KING & SPALDING

King & Spalding LLP
1700 Pennsylvania Avenue, NW
Washington, DC 20006-4706
www.kslaw.com

Seth Lundy
Partner
Direct Dial: 202.626.2924
slundy@kslaw.com

March 17, 2009

**VIA COURIER**

Centers for Medicare & Medicaid Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW,
Washington, DC 20201
Attention: CMS-1561-IFC

Re: **Comments on Proposed Rule, CMS-1561-IFC, Changes to the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics and Supplies (DMEPOS) by Certain Provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)**

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 Interim Final Rule Changes to the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics and Supplies ("DMEPOS") by Certain Provisions of the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA") published in the Federal Register on January 16, 2009 (hereinafter "Interim Final Rule"). The Interim Final Rule would implement certain MIPPA provisions that delay implementation of Round 1 of the Competitive Bidding Program; requires the Centers for Medicare and Medicaid Services ("CMS") to conduct a second Round 1 competition (the "Round 1 rebid") in 2009; and mandates certain changes for both the Round 1 rebid and subsequent rounds of the program, including a process for providing feedback to suppliers regarding missing financial documentation and requiring contractors to disclose to CMS information regarding subcontracting relationships. The Coalition and its members continue to have serious concerns about CMS's implementation of the DMEPOS Competitive Bidding Program ("Competitive Bidding Program" or "Program").

The Coalition believes that the Competitive Bidding Program is a complex and difficult program that poses numerous problems for beneficiaries, suppliers and the Medicare program itself, and remains disappointed that CMS did not take the opportunity provided by the Congressionally-mandated delay of the Competitive Bidding Program to address and substantially revise the substance of the Program, including, among other things, the lack of transparency in the agency's decision-making processes that contributed to many of the problems plaguing the Program's initial roll-out in 2007-2008. We are deeply concerned that CMS appears again to be rushing the implementation of the Competitive Bidding Program without truly addressing many of the flaws in the implementation and execution of the Program apparent during its initial roll-out.

CMS's apparent haste to enact a Competitive Bidding Program that is nearly identical to the program that was initially implemented for rollout in 2007-2008, including almost all of the same flaws, is at odds with Congress's decision to delay the Program's implementation through the passage of MIPPA. With this delay, Congress intended that CMS take the time necessary to promulgate a new competitive bidding rule that would ensure the Program's success, rather than rush to implement a flawed program that had been previously introduced and that was believed likely to lead to disastrous results for Medicare beneficiaries. While the Coalition believes that competitive bidding in almost any form is inherently flawed and should not be pursued, if Congress and the Agency are intent on moving forward with the Program, clearly there is significant room for improvement. We believe that, absent significant modifications to the Program's structure and implementation, including a fundamental overhaul of the bid process and increased transparency of the agency's metrics in determining supplier capacity, beneficiary demand and the financial viability of supplier bids, the Competitive Bidding Program promulgated in the 2009 Interim Final Rule will suffer from the same deficiencies that prompted Congress to delay the Program, and will only succeed in reducing competition, driving reputable DMEPOS suppliers out of business and sharply curtailing the availability of quality supplies and services for beneficiaries. In short, we believe the strong possibility of potential harm to beneficiaries and reputable suppliers argues against implementing the Program as currently structured. Accordingly, the Coalition urges CMS to rescind the Interim Final Rule and reissue the competitive bidding regulation as a proposed rule, ensuring meaningful and proper notice and comment.

In spite of the Program's current shortcomings, the Coalition applauds the Agency's recognition of the fact that diabetic testing supplies pose certain unique challenges with respect to their inclusion in the Competitive Bidding Program. We greatly appreciate the Agency's request for specific comments about the inclusion of diabetic testing supplies and provide below extensive comments on this subject, including the possibility that such items would not be included in the initial round of the Program.

For the ease of CMS, we divide our comments into three main sections: (1) an overview of our comments, summarizing our key positions with respect to the inclusion of diabetic testing supplies in the Competitive Bidding Program and other specific text in the preamble and interim

final regulations, as well as general comments on the Competitive Bidding Program; (2) our comments on the specific text of the preamble and interim final regulations; and (3) our comments on the DMEPOS Competitive Bidding Program generally, including issues not specifically addressed or defined by any section in the preamble or regulations of the Interim Final Rule.

## OVERVIEW

*Diabetic Testing Supplies Should be Excluded from Competitive Bidding*

We continue to believe that diabetic testing supplies should be excluded from competitive bidding, at least until further information is procured on competitive bidding's potential effects on beneficiary access, education and care management, for the following reasons:

- There are a large number of Medicare beneficiaries that currently use diabetic testing supplies, making this product category too difficult to manage and posing too great a risk to the Medicare program as a whole.
- There continues to be great uncertainty surrounding the Program's effect on beneficiary access to quality products and convenient, experienced suppliers.
- CMS does not have any experience with this product category with respect to competitive bidding.
- The current single bid price methodology does not lead to sustainable reimbursement levels for suppliers. Unrealistically low prices that are out of line with the true market will undoubtedly cause a number of suppliers to fail, forego or be precluded from participation in the Program.
- The 9.5% reduction in reimbursement for mail order diabetic supplies mandated by MIPPA, in conjunction with the current recession, has already forced a number of suppliers to eliminate jobs in a desperate attempt to stay afloat and continue to serve their patients. More industry layoffs are expected.
- A further reduction in Medicare reimbursement for diabetic testing supplies, especially one as severe as the 43% cut originally settled upon in the initial Round 1, will have dire consequences in this current economic climate: small businesses will be forced to shut down and a significant number of jobs will be lost. As a result, Medicare beneficiaries will lose access to trusted, reputable suppliers that for years have provided these beneficiaries with the care and support necessary to treat their condition.
- CMS has the authority to: (1) exclude product categories from competitive bidding; and (2) delay or forego a national mail order program. *See* 42 U.S.C. §§ 1395w-3(a)(1)(B)(ii), 1395w-3(a)(3). For the numerous reasons cited throughout these comments, CMS should exercise its authority and exclude diabetic testing supplies from competitive bidding altogether.

*If CMS Includes Diabetic Testing Supplies in the Competitive Bidding Program, the Agency Should Not Include This Product Category in the Round 1Rebid*

Should CMS decide to include diabetic testing supplies in the Competitive Bidding Program, we believe that:

- CMS should not include diabetic testing supplies in the Round 1 rebid.
- CMS should avoid bifurcating the diabetes testing supply market based on mode of delivery or any other marker.[1] Instead, CMS should solicit bids from both mail order and traditional storefront suppliers and evaluate these bids in the context of a single diabetic testing supplies product category for each CBA.
- CMS should not implement a national mail order program for diabetic testing supplies because such a program is unsustainable. If CMS decides to implement a national mail order program diabetic testing supplies, it should first engage in an extensive review and study of competitive bidding's effects on beneficiaries, suppliers and the Medicare program.[2]

*Should CMS Include Diabetic Testing Supplies in Competitive Bidding, Substantial Changes to the Program are Necessary*

We also believe that, if diabetic testing supplies are included in competitive bidding, substantial changes to both the administrative and substantive elements of the Program are necessary in order to avoid many of the same problems that plagued the initial rollout of the Program in 2007-2008. To that end, we recommend that CMS:

- Set the single payment amount for each product or supply at a level no less than the bid of the highest bidding supplier selected by CMS to meet the anticipated demand within a CBA, which demand has been reasonably assessed by the Agency with transparency to the industry.
- Eliminate a supplier's bid from consideration where such bid is objectively assessed as unreasonably low, given current market conditions, the financial condition of the bidding supplier, and the supplier's demonstrated experience (or

[1] The Coalition is unclear on whether CMS intends to include diabetic testing supplies in the Round 1 rebid or whether, if diabetic testing supplies are included, CMS plans again to bifurcate the market by delivery method. The Coalition continues to believe that Congress did not authorize CMS to divide or bifurcate product categories by mode of delivery, other than by providing an option to implement a national mail order program after implementation was attempted and successful in a limited number of CBAs.

