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(Original Signature of Member)

110TH CONGRESS
2D SESSION

# H. R. _____

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.

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IN THE HOUSE OF REPRESENTATIVES

Mr. STUPAK introduced the following bill; which was referred to the Committee on _____

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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.

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

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Medicare Clinical Diagnostic Laboratory Fee Schedule Modernization Act of 2008''.

**SEC. 2. 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 Medi-

care 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 and inflationary updates to the fee schedule for clinical diagnostic laboratory tests in order to reflect market conditions.

**SEC. 3. PROCESS FOR THE MODERNIZATION OF THE FEE SCHEDULE FOR CLINICAL DIAGNOSTIC LABORATORY TESTS.**

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

(1) establish under section 4(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 7(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 4(f)(2)(B) relating to such Medicare modernized clinical diagnostic fee schedule; and

(3) promulgate under section 5 final regulations establishing such Medicare modernized clinical diagnostic fee schedule.

(b) ELEMENTS TO CONSIDER.—The Medicare modernized clinical diagnostic laboratory fee schedule developed pursuant to this Act shall provide, to the greatest extent possible, for access by all individuals enrolled in part B of title XVIII of the Social Security Act to quality laboratory services in all settings and establish a new single, rational, and national fee schedule for clinical diagnostic laboratory tests under such part that incorporates the following elements:

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

(A) The payment rate is value-based on appropriate resource allocations to the administration of clinical laboratory tests for overall patient care management and based on potential cost-savings to the Medicare program under

such title XVIII resulting from the administration of clinical laboratory tests.

(B) The payment rate takes into account industry-wide clinical laboratory practice expenses, including liability costs and costs of collection and transportation of specimens.

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

(A) among various geographic areas;

(B) among various types of clinical laboratory settings for comparable services; and

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

(3) 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:

(A) The mechanism is sufficiently adaptable to incorporate new clinical laboratory tests

and technology into the fee schedule in a timely manner.

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

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

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

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

(4) 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 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).

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

(6) 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.

(7) The fee schedule shall provide 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.

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

**SEC. 4. 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 Act 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 7(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 15 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 one individual from each of the following categories:

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

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

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

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

(E) Organizations representing non-physicians with expertise in clinical diagnostic laboratory tests.

(F) Organizations representing manufacturers of equipment designed for clinical diagnostic laboratory tests.

(G) Organizations representing individuals enrolled under part B of title XVIII of the Social Security Act.

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

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

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

(K) Organizations representing patients.

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

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

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

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

(3) NONVOTING MEMBERS.—The Secretary shall appoint two nonvoting members 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 2(b), the elements listed in section 3(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. Nine members of the Committee shall constitute a quorum.

(2) FACILITATOR.—Not later than 30 days after the date on which all members of the Committee are appointed, a facilitator for the negotiations of the Committee shall be approved or selected in accordance with section 566(c) of title 5, United States Code. The facilitator shall be a voting member of the Committee.

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

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

(5) 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.

(6) 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 re-

quired 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 2(b) and address the elements described in section 3(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 2(b) and the elements described in section 3(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 2(b) and the elements described in section 3(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 Sec-

retary 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. 5. PROMULGATION OF FINAL REGULATIONS.**

(a) COMMITTEE CONSENSUS.—If the Committee reaches a consensus under section 4 on a proposed rule to establish a Medicare modernized clinical diagnostic laboratory fee schedule, the Secretary shall use such proposed rule as the basis to promulgate a proposed regulation with comment period and, not later than 36 months after the date of the enactment of this Act, subsequent 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 4 on a proposed rule to establish a Medicare modernized clinical diagnostic laboratory fee schedule, and legislation to establish such fee schedule is not enacted by the date that is 51 months after the date of the enactment of this Act, the Secretary shall promulgate, not later than 57 months after the date of the enactment of this Act, final regulations to establish such fee schedule, taking into account

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

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

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

(1) COMMITTEE CONSENSUS.—In the case that the Committee reaches consensus under section 4 on a proposed rule to establish a Medicare modernized clinical diagnostic laboratory fee schedule, with respect to the Secretary's proposed regulation submitted under section 4(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 are adequate to ensure beneficiary access to high quality testing;

(B) whether the periodic revision and inflationary update mechanisms in the proposed reg-

ulation are adequate to ensure beneficiary access to high quality testing; and

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

(2) LACK OF COMMITTEE CONSENSUS.—In the case that the Committee does not reach consensus under section 4 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 2(b) and the elements described in section 3(b), including with respect to such areas identified in the report submitted under section 4(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 are adequate to ensure beneficiary access to high quality testing;

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

posed revised fee schedule for clinical laboratory services are adequate to ensure beneficiary access to high quality testing; and

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

**SEC. 7. DEFINITIONS.**

For purposes of this Act:

(1) COMMITTEE.—The term ''Committee'' means the negotiated rulemaking committee established under section 4(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.