Center for Regulatory Effectiveness

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Ms. Charlene Frizzera
Administrator (Acting)
Center for Medicare and Medicaid Services
Room 314G
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS' Information Quality Responsibilities for the Round 1 Rebid

Dear Ms. Frizzera:

The Center for Regulatory Effectiveness (CRE), a regulatory watchdog, has analyzed CMS' DMEPOS competitive bidding Interim Final Rule (IFR) – and the comments received on the IFR – from a Data Quality perspective. Based on our analysis, we have identified certain specific CMS Data Quality responsibilities that the agency needs to address under the Information Quality Act with respect to the Round 1 Rebid. Moreover, in addition to our other recommendations to CMS, we also recommend that CMS charge the Program Advisory and Oversight Committee (PAOC) with evaluating and opining on these Data Quality issues discussed below.

CMS' Commitment to Data Quality

Quality information is an essential prerequisite for quality health care and for economically efficient health care. In short, information quality is the foundation for all health care reform initiatives including the Round 1 Rebid. Fortunately, CMS has long demonstrated a strong commitment to information quality. Moreover, CMS has set a federal precedent by insisting that the firms they provide funds to also adhere to information quality standards and correct, as needed, the information they disseminate.

Specifically, in response to a Request for Correction (RFC) filed under the IQA, CMS directed a Medicare fiscal intermediary to remove incorrect information from their website. As CMS explained to the petitioner:

> "*Upon reviewing the materials submitted, we have determined that sufficient clinical differences exist between Safeblood and Procuren to justify correction of the information contained in the LMRP on the Arkansas Blue Cross and Blue Shield website. We consequently have requested Arkansas Blue Cross and Blue Shield to remove immediately the incorrect information from their website, which they have done.*"[1]

[1] http://aspe.hhs.gov/infoquality/request&response/6e.shtml.

CMS Data Quality Responsibility 1: Determining Adequacy of the HCPCS Level II Codes

In October 2003, CMS was delegated authority by the Secretary of HHS, as provided under HIPAA, to maintain and distribute Healthcare Common Procedure Coding System (HCPCS) Level II codes. CMS explains that the Level II HCPCS codes are "used primarily to identify products, supplies, and services not included in the CPT codes, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office." The codes are used for submitting claims for these items.[2]

As the agency noted in their "Innovators' Guide to Navigating CMS, Version 1.0," the current Level II HCPCS codes "represent approximately 4,000 separate categories of like items or services that encompass millions of products from different manufacturers."[3]

Congress recognized the diversity of products within the same code and the potential impact this could have on program costs when they directed GAO to provide an "Analysis of the impact on utilization of different items and services paid within the same Healthcare Common Procedure Coding System (HCPCS) code."[4]

In the IFR, CMS noted that the agency has "made certain adjustments to reflect changes in the HCPCS codes consistent with § 414.426. We have made additional exceptions for obsolete codes and codes which, in light of the MIPPA amendments, are no longer separately payable. ... The final list of HCPCS codes will be published on the Competitive Bidding Implementation Contractor (CBIC) Web site...."[5]

Despite certain CMS actions on the HCPSC codes, the IFR record reveals substantial stakeholder concern regarding the adequacy of the Level II codes. For example, one stakeholder stated that:

> "*problems with the existing coding system used to describe DMEPOS products, the Level II Healthcare Common Procedure Coding System (HCPCS), and the use of a single code to describe a wide range of DMEPOS products, could impede beneficiary access or reduce the quality of care. ... CMS should thoroughly evaluate the extent of groupings of diverse products into the same HCPCS code before including that code or category of products in the DMEPOS competitive bidding program.*"[6]

The Level II HCPCS codes are the base on which competitive bids are developed. Thus, the codes disseminated by CMS need to be specific enough so that healthcare providers, equipment suppliers and CMS have sufficient detail to ensure that patients have the appropriate DMEPOS on a cost-effective basis.

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[2] http://www.cms.hhs.gov/MedHCPCSGeninfo/.

[3] CMS, "Innovators' Guide to Navigating CMS, Version 1.0," August 25, 2008, p. 26.

[4] 42 USC 1395w–3, note.

[5] 74 FR 2878, January 16, 2009.

