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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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SEC. 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Medicare Clinical Diagnostic Laboratory Fee Schedule Modernization Act of 2009''.

(b) TABLE OF CONTENTS.—The table of contents of 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 diagnostic 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.

TITLE I—UPDATING THE CLINICAL LABORATORY FEE SCHEDULE

SEC. 101. FINDINGS AND PURPOSE.

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

(1) The fee schedule for clinical diagnostic laboratory tests under part B of the Medicare program was developed in 1984 based on the local prevailing fees charged in 1983.

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

professional staff has increased exponentially in recent years.

(3) Clinical laboratories are currently reimbursed at levels below those provided in 1984 when adjusted for inflation.

(4) The fee schedule for clinical diagnostic laboratory tests is the last Medicare fee schedule that has not been made reliant on prospective payment or relative value as the primary payment methodology.

(5) Clinical laboratories provide vital information that influences 70 percent of all patient care decisions.

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

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

(2) to modernize the fee schedule for clinical diagnostic laboratory tests under part B of the Medicare program to reflect the increased cost and enhanced technology involved in laboratory testing and to reflect accurately and equitably the value of such testing to the health care system;

(3) to involve relevant stakeholders in the clinical laboratory industry in the process of such fee

schedule modernization, including Medicare beneficiaries, health care providers, and laboratories; and

(4) to create mechanisms for periodic revisions, inflationary updates, and inclusion of new methodologies to the fee schedule for clinical diagnostic laboratory tests in order to reflect market conditions.

SEC. 102. PROCESS FOR THE MODERNIZATION OF THE FEE SCHEDULE FOR CLINICAL DIAGNOSTIC LABORATORY TESTS.

(a) IN GENERAL.—Pursuant to the provisions of this title and consistent with the elements described in subsection (b), the Secretary of Health and Human Services shall—

(1) establish under section 103(a) a negotiated rulemaking committee to negotiate and develop a proposed rule for a Medicare modernized clinical diagnostic laboratory fee schedule (as defined in section 106(3));

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

(3) promulgate under section 104 final regulations establishing such Medicare modernized clinical diagnostic fee schedule if the Committee reaches consensus.

(b) ELEMENTS.—

(1) ELEMENTS FOR INCLUSION.—The negotiated rulemaking committee established under section 103 shall consider the following elements and include them in the proposed rule for a Medicare modernized clinical diagnostic laboratory fee schedule:

(A) Access, to the greatest extent possible, by all individuals enrolled in part B of title XVIII of the Social Security Act to quality laboratory services in all settings.

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

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

(i) The mechanism is sufficiently adaptable to incorporate new clinical laboratory tests and technology into the fee

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

(ii) The mechanism periodically and appropriately revises clinical laboratory reimbursement to reflect the evolution of costs, value, and utilization of such tests.

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

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

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

(D) For the first year for which the fee schedule is implemented, the fee schedule shall be designed to result in the same amount of aggregate payments under such schedule for clinical laboratory services furnished during such year for which payment is made under part B of title XVIII of the Social Security Act as would have been made under section 1833(h) of such Act for such services if this section had

not been enacted (taking into account annual adjustments under paragraph (2) of such section, the annual addition of new tests under paragraph (8) of such section, and any other utilization increases that would have been recognized under such section).

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

(F) A transition period to phase in the application of the payment rates under the fee schedule based on blended payment rates between such fee schedule and the fee schedule in effect on the day before the date of the enactment of this Act under section 1833(h) of the Social Security Act for clinical laboratory services, which is to be provided in an efficient and fair manner.

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

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

Medicare modernized clinical diagnostic laboratory fee schedule:

(A) A fee schedule that provides for greater administrative simplicity and efficiency by eliminating or reducing the number of differential payment rates in existence on the day before the date of the enactment of this Act under section 1833(h) of the Social Security Act for clinical diagnostic laboratory tests.

(B) A fee schedule that addresses the unique reimbursement problems laboratories face as indirect providers, including requirements that laboratories must rely on diagnosis codes provided by ordering providers.

SEC. 103. ESTABLISHMENT AND DUTIES OF NEGOTIATED RULEMAKING COMMITTEE.

