPOS program, the current proposed rule falls short in protecting access to DME for Medicare beneficiaries. Without a progression plan of the DMEPOS competitive bidding program, suppliers have little indication of long term stability for their businesses. CMS must issue polices which to bring sustainability in the marketplace in order to strengthen beneficiary access to cost saving durable medical equipment that we provide.

New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes

<u>Liquid Oxygen Classification</u>

This payment classification raises serious concerns with the proposed methodology which does not address the significant costs associated with delivering this life-saving equipment. Suppliers needing to deliver this equipment at least twice a month are going to be severely limited when it comes to servicing the patient properly.

With the added costs such as a commercial driver's license and hazmat labeling, the current payment methodology does not meet the costs associated with providing liquid oxygen. Suppliers who are providing liquid oxygen are delivering replacement equipment on a weekly basis, or more. Compared to the once per month deliver of traditional gas equipment, the differences of delivering liquid oxygen must be taken into account for this payment classification.

<u>Budget Neutrality</u>

Within the proposed rule, CMS has reaffirmed its position that “budget neutrality” must be applied with the establishment of new oxygen classes and equipment. This application of two separate payment methodologies has wrongly pushed oxygen reimbursements in non-bid areas below the rates in competitive bidding areas where they were set. This misapplication threatens access to oxygen equipment for patients as suppliers are being forced to accept these unsustainable rates.

Conclusion

These are the major provisions within the ESRD, which contains proposals for modifying the competitive bidding program. While CMS is calling this “modernizing” the DMEPOS program, disguising it as an overhaul. This proposed rule, as currently written is a missed opportunity for major regulatory reform to strengthen access to DME in urban, non-rural, and rural areas across the country. In reality, while the competitive bidding program is inevitably delayed until CMS conducts another round of bidding, CMS has effectively extended the current program, with no indication of when the next program will be. The status of the industry right now is not acceptable, as suppliers are at the mercy of CMS to make these crucial changes.

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As a supplier of durable medical equipment (DME), while some of the proposed changes make incremental improvements to the DMEPOS program, the current proposed rule falls short in protecting access to DME for Medicare beneficiaries. Without a progression plan of the DMEPOS competitive bidding program, suppliers have little indication of long term stability for their businesses. CMS must issue polices which to bring sustainability in the marketplace in order to strengthen beneficiary access to cost saving durable medical equipment that we provide.

Payment for Multi-Function Ventilators

The issue with the current competitive bid program is that the patient would have to use several different suppliers because most suppliers would not have all the contracts. While ventilators, suction machines, and cough assists are not part of competitive bid, oxygen and nebulizers are competitive bid items under separate categories. Depending on the supplier, the patient could essentially have to use five different suppliers to get the proper care and medical equipment as prescribed by their physician. Imagine dealing with five different suppliers as a patient or a physician, or even being one of those five suppliers.

Conclusion

These are the major provisions within the ESRD, which contains proposals for modifying the competitive bidding program. While CMS is calling this "modernizing" the DMEPOS program, disguising it as an overhaul, this proposed rule, as currently written is a missed opportunity for major regulatory reform to strengthen access to DME in urban, non-rural, and rural areas across the country. In reality, while the competitive bidding program is inevitably delayed until CMS conducts another round of bidding, CMS has effectively extended the current program, with no indication of when the next program will be. The status of the industry right now is not acceptable, as suppliers are at the mercy of CMS to make these crucial changes.

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Including the Northern Mariana Islands in Future National Mail Order CBPs.

The continued expansion of competitive bidding through the national mail order program for diabetic testing supplies ignores the fact that the program limits access to some of the most vulnerable areas in the United States and its territories. As one study conducted by the National Minority Quality Forum, published by the American Diabetes Association, this program has caused disruptions leading to higher health care costs and an increase in mortality. Limiting patient choice to where they receive their diabetes supplies does not reduce health care costs, nor does it improve patient health outcomes.

Conclusion

These are the major provisions within the ESRD, which contains proposals for modifying the competitive bidding program. While CMS is calling this "modernizing" the DMEPOS program, disguising it as an overhaul, this proposed rule, as currently written is a missed opportunity for major regulatory reform to strengthen access to DME in urban, non-rural, and rural areas across the country. In reality, while the competitive bidding program is inevitably delayed until CMS conducts another round of bidding, CMS has effectively extended the current program, with no indication of when the next program will be. The status of the industry right now is not acceptable, as suppliers are at the mercy of CMS to make these crucial changes.