

107TH CONGRESS  
1ST SESSION

# H. R. 1798

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 HOUSE OF REPRESENTATIVES

MAY 10, 2001

Ms. DUNN of Washington (for herself, Mr. EHRLICH, Mr. McDERMOTT, and Mr. RAMSTAD) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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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:

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

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

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

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

22 “(ii) the Secretary will determine whether  
23 the payment amount for such a test is estab-  
24 lished on the basis described in paragraph  
25 (10)(A) or the basis described in paragraph  
26 (10)(B) only after the process described in sub-

1 paragraph (B) has been completed with respect  
2 to such test.

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

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

11 “(ii) on the same day such list is made  
12 available, causes to have published in the Fed-  
13 eral Register notice of a meeting to receive  
14 comments and recommendations from the pub-  
15 lic on the appropriate basis under paragraph  
16 (10) for establishing payment amounts for the  
17 tests on such list;

18 “(iii) not less than 30 days after publica-  
19 tion of such notice, convenes a meeting to re-  
20 ceive such comments and recommendations,  
21 with such meeting—

22 “(I) including representatives of all  
23 entities within the Health Care Financing  
24 Administration (hereinafter in this para-  
25 graph referred to as ‘HCFA’) that will be

involved in determining the basis on which payment amounts will be established for such tests under paragraph (10) and implementing such determinations;

“(II) encouraging the participation of interested parties, including beneficiaries, device manufacturers, clinical laboratories, laboratory professionals, pathologists, and prescribing physicians, through outreach activities; and

“(III) affording opportunities for interactive dialogue between representatives of HCFA and the public;

“(iv) makes minutes of such meeting available to the public (through an Internet site and other appropriate mechanisms) not later than 15 calendar days after such meeting;

“(v) taking into account the comments and recommendations received at such meeting, develops and makes available to the public (through an Internet site and other appropriate mechanisms) a list of proposed determinations with respect to the appropriate basis for establishing a payment amount under paragraph (10) for each such code, together with an expla-

1 nation of the reasons for each such determina-  
2 tion, and the data on which the determination  
3 is based;

4 “(vi) on the same day such list is made  
5 available, causes to have published in the Fed-  
6 eral Register notice of a public meeting to re-  
7 ceive comments and recommendations from the  
8 public on the proposed determinations;

9 “(vii) not later than August 1 of each year,  
10 but at least 30 days after publication of such  
11 notice, convenes a meeting to receive such com-  
12 ments and recommendations, with such meeting  
13 being conducted in the same manner as the  
14 meeting under clause (iii);

15 “(viii) makes a transcript of such meeting  
16 available to the public (through an Internet site  
17 and other appropriate mechanisms) as soon as  
18 is practicable after such meeting; and

19 “(ix) taking into account the comments  
20 and recommendations received at such meeting,  
21 develops and makes available to the public  
22 (through an Internet site and other appropriate  
23 mechanisms) a list of final determinations of  
24 whether the payment amount for such tests will  
25 be determined on the basis described in para-

1 graph (10)(A) or the basis described in para-  
2 graph (10)(B), together with the rationale for  
3 each such determination, the data on which the  
4 determination is based, and responses to com-  
5 ments and suggestions received from the public.

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

8 “(i) identify the rules and assumptions to  
9 be applied by the Secretary in considering and  
10 making determinations of whether the payment  
11 amount for a new test should be established on  
12 the basis described in paragraph (10)(A) or the  
13 basis described in paragraph (10)(B);

14 “(ii) make available to the public the data  
15 (other than proprietary data) considered in  
16 making such determinations; and

17 “(iii) provide for a mechanism under  
18 which—

19 “(I) an interested party may request  
20 an administrative review of an adverse de-  
21 termination;

22 “(II) upon the request of an inter-  
23 ested party, an administrative review is  
24 conducted with respect to an adverse deter-  
25 mination; and

1 “(III) such determination is revised,  
2 as necessary, to reflect the results of such  
3 review.

4 “(D) For purposes of this paragraph and  
5 paragraph (10)—

6 “(i) the term ‘HCPCS’ refers to the  
7 Health Care Financing Administration  
8 Common Procedure Coding System; and

9 “(ii) a code shall be considered to be  
10 ‘substantially revised’ if there is a sub-  
11 stantive change to the definition of the test  
12 or procedure to which the code applies  
13 (such as a new analyte or a new method-  
14 ology for measuring an existing analyte-  
15 specific test).

16 “(10)(A) Notwithstanding paragraphs (1), (2),  
17 and (4), if a new test is clinically similar to a test  
18 for which a fee schedule amount has been estab-  
19 lished under paragraph (5), the Secretary shall pay  
20 the same fee schedule amount for the new test. In  
21 determining whether tests are clinically similar for  
22 purposes of this paragraph, the Secretary may not  
23 take into account economic factors.

24 “(B)(i) Notwithstanding paragraphs (1), (2),  
25 (4), and (5), if a new test is not clinically similar to

1 a test for which a fee schedule has been established  
2 under paragraph (5), payment under this subsection  
3 for such test shall be made on the basis of the lesser  
4 of—

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

6 “(II) an amount equal to 60 percent (or in  
7 the case of a test performed by a qualified hos-  
8 pital (as defined in paragraph (1)(D)) for out-  
9 patients of such hospital, 62 percent) of the  
10 prevailing charge level determined pursuant to  
11 the third and fourth sentences of section  
12 1842(b)(3) for the test for a locality or area for  
13 the year (determined without regard to the year  
14 referred to in paragraph (2)(A)(i), or any na-  
15 tional limitation amount under paragraph  
16 (4)(B), and adjusted annually by the percent-  
17 age increase or decrease under paragraph  
18 (2)(A)(i));

19 until the beginning of the third full calendar year  
20 that begins on or after the date on which an  
21 HCPCS code is first assigned with respect to such  
22 test, or, if later, the beginning of the first calendar  
23 year that begins on or after the date on which the  
24 Secretary determines that there are sufficient claims



1 data to establish a fee schedule amount pursuant to  
2 clause (ii).

