

110TH CONGRESS
2D SESSION

H. R. 6761

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.

IN THE HOUSE OF REPRESENTATIVES

JULY 31, 2008

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medicare Clinical Di-
5 agnostic Laboratory Fee Schedule Modernization Act of
6 2008”.

1 **SEC. 2. FINDINGS AND PURPOSE.**

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

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

7 (2) The cost of clinical diagnostic laboratory
8 tests, laboratory equipment, supplies, and medical
9 professional staff has increased exponentially in re-
10 cent years.

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

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

18 (5) Clinical laboratories provide vital informa-
19 tion that influences 70 percent of all patient care de-
20 cisions.

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

22 (1) to ensure Medicare beneficiary access to the
23 best laboratory services and most advanced testing
24 available;

25 (2) to modernize the fee schedule for clinical di-
26 agnostic laboratory tests under part B of the Medi-

1 care program to reflect the increased cost and en-
2 hanced technology involved in laboratory testing and
3 to reflect accurately and equitably the value of such
4 testing to the health care system;

5 (3) to involve relevant stakeholders in the clin-
6 ical laboratory industry in the process of such fee
7 schedule modernization, including Medicare bene-
8 ficiaries, health care providers, and laboratories; and

9 (4) to create mechanisms for periodic revisions
10 and inflationary updates to the fee schedule for clin-
11 ical diagnostic laboratory tests in order to reflect
12 market conditions.

13 **SEC. 3. PROCESS FOR THE MODERNIZATION OF THE FEE**
14 **SCHEDULE FOR CLINICAL DIAGNOSTIC LAB-**
15 **ORATORY TESTS.**

16 (a) IN GENERAL.—Pursuant to the provisions of this
17 Act and consistent with the elements described in sub-
18 section (b), the Secretary of Health and Human Services
19 shall—

20 (1) establish under section 4(a) a negotiated
21 rulemaking committee to negotiate and develop a
22 proposed rule for a Medicare modernized clinical di-
23 agnostic laboratory fee schedule (as defined in sec-
24 tion 7(3));

1 (2) not later than 24 months after the date of
2 the enactment of this Act and pursuant to such ne-
3 gotiated rulemaking process, submit to Congress a
4 report under section 4(f)(2)(B) relating to such
5 Medicare modernized clinical diagnostic fee schedule;
6 and

7 (3) promulgate under section 5 final regulations
8 establishing such Medicare modernized clinical diag-
9 nostic fee schedule.

10 (b) ELEMENTS TO CONSIDER.—The Medicare mod-
11 ernized clinical diagnostic laboratory fee schedule devel-
12 oped pursuant to this Act shall provide, to the greatest
13 extent possible, for access by all individuals enrolled in
14 part B of title XVIII of the Social Security Act to quality
15 laboratory services in all settings and establish a new sin-
16 gle, rational, and national fee schedule for clinical diag-
17 nostic laboratory tests under such part that incorporates
18 the following elements:

19 (1) A primary base payment rate computed in
20 accordance with the following:

21 (A) The payment rate is value-based on
22 appropriate resource allocations to the adminis-
23 tration of clinical laboratory tests for overall pa-
24 tient care management and based on potential
25 cost-savings to the Medicare program under

1 such title XVIII resulting from the administra-
2 tion of clinical laboratory tests.

3 (B) The payment rate takes into account
4 industry-wide clinical laboratory practice ex-
5 penses, including liability costs and costs of col-
6 lection and transportation of specimens.

7 (2) An adjustment to the primary base payment
8 rate to take into account variations in the cost of
9 furnishing such services—

10 (A) among various geographic areas;

11 (B) among various types of clinical labora-
12 tory settings for comparable services; and

13 (C) to various populations of individuals
14 enrolled in part B of such title, including such
15 populations served by skilled nursing facilities,
16 such populations served by hospital outpatient
17 departments, and such populations served by
18 physician offices.

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

23 (A) The mechanism is sufficiently adapt-
24 able to incorporate new clinical laboratory tests

1 and technology into the fee schedule in a timely
2 manner.

3 (B) The mechanism periodically and ap-
4 propriately revises clinical laboratory reimburse-
5 ment to reflect the evolution of costs, value, and
6 utilization of such tests.

7 (C) The mechanism is not based on an ar-
8 bitrary cap.

9 (D) The mechanism provides for revisions
10 to the fee schedule at least once every five
11 years, but not more frequently than annually.

12 (E) The mechanism provides for input
13 from relevant stakeholders, including patients,
14 health care providers, and clinical laboratories.

