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113TH CONGRESS
1ST SESSION

H. R. 2085

To create incentive for innovative diagnostics by improving the process for determining Medicare payment rates for new tests.

IN THE HOUSE OF REPRESENTATIVES

MAY 22, 2013

Mr. ROSKAM (for himself, Mr. NEAL, Mr. LANCE, Mr. KIND, Mr. GUTHRIE, Mr. PAULSEN, and Mr. TIBERI) 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 create incentive for innovative diagnostics by improving the process for determining Medicare payment rates for new 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 ''Diagnostic Innovation Testing and Knowledge Advancement Act of 2013''.

SEC. 2. CREATING INCENTIVES FOR INNOVATIVE DIAGNOSTICS.

(a) IMPROVEMENTS TO PROCESS FOR DETERMINING FEE SCHEDULE AMOUNTS FOR NEW TESTS.—

(1) CLARIFYING FACTORS FOR RATE-SETTING.—In determining the payment amount under gapfilling procedures (as described in section 414.508(b) of title 42, Code of Federal Regulations, or any successor regulation to such section) for new clinical diagnostic laboratory tests under section 1833(h)(8) of the Social Security Act (42 U.S.C. 1395l(h)(8)), the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall take into account, as applicable and available, the following factors with respect to such a new test:

(A) IMPACT ON PATIENT CARE.—The impact of the new test on patient care, patient management, or patient treatment.

(B) TECHNICAL CHARACTERISTICS.—The technical characteristics of the new test, and the resources required to develop, validate, and perform the new test.

(C) CLAIMS DATA.—Data from claims for which payment is made under part B of title XVIII of the Social Security Act.

(D) LABORATORY CHARGES.—Amounts charged by laboratories to self-pay patients for the new test.

(E) PRIVATE INSURANCE RATES.—Amounts paid to laboratories for such new test under private health insurance coverage offered in the group market and the individual market.

(F) ADVISORY PANEL RECOMMENDATIONS.—The findings and recommendations of the independent advisory panel convened under paragraph (2) with respect to that new test and any comments received during the open meeting of the advisory panel.

(G) ADDITIONAL FACTORS.—Such other factors as the Secretary may specify.

(2) INPUT FROM PATIENTS, CLINICIANS, AND TECHNICAL EXPERTS.—

(A) REQUIREMENT FOR INDEPENDENT ADVISORY PANEL.—The Secretary shall convene an independent advisory panel from which the Secretary shall request information and recommendations regarding any new test (as referred to under subparagraph (A) of section 1833(h)(8) of the Social Security Act (42 U.S.C. 1395l(h)(8))) for which payment is

made under such section, including technical, clinical, and quality information.

(B) COMPOSITION OF INDEPENDENT ADVISORY PANEL.—Subject to subparagraph (D), the independent advisory panel shall be comprised of 19 members, including—

(i) 7 individuals with expertise and experience with clinical diagnostic laboratory tests including expertise in the technical characteristics of the new test as well as expertise in the requirements to develop, validate, and perform the new test;

(ii) 3 representatives of patients, including a patient representative for rare disorders;

(iii) 3 clinicians who use results of the new test in patient care;

(iv) 2 laboratorians;

(v) 2 individuals with expertise in the area of pharmacoeconomics or health technology assessment; and

(vi) 2 individuals with expertise on the impact of new tests on quality of patient care, including genetic counselors.

(C) TERMS.—Subject to subparagraph (D), a member of the panel shall be appointed to serve a term of 6 years, except with respect to the members first appointed, whose terms of appointment shall be staggered evenly over 2-year increments.

(D) TEMPORARY APPOINTMENT OF EXPERTS.—Insofar as the Secretary determines with respect to a new test that there are an insufficient number of members of the panel with expertise with respect to that specific test, the Secretary may appoint individuals who have expertise pertaining to the new test involved to serve on the panel.

(E) OPEN MEETINGS.—The Secretary shall receive or review the findings and recommendations of the independent advisory panel with respect to the new tests described in subparagraph (A) involved during a meeting open to the public and provide opportunity for public comment.

