CMS Response to Public Comments Received for CMS-10169

We received several comments that were submitted as comments on the Paperwork Reduction Act (PRA) process that more appropriately pertained to the responses to the Medicare DMEPOS Competitive Bidding Program Notice of Proposed Rulemaking (NPRM) issued on May 1, 2006 (71 FR 25654). These comments are being addressed in the final rule.

General Comments

Numerous commenters commented on the overall requirements of the forms. Several commenters stated that the information required of suppliers is overly broad and, sanctions need to be defined further to allow suppliers to understand which occurrences to report on bid applications.

Commenters also stated that relative to the Federal Acquisition Regulation (FAR), Form A asks suppliers to go further than the NPRM to disclose information about past or pending investigations; this expansion on the requirement about past and pending investigations goes beyond the FAR, is arbitrary, is vague, and may affect a supplier's eligibility to submit bids without adequate process; as written, it would be completely impossible to comply with this requirement; suppliers have the right, like every other American, to be presumed innocent and should not be negatively impacted in the bidding process based on such criteria; Competitive Bidding should just be part of the Federal Acquisitions System; the FAR system was unable to establish a system for representations and certifications and we will not be able to do it either; the section on disclosure of prior findings does not include the option listed in the NPRM on providing certification.

Commenters also stated that financial standards, must be clearly defined and evaluated prior to consideration of any bid; specific steps should be established to allow a consistent evaluation of all suppliers; audited financial statements should not be required; the length of time a supplier has been supplying a specific product category should also be considered in determining a supplier's capacity; audited financial statements will add considerable cost to the supplier's bid application; should limit the reporting requirements for past or pending investigations to a period of 5 years; bank reference requirements should be deleted since we are also collecting financial statements and credit information

Response: We need detailed information on suppliers with whom we may enter into a contract. This information will be used to evaluate the suppliers. This is important since both Medicare and the beneficiaries will be dependent on the contract suppliers. We need to evaluate capacity issues in order to ensure suppliers' capacity meets beneficiary

demand; we need to evaluate financial stability in order to ensure contract suppliers are solvent and will be in business during the contract period; and we need to obtain identification information in order to ensure management is dependable and that they are not excluded from participating as a Medicare supplier**.**

Sanctions would include, but are not limited to, debarment from any Federal program, sanctions issued by the OIG, or sanctions issued at the State or local level. This includes any actions taken against any member of the board of directors, chief corporate officers, high level employees, affiliated companies, network members or subcontractors. In addition, we proposed that the bidder must have all State and local licenses required to furnish the items that are being bid. Finally, the supplier must agree to all of the terms in the contract outlined in the request for bids. We stated that we would suspend or terminate a contract if a supplier loses its good standing with us or any other government agency.

The commenter's statement on past and pending investigations falls out the scope of the Paperwork Reduction Act information collection. The information collection should 1) be the least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives; 2) not be duplicative of information otherwise accessible to the agency; and 3) have practical utility. However, we agree that investigations are not in itself evidence of guilt. Therefore, information on pending investigations will no longer be a requirement for completion of the RFB and, we will limit the reporting period to 5 years for sanctions.

Based on comments, we have revised our financial information requirements to include the following:

> Suppliers with a business that submit individual tax returns are required to submit the Schedule C (the profit and loss statement) from their 1040 Tax Return for the past 3 years. In addition to the tax return information, these suppliers are also required to submit a compiled balance sheet (Statement of Financial Position), a statement of cash flow (Statement of changes in Financial Position), and a statement of operations (Income statement) for the past 3 years. The supplier is also required to submit a copy of their current credit report which must have been completed within 90 days prior to the date on which the supplier submits its bid. The credit report must be prepared by one of the following: Experian, Equifax, or TransUnion.
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> Suppliers that submit corporate tax returns are required to submit the Schedule L (the balance sheet) from their tax returns for the past 3 years. In addition to the tax return information, these suppliers are also required to submit a statement of cash flow (Statement of Changes in Financial Position), and a statement of operations (Income Statement) for the past 3 years. Suppliers are also required to submit a copy of their current credit reports which must have been completed within 90 days prior to the date on which the supplier submits its bid. The credit

report must be prepared by one of the following: Experian; Equifax; or TransUnion.

