

110TH CONGRESS  
1ST SESSION

# H. R. 1321

To amend title XVIII of the Social Security Act to improve payments under the Medicare clinical laboratory fee schedule.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 5, 2007

Mr. RUSH 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 improve payments under the Medicare clinical laboratory fee schedule.

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 AND TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the  
5 “Medicare Advanced Laboratory Diagnostics Act of  
6 2007”.

7 (b) TABLE OF CONTENTS.—The table of contents of  
8 this Act is as follows:

Sec. 1. Short title and table of contents.

## TITLE I—NEAR-TERM CHANGES

- Sec. 101. Fee schedule and national limitation amounts for clinical diagnostic laboratory tests.
- Sec. 102. Issuance of regulations on gap-filling for medicare fee schedule for clinical diagnostic laboratory tests.
- Sec. 103. Increased transparency of process for determining fee schedule amounts for new tests.
- Sec. 104. Advance notice of clinical diagnostic laboratory test amounts being considered for adjustment under inherent reasonableness authority.

## TITLE II—FUTURE REFORM

- Sec. 201. Establishment of medicare demonstration project to evaluate new approaches to coding and payment for certain molecular diagnostic tests.

1 **TITLE I—NEAR-TERM CHANGES**2 **SEC. 101. FEE SCHEDULE AND NATIONAL LIMITATION**  
3 **AMOUNTS FOR CLINICAL DIAGNOSTIC LAB-**  
4 **ORATORY TESTS.**

5 (a) IN GENERAL.—Section 1833(h) of the Social Se-  
6 curity Act (42 U.S.C. 1395l(h)) is amended by adding at  
7 the end the following new paragraph:

8 “(9)(A) For purposes of this paragraph:

9 “(i) The term ‘an amount determined under  
10 this subsection’ means, with respect to a clinical lab-  
11 oratory test, the fee schedule amount determined  
12 under paragraph (2)(A)(i) for the test or the limita-  
13 tion amount determined under paragraph (4)(B) for  
14 the test.

15 “(ii) The terms ‘appropriate medicare adminis-  
16 trative contractor’ and ‘medicare administrative con-  
17 tractor’ have the meaning given to such terms under  
18 section 1874A(a)(3).

1           “(iii) The term ‘erroneous decision’ means, with  
2           respect to the determination of an amount deter-  
3           mined under this subsection, any decision, calcula-  
4           tion, judgment or other action by the Secretary or  
5           a medicare administrative contractor that, based  
6           upon consideration of currently known facts, needs  
7           to be modified to produce a fair and equitable pay-  
8           ment amount, except that such term does not in-  
9           clude typographical or clerical errors.

10           “(iv) The term ‘non-governmental party’ in-  
11           cludes—

12                   “(I) a provider of services (as defined in  
13                   section 1861(u)) that furnishes clinical diag-  
14                   nostic laboratory tests for which payment may  
15                   be made under this subsection;

16                   “(II) a supplier (as defined in section  
17                   1861(d)) that furnishes such tests; and

18                   “(III) a manufacturer of a test or of any  
19                   supplies or equipment that are used in per-  
20                   forming such test.

21           “(B) An amount determined under this subsection  
22           may be changed solely on the basis of—

23                   “(i) in the case of a change other than a change  
24                   to correct an erroneous decision in determining such  
25                   amount, the authority provided by the preceding

1 provisions of this subsection, section 1842(b)(8), or  
2 any regulations, manual instructions, or other regu-  
3 latory guidance implementing such provisions; or

4 “(ii) in the case of a change to correct an erro-  
5 neous decision in determining such an amount, the  
6 authority provided by subparagraphs (C), (D), and  
7 (E).

8 “(C) Any erroneous decision in determining an  
9 amount under this subsection may be corrected only if—

10 “(i) a non-governmental party submits a re-  
11 quest under subparagraph (D) or (E) for correction  
12 of the erroneous decision; and

13 “(ii) such party demonstrates, to an appro-  
14 priate medicare administrative contractor under sub-  
15 paragraph (D) or the Secretary under subparagraph  
16 (E), that an erroneous decision clearly was made.