[2] This could be accomplished through a limited demonstration project for competitively bid diabetic testing supplies, followed by discussion with the DMEPOS industry and beneficiaries of the demonstration project's results and an additional notice and comment rulemaking.

lack thereof) in furnishing items to patients at a price point equal to or close to the supplier's bid.

- 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. These standards must ensure that CMS: (1) carefully account for the continued growth in demand that is anticipated in key product areas, such as diabetes testing; (2) places increased weight on a supplier's demonstrated, rather than projected, ability to meet market demand; and (3) calculates demand based in part on a consideration of the breadth of brands and types of products and supplies that are currently available in each CBA, and which are used most often by beneficiaries.
- Communicate these financial standards 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.
- Set the anticipated demand benchmark for each product category within a CBA at 150% of Medicare utilization for the product category over the most recent 12-month period (for diabetic testing supplies, this number would be 150% of total beneficiary demand for the product category, including both mail order and traditional storefront purchases).
- Institute a hard cap on a supplier's projected capacity to service Medicare beneficiaries within a CBA at a 20% increase of the supplier's demonstrated capacity for the most recent 12-month period.
- Ensure that: (1) suppliers have the necessary information needed to submit informed, reasonable bids; (2) the bidding process and the Competitive Bidding Submission System ("CBSS") are streamlined and simplified; and (3) the bid submission process functions properly before moving forward with the Program by instituting proper notice and comment with regard to the bid process.

## SPECIFIC COMMENTS ON INTERIM FINAL RULE

The Coalition applauds CMS for considering alternatives for the competition of diabetic testing supplies and is pleased that the agency is considering some of the arguments we raised concerning the bifurcation of the method of delivery of diabetic testing supplies as well as the confusion surrounding the definition of the term "mail order." The Coalition, however, remains concerned about the potential effect of the DMEPOS Competitive Bidding Program on Medicare beneficiary access to medically necessary diabetic testing supplies. Please find below our recommendations concerning the competition of diabetic testing supplies and other comments addressing specific provisions contained in the 2009 Interim Final Rule.

**Considerations for Future Rulemaking under the Competitive Bidding Program**

*Diabetic Testing Supplies Should be Excluded from Competitive Bidding*

The Coalition is unclear on whether CMS intends to include diabetic testing supplies in the Round 1 rebid or whether, if diabetic testing supplies are included, CMS plans again to bifurcate the market by delivery method. Although the Interim Final Rule includes "mail-order diabetic supplies" in the list of product categories for the Round 1 rebid, the agency later states that it is "considering alternatives for the competition of diabetic supplies" and that "(t)his competition will potentially take place sometime after the Round 1 rebid." 74 Fed. Reg. 2873, 2878 (Jan. 16, 2009). CMS further states that it believes that employing competitive bidding for diabetic supplies in both the mail order and traditional retail markets is consistent with the implementing statute. *Id.* Therefore, it is difficult to discern the direction CMS plans to take with regard to diabetic testing supplies and the Round 1 rebid. Accordingly, the Coalition does not believe that the Interim Final Rule provides sufficient notice for reasonable comment pursuant to the Administrative Procedure Act. If CMS plans to include diabetic testing supplies in the Round 1 rebid, the Coalition strongly objects to this decision. We continue to believe that diabetic testing supplies should be excluded from competitive bidding, at least until further information is procured on competitive bidding's potential effects on beneficiary access, education and care management. This might be done, for example, through a demonstration project in a limited area.

Diabetes is a serious disease that afflicts, by conservative estimates, over 10 million seniors. Both Congress and CMS are well aware of the significant medical and financial problems caused by diabetes. The cost of hospitalizations and other care of diabetic patients are well over $132 billion per year. Since a cure for diabetes remains elusive, medical authorities universally agree that testing and monitoring of blood glucose levels by people with diabetes is the most effective means to minimize the complications and the huge medical costs commensurate with the care and treatment of this disease. Numerous clinical studies demonstrate that successful diabetes management is linked to effective patient education and compliance with a patient's physician-prescribed glucose testing regimen.

Unlike many of the product categories included in the Competitive Bidding Program's Round 1 rebid, there is no historical information, such as that which could be derived through demonstration projects or other limited pilot programs, detailing the effect that the inclusion of diabetic testing supplies in the Competitive Bidding Program may have on beneficiaries' efforts to manage and control their diabetes. Accordingly, there are no assurances that CMS's decision to include diabetic testing supplies in the Program will not impede beneficiary access to medically necessary testing supplies and services. If anything, the results of the Competitive Bidding Program's prior first round competition before the Congressionally-mandated delay shows that the Program's current structure all but guarantees that beneficiary access to medically necessary diabetic testing supplies will be frustrated, given the low number of diabetic testing suppliers selected to service each CBA and our understanding of the narrow selection of products these contract suppliers planned to make available to beneficiaries. As we stressed above, beneficiaries that cannot easily obtain the supplies that they need and are accustomed to will likely fall out of compliance with their physician-prescribed testing regimen, harming both the

beneficiaries and the Medicare program (which will ultimately absorb higher costs from increased Part A admissions).

Given the consistent recognition among scholars, advocacy organizations, physicians and even CMS that diabetes is a disease that deserves more attention and greater efforts directed at prevention, nothing should be done to discourage or prevent compliance with Medicare diabetic patients' physician-prescribed testing regimens, or limit access to the highest quality medically necessary testing supplies. Accordingly, if CMS plans to include diabetic testing supplies in the Round 1 rebid, we ask that the Agency rethink its decision and not include diabetes testing supplies as a product category in the Round 1 rebid until further review and study (such as a demonstration project) can be conducted. Simply put, further review and study (such as a demonstration project) in this instance is needed to ensure that the application of competitive bidding to this important category of supplies will not (1) unduly restrict access of beneficiaries to the supplies they currently use; (2) result in reduced compliance with prescribed testing regimens; and (3) lead to increased complications and Part A admissions and other forms of care at significant additional costs to the Medicare program that would more than offset any potential cost savings gained through this program. Should CMS decide to include diabetic testing supplies in the Competitive Bidding Program, we believe that the large number of beneficiaries that currently use diabetic testing supplies and the uncertainty surrounding the Program's effect on beneficiary access argue for, at the very least, the inclusion of diabetic testing supplies in the Program's later stages, rather than the Round 1 rebid.

