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July 5, 2006

CMS, Office of Strategic Operations and Regulatory Affairs,
Division of Regulations Development
Attention: Mr. William N. Parham, III, Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Proposed Collection Comments - CMS 10169

Dear Mr. Parham:

Enclosed for submission to the Centers for Medicare and Medicaid Services please find the Diabetes Access to Care Coalition's ("DACC") comments to the Centers for Medicare and Medicaid Services regarding a Proposed Information Collection concerning Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (CMS-10169, summarized at 71 Fed. Reg. 26543 (May 5, 2006)).

The DACC's comments are being submitted to you, per the instructions provided in the notice, and have been postmarked with today's date, July 5, 2006. During our conversation of 8:50 a.m. on July 5, 2006, you informed me that CMS will also accept submission of comments postmarked by today, July 5, 2006 for review. The DACC appreciates your flexibility, and respectfully submits the enclosed comments for review.

Best regards,

Uri Bilek

Uri Bilek

Enclosures

DACC

Diabetes Access to Care Coalition

July 5, 2006

Centers for Medicare and Medicaid Services
Office of Strategic and Regulatory Affairs
Division of Regulations Development—B
Attention: William N. Parham, III
Room: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on Proposed Information Collection: Request for Bids for Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program [CMS-10169]

Dear Mr. Parham:

The Diabetes Access to Care Coalition ("DACC")[1,2] respectfully submits these comments to the Centers for Medicare and Medicaid Services ("CMS") regarding a Proposed Information Collection concerning Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (summarized at 71 Fed. Reg. 26543) (May 5, 2006) ("Proposed Collection"). The Proposed Collection is related to a Proposed Rule on *Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues* that CMS published on May 1 (71 Fed. Reg. 25654) (May 1, 2006) ("Proposed Rule").

The DACC includes the leading manufacturers of blood glucose monitoring systems distributed in the United States. We therefore offer our comments with a special focus on the needs of people with diabetes. As DACC explains in separate comments submitted on the Proposed Rule, we believe that CMS should exclude blood glucose monitoring systems from competitive bidding, or, at a minimum, delay bidding for such systems until further studies are completed. In the event these systems are included in competitive bidding, DACC believes it is important to ensure beneficiary access to appropriate care. One key element in ensuring such

[1] Please note that DACC is distinct from a similarly named coalition, the Diabetes Care Coalition.
[2] Members of DACC are Abbott; Bayer HealthCare; BD (Becton, Dickinson and Company); LifeScan, Inc.; and Roche Diagnostics.

access is to avoid imposing unreasonable administrative burdens on suppliers. The Proposed Collection is directly pertinent to this topic, and we appreciate this opportunity to comment on it.

We note at the outset that the Proposed Collection notice seeks comments on information collection for a system that has not been finalized. That is, the requirements for competitive bidding – as well as associated supplier quality standards – are at this point unknown and unknowable. Without understanding the requirements with respect to which information will be collected, it is impossible to evaluate the soundness of the proposed collection measures themselves. We therefore suggest that CMS issue a new proposal on information collection after the regulatory requirements of the competitive bidding program have been determined and finalized. In the interest of informing such a future CMS information-collection proposal, we are pleased to offer these comments on the current Proposed Collection notice.

In our comments, we first explain that Medicare beneficiaries who use blood glucose monitoring systems comprise a unique population – one that obtains its supplies in a manner different from that of other DMEPOS users. Second, we address the subjects that CMS sets forth in the Proposed Collection and on which the agency directly solicits comments. Finally, we comment on additional issues associated with forms identified in the Proposed Collection.

I. Context

Supplying blood glucose monitoring systems to Medicare beneficiaries occurs in a special way, and collection of bid information for such systems therefore requires special tailoring. The majority of people with diabetes obtain glucose monitors and test strips from local neighborhood pharmacies. There are over 55,000 retail pharmacy outlets that currently supply self-monitoring blood glucose supplies.[3] On average, beneficiaries visit their pharmacy about once per month to obtain a range of diabetes supplies and care advice from their pharmacist.[4] The continuum of care provided by health care professionals, such as a retail pharmacist, is key to the care of persons with diabetes. This purchase pattern is different than that for most other DME.

As we discuss in more detail below, it appears that CMS contemplates that it will require 70 hours for suppliers to the complete the forms required to submit bids. We believe this 70-hour estimate understates the actual burden that prospective bidders will encounter. Even assuming, however, that 70 hours is accurate, we believe it poses a substantial barrier to participation in competitive bidding by the small neighborhood pharmacies on which beneficiaries have traditionally relied. We believe that the burden of completing bid forms will mean fewer neighborhood pharmacy bidders, which, in turn, will mean few contract suppliers that are geographically proximate to Medicare beneficiaries with diabetes.