17 “(D)(i) Any non-governmental party may request (in  
18 such form and manner as the Secretary may require) that  
19 the appropriate medicare administrative contractor change  
20 a fee schedule amount determined under paragraph  
21 (2)(A)(i) to correct an erroneous decision in determining  
22 such amount.

23 “(ii) Any request under this subparagraph shall in-  
24 clude a statement of the basis for the non-governmental  
25 party’s belief that an erroneous decision was made in de-

1 terminating such amount, together with supporting evidence  
2 and a description of any additional data (other than data  
3 already in the possession of the appropriate medicare ad-  
4 ministrative contractor) that—

5           “(I) is or may be in the possession of the Sec-  
6 retary or another medicare administrative con-  
7 tractor; and

8           “(II) is necessary to demonstrate that such an  
9 erroneous decision exists.

10          “(iii) If the Secretary or another medicare adminis-  
11 trative contractor is identified as possessing or potentially  
12 possessing additional data identified by a non-govern-  
13 mental party in a request under this subparagraph, the  
14 Secretary or such contractor, as the case may be, shall  
15 make available to the non-governmental party within 30  
16 days after the date of the submission of the request any  
17 data in their possession that meet the description of the  
18 additional data identified in such request, with appro-  
19 priate safeguards to protect confidential and proprietary  
20 information.

21          “(iv) If additional data are made available to a non-  
22 governmental party under clause (iii), such party may  
23 amend its request under this subparagraph to incorporate  
24 such data within 30 days after the date such data are  
25 made available to such party.

1       “(v) An appropriate medicare administrative con-  
2 tractor to which a request is submitted under this sub-  
3 paragraph shall make a determination with respect to  
4 whether to correct the decision that is identified as erro-  
5 neous in the request not later than 60 days after the date  
6 of the submission of such request, or if later, the date of  
7 the submission of an amended request under clause (iv).  
8 Such contractor shall determine that the non-govern-  
9 mental party submitting the request—

10           “(I) has demonstrated that an erroneous deci-  
11 sion clearly was made, correct such erroneous deci-  
12 sion, and increase the fee schedule amount as of the  
13 first day of the next calendar quarter to reflect the  
14 correction of such erroneous decision; or

15           “(II) has failed to demonstrate that an erro-  
16 neous decision clearly was made and decline to  
17 change the fee schedule amount,

18 and shall provide to the non-governmental party a written  
19 explanation of the basis for such determination.

20       “(vi) An appropriate medicare administrative con-  
21 tractor to which a request is submitted under this sub-  
22 paragraph may not reduce a fee schedule amount pursu-  
23 ant to such request, and may reduce such an amount only  
24 pursuant to section 1842(b)(8).

1       “(E)(i) Any non-governmental party may request (in  
2 such form and manner as the Secretary may require) that  
3 the Secretary—

4           “(I) reverse a determination of a medicare ad-  
5 ministrative contractor under subparagraph (D) that  
6 is adverse to the non-governmental party requesting  
7 it;

8           “(II) correct an erroneous decision in the deter-  
9 mination of a limitation amount under paragraph  
10 (4)(B); or

11          “(III) reverse a determination referred to in  
12 subclause (I) and correct an erroneous decision re-  
13 ferred to in subclause (II).

14          “(ii) Any request under this subparagraph shall in-  
15 clude a statement of the basis for the non-governmental  
16 party’s belief that an erroneous decision was made in de-  
17 termining such amount, together with supporting evidence  
18 and a description of any additional data (other than data  
19 already in the possession of the Secretary or the appro-  
20 priate medicare administrative contractor reviewing the  
21 request under subparagraph (D)) that—

22           “(I) are or may be in the possession of the Sec-  
23 retary or another medicare administrative con-  
24 tractor; and

1           “(II) are necessary to demonstrate that such an  
2           erroneous decision exists.

3           “(iii) If the Secretary or another medicare adminis-  
4           trative contractor is identified as possessing or potentially  
5           possessing additional data identified by a non-govern-  
6           mental party in a request under this subparagraph, the  
7           Secretary or such contractor, as the case may be, shall  
8           make available to the non-governmental party within 30  
9           days after the date of the submission of the request any  
10          data in their possession that meet the description of the  
11          additional data identified in such request, with appro-  
12          priate safeguards to protect confidential and proprietary  
13          information.

