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June 18, 2009

VIA ELECTRONIC MAIL

OMB
Office of Information and Regulatory Affairs
CMS Desk Officer
Attention: CMS-10169

Re: **CMS-10169, Agency Information Collection Activities; Submission for OMB Review; Comment Request**

Dear Madam or Sir:

The following comments are being submitted on behalf of the Diabetic Product Suppliers Coalition (the "Coalition"), an organization whose members are Medicare-participating, direct-to-consumer (sometimes referred to as "mail order") suppliers of diabetic testing products and supplies. The Coalition appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") Information Collection Request, published in the Federal Register on May 19, 2009, which sets forth a summary of proposed collections as part of the agency's implementation of the Durable Medical Equipment, Prosthetics and Supplies ("DMEPOS") Competitive Bidding Program Round 1 Rebid (hereinafter "Round 1 Rebid"). Specifically, these proposed collections include the proposed Request For Bids ("RFB") instructions and accompanying forms published by CMS for use in the Round 1 Rebid.

The Coalition and its members have repeatedly expressed our serious concerns about CMS' implementation of the DMEPOS Competitive Bidding Program ("Competitive Bidding Program" or "Program"). Our examination of the proposed RFB and accompanying forms does nothing to allay these concerns. On the contrary, it is apparent from the information requested and provided in the RFB and accompanying bid forms that CMS has failed to make the changes necessary to ensure that the severe problems which plagued the Competitive Bidding Program's initial roll-out in 2007-2008 do not resurface. We believe the strong possibility of potential harm to beneficiaries and reputable suppliers argues against implementing the Program as currently structured, and the Coalition urges CMS to revisit the contents of the proposed RFB and

accompanying bid forms in order to ensure that the agency selects a sufficient number of reputable, experienced contract suppliers to service a growing beneficiary population.

OVERVIEW

The RFB and accompanying bid forms do not appear to call for all of the information necessary for suppliers to submit informed, reasonable bids to participate in the Competitive Bidding Program, nor do these forms seem to solicit from suppliers the information necessary for CMS to implement a Program that avoids the severe flaws that prompted Congress to step in and delay competitive bidding's inception. Further, consistent with the problems that many suppliers had in submitting bids in the initial attempt at implementation of the Competitive Bidding Program, there are a number of questions on the form that are ambiguous and that will likely be either misunderstood by responding suppliers or answered in a manner that may not be consistent across suppliers. We believe that it is essential that the OMB-approved forms and their accompanying instructions be as explicit as possible to avoid both confusion and the exclusion of certain providers from the bidding process for understandable failures to respond as may be intended by CMS, as well as to ensure the consistency of responses necessary for fair evaluations of bids.

Specifically, we believe the RFB and accompanying bid forms are deficient in the following ways:

- The information CMS proposes to solicit from bidding suppliers is insufficient to allow the agency to effectively and objectively screen for and eliminate unrealistic, unsustainable bids.
- The RFB or accompanying bid forms do not communicate concrete, transparent standards as to how the information provided on the bid forms will be used to determine that a bid is in fact not bona-fide and, therefore, should not be used to calculate an item's single payment amount. This will likely lead to confusion and uncertainty among bidding suppliers.
- The RFB and accompanying bid forms fail to provide information or instruction with regard to many important issues that are necessary for suppliers to understand in order to submit accurate and consistent bids, such as: (1) how to correctly calculate a supplier's current capacity to service a CBA; (2) how to calculate the percentage of the CBA's total geographic area a supplier serves; and (3) how the parent company of commonly-owned DMEPOS suppliers that is not itself a DMEPOS supplier should submit its bid on behalf of its commonly-owned suppliers.
- The information CMS proposes to solicit from bidding suppliers regarding future capacity is not sufficient to accurately gauge a supplier's true ability to rapidly expand its capacity to serve a potentially significantly greater number of Medicare beneficiaries, should the supplier be selected as part of only a small number of winning bidders, as was the case in the original Round 1 bidding.