All documents that are not prepared as part of a tax return would have to be certified as accurate by the supplier and must be prepared on an accrual or cash basis of accounting.

Suppliers that are publicly traded companies must submit a copy of their10-K Filing Report with the Securities Exchange Commission.

New suppliers are required to submit projected financial statements to substitute for any year for which they do not have past financial information because they were not in business as a DMEPOS supplier.

They also need to meet the quality standards, which have very general business requirements.

The forms will be contained in an overall Request for Bids (RFB) package that will include instructions and a list of definitions. The evaluation steps are an administrative process and not part of rulemaking or the RFB.

Comment: One commenter stated that with respect to information collected from the supplier, they recommended that, under training and qualifications, suppliers be required to reflect whether they or another entity will provide required training, service and on-going support for a competitive bid item. The commenter stated that if it is a party other than the supplier, they recommend that the party be specifically identified.

Response: We understand the importance of training and qualifications for DMEPOS suppliers. We believe that the accreditation process and supplier standards will adequately determine whether suppliers provide appropriate levels of training, service, and ongoing support. It is not necessary to require this information to be submitted in the RFB.

Comment: Three commenters stated that CMS must release quality standards and/or the final regulation before the Request For Bids (RFB) can be properly reviewed.

Response: The Medicare Modernization Act of 2003 (MMA) requires competition under the DMEPOS competitive bidding program to begin in 2007. In order to meet this timeline, we proceeded simultaneously with this PRA submission. The policy recommendations we received on the NPRM have been reflected on the RFB forms. Moreover, the near simultaneous publication of the PRA submission and the NPRM may help stakeholders understand how the RFB forms are related to the program framework.

The quality standards were published on August 15, 2006. We do not believe the quality standards are necessary to review the RFB.

Comment: Several commenters stated that they could not fully comment on the forms without having reviewed the instructions. One commenter noted that no information is given regarding electronic submission of information and stated that the PRA requires alternatives to electronic submission. Another commenter recommended that we should refine our requests so they are more targeted, including providing a standard set of definitions. A commenter noted that the instructions for the RFB should be available for comment.

Response: The forms will be contained in an overall RFB package that includes instructions and a list of definitions. Comments on the forms are important since they are the vehicle to collect information; the instructions will not change the forms. Suppliers must submit bids electronically; however, on a case-by-case basis, we plan on using diskettes, CD-ROMS, or hard copy as an alternative means of bid submission.

Form A: Application

Comment: Two commenters suggested adding a new question asking "Will supplier be providing this product category as a retail supplier or mail order supplier"? One commenter stated that bids from mail-order suppliers should not be included in the same bid calculations as retail suppliers. Another commenter noted that CMS should make sure mail-order suppliers only provide approved services and that there is sufficient retail capacity in the market.

Response: We have expanded Form A to include a question on service arrangements. The question will ask the supplier whether they will serve Medicare beneficiaries through a retail location/office in the CBA or through retail location, mail order or home delivery. We will consider whether sufficient retail suppliers are selected to serve the market. We will expect suppliers to consider the cost of providing items by mail order, retail and home delivery when they develop their bids and determine what percentage is mail order/store front/home delivery.

Comment: One commenter noted that CMS does not say if all suppliers in a network must complete an application, while the NPRM says that each member of a network must be independently eligible to bid, which should require an application.

Response: We have revised the form to indicate the primary supplier is submitting on behalf of each member of the network. If bidding as a network, the primary supplier must complete the network application for all members of the Network. Each member must be eligible, meet quality standards and be accredited**.**

Comment: One commenter asked whether CBA and ZIP codes will be provided on the forms by CMS.

Response: Yes. CMS will provide the CBA broken down by county and ZIP Codes that cross county borders. This information will be listed on the website, or for those submitting paper claims, it can be requested from the CBIC.

Comment: One commenter asked how a single Form A could be sufficient for a company with multiple locations bidding in multiple product categories?"