14          “(iv) If additional data are made available to a non-  
15          governmental party under clause (iii), such party may  
16          amend its request under this subparagraph to incorporate  
17          such data within 30 days after the date such data are  
18          made available to such party.

19          “(v) The Secretary shall make a determination of  
20          whether to correct the erroneous decision that is the sub-  
21          ject of a request submitted under this subparagraph not  
22          later than 60 days after the date of the submission of such  
23          request, or if later, the submission of an amended request  
24          under clause (iv). The Secretary shall determine that the  
25          non-governmental party submitting the request—

1           “(I) has demonstrated that an erroneous deci-  
2           sion clearly was made, correct such erroneous deci-  
3           sion, and increase the fee schedule amount as of the  
4           first day of the next calendar quarter to reflect the  
5           correction of such erroneous decision; or

6           “(II) has failed to demonstrate that an erro-  
7           neous decision clearly was made and decline to  
8           change the fee schedule amount or national limita-  
9           tion amount, as the case may be,

10          and shall provide to the non-governmental party with a  
11          written explanation of the basis for such determination.

12          “(vi) The Secretary may not reduce a fee schedule  
13          amount pursuant to a request under this subparagraph  
14          and may reduce such an amount only pursuant to section  
15          1842(b)(8).

16          “(F)(i) There shall be no administrative or judicial  
17          review under section 1869, 1878, or otherwise of any de-  
18          termination made under subparagraph (D) or (E).

19          “(ii) Nothing in this paragraph shall be construed as  
20          precluding administrative or judicial review of determina-  
21          tions of the amount of benefits that are available to a  
22          Medicare beneficiary in a particular case.”.

23          (b) EFFECTIVE DATE.—The amendment made by  
24          subsection (a) shall take effect on the date of the enact-  
25          ment of this Act and shall apply to requests for corrections

1 submitted on or after such date, without regard to whether  
2 final regulations to carry out such amendment have been  
3 issued.

4 **SEC. 102. ISSUANCE OF REGULATIONS ON GAP-FILLING**  
5 **FOR MEDICARE FEE SCHEDULE FOR CLIN-**  
6 **ICAL DIAGNOSTIC LABORATORY TESTS.**

7 Not later than one year after the date of the enact-  
8 ment of this Act, the Secretary of Health and Human  
9 Services shall issue final regulations specifying how an ap-  
10 propriate medicare administrative contractor (as defined  
11 in section 1874A(a)(3)(B) of the Social Security Act (42  
12 U.S.C. 1395kk-1(a)(3)(B)) shall apply a gap-filling meth-  
13 odology in determining fee schedule amounts established  
14 under section 1833(h)(2)(A)(i) of such Act (42 U.S.C.  
15 1395l(h)(2)(A)(i)). Such regulations shall specify—

16 (1) a process for ensuring that the resulting fee  
17 schedule amounts are fair, including a description of  
18 the types of data to be collected for use in such  
19 methodology and the minimum requirements such  
20 data shall meet in order to ensure that the data are  
21 valid, meaningful, and unbiased;

22 (2) the principles to be employed to ensure that  
23 such data are statistically significant and alter-  
24 natives to follow if statistically significant data are  
25 unavailable;

1           (3) the principles to be followed in using data  
2           to calculate fee schedule amounts, including prin-  
3           ciples for excluding data that do not meet the re-  
4           quirements of paragraph (1) and (2);

5           (4) the methods the Secretary will use to over-  
6           see the application of a gap filling methodology by  
7           such contractors and the remedies that will be avail-  
8           able in cases in which such a contractor fails to com-  
9           ply with regulatory requirements; and

10          (5) a process that provides opportunities for the  
11          public to participate in the development of fee sched-  
12          ule amounts through the application of gap-filling  
13          methodologies, including release to the public of data  
14          collection protocols and the data derived from such  
15          protocols with an opportunity for public comment  
16          thereon.

