

111TH CONGRESS
1ST SESSION

H. R. 1452

To require the Secretary of Health and Human Services to enter into negotiated rulemaking to modernize the Medicare part B fee schedule for clinical diagnostic laboratory tests and to amend title XVIII of the Social Security Act to adjust the fee for collecting specimens for clinical diagnostic laboratory tests under the Medicare Program.

IN THE HOUSE OF REPRESENTATIVES

MARCH 11, 2009

Mr. STUPAK (for himself and Mr. BURGESS) 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 require the Secretary of Health and Human Services to enter into negotiated rulemaking to modernize the Medicare part B fee schedule for clinical diagnostic laboratory tests and to amend title XVIII of the Social Security Act to adjust the fee for collecting specimens for clinical diagnostic laboratory tests 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,*

1 **SEC. 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) SHORT TITLE.—This Act may be cited as the
3 “Medicare Clinical Diagnostic Laboratory Fee Schedule
4 Modernization Act of 2009”.

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

Sec. 1. Short title; table of contents.

TITLE I—UPDATING THE CLINICAL LABORATORY FEE
SCHEDULE

Sec. 101. Findings and purpose.

Sec. 102. Process for the modernization of the fee schedule for clinical diag-
nostic laboratory tests.

Sec. 103. Establishment and duties of negotiated rulemaking committee.

Sec. 104. Result of committee action.

Sec. 105. Report by MedPAC.

Sec. 106. Definitions.

TITLE II—UPDATING THE SPECIMEN COLLECTION FEE

Sec. 201. Adjustment in Medicare laboratory specimen collection fee.

7 **TITLE I—UPDATING THE CLIN-**
8 **ICAL LABORATORY FEE**
9 **SCHEDULE**

10 **SEC. 101. FINDINGS AND PURPOSE.**

11 (a) FINDINGS.—The Congress finds the following:

12 (1) The fee schedule for clinical diagnostic lab-
13 oratory tests under part B of the Medicare program
14 was developed in 1984 based on the local prevailing
15 fees charged in 1983.

16 (2) The cost of clinical diagnostic laboratory
17 tests, laboratory equipment, supplies, and medical

1 professional staff has increased exponentially in re-
2 cent years.

3 (3) Clinical laboratories are currently reim-
4 bursed at levels below those provided in 1984 when
5 adjusted for inflation.

6 (4) The fee schedule for clinical diagnostic lab-
7 oratory tests is the last Medicare fee schedule that
8 has not been made reliant on prospective payment or
9 relative value as the primary payment methodology.

10 (5) Clinical laboratories provide vital informa-
11 tion that influences 70 percent of all patient care de-
12 cisions.

13 (b) PURPOSE.—The purpose of this Act is—

14 (1) to ensure Medicare beneficiary access to the
15 best laboratory services and most advanced testing
16 available;

17 (2) to modernize the fee schedule for clinical di-
18 agnostic laboratory tests under part B of the Medi-
19 care program to reflect the increased cost and en-
20 hanced technology involved in laboratory testing and
21 to reflect accurately and equitably the value of such
22 testing to the health care system;

23 (3) to involve relevant stakeholders in the clin-
24 ical laboratory industry in the process of such fee

1 schedule modernization, including Medicare bene-
2 ficiaries, health care providers, and laboratories; and
3 (4) to create mechanisms for periodic revisions,
4 inflationary updates, and inclusion of new meth-
5 odologies to the fee schedule for clinical diagnostic
6 laboratory tests in order to reflect market condi-
7 tions.

