

**Committee on Ways and Means
Subcommittee on Health
Hearing on the Medicare Durable Medical Equipment Competitive Bidding Program
May 9, 2012**

**Questions for the Record for
Laurence Wilson, Centers for Medicare and Medicaid Services**

Chairman Herger

Question: One of the criticisms raised by suppliers during the initial Round 1 was that a 26 percent reduction in reimbursements wouldn't be sustainable. However, when suppliers rebid Round 1, the median winning bids were even lower, representing between 32 and 35 savings, on average. Can you explain why the rebid produced greater savings? Does CMS expect this trend to continue in Round 2?

Answer: CMS has not specifically investigated why the Round 1 Rebid resulted in greater savings than the initial Round 1 and has not yet completed bid evaluation for Round 2. However, the Department of Health and Human Services' Office of Inspector General, the Government Accountability Office, and other independent analysts have repeatedly warned¹ that the fee schedule prices paid by Medicare for many DMEPOS items are excessive, as much as three or four times the retail prices and amounts paid by commercial insurers or customers who purchase these items on their own. The competitive bidding program single payment amounts are based on suppliers' bids that have been carefully screened and evaluated to ensure that they are bona fide (rational and feasible). CMS' real-time claims monitoring program and subsequent follow-up have shown that beneficiaries' access to necessary and appropriate items and supplies has been preserved. This would indicate that the payment amounts established through the competition are sustainable.

Question: A concern frequently expressed is that winning suppliers may sign a contract with CMS with the expectation that it fulfill a certain amount of capacity within a market only sit on its hands and not supply the product. How many of the 356 suppliers have failed to supply even a single item? Has CMS tracked the expected market share identified in suppliers' bids against actual market share in the Round 1 re-bid?

Answer: The capacity estimates in a supplier's bid represent the maximum number of items the supplier estimates it could furnish annually throughout a competitive

¹ See, for example, *Comparison of Prices for Negative Pressure Wound Therapy Pumps*, OEI-02-07-00660, March 2009; *Power Wheelchairs in the Medicare Program: Supplier Acquisition Costs and Services*, OEI-04-07-00400, August 2009; *Medicare Home Oxygen Equipment: Cost and Servicing*, OEI-09-04-00420, September 2006.

bidding area (CBA) if awarded a contract. CMS validates these capacity estimates during the bid evaluation process and awards contracts to more than enough suppliers to meet beneficiary demand. The competitive bidding program contracts require each contract supplier to furnish items in its contract to any beneficiary who lives in or visits the competitive bidding area and requests those items from the contract supplier. Because of statutory requirements that guarantee beneficiary choice, beneficiaries may choose to obtain their items from any contract supplier. Therefore, competitive bidding program contracts do not guarantee any set volume of business, and contract suppliers must compete based on customer service and quality to gain market share. Thus, a contract supplier that furnishes items in its contract to any beneficiary who lives in or visits the CBA who requests them is in compliance with competitive bidding program rules even if that supplier has not furnished the maximum number of items in its bid. Contract suppliers can also furnish more than the maximum number of items in their bids. It is important to stress that CMS' real-time claims monitoring and subsequent follow up has indicated that beneficiaries' access to necessary and appropriate items and supplies has been preserved.

Twelve contract suppliers that have contracts only for the group 2 complex rehabilitative power wheelchair product category did not furnish any items in their contracts during 2011. CMS was required by law to bid this product category in the Round 1 Rebid, but the vast majority of beneficiaries who need complex rehabilitative power wheelchairs use group 3 or higher power wheelchairs, not group 2. Because of very low demand and low savings potential for these items, this product category was not included in the current Round 2 competition.

Thirteen suppliers that have contracts for other product categories did not furnish any items in their contracts during 2011. This is less than 4 percent of the 356 contract suppliers. CMS recently conducted secret shopping for these 13 suppliers and confirmed that most of them are prepared to meet their contractual obligations. CMS will take enforcement action against any supplier that is determined to be in breach of its contract.

We note that CMS has terminated the contracts of a few suppliers; some of these suppliers may not have furnished contract items before termination.

Question: I understand that many in the supplier industry are touting an analysis of claims information for the first nine months of 2011 showing beneficiary access problems and adverse outcomes. How do you respond to criticisms that this data analysis contradicts CMS' assertion that the program isn't harming beneficiaries?

Answer: CMS is aware of a January 20, 2012 paper that claims to have found evidence of beneficiary access problems in the Round 1 Rebid competitive bidding areas. The paper contains strikingly inaccurate results because it uses technically flawed

analysis; the actual results described in CMS and GAO testimony are significantly different. Here are examples of some of the deficiencies that caused the inaccurate conclusions in the paper:

- It assumes that the pre-competitive bidding market is optimal and should be preserved when in reality there have been numerous reports documenting problems with fraud and overutilization in the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) sector.
- It improperly analyzes claims data by:
 - failing to consider claims lag (the widespread practice of waiting to submit claims for a period of time (up to 12 months) after items are furnished) and thereby greatly underestimating the number of items furnished since the program began;
 - counting claim lines (which can each include a varying number of items) instead of allowed services;
 - failing to make any adjustments to consider typical DMEPOS billing patterns (i.e., more claims toward the end of the year after beneficiaries have met their deductible); and
 - using date of claims receipt to establish baseline utilization but switching to date of service for 2011 (not comparing “apples to apples”).

Together, these mistakes resulted in extremely inaccurate volume estimates.

- It misrepresents the health status outcomes data that is available on the CMS website in the following ways:
 - It looks only at data from competitive bidding areas and ignores comparator areas.
 - It does not examine historical trends where the CMS data track trends for four years.
 - It relies on incorrect assumptions about the equipment needs of beneficiaries being tracked in the monitoring data. Specifically, it incorrectly assumes that all people with a diagnosis that makes it likely that they may need competitively bid equipment actually do need the equipment. It also assumes that anyone who has not submitted a claim for the equipment is still in need of the equipment (beneficiaries may have received equipment unnecessarily or have been victims of fraud). Further, it assumes that beneficiaries who have not submitted a claim for an item are not using the item, but data show that beneficiaries had months of oversupply of certain items². It builds on these mistakes by

² CMS’s monitoring revealed declines in the use of mail-order diabetes test strips and continuous positive airway pressure (CPAP) supplies in the competitive bidding areas. In response to these declines, CMS initiated three rounds of calls to users of these supplies in the nine competitive areas, two rounds of calls for users of mail-order diabetes test strips and one round of calls to users of CPAP supplies. In each round, CMS staff randomly identified 100 beneficiaries who used the items before the program began but had no claims for the items in 2011. The calls revealed that in virtually every case, the beneficiary reported having more than enough supplies on hand, often

assuming that any negative health outcomes for beneficiaries who are not using the equipment result from lack of use.

In fact, the health status outcomes data, which are posted on the CMS website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html>, have consistently shown that the trends in competitive bidding areas are consistent with trends in comparison areas. No changes in health status outcomes resulting from the competitive bidding program have been observed to date.

Question: What factors went into CMS’ decision to select the nine geographic areas that would first be subjected to competitive bidding? Do you think the prior spending levels in these areas may have had something to do with the decreased utilization in these MSAs once competitive bidding was implemented?

Answer: The statute originally required that competition under the program begin in 10 of the largest Metropolitan Statistical Areas (MSAs) in 2007. The competitive bidding program regulations required a formula-driven methodology for selecting these MSAs. From the MSAs with the largest total populations, we identified the MSAs with the highest Medicare allowed charges for DMEPOS items. We scored these MSAs using criteria that equally weighed the allowed charges per beneficiary and the number of suppliers per beneficiary for an area. In selecting the MSAs for 2007, we excluded the largest MSA areas based on population (New York City, NY; Los Angeles, CA; Chicago, IL) to allow us to gain more experience with competitive bidding programs before we included these areas. We also excluded MSA areas that span more than one of the Durable Medical Equipment Medicare Administrative Contractors (DME MACs). The Medicare Improvements for Patients and Providers Act of 2008 required the Round 1 Rebid competition to occur in the same areas as the original Round 1 except for San Juan, Puerto Rico.