- The RFB and accompanying bid forms do not address how CMS plans to ensure that the products/brands currently available to beneficiaries will be available throughout the Round 1 Rebid contract period.
- The financial documentation CMS plans to solicit from suppliers in order to determine the viability of a supplier's bid and capacity to furnish supplies to Medicare beneficiaries in a particular CBA for the duration of the contract period does not provide a complete picture of a supplier's overall financial health.
- Form B does not properly distinguish between experienced suppliers and suppliers that have little to no experience furnishing items that comprise the product category for which the supplier bids.

Please find below a more detailed set of comments expanding on our points set forth above.

COMMENTS

Bona-Fide Bids

We continue to urge CMS to enact concrete, transparent standards for determining that a bid is in fact not bona-fide and, therefore, should not be used to calculate an item's single payment amount. The RFB only states that bids must be "rational and feasible for the bidder to furnish at the bid price" (RFB, page 5); however, no further information is provided on how CMS plans to judge whether this criteria is met.

The financial information sought by CMS from bidding suppliers does not allow the Agency to make an informed conclusion as to whether a particular supplier has submitted a "bona fide" bid. Further, the lack of any criteria in the RFB indicating how the agency will determine what constitutes a "bona fide" bid leaves suppliers uncertain as to whether or not they can effectively submit a complete bid that will be accepted and, therefore, whether the supplier should participate or not in the bidding process. Instead, the RFB and Form B simply ask for a supplier's total revenue and total number of customers served for a product category in a CBA and the corresponding percentage of revenue and customers served attributable to Medicare. (Surprisingly, given the fact that this is the only information CMS plans to use to determine supplier capacity, "good faith estimates" are accepted on the bid form.) What this data, whether actual or a "good faith estimate," fails to convey is any assurance that the supplier's cost structure is sufficient to sustain the bid being made (especially in consideration of competitive bidding's non-discrimination requirement). Without such information, CMS has no way to know whether a supplier's bids are indeed "rational and feasible for the bidder to furnish at the bid price" for the entire contract period. The RFB states that CMS may request that a supplier submit manufacturer invoices so that the Agency can verify that the supplier can furnish the item at the bid price. (RFB, page 5). However, there is no indication that CMS will be able to effectively identify those bids that warrant this additional scrutiny, given the limited information CMS solicits in the bid form itself. Furthermore, a supplier's costs of doing business encompass a great deal more than the cost of procuring product from one or two low-cost manufacturers.

First, such examples of product costs may not be representative of the supplier's current supply sales. Second, the RFB process wholly fails to address other costs that suppliers routinely incur in order to be able to furnish quality mail order supplies and first-rate service to beneficiaries, such as: (1) personnel for customer service, records maintenance, billing, and shipping; (2) packaging and delivery costs; (3) insurance; (4) general overhead expenses; (5) shipping and distribution costs; and (6) other administrative costs.

The RFB process must contain some more tangible methods for CMS to be able to objectively determine which bids are rational and feasible. Further, the basis by which these objective determinations will be made should be set forth in the RFB itself. We recommend that CMS eliminate a supplier's bid from consideration where such bid can be objectively determined to be unreasonably low, given current market conditions, the financial condition of the bidding supplier, and the supplier's demonstrated experience (or lack thereof) in furnishing items to patients at a price point equal to or close to the supplier's bid.

Access to Quality Brands and Specific Products

Although the proposed Form B requires a bidding supplier to provide the manufacturer names, model numbers and model names it currently makes available to its customers for the top HCPCS codes within the product category for which it submits a bid, winning suppliers are not required to continue furnishing these same products/brands for the duration of the contract period. Therefore, this information is of little, if any, value. The Competitive Bidding Program's non-discrimination clause (42 C.F.R. § 414.422(c)), which only mandates that contract suppliers give Medicare beneficiaries in a CBA access to the same products/brands the supplier makes available to non-Medicare beneficiaries, does not adequately protect beneficiaries' access to a sufficiently wide array of products in a CBA for the duration of the Round 1 Rebid contract period. And, while MIPPA requires CMS to reject a supplier's bid where the supplier fails to demonstrate that its bid covers types of diabetic testing strips that, in the aggregate and taking into account volume for different products, cover 50% (or such higher percentage as the Secretary may specify) of all such types of products, this provision does not apply to the Round 1 Rebid. Therefore, there is nothing to stop suppliers, driven by the artificially low single payment amounts derived through the competitive bidding process and unwillingness to lose a significant portion of their business, from furnishing only the least expensive devices within a HCPCS code to all patients once the Program commences - even in situations where a patient would benefit from a more expensive, sophisticated device. This scenario becomes even more likely when, as in the initial Round one process, CMS selects winning suppliers with little or no existing patient base or experience servicing the diabetic supply needs of Medicare beneficiaries. It is imperative that CMS ensure that beneficiaries in each CBA are guaranteed reasonable and convenient access to a sufficiently wide array of quality diabetic testing products, including, most importantly, the products that they currently use and trust. This can only be done through altering the bidding and selection process to ensure that the suppliers: (1) submit bids that are realistic based on the full array of products they currently provide (and if they have no sales history, that are currently provided in the market more generally); and (2) chosen to furnish a product category in a particular CBA carry a