8 **SEC. 102. PROCESS FOR THE MODERNIZATION OF THE FEE**
9 **SCHEDULE FOR CLINICAL DIAGNOSTIC LAB-**
10 **ORATORY TESTS.**

11 (a) IN GENERAL.—Pursuant to the provisions of this
12 title and consistent with the elements described in sub-
13 section (b), the Secretary of Health and Human Services
14 shall—

15 (1) establish under section 103(a) a negotiated
16 rulemaking committee to negotiate and develop a
17 proposed rule for a Medicare modernized clinical di-
18 agnostic laboratory fee schedule (as defined in sec-
19 tion 106(3));

20 (2) not later than 24 months after the date of
21 the enactment of this Act and pursuant to such ne-
22 gotiated rulemaking process, submit to Congress a
23 report under section 103(f)(2)(B) relating to such
24 Medicare modernized clinical diagnostic fee schedule;
25 and

1 (3) promulgate under section 104 final regula-
2 tions establishing such Medicare modernized clinical
3 diagnostic fee schedule if the Committee reaches
4 consensus.

5 (b) ELEMENTS.—

6 (1) ELEMENTS FOR INCLUSION.—The nego-
7 tiated rulemaking committee established under sec-
8 tion 103 shall consider the following elements and
9 include them in the proposed rule for a Medicare
10 modernized clinical diagnostic laboratory fee sched-
11 ule:

12 (A) Access, to the greatest extent possible,
13 by all individuals enrolled in part B of title
14 XVIII of the Social Security Act to quality lab-
15 oratory services in all settings.

16 (B) Establishment of a single, rational,
17 and national fee schedule for clinical diagnostic
18 laboratory tests.

19 (C) A mechanism to periodically revise the
20 fee schedule for years subsequent to the first
21 year in which the fee schedule is implemented
22 that includes the following components:

23 (i) The mechanism is sufficiently
24 adaptable to incorporate new clinical lab-
25 oratory tests and technology into the fee

1 schedule in a timely manner and to provide
2 appropriate reimbursement for these tests.

3 (ii) The mechanism periodically and
4 appropriately revises clinical laboratory re-
5 imbursement to reflect the evolution of
6 costs, value, and utilization of such tests.

7 (iii) The mechanism is not based on
8 an arbitrary cap.

9 (iv) The mechanism provides for revi-
10 sions to the fee schedule at least once
11 every five years, but not more frequently
12 than annually.

13 (v) The mechanism provides for input
14 from relevant stakeholders, including pa-
15 tients, health care providers, and clinical
16 laboratories.

17 (D) For the first year for which the fee
18 schedule is implemented, the fee schedule shall
19 be designed to result in the same amount of ag-
20 gregate payments under such schedule for clin-
21 ical laboratory services furnished during such
22 year for which payment is made under part B
23 of title XVIII of the Social Security Act as
24 would have been made under section 1833(h) of
25 such Act for such services if this section had

1 not been enacted (taking into account annual
2 adjustments under paragraph (2) of such sec-
3 tion, the annual addition of new tests under
4 paragraph (8) of such section, and any other
5 utilization increases that would have been rec-
6 ognized under such section).

7 (E) A mechanism to provide for automatic
8 annual inflationary updates to the fee schedule
9 for each year after the first year for which the
10 fee schedule is implemented.

11 (F) A transition period to phase in the ap-
12 plication of the payment rates under the fee
13 schedule based on blended payment rates be-
14 tween such fee schedule and the fee schedule in
15 effect on the day before the date of the enact-
16 ment of this Act under section 1833(h) of the
17 Social Security Act for clinical laboratory serv-
18 ices, which is to be provided in an efficient and
19 fair manner.

20 (G) A fee schedule that does not utilize
21 beneficiary cost sharing.

22 (2) ELEMENTS FOR CONSIDERATION.—Such
23 negotiated rulemaking committee shall consider
24 whether to include the following elements in the

1 Medicare modernized clinical diagnostic laboratory
2 fee schedule:

3 (A) A fee schedule that provides for great-
4 er administrative simplicity and efficiency by
5 eliminating or reducing the number of differen-
6 tial payment rates in existence on the day be-
7 fore the date of the enactment of this Act under
8 section 1833(h) of the Social Security Act for
9 clinical diagnostic laboratory tests.

