



## **ISSUE BRIEF**

### **Competitive Bidding**

#### **Legislative Background**

A demonstration of competitive bidding was first called for by Congress in the Balanced Budget Act of 1997 (BBA) and again in the “Medicare Prescription Drug, Improvement, and Modernization Act of 2003” (MMA). The MMA limited the demonstration to those clinical laboratory tests furnished without a face-to-face encounter between the Medicare beneficiary and the hospital personnel or physician performing the test. Two demonstration sites will be used to conduct this study.

Even though the demonstration projects have not started, the President's FY 09 HHS budget calls for: (1) a "national" competitive bidding program for clinical laboratory services in the 2009-2014 time period; and, (2) projected a savings of \$2.5 billion over ten years.

#### **Status of the Demonstration**

CMS and its contractor, the Research Triangle Institute (RTI) announced the first competitive bidding area, the San Diego-Carlsbad-San Marcos Metropolitan Statistical Area (MSA). Despite promises made by Centers for Medicare and Medicaid Services to the clinical laboratory industry to hold an Open Door Forum in the area before the bidders' conference, CMS just held the bidders' conference. Many of the questions that the Clinical Laboratory Coalition has repeatedly asked about the process were asked by the potential bidders and CMS could not answer all of the questions.

We do know that entities falling within the following categories must bid or would not be allowed to participate for the bid period: (1) independent clinical laboratories, (2) hospitals providing outreach services for nonpatients that receive more than \$100,000 annually in revenues from Medicare, (3) physician office laboratories generating more than \$100,000 annually in revenues from Medicare, and, (4) all other providers of clinical laboratory services that generate more than \$100,000 annually in revenues from Medicare where those services are provided as the result of a "face to face" encounter. This \$100,000 threshold is capturing laboratories that qualify as small businesses. Their test menus are small and specialized for certain segments of health care such as oncology and they will not be able to bid effectively on the 303 tests CMS is requiring.

#### **ASCLS, ASCP and CLMA Position:**

ASCLS, ASCP and CLMA oppose competitive bidding for procuring clinical laboratory services for the following reasons:

1. It is anti-competitive. The clinical laboratory is already highly competitive given the diversity of independent clinical laboratories, hospitals and physician office laboratory options available to

patients and physicians in most metropolitan areas. However, the effect of competitive bidding will be to reduce the number of clinical laboratory service providers in a community, by virtue of CMS allocating market share to the bid winners, which will enable the bid "winners" to subsequently hold a dominant position in the market following the demonstration.

2. It will restrict physician choice. Physicians select their preferred clinical laboratory for many reasons, including patient convenience, the quality of the service they receive, the accuracy and timeliness of the results. During the demonstration they may not longer be able to use the clinical laboratory of their choice if that laboratory service provider is not a "bid winner" under the demonstration.
3. It will impact patient care. Patients may have to travel considerable distances at great inconvenience in order to use the bid winning clinical laboratory. This may result in patients not receiving those services due to the hassle of using the bid winning laboratory. Further, there is great concern that the bid winning laboratory will seek to reduce the frequency of pick-ups or test turnaround times in hard to serve geographical areas or at sites where a high level of service is needed but the cost to provide that service is very high, such as skilled nursing facilities.

ASCLS, ASCP and CLMA are particularly concerned that The President's FY 2009 Budget proposes implementation of competitive bidding before the demonstration has even been conducted. Further, the FY 2009 Budget assumes budgetary savings from the implementation of competitive bidding before CMS can assess the demonstration to determine if savings are, in fact, realized or before it can be determined whether there are significant impacts to patients or providers that may result in greater overall costs to the Medicare program.

We urge Congress to repeal the demonstration project and to stop the implementation the demonstration. The first demonstration is scheduled to start on July 1, 2009. We urge you to join your colleagues in the House and the Senate and co-sponsor H.R.3453 or S.2099 as appropriate.