Response: We have designed Form A so that it can be filled out once for each CBA in which a supplier is bidding. Product-specific information will be provided in Form B, which will be filled out once for every product category in which a supplier bids. Form A allows for a supplier to provide two business locations and two different areas of accreditation. Additional information could be provided on Form A under additional information optional. Our goal is to allow for forms to be completed electronically, which will provide additional space for the supplier to enter information.

Comment: One commenter asked about Form A Item B. The commenter questioned how a supplier can answer the question regarding the length of time operating in a CBA if it has been operating for different time periods in different locations.

Response: The supplier should report how long it has been supplying DMEPOS items in the CBA. The length of time reported may be based on the supplier's first location serving the CBA.

Comment: One commenter suggested that Form A Item B should be modified to provide a definition for "doing business". The commenter stated that the RFB should also indicate if there is a particular amount of time that is required for suppliers to have been doing business in the market in order to bid.

Response: We have changed the form to indicate that "doing business" means "supplying DMEPOS items". There is no required amount of time that is required for suppliers to have been doing business in the market in order to bid.

Comment**:** One commenter asked how a supplier should identify the primary supplier address.

Response: The supplier should designate its primary supplier address. It may be its corporate address, if applicable; if not, it should be its local store address that is serving the CBA. This address may be included in the supplier directory.

Comment: One commenter asked if the NPI provided should relate to the address in the suppliers' identifying information or the suppliers' primary physical address.

Response: Each location must identify the corresponding NPI # and NSC # for that specific location.

Comment: One commenter questioned how they should report on Form A, Letter F, the doing business as name if they have more than one location with a DBA

Response: We have provided space for two locations with a DBA. Additional information could be provided on Form A under additional information optional. Our goal is to allow for forms to be completed electronically, which will provide additional space for the supplier to enter information.

Comment: One commenter asked if they need to provide on Form A Letter G the additional locations for all locations, or just those in the CBA. The commenter indicated there is only room for two additional locations.

Response: We have changed the instructions on the forms to clarify that only locations serving the CBA that are included in the bid need to be listed. We have provided space for two locations with a DBA. Additional information could be provided on Form A under additional information optional. Our goal is to allow for forms to be completed electronically, which will provide additional space for the supplier to enter information.

Comment: One commenter asked how they will report accreditation information on Form A, Letter H if it varies by location.

Response: We are collecting accreditation information for each site. We have provided space for two sites. Additional information could be provided on Form A under additional information optional. Our goal is to allow for forms to be completed electronically, which will provide additional space for the supplier to enter information

Comment: One commenter stated that the questions on accreditation cannot be included before accreditation is complete. Two commenters noted that Form A requires accreditation but that the NPRM allows for an unspecified grace period and stated that non-accredited suppliers should be barred from bidding.

Response: The forms contain boxes for pending accreditation. We expect that pending accreditation will primarily be an issue during the first rounds of bidding. In future rounds, all DMEPOS suppliers will be required to be accredited before they submit a bid.

Comment: One commenter stated that we should specify the period for which financial reports should be submitted. The commenter also stated that we should not duplicate any requests for information that are also required by accreditation organizations.

Response: We have changed the form to indicate that financial information for the last three complete calendar years is required. Like the commenter, we wish to avoid duplication of requests for information. However, we anticipate that the accreditation organizations will be most interested in ensuring that the supplier has appropriate

financial information processes, but less interested in what the financial statements say about the supplier's financial condition. We must evaluate the financial condition to ensure that the program selects enough financially sound suppliers to serve beneficiaries during bidding cycle.

Comment: One commenter stated that the Financial Information section contains a discrepancy –the certification states that financial statements must be prepared consistent with GAAP, but the form states that small businesses are required to provide reviewed, but not audited, statements. It is unclear how the reviewed statements would be prepared or who would review them. Another commenter stated that separate financial standards for small supplier pharmacies as defined by the Small Business Administration (SBA) be limited to the following queries: credit report, lien searches, credit references (three suppliers) and tax returns (3 years).

Response: Based on comments, we have revised our financial information requirements as noted above. Suppliers are no longer required to submit reviewed or audited financial statements; however, the information submitted must be certified as correct. We believe this information will lessen the burden on suppliers while providing us with the critical information to make a decision on the financial stability of the supplier, in order to ensure contract suppliers are solvent and will be in business during the contract period.