10 (B) A fee schedule that addresses the
11 unique reimbursement problems laboratories
12 face as indirect providers, including require-
13 ments that laboratories must rely on diagnosis
14 codes provided by ordering providers.

15 **SEC. 103. ESTABLISHMENT AND DUTIES OF NEGOTIATED**
16 **RULEMAKING COMMITTEE.**

17 (a) ESTABLISHMENT.—Not later than 30 days after
18 the date of the enactment of this Act, the Secretary shall
19 publish a notice in the Federal Register of intent to estab-
20 lish a negotiated rulemaking committee (in this title re-
21 ferred to as the “Committee”) in accordance with sub-
22 chapter III of chapter 5 of title 5, United States Code
23 (5 U.S.C. 561 et seq.) and this section to negotiate and
24 develop a proposed rule for a Medicare modernized clinical
25 diagnostic laboratory fee schedule (as defined in section

1 106(3)). Not later than 60 days after the day on which
2 such notice of intent is published, the Secretary shall ap-
3 point members to the Committee in accordance with sub-
4 section (b).

5 (b) COMPOSITION OF COMMITTEE.—

6 (1) IN GENERAL.—Notwithstanding section
7 565(b) of title 5, United States Code, the Committee
8 shall be composed of 19 voting members appointed
9 pursuant to paragraph (2) and 2 nonvoting members
10 appointed pursuant to paragraph (3).

11 (2) VOTING MEMBERS.—The Secretary shall
12 appoint as voting members of the Committee individ-
13 uals as follows:

14 (A) One individual from an organization
15 primarily representing independent clinical lab-
16 oratories operating on a national basis.

17 (B) One individual from an organization
18 primarily representing independent clinical lab-
19 oratories operating on a regional or local basis.

20 (C) One individual from an organization
21 representing hospitals that perform clinical di-
22 agnostic laboratory tests.

23 (D) Two individuals from organizations
24 representing physicians with expertise in clinical
25 diagnostic laboratory tests.

1 (E) Three individuals from organizations
2 representing non-physicians with expertise in
3 clinical diagnostic laboratory tests.

4 (F) One individual from an organization
5 representing manufacturers of equipment de-
6 signed for clinical diagnostic laboratory tests.

7 (G) One individual from an organization
8 representing individuals enrolled under part B
9 of title XVIII of the Social Security Act.

10 (H) One individual from an organization
11 representing private payers for clinical diag-
12 nostic laboratory tests.

13 (I) One individual with expertise in meas-
14 uring resource utilization by clinical diagnostic
15 laboratories in performing tests.

16 (J) One individual with a background in
17 health economics and the ability to quantify the
18 value of clinical diagnostic laboratory tests.

19 (K) Two individuals from organizations
20 representing generalist non-physicians with ex-
21 pertise in clinical diagnostic laboratory tests.

22 (L) One individual who is a physician or
23 clinician who prescribes clinical diagnostic lab-
24 oratory tests.

1 (M) One individual who is a physician or
2 clinician who performs point-of-care tests in the
3 physician's or clinician's office.

4 (N) One individual from an organization
5 representing individuals with scientific back-
6 ground and experience in clinical laboratory
7 health care services.

8 (O) One individual from an organization
9 representing managers or supervisors of clinical
10 laboratories.

11 (3) NONVOTING MEMBERS.—The Secretary
12 shall appoint one nonvoting member to the Com-
13 mittee. The Chairman of the Medicare Payment Ad-
14 visory Commission shall appoint one nonvoting mem-
15 ber to the Committee.

16 (c) DUTIES OF COMMITTEE.—The Committee shall
17 negotiate and attempt to reach a consensus (as defined
18 in section 562(2) of title 5, United States Code) con-
19 cerning a proposed rule with respect to establishing a
20 Medicare modernized clinical diagnostic laboratory fee
21 schedule and any other matter the committee determines
22 is relevant to the proposed rule. In its negotiations, the
23 Committee shall take into account the purpose described
24 in section 101(b), the elements listed in section 102(b),
25 and the input of relevant stakeholders.

