

108TH CONGRESS  
1ST SESSION

# H. R. 569

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.

---

## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 5, 2003

Ms. DUNN (for herself, Mr. McDERMOTT, Mr. RAMSTAD, Mr. DEUTSCH, and Mr. FERGUSON) 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

---

## 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 of 2003”.

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, 2004 (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 (including the  
15 data upon which such recommendations are  
16 based) from the public on the appropriate basis  
17 under paragraph (10) for establishing payment  
18 amounts for the tests on such list;

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

23 “(I) including representatives of all  
24 entities within the Centers for Medicare &  
25 Medicaid Services (hereinafter in this para-

1 graph referred to as ‘CMS’) that will be  
2 involved in determining the basis on which  
3 payment amounts will be established for  
4 such tests under paragraph (10) and im-  
5 plementing such determinations;

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

12 “(III) affording opportunities for  
13 interactive dialogue between representa-  
14 tives of CMS and the public; and

15 “(iv) taking into account the comments  
16 and recommendations received at such meeting,  
17 develops and makes available to the public  
18 (through an Internet site and other appropriate  
19 mechanisms) a list of proposed determinations  
20 with respect to the appropriate basis for estab-  
21 lishing a payment amount under paragraph  
22 (10) for each such code, together with an expla-  
23 nation of the reasons for each such determina-  
24 tion, and the data on which the determination  
25 is based.

1       The Secretary may convene such further public  
2       meetings to receive public comment on payment  
3       amounts for new tests under this subsection as the  
4       Secretary determines appropriate.

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

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

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

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

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

21                               “(II) upon the request of an inter-  
22                               ested party, an administrative review is  
23                               conducted with respect to an adverse deter-  
24                               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           Healthcare Common Procedure Coding  
8           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, 2004,” 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 2004, an  
6                   amount equal to the national limitation amount  
7                   for that test for 2003, 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 2004, 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) PROHIBITION ON ASSIGNMENT OF CERTAIN NEW  
14 CODES.—The Secretary may not assign a code for a new  
15 clinical diagnostic laboratory test that differs from the  
16 code recommended by the American Medical Association  
17 Common Procedure Terminology Editorial Panel and re-  
18 sults in lower payment than would be made if the Sec-  
19 retary accepted such recommendation solely on the basis  
20 that the test is a test that may be performed by a labora-  
21 tory with a certificate of waiver under section 353(d)(2)  
22 of the Public Health Service Act (42 U.S.C. 263a(d)(2)).

23 (e) PROHIBITION ON APPLICATION OF LEAST COST-  
24 LY ALTERNATIVE TO FEE SCHEDULE.—Section 1833(h)  
25 of the Social Security Act, as amended by subsections (a),

1 (b), and (c), is further amended by adding at the end the  
2 following:

3           “(12) Notwithstanding any other provision of  
4 this title, the Secretary may not substitute for the  
5 fee schedule amount otherwise established under this  
6 subsection for a test a least costly alternative fee  
7 schedule amount for the test.”.

8 (f) EFFECTIVE DATES.—

9           (1) IN GENERAL.—The Secretary of Health and  
10 Human Services shall establish the procedures re-  
11 quired to implement paragraphs (9), (10), and (11)  
12 of section 1833(h) of the Social Security Act (42  
13 U.S.C. 1395l(h)), as added by this section, by not  
14 later than October 1, 2003.

15           (2) PROHIBITIONS.—(A) Subsection (d) shall  
16 apply to code assignment determinations made on or  
17 after the date of the enactment of this Act.

18           (B) The amendment made by subsection (e)  
19 shall apply to tests furnished on or after the date of  
20 the enactment of this Act without regard to whether  
21 a determination to substitute a least costly alter-  
22 native fee schedule amount for a test was made be-  
23 fore, on, or after such date.

○