

107TH CONGRESS  
1ST SESSION

# S. 1066

To amend title XVIII of the Social Security Act to establish procedures for determining payment amounts for new clinical diagnostic laboratory tests for which payment is made under the medicare program.

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IN THE SENATE OF THE UNITED STATES

JUNE 20, 2001

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

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## A BILL

To amend title XVIII of the Social Security Act to establish procedures for determining payment amounts for new clinical diagnostic laboratory tests for which payment is made under the medicare program.

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 “Medicare Patient Ac-  
5       cess to Preventive and Diagnostic Tests Act”.

1 **SEC. 2. CODING AND PAYMENT PROCEDURES FOR NEW**  
2 **CLINICAL DIAGNOSTIC LABORATORY TESTS**  
3 **UNDER MEDICARE.**

4 (a) DETERMINING PAYMENT BASIS FOR NEW LAB  
5 TESTS.—Section 1833(h) of the Social Security Act (42  
6 U.S.C. 1395l(h)) is amended by adding at the end the fol-  
7 lowing new paragraph:

8 “(9)(A) The Secretary shall establish procedures for  
9 determining the basis for, and amount of, payment under  
10 this subsection for any clinical diagnostic laboratory test  
11 with respect to which a new or substantially revised  
12 HCPCS code is assigned on or after January 1, 2002 (in  
13 this subsection referred to as ‘new tests’). Such procedures  
14 shall provide that—

15 “(i) the payment amount for such a test will be  
16 established only on—

17 “(I) the basis described in paragraph  
18 (10)(A); or

19 “(II) the basis described in paragraph  
20 (10)(B); and

21 “(ii) the Secretary shall determine whether the  
22 payment amount for such a test is established on the  
23 basis described in paragraph (10)(A) or the basis  
24 described in paragraph (10)(B) only after the proc-  
25 ess described in subparagraph (B) has been com-  
26 pleted with respect to such test.

1 “(B) Determinations under subparagraph (A)(ii)  
2 shall be made only after the Secretary—

3 “(i) makes available to the public (through an  
4 Internet site and other appropriate mechanisms) a  
5 list that includes any such test for which the estab-  
6 lishment of a payment amount under paragraph  
7 (10) is being considered for a year;

8 “(ii) on the same day such list is made avail-  
9 able, causes to have published in the Federal Reg-  
10 ister notice of a meeting to receive comments and  
11 recommendations from the public on the appropriate  
12 basis under paragraph (10) for establishing payment  
13 amounts for the tests on such list;

14 “(iii) not less than 30 calendar days after publi-  
15 cation of such notice, convenes a meeting to receive  
16 such comments and recommendations, with such  
17 meeting—

18 “(I) including representatives of each enti-  
19 ty within the Health Care Financing Adminis-  
20 tration (in this paragraph referred to as  
21 ‘HCFA’) that will be involved in determining  
22 the basis on which payment amounts will be es-  
23 tablished for such tests under paragraph (10)  
24 and implementing such determinations;

1           “(II) encouraging the participation of in-  
2           terested parties, including beneficiaries, device  
3           manufacturers, clinical laboratories, laboratory  
4           professionals, pathologists, and prescribing phy-  
5           sicians, through outreach activities; and

6           “(III) affording opportunities for inter-  
7           active dialogue between representatives of  
8           HCFA and the public;

9           “(iv) makes minutes of such meeting available  
10          to the public (through an Internet site and other ap-  
11          propriate mechanisms) not later than 15 calendar  
12          days after such meeting;

13          “(v) taking into account the comments and rec-  
14          ommendations received at such meeting, develops  
15          and makes available to the public (through an Inter-  
16          net site and other appropriate mechanisms) a list of  
17          proposed determinations with respect to the appro-  
18          priate basis for establishing a payment amount  
19          under paragraph (10) for each such code, together  
20          with an explanation of the reasons for each such de-  
21          termination, and the data on which the determina-  
22          tion is based;

23          “(vi) on the same day such list is made avail-  
24          able, causes to have published in the Federal Reg-  
25          ister notice of a public meeting to receive comments

1 and recommendations from the public on the pro-  
2 posed determinations;

3 “(vii) not later than August 1 of each year, but  
4 at least 30 calendar days after publication of such  
5 notice, convenes a meeting to receive such comments  
6 and recommendations, with such meeting being con-  
7 ducted in the same manner as the meeting under  
8 clause (iii);

9 “(viii) makes a transcript of such meeting avail-  
10 able to the public (through an Internet site and  
11 other appropriate mechanisms) as soon as is prac-  
12 ticable after such meeting; and

13 “(ix) taking into account the comments and  
14 recommendations received at such meeting, develops  
15 and makes available to the public (through an Inter-  
16 net site and other appropriate mechanisms) a list of  
17 final determinations of whether the payment amount  
18 for such tests will be determined on the basis de-  
19 scribed in paragraph (10)(A) or the basis described  
20 in paragraph (10)(B), together with the rationale for  
21 each such determination, the data on which the de-  
22 termination is based, and responses to comments  
23 and suggestions received from the public.