As an alternative to competitive bidding, the Coalition offers to organize a meeting with CMS and key stakeholders in the diabetes supply industry to discuss other methods for maintaining reduced program costs. We believe that such a meeting could be used to explore creative alternatives that would not adversely affect beneficiaries and other stakeholders to the same degree.

*CMS Should Not Bifurcate the Diabetes Supply Product Category Based Upon Mode of Delivery*

Should CMS decide to move forward with competitive bidding for diabetic testing supplies, we strongly urge the agency to avoid bifurcating the diabetes testing supply market based on mode of delivery or any other marker. Implementing competitive bidding only for "mail order" suppliers, while allowing traditional retail suppliers to furnish items at higher reimbursement rates, severely disadvantages direct-to-consumer suppliers who furnish products and supplies primarily through the mail.

While the Coalition recognizes that mail order is neither appropriate for all patients nor all products and supplies, mail order delivery is essential for the timely receipt of many beneficiaries' medically necessary products and supplies. It would be a mistake to target this sector of the DMEPOS industry while excluding storefront suppliers from competitive bidding, as "mail order" businesses provide a number of unique benefits for beneficiaries and the Medicare program alike. These benefits are particularly important with regard to beneficiaries with diabetes. First of all, many mail order suppliers of diabetic testing products, including our Coalition members, specialize in these products and in the care of diabetes. Mail order suppliers are able to provide this specialized care by consolidating operations in one or a few select

locations and employing individuals knowledgeable about diabetes and appropriate care management. Second, mail order delivery allows many beneficiaries to obtain medically necessary supplies when other purchase options may not be available; a beneficiary's limited mobility or lack of proximity to storefront suppliers often require the beneficiary to use a mail order supplier to obtain his or her needed testing supplies. Mail order suppliers offer beneficiaries with immediate access to trained specialists in diabetes care, providing unparalleled diabetes education and care management services. Perhaps most importantly, mail order suppliers help to ensure that beneficiaries adhere to the testing regimens prescribed by their physicians by initiating regular and proactive contact with the beneficiaries. These benefits help beneficiaries while keeping costs down for the Medicare program as a whole.

With all of the benefits offered by the mail order model, mail order suppliers should not be held to different standards than other suppliers. In fact, mail order suppliers are generally indistinguishable in most important aspects from all other types of suppliers, so much so that CMS, as evidenced during the initial implementation of the Competitive Bidding Program, is hard pressed to offer a reasonable definition of a "mail order supplier." In addition, the current Medicare supplier standards (42 C.F.R. § 424.57) essentially require all suppliers to operate a walk-in storefront facility. Supplier standards (7) and (8) require all suppliers, including mail order suppliers, to maintain a physical facility on an appropriate site, which must be accessible during reasonable business hours to beneficiaries and to CMS, and maintain a visible sign and posted hours of operation. Thus, all "mail order" suppliers are required to operate the same types of bricks-and-mortar storefront locations as other suppliers. Finally, many (if not most) suppliers offer some items and supplies via mail or local delivery service. Accordingly, supplier standard (12) requires that all suppliers must be responsible for the delivery of Medicare-covered items to beneficiaries and maintain proof of delivery. Thus, no suppliers are exclusively mail order suppliers, and most suppliers furnish at least some items direct-to-consumer, making the term "mail order" virtually meaningless.

In addition, there is no valid data to support that mail order diabetic testing suppliers have lower costs or would necessarily be able to furnish supplies to Medicare beneficiaries at a lesser price than traditional storefronts solely because of the method of delivery employed. First, the cost structures of all suppliers, including each of the members of our Coalition, vary significantly. Second, many large retail pharmacy chains that purchase diabetic testing supplies in large volumes and are able to use regular pharmacy resources without extra costs to furnish diabetic supplies can have lower overall costs than mail order suppliers.

Further, CMS's belief that, despite lower reimbursement levels, mail order suppliers will be able to compete with storefront suppliers because a critical mass of beneficiaries will transition from retail to mail order suppliers is fundamentally flawed. Lower out-of-pocket costs for supplies alone will not drive a significant number of beneficiaries to mail order because most beneficiaries have supplemental policies (or are dual-eligibles) and thus pay no out-of-pocket expenses when purchasing diabetic testing supplies; in fact, fewer than 20% of Medicare beneficiaries actually pay out-of-pocket costs to mail order suppliers. In addition, the significant cut in Medicare reimbursement will force winning suppliers to cut costs and stop carrying popular, high-quality testing supplies in favor of inferior knock-offs which, while FDA-approved, lack any mail or retail market presence, are unsupported by the physician community,

and have not gained acceptance among consumers. This will result in the migration of many beneficiaries that currently use mail order suppliers to traditional retail suppliers in order to purchase their preferred brand of testing supplies. In turn, this will undercut the potential savings to the Medicare program generated by the disparate treatment of diabetic testing suppliers under the Competitive Bidding Program and make it more difficult for contract suppliers to remain in business.

Of course, the Coalition also recognizes that there are important benefits to ensuring that all beneficiaries also have convenient walk-in access to a pharmacist-operated supplier. While "mail order" suppliers all provide walk-in services, they are not conveniently located throughout cities and suburbs where most beneficiaries reside. Although the Coalition believes that direct-to-consumer delivery methods (such as "mail order") are important for many beneficiaries, due to the complexities of diabetes as a disease and the differences among the millions of Americans who suffer from this disease, we recognize that it is equally important for beneficiaries to have the option to have a face-to-face encounter with a pharmacist or to be able to have their supplies immediately (without waiting for shipping). Overall, the common goal of both CMS and the industry is to ensure that beneficiary needs are met so that physician prescribed testing regimens are followed and complications from diabetes are kept to a minimum.

Thus, for the aforementioned reasons, there is no logic in singling out "mail order" businesses for participation in the Competitive Bidding Program while favoring retail storefronts with higher levels of reimbursement. Accordingly, should CMS decide to include diabetic testing supplies in the Competitive Bidding Program, we do not believe that the Agency should bifurcate the industry on the basis of mode of delivery or any other artificial marker. Instead, CMS should solicit bids from both mail order and traditional storefront suppliers and evaluate these bids in the context of a single diabetic testing supplies product category for each CBA. In other words, there should only be one product category for diabetic testing supplies within a CBA, rather than separate product categories for "mail order diabetic testing supplies" and "non-mail order diabetic testing supplies." Under this single product category, all diabetic testing suppliers, regardless of their preferred method of delivery to beneficiaries, would submit bids to furnish competitively bid items to beneficiaries within the CBA. CMS would then evaluate the bids and select the number of winning suppliers that ensures that beneficiary demand, taking into account the unique beneficiary needs for both walk-in and mail order suppliers, within the CBA is satisfied. Importantly, in order to ensure that it selects a sufficient number of diabetic testing suppliers for each CBA, CMS must ensure that the winning suppliers possess the collective capacity to meet <u>total</u> beneficiary demand within a CBA for diabetic testing supplies (i.e. demand for both direct-to-consumer delivery <u>and</u> convenient storefront pickup).