3 “(ii) Notwithstanding paragraphs (2) and (4),  
4 and (5), the fee schedule amount for a clinical diag-  
5 nostic laboratory test described in clause (i) that is  
6 performed—

7 “(I) during the first calendar year after  
8 clause (i) ceases to apply to such test, shall be  
9 an amount equal to the national limitation  
10 amount that the Secretary determines (con-  
11 sistent with clause (iii)) would have applied to  
12 such test under paragraph (4)(B)(viii) during  
13 the preceding calendar year, adjusted by the  
14 percentage increase or decrease determined  
15 under paragraph (2)(A)(i) for such first cal-  
16 endar year; and

17 “(II) during a subsequent year, is the fee  
18 schedule amount determined under this clause  
19 for the preceding year, adjusted by the percent-  
20 age increase or decrease that applies under  
21 paragraph (5)(A) for such year.

22 “(iii) For purposes of clause (ii)(I), the national  
23 limitation amount for a test shall be set at 100 per-  
24 cent of the median of the payment amounts deter-  
25 mined under clause (ii)(I) for all payment localities

1 or areas for the last calendar year for which pay-  
2 ment for such test was determined under clause (i).

3 “(iv) Nothing in clause (ii) shall be construed  
4 as prohibiting the Secretary from applying (or au-  
5 thorizing the application of) the comparability provi-  
6 sions of the first sentence of such section 1842(b)(3)  
7 with respect to amounts determined under such  
8 clause.”.

9 (b) ESTABLISHMENT OF NATIONAL FEE SCHEDULE  
10 AMOUNTS.—

11 (1) IN GENERAL.—Section 1833(h) of the So-  
12 cial Security Act, as amended by subsection (a), is  
13 further amended—

14 (A) in paragraph (2), by striking “para-  
15 graph (4)” and inserting in lieu thereof “para-  
16 graphs (4), (5), and (10)”;

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

20 (C) by redesignating paragraphs (5), (6),  
21 and (7), as paragraphs (6), (7), and (8), re-  
22 spectively; and

23 (D) by inserting after paragraph (4) the  
24 following:

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

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

10          “(B) for tests performed during a year  
11       after 2002, the amount determined under this  
12       subparagraph for the preceding year, adjusted  
13       by the percentage increase or decrease deter-  
14       mined under paragraph (2)(A)(i) for such  
15       year.”.

16       (2) CONFORMING CHANGES.—Section 1833(a)  
17       of the Social Security Act (42 U.S.C. 1395l(a)) is  
18       amended—

19           (A) in paragraph (1)(D)(i), by striking  
20       “the limitation amount for that test determined  
21       under subsection (h)(4)(B),”; and

22           (B) in paragraph (2)(D)(i), by striking  
23       “the limitation amount for that test determined  
24       under subsection (h)(4)(B),”.

1       (c) MECHANISM FOR REVIEW OF ADEQUACY OF PAY-  
2     MENT AMOUNTS.—Section 1833(h) of the Social Security  
3     Act, as amended by subsections (a) and (b), is further  
4     amended by adding at the end the following:

5               “(11) The Secretary shall establish a mecha-  
6     nism under which—

7                       “(A) an interested party may request a  
8                       timely review of the adequacy of the existing  
9                       payment amount under this subsection fee for  
10                      a particular test; and

11                     “(B) upon the receipt of such a request, a  
12                     timely review is carried out.”.

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

17                   “(E)(i) The Secretary may not delegate  
18                   the authority to make determinations with re-  
19                   spect to clinical diagnostic laboratory tests  
20                   under this paragraph to a regional office of the  
21                   Health Care Financing Administration or to an  
22                   entity with a contract under subsection (a).

23                   “(ii) In making determinations with re-  
24                   spect to clinical diagnostic laboratory tests  
25                   under this paragraph, the Secretary—

1 “(I) shall base such determinations on  
2 data from affected payment localities and  
3 all sites of care; and

4 “(II) may not use a methodology that  
5 assigns undue weight to the prevailing  
6 charge levels for any one type of entity  
7 with a contract under subsection (a).”.

8 (e) PROHIBITION.—The Secretary may not assign a  
9 code for a new clinical diagnostic laboratory test that dif-  
10 fers from the code recommended by the American Medical  
11 Association Common Procedure Terminology Editorial  
12 Panel and results in lower payment than would be made  
13 if the Secretary accepted such recommendation solely on  
14 the basis that the test is a test that may be performed  
15 by a laboratory with a certificate of waiver under section  
16 353(d)(2) of the Public Health Service Act (42 U.S.C.  
17 263a(d)(2)).

18 (f) EFFECTIVE DATES.—

19 (1) ESTABLISHMENT OF PROCEDURES.—The  
20 Secretary of Health and Human Services shall es-  
21 tablish the procedures required to implement para-  
22 graphs (9), (10), and (11) of section 1833(h) of the  
23 Social Security Act (42 U.S.C. 1395l(h)), as added  
24 by this section, by not later than October 1, 2001.

1           (2) INHERENT REASONABLENESS; CODE AS-  
2       SIGNMENT.—The amendments made by subsections  
3       (d) and (e) shall apply to determinations made on or  
4       after the date of the enactment of this Act.

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