15 (4) For the first year for which the fee schedule
16 is implemented, the fee schedule shall be designed to
17 result in the same amount of aggregate payments
18 under such schedule for clinical laboratory services
19 furnished during such year for which payment is
20 made under part B of the Social Security Act as
21 would have been made under section 1833(h) of
22 such Act for such services if this section had not
23 been enacted (taking into account annual adjust-
24 ments under paragraph (2) of such section, the an-
25 nual addition of new tests under paragraph (8) of

1 such section, and any other utilization increases that
2 would have been recognized under such section).

3 (5) A mechanism to provide for automatic an-
4 nual inflationary updates to the fee schedule for
5 each fiscal year after the first fiscal year for which
6 the fee schedule is implemented.

7 (6) A transition period to phase in the applica-
8 tion of the payment rates under the fee schedule
9 based on blended payment rates between such fee
10 schedule and the fee schedule in effect on the day
11 before the date of the enactment of this Act under
12 section 1833(h) of the Social Security Act for clin-
13 ical laboratory services, which is to be provided in an
14 efficient and fair manner.

15 (7) The fee schedule shall provide for greater
16 administrative simplicity and efficiency by elimi-
17 nating or reducing the number of differential pay-
18 ment rates in existence on the day before the date
19 of the enactment of this Act under section 1833(h)
20 of the Social Security Act for clinical diagnostic lab-
21 oratory tests.

22 (8) The fee schedule does not utilize beneficiary
23 cost sharing.

1 **SEC. 4. ESTABLISHMENT AND DUTIES OF NEGOTIATED**
2 **RULEMAKING COMMITTEE.**

3 (a) **ESTABLISHMENT.**—Not later than 30 days after
4 the date of the enactment of this Act, the Secretary shall
5 publish a notice in the Federal Register of intent to estab-
6 lish a negotiated rulemaking committee (in this Act re-
7 ferred to as the “Committee”) in accordance with sub-
8 chapter III of chapter 5 of title 5, United States Code
9 (5 U.S.C. 561 et seq.) and this section to negotiate and
10 develop a proposed rule for a Medicare modernized clinical
11 diagnostic laboratory fee schedule (as defined in section
12 7(3)). Not later than 60 days after the day on which such
13 notice of intent is published, the Secretary shall appoint
14 members to the Committee in accordance with subsection
15 (b).

16 (b) **COMPOSITION OF COMMITTEE.**—

17 (1) **IN GENERAL.**—Notwithstanding section
18 565(b) of title 5, United States Code, the Committee
19 shall be composed of 15 voting members appointed
20 pursuant to paragraph (2) and 2 nonvoting members
21 appointed pursuant to paragraph (3).

22 (2) **VOTING MEMBERS.**—The Secretary shall
23 appoint as voting members of the Committee one in-
24 dividual from each of the following categories:

1 (A) Organizations primarily representing
2 independent clinical laboratories operating in
3 more than two States.

4 (B) Organizations primarily representing
5 independent clinical laboratories operating in no
6 more than two States.

7 (C) Organizations representing hospitals
8 that perform clinical diagnostic laboratory tests.

9 (D) Organizations representing physicians
10 with expertise in clinical diagnostic laboratory
11 tests.

12 (E) Organizations representing non-physi-
13 cians with expertise in clinical diagnostic lab-
14 oratory tests.

15 (F) Organizations representing manufac-
16 turers of equipment designed for clinical diag-
17 nostic laboratory tests.

18 (G) Organizations representing individuals
19 enrolled under part B of title XVIII of the So-
20 cial Security Act.

21 (H) Organizations representing private
22 payers for clinical diagnostic laboratory tests.

23 (I) Individuals with expertise in measuring
24 resource utilization by clinical diagnostic labora-
25 tories in performing tests.

1 (J) Individuals with backgrounds in health
2 economics with the ability to quantify the value
3 of clinical diagnostic laboratory tests.

4 (K) Organizations representing patients.

5 (L) Physicians or clinicians who prescribe
6 clinical diagnostic laboratory tests.

7 (M) Physicians or clinicians who perform
8 point-of-care tests in their offices.

9 (N) Organizations representing individuals
10 with scientific background and experience in
11 clinical laboratory health care services.

12 (O) Organizations representing managers
13 or supervisors of clinical laboratories.

14 (3) NONVOTING MEMBERS.—The Secretary
15 shall appoint two nonvoting members to the Com-
16 mittee.

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

1 in section 2(b), the elements listed in section 3(b), and
2 the input of relevant stakeholders.

3 (d) TERM; VACANCIES.—

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

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

9 (e) ADMINISTRATIVE PROVISIONS.—

10 (1) QUORUM.—A quorum shall be required to
11 conduct the business of the Committee. Nine mem-
12 bers of the Committee shall constitute a quorum.

13 (2) FACILITATOR.—Not later than 30 days
14 after the date on which all members of the Com-
15 mittee are appointed, a facilitator for the negotia-
16 tions of the Committee shall be approved or selected
17 in accordance with section 566(c) of title 5, United
18 States Code. The facilitator shall be a voting mem-
19 ber of the Committee.