The nine competitive bidding areas were among the most fraud-prone areas, with aberrant claims volume prior to selection of the competitive bidding areas as shown in the following table:

Comparison of Allowed Charges in Competitive Bidding Areas vs. Non Competitive Bidding Areas (2005)

MSA	FFS Pop	Allowed Charges	\$/bene
Miami*	517,370	\$221,660,443	\$428.44
Dallas*	470,562	\$139,910,862	\$297.33

multiple months’ worth, and therefore did not need to obtain additional supplies when the program began. This would suggest that beneficiaries received excessive replacement supplies before they became medically necessary. CMS concludes that the competitive bidding program may have curbed inappropriate distribution of these supplies that was occurring prior to implementation.

Riverside*	239,486	\$52,910,209	\$220.93
Chicago	1,085,254	\$173,922,952	\$160.26
Philadelphia	639,753	\$97,487,063	\$152.38
San Francisco	357,207	\$45,565,320	\$127.56

*Competitive Bidding Area

We believe that the implementation of the competitive bidding program has curbed inappropriate distribution of certain competitively bid items and that it helps prevent fraud and abuse.

Question: The agency indicates that beneficiaries continue to have access to needed products under competitive bidding and that they are not experiencing adverse health outcomes. Understanding how beneficiaries feel about their experience is also an important consideration. Can you describe what CMS has found in its effort to assess beneficiary satisfaction?

Answer: CMS conducted beneficiary satisfaction surveys in the Round 1 Rebid areas and comparison areas. The survey collected beneficiary satisfaction ratings for six issues: the beneficiary’s initial interaction with the supplier, the training received regarding the item, the delivery of the item, the quality of the item provided by the supplier, the customer service provided by the supplier, and the supplier’s overall complaint handling. Based on the survey results, the vast majority of beneficiaries (over 85 percent) in both competitive bidding areas and comparison areas are pleased with the quality of items and services. There were minor fluctuations in survey results in both competitive bidding areas and comparison areas before and after January 1, 2011, but we do not believe these are significant.

In its review of the beneficiary survey results, the GAO confirmed CMS’ finding that the survey did not show issues with beneficiary satisfaction. Here are the GAO’s findings³:

CMS’s beneficiary satisfaction survey did not reveal systemic beneficiary access or satisfaction problems with CBP. For all six questions in the competitive bidding areas, approximately 67 percent of beneficiaries reported their services as being “very good”. Beneficiaries in competitive bidding areas rated as “good” or “very good” their initial interaction with the DME supplier (89 percent), the training received (86 percent), delivery (91 percent), quality (90 percent), customer service (88 percent), and complaint handling (84 percent). Results within competitive bidding areas show a drop of one to three percentage points on each of the six questions from pre-implementation to post-implementation. Beneficiaries in the

³ *Review of the First Year of CMS’s Durable Medical Equipment Competitive Bidding Program’s Round 1 Rebid*, GAO-12-693

comparison markets rated their experiences similarly to those in competitive bidding markets: these beneficiaries rated as “good” or “very good” their initial interaction with the DME supplier (93 percent), the training received (89 percent), delivery (93 percent), quality (93 percent), customer service (91 percent), and complaint handling (88 percent).

Question: **The supplier industry is advocating for a “clearing price” reimbursement instead of the current “median bid price” structure. It seems to me that CMS has the authority to make this change. Has CMS considered such an approach and, if so, what did it conclude?**

Answer: It is very important to stress that the competitive bidding program has been carefully designed and balanced to ensure a sustainable program that achieves savings and preserves beneficiary access and choice. For example, the program’s method for estimating beneficiary demand results in a generous “cushion” of excess supplier capacity. The generous demand results in the selection of a larger number of winning suppliers than if demand were set more conservatively. In turn, the number of winning suppliers has a direct impact on the calculation of the single payment amounts. Any change to the pricing methodology would require reconsideration of the demand estimation methodology and other interconnected policies.

The competitive bidding program conducts bidding by product category rather than by individual item. CMS adopted this approach for many reasons, including beneficiary convenience and supplier business viability. Although bidding is by product category, the statute requires a single payment amount for each item based on bids submitted and accepted for that item. CMS uses a composite bid (the sum of a supplier’s weighted bids within a product category) for purposes of determining the winning suppliers and then determines the price for each item using the median bid of the winners. The bidder with the “market clearing” composite bid may have high or low bids for individual items.

CMS considered the use of the maximum winning bid to set the price for each item during notice and comment rulemaking. We were concerned about using the maximum bid for each item because this approach would have led to program payment amounts that were higher than necessary. In contrast, use of the median takes into consideration all bids submitted and accepted and not just the highest and lowest bids. The median is not influenced by outliers at the extremes of a data set. For this reason, the median is often used when there are a few extreme values that could distort what might be considered typical.

We recognized the need to ensure that all bids are rational and feasible, so we screen and evaluate all bids to make sure they are bona fide. If necessary, CMS requires bidders to submit supporting documentation (e.g., invoices and rationales) to prove that they can furnish items with very low bid amounts. Any

bids that are not bona fide are disqualified and are not used in the single payment amount calculations. We believe the median of the accepted bids represents a reasonable payment amount that does not favor large or small suppliers.

We note that 92 percent of suppliers offered contracts in the Round 1 Rebid accepted the contracts, and CMS had no difficulty in executing contracts with enough contract suppliers to meet beneficiary demand.

Question: CMS combined very different types of equipment into a single General Home Equipment product category in the Round 1 Recompete. This appears contrary to CMS regulations that say a product category will include related items used to treat similar medical conditions.

In the General Home Equipment category, TENS equipment and supplies are the only products that treat pain. The way the category is configured, however, a TENS manufacturer cannot bid to supply TENS equipment unless it also provides more than 60 other products that have nothing to do with pain care.

Why did CMS make this change? Will CMS work with stakeholders to rework the proposed product categories to separate distinct products treating different medical conditions into separate product categories?

Answer: CMS meets frequently with stakeholders interested in the competitive bidding program to understand their concerns and perspectives. CMS selected the Round 1 Recompete product categories after consideration of feedback from suppliers and referral agents and analysis of our statutory mandate to phase in bidding for additional DMEPOS items. We believe these product categories will be beneficial for suppliers and beneficiaries. Some suppliers in the Round 1 Rebid expressed concerns about winning in one product category and not another. Including several related products in one product category addresses this concern for suppliers. Larger, more consolidated product categories will promote one-stop shopping for beneficiaries, simplify the referral process and enhance the opportunities for winning suppliers. Furthermore, we note that CMS is required to continue to phase in bidding for DMEPOS items that are subject to competitive bidding. We believe that phasing in numerous, separate product categories for lower volume items would make the program overly complicated and could lead to non-viable competitions, particularly in smaller competitive bidding areas. Certain stakeholders have contacted CMS to express concern about some of the Round 1 Recompete product categories. CMS met with these stakeholders and is looking into their concerns.

Question: What is the status of the CMS effort to collect and make available information on the products, brands, and quantity of items that contract suppliers provide to beneficiaries in the competitive bidding areas? My understanding is that CMS requires contract suppliers to submit this “Form

C” data quarterly and that it was to be used by beneficiaries, Medicare customer service representatives, and referral sources to help patients get needed DME.

Answer: All contract suppliers must update the brands that they are providing on a quarterly basis on a report called “Form C.” This information is being collected to assist beneficiaries, Medicare customer services representatives, and referral agents and is available on the supplier locator tool at www.medicare.gov/supplier or by calling 1-800-MEDICARE [(800) 633-4227].

We note that Form C also originally collected the approximate number of each brand of competitively bid item furnished to beneficiaries during the previous quarter. This information was intended to help CMS monitor the program. However, after analysis of the first two quarterly submissions and reviewing contract supplier feedback, CMS determined that the information could not be used to monitor the program and was very burdensome for contract suppliers. More importantly, CMS implemented a comprehensive monitoring system, including real-time claims analysis which effectively measures beneficiary health status outcomes and access.