Comment: One commenter stated that review of financial information must occur before analysis of prices and CMS should publish criteria for assessing financial stability.

Response: This comment falls out the scope of the PRA process. However, the suggestions were taken under advisement as the rule was finalized.

Comment: One commenter stated that reviewing the resumes of key personnel is duplicative of the accreditation process.

Response: We no longer are requiring that resumes of key personnel are to be submitted.

Comment: Two commenters recommended that we must specify who it includes as key personnel and more precisely define the term "authorized official".

Response: Key personnel are defined as such staff as officers, partners, directors, managing employees or members of the board of directors. The authorized official is an appointed official to whom the supplier has granted the legal authority to submit a bid under the competitive bidding program, to enroll it in the Medicare program, to make changes and/or updates to the supplier’s status in the Medicare program (e.g., new practice locations, change of address, etc.) and to commit the supplier to fully abide by the laws, regulations, and program instructions to Medicare. The authorized official must be the supplier’s general partner, chairman of the board, chief financial officer, chief executive officer, president, direct owner of the supplier organization or must hold a position of similar status and authority within the supplier’s organization.

Form B: Bidding Sheet

Comment: One commenter noted that bidding sheet Form B asks suppliers to list the models of DMEPOS products for each HCPCS code, but there appears to be uncertainty about what this information is intended to imply and how it will be used to evaluate bids.

The commenter questioned the following: by listing a specific brand, would the bidding supplier be making a commitment to offer that brand throughout the contracting period; and, will CMS be using the information to determine whether a bidding supplier is offering an adequate range of brands or choices for each HCPCS code? If so, the commenter questioned how CMS plans to do this. The commenter questioned if the model information submitted by bidding suppliers would serve as a means for making an "up front" assessment of whether a supplier would be likely to satisfy the proposed non-discrimination term; would a bidder later be able to add new brands (for example, new products) or would Medicare beneficiaries be denied access to products brought to market after bids were submitted or awarded?

Another commenter stated that we should make clear the rules pertaining to offering different equipment during contract performance, including offering newer models in subsequent years.

Response: The information on Form B will allow us to monitor the types of items Medicare beneficiaries are receiving under the Competitive Bidding Program. For purposes of transparency, we will post the list of manufacturers, model names and numbers on the internet to allow beneficiary choice among suppliers and make informed decisions; we will ensure that there is non-discrimination against beneficiaries in a competitive bidding area, so that all beneficiaries inside and outside of a competitive bidding area receive the same products that the contract supplier would provide to other customers. We believe we are providing a service to the supplier in this regard by informing beneficiaries of the product lines that particular suppliers provide. Additionally, we recognize that suppliers may change models in later periods of the bidding cycle. To further monitor product range, we will collect quarterly information on the brands provided to beneficiaries.

Comment: One commenter suggested that Form B Question #1 ask what percentage of total revenue is represented by each product to ensure that suppliers have experience with items for which they are bidding. Another commenter suggested that in Form B Question #1, we need to define "Total revenue collected for this product category ". The commenter questioned if it is revenue recognized or revenue collected, and if it is just for Medicare or for all payers?

Response: Form B Question #1 provides a general measure of the supplier's experience with the product category. We are hesitant to increase supplier burden by requesting information on individual products within the product category. Form B Question #4, in addition to Question #1 helps us identify information. We would like suppliers to

provide an estimate of revenue collected. Because estimates are acceptable, it is permissible for suppliers to use their revenue recognized estimates if that is easier for the supplier to provide. The initial question focuses on total revenue for the product category from both Medicare and non-Medicare providers. The second part of the question focuses on the Medicare share.

Comment: A commenter suggested that Form B Question #2 ask what percentage of their customers for each product was Medicare or private pay customers. The commenter suggested that we consider the capacity of suppliers beyond the Medicare market, and noted that if competitive bidding causes too many suppliers to drop out of the market this will reduce access for other patients

Response: By collecting information on the supplier's total revenue and Medicare percentage, we will be able to calculate the percentage of total revenues accounted for by Medicare or private pay customers. We do not believe that requiring suppliers to itemize their Medicare and other payer percentages will provide sufficient additional information to warrant the burden on suppliers.