Neighborhood pharmacies unable to bear the administrative burden of completing bid forms – or deterred by the forms from bidding altogether -- may well be located in areas where beneficiary access to care is most at risk, such as inner-city, low-income neighborhoods. As a

[3] Knapp et al., California HealthCare Foundation, The Role of Community Pharmacies in Diabetes Care: Eight Case Studies (July 2005).
[4] *Id.*

result, within a given metropolitan statistical area, there could exist substantial geographic gaps separating beneficiaries from contract suppliers. While these gaps could impede access to care for all Medicare beneficiaries with diabetes, they could be particularly burdensome for disadvantaged center-city and minority populations. In these populations, beneficiaries not only may lack their own personal transportation or suitable public transportation, but they may also have special language or other communications needs traditionally addressed by their local pharmacies.

The profound adverse effects of even a slight increase in the difficulty of physically obtaining diabetes supplies should not be underestimated. Recognizing a similar risk in Medicare Part D, Congress and CMS have prudently provided for access standards based on beneficiaries' physical proximity to pharmacies.

In all, to the extent that competitive bidding applies to blood glucose monitoring systems, the Proposed Collection should be structured to encourage pharmacy participation, particularly in inner-city and other neighborhoods associated with disadvantaged beneficiaries. In the absence of these kinds of special precautions, there may as a practical matter be few contract suppliers accessible to Medicare beneficiaries with diabetes.

II. Subjects Set Forth in the Proposed Collection Notice for Comment by Interested Persons

In this section of our comments, we address the Proposed Collection subjects on which CMS has specifically solicited stakeholder views. Items A – D, below, correspond to the subject areas that CMS has set out in the Proposed Collection notice.

A. "The Necessity and Utility of the Proposed Information Collection for the Proper Performance of the Agency's Functions"

The Proposed Collection identifies a Form D Quarterly Report intended to "be used by the Competitive Bid Implementation Contractor [CBIC] to ensure Medicare beneficiaries have access to competitive bid items with specific features." Though Form D would allow the CBIC to track the supply of items by HCPCS code, manufacturer, make, and model, it is unclear how this information will ensure access to specific items. The DACC requests that CMS, in the Final Collection, provide a thorough explanation of how Form D will ensure access.

B. "The Accuracy of the Estimated Burden"

It appears from Section B.12 of the "Supporting Statement For Paperwork Reduction Act Submissions CMS-10169" that CMS projects a 70-hour burden for suppliers to complete the CMS-10169 forms for submission of bids. The Proposed Collection bases this projection on an estimated average for completing forms by suppliers that participated in a Polk County, FL, Competitive Bidding Demonstration.

CMS excluded blood glucose monitoring systems both from the Polk County demonstration, as well as from a similar demonstration conducted in San Antonio, TX.[5] The basis for these exclusions was the additional complexity inherent in ensuring that glucose monitors were matched with the appropriate testing supplies.[6] As such, the competitive bidding of blood glucose monitoring systems remains untested. More specifically, even to the extent the 70-hour average time attributed to the Polk County demonstration is accurate, it bears no documented relationship to the time that would be required to complete forms on blood glucose monitoring systems and their complex constituent parts.

Indeed, because of the greater subtlety associated with glucose monitoring – both technological subtlety, as well as subtlety in distribution patterns, as described above – DACC believes that the projected 70-hour burden is substantially understated. The fact that the Proposed Rule allows for neighborhood pharmacies and other small businesses to create networks, as noted in Section B.5 of the Supporting Statement for Paperwork Reduction Act Submissions CMS-10169, does not alleviate this burden. We say this for two reasons. First, it is unclear whether networks would be a feasible solution for most suppliers. We observe that while networks were offered as an option in the Polk County and San Antonio demonstrations, there were no bids submitted by networks in either of these projects. Moreover, even if networks were formed, the coordination of a single bid among multiple entities within a network might well *increase* the number of hours required for bid submission.

C. "Ways to Enhance the Quality, Utility, and Clarity of the Information to be Collected"

The request-for-bid forms identified by CMS in the Proposed Collection notice include a bidding sheet organized as a chart. In this chart, bidders would be required to list a product model for each HCPCS-designated item, along with the corresponding bid price. We recommend that this bidding sheet be revised to allow recording of more nuanced information about blood glucose monitoring systems. By facilitating collection of this more nuanced information, the Proposed Collection could encourage selection of products that ensure quality care for Medicare beneficiaries.