Question: **It seems to me that it would be more equitable if CMS could calculate the median single price payment amount by using only the bids of the contractors who actually end up signing a contract. This would require the agency to adjust the announced single price after all of the contracts were signed, but it seems feasible. What does the agency think about this approach?**

Answer: CMS carefully screens and evaluates bids to ensure that they are bona fide (rational and feasible) before determining the single payment amounts and offering contracts. Since only bona fide bids from qualified suppliers are included in the array of bids used to set prices, recalculating payment amounts based on contract rejections would not improve the validity of the single payment amounts. Additionally, 92 percent of suppliers that were offered contracts accepted those contracts. CMS analyzed the bid amounts for the most commonly used items in each product category from suppliers that chose not to accept any contract and found that approximately the same number of bids were above and below the single payment amounts. Such results indicate the single payment amounts are set at an appropriate level based on the bids received during the Round 1 Rebid.

CMS also has some concerns about the administrative feasibility of this reverse-contracting approach because it could require multiple iterative rounds of contract negotiations. We also note that suppliers may be unwilling to accept new contract offers if the prices go down as a result of an adjustment.

Question: CMS has stated that it adjusts the market capacity in supplier bids. What are the circumstances in which the agency makes such adjustments and does the agency use consistent guidelines in making these determinations?

Answer: CMS has issued a fact sheet that explains the process for review of supplier capacity and expansion plans. The fact sheet is available on the Competitive Bidding Implementation Contractor website at the following link:
[http://www.dmecompetitivebid.com/Palmetto/Cbicrd2.Nsf/files/R2_Fact_Sheet_Capacity_and_Expansion_Plan.pdf/\\$File/R2_Fact_Sheet_Capacity_and_Expansion_Plan.pdf](http://www.dmecompetitivebid.com/Palmetto/Cbicrd2.Nsf/files/R2_Fact_Sheet_Capacity_and_Expansion_Plan.pdf/$File/R2_Fact_Sheet_Capacity_and_Expansion_Plan.pdf).

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Mr. Price

The release of additional information regarding Round 1 of the DME competitive bidding program is necessary in order for Congress to fully evaluate this program and assess the validity of the structural concerns raised by so many experts. CMS should provide the House Ways and Means Health Subcommittee with the following information:

- 1. Provide the charts with the data appended that track the utilization for each DME competitive bidding product category, from 2008 to present, for each Competitive Bid Area (CBA) and its comparator city. Provide a full set of charts as follows for each product category:
 - A. Percent of the Access Group (e.g. Cardio-Pulmonary Narrow, Diabetic, Sleep Disorders, a set for each one) purchasing or renting (the product category, such as Oxygen, Mail Order Diabetes Supplies, CPAP, etc.);**
 - B. Percent of the Medicare A/B fee for service (FFS) population purchasing or renting (a set for each product category); and**
 - C. A set of graphs for each of the above that reflects, in total, all CBAs and comparator cities combined.****

Answer: CMS has a strong commitment to ensuring that beneficiaries have continued access to quality equipment under the program. For this reason, we developed a comprehensive monitoring system to assess access and health outcomes in near real time. We monitor over 3,400 data points to ensure that Medicare beneficiaries who use a competitively bid item and those who have conditions that may warrant use of a competitively bid item have continued access and do not suffer adverse health outcomes as a result of the competitive bidding program. Charts that show program results are regularly updated and posted on the CMS website at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html>. These charts are based on 100 percent of Medicare claims and provide valid and reliable data about beneficiary health status outcomes, control for broader trends, and would indicate if beneficiary access or quality had been threatened. The health status health outcomes being monitored include events such as deaths, hospitalizations, emergency room visits, physician visits, admissions to skilled nursing facilities, average number of days spent hospitalized in a month, and average number of days in a skilled nursing facility in a month. As shown in the charts, fluctuations in outcomes match closely in competitive bidding areas and

comparison areas both before and after the start of the competitive bidding program. Historic seasonal trends also continue to be reflected. There have been no changes in beneficiary health status outcomes resulting from the competitive bidding program observed to date.

Comparing trends in claims utilization data alone before and after the program began may not provide a valid and reliable way to measure the impact of the competitive bidding program because the number of claims does not necessarily provide a reliable measure of the number of medically necessary items furnished to Medicare beneficiaries. For years, the Office of Inspector General has issued reports finding frequent, widespread problems in the DMEPOS industry like claims for services to deceased beneficiaries and claims for excessive or duplicate services. CMS has been working hard to combat fraud and has also been taking steps to reduce the very high claims error rate in the DMEPOS arena; however, many claims for fraudulent or unnecessary services have been paid. Comparisons of 2011-2012 claims data to previous years could mislead observers because they have not been controlled for effects such as expansion of targeted anti-fraud efforts.

To ensure that beneficiaries continue to have access to all needed DMEPOS items, CMS has taken the precautionary step of directly contacting beneficiaries in competitive bidding areas who had claims for mail order diabetes test strips and continuous positive airway pressure (CPAP) supplies before but not after program implementation. Through our direct beneficiary outreach, we determined that in virtually every case, the beneficiary reported having more than enough supplies on hand, often multiple months' worth, and therefore did not need to obtain additional supplies when the program began. The results of CMS's real-time claims monitoring is also supported by the low number of beneficiary complaints the agency has received. For these reasons, we strongly believe that the best way to evaluate the program is to use the charts that are on the CMS website. We would be pleased to provide Members with a briefing to go over the health status outcomes in more detail and to explain the real time claims monitoring program methodology.

2. **Provide, by product category and for each CBA and each comparator city, the number of unique Medicare Beneficiaries with a claim submitted, and, separately, a claim paid, for the following two time periods:**
 - A. **Date of Service from October 1 through December 31, 2010**
 - B. **Date of Service from October 1 through December 31, 2011**

Answer: CMS has a strong commitment to ensuring that beneficiaries have continued access to quality equipment under the program. For this reason, we developed a comprehensive monitoring system to assess access and health outcomes in near real time. We monitor over 3,400 data points to ensure that Medicare beneficiaries who use a competitively bid item and those who have conditions that may warrant use of a competitively bid item have continued access and do not suffer adverse health outcomes as a result of the competitive bidding program. Charts that show program results are regularly updated and posted on the CMS website at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html>. These charts are based on 100 percent of Medicare claims and provide valid and reliable data about beneficiary health status outcomes, control for broader trends, and would indicate if beneficiary access or quality had been threatened. The health status health outcomes being monitored include events such as deaths, hospitalizations, emergency room visits, physician visits, admissions to skilled nursing facilities, average number of days spent hospitalized in a month, and average number of days in a skilled nursing facility in a month. As shown in the charts, fluctuations in outcomes match closely in competitive bidding areas and comparison areas both before and after the start of the competitive bidding program. Historic seasonal trends also continue to be reflected. There have been no changes in beneficiary health status outcomes resulting from the competitive bidding program observed to date.

Comparing trends in the number of beneficiaries for whom claims were submitted or paid alone before and after the program began may not provide a valid and reliable way to measure the impact of the competitive bidding program because the number of beneficiaries for whom claims were submitted or paid does not necessarily provide a reliable measure of the number of Medicare beneficiaries who need or receive these items. For years, the Office of Inspector General has issued reports finding frequent, widespread problems in the DMEPOS industry like claims for services to deceased beneficiaries and claims for excessive or duplicate services. CMS has been working hard to combat fraud and has also been taking steps to reduce the very high claims error rate in the DMEPOS arena; however, many claims for fraudulent or unnecessary services have been paid. Comparisons of 2011-2012 claims data to previous years could mislead observers because they have not been controlled for effects such as expansion of targeted anti-fraud efforts.

To ensure that beneficiaries continue to have access to all needed DMEPOS items, CMS has taken the precautionary step of directly contacting beneficiaries in competitive bidding areas who had claims for mail order diabetes test strips and continuous positive airway pressure (CPAP) supplies before but not after program implementation. Through our direct beneficiary outreach, we determined that in virtually every case, the beneficiary reported having more than enough supplies on hand, often multiple months' worth, and therefore did not need to obtain additional supplies when the program began. These targeted outreach efforts reflect the Agency's commitment to act on the health status outcomes information produced from our comprehensive claims monitoring system. This information is displayed in the charts available on the CMS website. We would be pleased to provide Members with a briefing to go over these health status outcomes in more detail and to explain the real time claims monitoring program methodology.