17 **SEC. 103. INCREASED TRANSPARENCY OF PROCESS FOR**  
18                           **DETERMINING FEE SCHEDULE AMOUNTS**  
19                           **FOR NEW TESTS.**

20          Section 1833(h)(8) of the Social Security Act (42  
21          U.S.C. 1395l(h)(8) is amended—

22           (1) in subparagraph (B)(iii), by inserting “to be  
23           conducted in an inter-active format,” after “meet-  
24           ing,”;

25           (2) in subparagraph (B)(iv)—

1 (A) by inserting “(I)” after “meeting,”;

2 (B) by striking “determination,” and in-  
3 serting “determination and”; and

4 (C) by striking “a request for” and insert-  
5 ing “(II) publishes in the Federal Register a  
6 notice of a period of not less than 60 days dur-  
7 ing which the Secretary will receive”; and

8 (3) in subparagraph (C), by striking “Under  
9 the procedures” and inserting “In the regulations”.

10 **SEC. 104. ADVANCE NOTICE OF CLINICAL DIAGNOSTIC LAB-**  
11 **ORATORY TEST AMOUNTS BEING CONSID-**  
12 **ERED FOR ADJUSTMENT UNDER INHERENT**  
13 **REASONABLENESS AUTHORITY.**

14 (a) **LIMIT ON INHERENT REASONABLENESS AU-**  
15 **THORITY.**—Section 1842(b)(9)(A) of the Social Security  
16 Act (42 U.S.C. 1395u(b)(9)(A)) is amended by adding at  
17 the end the following: “Before publishing a proposed no-  
18 tice under subparagraph (B) with respect to any clinical  
19 diagnostic laboratory test being considered for adjustment  
20 under paragraph (8), advance notice that such test is  
21 being considered for such an adjustment shall be provided  
22 to non-governmental parties (as defined in section  
23 1833(h)(9)(A)(iv)) at the meeting required by section  
24 1833(h)(8)(B)(iii), together with an opportunity for such  
25 representatives and other individuals to make oral com-

1 ments on the appropriateness of such an adjustment for  
2 such test.”.

3 (b) CONFORMING CHANGE.—Section 1833(h)(8)(B)  
4 of such Act (42 U.S.C. 1395l(h)(8)(B)) is amended by  
5 adding at the end the following:  
6 “At the meeting required by clause (iii), the Secretary  
7 shall provide advance notice of inherent reasonableness ad-  
8 justments under section 1842(b)(8) that are being consid-  
9 ered for clinical diagnostic laboratory tests, and afford an  
10 opportunity for non-governmental parties (as defined  
11 1833(h)(9)(A)(iv)) at the meeting to comment orally on  
12 the appropriateness of such an adjustment.”.

13 (c) EFFECTIVE DATE.—The amendments made by  
14 this section shall become effective on January 1, 2008,  
15 and shall apply to inherent reasonableness adjustments  
16 that have not been proposed as of such date.

## 17 **TITLE II—FUTURE REFORM**

### 18 **SEC. 201. ESTABLISHMENT OF MEDICARE DEMONSTRATION**

#### 19 **PROJECT TO EVALUATE NEW APPROACHES** 20 **TO CODING AND PAYMENT FOR CERTAIN MO-** 21 **LECULAR DIAGNOSTIC TESTS.**

22 (a) ESTABLISHMENT OF DEMONSTRATION.—

23 (1) DEMONSTRATION OF NEW APPROACHES TO  
24 CODING AND PAYMENT.—The Secretary of Health  
25 and Human Services (in this section referred to as

1 the “Secretary”) shall establish a demonstration  
2 project under this section (in this section referred to  
3 as the “demonstration”) to evaluate new approaches  
4 to coding and payment under the medicare program  
5 for clinical diagnostic laboratory tests included in  
6 the demonstration (in this section referred to as “in-  
7 cluded tests”).

8 (2) DURATION.—The demonstration and any  
9 payment amounts assigned under the demonstration  
10 shall apply solely to claims submitted for included  
11 tests during the 12-calendar-quarter period that be-  
12 gins with the first day of the first calendar quarter  
13 to begin at least 250 days after the date of the en-  
14 actment of this Act.

