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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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Allergy Testing Access Act of 2021''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) Allergies, when not properly diagnosed, cannot be effectively treated.

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

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

(4) According to clinical guidelines from the National Institutes of Health and recommendations from peer-reviewed literature, in vitro specific IgE tests and percutaneous tests are considered equivalent as confirmatory tests in terms of their sensitivity and accuracy.

(5) Despite these recommendations, some current Medicare local coverage determinations and Medicaid coverage policies deny equal access to in vitro specific IgE tests and percutaneous tests.

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

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

SEC. 3. MEDICARE COVERAGE FOR ALLERGY DIAGNOSTIC TESTING SERVICES.

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

(1) in subsection (s)(2)—

(A) in subparagraph (GG), by striking ''and'' at the end;

(B) in subparagraph (HH), by striking the period at the end and inserting ''; and''; and

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

''(B) allergy diagnostic testing services (as defined in subsection (lll));''; and

(2) by adding at the end the following new subsection:

''(lll) ALLERGY DIAGNOSTIC TESTING SERVICES.—

''(1) IN GENERAL.—The term 'allergy diagnostic testing services' means in vitro specific IgE tests and percutaneous tests—

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

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

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

''(A) any medical necessity or other coverage requirements established for such in vitro specific IgE and percutaneous tests;

''(B) any frequency limits established for such tests; and

''(C) any allergen unit limits established for a year for such tests.''.

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

''(z) ALLERGY DIAGNOSTIC TESTING SERVICES.—For purposes of payment only, in the case of allergy diagnostic testing services (as defined in section 1861(lll))—

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

''(2) percutaneous tests shall be treated as physicians' services.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to items and services furnished on or after January 1, 2022.

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

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

(1) in section 1902(a)—

(A) in paragraph (86), by striking ''and'' at the end;

(B) in paragraph (87), by striking the period at the end and inserting ''; and''; and

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

''(88) provide, with respect to the provision of allergy diagnostic testing services (as defined in section 1905(hh)) under the State plan, for equality in the treatment of in vitro specific IgE tests and percutaneous tests with respect to—

''(A) any medical necessity or other coverage requirements established for such in vitro specific IgE and percutaneous tests;

''(B) any frequency limits established for such tests; and

''(C) any allergen unit limits established for such tests.''; and

(2) in section 1905—

(A) in subsection (r)—

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

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

''(5) Allergy diagnostic testing services (as defined in subsection (hh)).''; and

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

''(hh) ALLERGY DIAGNOSTIC TESTING SERVICES DEFINED.—The term 'allergy diagnostic testing services' means in vitro specific IgE tests and percutaneous tests that—

''(1) have been cleared under section 501(k), classified under section 513(f)(2), or approved under section 515 of the Federal Food, Drug, and Cosmetic Act; and

''(2) are provided to individuals for the purpose of evaluating immunologic response to certain antigens.''.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Subject to paragraph (2), the amendments made by this section shall apply with respect to items and services provided on or after January 1, 2022.

(2) EXCEPTION FOR STATE LEGISLATION.—In the case of a State plan under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) that the Secretary of Health and Human Services determines requires State legislation in order for the respective plan to meet any requirement imposed by amendments made by this section, the respective plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet such an additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of the enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session shall be considered to be a separate regular session of the State legislature.

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