1 (d) TERM; VACANCIES.—

2 (1) TERM.—Each member of the Committee
3 shall be appointed for the life of the Committee.

4 (2) VACANCIES.—A vacancy on the Committee
5 shall be filled in the same manner in which the origi-
6 nal appointment was made.

7 (e) ADMINISTRATIVE PROVISIONS.—

8 (1) QUORUM.—A quorum shall be required to
9 conduct the business of the Committee. Twelve
10 members of the Committee shall constitute a
11 quorum.

12 (2) MEETINGS.—The Committee shall meet at
13 the call of the Facilitator (as chosen under section
14 566(c) of title 5, United States Code), the Secretary,
15 or a quorum of the members of the Committee.

16 (3) COMPENSATION.—The members of the
17 Committee may be compensated in accordance with
18 section 568(c) of title 5, United States Code.

19 (4) STAFFING.—

20 (A) DETAILING.—Any Federal Govern-
21 ment employee may be detailed to the Com-
22 mittee without reimbursement from the Com-
23 mittee, and such detailee shall retain the rights,
24 status, and privileges of their regular employ-
25 ment without interruption.

1 (B) TECHNICAL ASSISTANCE.—If author-
2 ized by the Secretary and approved by a major-
3 ity of the Committee, the Committee may retain
4 the services of experts and consultants under
5 section 3109(b) of title 5, United States Code,
6 but at rates not to exceed the daily equivalent
7 of the annual rate of basic pay for level IV of
8 the Executive Schedule under section 5315 of
9 such title.

10 (5) APPLICABILITY OF FACA.—The Federal Ad-
11 visory Committee Act (5 U.S.C. App.) shall apply to
12 the Committee in accordance with section 565(a)(1)
13 of title 5, United States Code.

14 (f) REPORTS.—

15 (1) COMMITTEE REPORTS.—

16 (A) INTERIM REPORTS.—

17 (i) INITIAL INTERIM REPORT.—Not
18 later than 6 months after the date on
19 which members are required to be ap-
20 pointed to the Committee under subsection
21 (a), the Committee shall submit to the Sec-
22 retary an initial interim report on the
23 Committee's progress in negotiating a pro-
24 posed rule to establish a Medicare modern-
25 ized clinical diagnostic laboratory fee

1 schedule, including the Committee's pre-
2 liminary determinations regarding the es-
3 tablishment of such fee schedule and in-
4 cluding preliminary determinations on the
5 information described in subparagraph
6 (B).

7 (ii) SUBSEQUENT INTERIM REPORT.—

8 The Committee shall submit to the Sec-
9 retary a subsequent interim report, which
10 shall include updates to the determinations
11 made in the report submitted under clause
12 (i). Such subsequent interim report shall
13 be submitted not later than 12 months
14 after the date on which members are re-
15 quired to be appointed to the Committee
16 under subsection (a).

17 (iii) EXCEPTION.—An interim report

18 described in this subparagraph is not re-
19 quired to be submitted in the case that a
20 final report under subparagraph (B) is
21 submitted before the date on which such
22 interim report is required to be submitted
23 under this subparagraph.

24 (B) FINAL REPORT.—Not later than 18

25 months after the date on which members are

1 required to be appointed to the Committee
2 under subsection (a), the Committee shall sub-
3 mit to the Secretary a final report, including
4 the following:

5 (i) If the Committee reaches con-
6 sensus by such 18-month date on a pro-
7 posed rule to establish a Medicare modern-
8 ized clinical diagnostic laboratory fee
9 schedule—

10 (I) the consensus proposed rule
11 reached by the Committee; and

12 (II) the Committee's determina-
13 tion regarding the extent to which,
14 and manner in which, the proposed
15 fee schedule will achieve the purpose
16 described in section 101(b) and ad-
17 dress the elements described in sec-
18 tion 102(b).

