



## Washington Update October 8, 2004

### **Competitive Bidding Committee at CMS Discusses Next Steps, Implementation**

The program advisory oversight committee on competitive bidding met on Wednesday. CMS announced it expects to publish a Notice of Proposed Rulemaking early next year that will solicit industry input on what selection criteria should be used to establish the first MSAs and products subject to competitive bidding.

The Wednesday meeting featured presentations from CMS staff and the demonstration contractors summarizing the results of the demonstration. CMS released the third report on the evaluation of the demonstrations. The report and handouts are available on the CMS web site.

RTI, the contractor charged with providing the competitive bidding implementation design, gave a brief presentation on the options for implementation. These included running the program in-house, delegating it to the DMERCs and designating a new, single entity contractor to run the program. The proposal to delegate the program to the DMERCs drew the most controversy. The broad sentiment was that the DMERCs were having a hard time doing a competent job as it is without adding one more responsibility to their plates. The group, however, did not object to assigning the limited role of claims processing to the DMERCs.

A presentation on possible options for developing the quality standards touched on whether CMS should develop its own baseline standards and allow the accrediting bodies to administer them, or whether CMS should simply adopt the standards currently in use by the accrediting bodies. The committee will meet

again on December 6 and 7. Pride Mobility is a new member of the committee.

For details, visit:

<http://www.cms.hhs.gov/suppliers/dmepos/com/bid/default.asp>

### **Coding Changes Are Proposed by CMS Council of Technology**

Wednesday, CMS announced some of the first actions of the new Council of Technology and Innovation (CTI). The CTI is intended to coordinate the activities of coverage, coding and payment processes. It was established per section 942 of the Medicare Modernization Act (MMA).

Some of the changes to the coding process referenced in CMS' press release include:

- Expansion of the public meetings to include all public requests for HCPCS products, supplies and services.
- Implementation of an appeals process in the 2007 coding cycle, that would allow denied applicants to appeal the decision and be afforded the opportunity to have their application reconsidered during the same coding cycle.
- Publication of all preliminary decisions on its website prior to public meetings, to facilitate effective public discussion and comment.
- Revision of the Healthcare Common Procedure Coding System (HCPCS) code application form to make it easier to use.

- Reduction in marketing the marketing requirement for durable medical equipment will be reduced from 6 months to 3.

To accommodate the improvements and pending new changes in the HCPCS coding system, the revised coding process will be phased in over the next 18 months, beginning with the 2006 coding cycle. The first change in the process is an earlier application deadline of January 3, 2005.

CMS plans to hold a special revising HCPCS Coding Process open door forum on Wednesday, October 27th from 2 to 4 p.m.

## **FDA Issues Draft Guidance on Quality Approach to Pharmaceuticals**

Earlier this week, FDA published a notice in the *Federal Register* announcing availability of its "Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations." The draft guidance is intended to encourage the use of modern quality management system principles by the regulated industry and foster innovation as well as continuous improvements in pharmaceutical management.

The AAHomecare Medical Gases Committee will be seeking an extension to this comment period and plans to submit comments to this proposed draft guidance. Comments on this draft guidance are due December 3, 2004 to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

For the *Federal Register* notice, see:  
<http://a257.g.akamaitech.net/7/257/2422/06jun20041800/edocket.access.gpo.gov/2004/pdf/04-22206.pdf>