24 “(C) Under the procedures established pursuant to  
25 subparagraph (A), the Secretary shall—

1 “(i) identify the rules and assumptions to be  
 2 applied by the Secretary in considering and making  
 3 determinations of whether the payment amount for  
 4 a new test should be established on the basis de-  
 5 scribed in paragraph (10)(A) or the basis described  
 6 in paragraph (10)(B);

7 “(ii) make available to the public the data  
 8 (other than proprietary data) considered in making  
 9 such determinations; and

10 “(iii) provide for a mechanism under which—

11 “(I) an interested party may request an  
 12 administrative review of an adverse determina-  
 13 tion;

14 “(II) upon the request of an interested  
 15 party, an administrative review is conducted  
 16 with respect to an adverse determination; and

17 “(III) such determination is revised, as  
 18 necessary, to reflect the results of such review.

19 “(D) For purposes of this subsection—

20 “(i) the term ‘HCPCS’ refers to the Health  
 21 Care Financing Administration Common Procedure  
 22 Coding System; and

23 “(ii) a code shall be considered to be ‘substan-  
 24 tially revised’ if there is a substantive change to the  
 25 definition of the test or procedure to which the code

1 applies (such as a new analyte or a new methodology  
2 for measuring an existing analyte-specific test).

3 “(10)(A) Notwithstanding paragraphs (1), (2), and  
4 (4), if a new test is clinically similar to a test for which  
5 a fee schedule amount has been established under para-  
6 graph (5), the Secretary shall pay the same fee schedule  
7 amount for the new test.

8 “(B)(i) Notwithstanding paragraphs (1), (2), (4),  
9 and (5), if a new test is not clinically similar to a test  
10 for which a fee schedule has been established under para-  
11 graph (5), payment under this subsection for such test  
12 shall be made on the basis of the lesser of—

13 “(I) the actual charge for the test; or

14 “(II) an amount equal to 60 percent (or in the  
15 case of a test performed by a qualified hospital (as  
16 defined in paragraph (1)(D)) for outpatients of such  
17 hospital, 62 percent) of the prevailing charge level  
18 determined pursuant to the third and fourth sen-  
19 tences of section 1842(b)(3) for the test for a local-  
20 ity or area for the year (determined without regard  
21 to the year referred to in paragraph (2)(A)(i), or  
22 any national limitation amount under paragraph  
23 (4)(B), and adjusted annually by the percentage in-  
24 crease or decrease under paragraph (2)(A)(i));

1 until the beginning of the third full calendar year that be-  
2 gins on or after the date on which an HCPCS code is  
3 first assigned with respect to such test, or, if later, the  
4 beginning of the first calendar year that begins on or after  
5 the date on which the Secretary determines that there are  
6 sufficient claims data to establish a fee schedule amount  
7 pursuant to clause (ii).

8 “(ii) Notwithstanding paragraphs (2), (4), and (5),  
9 the fee schedule amount for a clinical diagnostic labora-  
10 tory test described in clause (i) that is performed—

11 “(I) during the first calendar year after clause  
12 (i) ceases to apply to such test, shall be an amount  
13 equal to the national limitation amount that the Sec-  
14 retary determines (consistent with clause (iii)) would  
15 have applied to such test under paragraph  
16 (4)(B)(viii) during the preceding calendar year, ad-  
17 justed by the percentage increase or decrease deter-  
18 mined under paragraph (2)(A)(i) for such first cal-  
19 endar year; and

20 “(II) during a subsequent year, is the fee  
21 schedule amount determined under this clause for  
22 the preceding year, adjusted by the percentage in-  
23 crease or decrease that applies under paragraph  
24 (5)(A) for such year.



1       “(iii) For purposes of clause (ii)(I), the national limi-  
 2       tation amount for a test shall be set at 100 percent of  
 3       the median of the payment amounts determined under  
 4       clause (ii)(I) for all payment localities or areas for the last  
 5       calendar year for which payment for such test was deter-  
 6       mined under clause (i).

7       “(iv) Nothing in clause (ii) shall be construed as pro-  
 8       hibiting the Secretary from applying (or authorizing the  
 9       application of) the comparability provisions of the first  
 10       sentence of such section 1842(b)(3) with respect to  
 11       amounts determined under such clause.”.

