

**SEC. 3113 [42 U.S.C. 1395l note]. TREATMENT OF CERTAIN COMPLEX DIAGNOSTIC LABORATORY TESTS.**

**(a) DEMONSTRATION PROJECT.—**

(1) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the “Secretary”) shall conduct a demonstration project under part B title XVIII of the Social Security Act under which separate payments are made under such part for complex diagnostic laboratory tests provided to individuals under such part. Under the demonstration project, the Secretary shall establish appropriate payment rates for such tests.

(2) COVERED COMPLEX DIAGNOSTIC LABORATORY TEST DEFINED.—In this section, the term “complex diagnostic laboratory test” means a diagnostic laboratory test—

(A) that is an analysis of gene protein expression, topographic genotyping, or a cancer chemotherapy sensitivity assay;

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(B) that is determined by the Secretary to be a laboratory test for which there is not an alternative test having equivalent performance characteristics;

(C) which is billed using a Health Care Procedure Coding System (HCPCS) code other than a not otherwise classified code under such Coding System;

(D) which is approved or cleared by the Food and Drug Administration or is covered under title XVIII of the Social Security Act; and

(E) is described in section 1861(s)(3) of the Social Security Act (42 U.S.C. 1395x(s)(3)).

(3) SEPARATE PAYMENT DEFINED.—In this section, the term “separate payment” means direct payment to a laboratory (including a hospital-based or independent laboratory) that performs a complex diagnostic laboratory test with respect to a specimen collected from an individual during a period in which the individual is a patient of a hospital if the test is performed after such period of hospitalization and if separate payment would not otherwise be made under title XVIII of the Social Security Act by reason of sections 1862(a)(14) and 1866(a)(1)(H)(i) of the such Act (42 U.S.C. 1395y(a)(14); 42 U.S.C. 1395cc(a)(1)(H)(i)).

(b) DURATION.—Subject to subsection (c)(2), the Secretary shall conduct the demonstration project under this section for the 2-year period beginning on July 1, 2011.

(c) PAYMENTS AND LIMITATION.—Payments under the demonstration project under this section shall—

(1) be made from the Federal Supplemental Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t); and

(2) may not exceed \$100,000,000.

(d) REPORT.—Not later than 2 years after the completion of the demonstration project under this section, the Secretary shall submit to Congress a report on the project. Such report shall include—

(1) an assessment of the impact of the demonstration project on access to care, quality of care, health outcomes, and expenditures under title XVIII of the Social Security Act (including any savings under such title); and

(2) such recommendations as the Secretary determines appropriate.

(e) IMPLEMENTATION FUNDING.—For purposes of administering this section (including preparing and submitting the report under subsection (d)), the Secretary shall provide for the transfer, from the Federal Supplemental Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t), to the Centers for Medicare & Medicaid Services Program Management Account, of \$5,000,000. Amounts transferred under the preceding sentence shall remain available until expended.