

109TH CONGRESS
2^D SESSION

H. R. 5369

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

IN THE HOUSE OF REPRESENTATIVES

MAY 11, 2006

Mr. FERGUSON (for himself, Mr. ENGLISH of Pennsylvania, Mr. RUSH, and Mr. THOMPSON of California) 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 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 Clinical Laboratory Fee Schedule Improvement
6 Act of 2006”.

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-

1 tractor' have the meaning given to such terms under
2 section 1874A(a)(3).

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

12 “(iv) The term ‘non-governmental party’ in-
13 cludes—

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

18 “(II) a supplier (as defined in section
19 1861(d)) that furnishes such tests; and

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

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

1 “(i) in the case of a change other than a change
2 to correct an erroneous decision in determining such
3 amount, the authority provided by the preceding
4 provisions of this subsection, section 1842(b)(8), or
5 any regulations, manual instructions, or other regu-
6 latory guidance implementing such provisions; or

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

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

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

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

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

1 “(ii) Any request under this subparagraph shall in-
2 clude a statement of the basis for the non-governmental
3 party’s belief that an erroneous decision was made in de-
4 termining such amount, together with supporting evidence
5 and a description of any additional data (other than data
6 already in the possession of the appropriate medicare ad-
7 ministrative contractor) that—

8 “(I) is or may be in the possession of the Sec-
9 retary or another medicare administrative con-
10 tractor; and

11 “(II) is necessary to demonstrate that such an
12 erroneous decision exists.

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

24 “(iv) If additional data are made available to a non-
25 governmental party under clause (iii), such party may

1 amend its request under this subparagraph to incorporate
2 such data within 30 days after the date such data are
3 made available to such party.

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

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

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

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

23 “(vi) An appropriate medicare administrative con-
24 tractor to which a request is submitted under this sub-
25 paragraph may not reduce a fee schedule amount pursu-

1 ant to such request, and may reduce such an amount only
2 pursuant to section 1842(b)(8).

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

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

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

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

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

1 “(I) are or may be in the possession of the Sec-
2 retary or an another medicare administrative con-
3 tractor; and

4 “(II) are necessary to demonstrate that such an
5 erroneous decision exists.

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

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

22 “(v) The Secretary shall make a determination of
23 whether to correct the erroneous decision that is the sub-
24 ject of a request submitted under this subparagraph not
25 later than 60 days after the date of the submission of such

1 request, or if later, the submission of an amended request
2 under clause (iv). The Secretary shall determine that the
3 non-governmental party submitting the request—

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

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

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

15 “(vi) The Secretary may not reduce a fee schedule
16 amount pursuant to a request under this subparagraph
17 and may reduce such an amount only pursuant to section
18 1842(b)(8).

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

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

1 (b) EFFECTIVE DATE.—The amendment made by
2 subsection (a) shall take effect on the date of the enact-
3 ment of this Act and shall apply to requests for corrections
4 submitted on or after such date, without regard to whether
5 final regulations to carry out such amendment have been
6 issued.

7 **SEC. 102. ISSUANCE OF REGULATIONS ON GAP-FILLING**
8 **FOR MEDICARE FEE SCHEDULE FOR CLIN-**
9 **ICAL DIAGNOSTIC LABORATORY TESTS.**

10 Not later than one year after the date of the enact-
11 ment of this Act, the Secretary of Health and Human
12 Services shall issue final regulations specifying how an ap-
13 propriate medicare administrative contractor (as defined
14 in section 1874A(a)(3)(B) of the Social Security Act (42
15 U.S.C. 1395kk–1(a)(3)(B)) shall apply a gap-filling meth-
16 odology in determining fee schedule amounts established
17 under section 1833(h)(2)(A)(i) of such Act (42 U.S.C.
18 1395l(h)(2)(A)(i)). Such regulations shall specify—

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

1 (2) the principles to be employed to ensure that
2 such data are statistically significant and alter-
3 natives to follow if statistically significant data are
4 unavailable;