12       (b) ESTABLISHMENT OF NATIONAL FEE SCHEDULE  
 13       AMOUNTS.—

14               (1) IN GENERAL.—Section 1833(h) of the So-  
 15       cial Security Act, as amended by subsection (a), is  
 16       amended—

17                       (A) in paragraph (2), by striking “para-  
 18                       graph (4)” and inserting “paragraphs (4), (5),  
 19                       and (10)”;

20                       (B) in paragraph (4)(B)(viii), by inserting  
 21                       “and before January 1, 2002,” after “Decem-  
 22                       ber 31, 1997,”;

23                       (C) by redesignating paragraphs (5), (6),  
 24                       and (7), as paragraphs (6), (7), and (8), re-  
 25                       spectively; and

1 (D) by inserting after paragraph (4) the  
 2 following new paragraph:

3 “(5) Notwithstanding paragraphs (2) and (4), the  
 4 Secretary shall set the fee schedule amount for a test  
 5 (other than a test to which paragraph (10)(B) applies)  
 6 at—

7 “(A) for tests performed during 2002, an  
 8 amount equal to the national limitation amount for  
 9 that test for 2001, and adjusted by the percentage  
 10 increase or decrease determined under paragraph  
 11 (2)(A)(i) for such year; and

12 “(B) for tests performed during a year after  
 13 2002, the amount determined under this subpara-  
 14 graph for the preceding year, adjusted by the per-  
 15 centage increase or decrease determined under para-  
 16 graph (2)(A)(i) for such year.”.

17 (2) CONFORMING AMENDMENTS.—Paragraphs  
 18 (1)(D)(i) and (2)(D)(i) of section 1833(a) of the So-  
 19 cial Security Act (42 U.S.C. 1395l(a)) are each  
 20 amended by striking “the limitation amount for that  
 21 test determined under subsection (h)(4)(B),”.

22 (c) MECHANISM FOR REVIEW OF ADEQUACY OF PAY-  
 23 MENT AMOUNTS.—Section 1833(h) of the Social Security  
 24 Act (42 U.S.C. 1395l(h)), as amended by subsection (b),  
 25 is amended by adding at the end the following:

1 “(11) The Secretary shall establish a mechanism  
2 under which—

3 “(A) an interested party may request a timely  
4 review of the adequacy of the existing payment  
5 amount under this subsection for a particular test;  
6 and

7 “(B) upon the receipt of such a request, a time-  
8 ly review is carried out.”.

9 (d) USE OF INHERENT REASONABLENESS AUTHOR-  
10 ITY.—Section 1842(b)(8) of the Social Security Act (42  
11 U.S.C. 1395u(b)(8)) is amended by adding at the end the  
12 following:

13 “(E)(i) The Secretary may not delegate the authority  
14 to make determinations with respect to clinical diagnostic  
15 laboratory tests under this paragraph to a regional office  
16 of the Health Care Financing Administration or to an en-  
17 tity with a contract under subsection (a).

18 “(ii) In making determinations with respect to clin-  
19 ical diagnostic laboratory tests under this paragraph, the  
20 Secretary—

21 “(I) shall base such determinations on data  
22 from affected payment localities and all sites of care;  
23 and

24 “(II) may not use a methodology that assigns  
25 undue weight to the prevailing charge levels for any

1       1 type of entity with a contract under subsection  
2       (a).”.

3       (e) PROHIBITION.—Section 1833(h) of the Social Se-  
4       curity Act (42 U.S.C. 1395l(h)), as amended by sub-  
5       section (c), is amended by adding at the end the following  
6       new paragraph:

7       “(12)(1) Notwithstanding the preceding provisions of  
8       this subsection, the Secretary may not establish a payment  
9       level for a new test that is lower than the level for an  
10      existing, clinically similar test solely on the basis that the  
11      new test may be performed by a laboratory with a certifi-  
12      cate of waiver under section 353(d)(2) of the Public  
13      Health Service Act (42 U.S.C. 263a(d)(2)).

14      “(2) Nothing in paragraph (1) shall be construed to  
15      limit the authority of the Secretary to establish a payment  
16      level for a new test that is lower than the level for an  
17      existing, clinically similar test if such payment level is de-  
18      termined on a basis other than the basis described in such  
19      paragraph or on more than 1 basis.”.

20      (f) EFFECTIVE DATES.—

21           (1) ESTABLISHMENT OF PROCEDURES.—The  
22      Secretary of Health and Human Services shall es-  
23      tablish the procedures required to implement para-  
24      graphs (9), (10), (11), and (12) of section 1833(h)  
25      of the Social Security Act (42 U.S.C. 1395l(h)), as

1       added by this section, by not later than January 1,  
2       2002.

3           (2)       INHERENT       REASONABLENESS.—The  
4       amendments made by subsection (d) shall apply to  
5       determinations made on or after the date of enact-  
6       ment of this Act.

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