DACC
Diabetes Access to Care Coalition

June 18, 2009

Office of Management and Budget
Office of Information and Regulatory Affairs
Attention: Centers for Medicare & Medicaid Services Desk Officer
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RE: CMS-10169 Agency Information Collection Activities: Submission for OMB Review; Comment Request

The Diabetes Access to Care Coalition (DACC), a coalition of patient advocates, providers, suppliers and manufacturers of diabetes testing supplies, appreciates the opportunity to provide comments on CMS-10169 Paperwork Reduction Act Agency Information Collection Activities that will be undertaken by the Centers for Medicare & Medicaid Services (CMS) for purposes of the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program.

DACC was formed in 2005 to ensure that Medicare beneficiaries with diabetes maintain access to high quality products and services through avenues of their choice in order to help improve diabetes management, reduce diabetes complications, lower healthcare costs and manage their health. Disrupting the way that Medicare beneficiaries with diabetes obtain these supplies has the potential to reduce their compliance in monitoring blood glucose levels, thereby increasing the possibility for adverse health effects.

In addition to continued concerns that DACC has previously communicated to CMS regarding the Round 1 rebid and mail order diabetes testing supplies, we appreciate the opportunity to provide the following additional comments and concerns:

Opportunity for Informed Review and Comment of the Request for Bids Instructions and Forms

The Comment Request indicates that CMS intends to publish a slightly modified version of the Request for Bids (RFB) instructions and accompanying forms for 2009, so that suppliers will be better able to identify and understand the requirements to submit a bid in the competitive bidding program. The request further indicates that CMS has modified the format of some of the documents "to make them more reader-friendly and help ease the burden of bid submission."

While DACC appreciates CMS's efforts to make these refinements, we recommend CMS publish the modified instructions and accompanying forms to allow potential bidders and other stakeholders an opportunity to provide a more informed review and comment.

Bidding Process should be Subject to Rulemaking

DACC appreciates that CMS' tentative timeline for the Round 1 rebid does provide for a more considered process than occurred during the original program implementation in 2008. As part of comments on the Interim Final Rule and in direct dialogue with CMS, DACC has encouraged CMS to undertake through proposed rulemaking much needed changes to the program to better protect patients. Unfortunately, DACC's recommended changes are not reflected in the proposed bidding documents recently released.

Effective and enforceable beneficiary protections are tied, at least in part, to issues directly pertaining to the bidding process, the collection of data, and the appropriate and effective use of that data for program design, oversight and enforcement. Failing to include such measures will make it impossible to fulfill the goal of the Supporting Statement for CMS-10169 "to assure beneficiary access to quality DMEPOS as a result of the program" and "to contract with suppliers who conduct business in a manner that is beneficial for the program and Medicare beneficiaries."

Correcting Fundamental Flaws in the Bidding Process from Round 1

Lack of Patient Access to Most Commonly Prescribed Products

If competitive bidding had proceeded, most Medicare beneficiaries in competitive bidding areas would have lost access to their current diabetes testing supplies through the winning suppliers. The diversity of products offered by the winning suppliers was significantly narrower than the range of products currently being used by Medicare beneficiaries and was not representative of the market today.

The current rule and accompanying bidding documents do not address this weakness in the bidding procedures, including bidding rules and procedures in Round 1 that resulted in approving suppliers who were not experienced in the provision of diabetes testing supplies to Medicare beneficiaries.

Patient Access to a Broad Range of Diabetes Testing Supplies must be Protected in the Round 1 Rebid

From the initial experience in Round 1, Congress signaled its concern about maintaining a choice of products for Medicare beneficiaries with diabetes by including a specific statutory requirement in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) that winning bidders in future rounds should provide a range of diabetic supplies representing not less than 50% of the market volume. CMS has the authority to include this important protection in the Round 1 Rebid and we strongly recommend that CMS address Congressional concerns by doing so and reflecting that requirement in the bid documents. Thus the requirement that suppliers provide CMS with a listing of ALL diabetes testing products they intend to supply by make, model and manufacturer in their bidding forms, as well as a requirement to provide CMS with changes in specific product offerings, should be maintained.

Lack of Enforceable Requirements on Product Choice

CMS required bidders to indicate in their bids the products that they would provide. However, there were no apparent mechanisms to make these representations enforceable. Additional CMS oversight, including the use of enforceable contract provisions and monitoring of actual sales, is needed to ensure that patients have uninterrupted access to the diabetes testing supplies of their choice.

We urge CMS to develop bidding procedures that will ensure that the wide array of products with clinical features important to patients is readily and easily available to beneficiaries, including the following.

The bidding documents should be binding, bona fide bids that require contract suppliers to provide the range of products identified in their original bid. Bidding documents should also make clear that contract suppliers will be required to notify CMS in advance of making changes to the list of DMEPOS product brands they carry in order to make these changes publicly available. Oversight of this process is critical and needs to be in place prior to the initiation of Round 1.

At a minimum, suppliers should be required to account for the actual products placed as compared to the products they included in their bid. DACC offers the following recommendations with regard to the current documentation requirements with regard to the Medicare DMEPOS Competitive Bidding Contract Supplier Quarterly Report:

- Suppliers should be required to provide a detailed accounting at the beginning of the contract for actual products placed compared to the product list provided in the bidding process;
- Suppliers should be required to detail instances in which they provided equipment that is different from that ordered or requested by the beneficiary or healthcare professional in order to identify inappropriate product steerage; and
- On products placed, suppliers should provide actual figures, not approximated figures. The required signatures should be a high level person within the supplier organization to ensure a high level of accountability.