*Nationwide Mail Order Competitive Bidding Program Should Not be Implemented without Further Study of Competitive Bidding's Effects*

MIPPA delays any competition for a national mail order program until after 2010. While we believe that this delay is warranted, given the dearth of information concerning the effect that competitive bidding on a smaller scale in as few as 10 CBAs will have on beneficiaries and suppliers and more specifically the results of the prior attempt to implement Round 1 bidding, we

remain extremely concerned about any future implementation of a national mail order program for diabetic testing supplies or the bifurcation of the diabetes supply market in any manner based on mode of delivery. We believe that, given the large (and increasing) number of Medicare beneficiaries with diabetes and the importance of patient compliance with physician-prescribed testing regimens in the overall care and treatment of the disease, the diverse needs of that growing population, the differences in diabetic supply offerings and the undeniable need for compliance testing, diabetic testing supplies are a poor fit for competitive bidding. Certainly, such a program, especially one with a broad, national scope, should not be implemented without first obtaining additional information and insight into the program's potential effect on beneficiary access to medically necessary testing supplies and compliance with testing regimens, as well as whether the Program's reimbursement levels are truly sustainable for contract suppliers over the Program's duration. Accordingly, should CMS decide to move forward with national mail order competitive bidding for diabetic testing supplies, it should first engage in an extensive review and study of competitive bidding's effects on beneficiaries, suppliers and the Medicare program. This could be accomplished through a limited demonstration project for competitively bid diabetic testing supplies, followed by discussion with the DMEPOS industry and beneficiaries of the demonstration project's results and an additional notice and comment rulemaking.

*CMS Has the Authority to Exclude Diabetic Testing Supplies from Competitive Bidding*

Congress has not mandated that CMS include diabetic testing supplies in the Competitive Bidding Program. The competitive bidding implementing statute does not set forth specific DMEPOS items or services that must be included in the Program; rather, the statute states that the programs "may be phased in first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential." 42 U.S.C. §§ 1395w-3(a)(1)(B)(ii) (emphasis added). Thus, Congress has clearly given CMS discretion as to which items and services (but not which modes of delivery for such items and services) may be included. CMS has exercised this discretion in the Interim Final Rule by excluding other high cost product categories, such as negative pressure wound therapy and group 3 complex rehabilitative power wheelchairs. In addition, Congress has provided CMS the authority to exempt DMEPOS items and services "for which the application of competitive acquisition is not likely to result in significant savings." 42 U.S.C. §§ 1395w-3(a)(3). We believe these provisions and the general authority granted to the Agency to effectively operate the Medicare program provide CMS ample authority to exclude diabetic testing supplies from the Program, as it is likely that any savings to the Medicare program resulting from lower Part B reimbursement for diabetic testing supplies under competitive bidding will be negated by increased Part A expenditures resulting from increased hospital admissions due to beneficiaries' non-compliance with their physician-prescribed testing regimens. Even if CMS believes that subjecting diabetic testing supplies to competitive bidding could result in substantial savings to the Medicare program beyond those in already in place based upon the MIPPA-enacted cut, the Secretary is not required to competitively bid this (or any) product category solely because of its anticipated savings potential. In short, the Coalition believes that CMS has the authority to exclude diabetic testing supplies from competitive bidding, and should do so at least until further

information is obtained with respect to competitive bidding's potential effects on beneficiary access, education and care management.

## General Changes to the DMEPOS Competitive Bidding Program

*Supplier Feedback on Missing Covered Documents*

Section 154(a) of MIPPA adds a new paragraph (F) to section 1847(a)(1) of the Social Security Act, which establishes a process by which CMS must notify suppliers of missing "covered documents" - defined by MIPPA as financial, tax or other documents required to be submitted by a bidder as part of an original bid submission in order to meet required financial standards - if such documents are submitted within a specified time period. The Interim Final Rule sets forth CMS's plan to notify bidding suppliers of each covered document that is missing from the bidder's submission as of the "covered document review date," defined as the later of: (1) the date that is 30 days before the final date specified by the Secretary for submission of bids; or (2) the date that is 30 days after the first date specified by the Secretary for the submission of bids. Consistent with the notification requirement set forth in MIPPA, the Interim Final Rule states that CMS will notify bidders of any missing covered documents within 45 days after the covered document review date for the Round 1 rebid, and within 90 days after the covered document review date for all subsequent rounds. For all rounds of competition, bidders that are notified by CMS of the missing covered document(s) will have 10 business days after the date of notice to submit the missing covered document(s). Provided that such documentation is submitted to CMS within this time period, the agency is prohibited from rejecting a supplier's bid on the basis that any covered document is missing or has not been submitted on timely basis.

The Coalition supports this notification requirement. We continue to believe, however, that the best way to ensure that no willing supplier is foreclosed from the bidding process is to proactively eliminate the administrative inconsistencies and technical issues that plagued the initial bidding process. Although the notification requirement 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. Without increased transparency with regard to CMS's bid evaluation methodology and a formal rulemaking process addressing many important aspects of the Program that CMS chose to communicate through inadequate, inconsistent and delinquent subregulatory guidance, we fear that CMS's decision to promulgate an Interim Final Rule and quickly move forward with the Competitive Bidding Program will lead to many of the same issues and problems that thwarted suppliers' best efforts to participate in the Program. The fundamental flaws in the bidding process that slammed the door shut on many willing suppliers can only be remedied if CMS decides against a hasty implementation of the Program and instead takes the time necessary to formally solicit further feedback from the supplier community on the initial bidding process and apply the lessons learned from this feedback to the upcoming Round 1 rebid, so that the Agency does not inadvertently shut reputable, willing suppliers out of the bidding process.

Should CMS move forward with the Round 1 rebid process, we urge CMS to adopt the notification requirement outlined in MIPPA for all supplier documents and materials requested

as part of the Round 1 rebid process, including those that are not required as part of the original bid submission in order to meet required financial standards. Although MIPPA only requires CMS to notify suppliers of missing "covered" documents submitted during the "covered document review period," CMS is not prohibited from extending this notification requirement to cover any document requested from a bidding supplier by CMS as part of the bidding process. Such an extension makes sense because it would better ensure that all willing suppliers are given the opportunity to submit bids and participate in the Competitive Bidding Program on an equal basis. CMS should do everything in its power to avoid excluding reputable suppliers from the Program due to incomplete bid submissions stemming from administrative oversights or honest confusion on the part of suppliers. Indeed, given the many problems confronting suppliers during the previous bidding process, it is likely that, absent significant changes to the process, suppliers will again submit incomplete bid applications through no fault of their own.

The Interim Final Rule indicates that CMS is also modifying the financial document provisions to require only one year of financial documentation from suppliers, rather than three years. The Coalition supports this modification, but again urges CMS to include the precise financial standards used when evaluating such documentation in a formal rulemaking that allows for notice and comment. Further, while we agree that three years of financial data was burdensome, we continue to believe that CMS should, and, indeed must have a transparent process for taking into account a supplier's operating history when evaluating bids. This must include not just financial history, but actual experience furnishing products in the bid category in question. Such a process is necessary to ensure that beneficiary demands can be properly met.