[6] http://www.thecre.com/blog/wp-content/uploads/2009/05/cms-reimbursement-advmed.pdf.

CMS' "Guidelines for Ensuring the Quality of Information Disseminated to the Public" define objectivity includes the statement that "information products are presented in an accurate, clear, complete and unbiased manner." The Level II HCPCS codes are a CMS information product subject to the standards contained in the OMB and CMS Guidelines.

In discussing their pre-dissemination review process, CMS's Guidelines explain that the agency "reviews the quality (including the objectivity, utility, and integrity) of information before it is disseminated and treats information quality as integral to every step of the development of information, including its creation, collection, maintenance and dissemination." [Emphasis added.]

- To ensure that the Level II HCPCS codes comply with Data Quality standards, CMS should provide the pre-dissemination review record demonstrating compliance to the PAOC and the public for review and comment prior to their publication on the CBIC website.

CMS Data Quality Responsibility 2: Beneficiary Demand

CMS has stated in the IFR that they will use the same bid evaluation process that was established in their April 10, 2007 final rule on competitive bidding.[7] In their May 1, 2006 proposed rule which explained the planned bid evaluation process, CMS stated that the agency is required by statute to "select the number of contract suppliers necessary to furnish items to meet the projected demand in the geographic area. Therefore, the first step is for us to determine the expected demand for an item in a competitive bidding area."[8] The FR notice goes on to explain that CMS proposes "to calculate two years worth of claims on a monthly basis to determine beneficiary demand." Potential adjustment mechanisms are also discussed by CMS. For example,

> "*If there are seasonal effects or changes identified only during certain months, the maximum monthly total and new patient figures would be used as the market demand measures. If trends show that there is noticeable growth or reduction in beneficiary demand for products in an area, we would take these factors into consideration when developing estimates of beneficiary demand for competitively bid items.*"

In their response to comments published in the preamble to the final rule, CMS related that "Some commenters stated that CMS must consider how changes in coding, utilization, and documentation may affect the utilization data for the last 2 years." CMS explains that

> "*After consideration of the comments received, we are adopting as final § 414.414(e)(1), which provides that we will calculate the expected beneficiary demand for items within a product category in each CBA as part of the bid evaluation process.*"[9]

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[7] 74 FR 2875, January 16, 2009.

[8] 71 FR 25675, May 1, 2006.

[9] 72 FR 18040, April 10, 2007.

CMS' determination of winning bidders is unquestionably "influential" information which the agency has defined as meaning "that CMS can reasonably determine that dissemination of the information will have a substantial impact on important public policies or important private sector decisions or will have important consequences for specific health practices, technologies, substances, produces, or firms."[10]

The CMS Guidelines further explain that, with respect to influential information, the agency needs to include "a high degree of transparency about data and methods to facilitate its reproducibility by qualified third parties" consistent with ensuring protection of confidential data.

- In that Medicare demand data and adjustment factors are not confidential, prior to determining the winning bidders, CMS should release for PAOC and public review and comment the agency's:

    1. Estimates of the "expected beneficiary demand for items within a product category in each CBA;"

    2. Algorithm for calculating the expected demand within each product category; and

    3. Pre-dissemination review record demonstrating that their demand estimates comply with Data Quality standards.

CMS Data Quality Responsibility 3: Supplier Capacity

CMS initially proposed a three-part process for determining supplier capacity:

1. Analyzing "Medicare claims to determine how many items a supplier is currently providing in the competitive bidding area, as well as in total."

2. Asking suppliers, as part of the bid, "to say how many units they are willing and capable of supplying at the bid price in the CBA." and

3. Comparing "expected capacity and Medicare volume to determine how many suppliers we would need in an area. For new suppliers, we would ask them for their expected capacity, look at trend data for new suppliers in that area, and examine the capacity of other suppliers in that area. We would need to use this data to make estimates about capacity because suppliers may have more capacity potential than they are currently exhibiting."[11]

Multiple stakeholder raised concerns that CMS had not provided sufficient information about the capacity determination process. As CMS notes in their response to comments,

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[10] CMS, "Guidelines for Ensuring the Quality of Information Disseminated to the Public."

[11] 71 FR 25676, May 1, 2006.

