

117TH CONGRESS
1ST SESSION

H. R. 4114

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

JUNE 24, 2021

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 “Allergy Testing Access
5 Act of 2021”.

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. MEDICARE COVERAGE FOR ALLERGY DIAGNOSTIC**
 4 **TESTING SERVICES.**

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

7 (1) in subsection (s)(2)—

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

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

12 (C) by adding at the end the following new
 13 subparagraph:

14 “(B) allergy diagnostic testing services (as de-
 15 fined in subsection (lll));”; and

16 (2) by adding at the end the following new sub-
 17 section:

18 “(lll) ALLERGY DIAGNOSTIC TESTING SERVICES.—

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

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

1 “(B) which are furnished to individuals for
 2 the purpose of evaluating immunologic response
 3 to certain antigens, as determined appropriate
 4 by the practitioner ordering such test.

5 “(2) EQUAL ACCESS TO TESTING METHODS.—
 6 The Secretary shall ensure equality in the treatment
 7 of in vitro specific IgE tests and percutaneous tests
 8 described in paragraph (1) with respect to—

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

12 “(B) any frequency limits established for
 13 such tests; and

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

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

19 “(z) ALLERGY DIAGNOSTIC TESTING SERVICES.—
 20 For purposes of payment only, in the case of allergy diag-
 21 nostic testing services (as defined in section 1861(l))—

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

24 “(2) percutaneous tests shall be treated as phy-
 25 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, 2022.

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

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

8 (1) in section 1902(a)—

9 (A) in paragraph (86), by striking “and”
10 at the end;

11 (B) in paragraph (87), by striking the pe-
12 riod at the end and inserting “; and”; and

13 (C) by inserting after paragraph (87) the
14 following new paragraph:

15 “(88) provide, with respect to the provision of
16 allergy diagnostic testing services (as defined in sec-
17 tion 1905(hh)) 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 (hh)).”; and

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

13 “(hh) 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, 2022.

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.

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