15 (3) SCOPE.—The demonstration shall apply on  
16 a national basis to included tests in all settings for  
17 which payment for such tests would (but for the  
18 demonstration) be made under the fee schedules and  
19 limitation amounts established under section  
20 1833(h) of the Social Security Act (42 U.S.C.  
21 1395l(h)).

22 (4) ISSUANCE OF TEMPORARY HCPCS CODES;  
23 CONTINUED APPLICATION OF SUCH CODES.—The  
24 Secretary shall issue a temporary code or codes  
25 under the Health Care Procedure Coding System

1 (HCPCS) when needed for an included test, and  
2 such code or codes—

3 (A) shall continue to apply to the test until  
4 a permanent code or codes is assigned; and

5 (B) shall not cease to apply solely because  
6 the demonstration ends.

7 (b) INCLUDED TESTS.—

8 (1) ELIGIBLE TESTS.—A clinical diagnostic lab-  
9 oratory test is eligible to be an included test under  
10 the demonstration if—

11 (A) the test is a new or existing molecular  
12 diagnostic test that (but for its inclusion in the  
13 demonstration) could be paid under the fee  
14 schedules and national limitation amount estab-  
15 lished under section 1833(h) of the Social Secu-  
16 rity Act (42 U.S.C. 1395l(h)) for the test; and

17 (B) there is the prospect—

18 (i) for wide usage of the test in mul-  
19 tiple geographic areas; and

20 (ii) that development of a new code,  
21 or payment, or both, for the test under the  
22 demonstration will result in reduced ad-  
23 ministrative complexity and improved effi-  
24 ciency.

1           (2) INCLUDED TESTS.—A clinical diagnostic  
2 laboratory test shall be treated as an included test  
3 if—

4           (A) an interested party submits a request  
5 to the standing panel established under sub-  
6 section (c) that the test be included in the dem-  
7 onstration; and

8           (B) the standing panel determines that the  
9 test is an eligible test under paragraph (1); or

10          (3) DEFINITIONS.—For purposes of this sec-  
11 tion—

12           (A) the term “molecular diagnostic test”  
13 means a clinical diagnostic laboratory test per-  
14 formed on deoxyribonucleic (DNA), ribonucleic  
15 acid (RNA), or protein that is drawn from a  
16 human being or from a disease-causing orga-  
17 nism for genomic or proteomic analysis; and

18           (B) the term “interested party” means,  
19 with respect to a request for inclusion of molec-  
20 ular diagnostic test in the demonstration, an in-  
21 dividual entitled to benefits under title XVIII of  
22 the Social Security Act, a manufacturer of the  
23 test, a clinical laboratory offering the test, a  
24 professional society, the Centers for Medicare &  
25 Medicaid Services, a private payer for such test,

1           and a physician or other health care practi-  
2           tioner.

3           (c) STANDING PANEL.—

4           (1) APPOINTMENT.—Not later than 60 days  
5           after the date of the enactment of this section, the  
6           Secretary shall appoint a standing panel (in this sec-  
7           tion referred to as the “standing panel” or “panel”)  
8           to determine whether a test is an included test and  
9           make recommendations to the Secretary on the ap-  
10          propriate coding of, and payment for, designated  
11          clinical diagnostic laboratory tests under the dem-  
12          onstration.

13          (2) COMPOSITION OF PANEL.—

14           (A) IN GENERAL.—The standing panel  
15          shall be comprised of 12 members. Two of such  
16          members shall be non-voting representatives of  
17          the Administrator of the Centers for Medicare  
18          & Medicaid Services. The Secretary shall ap-  
19          point the other 10 members from—

20                   (i) organizations representing large  
21                   clinical laboratories;

22                   (ii) organizations representing small  
23                   clinical laboratories;

1 (iii) organizations representing physi-  
2 cians with expertise in clinical diagnostic  
3 laboratory tests;

4 (iv) organizations representing non-  
5 physician laboratorians with expertise in  
6 such tests;

7 (v) organizations representing manu-  
8 facturers of such tests;

9 (vi) organizations representing indi-  
10 viduals entitled to benefits under title  
11 XVIII of the Social Security Act;

12 (vii) organizations representing pri-  
13 vate payers for such tests (but not more  
14 than one member may be appointed to rep-  
15 resent such organizations);

16 (viii) individuals with expertise in  
17 measuring resource utilization by clinical  
18 laboratories in performing tests; and

19 (ix) individuals with other relevant ex-  
20 pertise.

