

Frequently Asked Questions (Updated 5/1/2007)

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

These FAQs start with a nutshell summary regarding which diabetes and certain Part B supplies, and which pharmacists, are impacted by the CMS DMEPOS/diabetes competitive bidding rule, followed by a more detailed analysis of the rule.

NUTSHELL SUMMARY

I. THE FINAL RULE

- On April 2, 2007, CMS issued CMS-1270-F, a final rule regarding competitive bidding for 2008 that named the first 10 Metropolitan Statistical Areas that will participate in the competitive bidding process, as well as the first 10 product categories that will be subject to competitive bidding. The rule reflects a victory for retail community pharmacy in that it is exempted from having to undergo competitive bidding to provide diabetes supplies to their patients.

II. EXCEPTIONS:

- At least until 2009, If you sell only Part B drugs or only vaccinations, you do not have to obtain accreditation, nor do you have to competitively bid
 - respiratory, chemotherapeutic and anti nausea drugs are part of this exemption from competitive bidding and accreditation
- Non-mail-order diabetes supplies (see V, below) are exempt from COMPETITIVE BIDDING ONLY

III. COMPETITIVE BIDDING:

A. Those in the 10 MSAs that sell one of the 10 identified supplies must, in order to continue selling, win a competitive bid. To be eligible to submit a bid, the pharmacist must obtain accreditation by August 31, 2007.

B. So a retail community pharmacist, inside or outside of the 10 MSAs, does NOT have to competitively bid to sell supplies that are not on the 10-supply list (or are Part B drugs or vaccinations).

C. Keep in mind that CMS will choose 70 more MSAs for 2009.

IV. ACCREDITATION

All DMEPOS - except for Part B drugs and vaccination - suppliers must eventually obtain accreditation by at least 2010. Again, those submitting bids in the first 10 MSAs will be the first to have to obtain accreditation, by 8/31/07.

V. DIABETES SUPPLIES

A. In the 10 MSAs, retail community pharmacies are not subject to the competitive bidding requirements, but participating suppliers, including pharmacists, will have to eventually obtain accreditation. Strips and lancets (not meters) sold through mail order are subject to competitive bidding requirements. The fee schedule will continue to apply at retail pharmacies.

B. All diabetes suppliers - not just those in the first 10 MSAs - will also have to eventually obtain accreditation (by at least 2010).

FAQs

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 Part B supplies and services.

2. 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.

3. How will competitive bidding impact beneficiaries?

- Beneficiaries may lose access to essential products and services, 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.

4. What is the current status of the final rule?

- CMS issued its final rule, CMS-1270-F, on April 2, 2007. It named the first 10 Metropolitan Statistical Areas that will participate in the competitive bidding process, as well as the first 10 product categories that will be subject to competitive bidding.

5. 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. However, small businesses will garner protection from CMS's "30 percent rule," which ensures that at least 30 percent of bid winners are small businesses.
- Additionally, the rule states ALL suppliers must obtain accreditation to provide some Part B billed services. The only exception to the rule is a pharmacy that maintains a Part B supplier billing number to submit Part B drug claims and administer vaccinations. These supplier pharmacies must meet the current 21 national supplier clearinghouse (NSC) standards, but do not have to obtain any further accreditation. This may impact diabetes self management training and pharmacists providing therapeutic shoes, enteral nutrition, and off-the-shelf orthotic supplies.
- Pharmacists who wish to participate in the competitive acquisition program must comply with the regulations requiring suppliers to obtain accreditation and submit a competitive bid application by August 31, 2007

6. When will competitive bidding be phased in throughout the country?

- Ten Metropolitan Statistical Areas (MSAs) have been selected for 2007. The bidding process for those MSAs is set to begin in late April 2007 with winners being announced in December 2007. Seventy MSAs will be selected in 2008 for contract year (CY) 2009, and CMS intends to launch the program nationwide thereafter. The first round excludes the top three (3) MSAs - New York, Los Angeles and Chicago.

7. What are the first 10 MSAs?

- Charlotte-Gastonia-Concord, NC-SC
- Cincinnati-Middletown, OH-KY-IN
- Cleveland-Elyria-Mentor, OH
- Dallas-Fort Worth-Arlington, TX
- Kansas City, MO-KS
- Miami-Fort Lauderdale-Miami Beach, FL
- Orlando, FL
- Pittsburgh, PA
- Riverside-San Bernardino-Ontario, CA
- San Juan-Caguas-Guaynabo, PR

8. What are the 10 product categories included in the first round of competitive bidding?

- Oxygen Supplies and Equipment
- Standard Power Wheelchairs, Scooters, and Related Accessories
- Complex Rehabilitative Power Wheelchairs and Related Accessories
- Mail-Order Diabetic Supplies
- Enteral Nutrients, Equipment, and Supplies
- Continuous Positive Airway Pressure (CPAP) Devices, Respiratory Assist Devices (RADs), and Related Supplies and Accessories
- Hospital Beds and Related Accessories
- Negative Pressure Wound Therapy (NPWT) Pumps and Related Supplies and Accessories
- Walkers and Related Accessories
- **(Miami and San Juan Only)** – Support Surfaces (group 2 and 3 mattresses and overlays)

A listing of the items contained in each product category will be available in the near future.