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

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

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

21 **SEC. 103. INCREASED TRANSPARENCY OF PROCESS FOR**
22 **DETERMINING FEE SCHEDULE AMOUNTS**
23 **FOR NEW TESTS.**

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

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

4 (2) in subparagraph (B)(iv)—

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

6 (B) by striking “determination,” and in-
7 serting “determination and”; and

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

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

14 **SEC. 104. ADVANCE NOTICE OF CLINICAL DIAGNOSTIC LAB-**
15 **ORATORY TEST AMOUNTS BEING CONSID-**
16 **ERED FOR ADJUSTMENT UNDER INHERENT**
17 **REASONABLENESS AUTHORITY.**

18 (a) **LIMIT ON INHERENT REASONABLENESS AU-**
19 **THORITY.**—Section 1842(b)(9)(A) of the Social Security
20 Act (42 U.S.C. 1395u(b)(9)(A)) is amended by adding at
21 the end the following: “Before publishing a proposed no-
22 tice under subparagraph (B) with respect to any clinical
23 diagnostic laboratory test being considered for adjustment
24 under paragraph (8), advance notice that such test is
25 being considered for such an adjustment shall be provided

1 to non-governmental parties (as defined in section
2 1833(h)(9)(A)(iv)) at the meeting required by section
3 1833(h)(8)(B)(iii), together with an opportunity for such
4 representatives and other individuals to make oral com-
5 ments on the appropriateness of such an adjustment for
6 such test.”.

7 (b) CONFORMING CHANGE.—Section 1833(h)(8)(B)
8 of such Act (42 U.S.C. 1395l(h)(8)(B)) is amended by
9 adding at the end the following:

10 “At the meeting required by clause (iii), the Secretary
11 shall provide advance notice of inherent reasonableness ad-
12 justments under section 1842(b)(8) that are being consid-
13 ered for clinical diagnostic laboratory tests, and afford an
14 opportunity for non-governmental parties (as defined
15 1833(h)(9)(A)(iv)) at the meeting to comment orally on
16 the appropriateness of such an adjustment.”.

17 (c) EFFECTIVE DATE.—The amendments made by
18 this section shall become effective on January 1, 2007,
19 and shall apply to inherent reasonableness adjustments
20 that have not been proposed as of such date.

TITLE II—FUTURE REFORM**SEC. 201. ESTABLISHMENT OF MEDICARE DEMONSTRATION
PROJECT TO EVALUATE NEW APPROACHES
TO CODING AND PAYMENT FOR CERTAIN MO-
LECULAR DIAGNOSTIC TESTS.**

(a) ESTABLISHMENT OF DEMONSTRATION.—

(1) DEMONSTRATION OF NEW APPROACHES TO CODING AND PAYMENT.—The Secretary of Health and Human Services (in this section referred to as the “Secretary”) shall establish a demonstration project under this section (in this section referred to as the “demonstration”) to evaluate new approaches to coding and payment under the medicare program for clinical diagnostic laboratory tests included in the demonstration (in this section referred to as “included tests”).

(2) DURATION.—The demonstration and any payment amounts assigned under the demonstration shall apply solely to claims submitted for included tests during the 12-calendar-quarter period that begins with the first day of the first calendar quarter to begin at least 250 days after the date of the enactment of this Act.

(3) SCOPE.—The demonstration shall apply on a national basis to included tests in all settings for

1 which payment for such tests would (but for the
2 demonstration) be made under the fee schedules and
3 limitation amounts established under section
4 1833(h) of the Social Security Act (42 U.S.C.
5 1395l(h)).

6 (4) ISSUANCE OF TEMPORARY HCPCS CODES;
7 CONTINUED APPLICATION OF SUCH CODES.—The
8 Secretary shall issue a temporary code or codes
9 under the Health Care Procedure Coding System
10 (HCPCS) when needed for an included test, and
11 such code or codes—

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

14 (B) shall not cease to apply solely because
15 the demonstration ends.

16 (b) INCLUDED TESTS.—

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

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

1 (B) there is the prospect—

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

4 (ii) that development of a new code,
5 or payment, or both, for the test under the
6 demonstration will result in reduced ad-
7 ministrative complexity and improved effi-
8 ciency.

