Report to Congress—Initial Report on the Medicare Clinical Laboratory Competitive Bidding Demonstration

This design report summarizes the recommended plan for the Medicare Clinical Laboratory Competitive Bidding Demonstration developed by Research Triangle Institute, International (RTI) for the Centers for Medicare & Medicaid Services (CMS). The purpose of the demonstration is to determine whether competitive bidding can be used to provide quality laboratory services at prices below current Medicare reimbursement rates.

Background

Section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires the Secretary of Health and Human Services to conduct a demonstration project on the application of competitive acquisition for payment of clinical laboratory services that would otherwise be made under Medicare Part B fee schedule. Under this statute, pap smears and colorectal cancer screening tests are excluded from this demonstration. Requirements under the Clinical Laboratory Improvement Amendments (CLIA) as mandated in section 353 of the Public Health Service Act are applicable. The aggregate amounts to be paid to contractors in a competitive acquisition area are expected to be less than the aggregate amounts that would otherwise be paid under the laboratory fee schedule. The payment basis determined for each competitive acquisition area will be substituted for payment under the existing clinical laboratory fee schedule. The contracts are to be re-competed every three years, and multiple winners are expected in each competitive acquisition area.

The proposed design was reviewed by a Technical Expert Panel established by RTI and shared with the public at a CMS Open Door Forum Special Listening Session. The design recommendations address the structure of the demonstration, selection criteria for the demonstration sites, bidding process, selecting winners, reimbursement, quality, and access.

Structure of the Demonstration

The recommended structure of the demonstration uses Metropolitan Statistical Areas (MSAs) to define demonstration sites. The demonstration will set competitively bid fees in the demonstration areas for all tests paid under the Medicare Part B clinical laboratory fee schedule, with the exception of pap smears, colorectal cancer screening tests, and new tests added to the Medicare Part B clinical laboratory fee schedule during the course of the demonstration.

The demonstration will cover demonstration tests for all Medicare Part B beneficiaries who live in the demonstration sites. Hospital inpatient testing is covered by Medicare Part A and therefore exempt from the demonstration. Physician office laboratory testing and hospital outpatient testing are not included in the demonstration, except where the physician office or hospital laboratory functions as an independent laboratory performing testing for a beneficiary who is not a patient of the physician or hospital outpatient department.

There will be ongoing monitoring of the demonstration sites, and the demonstration will last three years. Early data from the demonstration may be used to assess the feasibility of expanding competitive acquisition areas and to estimate the range of achievable savings from competitive bidding. There will be two demonstration sites, and the demonstration will have a staggered start.

Selection of Demonstration Sites

The fundamental criteria for the proposed demonstration sites allow for potential Medicare program savings from the demonstration, are administratively feasible, are representative of the laboratory market, and will yield demonstration results that can be generalized to other MSAs. RTI recommends selecting an MSA that is located within a single State because MSAs that cross state boundaries increase administrative costs when two carriers and two fiscal intermediaries are responsible for administering claims for the MSAs. Although higher population raises potential savings, it also increases administrative complexity and potential disruption. Therefore, RTI recommends an MSA that has a moderately large Medicare population. An MSA that has neither very low nor very high Medicare-managed care penetration (defined as greater than five percent but less than 50 percent penetration) also is recommended to enhance the representativeness and generalizability of the demonstration.

Bidding

Independent, hospital and/or physician office laboratories with $100,000 or more in annual Medicare Part B (fee-for-service) payment for nonpatient services will be required to participate in the demonstration. Small laboratories, which will be defined as independent laboratories, hospital and/or physician office laboratories with less than $100,000 in annual Medicare Part B (fee-for-service) payment for nonpatient services will not be required to bid. Demonstration test annual payments will be based on the most recent 12-month period prior to demonstration for which data is available.

Bidding laboratories will not be required to bid to provide coverage to the entire demonstration site; but, they will be required to provide information on their capacity and geographic service area. This information will be used during the winner selection process to ensure that the demonstration does not adversely affect beneficiary access to laboratory services. Bidding behavior will be subject to anti-trust laws and regulations prohibiting collusion or anti-competitive behavior (under the jurisdiction of the Federal Trade Commission and the Department of Justice).

After release of the Bid Solicitation Package and prior to bidding, a "Bidders Conference" will be held for potential bidders to learn about the rules and ask questions about the bidding process. There will be a single bidding competition covering all demonstration tests. Bidders will be required to submit a bid price for each Health Care Procedure Coding System code in the demonstration test menu. Bidding laboratories will be asked to identify demonstration tests that they do not perform, and will be asked to explain their plans for responding to requests for demonstration tests that they do not perform in house (e.g., subcontracting and referrals). As

part of their bid, laboratories will provide information on ownership, location of affiliated laboratories and drawing stations, CLIA certification, laboratory finances, and quality.