- 3. Provide for each product category in Rebid areas the number of unique DMEPOS suppliers that submitted a claim for a date of service in December 2010 and, separately, in December 2011 as follows:**
 - A. Number of Contracted suppliers in each CBA submitting a claim;**

- B. Number of non-contracted suppliers in each CBA submitting a claim; and**
- C. For each comparator city, the number of suppliers submitting a claim.**

Answer: The attached Excel document shows the number of unique DMEPOS suppliers with any allowed charges for competitively bid items in 2010 and 2011 in CBAs and comparator areas. We note that many of these suppliers had very small allowed charges. To help provide perspective about suppliers with a more meaningful presence in the area, we have also provided the number of unique DMEPOS suppliers with allowed charges for competitively bid items of at least \$10,000 in these years.

- 4. Provide for the product categories of oxygen, CPAP and enteral nutrition, charts that track the health outcomes (https://www.cms.gov/DMEPOSCompetitiveBid/01A3_Monitoring.asp) of beneficiaries in each CBA and comparator city who:**
 - A. Had a claim for the product category with a date of service between October 1, 2010 and January 31, 2011, and**
 - B. Did NOT have a claim for the product category with a date of service between October 1, 2011 and January 31, 2012, and**
 - C. Are not deceased.**

Answer: CMS does not currently compile claims data in the manner requested. CMS understands the Subcommittee's interest in assessing the health status of beneficiaries with a history of equipment use who no longer use the product. We note that it is difficult to measure "non-use" with Medicare claims data. Instead, we identify individuals that are not *billing* for a particular product. These people may have excess replacement supplies, may have reached the end of their billing period, or may no longer need the product. It is possible that these beneficiaries may have changes in health status over time. However, these changes could occur for many reasons which may not be related to competitive bidding. This will make the results of this analysis difficult to interpret. We have summarized two hypothetical examples below.

Example 1: A beneficiary receives a CPAP device in 2010. Over the next few months, the person's health status improves and the CPAP device is no longer necessary. The beneficiary does not have a CPAP-related claim in 2011-2012. Since the beneficiary's health status has improved, he has decreased rates of emergency department utilization and fewer physician visits in 2011 compared to 2010. We cannot conclude that the beneficiary's improved health status outcomes are the result of the competitive bidding program.

Example 2: In 2010, a beneficiary is in her 36th month of a rental period for a portable oxygen concentrator. Since Medicare pays for oxygen using a 36 month capped rental, the beneficiary does not have an oxygen-related claim between October 1, 2011 and January 31, 2012, even though she is continuing to receive oxygen. The beneficiary has severe COPD along with several other conditions, and her health status is deteriorating with age. The beneficiary visits the hospital

more often in 2011 than 2010 as a result of her worsening health status; however, we cannot use claims data to conclude that this is related to competitive bidding.

CMS agrees that it is very important to monitor access and outcomes for all beneficiaries who are likely to need a competitively bid item based on their medical needs, including beneficiaries who do not have a claim for the item. The CMS real-time claims analysis program is currently tracking this information; the relevant information can be found on the “Access Group” charts in the health status outcomes charts on the CMS website (see: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html>). The “Access Group” tracking has been designed to control for non-competitive bidding program effects and provide an accurate picture of program results.

Despite the difficulty in measuring the “non-use” of a product, we have estimated the cost of compiling the requested data to be approximately \$20,000 to \$40,000. The compilation would take at least several weeks.

To follow up on the May 9 House Ways and Means Health Subcommittee hearing on the DME competitive bidding program and alternative bid program support by the DME sector, CMS should answer the following questions –

Question: Can you give examples of other government agencies that do not require binding bids for auctions and/or use the median bid price to set reimbursement?

Answer: The DMEPOS Competitive Bidding Program is not an auction program. It is a competition-based methodology for determining Medicare payment amounts for equipment and services furnished to beneficiaries in their homes. CMS is unaware of any other government program that uses a competitive bidding program structure similar to the one mandated by section 1847 of the Social Security Act. There are unique statutory requirements for the program that make it very different from procurement auctions. For example, the Medicare statute does not provide any authority that would permit CMS to require winning suppliers to accept contracts. Further, the statute requires the selection of multiple contract suppliers even if only one supplier could satisfy beneficiary demand on its own. Also, because of statutory requirements that guarantee beneficiary choice, beneficiaries may choose to obtain their items from any contract supplier. Therefore, competitive bidding program contract suppliers are not guaranteed to receive any Medicare business.

We note that the competitive bidding program has been designed to conduct bidding by product category rather than by individual item. CMS adopted this approach for many reasons, including beneficiary convenience and supplier business viability. Although bidding is by product category, the statute requires a single payment amount for each item based on bids submitted and accepted for that item. CMS uses a composite bid (the sum of a supplier’s weighted bids

within a product category) for purposes of determining the winning suppliers and then determines the price for each item using the median bid of the winners. Setting the single payment amount for each item at the median of accepted bids for that item ensures that all accepted bids are reflected and protects against outlier bids for particular items.

Question: Does CMS support the use of binding bids for the competitive bidding program? If CMS believes it lacks statutory authority to require binding bids, would the agency support legislation to address this issue?

Answer: The Medicare statute does not provide any authority that would permit CMS to require winning suppliers to accept contracts. This is consistent with other provisions of the Medicare statute that make supplier participation in Medicare voluntary. Although the law does not provide any authority for requiring suppliers to accept contracts, it is not clear that such authority is needed. In the Round 1 Rebid, 92 percent of suppliers that were offered contracts accepted those contracts. There have been no indication of any beneficiary access problems, and CMS has not had to add any new suppliers to meet demand.

Question: CMS has claimed that there have only been 151 complaints, but 127,466 inquiries from Medicare beneficiaries regarding Round 1 of competitive bidding. Can CMS explain what constitutes a complaint versus an inquiry? Can CMS give details how it addressed the complaints and inquires?

Answer: Complaints are inquiries that express dissatisfaction and cannot be resolved by a 1-800-MEDICARE call center operator. The vast majority of inquiries were about routine matters, such as questions about the program or finding a contract supplier. All complaints were assigned to program experts for prompt resolution. Most of the issues that were elevated involved providing assistance in finding a contract supplier (particularly mail order diabetic supplies contract suppliers) or finding a supplier to perform a repair of beneficiary-owned equipment (particularly a repair of a power wheelchair). We note that repairs are not a competitively bid service, but we are tracking repair issues in competitive bidding areas. We also note that we modified⁴ our educational fact sheet on repairs of beneficiary-owned equipment in response to the complaints; the number of complaints about repairs went down dramatically after the issuance of the revised fact sheet.

Question: CMS planned to collect the type of products that were being provided to Medicare beneficiaries in bid areas using something called Form C. Regardless of the reason CMS canceled the collection of this information, how is CMS ensuring that beneficiaries get high quality DME when the average price decreased by 32 percent?

⁴ CMS clarified the distinction between repairs, which can be performed by any enrolled suppliers, and replacements, which can only be furnished by contract suppliers.

Answer: The competitive bidding program has been designed to ensure that beneficiaries have continued access to quality items that meet their needs. Contract suppliers are required to meet quality standards, be licensed and be accredited by an approved independent accrediting organization. As a term of the contract, suppliers must make available the same range of products to beneficiaries that they make available to non-Medicare customers.

A quality item is an item that meets applicable Food and Drug Administration regulations and medical device effectiveness and safety standards and that meets the needs of the beneficiary receiving that item. CMS believes beneficiaries are receiving quality items under the competitive bidding program because we have received few inquiries and complaints about the program and because our real-time monitoring shows that there have been no significant changes in beneficiary health status outcomes resulting from the competitive bidding program.

Question: **In Round 2, CMS included power and manual wheelchairs in one very large product category, this seems to discriminate against smaller providers who are less likely to provide all items in this very large product category. Can CMS explain the rationale for such large product categories and how even larger bid categories in the Round 1 recompetete process may negatively impact small DME providers and patients? Did you seek input from the DME sector or Program Advisory and Oversight Committee (PAOC) on these broad Round 1 recompetete categories?**

Answer: CMS meets frequently with stakeholders interested in the competitive bidding program to understand their concerns and perspectives. CMS selected the Round 1 Recompetete product categories after consideration of feedback from suppliers and referral agents and analysis of our statutory mandate to phase in bidding for additional DMEPOS items. We believe these product categories will be beneficial for suppliers and beneficiaries. Some suppliers in the Round 1 Rebid expressed concerns about winning in one product category and not another. Including several related products in one product category addresses this concern for suppliers. Larger, more consolidated product categories will promote one-stop shopping for beneficiaries, simplify the referral process and enhance the opportunities for winning suppliers. Furthermore, we note that CMS is required to continue to phase in bidding for DMEPOS items that are subject to competitive bidding. We believe that phasing in numerous, separate product categories for lower volume items would make the program overly complicated and could lead to non-viable competitions, particularly in smaller competitive bidding areas. Certain stakeholders have contacted CMS to express concern about some of the Round 1 Recompetete product categories. CMS met with these stakeholders and is looking into their concerns.