(a) ESTABLISHMENT.—Not later than 30 days after the date of the enactment of this Act, the Secretary shall publish a notice in the Federal Register of intent to establish a negotiated rulemaking committee (in this title referred to as the ''Committee'') in accordance with subchapter III of chapter 5 of title 5, United States Code (5 U.S.C. 561 et seq.) and this section to negotiate and develop a proposed rule for a Medicare modernized clinical diagnostic laboratory fee schedule (as defined in section

106(3)). Not later than 60 days after the day on which such notice of intent is published, the Secretary shall appoint members to the Committee in accordance with subsection (b).

(b) COMPOSITION OF COMMITTEE.—

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

(2) VOTING MEMBERS.—The Secretary shall appoint as voting members of the Committee individuals as follows:

(A) One individual from an organization primarily representing independent clinical laboratories operating on a national basis.

(B) One individual from an organization primarily representing independent clinical laboratories operating on a regional or local basis.

(C) One individual from an organization representing hospitals that perform clinical diagnostic laboratory tests.

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

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

(F) One individual from an organization representing manufacturers of equipment designed for clinical diagnostic laboratory tests.

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

(H) One individual from an organization representing private payers for clinical diagnostic laboratory tests.

(I) One individual with expertise in measuring resource utilization by clinical diagnostic laboratories in performing tests.

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

(K) Two individuals from organizations representing generalist non-physicians with expertise in clinical diagnostic laboratory tests.

(L) One individual who is a physician or clinician who prescribes clinical diagnostic laboratory tests.

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

(N) One individual from an organization representing individuals with scientific background and experience in clinical laboratory health care services.

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

(3) NONVOTING MEMBERS.—The Secretary shall appoint one nonvoting member to the Committee. The Chairman of the Medicare Payment Advisory Commission shall appoint one nonvoting member to the Committee.

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

(d) TERM; VACANCIES.—

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

(2) VACANCIES.—A vacancy on the Committee shall be filled in the same manner in which the original appointment was made.

(e) ADMINISTRATIVE PROVISIONS.—

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

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

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

(4) STAFFING.—

(A) DETAILING.—Any Federal Government employee may be detailed to the Committee without reimbursement from the Committee, and such detailee shall retain the rights, status, and privileges of their regular employment without interruption.

(B) TECHNICAL ASSISTANCE.—If authorized by the Secretary and approved by a majority of the Committee, the Committee may retain the services of experts and consultants under section 3109(b) of title 5, United States Code, but at rates not to exceed the daily equivalent of the annual rate of basic pay for level IV of the Executive Schedule under section 5315 of such title.

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

(f) REPORTS.—

(1) COMMITTEE REPORTS.—

(A) INTERIM REPORTS.—

(i) INITIAL INTERIM REPORT.—Not later than 6 months after the date on which members are required to be appointed to the Committee under subsection (a), the Committee shall submit to the Secretary an initial interim report on the Committee's progress in negotiating a proposed rule to establish a Medicare modernized clinical diagnostic laboratory fee

schedule, including the Committee's preliminary determinations regarding the establishment of such fee schedule and including preliminary determinations on the information described in subparagraph (B).

(ii) SUBSEQUENT INTERIM REPORT.—The Committee shall submit to the Secretary a subsequent interim report, which shall include updates to the determinations made in the report submitted under clause (i). Such subsequent interim report shall be submitted not later than 12 months after the date on which members are required to be appointed to the Committee under subsection (a).

(iii) EXCEPTION.—An interim report described in this subparagraph is not required to be submitted in the case that a final report under subparagraph (B) is submitted before the date on which such interim report is required to be submitted under this subparagraph.

(B) FINAL REPORT.—Not later than 18 months after the date on which members are

required to be appointed to the Committee under subsection (a), the Committee shall submit to the Secretary a final report, including the following:

(i) If the Committee reaches consensus by such 18-month date on a proposed rule to establish a Medicare modernized clinical diagnostic laboratory fee schedule—

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

(II) the Committee's determination regarding the extent to which, and manner in which, the proposed fee schedule will achieve the purpose described in section 101(b) and address the elements described in section 102(b).