Selecting Winners

Key recommendations for the winner selection process include selecting multiple winners. A laboratory's bids for individual tests will be weighted and summed to form a single composite bid. Weights for each demonstration test will be based on the test's share of total expected demonstration volume. The composite bids will be arrayed from lowest to highest, and the array will be used in conjunction with other criteria to determine the "pivotal" composite bid that will determine the winners. Bidders with composite bids less than or equal to the pivotal composite bid will be winners. Bidders with composite bids greater than the pivotal composite bid will be losers.

Multidimensional selection criteria will be used to determine the winners, including: composite bid prices; capacity; geographic coverage; quality; number of winners; distribution of composite bids; and gaming behavior. A maximum acceptable composite bid, or "reservation bid," will be set. The reservation bid will be slightly less than the composite bid that would be obtained using the Medicare Part B clinical laboratory fee schedule. Laboratories whose composite bids exceed the reservation bid will automatically be determined losers.

Reimbursement

Recommendations for the reimbursement rules include a new fee schedule for individual demonstration tests, which will be set after the pivotal bid is selected and winning laboratories are determined. After considering quality, capacity, geographic coverage, and other non-price criteria, winner laboratories will be selected that can offer the full menu of demonstration tests at lower total costs than under the existing clinical laboratory fee schedule. While the recommendations for the demonstration project differ somewhat from CMS programs for Part B Drugs and Biologicals, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, they are consistent with CMS's approach to competitive acquisition, which uses a bidding process that encourages cost savings and seeks opportunities for sharing those savings with beneficiaries. However, as there is no coinsurance for laboratory services, all winning laboratories will be paid the same price for each test under the demonstration.

For nonpatient testing, small laboratories will receive payment for demonstration tests under the demonstration fee schedule (not to exceed $100,000 in annual Medicare Part B payment for nonpatient services). The existing Medicare Part B clinical laboratory fee schedule will continue to apply to non-demonstration tests. Payment for non-demonstration tests will be unaffected by a laboratory's status as a winner or loser in the demonstration.

Quality

Key recommendations on quality of care can be divided into (1) protective demonstration design elements, and (2) monitoring.

The demonstration will rely on the existing system of CLIA regulations already in place. The existing quality requirements provided under CLIA are intended to ensure the quality of laboratory testing, and all clinical laboratories must be properly certified to receive Medicare or Medicaid payments. CLIA specifies quality standards for proficiency testing (PT), patient test management, quality control, personnel qualifications and quality assurance for laboratories. Under the demonstration, additional measures such as turn-around-time are intended to supplement what is not monitored by existing CLIA requirements.

In addition to the CLIA requirements that apply to virtually all clinical laboratories, laboratories participating in the demonstration will each designate a quality assurance staff member who will serve as a point of contact for CMS, physicians, and beneficiaries. The CMS will maintain a toll-free hotline to receive complaints about the demonstration from beneficiaries, physicians, or laboratories. Multiple laboratories will be determined winners to maintain quality of service competition between laboratories. Each winning laboratory will be required to submit information on service and quality standards that CMS will send to physicians in their communities. Quality is considered in the winner selection process. The choice of multiple winners will help to assure quality since the laboratories will compete with each other on the basis of quality testing and service.

Specific recommendations on quality monitoring include reviewing PT data currently monitored through the CLIA program. Results of CLIA survey inspections will be monitored with the assistance of CMS Regional Offices. Winning laboratories will be required to report data on six different but standardized measures of test turnaround time: (1) total turnaround time; (2) transport turnaround time; (3) processing turnaround time; (4) total turnaround time for "statim" (immediate or "STAT") testing; (5) reporting turnaround time for critical values; and, (6) reporting turnaround time for public health disease notification.

Log-in error rates will be standardized and monitored. Physician satisfaction regarding quality of testing and service will be monitored. The number of specimens found unusable or lost in winning laboratories will be monitored.

Access

Recommendations to ensure beneficiary access to care include protective design elements. Demonstration sites will be selected to ensure sufficient numbers of laboratories exist to provide for both successful competitive bidding and assurance of access for beneficiaries. Multiple winning laboratories will be awarded so that the winners will have sufficient capacity to serve all of the beneficiaries in their site.

Capacity and geographic coverage are considered in the winner selection process. The rates of testing for five different types of laboratory tests per beneficiary will be monitored in each demonstration site. Physician satisfaction regarding access will be monitored.