As background for our recommendation, we note that the relationship between product selection and quality of care is particularly direct for blood glucose monitoring systems. In contrast to other DMEPOS industry segments, it is more appropriate for the blood glucose monitoring system *manufacturer* – not the supplier – to provide multi-lingual technical support for the patients who use these systems. It is simply infeasible for a supplier to understand the intricacies of each of the diverse collection of monitoring systems in use within the Medicare beneficiary population.

In our comments on the Proposed Rule, we recommended that if CMS implements competitive bidding for blood glucose monitoring systems, it should also apply minimum

[5] We note that the competitive bidding experience in the San Antonio demonstration appears to play no role in CMS's calculation of the 70-hour average.

[6] U.S. Gov't Accountability Office, Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies 10 (2004).

standards of manufacturer-supplied 24-hours-per-day, 7-days-per-week multi-lingual technical support. Specifically, we recommended that supplier bids on any category or sub-category of monitors or test strips not be eligible for consideration or acceptance unless the products proposed to be bid are accompanied by an assurance of 24-hours-per-day, 7-days-per-week manufacturer multi-lingual technical support. CMS should also be open to other, similar suggestions.

To facilitate the implementation of our recommendation on the Proposed Rule, the bidding sheets identified in the Proposed Collection should be revised to permit recording of information on whether products proposed for bid satisfy specified manufacturer quality standards.

The forms should also make clear whether a supplier's identification of particular makes and models commits the supplier to providing only those particular makes and models – or whether this information is intended to be representative of a range of products the supplier would provide. For example, a new product might become available between the time of bidding and the time of bid implementation. The forms should make clear whether a winning bidder is limited to providing only those makes and models identified on the forms or whether there is latitude to offer a broader product selection.

D. "The Use of Automated Collection Techniques or Other Forms of Information Technology to Minimize the Information Collection Burden."

The notice of Proposed Collection provides very little information on the use of information technology in the collection process, other than to state CMS's intention to require that all forms be submitted electronically and to indicate that technical support will be offered. Section B.3 of the Supporting Statement For Paperwork Reduction Act Submissions CMS-10169 indicates that exceptions to the requirement of electronic submission are to be made. No details are provided as to when this type of exception may be applied. Section B.3 also fails to indicate how the required electronic submission will be aided by technical support, and how CMS will ensure that the electronic submission technology is compatible with respondents' information technology systems.

III. Additional Issues Raised by Forms

In this final section of our comments, we address additional issues raised by the Proposed Collection.

The first such issue concerns Form A of CMS-10169, the Bid Application. This form requests that respondents provide information about their accreditation. To the extent this is intended to query bidders on their accreditation with respect to the quality standards associated with competitive bidding, we note that procedures for this type of accreditation are not yet fully developed or implemented. The form therefore appears to request information that cannot now be provided and that is unlikely to be available, even upon initiation of a competitive bidding program.

Form A also requires a bidder to designate "Key Personnel." We suggest that CMS describe more clearly the exact information sought. Similarly, we recommend that Form A more precisely define the term, "Authorized Official."

We suggest revision of another form that CMS identifies in the Proposed Collection. Specifically, Form E of CMS-10169, the "Medicare DMEPOS Competitive Bidding Program Beneficiary Survey," lacks the proper focus for obtaining meaningful information from beneficiaries who use blood glucose monitoring systems. For example, as noted above, most beneficiaries travel to retail establishments for their glucose monitoring supplies. Yet the form does not attempt to solicit feedback on such key issues as the degree of geographic proximity of a beneficiary to a contract supplier. As such, the form will yield no information on a key risk that competitive bidding poses for beneficiaries with diabetes: that they will be so geographically remote from contract suppliers that it will be difficult for them to comply with their diabetes care regimens. While Form E may be suitable for other types of DMEPOS, its lack of focus with respect to glucose monitoring systems underscores the fundamental incompatibility between these systems and the CMS competitive bidding program.

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We conclude by reiterating that this Proposed Collection notice is premature because it seeks to describe information collection requirements associated with a competitive bidding program – and related supplier quality standards – that do not yet exist. As such, we recommend that CMS issue a new proposed collection notice after the competitive bidding and supplier quality standards have been finalized. Beyond this, as more details on competitive bidding and quality standards become available, CMS may wish to consider organizing a public forum for securing additional stakeholder feedback on proposed information-collection activities.

We appreciate this opportunity to comment. We look forward to working with CMS to ensure that any application of competitive bidding to blood glucose monitoring systems is accompanied by reasonable information collection requirements.

If you would like to discuss this issue further, please contact me at Epstein Becker & Green at 202-861-0900.

Very truly yours,

Bradley Merrill Thompson,
For the Diabetes Access to Care Coalition

cc: Herb Kuhn
Laurence Wilson
Lorrie Ballantine
Joel Kaiser
Michael Keane
Walter Rutemueller
Linda Smith