*Disclosure of Subcontractors and Their Accreditation Status under the Competitive Bidding Program*

CMS is proposing to amend 42 C.F.R §§ 414.414 and 414.422 in order to set forth MIPPA's requirements concerning the disclosure of subcontractors and their accreditation requirements under the Competitive Bidding Program. MIPPA requires contractor suppliers to disclose information on: (1) each subcontracting arrangement the supplier has in furnishing items and services under the contract; and (2) whether each subcontractor meets the accreditation requirement of the Social Security Act, if applicable to such subcontractor. MIPPA also requires that the contract supplier make this disclosure not later than 10 days after the date a supplier enters into a contract with CMS and that, if the contract supplier subsequently enters into a subcontracting relationship, the supplier must disclose this information no later than 10 days after entering into the subcontracting relationship. CMS has amended the competitive bidding regulations to reflect these requirements, and states that it will issue subregulatory guidance regarding the need to keep CMS current on all subcontracting relationships and the methods for disclosure of these relationships.

We continue 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. 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.

Perhaps more importantly, we believe that CMS should use the rulemaking process to clarify the types of subcontracting relationships that are allowed under the Program. CMS has always acknowledged and accepted, and continues to acknowledge and accept, that a supplier may contract with a third party to provide certain services that are not specifically part of the core services that must be furnished with respect to a covered item, such as shipping services or billing services. The current supplier standards provide that a supplier "[f]ills orders, fabricates, or fits items from its own inventory *or by contracting with other companies* for the purchase of items necessary to fill the order." (42 C.F.R. § 424.57(c)(4); emphasis added.) However, we understand that some winning suppliers in the Program's initial implementation planned to subcontract some or all of the core reimbursable services required when furnishing a competitively bid item to another non-contract supplier. In fact, in some instances, we understand that the winning supplier had no history of furnishing the competitively bid items, but was awarded a contract on the basis of its low bid and its plan to meet beneficiary demand for the item through a subcontracting relationship with a supplier that did in fact furnish the items.

We believe CMS must clarify in a further rulemaking that the agency will not award contracts to furnish items under the Competitive Bidding Program to any supplier that subcontracts any part of the "core services" that must be furnished with respect to a covered item, and that bids from these suppliers will be thrown out and will not be considered in the calculation of the item's single payment amount. Further, CMS must define what are these "core services," as such term is ambiguous and currently without any commonly understood meaning. Because competitive bidding necessarily decreases the number of suppliers a Medicare beneficiary can choose from that to purchase medically necessary items and services, it is important to limit participation in the Program to suppliers that, at the time their bid is submitted, furnish all of the required core services for an item.

*Exemption from Competitive Bidding for Certain DMEPOS*

CMS intends to exempt crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps that are DME from competitive bidding when furnished by a hospital to a hospital's own patients during an admission or on the date of discharge and paid for under Part B of the Medicare program. The Coalition supports this exemption.

*Exclusion of Group 3 Complex Rehabilitative Power Wheelchairs*

Section 154(a) of MIPPA exempts group 3 complex rehabilitative power wheelchairs from competitive bidding. The Interim Final Rule amends the definition of "item" under the Competitive Bidding Program to exclude group 3 complex rehabilitative wheelchairs from the Program. While the Coalition does not wish to comment on this particular provision, we note that CMS is well within its power to exempt diabetic testing supplies from competitive bidding,

either permanently or at least until sufficient data on the competitive bidding's effect on access to quality testing supplies and the ability of suppliers to sustain service to a growing number of Medicare diabetes patients at substantially reduced reimbursement levels can be determined. We believe CMS should take this step to protect Medicare beneficiaries and the supplier community from an uncertain fate. As indicated above, we believe that similar steps should be taken for diabetic supplies.

## GENERAL COMMENTS ON COMPETITIVE BIDDING PROGRAM

### Beneficiary Access and Supplier Pricing

The Coalition remains concerned about the potential effect the DMEPOS Competitive Bidding Program may have on Medicare beneficiary access to medically necessary diabetic testing supplies. Specifically, we believe the DMEPOS Competitive Bidding Program's current pricing structure is unsustainable and will lead to fewer suppliers available to serve a growing Medicare population and a dearth of quality products in the marketplace, thereby placing Medicare beneficiaries at risk.

Congress' overarching purpose in enacting the competitive bidding portions of the MMA were to allow market forces to determine the price of DMEPOS rather than a somewhat artificial system based on allowables, fee schedules and gap-filling. Congress' view was that a robust competitive bidding process would enable the Medicare program to get a competitive market price without compromising the quality of products and services received by Medicare beneficiaries. For example, Senator Kyl, during the debate on the MMA, stated "What is the solution? . . . . Simply allow competitive bidding. Let the markets decide what the right levels are." (Cong. Rec. S8544 (daily ed. June 25, 2003) (Statement of Sen. Kyl)).

*The Current Single Payment Amount Calculation Results in Unsustainable Reimbursement Levels*

CMS's decision to set the single payment amount for a competitively bid item at the median of the bids for the winning bidders for the selected item does not truly allow the market to set the price for a particular product and violates traditional economic theory on multiple bidder/multiple item purchasing. CMS' contract awards are contingent upon the notion that the services of all winning bidders are needed to meet the anticipated demands of beneficiaries in the CBA. If each of these suppliers is necessary to ensure sufficient access for beneficiaries, then at least the single payment amounts must be set at a level so that each winning bidder is able to furnish all items within a product category at a price that is sustainable for that supplier for the duration of the Program (i.e. a price that is at or above the supplier's bid price).

CMS's decision to set the single payment amount for a competitively bid item at the median of the bids for the winning bidders for the selected item means that up to one half or more of the winning suppliers will be paid less than their bids. A supplier's bid generally reflects the lowest level of reimbursement the supplier believes (rightly or wrongly) it can receive for furnishing an item or service to Medicare beneficiaries while remaining a viable

business. As evidenced in the prior Round 1 bid process, a number of winning suppliers decided against contracting with CMS to furnish items and services in a particular CBA because the final single payment amounts were not sustainable for the suppliers' businesses. With regard to diabetic testing supplies, the large reduction in reimbursement (43%) to winning suppliers undoubtedly convinced some of these suppliers to forego participation in the program. Although we recognize that the goal of competitive bidding is to reduce the price paid by CMS to suppliers for DMEPOS items and services, CMS should not attempt to accomplish this goal by reducing Medicare reimbursement to a level below the suppliers' true cost. Simply put, the current single bid price methodology simply does not lead to sustainable reimbursement levels for suppliers. Such unrealistically low prices that are out of line with the true market will undoubtedly cause a number of suppliers to fail, forego or be precluded from participation in the Program. Ultimately, this exodus of proven, reputable suppliers from the Medicare program will result in the displacement of beneficiaries and the reduction of suppliers that can conveniently furnish the same quality supplies and services that beneficiaries within each CBA are accustomed to receiving.[3]

*The Single Payment Amount Must be Sufficient to Allow All Winning Suppliers to Both Participate and Remain Competitive in the Marketplace*

We believe that, in order to ensure that there will be sufficient beneficiary access to medically necessary DMEPOS products in each CBA, particularly with regard to diabetic testing supplies, the competitively bid single payment amount must be sufficient to allow all selected suppliers to both participate and remain competitive in the marketplace. Thus, the single payment amount for each product or supply should be set at a level no less than the bid of the highest bidding supplier selected by CMS to meet the anticipated demand within a CBA, which demand has reasonably assessed by the Agency with transparency to the industry. Because all bids for furnishing items and supplies under the program must be at or below the current fee schedule amount, setting the single payment amount at a level no less than the bid of the highest bidding supplier will generate savings to the Medicare program while at the same time preserving beneficiary access to quality products and suppliers.