20 (3) MEETINGS.—The Committee shall meet at
21 the call of the facilitator approved or selected under
22 paragraph (2), the Secretary, or a quorum of the
23 members of the Committee.

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

4 (5) STAFFING.—

5 (A) DETAILING.—Any Federal Govern-
6 ment employee may be detailed to the Com-
7 mittee without reimbursement from the Com-
8 mittee, and such detailee shall retain the rights,
9 status, and privileges of their regular employ-
10 ment without interruption.

11 (B) TECHNICAL ASSISTANCE.—If author-
12 ized by the Secretary and approved by a major-
13 ity of the Committee, the Committee may retain
14 the services of experts and consultants under
15 section 3109(b) of title 5, United States Code,
16 but at rates not to exceed the daily equivalent
17 of the annual rate of basic pay for level IV of
18 the Executive Schedule under section 5315 of
19 such title.

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

24 (f) REPORTS.—

25 (1) COMMITTEE REPORTS.—

1 (A) INTERIM REPORTS.—

2 (i) INITIAL INTERIM REPORT.—Not
3 later than 6 months after the date on
4 which members are required to be ap-
5 pointed to the Committee under subsection
6 (a), the Committee shall submit to the Sec-
7 retary an initial interim report on the
8 Committee’s progress in negotiating a pro-
9 posed rule to establish a Medicare modern-
10 ized clinical diagnostic laboratory fee
11 schedule, including the Committee’s pre-
12 liminary determinations regarding the es-
13 tablishment of such fee schedule and in-
14 cluding preliminary determinations on the
15 information described in subparagraph
16 (B).

17 (ii) SUBSEQUENT INTERIM REPORT.—
18 The Committee shall submit to the Sec-
19 retary a subsequent interim report, which
20 shall include updates to the determinations
21 made in the report submitted under clause
22 (i). Such subsequent interim report shall
23 be submitted not later than 12 months
24 after the date on which members are re-

1 required to be appointed to the Committee
2 under subsection (a).

3 (iii) EXCEPTION.—An interim report
4 described in this subparagraph is not re-
5 quired to be submitted in the case that a
6 final report under subparagraph (B) is
7 submitted before the date on which such
8 interim report is required to be submitted
9 under this subparagraph.

10 (B) FINAL REPORT.—Not later than 18
11 months after the date on which members are
12 required to be appointed to the Committee
13 under subsection (a), the Committee shall sub-
14 mit to the Secretary a final report, including
15 the following:

16 (i) If the Committee reaches con-
17 sensus by such 18-month date on a pro-
18 posed rule to establish a Medicare modern-
19 ized clinical diagnostic laboratory fee
20 schedule—

21 (I) the consensus proposed rule
22 reached by the Committee; and

23 (II) the Committee’s determina-
24 tion regarding the extent to which,
25 and manner in which, the proposed

1 fee schedule will achieve the purpose
2 described in section 2(b) and address
3 the elements described in section 3(b).

4 (ii) If the Committee fails to reach
5 consensus by such 18-month date on a pro-
6 posed rule to establish a Medicare modern-
7 ized clinical diagnostic laboratory fee
8 schedule—

9 (I) any components of a fee
10 schedule or other areas upon which
11 consensus was achieved in accordance
12 with the purpose described in section
13 2(b) and the elements described in
14 section 3(b); and

15 (II) any components of a fee
16 schedule or other areas upon which
17 disagreement prevented consensus
18 from being achieved in accordance
19 with the purpose described in section
20 2(b) and the elements described in
21 section 3(b).

22 (2) SECRETARIAL REPORTS.—

23 (A) INTERIM REPORTS.—Not later than 30
24 days after the date of the submission of each
25 interim report under paragraph (1)(A), the Sec-

1 retary shall submit to the Committee on Energy
2 and Commerce and the Committee on Ways
3 and Means of the House of Representatives and
4 the Committee on Finance of the Senate an in-
5 terim report on the progress of the negotiated
6 rulemaking process under this section to estab-
7 lish a Medicare modernized clinical diagnostic
8 laboratory fee schedule. Each such report shall
9 include the corresponding interim report sub-
10 mitted by the Committee under such paragraph.

11 (B) FINAL REPORT.—Not later 24 months
12 after the date of the enactment of this Act, the
13 Secretary shall submit to the Committee on En-
14 ergy and Commerce and the Committee on
15 Ways and Means of the House of Representa-
16 tives and the Committee on Finance of the Sen-
17 ate a final report, including—

18 (i) the final report of the Committee
19 submitted under paragraph (1)(B); and

20 (ii) in the case that the Committee
21 reaches a consensus on a proposed rule to
22 establish a Medicare modernized clinical
23 diagnostic laboratory fee schedule, the Sec-
24 retary’s proposed regulation to implement
25 the proposed rule.