Question: Recently, there were a number of indictments in Miami, Florida related to Medicare fraud, where several individuals had prior criminal/felony records. Can CMS explain how these individuals received Medicare billing numbers?

Answer: CMS has the authority to deny or revoke Medicare billing privileges for certain felony offenses. Examples of felony convictions that may lead to denial or revocation in Medicare include felony crimes against persons, financial crimes, or felonies that have placed Medicare beneficiaries at immediate risk. Not all felony convictions result in revocation of Medicare billing privileges.

In addition, the Department of Health and Human Services Office of Inspector General (OIG) also excludes individuals and entities from Medicare, Medicaid, and the Children's Health Insurance Program based on felony or misdemeanor convictions related to the Medicare or Medicaid programs or related to the abuse or neglect of patients. When the OIG excludes an individual, CMS revokes the billing privileges for the same individual.

Without the names of specific individuals, it is difficult for CMS to determine whether their particular prior felony convictions would require a revocation of Medicare billing privileges. We are happy to provide additional information if the Committee would provide the names of the specific individuals referenced in the question.

Question: In the testimony you stated that "Small suppliers do not account for that much of the market now so to meet this requirement, beneficiaries would have to be assigned to small suppliers, under CMS' current bid program, beneficiaries choose suppliers." Can you please advise us what percent of the total supplier number fall in the less than \$3.5 million category? Additionally, what percent of total suppliers fall in the less than \$10 million category?

Answer: First, please note that Mr. Wilson's testimony referred to the percent of beneficiary demand met by small suppliers, not the number of small suppliers. Also, the small supplier definition (a supplier that generates gross revenue of \$3.5 million or less in annual receipts from Medicare and non-Medicare revenue) applies only to the competitive bidding program. CMS does not collect supplier gross receipt data outside of the competitive bidding program, so we are unable to provide the requested data. However, in the Round 1 Rebid small suppliers make up about 51 percent of the contract suppliers. In 2011, small suppliers furnished 13.88 percent of the market share for competitively bid items.

Question: CMS has "grandfathered" most product categories subject to the competitive bidding program. However, the one product in competitive bidding that is provided in nursing facilities, enteral nutrition, was not grandfathered. As a result, wherever competitive bidding has been instituted or will be in the future, all enteral nutrition patients lose their enteral

suppliers if they are not bid winners. Grandfathering was promoted by CMS as a means to ensure that patients do not fall through the cracks, but that safeguard simply does not exist for enteral patients who are residing in nursing facilities.

Will CMS explain why it decided not to grandfather enteral nutrition patients in the competitive bidding program? Will CMS extend this protection in the future expansions of the program? If not, will the agency explain why?

Answer: The statute does not give CMS the authority to grandfather enteral nutrition. Section 1847(a)(4) of the Social Security Act requires CMS to establish a process by which rental agreements for durable medical equipment (DME) and supply arrangements for suppliers of oxygen and oxygen equipment entered into before the implementation of a competitive bidding program may be continued. This statutory authority does not apply to other DMEPOS, such as enteral nutrition, equipment, and supplies that are covered under the prosthetic device benefit and not the DME benefit.

Question: **How many suppliers who billed Medicare in the Round 1 CBAs in last quarter of calendar 2010 were also billing Medicare in the last calendar quarter of 2011?**

Answer: The following tables show the number of suppliers that furnished durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items in the Round 1 Rebid competitive bidding areas and comparator areas annually and per month in 2010 and 2011. We have not analyzed these numbers to determine the reasons for the change in the number of suppliers but note that the percent change in the number of suppliers in Table 1 is similar in competitive bidding areas and comparators. This would indicate that forces beyond competitive bidding played a role in the change.

Table 1: Yearly Supplier Summary, 2010-2011
Suppliers by 10-digit Provider Transaction Access Number

Year	Number of Suppliers	CBAs					Number of Suppliers	Comparator		
		Number of Suppliers within Allowable Charge Range*						Number of Suppliers within Allowable Charge Range*		
		< \$10,000	\$10,000 - \$50,000	\$50,000 - \$100,000	\$100,000 - \$500,000	> \$500,000		< \$10,000	\$10,000 - \$50,000	\$50,000 - \$100,000
2010	23,059	17,890	3,083	1,060	607	419	19,994	15,689	2,613	798
2011	22,703	17,879	3,038	906	543	337	19,758	15,462	2,635	819

* Allowable charge ranges exclude the upper bound

Table 2: Monthly Supplier Summary, 2010-2011⁵
*Suppliers by 10-digit Provider Transaction Access
 Number*

Month	CBAs						Comparat			
	Number of Suppliers	Number of Suppliers within Allowable Charge Range*					Number of Suppliers	Number of Suppliers R		
		< \$1,000	\$1,000 - \$5,000	\$5,000 - \$10,000	\$10,000 - \$50,000	\$50,000 +		< \$1,000	\$1,000 - \$5,000	\$5,000 - \$10,000
Jan-10	11,467	7,322	2,374	883	551	337	10,081	6,668	2,006	
Feb-10	11,480	7,297	2,399	927	512	345	10,149	6,694	2,009	
Mar-10	11,932	7,333	2,669	973	564	393	10,647	6,796	2,245	
Apr-10	11,879	7,438	2,557	980	552	352	10,453	6,724	2,159	
May-10	11,954	7,585	2,528	953	531	357	10,378	6,703	2,123	
Jun-10	12,361	7,817	2,650	962	545	387	10,716	6,858	2,285	
Jul-10	12,377	7,958	2,560	976	524	359	10,780	7,097	2,149	
Aug-10	12,570	8,135	2,551	965	559	360	10,811	7,043	2,193	
Sep-10	12,392	8,045	2,486	949	538	374	10,774	7,008	2,168	
Oct-10	12,163	8,013	2,380	942	494	334	10,474	6,931	1,997	
Nov-10	11,765	7,778	2,255	913	480	339	10,275	6,858	1,917	
Dec-10	11,931	7,691	2,362	970	515	393	10,374	6,783	2,012	
Jan-11	11,485	7,633	2,331	791	475	255	10,317	6,838	2,042	
Feb-11	11,502	7,608	2,330	781	520	263	10,270	6,823	2,023	
Mar-11	11,859	7,566	2,616	860	516	301	10,669	6,821	2,280	
Apr-11	11,546	7,393	2,531	834	506	282	10,430	6,810	2,115	
May-11	11,814	7,530	2,641	825	533	285	10,545	6,782	2,235	
Jun-11	12,100	7,823	2,626	824	523	304	10,697	6,905	2,248	
Jul-11	12,005	7,881	2,550	785	503	286	10,573	6,894	2,179	
Aug-11	12,082	7,803	2,672	801	509	297	10,817	6,963	2,299	
Sep-11	11,981	7,766	2,639	760	525	291	10,722	6,981	2,209	
Oct-11	11,498	7,625	2,410	750	454	259	10,380	6,849	2,073	
Nov-11	11,049	7,363	2,204	763	452	267	10,089	6,723	1,953	
Dec-11	11,140	7,263	2,323	769	498	287	10,213	6,700	2,003	

⁵This provides an unduplicated count of unique suppliers that had allowed charges in these areas during a month; the suppliers furnishing items in a given month may not be the same suppliers furnishing items in another month.

* Allowable charge ranges exclude the upper bound

Question: For how many bidders in Round 1 did CMS adjust the capacity to arrive at the final number of contract suppliers?

Answer: CMS examines bidders' capacity estimates by item, not by product category. CMS adjusted the capacity of at least one item for 256 of the 356 contract suppliers. For the 256 suppliers that had at least one capacity estimate adjusted, 56 percent of the items were not adjusted, 16 percent of the items were reduced to 20 percent of demand for the item in the competitive bidding area, and 28 percent were adjusted to the bidder's historic levels.

