

116TH CONGRESS  
1ST SESSION

# S. 2246

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 SENATE OF THE UNITED STATES

JULY 24, 2019

Mr. MORAN introduced the following bill; which was read twice and referred to the Committee on Finance

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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 “Allergy Testing Access  
5 Act of 2019”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

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

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

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

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

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

21           (6) In vitro specific IgE tests and percutaneous  
22 tests must be equally accessible for clinicians and  
23 patients to improve health outcomes, reduce system  
24 costs, and reduce current health care disparities  
25 caused by the lack of equal coverage.

1 **SEC. 3. MEDICAID COVERAGE FOR ALLERGY DIAGNOSTIC**  
2 **TESTING SERVICES.**

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

5 (1) in section 1902(a)—

6 (A) in paragraph (85), by striking “and”  
7 at the end;

8 (B) in paragraph (86), by striking the pe-  
9 riod at the end and inserting “; and”; and

10 (C) by inserting after paragraph (86) the  
11 following new paragraph:

12 “(87) provide, with respect to the provision of  
13 allergy diagnostic testing services (as defined in sec-  
14 tion 1905(ff)) under the State plan, for equality in  
15 the treatment of in vitro specific IgE tests and  
16 percutaneous tests with respect to—

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

20 “(B) any frequency limits established for  
21 such tests; and

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

24 (2) in section 1905—

25 (A) in subsection (r)—

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

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

5 “(5) Allergy diagnostic testing services (as de-  
6 fined in subsection (ff)).”; and

7 (B) by adding at the end the following new  
8 subsection:

9 “(ff) ALLERGY DIAGNOSTIC TESTING SERVICES DE-  
10 FINED.—The term ‘allergy diagnostic testing services’  
11 means in vitro specific IgE tests and percutaneous tests  
12 that—

13 “(1) have been cleared under section 501(k),  
14 classified under section 513(f)(2), or approved under  
15 section 515 of the Federal Food, Drug, and Cos-  
16 metic Act; and

17 “(2) are provided to individuals for the purpose  
18 of evaluating immunologic response to certain anti-  
19 gens.”.

20 (b) EFFECTIVE DATE.—

21 (1) IN GENERAL.—Subject to paragraph (2),  
22 the amendments made by this section shall apply  
23 with respect to items and services provided on or  
24 after January 1, 2021.

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

19 **SEC. 4. MEDICARE COVERAGE FOR ALLERGY DIAGNOSTIC**  
20 **TESTING SERVICES.**

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

23                   (1) in subsection (s)(2)—

24                           (A) in subparagraph (GG), by striking  
25                           “and” at the end;

1 (B) in subparagraph (HH), by striking the  
2 period at the end and inserting “; and”; and

3 (C) by adding at the end the following new  
4 subparagraph:

5 “(II) allergy diagnostic testing services (as de-  
6 fined in subsection (kkk));”; and

7 (2) by adding at the end the following new sub-  
8 section:

9 “(kkk) ALLERGY DIAGNOSTIC TESTING SERVICES.—

10 “(1) IN GENERAL.—The term ‘allergy diag-  
11 nostic testing services’ means in vitro specific IgE  
12 tests and percutaneous tests—

13 “(A) that have been cleared under section  
14 501(k), classified under section 513(f)(2), or  
15 approved under section 515 of the Federal  
16 Food, Drug, and Cosmetic Act; and

17 “(B) which are furnished to individuals for  
18 the purpose of evaluating immunologic response  
19 to certain antigens, as determined appropriate  
20 by the practitioner ordering such test.

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

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

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

4           “(B) any frequency limits established for  
5           such tests; and

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

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

11          “(x) ALLERGY DIAGNOSTIC TESTING SERVICES.—  
12          For purposes of payment only, in the case of allergy diag-  
13          nostic testing services (as defined in section 1861(kkk))—

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

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

18          (c) EFFECTIVE DATE.—The amendments made by  
19          this section shall apply with respect to items and services  
20          furnished on or after January 1, 2021.

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