Comment: A commenter asked how, in Form B Question #4, the top 3 HCPCS will be determined?

Response: We will provide these numbers in the actual RFB. We will use claims data for the latest years available to determine volume.

Comment: A commenter stated that Form B Question #5a is an open-ended question that will generate invalid and variable responses. The commenter also believed the RFB should inform bidders of the number of patients and of the number of patients coming off of rental for each month.

Response**:** We believe that suppliers should be able to provide an estimate of their ability to expand. We will provide data in the RFB on patient volume and allowed charges in the CBA, as well as information on the number of new patients served each month.

Comment: A commenter recommended that question Form B Question #5b needs significantly more space.

Response: We have expanded the space for this answer. Our goal is to allow for forms to be completed electronically, which will provide additional space for the supplier to enter information.

Comment: A commenter stated that CMS should require suppliers to list their subcontractor credentialing process in Form B Question #5d. The commenter stated that CMS should not need to know the agreed upon price that they pay the subcontractor.

Response: We agree that pricing information is not necessary and have removed the requirement to submit it. Using the information requested in the RFB, we will review the supplier's subcontracting plans to ensure it is appropriate.

Comment: A commenter suggested moving Question #6 on Form B up so physicians and Skilled Nursing Facilities (SNFs) can skip sections on commercial suppliers.

Response: We need to form estimates of supplier capacity, including the capacity of those that plan to serve only their existing patients to ensure that we select enough suppliers to serve the market. We believe that the sections can be filled out relatively quickly by specialty suppliers. We have modified the question and moved it to Form A.

Comment: A commenter stated that CMS is not capturing capacity information for networks. They suggest that CMS should estimate expected capacity of networks based on historical trends, even if historical information is available for member suppliers.

Response: We agree with this comment. On Form B Question #5a, we now say "Indicate for the product category the percentage increase in volume you or your network…"

Comment: A commenter recommended making it clear on the bid sheet, Form B Bullet #1, that the cost is actually the bid price.

Response: We have defined bid in the rule and in the RFB instructions and will detail what needs to be included in the bid price in the instructions.

Comment: A commenter questioned if prices on bid sheet, Form B Bullet #3 are for new items. The commenter questioned if bids for rentals are for new items. The commenter further asked if we require all items to be furnished new.

Response: Payments for many items in the competitive bidding program will continue to be made on a rental basis. The program does not require that only new items be furnished. The final rule requires that bids be submitted for new items and provides a formula for converting the single payment amount for new items into fees for used and rental items.

Comment: A commenter noted that Column B of Form B on the bid sheet does not state how products will be specified.

Response: The RFB lists the HPCPS codes and item descriptions that are applicable to those codes for each item in a product category in a CBA.

Comment: A commenter suggested that Form B Column F on the bid sheet should clarify that "Total Estimated Capacity" is the volume that the supplier is bidding to furnish, rather than current capacity.

Response: We agree that “Total Estimated Capacity” is the volume that the supplier is capable of furnishing rather than current capacity. This is spelled out in the instructions.

Comment: A commenter presented a number of specific concerns about specific HCPCS codes that may be included in the product categories of diabetic supplies and enteral nutrition. The commenter’s concerns included the following: if we do not exclude blood glucose monitors, they should either exclude or differentiate advanced systems using the following subcodes for codes A4253 (blood glucose test or reagent strips for home blood glucose monitor, per 50 strips) and E0607 (home blood glucose monitor): A) protection against interfering substances; B: safe with commonly used dialysis solutions; C: Small blood sample size - 1.0 microliter or less; D: Blood samples accessed from multiple/alternative body sites; E: Aids for visual impairment; F: Testing alarms.

