

Dear PMC Members:

The following is a more detailed analysis of the interim final rule on national government consolidation of DME providers that was released in today's Federal Register. The rule can be found at: <http://edocket.access.gpo.gov/2009/E9-863.htm>.

- This is an interim final rule; effective 30 days after publication (February 15<sup>th</sup>); CMS states that they have good cause to waive the rule making process because the statute requires implementation to occur in 2009;
- There is a 60 day comment period;
- There is no indication of when the bidding process will start; only in 2009; every MSA is subject to re-bid; Round 2 competition will occur in 2011;
- The bidding would apply to 9 of the original 10 metropolitan statistical areas (MSAs). San Juan, P.R. is not in the new list.
- Excluded from Round One is negative pressure wound therapy and Group 3 (only) power wheelchairs; Group 2 complex rehab is still included;
- Financial Submissions: CMS lowered the proof of financial records requirement from 3 years to one. Their reason: "we believe that we can determine whether a supplier demonstrates financial soundness by reviewing one year of documentation."
- CMS will notify suppliers who submit their bids on any missing required financial documents within 45 days after the covered document review for the Round One re-bid; documents can include tax forms, financial statements or other required documents; CMS will allow 10 days to submit missing financial documents; Certain limitations on the covered document review process include:
  - Covered document review process applies only to the timely submission of covered items;
  - Process does not apply to any determination as to the accuracy or completeness of the covered documents submitted or whether such documents meet applicable financial requirements;
  - The process does not prevent CMS from rejecting a bid for reasons other than described in section 1847 (a)(1)(F)(i)(II); and
  - Covered document review process shall not be construed as permitting a bidder to change bidding amounts or to make changes in a bid submission.
- If a supplier submits the missing information within the specified timeframe (10 days), CMS may not reject the suppliers bid;
- Winning suppliers must notify CMS of any subcontracting relationships they have encountered into for the purpose of furnishing items in the bidding program. Winning suppliers must also inform CMS whether each subcontractor meets the accreditation requirements as required by law (1834 (a)(20)(F)(i) if applicable;
- Winning suppliers must notify CMS within 10 days of a subcontracting agreement; there is no mention of any timeframe in which CMS must approve the agreement;

- CMS states that they will issue sub-regulatory guidance regarding the need to keep CMS current on all subcontracting relationships;
- Both winning suppliers and subcontractors that furnish items and services under the bidding program must do so in accordance with the applicable supplier standards;
- The IFR exempts certain DME items when furnished by a physician or treating practitioner to his or her own patients as part of his/her professional services;
- Hospitals that furnish certain types of competitively bid DME to their own patients during an admission or on the date of discharge from the bidding program, are exempt;
- There will be consideration made for competition of diabetic supplies; potentially after the Round One rebid;
- According to CMS, section 154 of the MIPPA amended section 1847 of the Act to make limited changes to the Medicare DMEPOS Competitive Bidding Program; this merely incorporates limited statutory changes to the Medicare DMEPOS Competitive Bidding Program and does not change the fundamental requirements of the program.

### **9 MSAs Set for Bidding in 2009**

- Cincinnati-Middletown (Parts of Ohio, Kentucky, Indiana)
- Cleveland-Eyria, Ohio
- Charlotte-Gastonia-Concord (North Carolina and parts of South Carolina)
- Dallas-Ft. Worth, Texas
- Kansas City, Missouri (and parts of Kansas)
- Miami-Ft. Lauderdale-Miami Beach, Florida
- Orlando, Florida
- Pittsburgh, Pennsylvania

As always, feel free to contact me with any questions.