

115TH CONGRESS  
2D SESSION

# H. R. 5541

To amend titles XVIII and XIX of the Social Security Act to provide equal coverage of in vitro specific IgE tests and percutaneous tests for allergies under the Medicare and Medicaid programs, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

APRIL 17, 2018

Mr. UPTON (for himself and Ms. CLARKE of New York) 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 amend titles XVIII and XIX of the Social Security Act to provide equal coverage of in vitro specific IgE tests and percutaneous tests for allergies under the Medicare and Medicaid programs, and for other purposes.

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 “Removing Barriers to  
5 Allergy Diagnostic Testing Act of 2018”.

1 **SEC. 2. FINDINGS.**

2 Congress finds the following:

3 (1) Allergies, when not properly diagnosed, can-  
4 not be effectively treated.

5 (2) Allergies to food, inhaled particles, or other  
6 sources can cause debilitating and, in some cases,  
7 fatal reactions.

8 (3) Allergies can substantially compound other  
9 illnesses, including asthma, emphysema, and adult  
10 obstructive pulmonary diseases, leading to social and  
11 economic costs for families and our Nation's health  
12 care system.

13 (4) According to clinical guidelines from the  
14 National Institutes of Health and recommendations  
15 from peer-reviewed literature, in vitro specific IgE  
16 tests and percutaneous tests are considered equiva-  
17 lent as confirmatory tests in terms of their sensi-  
18 tivity and accuracy.

19 (5) Despite these recommendations, some cur-  
20 rent Medicare local coverage determinations and  
21 Medicaid coverage policies deny equal access to in  
22 vitro specific IgE tests and percutaneous tests.

23 (6) In vitro specific IgE tests and percutaneous  
24 tests must be equally accessible for clinicians and  
25 patients to improve health outcomes, reduce system

1 costs, and reduce current health care disparities  
2 caused by the lack of equal coverage.

3 **SEC. 3. MEDICAID COVERAGE FOR ALLERGY DIAGNOSTIC**  
4 **TESTING SERVICES.**

5 (a) IN GENERAL.—Title XIX of the Social Security  
6 Act (42 U.S.C. 1396 et seq.) is amended—

7 (1) in section 1902(a)—

8 (A) in paragraph (82), by striking “and”  
9 at the end;

10 (B) in paragraph (83), by striking the pe-  
11 riod at the end and inserting “; and”; and

12 (C) by inserting before the matter fol-  
13 lowing paragraph (83) the following new para-  
14 graph:

15 “(84) provide, with respect to the provision of  
16 allergy diagnostic testing services (as defined in sec-  
17 tion 1905(ee)) under the State plan, for equality in  
18 the treatment of in vitro specific IgE tests and  
19 percutaneous tests with respect to—

20 “(A) any medical necessity or other cov-  
21 erage requirements established for such in vitro  
22 specific IgE and percutaneous tests;

23 “(B) any frequency limits established for  
24 such tests; and

1           “(C) any allergen unit limits established  
2           for such tests.”; and

3           (2) in section 1905—

4           (A) in subsection (r)—

5           (i) by redesignating paragraph (5) as  
6           paragraph (6); and

7           (ii) by inserting after paragraph (4)  
8           the following new paragraph:

9           “(5) Allergy diagnostic testing services (as de-  
10          fined in subsection (ee)).”; and

11          (B) by adding at the end the following new  
12          subsection:

13          “(ee) ALLERGY DIAGNOSTIC TESTING SERVICES DE-  
14          FINED.—The term ‘allergy diagnostic testing services’  
15          means in vitro specific IgE tests and percutaneous tests  
16          that—

17                 “(1) have been cleared under section 501(k),  
18                 classified under section 513(f)(2), or approved under  
19                 section 515 of the Federal Food, Drug, and Cos-  
20                 metic Act; and

21                 “(2) are provided to individuals for the purpose  
22                 of evaluating immunologic response to certain anti-  
23                 gens.”.

24          (b) EFFECTIVE DATE.—

1           (1) IN GENERAL.—Subject to paragraph (2),  
2           the amendments made by this section shall apply  
3           with respect to items and services provided on or  
4           after January 1, 2019.

5           (2) EXCEPTION FOR STATE LEGISLATION.—In  
6           the case of a State plan under title XIX of the So-  
7           cial Security Act (42 U.S.C. 1396 et seq.) that the  
8           Secretary of Health and Human Services determines  
9           requires State legislation in order for the respective  
10          plan to meet any requirement imposed by amend-  
11          ments made by this section, the respective plan shall  
12          not be regarded as failing to comply with the re-  
13          quirements of such title solely on the basis of its  
14          failure to meet such an additional requirement be-  
15          fore the first day of the first calendar quarter begin-  
16          ning after the close of the first regular session of the  
17          State legislature that begins after the date of the en-  
18          actment of this Act. For purposes of the previous  
19          sentence, in the case of a State that has a 2-year  
20          legislative session, each year of the session shall be  
21          considered to be a separate regular session of the  
22          State legislature.

1 **SEC. 4. MEDICARE COVERAGE FOR ALLERGY DIAGNOSTIC**  
2 **TESTING SERVICES.**

3 (a) **COVERAGE.**—Section 1861 of the Social Security  
4 Act (42 U.S.C. 1395x) is amended—

5 (1) in subsection (s)(2)—

6 (A) in subparagraph (FF), by striking  
7 “and” at the end;

8 (B) in subparagraph (GG), by striking the  
9 semicolon at the end and inserting “; and”; and

10 (C) by adding at the end the following new  
11 subparagraph:

12 “(HH) allergy diagnostic testing services (as  
13 defined in subsection (jjj));”; and

14 (2) by adding at the end the following new sub-  
15 section:

16 “(jjj) **ALLERGY DIAGNOSTIC TESTING SERVICES.**—

17 “(1) **IN GENERAL.**—The term ‘allergy diag-  
18 nostic testing services’ means in vitro specific IgE  
19 tests and percutaneous tests—

20 “(A) that have been cleared under section  
21 501(k), classified under section 513(f)(2), or  
22 approved under section 515 of the Federal  
23 Food, Drug, and Cosmetic Act; and

24 “(B) which are furnished to individuals for  
25 the purpose of evaluating immunologic response

1 to certain antigens, as determined appropriate  
2 by the practitioner ordering such test.

3 “(2) EQUAL ACCESS TO TESTING METHODS.—

4 The Secretary shall ensure equality in the treatment  
5 of in vitro specific IgE tests and percutaneous tests  
6 described in paragraph (1) with respect to—

7 “(A) any medical necessity or other cov-  
8 erage requirements established for such in vitro  
9 specific IgE and percutaneous tests;

10 “(B) any frequency limits established for  
11 such tests; and

12 “(C) any allergen unit limits established  
13 for a year for such tests.”.

14 (b) PAYMENT.—Section 1834 of the Social Security  
15 Act (42 U.S.C. 1395m) is amended by adding at the end  
16 the following new subsection:

17 “(v) ALLERGY DIAGNOSTIC TESTING SERVICES.—

18 For purposes of payment only, in the case of allergy diag-  
19 nostic testing services (as defined in section 1861(jjj))—

20 “(1) in vitro specific IgE tests shall be treated  
21 as clinical diagnostic laboratory tests; and

22 “(2) percutaneous tests shall be treated as phy-  
23 sicians’ services.”.

1           (c) EFFECTIVE DATE.—The amendments made by  
2 this section shall apply with respect to items and services  
3 furnished on or after January 1, 2019.

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