

Section 302(b) of the “Medicare Prescription Drug, Improvement and Modernization Act of 2003” under “Competitive Acquisition of Certain Items and Services” includes a demonstration project for Part B clinical laboratory services

Statutory Language

“(e) DEMONSTRATION PROJECT FOR CLINICAL LABORATORY SERVICES.—

“(1) IN GENERAL.—The Secretary shall conduct a demonstration project on the application of competitive acquisition under this section to clinical diagnostic laboratory tests—

“(A) for which payment would otherwise be made under section 1833(h) (other than for pap smear laboratory tests under paragraph (7) of such section) or section 1834(d)(1) (relating to colorectal cancer screening tests); and

“(B) which are furnished by entities that did not have a face-to-face encounter with the individual.

“(2) TERMS AND CONDITIONS.—

“(A) IN GENERAL.—Except as provided in subparagraph (B), such project shall be under the same conditions as are applicable to items and services described in subsection (a)(2), excluding subsection (b)(5)(B) and other conditions as the Secretary determines to be appropriate.

“(B) APPLICATION OF CLIA QUALITY STANDARDS.—The quality standards established by the Secretary under section 353 of the Public Health Service Act for clinical diagnostic laboratory tests shall apply to such tests under the demonstration project under this section in lieu of quality standards described in subsection (b)(2)(A)(i).

“(3) REPORT.—The Secretary shall submit to Congress—

“(A) an initial report on the project not later than December 31, 2005; and

“(B) such progress and final reports on the project after such date as the Secretary determines appropriate.”.

Summary of Legislation Provided by CMS

Section 302(e) of the Act amends section 1847 (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 (section 1833(h) or section 1834(d)). 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 Services 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. A General Accounting Office (GAO) report is due July 1, 2009. The total amounts to be paid to contractors in a 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 site.