



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"). The BBA directed the Health Care Financing Administration (now the Centers for Medicare and Medicaid Services ("CMS")) to implement up to five demonstrations of competitive bidding, including one for clinical laboratory services. The "Medicare Prescription Drug, Improvement, and Modernization Act of 2003" ("MMA") directed the Secretary of the Department of Health and Human Services ("HHS") to conduct the demonstration program called for in the BBA. Further, 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. An initial report to Congress from HHS on the demonstration was due no later than December 31, 2005, but this report has not yet been prepared.

The President's FY 07 HHS budget calls for: (1) a "national" competitive bidding program for clinical laboratory services in the 2008-2011 time period; and, (2) a five percent decrease in the reimbursement of clinical laboratory services in that period - a cut of \$1.5 billion over five years.

Status of the Demonstration

CMS has named Research Triangle Institute ("RTI") as its research contractor for the demonstration and announced its selections for the Technical Expert Panel ("TEP"), which will provide recommendations to CMS and RTI on technical, operational, and laboratory performance issues. The TEP met more than once in 2005. CMS and representatives of RTI and the TEP conducted an Open Door Forum in August 24, 2005, to update the clinical laboratory industry on the status of the demonstration and their proposed framework for the implementation of the demonstration.

Despite promises made by Centers for Medicare and Medicaid Services ("CMS") Mark McClellan to the clinical laboratory industry, there have been no further Open Door Forums or other communication regarding the metropolitan statistical areas selected, the tests to be included within the demonstration, the steps taken to assure patient access to services, the measures for maintaining the quality of services provided, and the bid package. 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.

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 2007 Budget proposes implementation of competitive bidding before the demonstration has even been conducted. Further, the FY 2007 Budget assumes budgetary savings from the implementation of competitive bidding before CMS has received a single bid and the demonstration can be assessed 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 oppose the demonstration project and any attempt to implement the demonstration. It is also premature to fully implement competitive bidding until the impact of the demonstration project, if it goes forward, can be fully analyzed.