Question: You noted that the Cramton auction was designed for commodities and not for "services to patients in their homes". Since the benefit specifies that payment is for the equipment and Medicare does not pay for services, is this a change in policy? If so, will CMS identify which services suppliers are required to provide?

Answer: Medicare's payment for the equipment includes costs that are associated with furnishing the equipment in accordance with Medicare requirements, such as the supplier standards, quality standards, and coverage policies. For example, Medicare's rental payment for a hospital bed includes delivery, set-up, patient training, and any needed repairs. These requirements apply regardless of whether the equipment is paid under the fee schedule or the competitive bidding program; there has been no change in policy.

Question: Can CMS explain the impact on state Medicaid recipients and their access to DME items and services as a result of the bidding program? If there is a drastic reduction in the number of DME providers in the United States caused by the current bid program, and rates are reduced significantly, can you explain how this will not negatively impact patients' access to DME in Medicare, Medicaid, and private insurance plans?

Answer: CMS has not heard complaints of access problems for Medicaid recipients resulting from the competitive bidding program or observed a drastic reduction in the number of DMEPOS suppliers. Please see Table 1 (above) for the number of suppliers that furnished durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items in the Round 1 Rebid competitive bidding areas and comparator areas in 2010 and 2011. CMS continues to monitor DME supplier data to monitor any change in the number of suppliers.

**Committee on Ways and Means
Subcommittee on Health
Hearing on the Medicare Durable Medical Equipment Competitive Bidding Program
May 9, 2012**

**Questions for the Record for
Laurence Wilson, Centers for Medicare and Medicaid Services**

Mr. Roskam & Mr. Nunes

Mr. Roskam

As the competitive bidding program for DMEPOS continues to move forward, we have heard from more and more companies in the Chicago land area that may be forced to close due to losing bids in round 2 because of the parameters of the existing competitive bidding program. During your testimony you stated that CMS reviews the bids and scrutinizes suppliers. However, I have heard anecdotally that, in 2011 (the first year of the competitive bidding program), a single supplier went from providing approximately 41 to 64 percent (Cincinnati) and 51 to 81 percent (Pittsburgh) of certain supplies in a competitive bidding area and that several winning suppliers have not provided *any* products in these (and other) areas during the first year of the program.

Question: Why is a single supplier dominating a number of markets and some suppliers not providing products at all? This would seem to lead to the conclusion that other suppliers have either not been able to meet their commitments, have had to close, or the winning bidders were not thoroughly screened, can you speak to which is true?

Answer: CMS awards contracts to qualified suppliers with sufficient capacity to meet beneficiary demand for each product category in each competitive bidding area. The competitive bidding program contracts do not guarantee a set volume of business. When contracts go into effect, the contract suppliers must compete against each other for Medicare beneficiaries' business on the basis of quality and customer service.

Question What penalties are levied on contracted suppliers who do not come close to meeting their bid capacities?

Answer: The competitive bidding program contracts require each contract supplier to furnish items in its contract to any beneficiary who lives in or visits the competitive bidding area and requests those items from the contract supplier. If a supplier does not meet its contractual obligation, CMS may take one or more of the following actions: require the contract supplier to submit a corrective action plan; suspend the contract supplier's contract; terminate the contract; preclude the contract supplier from participating in the competitive bidding program; revoke

the supplier's billing privileges; or impose other remedies allowed by law. (See 42 CFR 414.422(g).)

The capacity estimates in a supplier's bid represent the maximum number of items the supplier estimates it could furnish annually if awarded a contract. CMS validates these capacity estimates during the bid evaluation process and awards contracts to more than enough suppliers to meet beneficiary demand. Because of statutory requirements that guarantee beneficiary choice, beneficiaries may choose to obtain their items from any contract supplier. Therefore, competitive bidding program contracts do not guarantee any set volume of business. Thus, a contract supplier that furnishes items in its contract to any beneficiary who requests them is in compliance with competitive bidding program rules even if that supplier has not furnished the maximum number of items in its bid.

Question: **I am concerned that the market will contract to a point where there are only a handful of DME providers left which could potentially lead to higher prices and less competition. What is CMS doing to prevent this from occurring?**

Answer: The competitive bidding program includes numerous provisions to ensure a robust, competitive market. For example, CMS selects more than enough suppliers to meet demand. As a general rule for contract supplier selection purposes, we do not credit more than 20 percent of the total Medicare demand for a product category in a competitive bidding area to any one supplier, meaning at least five suppliers serve most product categories in most areas. Also, CMS has taken specific steps to ensure that small suppliers have the opportunity to be considered for participation in the competitive bidding program. These steps include offering small suppliers the opportunity to form networks, a small supplier target, and not requiring suppliers to submit bids for all product categories.

Question: **Why did the agency not exclude suicide bids from the single payment amount (for example, where a supplier did not accept a bid amount, yet their bid remained in the single payment amount)? Why are bids not binding on suppliers?**

Answer: Only legitimate, sustainable bids were included in the single payment amount determinations. We recognize the need to ensure that the single payment amounts are appropriate and viable, and through our bid evaluation process, identified and eliminated any irrational, infeasible bids. All bids are screened and evaluated to ensure that they are bona fide. During the Round 1 Rebid bid evaluation, we found that about 8 percent of bids were extremely low in comparison to other bids, so we asked these bidders to send us invoices and rationales explaining how they could furnish items at the bid price. Bidders were able to prove that 67 percent of these comparatively low bids were feasible. We rejected all of the bids that were not proven feasible, and we did not offer contracts to these suppliers or include the rejected bids in the calculation of single payment amounts.

The Medicare statute does not provide any authority that would permit CMS to require winning suppliers to accept contracts. This is consistent with other provisions of the Medicare statute that make supplier participation in Medicare voluntary. Although the statute does not provide any authority for requiring suppliers to accept contracts, it is not clear that such authority is needed. In the Round 1 Rebid, 92 percent of suppliers that were offered contracts accepted those contracts. CMS analyzed the bid amounts for the most commonly used items in each product category from suppliers that chose not to accept any contract and found that approximately the same number of bids were above and below the single payment amounts. Such results indicate the single payment amounts are set at an appropriate level based on the bids received during the Round 1 Rebid. There also have been no indications of any beneficiary access problems, and CMS has not had to add any new suppliers to meet demand.

During your testimony you also spoke to conversations you have had with Peter Crampton (sic) about his letter signed by 244 economists and 4 Nobel Laureates pointing to flaws in the competitive bidding program. Further, Tom Bradley, Chief of Medicare Cost Estimates for the Congressional Budget Office while attending a briefing stated the following, “If they (CMS) don't change the mechanism they use, I think there is a high probability of failure in the near future. There is a near certainty of failure sometime down the road”.

Question: What were the specific concerns you had with Mr. Crampton’s proposal relating to Market Clearing Price and binding bonded proposals, which is the accepted standard in other federal government contracting bidding processes? If others have stated the program cannot stand as it is currently implemented why would CMS not adopt a different method before expanding the program to an additional 91 areas?

Answer: The current competitive bidding program is the successful result of decades of research and testing by economists and health policy experts. The program offers improved value to Medicare and taxpayers by using prices set through competition and ensuring access to quality items furnished by licensed, accredited suppliers that must meet strict quality and financial standards. As indicated in CMS testimony, the program has already yielded significant savings for taxpayers and Medicare beneficiaries while preserving beneficiary access and health status outcomes.

CMS staff reviewed a January 16, 2012 version of the “market pricing” program. We have grave concerns with many aspects of this proposal. For example, as discussed in the following bullets, we are concerned that this proposal would result in auction failure in all, or nearly all areas, would not result in accurate pricing in those auctions if any were successful, and would not guarantee beneficiary access to needed items.