9 (2) INCLUDED TESTS.—A clinical diagnostic
10 laboratory test shall be treated as an included test
11 if—

12 (A) an interested party submits a request
13 to the standing panel established under sub-
14 section (c) that the test be included in the dem-
15 onstration; and

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

18 (3) DEFINITIONS.—For purposes of this sec-
19 tion—

20 (A) the term “molecular diagnostic test”
21 means a clinical diagnostic laboratory test per-
22 formed on deoxyribonucleic (DNA), ribonucleic
23 acid (RNA), or protein that is drawn from a
24 human being or from a disease-causing orga-
25 nism; and

1 (B) the term “interested party” means,
2 with respect to a request for inclusion of molec-
3 ular diagnostic test in the demonstration, an in-
4 dividual entitled to benefits under title XVIII of
5 the Social Security Act, a manufacturer of the
6 test, a clinical laboratory offering the test, a
7 professional society, the Centers for Medicare &
8 Medicaid Services, a private payer for such test,
9 and a physician or other health care practi-
10 tioner.

11 (c) STANDING PANEL.—

12 (1) APPOINTMENT.—Not later than 60 days
13 after the date of the enactment of this section, the
14 Secretary shall appoint a standing panel (in this sec-
15 tion referred to as the “standing panel” or “panel”)
16 to determine whether a test is an included test and
17 make recommendations to the Secretary on the ap-
18 propriate coding of, and payment for, designated
19 clinical diagnostic laboratory tests under the dem-
20 onstration.

21 (2) COMPOSITION OF PANEL.—

22 (A) IN GENERAL.—The standing panel
23 shall be comprised of 12 members. Two of such
24 members shall be non-voting representatives of
25 the Administrator of the Centers for Medicare

1 & Medicaid Services. The Secretary shall ap-
2 point the other 10 members from—

3 (i) organizations representing large
4 clinical laboratories;

5 (ii) organizations representing small
6 clinical laboratories;

7 (iii) organizations representing physi-
8 cians with expertise in clinical diagnostic
9 laboratory tests;

10 (iv) organizations representing other
11 health professionals with expertise in such
12 tests;

13 (v) organizations representing manu-
14 facturers of such tests;

15 (vi) organizations representing indi-
16 viduals entitled to benefits under title
17 XVIII of the Social Security Act;

18 (vii) organizations representing pri-
19 vate payers for such tests (but not more
20 than one member may be appointed to rep-
21 resent such organizations);

22 (viii) individuals with expertise in clin-
23 ical laboratory cost accounting (both macro
24 and micro); and

1 (ix) individuals with other relevant ex-
2 pertise.

3 (B) TERMS OF OFFICE.—Each member of
4 the panel shall be appointed for the life of the
5 panel, except that any individual appointed to
6 fill a vacancy shall be appointed for the remain-
7 der of the term of the individual who is being
8 replaced. Any vacancy shall be filled in the
9 same manner, and with a representative of the
10 same category under subparagraph (A), as the
11 individual being replaced.

12 (3) RULES GOVERNING PANEL.—

13 (A) IN GENERAL.—The panel shall elect its
14 chair. A quorum shall be required to conduct
15 the business of the panel, and eight members of
16 the panel shall constitute a quorum.

17 (B) COMPENSATION.—While serving on
18 the business of the panel (including travel
19 time), a member of the panel shall be entitled
20 to compensation at the per diem equivalent rate
21 provided for level IV of the Executive Schedule
22 under section 5315 of title 5, United States
23 Code, and while so serving away from home and
24 the member's regular place of business, a mem-

1 ber may be allowed travel expenses as author-
2 ized by the chair of the panel.

3 (C) STAFFING.—

4 (i) DETAILING.—The panel may seek
5 such assistance and support of its duties
6 from appropriate Federal Departments
7 and agencies.

8 (ii) OUTSIDE EXPERTS.—The panel
9 may retain the services of such outside ex-
10 perts as are necessary for the evaluation of
11 a request under this section, and such ex-
12 perts shall not be voting members of the
13 panel.

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

23 (E) FACA.—The Federal Advisory Com-
24 mittee Act (5 U.S.C. App.) shall not apply to
25 the panel, but the panel may close any portion

1 of a meeting that could be closed if such Act
2 applied.

3 (F) TERMINATION OF PANEL.—The panel
4 shall terminate not more than 180 days after
5 the close of the demonstration.

