

116TH CONGRESS
1ST SESSION

H. R. 2009

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.

IN THE HOUSE OF REPRESENTATIVES

APRIL 1, 2019

Ms. CLARKE of New York (for herself and Mr. UPTON) 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

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 2019”.

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 (85), by striking “and”
9 at the end;

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

12 (C) by inserting after paragraph (86) the
13 following new paragraph:

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

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

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

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

1 (2) in section 1905—

2 (A) in subsection (r)—

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

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

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

9 (B) by adding at the end the following new
10 subsection:

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

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

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

22 (b) EFFECTIVE DATE.—

23 (1) IN GENERAL.—Subject to paragraph (2),
24 the amendments made by this section shall apply

1 with respect to items and services provided on or
2 after January 1, 2021.

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

21 **SEC. 4. MEDICARE COVERAGE FOR ALLERGY DIAGNOSTIC**
22 **TESTING SERVICES.**

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

25 (1) in subsection (s)(2)—

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

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

5 (C) by adding at the end the following new
 6 subparagraph:

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

9 (2) by adding at the end the following new sub-
 10 section:

11 “(kkk) ALLERGY DIAGNOSTIC TESTING SERVICES.—

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

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

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

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

24 The Secretary shall ensure equality in the treatment

1 of in vitro specific IgE tests and percutaneous tests
 2 described in paragraph (1) with respect to—

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

6 “(B) any frequency limits established for
 7 such tests; and

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

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

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

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

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

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

○