

Summary

Section 302(b) of the Act amends section 1847(e) (42 U.S.C. 1395w-3) --“Competitive Acquisition of Certain Items and Services,” to include a demonstration project for clinical laboratory services. The demonstration must apply competitive acquisition for payment for clinical laboratory services, which would otherwise be made under Medicare Part B fee schedule. Under this statute, pap smears and colorectal 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 statute does not specify an implementation date. An initial report to Congress is due not later than December 31, 2005. Progress reports and final reports are required. The total amounts to be paid to contractors in a competitive acquisition area are expected to be less than the total amounts that would otherwise be paid. The payment basis determined for each competitive acquisition area will be substituted for the payment basis. Contracts are to be re-competed every 3 years, and multiple winners are expected in each competitive acquisition area. The statute does not specify the number or location of demonstration sites.

Current Status

CMS awarded a task order contract to RTI International (and their subcontractor Palmetto GBA, LLC) on September 30, 2004. John Kautter, Ph.D. is the Project Director. CMS awarded a task order contract to RTI International (and their subcontractor Palmetto GBA, LLC) on September 30, 2004. John Kautter, Ph.D. is the Project Director. The purposes of this task order are to assist CMS in the design (Phase I: demonstration design, develop solicitation and bid process, claims processing plan, management), and operation (Phase II: operate bid sites of the demonstration).

There will be a Special **Open Door Forum public meeting** (See Related Links Inside CMS area below for more information) on Wednesday, August 24, 2005 from 1:00 pm to 3:00 pm (ET) At this Special Open Door Forum Listening Session (full announcement) (See Related Links Inside CMS area below for more information) , the CMS research contractor, RTI will present a summary of the draft demonstration design for the Medicare Clinical Laboratory Competitive Bidding Demonstration project. CMS is interested in holding this session to gather your input related to this demonstration project milestone. The handout for the RTI presentation regarding the draft of the demonstration is available. (See downloads area below for more information: Handout).

There is also an ongoing dedicated email box that provides a way to the public for ongoing and direct communication with CMS regarding this demonstration project. (See downloads area below for more information: Contact Information).

Technical Expert Panel

The Technical Expert Panel (TEP) was established and is managed by our research contractor (Research Triangle International, Inc.) The TEP provides assistance to RTI on technical, operational, and laboratory performance issues for this project. The public may

submit comments through the dedicated email box (See downloads area below for more information: Contact Information).

TEP members were asked to participate based on their personal expertise, and are drawn from the stakeholder community. Areas of expertise include laboratory medicine, advocacy for Medicare beneficiaries, quality of care, independent regional clinical laboratories, hospital based laboratory services, purchasers of clinical laboratory services, and laboratory management and administration. The TEP will operate during the design and startup of the operational phase. (See downloads area below for more information: Technical Expert Panel).

Submission of written materials pertaining to this demonstration

Anyone wishing to share information should send written materials to Linda Lebovic, the project officer for the demonstration