> "*Several commenters argued that there was insufficient information given as to how CMS will determine a supplier's capacity. The commenters wanted to know if the projected capacity that suppliers must identify in their responses to the RFB form was a bid commitment or estimation. The commenters also noted that CMS did not describe what criteria it will use to compare bidders (aside from bid price) and how these criteria will be applied.*"[12]

In their response to the above concerns, CMS provided themselves with the option of using additional capacity adjustment factors. Specifically, CMS stated that "We might, however, make two types of adjustments to a supplier's projected capacity for purposes of finalizing the pivotal bid." [The "pivotal bid" Data Quality issues are discussed further below.] The first type of potential adjustment is that "if a supplier estimates that it can furnish more than 20 percent of what we determine to be the expected beneficiary demand for the product category in the CBA, we will lower that supplier's capacity estimate to 20 percent" to ensure that there are at least five bidders are awarded contracts. Second, CMS "might further adjust a supplier's capacity if, after making the initial adjustment discussed above, we conclude that the supplier's financial and business expansion documentation do not support the projected capacity stated in its bid."[13]

Thus, while CMS has taken steps to ensure that there are a sufficient number of suppliers and sufficient capacity in each CBA, the concerns remain regarding "insufficient information given as to how CMS will determine a supplier's capacity."

- In order to fulfil its Data Quality responsibilities, CMS needs to release for PAOC and public review and comment the agency's algorithm for calculating the supplier capacity for each product category in each of the bidding areas as well as the pre-dissemination review record demonstrating the algorithm meets Data Quality standards.

CMS Data Quality Responsibility 4: Composite Bids

CMS develops "composite bids" based on a method for weighting bids for different items in the same product category. CMS defines composite bid in the final rule as "the sum of a bidding supplier's weighted bids for all items within a product category for purposes of allowing a comparison across bidding suppliers."[14] Thus, the goal of composite bid process is to allow CMS "to determine which suppliers can offer the lowest expected costs to Medicare for all items in a product category."[15]

The crux of the process for determining composite bids is the "weight" CMS assigns to each item on which bids are placed. The final rule defines item weight as "a number assigned to an item based on its

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[12] 72 FR 18039, April 10, 2007.

[13] 72 FR 18039-40, April 10, 2007.

[14] 72 FR 17997, April 10, 2007.

[15] 71 FR 25676, May 1, 2006.

beneficiary utilization rate using national data when compared to other items in the same product category."[16]

The final rule explains that, to compute a composite bid, CMS would,

> "*would multiply a supplier's bid for each item in a product category by the item's weight and sum these numbers across items. The weight of an item would be based on the utilization of the individual item compared to other items within that product category based on historic Medicare claims. Item weights would be used to reflect the relative market importance of each item in the product category. We would select item weights that ensure that the composite bid is directly comparable to the costs that Medicare would pay if it bought the expected bundle of items in the product category from the supplier. The sum of each supplier's weighted bids for every item in a product category would become the supplier's composite bid for that product category.*"[17]

tThe methodology appears to potentially allow CMS discretion in assigning weights and, thus, in determining composite bids. The specific process and data quality checks CMS would use in determining item weights and ensuring that the item weights selected by the agency result in composite bids that are "directly comparable to the costs that Medicare would pay if it bought the expected bundle of items" is not described in the final rule or the IFR.

Even though the IFR does not discuss the agency development of composite bids or other aspects of the bid evaluation process, multiple stakeholders raised item weighting and other bid evaluation issues *sua sponte* in response to the IFR. For example, the Medicare Payment Advisory Commission advised CMS to make weighting-related changes to the bid process, telling the agency that they,

> "*could simplify bidding for the many items that have very little weight in the bid and are rarely requested. Suppliers could bid explicitly for the important items in a category and an aggregate discount from fee schedule rates could be computed from those bids. For the other items in the category, suppliers could be deemed to bid the same percentage discount from the fee schedule as was bid on the important items.*"[18]

Another stakeholder, based on experience gained during the initial Round 1 competitive bidding, noted that technical difficulties combined with "CMS's refusal to shed light on its bid evaluation process, generated frustration and confusion within the supplier community."[19]

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[16] 42 CFR § 414.402

[17] 72 FR 18040, April 10, 2007.