21 (B) TERMS OF OFFICE.—Each member of  
22 the panel shall be appointed for the life of the  
23 panel, except that any individual appointed to  
24 fill a vacancy shall be appointed for the remain-  
25 der of the term of the individual who is being

1 replaced. Any vacancy shall be filled in the  
2 same manner, and with a representative of the  
3 same category under subparagraph (A), as the  
4 individual being replaced.

5 (3) RULES GOVERNING PANEL.—

6 (A) IN GENERAL.—The panel shall elect its  
7 chair. A quorum shall be required to conduct  
8 the business of the panel, and eight members of  
9 the panel shall constitute a quorum.

10 (B) COMPENSATION.—While serving on  
11 the business of the panel (including travel  
12 time), a member of the panel shall be entitled  
13 to compensation at the per diem equivalent rate  
14 provided for level IV of the Executive Schedule  
15 under section 5315 of title 5, United States  
16 Code, and while so serving away from home and  
17 the member's regular place of business, a mem-  
18 ber may be allowed travel expenses as author-  
19 ized by the chair of the panel.

20 (C) STAFFING.—

21 (i) DETAILING.—The panel may seek  
22 such assistance and support of its duties  
23 from appropriate Federal Departments  
24 and agencies.

1                   (ii) OUTSIDE EXPERTS.—The panel  
2                   may retain the services of such outside ex-  
3                   perts as are necessary for the evaluation of  
4                   a request under this section, and such ex-  
5                   perts shall not be voting members of the  
6                   panel.

7                   (D) MEETINGS.—The panel shall meet at  
8                   the call of the chair and at such intervals  
9                   (which shall not be less than quarterly) as may  
10                  be necessary for the conduct of its business.  
11                  The agenda of each meeting and a notice of its  
12                  date shall be published at least 30 days before  
13                  the date the meeting occurs, and, except as pro-  
14                  vided in subparagraph (E), meetings of the  
15                  panel shall be open to the public.

16                  (E) FACA.—The Federal Advisory Com-  
17                  mittee Act (5 U.S.C. App.) shall not apply to  
18                  the panel, but the panel may close any portion  
19                  of a meeting that could be closed if such Act  
20                  applied.

21                  (F) TERMINATION OF PANEL.—The panel  
22                  shall terminate not more than 180 days after  
23                  the close of the demonstration.

24                  (d) FORM AND CONTENT OF REQUESTS FOR INCLU-  
25                  SION IN THE DEMONSTRATION.—A request for inclusion

1 of a clinical diagnostic laboratory test in the demonstra-  
2 tion shall be submitted in such form, and shall contain  
3 such information as the standing panel may require, in-  
4 cluding at least—

5 (1) any coding and payment determinations re-  
6 quested with respect to the test; and

7 (2) any documentation in support of—

8 (A) the eligibility of the test for inclusion  
9 in the demonstration; and

10 (B) any coding and payment determina-  
11 tions requested with respect to the test, includ-  
12 ing data on the typical resources necessary to  
13 perform the test.

14 The Secretary shall cause to have published in the  
15 Federal Register and on an appropriate internet site  
16 public notice of each such request. Such information  
17 shall be supplied to the Secretary by the standing  
18 panel.

19 (e) CRITERIA FOR EVALUATING REQUESTS FOR DE-  
20 TERMINATIONS IN CODING AND PAYMENT.—

21 (1) IN GENERAL.—In determining whether a  
22 requested payment determination should be granted,  
23 and what the new payment amount for a test should  
24 be, the standing panel (in making its recommenda-  
25 tions to the Secretary) and the Secretary (in deter-

1 mining whether to grant such a determination) shall  
2 take into account typical resources necessary to per-  
3 form the test, the expected impact of the test on,  
4 and value of the test to, patient care management,  
5 and such other factors as the standing panel and the  
6 Secretary, respectively, determine to be relevant to  
7 the determination.