- Auction Failure: The program would result in nearly universal auction failure. Bidders' capacities would be artificially capped at historic levels (for suppliers in the area) or a minute fraction of demand (for suppliers not in the area). In effect, it assumes that suppliers would be unable to expand their businesses. The sum of all of the historic capacities of eligible, legitimate suppliers would be unlikely to reach the demand target. At a minimum, contracts would need to be awarded to every supplier in the area currently furnishing the item. Suppliers would know this ahead of time since the capacity of every bidding supplier would be disclosed prior to bidding. There would be no incentive to bid competitively since suppliers would be virtually assured of being awarded a contract.
- Inaccurate pricing. Bidders would only submit bids for one item in the product category. Prices for the other items would be based on the price for the lead item. Prices could end up too high or too low for the other items, resulting in lost savings or access problems.
- Failure to guarantee access: The program fails to guarantee beneficiary access. In fact, it explicitly permits a supplier to turn beneficiaries away if the predicted demand in an area has been met even if that supplier has not furnished up to the level in its bid.

We note that the auction model used in the January 16, 2012 proposal has been used for commodities like diamonds and timber but has never been tested in the healthcare arena. This is a concern since applying this model could have a significant effect on the quality of items and services Medicare beneficiaries receive, Medicare expenditures, and the Medicare DMEPOS market overall.

Finally, we note that this proposal would take many years to implement due to need to comply with the requirements of procedural laws like the Administrative Procedures Act and the Paperwork Reduction Act and the time it would take to develop the infrastructure to support the program. These delays could have serious cost implications since the current DMEPOS competitive bidding program is working to replace Medicare's outdated fee schedule amounts with fair payment amounts. The Department of Health and Human Services' Office of Inspector General (OIG)⁶, the Government Accountability Office (GAO), and other independent analysts have repeatedly warned that the fee schedule prices paid by Medicare for many DMEPOS items are excessive, as much as three or four times the retail prices and amounts paid by commercial insurers or customers who purchase these items on their own. These inflated prices in turn increase the amount beneficiaries must pay out-of-pocket for these items. CMS' Office of the Actuary (OACT) estimates that the current DMEPOS competitive bidding program will save the Medicare Part B Trust Fund \$25.7 billion between 2013 and 2022. Beneficiaries are expected to save an estimated \$17.1 billion due to the reduction in coinsurance and the downward effect on premium payments.

⁶ See, for example, *Comparison of Prices for Negative Pressure Wound Therapy Pumps*, OEI-02-07-00660, March 2009; *Power Wheelchairs in the Medicare Program: Supplier Acquisition Costs and Services*, OEI-04-07-00400, August 2009; *Medicare Home Oxygen Equipment: Cost and Servicing*, OEI-09-04-00420, September 2006.

**Committee on Ways and Means
Subcommittee on Health
Hearing on the Medicare Durable Medical Equipment Competitive Bidding Program
May 9, 2012**

**Questions for the Record for
Laurence Wilson, Centers for Medicare and Medicaid Services**

Mr. Roskam & Mr. Nunes

Mr. Devin Nunes

Question: After one year of competitive bidding for diabetic testing supplies, CMS claims that there was no evidence of negative health care outcomes for diabetes testing supply users. How confident is CMS that such negative health outcomes will not be apparent until 2013 or 2014 or later? Doesn't it take time for negative health outcomes to appear in a diabetes patient, who fails to be less adherent? Especially, higher mortality rates?

Answer: CMS is monitoring both short term and long term health care outcomes for diabetic patients. Diabetes is a chronic disease, and the manifestations of the disease are not all immediate. However, the comprehensive nature of our monitoring of health outcomes and the sensitivity to detect changes would detect any acute changes that could occur. For example, a rise in emergency department visits or physician visits would be precursors to the more chronic changes that would impact health outcomes. As we have not seen an increase in any short term negative health outcomes, it is unlikely that there would be an increase in negative long term outcomes. Since our monitoring is ongoing, we will be able to detect as early as possible such long-term outcomes, should they occur.

Question: The CMS report on Round 1 results showing that beneficiaries reported having more than enough supplies on hand and therefore did not need to obtain additional supplies when the program began. Does this indicate that mail order diabetic testing supply waste via auto-shipping is a major problem?

Answer: Diabetes monitoring supplies have historically had high error rates. A recent report by the HHS Office of the Inspector General found that 76 percent of a sample of claims for diabetes test strips and/or lancets were improperly paid.⁷ Our findings suggest that beneficiaries received excessive replacement supplies before they became medically necessary. While more investigation is

⁷ <http://oig.hhs.gov/oas/reports/region9/91102027.pdf>

needed to verify the cause or causes of inappropriate distribution, waste via auto-shipping is a serious concern.

Question: **Outside of 1-800-MEDICARE how does CMS collect patient complaints about the competitive bidding program for diabetic testing supplies? Does CMS collect complaint data based on patients who complain to their pharmacists or suppliers regarding the competitive bidding program?**

Answer: CMS has a comprehensive monitoring program that includes the 1-800-MEDICARE call center; local, on-the-ground presence in each competitive bidding area through the CMS regional offices and local ombudsmen; a formal complaint process for beneficiaries, caregivers, providers and suppliers to use for reporting concerns about contract suppliers or other competitive bidding implementation issues; and a CMS Competitive Acquisition Ombudsman who responds to complaints and inquiries from beneficiaries and suppliers about the application of the program. These CMS customer service entities follow an integrated inquiry and complaint management process to ensure that any person who contacts CMS about the competitive bidding program will be promptly assisted. CMS has conducted extensive outreach to beneficiaries, suppliers, referral agents, and beneficiary advocacy groups like the local State Health Insurance and Assistance Program (SHIP) offices so that they understand how to how to contact CMS with any questions, concerns, or complaints about the program.

Question: **Early data seemed to indicate that, in the competitive bidding areas, utilization of mail order pharmacies for diabetic testing supplies is decreasing, while the utilization of retail pharmacies for these supplies is increasing. This would seem to indicate that mail order suppliers in the competitive bidding areas are unable to meet the demands of the beneficiaries who need diabetic testing supplies. Is this the case? If it is, wouldn't it make sense to maintain access to diabetic testing supplies at retail pharmacies as a necessary safety valve in the competitive bidding program?**

Answer: CMS has not seen any evidence that the Round 1 Rebid mail order contract suppliers have capacity problems. However, manufacturers and suppliers have stated to CMS on numerous occasions that the option for beneficiaries to obtain diabetic supplies from local pharmacies with licensed pharmacists in house who can provide instructions and guidance to beneficiaries related to their testing needs is important and should be preserved. In recognition of these concerns, CMS has elected not to include retail (non-mail order) diabetic supplies in any currently scheduled competitions. We note that retail diabetic supplies are a high-volume item with over \$500 million in annual Medicare allowed charges and that there is a large disparity between the Medicare fee schedule amount for retail diabetic supplies and the Round 1 Rebid single payment amounts.

Question: Diabetic testing supplies obtained at a retail pharmacy are not currently included in the competitive bidding program. Therefore, beneficiaries can still obtain their diabetic testing supplies at their local pharmacy. Mandating that diabetic testing supplies could only be obtained through mail order suppliers would mean that the pharmacist and the beneficiary would no longer meet face-to-face, as they do now. Would such a restriction increase the possibility that the beneficiary may become less adherent with his or her medications or that other health care issues may not be identified because they are no longer meeting face-to-face?

Answer: Please see answer to previous question above.

**Committee on Ways and Means
Subcommittee on Health
Hearing on the Medicare Durable Medical Equipment Competitive Bidding Program
May 9, 2012**

**Questions for the Record for
Laurence Wilson, Centers for Medicare and Medicaid Services**

Mr. Tiberi

Mr. Tiberi

I would like to request additional information regarding Round 1 of the DME competitive bidding program in order for Congress to better evaluate the program and assess the validity of concerns raised by some. Please provide the following information:

1. Provide the charts with the data appended that track the utilization for each DME competitive bidding product category, from 2008 to present, for each Competitive Bid Area (CBA) and its comparator city. Provide a full set of charts as follows for each product category:

A. Percent of the Access Group (e.g. Cardio-Pulmonary Narrow, Diabetic, Sleep Disorders, a set for each one) purchasing or renting (the product category, such as Oxygen, Mail Order Diabetes Supplies, CPAP, etc.);

B. Percent of the Medicare A/B fee for service (FFS) population purchasing or renting (a set for each product category); and

C. A set of graphs for each of the above that reflects, in total, all CBAs and comparator cities combined.

Answer: CMS has a strong commitment to ensuring that beneficiaries have continued access to quality equipment under the program. For this reason, we developed a comprehensive monitoring system to assess access and health outcomes in near real time. We monitor over 3,400 data points to ensure that Medicare beneficiaries who use a competitively bid item and those who have conditions that may warrant use of a competitively bid item have continued access and do not suffer adverse health outcomes as a result of the competitive bidding program. Charts that show program results are regularly updated and posted on the CMS website at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html> . These charts are based on 100 percent of Medicare claims provide valid and reliable data about beneficiary health status outcomes, control for broader trends, and would indicate if beneficiary access or quality had been threatened. The health status health outcomes being monitored include events such as deaths, hospitalizations, emergency room visits, physician visits, admissions to skilled nursing facilities, average number of days spent hospitalized in a month, and average number of days in a skilled nursing facility in a month. As shown in the charts, fluctuations in outcomes match closely in competitive bidding

areas and comparison areas both before and after the start of the competitive bidding program. Historic seasonal trends also continue to be reflected. There have been no changes in beneficiary health status outcomes resulting from the competitive bidding program observed to date.