sufficiently wide array of popular, quality products. Further, the single payment amounts must be set at a level that allow the contract suppliers to continue furnishing substantially the same product lines that they carried prior to participating in the program. Particularly with products used for chronically ill beneficiaries, such as diabetes supplies, a drastic change in the products available on the market will adversely affect beneficiaries and could result in increased health care costs overall, should beneficiaries fail to adapt to the product changes.

Bidding Process

The proposed RFB and accompanying bid forms leave several important questions unanswered with respect to the bidding process. For instance, Form B's Question 3 asks the bidding supplier to "(i)ndicate the percentage of total geographic area (all counties) where you currently furnish items in this product category to Medicare beneficiaries." This instruction is very unclear. It is uncertain whether a supplier should make this calculation using zip codes or total surface area, or whether a supplier should indicate that it furnishes items in 100% of the geographic area of the CBA if it furnishes items to beneficiaries located in each county in the CBA, even though it may only have one current customer in each county. Again, a bidding supplier is unable to make these determinations using the information provided in the proposed RFB or bidding forms. The same is true for Form B's Question 4(b), which asks a supplier to indicate "the percentage increase in Medicare business" that the supplier would be capable of providing for the product category in the CBA during a projected 12-month period. It is not clear whether this question asks for the supplier's percentage increase in total units furnished to all Medicare beneficiaries, or percentage increase with respect to total number of Medicare beneficiaries served. It is also unclear how a parent company of commonly-owned DMEPOS suppliers that is not itself a DMEPOS supplier (and therefore is not able to enter an "NSC identification number" for Form A's Question A) should submit a bid on behalf of its commonly-owned suppliers.

The solicitation of this information must be explicitly clear so that suppliers can accurately submit consistent information that will allow for an effective review of the bids. Therefore, we encourage CMS to reissue the RFB and accompanying bid forms with all information necessary for suppliers to submit informed bids, and to do so well in advance of the bid window.

Financial Documentation

The financial documentation CMS plans to solicit from suppliers in order to determine the viability of a supplier's bid and capacity to furnish supplies to Medicare beneficiaries in a particular CBA for the duration of the contract period does not provide a complete picture of a supplier's overall financial health. This documentation includes: (1) an Income Statement, Balance Sheet and Statement of Cash Flow for the last calendar year; (2) a Credit Report with numerical Credit Score completed within 90 days prior to the date on which the supplier submits its bid; and (3) a Tax Return Extract for the last calendar year. (RFB, page 15). We understand that, under certain circumstances, CMS may also solicit manufacturer invoices from a supplier in

order to determine the appropriateness of its bids to furnish items within a particular CBA. (RFB, page 5). This requested information provides an incomplete picture of a supplier's true costs of maintaining its business. What is particularly troubling is that, for new suppliers (those suppliers that have been in business [we note that this should be clarified to pertain to business in the relevant product category] for less than one (1) year from the date on which the bid is submitted, according to the RFB), CMS only requires "the appropriate combination of actual or pro forma data equal to the length of time it has been in business to represent the three types of financial statements. For example, a supplier in business in the relevant product category (again, this must be clarified) for six months would submit actual financial statements for the six months prior to bid submission and pro forma or prospective financial statements for the following six months." (RFB, page 16). We are very concerned that the agency plans to base its decision on whether a new supplier is eligible for participation in the Program in part on prospective (and possibly self-serving) data which is impossible to objectively verify.

