

Wound Care Manufacturers

August 22, 2016

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1651-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically to: www.regulations.gov

RE: CMS-1651-P: Medicare Program: End-Stage Renal Disease Prospective Payment System, Coverage and 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 Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model

Dear Acting Administrator Slavitt,

On behalf of the Coalition of Wound Care Manufacturers (“Coalition”), I am pleased to submit the following comments in response to the proposed rule regarding “Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment”. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including those products that are subject to the competitive bidding program. Since our members have a vested interest in the provision of quality, coverage and payment of negative pressure wound therapy, this regulation is of interest and concern to us. The Coalition appreciates the opportunity to offer our comments.

While this proposed rule addresses ESRD and DMEPOS, our comments solely will be focused on the competitive bidding program for DMEPOS.

General Comments

The Coalition continues to have significant concerns with the competitive bidding program. We have been consistent in our comments: CMS is not doing an adequate job vetting the vendors that are chosen in the competitive bidding program, or taking steps to ensure quality standards are implemented or quality products are delivered. Furthermore, we have raised issues with the Agency that it does not have in place mechanisms to ensure that vendors are providing quality service or maintenance, to adequately monitor access to products with the current existing program and finally, how the program disrupts patient care.

The Coalition would like to commend CMS in making strides towards addressing some of our previous concerns. We are in agreement with the following provisions:

- Bidders will forfeit the bond if they decline to accept a contract and their composite bid is at or below the offer.
- Penalties will be imposed for bidding suppliers that falsify a bid bond, does not accept a contract award, or accepts a contract and then breaches the contract in order to avoid bond forfeiture.
- Implementation of an appeals process for breach of contract actions.

All of the provisions above will help to ensure that bona fide bids are submitted.

Furthermore, although the Coalition is in agreement that bidders should obtain a bond for each competitive bidding area in order to ensure realistic bids, we do not agree that the bond amount should be \$100,000. While this amount may be appropriate for national mail order suppliers, this amount is not realistic for suppliers furnishing negative pressure wound therapy in each competitive bid area. As such, the Coalition recommends a bond in the amount of \$50,000. This amount seems more realistic. The Coalition further recommends that CMS set a limit on the amount large suppliers bidding in multiple competitive bid areas would need to obtain in bid bonds.

While the Coalition agrees with the provision in which CMS will not award a contract to a bidding entity that does not meet applicable state licensure requirements, CMS does not do an adequate job in determining whether a supplier meets state licensure requirements. This statement is substantiated by a recent OIG audit report entitled “Incomplete and Inaccurate Licensure Data Allowed Some Suppliers in Round 2 of the DME Competitive Bidding Program That Did Not Have Required Licenses”. Issued in May 2016, the OIG found that internal databases on state and local licensure requirements used by CMS and its contractors when awarding contracts to suppliers are inaccurate and inconsistent. We urge CMS to coordinate with State Licensure Boards in order to identify, and maintain an accurate and complete licensure database of currently required State licenses. Furthermore, we urge CMS to work with the state licensing agencies to ensure that bidders are properly licensed.

Finally, the Coalition would like to commend CMS for proposing to set the bid ceiling at the 2015 unadjusted fee schedule. By setting the bid limit at the 2015 unadjusted fee schedule, reimbursement rates will fluctuate parallel to the cost of the items and services being furnished. The Coalition would like to recommend however, that since CMS is making such efforts to ensure that bona fide bids are submitted and allowing the fluctuation of the reimbursement rates, the only way this can be equitable is if the Single Payments Amount (SPA) composite rates are re-based if an awarded bidder is subsequently removed from the competitive bidding program. This will ensure that the rates are reflective of the awarded bids and not inclusive of those that are removed from the program – but whose bid was used to establish the composite rates. The Coalition further recommends that when an awarded bidder is removed from the competitive bidding program, that new awardees are added to replace them. This will ensure that there are an adequate number of suppliers in the competitive bidding program.

Specific Concerns

Quality

Most of the provisions above are attempts to safeguard the program and protect the beneficiary from bidders who: are not present in the marketplace, or do not have any history in the product categories that they bid upon, or submit low-ball bids so they can get contracts under the competitive bidding program. However, in other program areas, CMS has identified quality standards or measures that are required to be met as part of the payment. This has been an important concern for the Coalition in the area of competitive bidding. In fact, we advocated for more stringent guidelines for CMS to put in place so as to ensure that suppliers who were awarded bid contracts were qualified to furnish NPWT both in, and out, of competitive bidding. The Coalition and the Alliance of Wound Care Stakeholders (Alliance) presented these guidelines and accreditation checklist to CMS several years ago. At that time, CMS officials agreed that contracts would only be awarded to suppliers that met the Medicare quality standards and that are accredited specifically for furnishing covered NPWT items and services under the competitive bidding program. However, some vendors that have been chosen as contract suppliers for NPWT not only did not meet the quality standards – they were not accredited, nor have they ever provided NPWT in the past. We continue to urge CMS to utilize the guidelines and accreditation checklist provided by the Coalition and the Alliance. Moreover, we urge CMS to award contracts to suppliers that meet the Medicare quality standards and are accredited for furnishing covered NPWT items and services.

NPWT

CMS has consistently decreased the payment amount for NPWT. This year is no exception. This constant decrease in reimbursement has caused issues with access to

NPWT for many beneficiaries – especially in rural areas. In this proposed rule, while CMS proposes to establish future bid ceilings at the higher 2015 fee schedule amounts, (which we support), Round 2 pricing is being used by CMS to establish pricing for rural areas which were not subject to competitive bidding. Round 2 pricing for NPWT is low and as a result of the inappropriately low rates, the quality and availability of NPWT services to Medicare beneficiaries in those areas may now be jeopardized.

The Coalition believes the establishment of future bid ceilings at the higher 2015 fee schedule amounts would avoid continued downward trends in payment for NPWT. As such, we support this proposal but are concerned about those beneficiaries in rural areas who need NPWT therapy and their continued access to care.

Conclusion

The Coalition appreciates the opportunity to provide our comments. If you need further information or have any questions, please do not hesitate to contact me.

Sincerely,

A handwritten signature in grey ink, appearing to read "Karen S. Ravitz".

Karen S. Ravitz J.D.
Senior Policy Advisor
301-807-5296