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February 15, 2011

Ms. Sally A. Howard
General Counsel (Acting)
US Department of Health and Human Services
Room 713-F
200 Independence Avenue, S.W
Washington, DC 20201

**Re: Retrospective Review of DME Competitive Bidding Under Executive Order 13563:
A Test of HHS' Compliance with the President's Regulatory Strategy**

Dear Ms. Howard:

The centerpiece of President Obama's new regulatory strategy is Executive Order 13563, Improving Regulation and Regulatory Review. A central element of the Order is retrospective review of existing regulations. OIRA Administrator Sunstein explained in a Memorandum to head of agencies that "Section 6 of Executive Order 13563 emphasizes the importance of retrospective analysis of rules and contains a 'look back' requirement" that directs agencies to develop and submit to OIRA, "[w]ithin 120 days...a preliminary plan...under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified, expanded, streamlined, or repealed...."

The Retrospective Review Plan developed by HHS needs to provide highest priority to conducting a retrospective review of CMS' Durable Medical Equipment (DME) Competitive Bidding regulations because they are poorly designed, contradicting the President's regulatory goals by needlessly sacrificing thousands of small businesses and tens of thousands of jobs.

It is important to note that the problems with CMS' competitive bidding program are specific to the implementing regulations, not to the statutory mandate requiring competitive bidding.

The Rule Destroys Jobs

Protecting jobs is the focal point of the President's new regulatory strategy. In his Wall Street Journal Op-Ed, President Obama stated that "today I am directing federal agencies to do more to account for—and reduce—the burdens regulations may place on small businesses. Small firms drive growth and create most new jobs in this country. We need to make sure nothing stands in their way." CMS competitive bidding rule stands squarely in the way of saving tens of thousands of small business and their jobs.

The home medical equipment supply industry, until now, has been composed primarily of diverse small companies across the country although there are also some larger companies providing high quality DME services and equipment. In 2007, CMS estimated that there were over 100,000 DME suppliers. The agency also estimated that approximately “85 percent” of DME suppliers “are considered small businesses according to the Small Business Administration.” Many of the companies and associated jobs will be destroyed by the consolidation forced by CMS’ competitive bidding program.

By CMS’ own admission, “this final rule will have a significant impact on a substantial number of small suppliers.” One industry estimate attempting to quantify that significant impact is that the CMS regulations will cost over 80,000 jobs.¹ Irrespective of the specific number of job losses, it is clear that tens of thousands of jobs are at stake and depending on HHS action to reform the competitive bidding program. CMS competitive bidding regulatory program as currently constituted is antithetical to the President’s regulatory and economic agenda.

The Rule Creates Needless Burdens

The first section of the Order requires that agencies tailor “regulations to impose the least burden on society, consistent with obtaining regulatory objectives....” CMS’ home medical equipment competitive bidding program, however, uses a competitive bidding regulatory scheme that imposes needless burdens on Medicare beneficiaries and on companies that have a proven track record of reliably, efficiently and honestly meeting beneficiary needs. For example, at least some beneficiaries will not only need to change their home medical equipment provider but also will need to change from a single provider to multiple providers, a needless burden on beneficiaries and family members with caregiving responsibilities.

The Rule Strips Medicare Beneficiaries of Freedom of Choice

Section 4 of the Executive Order calls on agencies to “identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public.” The rule terminates Medicare beneficiaries’ ability to choose the licensed, qualified, Medicare-approved equipment provider of their choice – even if the company is willing to meet the competitively determined price.

Maintaining, adjusting and otherwise servicing home medical equipment requires that the care company representative enter the home of the beneficiary and take care of some of their personal and even intimate medical needs involving oxygen tanks, enteral feeding, catheters, and other medical equipment and supplies. CMS’ regulatory decision to require that many beneficiaries find new people to take care of their DME needs takes away their freedom of choice. Moreover, forcing beneficiaries to find and trust new care providers can strip them of their dignity.

The DME Competitive Bidding Rule Violates Accepted Auction Principles

Competitive bidding is an extensively analyzed academic discipline. When agencies have had questions and concerns regarding current or planned auctions, they have sought expert advice from scientists and

¹ <http://homecaremag.com/topics/competitive-bidding/hme-job-loss-prediction-20100302/index.html>

other academicians. For example, the Federal Communications Commission held a series of conferences on combinatorial auctions in conjunction with the National Science Foundation and other outside experts.²

CMS, by contrast, has refused outside advice on how to improve their competitive bidding system.

The Executive Order includes a section requiring that agencies “ensure the objectivity of any scientific and technological information and processes used to support the agency’s regulatory actions.” [Emphasis added.] CMS’ regulatory implementation of competitive bidding has been reviewed, and harshly criticized, by auction experts. Over 160 academicians, including two Nobel laureates, signed a letter detailing crucial failings in the way in which CMS implemented the competitive bidding mandate.³

The letter noted that signatories “believe that competitive bidding can be an effective method of controlling Medicare costs without sacrificing quality” but went on to note that CMS’ “current auction program has flaws that need to be fixed before it can achieve the objectives of low cost and high quality.” The letter warned that “Implementation of the current design will result in a failed government program.”

The auction experts concluded that there “is no need for a bad outcome. With state-of-the-art auction methods and careful implementation, the auction program can succeed in reducing costs while maintaining quality—a win-win for both taxpayers and Medicare beneficiaries.” The retrospective regulatory review provisions of President Obama’s Executive Order provide HHS the opportunity – and the duty – to revisit the DME competitive bidding program, to correct mistakes and to make this regulatory program work for Medicare beneficiaries and taxpayers.

Accordingly, I call on you in your role as General Counsel of the Department of Health and Human Services to ensure that retrospective review plan delivered to OIRA provides the highest level of priority to reviewing and fixing the DME competitive bidding program. As a former OMB official who was responsible for reviewing all federal regulatory programs, I understand both the challenges of overseeing this type of review and the ability of committed civil servants to accomplish it. For more information about my background, please see http://www.thecre.com/emerging/Jim_Tozzi_Bio.html.

CRE will be reporting on HHS’ implementation of the President’s Executive Order on our Competitive Bidding Interactive Public Docket, <http://www.thecre.com/blog/>.

Sincerely,

/s/

Jim Tozzi, Ph.D.
Member, Board of Advisors

cc: The Honorable Cass R. Sunstein, Administrator, Office of Information and Regulatory Affairs

² See, for example, http://wireless.fcc.gov/auctions/default.htm?job=conference_summary&y=2003.

³ <http://thecre.com/pdf/comments-of-concerned-auction-experts-on-medicare-bidding.pdf>.