While the Coalition supports requiring only one year of financial documentation from suppliers, we urge CMS to include the precise financial standards used when evaluating such documentation in a revised RFB. Further, in order to acquire more reliable financial data, we urge CMS to require that bidding suppliers submit: (1) an IRS Form 4506-T; and (2) independently audited financial statements for the previous year. Such requirements provide better verification of a supplier's true financial health, and are a further safeguard against bidder fraud.

We also recommend that CMS require suppliers to provide information on the number of years they have furnished items in the product category for which they are submitting a bid to both Medicare beneficiaries and other patients. A supplier's demonstrated experience furnishing items in the product category for which they are submitting a bid, submitting claims for payment to third-party payors and providing appropriate patient care services with respect to these items should be an important factor in the selection of contract suppliers. Simply put, price should not be the sole determining factor in whether a supplier is awarded a contract, and CMS should work to avoid a scenario in which the majority of contract suppliers for a product category have little or no experience actually furnishing these items to patients. Further, while new suppliers with only speculative financial data should not be excluded from the bidding process, their uninformed bids made without any demonstrable experience should be excluded from the calculation of the pivotal bid.

Similarly, for purposes of calculating total supplier capacity, CMS should require each bidding supplier to identify whether it is a "new supplier." A "new supplier" should be defined as any DMEPOS supplier that has not furnished the totality of items included in the product category for which the supplier is submitting its bid for more than one (1) year from the date on which the bid is submitted. CMS should assign 0% capacity to all new suppliers that are deemed eligible for the Program, and should not factor a new supplier's bid into the calculation of the pivotal bid.

Financial Standards

The proposed RFB and accompanying bid forms shed no light on the financial standards to be used by CMS to evaluate bidding suppliers. Although, as indicated above, page 16 of the proposed RFB details the hard-copy financial documentation a supplier must submit along with its bid, nowhere does the RFB or accompanying bid forms shed any light on the standards CMS plans to use to guide its evaluation of the financial information it receives from bidding suppliers. The Coalition continues to believe that the absence of any transparency with respect to the financial standards used by CMS is inappropriate in view of the centrality of the standards in the bid process, and leaves open the possibility that such standards could be used to unfairly discriminate against and eliminate many willing and respectable businesses from participation in the Competitive Bidding Program. Since such financial standards have not been included in CMS' formal rulemaking, we believe that the financial standards should be made public by including them in a revised RFB, so that suppliers can assess their current financials in relation to the standards in order to submit informed bids to CMS.

Market Demand and Supplier Capacity

CMS's methods of calculating current and projected beneficiary demand for a product category in a particular CBA were not included in CMS rulemaking, have not been made public, and are not included or described in the proposed RFB and accompanying bid forms. This makes it extraordinarily difficult for suppliers to properly calculate their future capability to meet market demand, and thus to properly gauge their ability to participate in the Competitive Bidding Program at a particular price. As a result, it is likely that a number of suppliers will submit to CMS uninformed bids, as occurred during the initial Round 1 implementation, and that CMS will accept many of these bids at face value without appropriate due diligence. We recommend that CMS include a detailed explanation of the methodology it uses to calculate current and projected beneficiary demand in a revised RFB and communicate this methodology to suppliers long before the bidding process begins, so that suppliers can submit reasonable, informed bids at levels that can be sustained throughout the contract period.

The Coalition also believes that the information solicited by CMS to determine a supplier's projected capacity and ability to expand provides insufficient verification of a supplier's future capabilities. Indeed, the proposed Form B simply requires that a supplier "discuss" its future expansion plans, if any, with regard to staffing, financing, facilities and other items. (Form B, page 3). Such a summary is self-serving and difficult, if not impossible, to objectively evaluate and verify absent additional documentation, which is not required by Form B; accordingly, this summary cannot and should not be given much weight in determining a supplier's true ability to ramp up its capacity to furnish items as a contract supplier. Form B and the RFB should require additional documentation supporting a supplier's intended expansion plans, and should make clear that a supplier's capacity will be capped at 120% of its demonstrated capacity for the prior year.