*The Current Pivotal Bid Calculation Does Not Sufficiently Allow for Supplier Attrition*

Offering suppliers whose bids are higher than the pivotal bid the opportunity to participate in the Competitive Bidding Program and accept reimbursement at the single payment amount does not solve the problem of supplier attrition. It does not change the fact that the single bid price methodology as implemented by CMS results in an unreasonably low price. For

[3] Notably, the processes used in the two completed demonstration projects (Polk County, Florida and San Antonio, Texas) avoided these issues by allowing all contracted suppliers to furnish competitively bid items at or above their bid price. We recognize that, because the MMA requires a single payment amount, this approach is no longer viable. However, the concept of the demonstration projects, which ensured that no winning bidder would be required to furnish supplies at a price lower than their winning bid, must be sustained.

starters, many of these suppliers may be forced out of business if they are not awarded a contract under the program; therefore, the pool of suppliers CMS is able to choose from at this stage will likely be significantly diminished. This outcome is even more likely today, given that suppliers and the rest of the country are currently confronted with the most severe economic recession since the 1930s. As a result of the 9.5% reduction in reimbursement for mail order diabetic supplies mandated by MIPPA, a number of suppliers have already been forced to eliminate jobs in a desperate attempt to stay afloat and continue to serve their patients, and more industry layoffs are expected in the near term as profits and revenue have been dramatically reduced. A further reduction in Medicare reimbursement, especially one as severe as originally settled upon in the initial Round 1 of competitive bidding, will have dire consequences. Small businesses will be forced to shut down, a significant number of jobs will be lost, and as a result Medicare beneficiaries will lose access to trusted, reputable suppliers that for years have provided these beneficiaries with the care and support necessary to treat their condition.

In addition, it is unlikely that those winning suppliers that manage to continue furnishing supplies to Medicare beneficiaries would be able to provide the service, training and other beneficiary education necessary in order to use the DMEPOS items safely and effectively at an inappropriately low single price that is well below their original bid. Moreover, this problem will be exacerbated if a significant number of suppliers begin to withdraw from the market, forcing the remaining suppliers to attempt to expand rapidly. If CMS truly anticipates the need to go back to suppliers above the pivotal bid at some point, CMS should be setting the pivotal bids at a high enough level (i.e. at a level where combined capacity of the CBA's winning suppliers is greater than 100%) such that the CBA will be able to sustain some level of supplier attrition.

## Bona-Fide Bids

*Transparent, Concrete Standards are Necessary to Evaluate Bids*

We continue to urge that CMS 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. Because CMS provided no information on its process for determining what constitutes a bona-fide bid during the Program's initial implementation, we are unable to comment on the specific process or calculation used by CMS, other than to express disappointment over the fact that this "black box" process was not addressed further in the Interim Final Rule. However, because the agency arrived at single payment amounts for diabetic testing supplies that were 43% below then-current fee schedule reimbursement levels, the initial round one bid submission process clearly showed that the process CMS had in place was woefully inadequate, as it allowed irresponsible or unsophisticated suppliers to submit unrealistic, low-ball bids in an attempt to prevent reputable suppliers from participating in the Program and drive such suppliers out of business altogether. This is evidenced by the fact that the minority of "winning" suppliers had little or no experience with providing diabetic testing supplies and the current financial troubles of many suppliers today who are only dealing with much more modest cuts at 9.5%. Simply put, absent workable standards to guide its evaluation of each bid's validity, CMS was either unable or unwilling to weed out those suppliers that bid

well below their true costs of providing competitively bid items and services to Medicare beneficiaries in the initial Round 1 bid process.

*Unreasonably Low Bids Hurt the Medicare Program*

Fortunately, Congress stepped in to delay the Program before permanent damage to proven, reputable suppliers and the beneficiaries they serve could take root. However, we believe that the presence of these low-ball bids completely disrupted the integrity of the bidding process and, absent Congressional intervention, would have likely led to a scenario where most, if not all, contract suppliers would have been forced to drop out of the Program altogether because they were losing money with every item furnished to a Medicare beneficiary within a CBA. Again, many diabetic testing suppliers, including members of the Coalition, are already struggling to stay afloat due to the 9.5% reduction in reimbursement that became effective January 1, 2009; suppliers have been forced to eliminate staff and stop carrying brand name products due to declining Medicare revenue. As a result, service to beneficiaries has been impaired. Some reputable suppliers with outstanding records of service to beneficiaries and the Medicare program will not survive, thereby impairing beneficiary access to quality products and suppliers. A reduction in reimbursement along the lines of the 43% cut in the failed implementation of Round 1 would decimate the industry and leave millions of Medicare beneficiaries who depend on mail order delivery of diabetic testing supplies without a viable option.[4]

*Both a "Floor" and "Ceiling" for Bids are Necessary*

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. Setting both a ceiling (the item's current fee schedule amount) and a floor (an unreasonably low bid, given the unique characteristics of the supplier's business and the product category) and communicating this standard to suppliers in the final rule along with an objective standard for making such determinations would make the bidding process more transparent and easier to navigate for suppliers while ensuring that unrealistic bids are disposed of before they cause lasting harm to the Medicare program.

We recognize that cutting Medicare program costs is one of the impetuses for enacting the Competitive Bidding Program. The Coalition supports CMS and Congress in finding ways to equitably and appropriately achieve that important goal. However, a single-minded determination to cut costs to the Medicare program without a corresponding concern for ensuring there are enough suppliers that can sustain their businesses and meet beneficiary demand in each

[4] We note that such severe cuts in reimbursement all but guarantees that price will be the sole factor in determining which suppliers remain in business. Medicare beneficiaries that choose a supplier on the basis of customer service, rather than using price as the sole factor, will be left out in the cold.

of the CBAs at the Program's reduced reimbursement levels is not in the best interest of beneficiaries or the Medicare program.

**Access to Quality Brands and Specific Products**

*Diabetic Testing Supplies Present Unique Challenges under Competitive Bidding*

The inclusion of diabetic testing supplies in the Competitive Bidding Program presents unique challenges with regard to accessing quality products. Because the diabetes supply market is quite large, there are many brands/products for diabetic patients to choose from. These testing supplies are often proprietary to a particular brand of meter, and the quality and ease-of-use of meters and testing supplies varies significantly among different brands. As a result, many beneficiaries are loyal to a particular brand and are loathe to change brands because, through experience, these beneficiaries have come to find that their preferred brand of testing supplies is the best available option, taking into account their own unique plan of care and individual needs. Because of the size of the testing market, the large and growing number of beneficiaries with diabetes, and the importance of ensuring that these beneficiaries remain compliant with their physician-prescribed plan of care, we believe that diabetic testing supplies should not be included in any phase of the Competitive Bidding Program, let alone the first round.