(F) CLARIFICATION OF AUTHORITY OF SECRETARY TO CONSULT CARRIERS.—Nothing in this section shall be construed as affecting the authority of the Secretary to consult with

appropriate Medicare administrative contractors.

(3) JUSTIFICATION FOR PAYMENT DETERMINATIONS.—

(A) INITIAL JUSTIFICATION.—With respect to decisions regarding payments made under the clinical laboratory fee schedule for new clinical diagnostic laboratory tests, the Secretary shall publicly provide a justification for the payment basis and payment rate determination, including a detailed summary of the information submitted to, or obtained by, the Secretary regarding the factors specified in paragraph (1), such that interested stakeholders can readily understand the Secretary's rationale for the payment basis and rate determinations.

(B) RECONSIDERATION PERIOD.—After providing such justification for a payment basis and payment rate determination, the Secretary shall provide for a reasonable period of reconsideration to receive any appeal of the determination and to evaluate any additional information received regarding the justification and the factors specified in paragraph (1).

(C) FINAL DETERMINATION.—After the period of reconsideration the Secretary shall make a final payment basis and payment rate determination and provide a justification for such final determination explaining what additional information was evaluated during the reconsideration and how such information was taken into account with respect to the final determination. Nothing in this paragraph shall be construed as authorizing the Secretary to reveal proprietary information which is otherwise prohibited from disclosure under law.

(b) PROCESS FOR ASSIGNMENT OF TEMPORARY CODES FOR DIAGNOSTIC TESTS.—The Secretary shall establish a process for application for the assignment of a temporary national HCPCS code to uniquely identify a diagnostic test until a permanent national HCPCS code is available for assignment to that test. Assignments of a temporary national HCPCS code shall occur on a quarterly basis. The Secretary shall provide public notice through the Centers for Medicare & Medicaid Services Web site of applications made for such temporary national HCPCS codes. Upon assignment of a temporary code under this process, the Secretary shall treat such test as

a new test for purposes of section 1833(h)(8) of the Social Security Act.

(c) DEVELOPMENT OF FURTHER IMPROVEMENTS IN RATE-SETTING PROCESSES.—The Secretary shall analyze the process used for the gapfilling procedure used in determining payment amounts for new clinical diagnostic laboratory tests under section 1833(h)(8) of the Social Security Act. Taking into account the changes made by this section, the Secretary shall identify further changes to improve the accuracy and appropriateness of resulting rates and the openness, transparency, and predictability of the process. The Secretary shall examine what and how many entities should perform gapfilling, under contract or otherwise, and how to ensure that the process is informed by appropriate expertise and proceeds in a transparent and accountable manner. The Secretary shall implement improvements in the process, insofar as these are possible under the law through regulations, after public notice and opportunity for comment. For changes the Secretary determines would require a change in law, the Secretary shall transmit recommendations to the Speaker of the House and the President of the Senate not later than July 1, 2014.

(d) DEFINITIONS.—For purposes of this section:

(1) NEW CLINICAL DIAGNOSTIC LABORATORY TESTS.—The term ''new clinical diagnostic laboratory test'' means a clinical diagnostic laboratory test—

(A) that is assigned a new or substantially revised code on or after January 1, 2013; or

(B) for which a temporary national HCPCS code is granted under subsection (b) on or after January 1, 2014.

(2) SELF-PAY PATIENT.—The term ''self-pay patient'' means, with respect to a health care item or service, an individual who pays out of pocket for such item or service and who does not have health insurance coverage for such item or service.

(e) EFFECTIVE DATE.—

(1) IN GENERAL.—Subject to paragraph (2), this section shall take effect on the date of enactment of this Act and shall apply with respect to new clinical diagnostic laboratory tests.

(2) APPLICATION OF JUSTIFICATIONS TO CURRENT RATE DETERMINATIONS.—Subsection (a)(3) shall apply to payment basis and payment rate determinations made on or after January 1, 2013.

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