The commenter stated that if we include enteral nutrition items, we should ensure that items being supplied are designed specifically for enteral nutrition, as some suppliers use unsafe alternatives. The commenter stated that we should not include specialized nutritional products (B4153, B4154 & B4155). The commenter also noted that if we include these products, then we should work with clinical specialists to develop access requirements for these specialized nutritionals. The commenter also stated that we should require suppliers bidding on B4150 & B4152 to provide these both as pre-mixed ready to hang bags and in cans, based on customer request. The commenter noted that we should specify that suppliers will provide products under B9002 with an automatic flush feature, are ambulatory, have an anti-free flow feature, and a lockout option at the request of the beneficiary's clinician, and they should state which products they will provide to meet these requirements. The commenter noted that we should specify that suppliers will provide products under B4086 that are composed of polyurethane and silicone, include radiopaque material, and weighted tips, eyelet design/flow thru tips, Y-port/interlocking connectors, skink disk or external retention hub, and/or internal bumper at the request of the beneficiary's clinician, and they should state which products they will provide to meet these requirements. The commenter stated that we should specify that suppliers provide products under B4081 & B4082 that are composed of polyurethane and features at the request of the beneficiary's clinician, and they should state which products they will provide to meet these requirements. The commenter also noted that we should specify that suppliers provide products under B4035 & B4036 that are manufacturer-researched and tested for safety, and if a supplier begins servicing a patient that already owns enteral equipment, the suppliers should provide the appropriate supply kit.

Response: The commenter presents a number of specific concerns about features of products with specific HCPCS codes that may be included in the product categories of diabetic supplies and enteral nutrition. These issues are not the focus of the PRA submission, which instead focuses on the bidding forms.

Comment: A commenter suggested that the bidding sheet should include more nuanced information about blood glucose equipment.

Response: We intend to reimburse suppliers on the basis of HCPCS codes, as we have in the past. These HCPCS codes include a definition of the types of items that fit a particular code. To receive reimbursement for an item that is supplied, the item must meet the definition of that HCPCS code. We have established quality standards for DMEPOS suppliers that will enhance the safety and quality of DMEPOS for beneficiaries.

Comment: A commenter stated that blood glucose is unique in that it is manufacturers, not the suppliers, that provide technical support to beneficiaries. The commenter stated that we should require that equipment provided by suppliers comes with 24/7 manufacturer support.

Response: We appreciate this concern. However, it is more applicable to the newly established quality standards than to the RFB forms that are the focus of this PRA submission. Quality Standards state that when providing equipment, items and services to beneficiaries, the supplier shall ensure that it provides the beneficiary with information and telephone numbers for customer service assistance regarding regular business hours, after-hours access, item repair and emergency coverage.

Form C: Bank Reference

Comment: One commenter stated that the bank questionnaire would be unnecessary, burdensome, and redundant because of the collection of financial statements. In addition, the commenter stated that many banks will not complete the required questionnaire. The supplier suggested that large organizations should be able to just provide the financial statements they provide to the SEC.

Response: Bank References are no longer a requirement of the RFB.

Form D: Contractor Supplier Quarterly Report

Comment: Four commenters stated that this form should be eliminated, calling it burdensome, costly, and unnecessary. Another organization questioned how the information would be used to ensure access to specific items.

Response: We appreciate the concerns about burden. The purpose of Form D (now Form C) is to monitor whether patients have access to a range of products within the CBA. To reduce burden, we have simplified Form D (now Form C) in the following ways. We have changed the first column heading to "Approximate No. Supplied". The purpose of this change is to let suppliers know that we do not require them to keep track of and report exact numbers.

For purposes of transparency, we will post the list of manufacturers, model names and numbers on the internet to allow beneficiary choice among suppliers and make informed decisions; we will ensure that there is non-discrimination against beneficiaries in a competitive bidding area, so that all beneficiaries inside and outside of a competitive bidding area receive the same products that the contract supplier would provide to other customers. We believe we are providing a service to the supplier in this regard by informing beneficiaries of the product lines that particular suppliers provide. Additionally, we recognize that suppliers may change models in later periods of the bidding cycle. To further monitor product range, we will collect quarterly information on the brands provided to beneficiaries.

Form E: Beneficiary Survey

Comment: A commenter suggested that CMS should use an industry standard survey instead of developing a new one. The supplier provided an example survey that it uses.

Response: We appreciate this comment. We have incorporated some of the elements from the industry standard survey into our beneficiary survey.