Competitive Bidding

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One of the provisions of the Medicare Modernization Act of 2004 (MMA) was a Congressional mandate for the Center for Medicare and Medicaid Services (CMS) to conduct a competitive bidding project for clinical laboratory services. Many may remember that this is a project which has been proposed several times over recent years, but no demonstration has been conducted for the laboratory. (A demonstration was conducted for durable medical equipment – DME.) It has been our impression in past years that CMS was somewhat reluctant to hold the laboratory demonstration.

ASCLS has vigorously opposed the concept of competitive bidding for laboratory services, holding that laboratory tests are services, not commodities. Quality and access are important features of laboratory testing and as important, or more important, than price. ASCLS members have carried this message to Capitol Hill during many years of Legislative Symposium visits.

To comply with the MMA legislation, CMS has appointed a director of the project and hired a contractor, Research Triangle Institute, to plan and conduct the bidding process. An initial report was due to Congress by December 31, 2005. CMS held an Open Door Forum in August to unveil the conditions for the bidding and listen to questions and feedback from the laboratory community.

The purpose of the demonstration is twofold:

- To determine whether competitive bidding can be used to provide Part B clinical laboratory services at fees below current Medicare reimbursement rates while simultaneously maintaining quality and access to care

- To gain valuable information on the relative costs of laboratory tests

It now appears that the competitive bidding demonstration will begin during 2006, with bids being sought in two metropolitan statistical areas (MSAs) to be selected from a list of 22 MSAs that meet the criteria in terms of population, number of Medicare beneficiaries, and percentage of Medicare beneficiaries participating in a managed care plan. The two demonstration sites will be in different states. Speculation is that one will be in the Midwest and one in the South or Southwest. The demonstration will last for three years, during which measures of quality and access will be monitored.

The project will include all laboratories in the selected MSA that bill more than $100,000 worth of laboratory tests annually to Medicare. These laboratories will be required to bid or will lose the opportunity to do laboratory work for Medicare beneficiaries. The bidders will be required to bid on **all tests** on the Medicare clinical laboratory fee schedule (except for Pap smears and colorectal screening tests, which are excluded by the law). Laboratories must bid on all tests found in the CPT manual, even if they do not perform all of the tests in-house. They must contract with a reference laboratory to perform any tests not performed in-house. Medicare states that 97% of allowed charges are accounted for by the top 200 tests. However, including just those tests in the project might lead to splitting samples between laboratories, with potential for error and sample loss. In the design, winning bidders will be paid for any Medicare test; losers will be paid for no Medicare tests.

The testing to be covered includes tests billed by independent laboratories or furnished by a hospital laboratory to hospital non-patients (otherwise known as outreach patients). There has been much confusion over the definition of a non-patient, and the proposed design of the project includes the term "face to face encounter", which to most laboratorians would include specimen collection. However, CMS says that remote collection stations will not be considered to qualify as a face to face encounter.

Once bids have been submitted, CMS reserves the right to conduct follow-up negotiations or a second round of bidding.

There are complex formulas that will be used to determine winners. For each bidder, bid prices for individual tests will be weighted (based on expected test volume) and summed to derive a single composite bid. The composite bids will be arrayed from lowest to highest and a "pivotal" composite bid will be determined, using bid amounts and other criteria. Bidders with composite bids less than the pivotal bid will be

winners, and those with bids greater than the pivotal bid are losers. All winning laboratories will be paid the same price for each test. Medicare will reject bids if they do not meet a maximum acceptable amount, which will presumably be lower than the current fee schedule would have paid.

Passive laboratories are those not required to bid because they do a small volume of Medicare business (under $100,000 per year). They will have the option of continuing to do Medicare work at the winning bid price.

Although CMS says that laboratory quality will be part of the selection criteria, the criteria so far seem to include more service-related than quality-related measures:

- Six measures of turnaround time:
  - Total turnaround time
  - Transport turnaround time
  - Processing turnaround time
  - Total turnaround time for stat tests
  - Reporting time for critical values
  - Reporting turnaround time for public health disease notification
- Proficiency testing data monitored through the Clinical Laboratory Improvement Amendments (CLIA)
- Results of survey inspections
- Log-in error rates
- Number of specimens unusable or lost
- Physician satisfaction with quality

The success of the project will be evaluated by:

- Overall tests per beneficiary
- Tests per beneficiary by winning laboratories
- Overall tests per beneficiary with diabetes
- Overall tests per beneficiary with chronic heart failure
- Overall tests per beneficiary with coronary artery disease (CAD)
- Physician satisfaction regarding access
- Compliance with clinical guidelines, including:
  - Percentage of diabetics with one LDL cholesterol test per year
  - Percentage of diabetics with one Hemoglobin A1C test per year
  - Percent of CAD patients with one lipid profile test per year

ASCLS continues to gather comments about member concerns about the bidding process and its potential effect on laboratories in the demonstration MSAs. It is very possible that losing hospital outreach programs might close. We also have concerns about how this process, if deemed successful, would be extended to nationwide implementation, and the impact of this on smaller rural laboratories. Or, if the demonstration is deemed unsuccessful, it is unlikely that laboratories or outreach programs that closed during the three year demonstration period would be able to reopen.

One of the most troublesome areas of reimbursement has been the lack of a timely and fair process for making tests that use new technology available and paying for them at an appropriate rate. The competitive bidding process does not address this issue.

It will be difficult for laboratories that must bid to determine what price they can afford to bid, since price per test is affected by volume of testing. Since no one knows how many winning laboratories there will be, test volume cannot be guaranteed, making the process even more of a gamble for the bidding laboratories.

At this writing, we are waiting for the announcement of which MSAs will be chosen for the project. The ASCLS Government Affairs Committee and individual ASCLS members continue to monitor and comment on this process.