8 (2) STANDING PANEL.—Not later than 180  
9 days after the appointment of all of the members of  
10 the panel, the panel shall, after consultation with the  
11 Secretary, establish and make available to the pub-  
12 lic—

13 (A) standards and parameters for deter-  
14 mining whether to recommend to the Secretary  
15 a coding or payment determination specified in  
16 a request for inclusion of a test in the dem-  
17 onstration, which shall include a listing of data  
18 elements necessary to support a request and a  
19 standardized procedure for collecting and sub-  
20 mitting data to the panel on typical resources  
21 necessary to perform a test;

22 (B) policies and procedures for protecting  
23 the confidentiality of financial and other propri-  
24 etary data submitted to the panel in support of  
25 a request; and

1           (C) resource intervals or resource bands  
2           (as described in subsection (g)(1)) that the  
3           panel recommends that the Secretary should  
4           use for the assignment of included tests under  
5           the demonstration.

6           (3) SECRETARIAL DETERMINATIONS.—The Sec-  
7           retary shall develop and make available to public on  
8           an internet site guidance documents on the stand-  
9           ards and parameters that will be applied in making  
10          Secretarial determinations and on the resource inter-  
11          vals or resource bands to be used under the dem-  
12          onstration and on whether to grant a request for a  
13          payment or coding determination. Such guidance  
14          documents shall be developed, which shall be made  
15          available to the public at least 10 days before the be-  
16          ginning of the demonstration, in a manner similar to  
17          the manner in which guidance documents are devel-  
18          oped under section 701(h) of the Federal Food,  
19          Drug, and Cosmetic Act (21 U.S.C. 371(h)).

20          (4) AUTHORITY TO RECOMMEND REVISIONS TO,  
21          AND TO REVISE, RESOURCE INTERVALS OR RE-  
22          SOURCE BANDS.—Nothing in this section shall be  
23          construed as limiting the authority of the standing  
24          panel to recommend, or the Secretary to adopt, new

1 resource intervals or resource bands to accommodate  
2 changes in technology.

3 (f) REVIEW PROCESS.—

4 (1) REQUESTS FOR INCLUSION IN DEMONSTRA-  
5 TION.—An interested party may submit a request  
6 for inclusion of a test in the demonstration to the  
7 standing panel at any time during a calendar year  
8 for which the demonstration is in effect, except that  
9 the standing panel may decline to review and make  
10 recommendations or determinations with respect to  
11 any request that would result in a requested coding  
12 or payment determination being effective for a pe-  
13 riod of less than 4 calendar quarters.

14 (2) RECOMMENDATIONS OF STANDING  
15 PANEL.—The standing panel shall review each re-  
16 quest for a coding or payment determination that is  
17 made with respect to an included test. Applying the  
18 standards and parameters developed under sub-  
19 section (e)(2)(A), the panel shall make a rec-  
20 ommendation to the Secretary with respect to each  
21 requested determination.

22 (3) SECRETARIAL DETERMINATIONS.—

23 (A) QUARTERLY DETERMINATIONS.—The  
24 Secretary shall make determinations on whether  
25 to grant requested coding and payment deter-

1           minations on a quarterly basis, but is not re-  
2           quired to make such a determination for every  
3           request made (or with respect to which a rec-  
4           ommendation is received from the standing  
5           panel) during a particular quarter.

6                   (B) TIME FRAMES FOR DETERMINA-  
7           TIONS.—Determinations of the Secretary shall  
8           be made in a timely manner in accordance with  
9           time frames developed by the standing panel  
10          taking into account factors such as when a re-  
11          quest (and a recommendation with respect to  
12          the request) is made during a quarter, the par-  
13          ticular type of test involved, and the staffing  
14          and resources that may be required to review  
15          the request.

16          (g) PAYMENT METHODOLOGY.—

17                   (1) IN GENERAL.—Included tests shall be paid  
18          in accordance with a methodology, developed by the  
19          standing panel, that establishes resource intervals or  
20          resource bands in a manner similar to those that are  
21          used as new technology ambulatory payment classi-  
22          fication groups for hospital outpatient services under  
23          section 1833(t) of the Social Security Act (42  
24          U.S.C. 1395l(t)), with a test being assigned to the  
25          interval or band that most closely approximates the

1 typical resources necessary for a laboratory to per-  
2 form the test. Tests that are included tests for pur-  
3 poses of this section shall be excluded from any dem-  
4 onstration project under section 1847(e) of such Act  
5 (42 U.S.C. 1395w-3(e)).