19 (ii) If the Committee fails to reach
20 consensus by such 18-month date on a pro-
21 posed rule to establish a Medicare modern-
22 ized clinical diagnostic laboratory fee
23 schedule—

24 (I) any components of a fee
25 schedule or other areas upon which

1 consensus was achieved in accordance
2 with the purpose described in section
3 101(b) and the elements described in
4 section 102(b); and

5 (II) any components of a fee
6 schedule or other areas upon which
7 disagreement prevented consensus
8 from being achieved in accordance
9 with the purpose described in section
10 101(b) and the elements described in
11 section 102(b).

12 (2) SECRETARIAL REPORTS.—

13 (A) INTERIM REPORTS.—Not later than 30
14 days after the date of the submission of each
15 interim report under paragraph (1)(A), the Sec-
16 retary shall submit to the Committee on Energy
17 and Commerce and the Committee on Ways
18 and Means of the House of Representatives and
19 the Committee on Finance of the Senate an in-
20 terim report on the progress of the negotiated
21 rulemaking process under this section to estab-
22 lish a Medicare modernized clinical diagnostic
23 laboratory fee schedule. Each such report shall
24 include the corresponding interim report sub-
25 mitted by the Committee under such paragraph.

1 (B) FINAL REPORT.—Not later 24 months
2 after the date of the enactment of this Act, the
3 Secretary shall submit to the Committee on En-
4 ergy and Commerce and the Committee on
5 Ways and Means of the House of Representa-
6 tives and the Committee on Finance of the Sen-
7 ate a final report, including—

8 (i) the final report of the Committee
9 submitted under paragraph (1)(B); and

10 (ii) in the case that the Committee
11 reaches a consensus on a proposed rule to
12 establish a Medicare modernized clinical
13 diagnostic laboratory fee schedule, the Sec-
14 retary's proposed regulation to implement
15 the proposed rule.

16 (3) PUBLIC AVAILABILITY OF REPORTS.—The
17 Secretary shall make each report submitted under
18 this subsection available to the public on the official
19 Internet website of the Department of Health and
20 Human Services.

21 **SEC. 104. RESULT OF COMMITTEE ACTION.**

22 (a) COMMITTEE CONSENSUS.—If the Committee
23 reaches a consensus under section 103 on a proposed rule
24 to establish a Medicare modernized clinical diagnostic lab-
25 oratory fee schedule, the Secretary shall, to the maximum

1 extent possible consistent with the legal obligations of the
2 agency, use the consensus of the Committee as the basis
3 for the rule proposed by the agency for notice and com-
4 ment and, not later than 36 months after the date of the
5 enactment of this Act, issue final regulations to apply to
6 items and services furnished on or after the first January
7 1st following the date of the promulgation of such final
8 regulations.

9 (b) LACK OF COMMITTEE CONSENSUS.—If the Com-
10 mittee fails to reach a consensus under section 103 on a
11 proposed rule to establish a Medicare modernized clinical
12 diagnostic laboratory fee schedule, authority remains with
13 the Congress to establish such fee schedule, taking into
14 account the purpose described in section 101(b) and the
15 elements described in section 102(b) and the report pro-
16 vided by the Medicare Payment Advisory Commission
17 under section 105(2).

18 **SEC. 105. REPORT BY MEDPAC.**

19 Not later than 39 months after the date of the enact-
20 ment of this Act, the Medicare Payment Advisory Com-
21 mission shall submit to Congress a report, including the
22 following recommendations:

23 (1) COMMITTEE CONSENSUS.—In the case that
24 the Committee reaches consensus under section 103
25 on a proposed rule to establish a Medicare modern-

1 ized clinical diagnostic laboratory fee schedule, with
2 respect to the Secretary’s proposed regulation sub-
3 mitted under section 103(f)(2)(B)(ii) to implement
4 such proposed rule—

5 (A) whether the overall level of expendi-
6 tures under title XVIII of the Social Security
7 Act for clinical laboratory services under the re-
8 vised fee schedule under such proposed regula-
9 tion is adequate to ensure beneficiary access to
10 high quality testing; and

11 (B) whether the periodic revision and infla-
12 tionary update mechanisms in the proposed reg-
13 ulation are adequate to ensure beneficiary ac-
14 cess to high quality testing.

