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To Whom It May Concern

Via email: OIRA_submission@omb.eop.gov

This document is being submitted by the Quality Diabetes Care Coalition (QDCC) which is comprised of Liberty Medical & CCS Medical. For any questions, contact Stacey Hughes, Coordinator of the QDCC at 202-742-6981.

RE: Comments to Request for Bids Instructions for the Medicare DMEPOS Competitive Bidding Program

II. A. Eligibility to Submit a Bid

CMS has made great strides in its efforts to combat fraud and abuse including requirements related to DMEPOS accreditation. CMS should clarify in section 2 that the supplier must be accredited to supply the items that it is bidding.

II. D. No Discrimination Against Beneficiaries

We believe that CMS must clarify its position regarding non-discrimination and clearly indicate that bidders are bound by this requirement. This was previously an area of significant confusion for the supplier community. CMS must address this issue within the context of the broader formulary issue to ensure that the bidders are operating on a level playing field. This clarification is essential as bidders must know prior to bidding whether they must supply every model that is currently being used by Medicare and non-Medicare populations for patients they service or whether the bidder can bid a preferred formulary.

Requiring established suppliers to bid all of the products they provide to their patients while allowing new to market bidders to bid a limited formulary disadvantages experienced providers and create increased disruption for beneficiaries in the CBA.

II. E. Single Payment Amount

We urge CMS to explicitly indicate that it will not consider any non bona fide bid in calculating the pivotal bid or single payment amount. We believe it is not a sustainable

process to allow a non bona fide bid price to be used in the calculation of the pivotal bid or the single payment amount. Since non bona fide bids are *per se* unsustainable, including such non bona fide bids in the payment calculations artificially deflates the payment amounts. (See below our additional comments regarding bona fide bid)

II. F. Bona Fide Bids

We appreciate the additional clarity the agency has provided to its criteria it will use to determine if a bid is bona fide (“rational and feasible for the bidder to furnish at the bid price”) We recognize that there was significant criticism of the 2008 process because of numerous claims that the bids were not bona fide. We recommend that CMS provide additional transparency into the process it will use to determine if a bid is bona fide. Furthermore, CMS should provide a further description of the parameters by which it will identify anomalous bids.

We believe that CMS should go beyond merely telling suppliers they “should not bid for an item at a loss” to requiring suppliers to certify that they have not bid at a loss. This will serve to protect against potentially injecting predatory pricing into a competitively bid government program.

Additionally, every bid that is identified as at or below the pivotal bid should be verified by the Agency to ensure that the supplier has a manufacturer contract in place to purchase the items under the top three HCPCS codes at a reasonable and sustainable margin; taking into account reasonable operating costs over the proposed contract term. Finally, before being awarded contracts, suppliers should be required to demonstrate that they have either an executed purchase contract for all of the items bid at a cost that is less than the bid price or alternatively should have a one year history of purchases of the item for a cost that is less than the bid price.

II. I. Common Ownership or Control

The Agency should clarify this provision to indicate it applies not only to suppliers that have an ownership or control interest in each other, but also suppliers that are commonly owned by parent corporations, partnership, or individual. We believe this clarification is essential to prevent a commonly owned group of suppliers bidding against each other and undermining the bid process.

Form B

We recommend that the Agency require the supplier to indicate the total number of applicable HCPCS units billed in the CBA for the prior 12 months, in addition to the reporting of “revenue”. While the Agency requires this for the “top HCPCS” codes, it should publish what it considers the “top HCPCS” codes to be in each category well in advance.

Capacity

We urge the CMS to take into account the supplier' bids in other regions as it considers whether the supplier can deliver on its promised capacity. For example if a supplier by being awarded a bid have to increase the suppliers capacity over demonstrated historical levels that increase should not be counted as capacity in any other region.