Similarly, under the Beneficiary Survey, DACC recommends that:

- There should be an additional question asking the beneficiary if the product they requested/ordered was actually supplied, or not;
- If a new product is supplied, the beneficiary should also be asked whether or not they were adequately trained on this product. The supplier is responsible for documenting that it has provided the beneficiary with the necessary information and instruction on how to use the item safely and effectively (42 CFR 424.57(c) (12)) and answering questions and responding to complaints about the item (42 CFR 424.57(c) (13)) and beneficiaries should be queried on these issues to ensure that compliance or noncompliance with these requirements is documented; and,
- In addition, the survey as outlined should be rewritten with the beneficiary in mind. The language within the survey should be examined for clarity as well as content.

Lack of Experience and Capacity of Winning Bidders

Round 1 also demonstrated that more needs to be done to ensure that winning suppliers have the experience and capacity to properly serve Medicare beneficiaries in a competitive bidding area. This issue was the subject of extensive discussion and stakeholder comments and concern at the recent meeting of the Program Advisory and Oversight Committee (PAOC) that took place on June 4, 2009.

Specifically, DACC recommends the following changes to the RFB Instructions:

- On page 5 of 21 Section F, "Bona Fide Bids," definitions are needed in the accompanying 'Appendix A Definitions' that describes the criteria for bona fide bids and the instances where additional information may be requested, and information is needed on the process for requesting additional supplier information, what information that would entail and how the information supplied would be verified;

- On page 12, “Revenue from Product Category,” if a supplier indicates “zero” as an amount supplied, DACC believes that should constitute a trigger by CMS for exclusion, or at minimum, further review. As proved true in Round 1, patients were not protected from suppliers with little to no experience in the provision of diabetes testing supplies. DACC has similar recommendations when bidders indicate minimal or no experience working specifically with Medicare beneficiaries. Beyond the collection of the data in the bid process, there is no indication that data showing little to no experience with the patient population or products will trigger any specific action or outcome by CMS that would protect patients whose access to diabetes testing supplies and education could be at risk. CMS’ criteria in this regard should be detailed and transparent;
- On page 13, “Bid Price,” DACC notes reference to "bid price must also be rational," but documentation is needed to describe what constitutes rational;
- On page 14, “Manufacturer Information,” there should be some discussion of the importance of oversight for this requirement. Further, there should be reference to existing or anticipated program requirements, such as the 50% requirement for diabetes supplies that could be implemented in the Round 1 Rebid and is mandated for future rounds. DACC recommends that suppliers be required to provide to CMS a letter of credit from the manufacturers listed in its bid;
- Similarly, DACC is concerned that a supplier’s product demand calculations should focus not just on enrollment, but on patient needs. The growth rate in demand for a product is not just driven according to the number of beneficiaries but also by a beneficiary’s unique needs and medical condition. This requires experience and knowledge of the patient population; and,
- For Supplier Capacity Calculations, DACC is concerned about the capacity of inexperienced and new suppliers to meet the demands of patients; DACC recommends that suppliers be required to submit as part of the bid package a plan of care for beneficiaries with diabetes.

Unfortunately, even if all of these items noted above are addressed, the bidding process still fails to put in place the kind of patient protections implemented to protect beneficiaries in other Medicare programs. For example, the above amended patient protections are not comparable to the provisions that CMS has put in place under Part D to protect Medicare beneficiaries from suppliers who lack adequate capacity, who do not provide product choice, who engage in unfair and deceptive marketing practices, or who provide inadequate support services and information. Patient protections should be uniform across the Medicare program.

Specifically, DACC is concerned that the limited protections currently in place rely almost entirely on “after the fact” monitoring of beneficiary access and product quality. Further, these protections rely on self-reporting mechanisms by suppliers and complaints received from beneficiaries.

CMS has the opportunity to more effectively monitor these issues before beneficiaries would be affected by incorporating the minimum 50% provision, the use of enforceable contract provisions, verification of supplier experience and capacity, requirements for wide product availability and strong anti-switching/steering language directly in the Round 1 rebidding process.

Looking beyond the bidding process, to facilitate CMS monitoring of contract supplier product offerings, DACC further recommends that CMS direct contract suppliers to include the pertinent product UPC or NDC-like codes on their CMS 1500 claim forms. This is a practice that many private payers and State Medicaid programs already undertake. Collecting this information on the CMS 1500 claim forms would greatly facilitate CMS oversight of how the program is

actually being implemented and enhance its understanding of how patients' access to products is being protected. Furthermore, it may also lessen the paperwork burden to suppliers and CMS, as the potential to automatically capture this data can be accomplished more readily once incorporated into existing electronic forms currently being submitted to CMS. CMS should audit actual sales regularly and often, for example after each quarter, to determine whether the Congressional intent under MIPPA to maintain broad product choice for consumers has been achieved. By instructing its contractors to capture this information, CMS will have reliable, credible Medicare claims data on which to rely when making determinations about product availability.

Conclusion

DACC believes that CMS should be transparent and develop a more comprehensive and appropriate approach to competitive bidding for diabetes testing supplies. DACC believes CMS should issue a proposed rule with the details of the bidding process and substantially revise the bidding process to include important patient protections.

DACC appreciates the opportunity to submit these comments and we urge CMS to address the above issues before the onset of the bidding process.

Sincerely,

Abbott Diabetes Care
American Association of Diabetes Educators
Bayer Healthcare Diabetes Care
LifeScan, Inc.
National Association of Chain Drug Stores
National Community Pharmacists Association
Rite Aid
Roche Diagnostics Corporation