6 (d) FORM AND CONTENT OF REQUESTS FOR INCLU-
7 SION IN THE DEMONSTRATION.—A request for inclusion
8 of a clinical diagnostic laboratory test in the demonstra-
9 tion shall be submitted in such form, and shall contain
10 such information as the standing panel may require, in-
11 cluding at least—

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

14 (2) any documentation in support of—

15 (A) the eligibility of the test for inclusion
16 in the demonstration; and

17 (B) any coding and payment determina-
18 tions requested with respect to the test, includ-
19 ing data on the typical direct and indirect lab-
20 oratory costs (including test acquisition costs)
21 of the test.

22 The Secretary shall cause to have published in the
23 Federal Register and on an appropriate internet site
24 public notice of each such request. Such information

1 shall be supplied to the Secretary by the standing
2 panel.

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

5 (1) IN GENERAL.—In determining whether a
6 requested payment determination should be granted,
7 and what the new payment amount for a test should
8 be, the standing panel (in making its recommenda-
9 tions to the Secretary) and the Secretary (in deter-
10 mining whether to grant such a determination) shall
11 take into account typical direct and indirect labora-
12 tory costs (including test acquisition costs), the ex-
13 pected impact of the test on patient care manage-
14 ment, and such other factors as the standing panel
15 and the Secretary, respectively, determine to be rel-
16 evant to the determination.

17 (2) STANDING PANEL.—Not later than 180
18 days after the appointment of all of the members of
19 the panel, the panel shall, after consultation with the
20 Secretary, establish and make available to the pub-
21 lic—

22 (A) standards and parameters for deter-
23 mining whether to recommend to the Secretary
24 a coding or payment determination specified in
25 a request for inclusion of a test in the dem-

1 onstration, which shall include a listing of data
2 elements necessary to support a request and a
3 standardized procedure for collecting and sub-
4 mitting data on typical costs to the panel;

5 (B) policies and procedures for protecting
6 the confidentiality of financial and other propri-
7 etary data submitted to the panel in support of
8 a request; and

9 (C) cost intervals or cost bands (as de-
10 scribed in subsection (g)(1)) that the panel rec-
11 ommends that the Secretary should use for the
12 assignment of included tests under the dem-
13 onstration.

14 (3) SECRETARIAL DETERMINATIONS.—The Sec-
15 retary shall develop and make available to public on
16 an internet site guidance documents on the stand-
17 ards and parameters that will be applied in making
18 Secretarial determinations and on the cost intervals
19 or cost bands to be used under the demonstration
20 and on whether to grant a request for a payment or
21 coding determination. Such guidance documents
22 shall be developed, which shall be made available to
23 the public at least 10 days before the beginning of
24 the demonstration, in a manner similar to the man-
25 ner in which guidance documents are developed

1 under section 701(h) of the Federal Food, Drug,
2 and Cosmetic Act (21 U.S.C. 371(h)).

3 (4) AUTHORITY TO RECOMMEND REVISIONS TO,
4 AND TO REVISE, COST INTERVALS OR COST
5 BANDS.—Nothing in this section shall be construed
6 as limiting the authority of the standing panel to
7 recommend, or the Secretary to adopt, new cost in-
8 tervals or cost bands to accommodate changes in
9 technology.

10 (f) REVIEW PROCESS.—

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

21 (2) RECOMMENDATIONS OF STANDING
22 PANEL.—The standing panel shall review each re-
23 quest for a coding or payment determination that is
24 made with respect to an included test. Applying the
25 standards and parameters developed under sub-

1 section (e)(2)(A), the panel shall make a rec-
2 ommendation to the Secretary with respect to each
3 requested determination.

4 (3) SECRETARIAL DETERMINATIONS.—

5 (A) QUARTERLY DETERMINATIONS.—The
6 Secretary shall make determinations on whether
7 to grant requested coding and payment deter-
8 minations on a quarterly basis, but is not re-
9 quired to make such a determination for every
10 request made (or with respect to which a rec-
11 ommendation is received from the standing
12 panel) during a particular quarter.