*CMS Must Ensure that Medicare Beneficiaries Continue to Have Access to Their Preferred Brands/Products*

Should CMS decide to include diabetic testing supplies in the Program, it is imperative that CMS restructure the DMEPOS Competitive Bidding Program in order to ensure that Medicare beneficiaries are assured access to their preferred brand of diabetic testing supplies. Not all diabetic testing supplies are alike; even if many testing supplies purport to have the same clinical benefits, there is significant variation in terms of their quality and functionality. In many cases, these differences may be insufficient to allow a prescribing physician to justify the need for one brand over another; however, from the beneficiary's standpoint, these differences may be the difference between testing as prescribed and not testing at all. As you know, Medicare beneficiaries are elderly, and many have difficulty adjusting to changes of products that they have used for years. Also, because many diabetic testing supplies (and all testing strips) are proprietary to a particular brand (and often model) of home blood glucose monitor, there is currently no assurance that selected suppliers of diabetic testing supplies will even offer the brand of testing strips necessary to fit a beneficiary's current monitor. If beneficiaries cannot easily obtain the supplies that they need and are accustomed to, it is likely that their testing compliance will decline, resulting in significant harm to those beneficiaries and the Medicare program (which will ultimately absorb higher costs due to increased Part A admissions).

The Competitive Bidding Program's non-discrimination clause (42 C.F.R. § 414.422(c)), which 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. In addition, 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, should CMS include diabetic testing supplies in the Round 1 rebid, 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 - even in situations where a patient would benefit from a more expensive, sophisticated device. This 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 beneficiaries . Such suppliers will quickly abandon all of the brands that beneficiaries know and trust. In doing so, these suppliers are technically in compliance with the non-discrimination provision. However, the decision to jettison quality product lines in favor of untested, inexpensive knock-offs that are often of lower quality, while making it easier for contract suppliers to shoulder the burden of inappropriately low reimbursement levels, will have a detrimental effect on both beneficiaries and the Medicare program. Because so many DMEPOS items, like diabetic testing supplies, are used for preventive care aimed at keeping beneficiaries functioning safely in their own homes, and out of the inpatient setting, such a decision could increase, rather than decrease, the total cost to Medicare of treating a particular beneficiary.

In addition, MIPPA's requirement that a supplier demonstrate that its bid covers a certain range of diabetic testing products will not adequately protect beneficiary access to popular brands/products if a similar requirement is not imposed for the Round 1 rebid. This is because, without this requirement in Round 1, the types of products available to beneficiaries during Round 1 will not truly reflect beneficiary demand or product quality and efficacy; rather, the array of products available will be driven solely by cost. Therefore, the product utilization data available for subsequent bidding cycles will be skewed toward lower-quality testing supplies, and will bear no relation to the preferences beneficiaries exhibited prior to competitive bidding.

For the reasons set forth above, it is imperative that, should CMS decide to include diabetic testing supplies as a competitive bidding product category in the Round 1 rebid, it ensure that beneficiaries in each CBA are guaranteed reasonable and convenient access to a sufficiently wide array of quality products. This can only be done through altering the selection process to ensure that the suppliers chosen to furnish a product category in a particular CBA carry a sufficiently wide array of popular, quality products, and that single payment amounts are set at a level that allows the contract suppliers to continue furnishing substantially the same product lines that they carried prior to participating in the program.

**Bidding Process**

*Technical and Administrative Issues Plagued the Initial Round 1 Bidding Process and Must be Fixed in the Final Rule*

As the Agency is aware, during the brief period provided during the initial Round 1 bidding process for DMEPOS suppliers to digest the details and complexities of the Competitive Bidding Program, successfully register in order to submit a bid, and then prepare and submit informed, reasonable bids in CBSS, suppliers attempting to participate in the Program were met with a host of serious administrative and technical problems. Both the CBSS and the Competitive Bidding Implementation Contractor ("CBIC") websites were plagued from the outset with technical glitches and poor functionality that prevented some suppliers from registering with the CBIC site and accessing the bidding system, while preventing others that successfully registered from submitting bids prior to the deadline. These technical issues, combined with CMS's refusal to shed light on its bid evaluation process, generated frustration and confusion within the supplier community. Ultimately, many suppliers were forced to scramble to submit their bids at the last minute because of these issues, only to encounter further problems such as the inability to communicate directly with the CBIC in the days leading up to the bid deadline or constant error messages on the CBSS website.

Additionally, CMS's efforts to educate suppliers on the bidding process were repeatedly undermined by incomplete (and sometimes conflicting) guidance from both the agency and the CBIC on a number of important competitive bidding topics, including questions concerning: (1) the definition of a "mail order" supplier; (2) how to correctly calculate a supplier's current capacity to service a CBA; (3) how to calculate the percentage of the CBA's total geographic area a supplier serves; (4) supplying information concerning the products/brands a supplier furnishes in a CBA; and (5) whether the parent company of commonly-owned DMEPOS suppliers that is not itself a DMEPOS supplier should submit one combined bid or separate bids for each supplier. We believe this exposes one of the fundamental problems inherent in CMS's decision to issue subregulatory guidance and instructions for suppliers on important aspects of the Program rather than appropriately include such guidance in the formal rulemaking process. Although CMS's strategy may save time for the Agency in the short term, the piecemeal delivery of essential information is a disservice to DMEPOS suppliers and the Medicare program as a whole. The agency's heavy reliance on oral and web-based subregulatory guidance, much of which is updated at the very tail end of the bidding process, all but guarantees that some suppliers will not receive timely answers to fundamental questions and, because there are several sources of Competitive Bidding Program information, often leads to inconsistencies that confound suppliers as they formulate their bids. It also discourages suppliers from submitting and certifying bids early in the bid process because suppliers often must wait on the agency or the CBIC for answers to important questions.

Once suppliers obtained what they believed to be satisfactory answers to these and other questions on the Program and the bid submission process, they confronted hard copy and electronic bid forms with incomplete instructions or technical problems with the CBSS itself. For example, some members of the Coalition were unable to enter information into the electronic version of Form B, which prevented these suppliers from completing Form B and certifying their

bid in a timely fashion. Other suppliers who wished to submit additional information to supplement an answer on the electronic bid form were unable to do so because, unlike the hard copy bid form, the electronic bid form did not provide a space for additional information. (Suppliers that contacted the CBIC concerning this issue were given conflicting information: some suppliers were told that they could not submit any additional information on the electronic bid form to supplement an answer, whether on the electronic form itself or through an attachment to the hard copy form, while many other suppliers were informed by the CBIC that such additional information could be submitted with the hard copy documentation). We understand that other suppliers submitted all of the bid information requested by CMS, only to be informed later that their bids were not under consideration because entire sections of their submissions were shown as incomplete.

