

## **Frequently Asked Questions – revised 10/27/06**

*Regarding the Durable Medical Equipment Prosthetics, Orthotics and Medical Supplies (DMEPOS) Competitive Acquisition Program (CAP) aka “Competitive Bidding” Rules*

### **1. What is the genesis of the new rule?**

- The Medicare Modernization Act of 2003 mandated that the Secretary issue a final rule requiring accreditation and competitive bidding for DMEPOS, diabetes and some Part B supplies and services.

### **2. What are the potential costs of the new rule?**

- Considering diabetes beneficiaries alone, decreased access to diabetes health care that will result from implementation of competitive bidding for diabetes supplies will result in a conservative additional cost to total Medicare health care costs of between \$230 million to over \$1 billion per year.

### **3. What are CMS’s stated objectives in competitively bidding DMEPOS and what is the NCPA position regarding how the rule is counterproductive to those goals? (NCPA stated these objections back in June in its comments to the proposed rule).**

- *Secure beneficiary access to quality DMEPOS*
  - NCPA maintains that an expensive accreditation requirement and burdensome bid application process will force small supplier pharmacies to exit the DMEPOS market limiting beneficiary access to vital Part B supplies and services.
- *Decrease Medicare and beneficiary payments*
  - NCPA maintains that limiting access to DMEPOS (i.e. diabetes testing supplies) will actually increase health care expenditures.
- *Reflect a competitive market*
  - NCPA maintains that large volume publicly held suppliers and mail order companies have a competitive and monopolistic advantage over small supplier pharmacies.
- *Contract with suppliers favorable to the program and beneficiaries*
  - NCPA maintains that small supplier pharmacies provide convenient access for beneficiaries and should not be considered unfavorable to the program because they are unable to afford the burdensome and expensive accreditation and competitive bid application processes.
- *Limit fraud*
  - NCPA maintains that protecting the beneficiary is a noble goal but believes limiting access to Part B supplies and services may actually harm beneficiaries more than a fraudulent supplier would.

**4 What is the current status of the new rule?**

- CMS issued CMS-1540-F on August 18, 2006. It set accreditation requirements and outlined the basics of the upcoming competitive bidding requirements. The implementing details of competitive bidding will be released in a final rule that CMS will likely issue any time from very soon to early 2007. CMS has not yet established which accreditation organizations will be authorized to provide accreditation services for DMEPOS. Diabetes supplies and services are subject to accreditation and are currently scheduled for competitive bidding.

**5. What action has NCPA taken to oppose the accreditation and competitive bidding requirements?**

- NCPA submitted written comments on June 30, 2006 raising concerns and objections to the proposed rule.
- NCPA has played a leadership role in the Diabetes Access to Care Coalition, which is attempting to convince the Secretary of HHS to exercise his discretion to exempt diabetes supplies and services from the upcoming competitive bidding rule. DACC members also include NACDS, the American Association of Clinical Endocrinologists, the American Association of Diabetes Educators and industry members, such as Abbott, Bayer HealthCare; BD (Becton, Dickinson and Company), LifeScan, Inc. and Roche Diagnostics. The American Diabetes Association has also supported DACC's positions.
- In addition to taking part in some of the DACC's over 100 Hill visits and also conducting separate Hill meetings, NCPA has participated in DACC's and additional meetings with HHS, CMS and the White House regarding this issue. Well over 40 Members of Congress have signed onto various letters to Secretary Leavitt, asking him to exempt diabetes supplies from the competitive bidding rule. NCPA has also been instrumental in getting its membership to help with grass roots efforts in several key states.
  - During the summer, NCPA sent out email and fax alerts asking its members to both write their members of Congress to ask the Secretary to exempt diabetes supplies and services, and also to write to the Secretary directly.

**6. When will competitive bidding be phased in throughout the country and how will areas be selected?**

- Ten (10) Metropolitan Statistical Areas (MSAs) will be selected in 2007 and eighty (70) in 2008, and ten (10) each in 2009 and 2010. The first round excludes the top three (3) MSAs - New York, Los Angeles and Chicago.

**7. How will competitive bidding impact pharmacies maintaining Medicare Part B supplier numbers to bill DMEPOS?**

- Many pharmacies and many DMEPOS products will be subject to competitive bidding requirements. CMS estimates 90% of suppliers will participate in competitive bidding, but CMS estimates that only 50% will win. Technically speaking, Medicare is free to select as few as two suppliers per MSA to offer services.
- Additionally, the rule states that ALL suppliers must obtain accreditation to provide some Part B billed services (Part B drugs and immunizations are not subject to the accreditation requirements). This may impact diabetes self management training and pharmacists providing therapeutic shoes, enteral nutrition, and off-the-shelf orthotic supplies.
- Pharmacists inclined to participate in the competitive acquisition program must comply with overly burdensome regulations requiring suppliers to obtain accreditation and submit a time consuming competitive bid application.

