

111TH CONGRESS
1ST SESSION

S. 1220

To require that certain complex diagnostic laboratory tests performed by an independent laboratory after a hospital outpatient encounter or inpatient stay during which the specimen involved was collected shall be treated as services for which payment may be made directly to the laboratory under part B of title XVIII of the Social Security Act.

IN THE SENATE OF THE UNITED STATES

JUNE 9, 2009

Mr. SPECTER (for himself and Mr. WYDEN) introduced the following bill;
which was read twice and referred to the Committee on Finance

A BILL

To require that certain complex diagnostic laboratory tests performed by an independent laboratory after a hospital outpatient encounter or inpatient stay during which the specimen involved was collected shall be treated as services for which payment may be made directly to the laboratory under part B of title XVIII of the Social Security Act.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Patient Access to Crit-
5 ical Lab Tests Act”.

1 **SEC. 2. FINDINGS; SENSE OF CONGRESS.**

2 (a) FINDINGS.—The Congress finds as follows:

3 (1) Timely access to laboratory testing is essen-
4 tial to ensure quality of care for patients.

5 (2) Genetic and molecular laboratory testing
6 are the new cornerstones of high-quality, cost-effec-
7 tive preventive medicine.

8 (3) The completion of the Human Genome
9 Project in 2003 paved the way for a more sophisti-
10 cated understanding of disease causation, which has
11 contributed to the advent of “personalized medi-
12 cine”.

13 (4) Personalized medicine is the application of
14 genomic and molecular data to better target the de-
15 livery of health care, facilitate the discovery and clin-
16 ical testing of new products, and help determine a
17 patient’s predisposition to a particular disease or
18 condition.

19 (5) Personalized medicine offers the promise of
20 smarter, more effective, and safer care as physicians
21 and patients become equipped with better informa-
22 tion to guide treatment decisions.

23 (6) Some of the most encouraging personalized
24 medicine developments involve highly specialized lab-
25 oratory tests that, using biomarkers and vast stores
26 of historical data, provide individualized information

1 that enable physicians and patients to develop per-
2 sonalized treatment plans.

3 (7) Several outdated Medicare regulations for
4 laboratory billing are obstructing access to highly
5 specialized laboratory tests and delaying patients' di-
6 agnoses and treatments. These same rules are dis-
7 couraging investments in development of new tests.

8 (8) Realizing the promise of personalized medi-
9 cine will require improved regulation that appro-
10 priately encourages development of and access to
11 these specialized tests.

12 (b) SENSE OF CONGRESS.—It is the sense of Con-
13 gress that—

14 (1) where practical, Medicare regulations and
15 policies should be written to promote development of
16 and access to the highly specialized laboratory tests
17 referred to in subsection (a)(6); and

18 (2) the Medicare regulation described in section
19 414.510 of title 42, Code of Federal Regulations, is
20 one such regulation that should be revised to permit
21 laboratories furnishing certain specialized tests to
22 bill for and be paid directly by Medicare for fur-
23 nishing such tests.

1 **SEC. 3. TREATMENT OF CERTAIN COMPLEX DIAGNOSTIC**
2 **LABORATORY TESTS.**

3 (a) IN GENERAL.—Notwithstanding sections
4 1862(a)(14) and 1866(a)(1)(H)(i) of the Social Security
5 Act (42 U.S.C. 1395y(a)(14) and 1395cc(a)(1)(H)(i)), in
6 the case that a laboratory performs a covered complex di-
7 agnostic laboratory test, with respect to a specimen col-
8 lected from an individual during a period in which the in-
9 dividual is a patient of a hospital, if the test is performed
10 after such period the Secretary of Health and Human
11 Services shall treat such test, for purposes of providing
12 direct payment to the laboratory under section 1833(h)
13 or 1848 of such Act (42 U.S.C. 1395l(h) or 1395w-4),
14 as if such specimen had been collected directly by the lab-
15 oratory.

16 (b) COVERED COMPLEX DIAGNOSTIC LABORATORY
17 TEST DEFINED.—For purposes of this section, the term
18 “covered complex diagnostic laboratory test” means an
19 analysis—

20 (1) of DNA, RNA, chromosomes, proteins, or
21 metabolites that detects, identifies, or quantitates
22 genotypes, mutations, chromosomal changes, bio-
23 chemical changes, cell response, protein expression,
24 or gene expression or similar method or is a cancer
25 chemotherapy sensitivity assay or similar method,

1 but does not include methods principally comprising
2 routine chemistry or routine immunology;

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

5 (3) that is developed and performed by a lab-
6 oratory which is independent of the hospital in which
7 the specimen involved was collected and not under
8 any arrangements (as defined in section 1861(w)(1)
9 of such Act (42 U.S.C. 1395x(w)(1))); and

10 (4) that is not furnished by the hospital where
11 the specimen was collected to a patient of such hos-
12 pital, directly or under arrangements (as defined in
13 section 1861(w)(1) of such Act (42 U.S.C.
14 1395x(w)(1))) made by such hospital.

15 **SEC. 4. EFFECTIVE DATE.**

16 The provisions of section 3 shall apply to tests fur-
17 nished on or after the date of the enactment of this Act.

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