9. Who are the approved accreditation organizations?

- Accreditation Commission for Healthcare, Inc (ACHC)
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- Community Health Accreditation Program (CHAP)
- Healthcare Quality Association on Accreditation (HQAA)
- National Board of Accreditation for Orthotic Suppliers (NBAOS)
- Board for Orthotist/Prosthetist Certification (BOC)
- National Association of Boards of Pharmacy (NABP)
- Commission on Accreditation of Rehabilitation Facilities (CARF)
- American Board for Certification in Orthotics and Prosthetics, Inc. (ABC)
- The Compliance Team, Inc.

10. What is the current timeline for implementation of the final rule?

4/2/2007	CMS announces Medicare DMEPOS Competitive Bidding Program final rule and first round competitive bid areas and product categories.
4/9/2007	CMS opens initial registration for first round bidders to get USER IDs and passwords.
4/10/2007	CMS publishes final rules for the new Medicare DMEPOS Competitive Bidding Program.
4/11/2007	CMS holds Special Open Door Forum.
Late April 2007	CMS holds educational Web cast.
Late April 2007	CMS opens 60-day bid window for first round of Medicare DMEPOS Competitive Bidding Program – all suppliers must be accredited or pending accreditation to submit a bid.
Late June 2007	60-day bid window closes.
8/31/2007	Last day for first round bidders to obtain accreditation.
Late September 2007	CMS concludes bid evaluation and begins contracting process.
December 2007	CMS announces winning suppliers for first round.
1/1/2008 – 4/1/2008	CMS conducts intensive beneficiary and referral agent education campaign.
4/1/2008	New program begins – New pricing goes into effect for 10MSAs
April 2009	Second round of bidding in effect for 70 MSAs
January 2010	CMS has ability to set national price
April 2010	New prices for the 70 new MSAs go into effect

11. What did the new final rule say about diabetes supplies?

- Only mail order diabetes supplies in the 10 MSAs are subject to competitive bidding; retail community pharmacists both in and out of the 10 MSAs can continue to sell under CMS' supply schedules.
- Retail community pharmacies must still obtain accreditation to sell diabetes supplies.

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

- Yes. The only exception to the rule is a pharmacy that maintains a Part B supplier billing number to submit Part B drug claims and administer vaccinations. These supplier pharmacies must meet the current 21 national supplier clearinghouse (NSC) standards, but do not have to obtain any further accreditation.

13. Competitive bidding is scheduled to begin in 2007. I live in a selected MSA, must I be accredited before I can submit a bid?

- Bidding suppliers will have to be accredited by August 31, 2007 in order to win Medicare bids.

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?

- It depends on how prepared, in a business sense, the pharmacy is to meet the requirements. Based on the proposed rule, CMS had 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 had been estimated at \$7,000-17,000.

- It is clear that accreditation costs will in general be significantly lower than had been projected under the proposed rule. As a result of education and grass roots advocacy by NCPA and others, CMS in the fall of 2006 announced that the accreditation requirements would be less stringent than had been stated in the proposed rule. NCPA has also formed partnerships with NABP, PRS and VGM for special accreditation pricing deals for NCPA members.
- While the final rule regarding accreditation, found in the CMS fall 2006 announcement and in the April 2, 2007 CMS-1540-F, loosens the accreditation requirements 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. Under the final rule, they are the only suppliers required to bid on diabetes testing supplies.

18. Where can I learn more about competitive bidding and accreditation?

- Community pharmacists with questions about CMS regulations and proposals concerning accreditation and competitive bidding can get the facts by visiting NCPA's DME Resource Center (www.pharmacistelink.com/medicareme). NCPA, through Pharmacist e-Link™ and with support from Bayer HealthCare, Diabetes Care, is providing this online resource to help clear the confusion and provide up-to-date, accurate information on DMEPOS accreditation and competitive bidding.
- This one-stop site includes:
 - Information on and explanation of accreditation and competitive bidding
 - Forms and documentation to begin the accreditation process
 - *DME-alerts*: Register for this service and you will receive the latest on accreditation and competitive bidding delivered to your computer desktop, as it becomes available.

- DME Alert Blog: Bill Popomaronis, R.Ph., NCPA vice president, home health and long term care pharmacy services, will be blogging his thoughts, interpretations, and explanations on the latest DME information from CMS on the site.