(ii) If the Committee fails to reach consensus by such 18-month date on a proposed rule to establish a Medicare modernized clinical diagnostic laboratory fee schedule—

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

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

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

(2) SECRETARIAL REPORTS.—

(A) INTERIM REPORTS.—Not later than 30 days after the date of the submission of each interim report under paragraph (1)(A), the Secretary shall submit to the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate an interim report on the progress of the negotiated rulemaking process under this section to establish a Medicare modernized clinical diagnostic laboratory fee schedule. Each such report shall include the corresponding interim report submitted by the Committee under such paragraph.

(B) FINAL REPORT.—Not later 24 months after the date of the enactment of this Act, the Secretary shall submit to the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate a final report, including—

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

(ii) in the case that the Committee reaches a consensus on a proposed rule to establish a Medicare modernized clinical diagnostic laboratory fee schedule, the Secretary's proposed regulation to implement the proposed rule.

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

SEC. 104. RESULT OF COMMITTEE ACTION.

(a) COMMITTEE CONSENSUS.—If the Committee reaches a consensus under section 103 on a proposed rule to establish a Medicare modernized clinical diagnostic laboratory fee schedule, the Secretary shall, to the maximum

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

(b) LACK OF COMMITTEE CONSENSUS.—If the Committee fails to reach a consensus under section 103 on a proposed rule to establish a Medicare modernized clinical diagnostic laboratory fee schedule, authority remains with the Congress to establish such fee schedule, taking into account the purpose described in section 101(b) and the elements described in section 102(b) and the report provided by the Medicare Payment Advisory Commission under section 105(2).

SEC. 105. REPORT BY MEDPAC.

Not later than 39 months after the date of the enactment of this Act, the Medicare Payment Advisory Commission shall submit to Congress a report, including the following recommendations:

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

ized clinical diagnostic laboratory fee schedule, with respect to the Secretary's proposed regulation submitted under section 103(f)(2)(B)(ii) to implement such proposed rule—

(A) whether the overall level of expenditures under title XVIII of the Social Security Act for clinical laboratory services under the revised fee schedule under such proposed regulation is adequate to ensure beneficiary access to high quality testing; and

(B) whether the periodic revision and inflationary update mechanisms in the proposed regulation are adequate to ensure beneficiary access to high quality testing.

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

(A) how to modernize such clinical laboratory fee schedule in accordance with the purpose described in section 101(b) and the elements described in section 102(b), including with respect to such areas identified in the report submitted under section 103(f)(1)(B)(ii) as

areas in which consensus was not reached by the Committee;

(B) how to ensure the overall level of expenditures under part B of title XVIII of such Act for clinical laboratory services under a revised fee schedule is adequate to ensure beneficiary access to high quality testing; and

(C) how to ensure that periodic revision and inflationary update mechanisms in a proposed revised fee schedule for clinical laboratory services are adequate to ensure beneficiary access to high quality testing.

SEC. 106. DEFINITIONS.

For purposes of this title:

(1) COMMITTEE.—The term ''Committee'' means the negotiated rulemaking committee established under section 103(a).

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

(3) MEDICARE MODERNIZED CLINICAL DIAGNOSTIC LABORATORY FEE SCHEDULE.—The term ''Medicare modernized clinical diagnostic laboratory fee schedule'' means a modernized fee schedule for payment under part B of title XVIII of the Social

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

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

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

(6) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

TITLE II—UPDATING THE SPECIMEN COLLECTION FEE

SEC. 201. ADJUSTMENT IN MEDICARE LABORATORY SPECIMEN COLLECTION FEE.

(a) IN GENERAL.—Section 1833(h) of the Social Security Act (42 U.S.C. 1395l(h)) is amended—

(1) in paragraph (3)(A), by inserting ''in the amount specified in paragraph (8)'' after ''a nominal fee''; and

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

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

''(A) 2010, is $6.04; or

''(B) a subsequent year, is the amount specified in this paragraph for tests performed in the preceding year adjusted by the annual percentage increase or decrease in the Consumer Price Index for All Urban Consumers (United States city average).''.

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

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