15 (2) LACK OF COMMITTEE CONSENSUS.—In the
16 case that the Committee does not reach consensus
17 under section 103 on a proposed rule to establish a
18 Medicare modernized clinical diagnostic laboratory
19 fee schedule—

20 (A) how to modernize such clinical labora-
21 tory fee schedule in accordance with the pur-
22 pose described in section 101(b) and the ele-
23 ments described in section 102(b), including
24 with respect to such areas identified in the re-
25 port submitted under section 103(f)(1)(B)(ii) as

1 areas in which consensus was not reached by
2 the Committee;

3 (B) how to ensure the overall level of ex-
4 penditures under part B of title XVIII of such
5 Act for clinical laboratory services under a re-
6 vised fee schedule is adequate to ensure bene-
7 ficiary access to high quality testing; and

8 (C) how to ensure that periodic revision
9 and inflationary update mechanisms in a pro-
10 posed revised fee schedule for clinical laboratory
11 services are adequate to ensure beneficiary ac-
12 cess to high quality testing.

13 **SEC. 106. DEFINITIONS.**

14 For purposes of this title:

15 (1) COMMITTEE.—The term “Committee”
16 means the negotiated rulemaking committee estab-
17 lished under section 103(a).

18 (2) CONSENSUS.—The term “consensus” has
19 the meaning given such term under section 562(2)
20 of title 5, United States Code.

21 (3) MEDICARE MODERNIZED CLINICAL DIAG-
22 NOSTIC LABORATORY FEE SCHEDULE.—The term
23 “Medicare modernized clinical diagnostic laboratory
24 fee schedule” means a modernized fee schedule for
25 payment under part B of title XVIII of the Social

1 Security Act for clinical diagnostic laboratory tests,
 2 the payment for which, as of the day before the date
 3 of the enactment of this Act, is provided for under
 4 section 1833(h) of the Social Security Act (42
 5 U.S.C. 1395l(h)).

6 (4) NEGOTIATED RULEMAKING.—The term
 7 “negotiated rulemaking” has the meaning given
 8 such term under section 562(6) of title 5, United
 9 States Code.

10 (5) NEGOTIATED RULEMAKING COMMITTEE.—
 11 The term “negotiated rulemaking committee” has
 12 the meaning given such term under section 562(7)
 13 of title 5, United States Code.

14 (6) SECRETARY.—The term “Secretary” means
 15 the Secretary of Health and Human Services.

16 **TITLE II—UPDATING THE** 17 **SPECIMEN COLLECTION FEE**

18 **SEC. 201. ADJUSTMENT IN MEDICARE LABORATORY SPECI-** 19 **MEN COLLECTION FEE.**

20 (a) IN GENERAL.—Section 1833(h) of the Social Se-
 21 curity Act (42 U.S.C. 1395l(h)) is amended—

22 (1) in paragraph (3)(A), by inserting “in the
 23 amount specified in paragraph (8)” after “a nominal
 24 fee”; and

1 (2) by adding at the end the following new
2 paragraph:

3 “(8) The amount specified in this paragraph,
4 for the nominal fee under paragraph (3)(A) for tests
5 performed in—

6 “(A) 2010, is \$6.04; or

7 “(B) a subsequent year, is the amount
8 specified in this paragraph for tests performed
9 in the preceding year adjusted by the annual
10 percentage increase or decrease in the Con-
11 sumer Price Index for All Urban Consumers
12 (United States city average).”.

13 (b) EFFECTIVE DATE.—The amendments made by
14 subsection (a) shall apply to fees for tests performed on
15 or after January 1, 2010.

○