Comparing trends in claims utilization data alone before and after the program began may not provide a valid and reliable way to measure the impact of the competitive bidding program because the number of claims does not necessarily provide a reliable measure of the number of medically necessary items furnished to Medicare beneficiaries. For years, the Office of Inspector General has issued reports finding frequent, widespread problems in the DMEPOS industry like claims for services to deceased beneficiaries and claims for excessive or duplicate services. CMS has been working hard to combat fraud and has also been taking steps to reduce the very high claims error rate in the DMEPOS arena; however, many claims for fraudulent or unnecessary services have been paid. Comparisons of 2011-2012 claims data to previous years could mislead observers because they have not been controlled for effects such as expansion of targeted anti-fraud efforts.

To ensure that beneficiaries continue to have access to all needed DMEPOS items, CMS has taken the precautionary step of directly contacting beneficiaries in competitive bidding areas who had claims for mail order diabetes test strips and continuous positive airway pressure (CPAP) supplies before but not after program implementation. Through our direct beneficiary outreach, we determined that in virtually every case, the beneficiary reported having more than enough supplies on hand, often multiple months' worth, and therefore did not need to obtain additional supplies when the program began. The results of CMS's real-time claims monitoring is also supported by the low number of beneficiary complaints the agency has received. For these reasons, we strongly believe that the best way to evaluate the program is to use the charts that are on the CMS website. We would be pleased to provide Members with a briefing to go over the health status outcomes in more detail and to explain the real time claims monitoring program methodology.

2. Provide, by product category and for each CBA and each comparator city, the number of unique Medicare Beneficiaries with a claim submitted, and, separately, a claim paid, for the following two time periods:

A. Date of Service from October 1 through December 31, 2010

B. Date of Service from October 1 through December 31, 2011

Answer: CMS has a strong commitment to ensuring that beneficiaries have continued access to quality equipment under the program. For this reason, we developed a comprehensive monitoring system to assess access and health outcomes in near real time. We monitor over 3,400 data points to ensure that Medicare beneficiaries who use a competitively bid item and those who have conditions that may warrant use of a competitively bid item have continued access and do not suffer adverse health outcomes as a result of the competitive bidding program. Charts that show program results are regularly updated and posted on the CMS website at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html>. These charts are based on 100 percent of

Medicare claims and provide valid and reliable data about beneficiary health status outcomes, control for broader trends, and would indicate if beneficiary access or quality had been threatened.

Comparing trends in the number of beneficiaries for whom claims were submitted or paid alone before and after the program began may not provide a valid and reliable way to measure the impact of the competitive bidding program because the number of beneficiaries for whom claims were submitted or paid does not necessarily provide a reliable measure of the number of Medicare beneficiaries who need or receive these items. For years, the Office of Inspector General has issued reports finding frequent, widespread problems in the DMEPOS industry like claims for services to deceased beneficiaries and claims for excessive or duplicate services. CMS has been working hard to combat fraud and has also been taking steps to reduce the very high claims error rate in the DMEPOS arena; however, many claims for fraudulent or unnecessary services have been paid. Comparisons of 2011-2012 claims data to previous years could mislead observers because they have not been controlled for effects such as expansion of targeted anti-fraud efforts.

To ensure that beneficiaries continue to have access to all needed DMEPOS items, CMS has taken the precautionary step of directly contacting beneficiaries in competitive bidding areas who had claims for mail order diabetes test strips and continuous positive airway pressure (CPAP) supplies before but not after program implementation. Through our direct beneficiary outreach, we determined that in virtually every case, the beneficiary reported having more than enough supplies on hand, often multiple months' worth, and therefore did not need to obtain additional supplies when the program began. These targeted outreach efforts reflect the Agency's commitment to act on the health status outcomes information produced from our comprehensive claims monitoring system. This information is displayed in the charts available on the CMS website. We would be pleased to provide Members with a briefing to go over these health status outcomes in more detail and to explain the real time claims monitoring program methodology.

3. Provide for each product category in Rebid areas the number of unique DMEPOS suppliers that submitted a claim for a date of service in December 2010 and, separately, in December 2011 as follows:

- A. Number of Contracted suppliers in each CBA submitting a claim;**
- B. Number of non-contracted suppliers in each CBA submitting a claim; and**
- C. For each comparator city, the number of suppliers submitting a claim.**

Answer: The attached Excel document shows the number of unique DMEPOS suppliers with any allowed charges for competitively bid items in 2010 and 2011 in CBAs and comparator areas. We note that many of these suppliers had very small allowed charges. To help provide perspective about suppliers with a more meaningful presence in the area, we have also provided the number of unique DMEPOS suppliers with allowed charges for competitively bid items of at least \$10,000 in these years.

4. Provide for the product categories of oxygen, CPAP and enteral nutrition, charts that track the health outcomes

(https://www.cms.gov/DMEPOSCompetitiveBid/01A3_Monitoring.asp) of beneficiaries in each CBA and comparator city who:

- A. Had a claim for the product category with a date of service between October 1, 2010 and January 31, 2011, and**
- B. Did NOT have a claim for the product category with a date of service between October 1, 2011 and January 31, 2012, and**
- C. Are not deceased.**

Answer: CMS does not currently compile claims data in the manner requested. CMS understands the Subcommittee’s interest in assessing the health status of beneficiaries with a history of equipment use who no longer use the product. We note that it is difficult to measure “non-use” with Medicare claims data. Instead, we identify individuals that are not *billing* for a particular product. These people may have excess replacement supplies, may have reached the end of their billing period, or may no longer need the product. It is possible that these beneficiaries may have changes in health status over time. However, these changes could occur for many reasons which may not be related to competitive bidding. This will make the results of this analysis difficult to interpret. We have summarized two hypothetical examples below.

Example 1: A beneficiary receives a CPAP device in 2010. Over the next few months, the person’s health status improves and the CPAP device is no longer necessary. The beneficiary does not have a CPAP-related claim in 2011-2012. Since the beneficiary’s health status has improved, he has decreased rates of emergency department utilization and fewer physician visits in 2011 compared to 2010. We cannot conclude that the beneficiary’s improved health status outcomes are the result of the competitive bidding program.

Example 2: In 2010, a beneficiary is in her 36th month of a rental period for a portable oxygen concentrator. Since Medicare pays for oxygen using a 36 month capped rental, the beneficiary does not have an oxygen-related claim between October 1, 2011 and January 31, 2012, even though she is continuing to receive oxygen. The beneficiary has severe COPD along with several other conditions, and her health status is deteriorating with age. The beneficiary visits the hospital more often in 2011 than 2010 as a result of her worsening health status; however, we cannot use claims data to conclude that this is related to competitive bidding.

CMS agrees that it is very important to monitor access and outcomes for all beneficiaries who are likely to need a competitively bid item based on their medical needs, including beneficiaries who do not have a claim for the item. The CMS real-time claims analysis program is currently tracking this information; the relevant information can be found on the “Access Group” charts in the health status outcomes charts on the CMS website (see:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html>). The “Access Group” tracking has been

designed to control for non-competitive bidding program effects and provide an accurate picture of program results.

Despite the difficulty in measuring the “non-use” of a product, we have estimated the cost of compiling the requested data to be approximately \$20,000 to \$40,000. The compilation would take at least several weeks.