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

23 (g) PAYMENT METHODOLOGY.—

24 (1) IN GENERAL.—Included tests shall be paid
25 in accordance with a methodology, developed by the

1 standing panel, that establishes cost intervals or cost
2 bands in a manner similar to those that are used as
3 new technology ambulatory payment classification
4 groups for hospital outpatient services under section
5 1833(t) of the Social Security Act (42 U.S.C.
6 1395l(t)), with a test being assigned to the cost in-
7 terval or cost band that most closely approximates
8 the typical direct and indirect costs (including test
9 acquisition costs) of the test for a laboratory. Tests
10 that are included tests for purposes of this section
11 shall be excluded from any demonstration project
12 under section 1847(e) of such Act (42 U.S.C.
13 1395w-3(e)).

14 (2) PANEL RECOMMENDATIONS; SECRETARIAL
15 DETERMINATIONS.—

16 (A) RECOMMENDATIONS; SECRETARIAL
17 DETERMINATIONS.—The standing panel shall
18 recommend to the Secretary a cost interval or
19 cost band to which an included test should be
20 assigned, and the Secretary may assign such
21 test to such band or interval or to another band
22 or interval the Secretary determines to more
23 closely approximate the typical direct and indi-
24 rect costs (including test acquisition costs) of
25 the test.

1 (B) EXPLANATION OF DETERMINATION
2 THAT DIFFERS FROM RECOMMENDATION.—If
3 the Secretary assigns a test to a cost interval
4 or band other than that recommended by the
5 standing panel, the Secretary shall provide a
6 detailed written explanation of the reasons for
7 determining that such other interval or band is
8 more appropriate.

9 (3) EFFECTIVE DATE OF SECRETARIAL DETER-
10 MINATION.—A determination by the Secretary with
11 respect to a coding or payment determination for an
12 included test shall become effective as of the first
13 day of the calendar quarter following the calendar
14 quarter in which the determination is made.

15 (4) PERIODIC LOOK-BACKS OF INTERVAL OR
16 BAND ASSIGNMENTS.—At the request of the inter-
17 ested party that submitted the initial request for a
18 test to be included in the demonstration or of a
19 member of the standing panel, the standing panel
20 may review the appropriateness of the payment in-
21 terval or band to which the test is assigned and
22 make a recommendation to the Secretary that the
23 assignment be changed. The Secretary may accept
24 or reject such recommendation, and if the rec-
25 ommendation is rejected, the Secretary shall provide

1 a detailed explanation of the reasons for such rejection.
2

3 (5) PUBLICATION OF DETERMINATIONS.—The
4 Secretary shall publish determinations under this
5 subsection in a timely manner on an appropriate
6 internet site.

7 (h) REPORTS TO CONGRESS.—

8 (1) IN GENERAL.—The Secretary shall submit
9 interim and final reports on the demonstration to
10 the Committees on Ways and Means and Energy
11 and Commerce of the House of Representatives and
12 the Committee on Finance of the Senate. The in-
13 terim report shall be submitted not later than the
14 close of the second year of the demonstration, and
15 the final report shall be submitted not later than
16 180 days after the close of the demonstration.

17 (2) CONTENT OF REPORTS.—The reports sub-
18 mitted under paragraph (1) shall include interim
19 and final—

20 (A) determinations on whether coding and
21 payment assignments under the demonstration
22 provide for—

23 (i) more equitable and accurate pay-
24 ment for included tests; and

1 (ii) reduced administrative complexity,
2 improved efficiency, and improved access
3 to care; and

4 (B) recommendations on—

5 (i) whether the alternative mechanism
6 for determining payment and coding for in-
7 cluded tests should be continued for such
8 tests beyond the 12-calendar-quarter pe-
9 riod the demonstration is in effect; and

10 (ii) whether the application of such
11 mechanism should be expanded to include
12 other new clinical diagnostic laboratory
13 tests for which payment would otherwise
14 be made under the fee schedules and limits
15 established under section 1833(h) of the
16 Social Security Act (42 U.S.C. 1395l(h)).

17 (3) COMMENTS BY STANDING PANEL.—The
18 standing panel shall submit comments to the com-
19 mittees referred to in paragraph (1) on the interim
20 and final reports of the Secretary.

21 (i) AUTHORIZATION OF APPROPRIATIONS.—There
22 are authorized to be appropriated for each of fiscal years
23 2007 through 2012, such sums as may be necessary to
24 carry out this section.

○