[18] http://www.thecre.com/blog/wp-content/uploads/2009/05/cms-reimbursement-mpac.pdf.

[19] http://www.thecre.com/blog/wp-content/uploads/2009/05/cms-reimbursement-coaltion.pdf.

The Data Quality conclusion that CRE draws from the final rule, the IFR and the stakeholder comments on the IFR with respect to CMS's methodology for establishing composite bids is that the process is not yet transparent.

- CMS needs to release for PAOC and public review and comment the agency's:

    1. Specific, reproducible algorithm for determining item weights in the composite bid; and

    2. The pre-dissemination review record demonstrating that the methodology produces results consistent with the agency's stated policy goal of ensuring that the "composite bid is directly comparable to the costs that Medicare would pay if it bought the expected bundle of items in the product category from the supplier."

CMS Data Quality Responsibility 5: Pivotal Bids

The "pivotal bid" is the composite bid which CMS believes will balance supply and demand. More specifically, the agency defined pivotal bid to mean "the lowest composite bid based on bids submitted by suppliers for a product category that includes a sufficient number of suppliers to meet beneficiary demand for the items in that product category." Thus, based on the bid data received suppliers, CMS first constructs composite bids for each firm and then calculates the pivotal bid.

Calculation of the pivotal bid is at the heart of the competitive bidding system since the pivotal bid determines:

1. The winning contractors; and

2. The "single payment amount" which is what suppliers actually get paid for a DMEPOS item. CMS determines the "single payment amounts for individual items by using the median of the supplier bids that are at or below the pivotal bid for each individual item within each product category."[20]

The pivotal bid determination is based on the supply capacity of each bidder in contention. Thus, in order for CMS' pivotal calculation to achieve its stated goal of ensuring that beneficiary demand can be met, the agency's capacity determination discussed above in Data Quality Responsibility 3 must be accurate.

In their response to comments on "Determining the Pivotal Bid," CMS stated that "the only suppliers we will select for contract award purposes will be those suppliers that have satisfied our eligibility, quality, accreditation (unless a grace period applies), and financial requirements."[21]

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[20] 72 FR 18045, April 10, 2007.

[21] 72 FR 18043, April 10, 2007.

Thus, as part of their pre-dissemination review record in which they demonstrate that their pivotal bid calculation methodology complies with OMB and CMS Information Quality guidelines, the agency will need to demonstrate that their methodology ensures that potential suppliers meet all of the agency's eligibility, quality, accreditation and financial standards.

- CMS needs to provide for PAOC and public review and the agency's pre-dissemination review record verifying that their methodology for ensuring that potential suppliers meet all of CMS' eligibility criteria will result in the agency only accepting bids from qualified companies that are demonstrably able to meet capacity requirements.

Recommendations and Next Steps

CMS needs to provide to the PAOC and the public, for review and comment:

- Level II HCPCS codes. The agency's pre-dissemination review record demonstrating that the codes comply with Data Quality standards.

- Beneficiary Demand. Estimates of the expected beneficiary demand in each CBA; the algorithm for calculating the expected demand within each product category; and the pre-dissemination review record demonstrating that CMS' demand estimates comply with Data Quality standards.

- Supplier Capacity. The agency's algorithm for calculating the supplier capacity for each product category in each of the bidding areas the pre-dissemination review record demonstrating the algorithm meets Data Quality standards.

- Composite Bids. The specific algorithm for determining item weights in the composite bid; and the agency's pre-dissemination review record demonstrating that the methodology produces results consistent with the agency's stated policy goal of ensuring that the "composite bid is directly comparable to the costs that Medicare would pay if it bought the expected bundle of items in the product category from the supplier."

- Pivotal Bid. The agency's pre-dissemination review record demonstrating that their methodology for ensuring that potential suppliers meet all of CMS' eligibility criteria does result in the agency only accepting bids from companies that are able to meet capacity requirements.

CRE will be reporting on and accepting public comment on CMS's Competitive Bidding Rule on our CMS Interactive Public Docket found at http://www.thecre.com/blog/.

Sincerely,

/s/
Jim Tozzi
Member, Board of Advisors