*CMS Must Ensure that All Suppliers are Afforded an Equal Opportunity to Participate in the Program*

It is imperative that CMS ensure that willing, reputable suppliers are not shut out of the Program due to administrative inconsistencies, incomplete instructions or technical issues with the CBSS. We cannot endorse a program that does not allow that every supplier that wishes to participate in the Competitive Bidding Program the opportunity to do so. We fear that CMS's decision to promulgate an Interim Final Rule without addressing any of these issues in the rulemaking itself, presumably in order to more quickly move forward with the Competitive Bidding Program, will lead to many of the same issues and problems that thwarted suppliers' best efforts to participate in the Program. Without including these important process-related issues within the formal rulemaking and allowing for full and fair public comment of the bidding process, which process then should be locked down without material changes to ensure fairness to all, there can be no assurance of a fair, effective and transparent bidding process. In addition, the current bidding process and requisite administrative hurdles work an undue burden on small suppliers that do not possess the same staffing and technical resources of larger companies. Without a more streamlined, transparent bidding process, small suppliers are put at a disadvantage vis-à-vis large suppliers that are more likely to be able to devote additional resources to complete the bidding process in a timely fashion. Therefore, the Coalition strongly urges CMS to take the time necessary to ensure that: (1) suppliers have the necessary information needed to submit informed, reasonable bids; (2) the bidding process and CBSS is streamlined and simplified; and (2) the bid submission process functions properly before moving forward with the Program. Proper notice and comment would ensure that industry stakeholders have the ability to publicly identify problems in the bidding process and make recommendations to ensure that history does not repeat itself.

Once CMS elicits the feedback necessary to improve the bidding process through the notice and comment process, it should begin the bidding process by issuing an official Request for Bids document, detailing the standards for submitting the bid and detailed instructions for doing so. This document would help guide the process, and would ultimately improve the chances that CMS receives informed bids from all reputable suppliers who wish to participate in the Program. We also recommend that, after the Round 1 rebid is complete, CMS make the aggregated data from the bids available for public inspection so that those suppliers that were not

selected are better informed for future bidding. Financial data, the bidding company's identity and any other proprietary information would remain sealed.

**Financial Standards**

The Coalition continues to believe that the absence of any transparency with respect to the financial standards used by CMS to evaluate bidding suppliers 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. If the standards are too restrictive, fewer suppliers will be able to participate in the bid process, diminishing beneficiary choice and potentially adversely affecting the single payment amount. If the standards are not restrictive enough, unsound suppliers may be awarded contracts. Accordingly, we believe that the financial standards are another issue that would benefit from inclusion in a formal rulemaking process that allows suppliers to examine and comment on the proposed financial standards. Public dialogue with industry stakeholders is important to ensure that CMS receive the information necessary to formulate a set of concrete, objective financial standards that will help safeguard the Medicare program. Equally as important, CMS must make these standards public, 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**

*A Complete Overhaul of CMS's Method of Calculating Supplier Capacity and Market Demand is Necessary*

The results of the Competitive Bidding Program's initial implementation argue strongly for a complete overhaul of how CMS determines current and anticipated future market demand for product categories within a CBA and the corresponding supplier capacity necessary to satisfy market demand. Of the more than 4,000 suppliers servicing the 10 CBAs included in the initial round of bidding, only 325 were offered contracts to continue furnishing medically necessary supplies and services to Medicare beneficiaries within the CBAs. CMS's methods of calculating beneficiary demand and supplier capacity were not made public. This made it extraordinarily difficult for suppliers to properly calculate their future capability to meet market demand. As a result, a number of suppliers submitted to CMS uninformed bids that failed to accurately reflect the true number of beneficiaries the supplier would be able to service over the contract period. Although we cannot comment on the precise calculations CMS used to determine market demand and expected supplier capacity in each CBA, the low number of suppliers selected to service Medicare beneficiaries, which in most bidding categories excluded most of the largest suppliers in the market (i.e. the only ones that can truly demonstrate the ability to meet demand based on a real track record) is evidence of either a flawed methodology or inaccurate supplier projections that were taken at face value by CMS without appropriate due diligence.

In order to avoid these same problems in the future, CMS must delay implementation of the Competitive Bidding Program and seek input from the Program Advisory and Oversight Committee and other industry stakeholders in order to enact concrete, transparent standards for determining beneficiary demand and supplier capacity that suppliers can use a guide when submitting bids. These standards must ensure that CMS: (1) carefully account for the continued growth in demand that is anticipated in key product areas, such as diabetes testing; (2) places increased weight on a supplier's demonstrated, rather than projected, ability to meet market demand; and (3) calculates demand based in part on a consideration of the breadth of brands and types of products and supplies that are currently available in each CBA, and which are used most often by beneficiaries. Further, CMS must communicate these standards 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. Without these assurances, the Program will work great harm on Medicare beneficiaries and the Medicare program itself.

The Coalition recommends that CMS set the benchmark for beneficiary demand for each product category within a CBA at 150% of Medicare utilization for the product category over the most recent 12-month period (for diabetic testing supplies, this number would be 150% of total beneficiary demand for the product category, including both mail order and traditional storefront purchases). In so doing, CMS would better ensure that it selects a sufficient number of suppliers for each product category within a CBA that would truly satisfy beneficiary demand, taking into account the growing numbers of both Medicare beneficiaries and diabetics. Using 150% of the most recent 12-month period's utilization as the benchmark will also help ensure that an allowance is made for certain events, such as financial mismanagement or other problems, which could lead to a lower number of contract suppliers servicing the CBA than CMS originally anticipated. It is imperative that CMS set the capacity benchmark at a number high enough so that increased demand and unforeseen supplier attrition are accounted for. The Coalition believes 150% of the most recent 12-month utilization for the product category in a CBA is a workable benchmark.

We also recommend that CMS institute a hard cap on a supplier's projected capacity to service Medicare beneficiaries at 20% of the supplier's capacity level for the most recent 12-month period. In other words, if a supplier furnished items in a product category to 100,000 Medicare beneficiaries in a CBA during the most recent 12-month period prior to submitting its bid, the supplier's projected capacity for the contract period can be no greater than 120,000 Medicare beneficiaries for the same product category within the same CBA.

## CONCLUSION

The Diabetic Product Suppliers Coalition appreciates being afforded the opportunity to comment on the DMEPOS Competitive Bidding 2009 Interim Final Rule. 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 not well-suited to diabetic supplies. The failure to implement a reasonable, workable Competitive Bidding Program that protects

beneficiaries, provides cost savings for the Medicare program and does not unduly, adversely affect the supplier industry as a whole or disproportionately one or more sectors of the industry would be a disservice to Medicare beneficiaries and the Medicare program as a whole, and could cause significant damage to the competitive abilities of certain sectors of the DMEPOS supplier industry over the long run. Because the Program is so essential to the future of the DMEPOS industry, its implementation should neither be rushed nor forced. Accordingly, we ask that CMS carefully consider these comments and allow adequate time and further industry comment 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 believe that CMS should exclude diabetes supplies altogether from the Competitive Bidding Program. At the very least, diabetic supplies should be excluded from Round 1 and studied much more carefully before being included in any manner in future phases of the program. Should CMS decide to include diabetic testing supplies in any phase of the Program, it is imperative that CMS (1) refrain from bifurcating the product category based on mode of delivery and (2) ensure that the winning suppliers possess the collective capacity to meet total beneficiary demand within a CBA for diabetic testing supplies (i.e. demand for both direct-to-consumer delivery and convenient storefront pickup).

Clearly, competitive bidding is the wrong way to reduce costs for this product category. We recognize, however, the costs to the Medicare program related to reimbursement for diabetic supplies and are willing to work with CMS and Congress to find reasonable alternative methods to help reduce those costs. In addition, we reiterate that we are willing and available at any time to provide additional information about "mail order" suppliers or diabetic testing suppliers in general. 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