

Frequently Asked Questions Regarding the Status of CMS's Medicare Part B DMEPOS Accreditation, Surety Bond, and Competitive Bidding Requirements

August 3, 2009

1. What are the basic requirements for me to continue providing and billing for Medicare Part B DMEPOS?

- After September 30, 2009, all suppliers of Part B Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS), including pharmacies, must obtain both accreditation and a surety bond if they wish to continue providing these supplies to their patients. Even those pharmacies that are only providing diabetes test supplies must meet these requirements.
- Suppliers providing only Part B drugs and vaccinations do not have to meet the accreditation requirements, but they must meet the surety bond requirements.
- Participation in upcoming Round 1 of the competitive bidding program for certain DMEPOS products is a separate matter, and submitting bids is only required if a supplier wishes to continue supplying those selected products. Those wishing to participate in this competitive bidding program, however, must also have obtained accreditation and the surety bond (see more info in #4).

2. Will CMS or Congress create any exceptions to these deadlines?

- **Because we do not know when or if exceptions will be enacted, in preparing for these deadlines, you should assume that there will be no exceptions available.** We are hopeful that the House and Senate will pass legislation enacting certain exemptions for pharmacies.
- CMS has firmly stated recently that it considers September 30 a firm statutory deadline. The Agency has told NCPA that it believes that all suppliers who have submitted a “completed” application by January 31, 2009, will receive a decision on their application by the September 30 deadline. CMS said that it is regularly consulting with the Accreditation Organizations (AOs) regarding the status of submitted applications. The Agency also told us that it is monitoring this process and could possibly be flexible.
- We have worked to get language included in the House health care reform bill that would exempt pharmacies with clean records from the surety bond requirement; would exempt pharmacies providing only diabetes test supplies, canes or walkers from the accreditation process; and would enable suppliers applying for accreditation by August 1 to have a chance to go through the accreditation process without initial loss of supplier status on October 1. In the Senate, we have received indications that pharmacy accreditation exemption language will be included in the Senate Finance Committee health care reform bill, but that will likely not be agreed to and released until September.
 - Pharmacies cannot rely on legislation passing, and should assess their situation promptly and act prudently, as described in #3.

3. I have not yet received accreditation; what should I do?

- CMS made it clear that those who are working with their AO and have met the January 31, 2009, “completed” application deadline should continue working closely with their AO and they will receive a decision by the September 30 deadline.

- For those suppliers that are currently going through the accreditation process and do not yet know the likely outcome of their application, CMS cautioned against voluntary termination at this time. CMS said that after it consults with the AOs in mid-September, it will be in a better position to provide guidance on the voluntary termination process to these suppliers. Those pharmacies in this category should therefore continue to consult with their AO.
- Those pharmacies that do not want to become accredited or decide, after careful consultation with their AO, that they will not meet the accreditation deadline, should file a CMS-855s voluntary termination application (amendment) to the National Supplier Clearinghouse (NSC) by September 30. CMS said they would begin initiating their revocation letters to suppliers in violation immediately after the September 30 deadline - therefore the importance of filing a voluntary termination amendment before this time. Again, it makes sense for many of you to wait until mid-September to make this decision.
- For those who submit a CMS-855s voluntary termination application (amendment), CMS would not specify how quickly it would process a subsequent application to reenter the program. It is clear, however, that the process would be shorter than if you allow CMS to initiate termination of your billing status. You can reenter once you receive accreditation.
- A final option is, of course, to completely terminate and plan not to reenter the program.

4. What should I know about the competitive bidding program, and will it affect me?

- In the summer of 2008, Congress delayed the first round of competitive bidding by about 18 months. CMS recently announced that the 60-day supplier bidding period will begin in late October for the Round One rebid. It is conducting supplier outreach and education: www.dmecompetitivebid.com.
- The restarted first round of competitive bidding will cover 9 product categories (including mail order diabetes testing supplies and oxygen equipment) in only the first 9 Metropolitan Statistical Areas (MSAs). A list of those categories and MSAs is clarified in #5. The winning bid prices in those 9 categories in last year's round one (aborted after only a couple of weeks) were significantly lower than current pricing schedules (there were actually 10 product categories and 10 MSAs in the discontinued 2008 round 1).
- While bidding requirements and expected low winning bid prices will make it likely that most pharmacies will NOT want to bid for these products, competitive bidding is important because:
 - It sets a precedent for future rounds – and CMS intends for round two, which is likely to begin in 2011, to commence in 70 additional MSAs.
 - **Community pharmacy provision of diabetes test supplies is in danger:** CMS stated in the final competitive bidding rule that for round two, it is looking to have national mail order programs, and it invited comments on the “inconsistency” of having mail order diabetes test supplies in competitive bidding, but retail diabetes test supplies outside of competitive bidding. NCPA has of course advocated keeping retail supplies out of both round one and future rounds of competitive bidding.
- We will continue advocating for fair treatment of community pharmacies and their patients on this issue, and other competitive bidding developments.

5. What are the first 9 product categories subject to competitive bidding and what are the 9 MSAs in which it will occur?

The 9 product categories included in the upcoming renewed first round of competitive bidding:

- Oxygen Supplies and Equipment
- Standard Power Wheelchairs, Scooters, and Related Accessories
- Complex Rehabilitative Power Wheelchairs and Related Accessories (Group 2)
- 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
- Walkers and Related Accessories
- **(Miami Only)** – Support Surfaces (Group 2 mattresses and overlays)

The first 9 MSAs:

- The first round excludes the top three (3) MSAs - New York, Los Angeles and Chicago.
- 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

6. Where can I find answers to more specific questions?

CMS has a FAQ webpage, and you can review NCPA's DME Resource Center or contact the NCPA Government Affairs department at (703) 683-8200. Here are citations to relevant CMS and NCPA webpages:

CMS:

CMS' FAQs:

http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_alp.php?p_pv=3.754&p_prods=8%2C60%2C754&p_cats=&p_hiddden_prods=&prod_lv1=8&prod_lv2=60&prod_lv3=754

NCPA:

- Community pharmacists with questions about CMS accreditation and competitive bidding can visit NCPA's DME Resource Center (www.pharmacistelink.com/medicaremedme). 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, has been blogging his thoughts, interpretations, and explanations on the latest DME information from CMS on the site.