60-day Bid Window

The proposed RFB states that suppliers will only be given 60 days in which to submit their bids under the Round 1 Rebid. (RFB, p. 20). We believe this bid window does not provide sufficient time to craft informed, reasonable bids, especially given the administrative inconsistencies and technical issues that plagued the initial bidding process, and are likely to recur in the Round 1 Rebid, given the concerns raised in these comments. Although the Covered Document Review Process and corresponding notification requirement with respect to required financial documentation set forth in MIPPA is a step in the right direction, it is not sufficient to address the root causes of the confusion and uncertainty in the supplier community that contributed to incomplete bids in the initial bidding process. Neither the proposed RFB nor the accompanying bid forms contain all of the information necessary for suppliers to submit informed bids. Without increased transparency with regard to CMS's bid evaluation methodology, and more explicit instruction, we fear that CMS's decision to only give bidding suppliers 60 days to submit their bids will lead to many of the same issues and problems that thwarted suppliers' best efforts to participate in the Program in 2007-2008. Further, the continued extensions to the bidding window in the initial Round 1, and "clarifications" or outright changes to the bidding process made during those extended bid periods, prejudiced bidders that attempted to meet the initially stated bid timeline. A sufficient bidding period must be set to allow for clarifications to be made as needed without prejudicing suppliers attempting to adhere to a moving target. Accordingly, the bid window should remain open for at least 120 days.

Disclosure of Subcontractors

The proposed RFB requires signed letters of intent from bidding suppliers that plan to enter into a subcontracting agreement, including the following information: (1) identification of the parties; (2) language clearly indicating that the subcontractor has agreed to supply items/functions/services; (3) anticipated length of agreement; (4) an attestation that the subcontractor currently possesses all required state license(s) for every state in the CBA for which it will be servicing; (5) an attestation that the subcontractor currently meets all applicable quality standards and is accredited by a CMS-approved accreditation organization; and (6) language obligating the subcontractor to abide by state and federal privacy and security requirements, including the privacy provisions stated in the regulation for the Program. The proposed RFB also states that, "(i)n general, functions that a subcontractor can perform are limited to those functions described in the DMEPOS supplier standards found at 42 CFR 424.57(c)(4), (12) and (14); all other services should be provided directly by a Medicare enrolled DMEPOS supplier." (RFB, page 20).

We commend CMS for improving its information collection with respect to the use of subcontractors and clarifying with specificity the types of subcontracting relationships that are allowed under the Program. We continue, however, to have concerns with CMS's reliance on subregulatory guidance to communicate information to suppliers on important aspects of the Program. As noted earlier, using subregulatory guidance in this manner all but guarantees that a

significant number of suppliers will not receive timely answers to fundamental questions on the Program and, thus, unfairly prejudices the bidding process. In addition, because there are several sources of Competitive Bidding Program information, using subregulatory guidance as a means to communicate important program requirements could lead to confusion among suppliers if different answers to the same question are issued. Both problems occurred during the initial bidding and implementation process.

CONCLUSION

The Diabetic Product Suppliers Coalition appreciates being afforded the opportunity to comment on the Information Request and proposed RFB and accompanying bid forms for the Round 1 Rebid. While we commend CMS for the work that it has done to date in preparing to implement the Program, and certainly understand the difficult nature of CMS's task, we are very concerned that the Competitive Bidding Program is fundamentally flawed in many areas and currently not well-suited to diabetic supplies. Unfortunately, our examination of the proposed RFB and accompanying bid forms reinforces our concerns. In short, these competitive bidding forms do not provide all of the information necessary for suppliers to submit informed, reasonable bids to participate in the Competitive Bidding Program, nor do these forms solicit from suppliers the information necessary for CMS to fairly and objectively implement a Program that avoids the same severe flaws that prompted Congress to step in and delay competitive bidding's inception. Accordingly, we ask that OMB require CMS to carefully consider these comments and revise its RFB and accompanying bid forms to ensure that the Competitive Bidding Program will meet its intended goals without causing undue hardship to suppliers, beneficiaries or the Medicare program as a whole.

We hope that CMS will consider seeking informal comment and information from us as this process moves forward. Any questions or requests for additional information may be directed to Seth Lundy (202-626-2924 or slundy@kslaw.com) or Scott Strickland (202-626-9247 or csstrickland@kslaw.com). Your careful consideration is greatly appreciated.

Respectfully submitted,

Seth H. Lundy

C. Scott Strickland

SHL/CSS