

112TH CONGRESS  
2D SESSION

# H. R. 6446

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

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## IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 20, 2012

Mr. ROSKAM (for himself and Mr. LANCE) 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.

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 “Improving Diagnostic  
5 Innovations Act of 2012”.

1 **SEC. 2. CREATING INCENTIVES FOR INNOVATIVE**  
2 **DIAGNOSTICS.**

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

5 (1) CLARIFYING FACTORS FOR RATE-SET-  
6 TING.—

7 (A) IN GENERAL.—In determining the pay-  
8 ment amount under gapfilling procedures (as  
9 described in section 414.508(b) of title 42,  
10 Code of Federal Regulations, or any successor  
11 regulation to such section) for new clinical diag-  
12 nostic laboratory tests under section 1833(h)(8)  
13 of the Social Security Act (42 U.S.C.  
14 1395l(h)(8)), the Secretary of Health and  
15 Human Services (in this section referred to as  
16 the “Secretary”) shall take into account, as ap-  
17 plicable and available, the following factors with  
18 respect to such a new test:

19 (i) IMPACT ON PATIENT CARE.—The  
20 impact of the new test on patient care, pa-  
21 tient management, or patient treatment.

22 (ii) TECHNICAL CHARACTERISTICS.—  
23 The technical characteristics of the new  
24 test, and the resources required to develop,  
25 validate, and perform the new test.

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

4 (iv) LABORATORY CHARGES.—  
5 Amounts charged by laboratories to self-  
6 pay patients for the new test.

7 (v) PRIVATE INSURANCE RATES.—  
8 Amounts paid to laboratories for such new  
9 test under private health insurance cov-  
10 erage offered in the group market and the  
11 individual market.

12 (vi) ADVISORY PANEL RECOMMENDA-  
13 TIONS.—The findings and recommenda-  
14 tions of the independent advisory panel  
15 convened under paragraph (2) with respect  
16 to that new test and any comments re-  
17 ceived during the open meeting of the advi-  
18 sory panel.

19 (vii) ADDITIONAL FACTORS.—Such  
20 other factors as the Secretary may specify.

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

23 (A) REQUIREMENT FOR INDEPENDENT AD-  
24 VISORY PANEL.—The Secretary shall convene  
25 an independent advisory panel from which the

1 Secretary shall request information and rec-  
2 ommendations regarding any new test (as re-  
3 ferred to under subparagraph (A) of section  
4 1833(h)(8) of the Social Security Act (42  
5 U.S.C. 1395l(h)(8))) for which payment is  
6 made under such section, including technical,  
7 clinical, and quality information.

8 (B) COMPOSITION OF INDEPENDENT ADVI-  
9 SORY PANEL.—The independent advisory panel  
10 shall be comprised of 19 members, including—

11 (i) 4 individuals with expertise and ex-  
12 perience with advanced clinical diagnostic  
13 laboratory tests, including expertise in the  
14 technical characteristics of the new test;

15 (ii) 3 representatives of patients, in-  
16 cluding a patient representative for rare  
17 disorders;

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

20 (iv) 3 individuals with expertise in the  
21 requirements to develop, validate, and per-  
22 form the new test;

23 (v) 2 laboratorians;

1 (vi) 2 experts in the area of  
2 pharmacoeconomics or health technology  
3 assessment; and

4 (vii) 2 individuals with expertise on  
5 the impact of new tests on quality of pa-  
6 tient care, including genetic counselors.

7 (C) TERMS.—A member of the panel shall  
8 be appointed to serve a term of 6 years, except  
9 with respect to the members first appointed,  
10 whose terms of appointment shall be staggered  
11 evenly over 2-year increments.

12 (D) EXPERT CONSULTANTS.—The Sec-  
13 retary may include to serve temporarily on the  
14 panel individuals who have expertise pertaining  
15 to the new test involved.

16 (E) OPEN MEETINGS.—The Secretary shall  
17 receive or review the findings and recommenda-  
18 tions of the independent advisory panel with re-  
19 spect to the new tests described in subpara-  
20 graph (A) involved during a meeting open to  
21 the public and provide opportunity for public  
22 comment.

23 (F) CLARIFICATION OF AUTHORITY OF  
24 SECRETARY TO CONSULT CARRIERS.—Nothing  
25 in this section shall be construed as affecting

1           the authority of the Secretary to consult with  
2           appropriate Medicare administrative contrac-  
3           tors.

4           (b) PROCESS FOR ASSIGNMENT OF TEMPORARY  
5 CODES FOR DIAGNOSTIC TESTS.—The Secretary shall es-  
6 tablish a process for application for the assignment of a  
7 temporary national HCPCS code to uniquely identify a di-  
8 agnostic test until a permanent national HCPCS code is  
9 available for assignment to that test. Assignments of a  
10 temporary national HCPCS code shall occur on a quar-  
11 terly basis. The Secretary shall provide public notice  
12 through the Centers for Medicare & Medicaid Services  
13 Web site of applications made for such temporary national  
14 HCPCS codes. Upon assignment of a temporary code  
15 under this process, the Secretary shall treat such test as  
16 a new test for purposes of section 1833(h)(8) of the Social  
17 Security Act.

18           (c) DEVELOPMENT OF FURTHER IMPROVEMENTS IN  
19 RATE-SETTING PROCESSES.—The Secretary shall analyze  
20 the process used for the gapfilling procedure used in deter-  
21 mining payment amounts for new clinical diagnostic lab-  
22 oratory tests under section 1833(h)(8) of the Social Secu-  
23 rity Act. Taking into account the changes made by this  
24 section, the Secretary shall identify further changes to im-  
25 prove the accuracy and appropriateness of resulting rates

1 and the openness, transparency, and predictability of the  
2 process. The Secretary shall examine what and how many  
3 entities should perform gapfilling, under contract or other-  
4 wise, and how to ensure that the process is informed by  
5 appropriate expertise and proceeds in a transparent and  
6 accountable manner. The Secretary shall implement im-  
7 provements in the process, insofar as these are possible  
8 under the law through regulations, after public notice and  
9 opportunity for comment. For changes the Secretary de-  
10 termines would require a change in law, the Secretary  
11 shall transmit recommendations to the Speaker of the  
12 House and the President of the Senate not later than July  
13 1, 2013.

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

15 (1) NEW CLINICAL DIAGNOSTIC LABORATORY  
16 TESTS.—The term “new clinical diagnostic labora-  
17 tory test” means a clinical diagnostic laboratory  
18 test—

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

21 (B) for which an application for a tem-  
22 porary national HCPCS code is made under  
23 subsection (b) on or after January 1, 2013.

24 (2) SELF-PAY PATIENT.—The term “self-pay  
25 patient” means, with respect to a health care item

1 or service, an individual who pays out of pocket for  
2 such item or service and who does not have health  
3 insurance coverage for such item or service.

4 (e) EFFECTIVE DATE.—This section shall take effect  
5 on the date of enactment of this Act, and shall apply with  
6 respect to new clinical diagnostic laboratory tests.

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