**8. How will competitive bidding impact beneficiaries?**

- Beneficiaries may lose access to essential products and services like diabetes testing supplies, currently available from all community pharmacies maintaining Part B supplier numbers. CMS's active supplier report for April 2006 identifies 52,519 pharmacy suppliers out of the total of 165,981 suppliers. Nearly one-third of all suppliers (32%) are therefore pharmacists.
- NCPA has grave concerns that CMS may have overestimated the number of suppliers that will continue to participate in the competitive acquisition program. A three-day survey conducted June 23, 2006 – June 26, 2006 shows that CMS's assumption of 90 percent participation in competitive bid by small suppliers is some three times overly optimistic. **Only 31 percent of pharmacists responding from the 10 MSAs likely to be selected said they will participate in the competitive acquisition program (CAP).** The primary reasons they stated for their intention not to participate are concerns about profitability and lack of resources to commit to the CAP bid process and accreditation.

**9. What criteria are used to rank MSAs?**

- MSA are ranked in terms of general population, then scored by greatest number of suppliers and allowed charges per beneficiary.

**10. Who are the approved accreditation organizations?**

- As of 10/25/06, CMS has not identified approved accreditation organizations.

**11. Have the top 10 MSAs been identified for the first round of bidding to begin in 2007?**

As of 10/25/06, CMS has not identified the top 10 MSAs for the first round of bidding to begin in 2007. 2003 data would suggest that among the most likely areas to be chosen are Miami-Ft. Lauderdale-Miami Beach; Houston-Baytown-Sugarland; Dallas-Fort Worth-Arlington; Riverside-San Bernardino-Ontario; Charlotte-Gastonia-Concord; Orlando; San Juan, Puerto Rico; Atlanta-Sandy Springs-Marietta; Pittsburg; Cincinnati-Middletown. Other areas that are candidates to be selected in the first 10 MSAs include Seattle, San Francisco, Kansas City, St. Louis, Detroit, Cleveland, Philadelphia, Boston, Washington, Virginia Beach and Tampa.

**12. Must I obtain accreditation to acquire or retain my Medicare Part B supplier billing number?**

- Yes, but when that accreditation is required is unclear. Also see numbers 12 and 13, below.

**13. Competitive bidding is scheduled to begin in 2007. Do I have to obtain accreditation by January 1, 2007 to continue billing Part B for DMEPOS?**

- No, but some bidding suppliers will have to obtain accreditation in 2007, some in 2008 and the rest by 2010. Only suppliers from the 10 MSAs selected in 2007 and participating in the competitive acquisition program are required to obtain accreditation, by a yet-to-be-determined date in late 2007. For those suppliers in the first 10 MSAs, to even be considered as a bidder, your pharmacy must be accredited by a CMS approved accreditation organization. Bidding suppliers located in the top 10 MSAs will be prioritized by the accreditation organizations

**14. My pharmacy is located in an area that might be identified as one of the first 10 MSAs, however, I am not participating in the competitive acquisition program for DMEPOS. When do I have to obtain accreditation?**

- CMS has not yet determined this date. The CMS final rule states only that every supplier must obtain accreditation to acquire or renew their Part B supplier number. Non-bidding suppliers must obtain accreditation sometime before January 1, 2010.

**15. I want to participate in the competitive acquisition program for DMEPOS. How long will it take to obtain accreditation and complete the bid application process?**

- Based on the proposed rule, CMS estimated that the entire bid submission process to average 70 hours and cost suppliers almost \$2,200 of auditor and accountant time to prepare the bid. The entire accreditation process including survey and preparation to come into compliance will vary based by current supplier preparedness, and the DMEPOS services provided. Total charges to obtain accreditation and prepare the bid were estimated at \$7,000-17,000.

- NCPA's comments to the proposed rule and advocacy had some influence upon CMS. The final rule regarding accreditation, CMS-1540-F, loosens the accreditation requirements, but it remains to be seen how they will be applied by accreditation organizations in real life practice.

**16. What financial information must I provide CMS to demonstrate solvency?**

- Suppliers must provide specific financial information to demonstrate solvency including:
  1. Bank references
  2. Credit history
  3. Insurance documentation
  4. Line of credit
  5. Ability to accept 20 percent more in increased capacity to serve beneficiaries

**17. Are mail order suppliers eligible to participate in the competitive acquisition program?**

- Yes, as long as they obtain accreditation and meet CMS bid application requirements

**18. What products are the likely targets of the CMS competitive acquisition program?**

- Likely targets include but are not limited to the top five DMEPOS allowed charges by policy group. The top 5 account for 57.1 percent of beneficiary purchases.
  - Oxygen Supplies/Equipment – 21.3 percent
  - Wheelchairs/POV – 16.9 percent
  - Diabetic Supplies & Equipment – 9.7 percent
  - Enteral Nutrition – 5.9 percent
  - Hospital Beds – 3.3 percent

**19. Where can I learn more about competitive bidding and NCPA actions addressing community pharmacies concerns?**

- Please go to the Government Affairs section of the NCPA website (<http://www.ncpanet.org/leggovaffairs/>) for several documents highlighting NCPA's position and actions on the issue, and how you can voice your opinions to decision makers.