1 (3) PUBLIC AVAILABILITY OF REPORTS.—The
2 Secretary shall make each report submitted under
3 this subsection available to the public on the official
4 Internet website of the Department of Health and
5 Human Services.

6 **SEC. 5. PROMULGATION OF FINAL REGULATIONS.**

7 (a) COMMITTEE CONSENSUS.—If the Committee
8 reaches a consensus under section 4 on a proposed rule
9 to establish a Medicare modernized clinical diagnostic lab-
10 oratory fee schedule, the Secretary shall use such proposed
11 rule as the basis to promulgate a proposed regulation with
12 comment period and, not later than 36 months after the
13 date of the enactment of this Act, subsequent final regula-
14 tions to apply to items and services furnished on or after
15 the first January 1st following the date of the promulga-
16 tion of such final regulations.

17 (b) LACK OF COMMITTEE CONSENSUS.—If the Com-
18 mittee fails to reach a consensus under section 4 on a pro-
19 posed rule to establish a Medicare modernized clinical di-
20 agnostic laboratory fee schedule, and legislation to estab-
21 lish such fee schedule is not enacted by the date that is
22 51 months after the date of the enactment of this Act,
23 the Secretary shall promulgate, not later than 57 months
24 after the date of the enactment of this Act, final regula-
25 tions to establish such fee schedule, taking into account

1 the purpose described in section 2(b) and the elements de-
2 scribed in section 3(b). Such final regulations shall apply
3 to items and services furnished on or after the first Janu-
4 ary 1st following the date of the promulgation of such
5 final regulations.

6 **SEC. 6. REPORT BY MEDPAC.**

7 Not later than 39 months after the date of the enact-
8 ment of this Act, the Medicare Payment Advisory Com-
9 mission (MedPAC) shall submit to Congress a report, in-
10 cluding the following recommendations:

11 (1) COMMITTEE CONSENSUS.—In the case that
12 the Committee reaches consensus under section 4 on
13 a proposed rule to establish a Medicare modernized
14 clinical diagnostic laboratory fee schedule, with re-
15 spect to the Secretary’s proposed regulation sub-
16 mitted under section 4(f)(2)(B)(ii) to implement
17 such proposed rule—

18 (A) whether the overall level of expendi-
19 tures under title XVIII of the Social Security
20 Act for clinical laboratory services under the re-
21 vised fee schedule under such proposed regula-
22 tion are adequate to ensure beneficiary access
23 to high quality testing;

24 (B) whether the periodic revision and infla-
25 tionary update mechanisms in the proposed reg-

1 ulation are adequate to ensure beneficiary ac-
2 cess to high quality testing; and

3 (C) possible future options in addressing
4 beneficiary cost sharing under part B of such
5 title that do not require clinical laboratories to
6 collect copays on every individual test.

7 (2) LACK OF COMMITTEE CONSENSUS.—In the
8 case that the Committee does not reach consensus
9 under section 4 on a proposed rule to establish a
10 Medicare modernized clinical diagnostic laboratory
11 fee schedule—

12 (A) how to modernize such clinical labora-
13 tory fee schedule in accordance with the pur-
14 pose described in section 2(b) and the elements
15 described in section 3(b), including with respect
16 to such areas identified in the report submitted
17 under section 4(f)(1)(B)(ii) as areas in which
18 consensus was not reached by the Committee;

19 (B) how to ensure the overall level of ex-
20 penditures under part B of title XVIII of such
21 Act for clinical laboratory services under a re-
22 vised fee schedule are adequate to ensure bene-
23 ficiary access to high quality testing;

24 (C) how to ensure that periodic revision
25 and inflationary update mechanisms in a pro-

1 posed revised fee schedule for clinical laboratory
2 services are adequate to ensure beneficiary ac-
3 cess to high quality testing; and

4 (D) possible future options in addressing
5 beneficiary cost sharing under such part that
6 do not require clinical laboratories to collect
7 copays on every individual test.

8 **SEC. 7. DEFINITIONS.**

9 For purposes of this Act:

10 (1) COMMITTEE.—The term “Committee”
11 means the negotiated rulemaking committee estab-
12 lished under section 4(a).

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

16 (3) MEDICARE MODERNIZED CLINICAL DIAG-
17 NOSTIC LABORATORY FEE SCHEDULE.—The term
18 “Medicare modernized clinical diagnostic laboratory
19 fee schedule” means a modernized fee schedule for
20 payment under part B of title XVIII of the Social
21 Security Act for clinical diagnostic laboratory tests,
22 the payment for which, as of the day before the date
23 of the enactment of this Act, is provided for under
24 section 1833(h) of the Social Security Act (42
25 U.S.C. 1395l(h)).

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

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

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

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