6 (2) PANEL RECOMMENDATIONS; SECRETARIAL  
7 DETERMINATIONS.—

8 (A) RECOMMENDATIONS; SECRETARIAL  
9 DETERMINATIONS.—The standing panel shall  
10 recommend to the Secretary a resource interval  
11 or resource band to which an included test  
12 should be assigned, and the Secretary may as-  
13 sign such test to such band or interval or to an-  
14 other band or interval the Secretary determines  
15 to more closely approximate the typical re-  
16 sources necessary to perform the test.

17 (B) EXPLANATION OF DETERMINATION  
18 THAT DIFFERS FROM RECOMMENDATION.—If  
19 the Secretary assigns a test to an interval or  
20 band other than that recommended by the  
21 standing panel, the Secretary shall provide a  
22 detailed written explanation of the reasons for  
23 determining that such other interval or band is  
24 more appropriate.

1           (3) EFFECTIVE DATE OF SECRETARIAL DETER-  
2           MINATION.—A determination by the Secretary with  
3           respect to a coding or payment determination for an  
4           included test shall become effective as of the first  
5           day of the calendar quarter following the calendar  
6           quarter in which the determination is made.

7           (4) PERIODIC LOOK-BACKS OF INTERVAL OR  
8           BAND ASSIGNMENTS.—At the request of the inter-  
9           ested party that submitted the initial request for a  
10          test to be included in the demonstration or of a  
11          member of the standing panel, the standing panel  
12          may review the appropriateness of the payment in-  
13          terval or band to which the test is assigned and  
14          make a recommendation to the Secretary that the  
15          assignment be changed. The Secretary may accept  
16          or reject such recommendation, and if the rec-  
17          ommendation is rejected, the Secretary shall provide  
18          a detailed explanation of the reasons for such rejec-  
19          tion.

20          (5) PUBLICATION OF DETERMINATIONS.—The  
21          Secretary shall publish determinations under this  
22          subsection in a timely manner on an appropriate  
23          internet site.

24          (h) REPORTS TO CONGRESS.—

1           (1) IN GENERAL.—The Secretary shall submit  
2 interim and final reports on the demonstration to  
3 the Committees on Ways and Means and Energy  
4 and Commerce of the House of Representatives and  
5 the Committee on Finance of the Senate. The in-  
6 terim report shall be submitted not later than the  
7 close of the second year of the demonstration, and  
8 the final report shall be submitted not later than  
9 180 days after the close of the demonstration.

10           (2) CONTENT OF REPORTS.—The reports sub-  
11 mitted under paragraph (1) shall include interim  
12 and final—

13                   (A) determinations on whether coding and  
14 payment assignments under the demonstration  
15 provide for—

16                           (i) more equitable and accurate pay-  
17 ment for included tests; and

18                           (ii) reduced administrative complexity,  
19 improved efficiency, and improved access  
20 to care; and

21                   (B) recommendations on—

22                           (i) whether the alternative mechanism  
23 for determining payment and coding for in-  
24 cluded tests should be continued for such

1 tests beyond the 12-calendar-quarter pe-  
2 riod the demonstration is in effect; and

3 (ii) whether the application of such  
4 mechanism should be expanded to include  
5 other new clinical diagnostic laboratory  
6 tests for which payment would otherwise  
7 be made under the fee schedules and limits  
8 established under section 1833(h) of the  
9 Social Security Act (42 U.S.C. 1395l(h)).

10 (3) COMMENTS BY STANDING PANEL.—The  
11 standing panel shall submit comments to the com-  
12 mittees referred to in paragraph (1) on the interim  
13 and final reports of the Secretary.

14 (i) AUTHORIZATION OF APPROPRIATIONS.—There  
15 are authorized to be appropriated for each of fiscal years  
16 2008 through 2013, such sums as may be necessary to  
17 carry out this section.

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