

117TH CONGRESS
1ST SESSION

H. R. 5745

To clarify Medicare coverage for COVID–19 testing and to provide support for cellular immune response research for COVID–19, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 27, 2021

Mr. DUNN (for himself and Mr. JACKSON) 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 clarify Medicare coverage for COVID–19 testing and to provide support for cellular immune response research for COVID–19, 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 “COVID–19 Access to
5 Testing and Support for Immune Response Research Act
6 of 2021”.

7 **SEC. 2. FINDINGS.**

8 Congress finds the following:

1 (1) A public health emergency regarding the
2 COVID–19 pandemic was first declared on January
3 31, 2020, and has been subsequently renewed re-
4 peatedly, most recently on July 19, 2021, by the
5 Secretary of Health and Human Services under both
6 Republican and Democratic administrations.

7 (2) In the spring of 2020, the only tests avail-
8 able to determine whether a person had a recent or
9 prior infection of SARS–CoV–2 were serology tests
10 which could identify whether a person had antibodies
11 specific to the SARS–CoV–2 virus.

12 (3) On May 8, 2020, the Centers for Medicare
13 & Medicaid Services (CMS), citing the ongoing
14 COVID–19 public health emergency, issued an in-
15 terim final rule which recognized on an interim basis
16 that certain Food and Drug Administration-author-
17 ized serology tests fall under the Medicare benefit
18 category for diagnostic laboratory tests.

19 (4) On March 5, 2021, the Food and Drug Ad-
20 ministration issued the first authorization for the
21 emergency use of a cellular (T-cell) immune re-
22 sponse COVID–19 test intended for use as an aid in
23 identifying individuals with an adaptive T-cell im-
24 mune response to SARS–CoV–2, indicating recent or
25 prior infection with SARS–CoV–2.

1 (5) CMS has yet to update its May 8, 2020, in-
2 terim final rule or provide separate guidance to clar-
3 ify that Medicare coverage extends to other Food
4 and Drug Administration-authorized tests, including
5 T-cell tests, that are intended for diagnosing recent
6 or prior infection with SARS-CoV-2.

7 (6) In research and development related to in-
8 fectious diseases and vaccines, including SARS-
9 CoV-2, historically the antibody response, which is
10 only half of the adaptive immune system, has been
11 the primary tool for assessment.

12 (7) The other half of the adaptive immune re-
13 sponse, the T-cell response, has historically been
14 more difficult to assess, but scientific and techno-
15 logical advances now allow for standardized and sen-
16 sitive methods to measure T-cells.

17 (8) The National Institutes of Health have inte-
18 grated T-cell testing into certain studies regarding
19 the impact of T-cells in detecting and defending
20 against SARS-CoV-2 variants, and there exist addi-
21 tional research opportunities regarding the cellular
22 immune response to SARS-CoV-2, including—

23 (A) identifying the type and duration of T-
24 cell response that confers immunity (including

1 to variants) following natural infection, vaccina-
2 tion, or both;

3 (B) understanding the T-cell response in
4 different populations, including children, the el-
5 derly, and immunocompromised individuals; and

6 (C) understanding the T-cell response in
7 patients facing long-term COVID–19 symp-
8 toms.

9 (9) Evidence shows T-cells play an important
10 role in the immune response to COVID–19 and
11 points to the need for a concerted research effort,
12 which could have profound consequences on public
13 health, such as policies on boosters or the develop-
14 ment of therapeutics for patients suffering from
15 post-acute sequelae of COVID–19 infection.

16 **SEC. 3. CLARIFYING MEDICARE COVERAGE OF COVID–19 DI-**
17 **AGNOSTIC LABORATORY TESTS.**

18 (a) IN GENERAL.—The Administrator of the Centers
19 for Medicare & Medicaid Services shall by interim rule,
20 subregulatory guidance, or otherwise, provide for coverage
21 of T-cell diagnostic laboratory tests furnished during the
22 period beginning on January 1, 2022, and ending on the
23 last date of the public health emergency period (described
24 in section 1135(g)(1)(B) of the Social Security Act (42
25 U.S.C. 1320b–5(g)(1)(B))) for beneficiaries with current

1 or known prior COVID–19 infection or suspected current
2 or suspected past COVID–19 infection.

3 (b) T-CELL DIAGNOSTIC LABORATORY TEST DE-
4 FINED.—For purposes of subsection (a), the term “T-cell
5 diagnostic laboratory test” means a clinical laboratory test
6 that is—

7 (1) intended to identify an adaptive T-cell im-
8 mune response to SARS–CoV–2 indicative of recent
9 or prior infection with SARS–CoV–2; and

10 (2) cleared, approved, or otherwise authorized
11 pursuant to the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 301 et seq.).

13 **SEC. 4. NATIONAL STRATEGY FOR COVID–19 CELLULAR IM-**
14 **MUNE RESPONSE RESEARCH.**

15 (a) IN GENERAL.—The Secretary of Health and
16 Human Services (in this section referred to as the “Sec-
17 retary”)—

18 (1) shall—

19 (A) expand, intensify, and coordinate the
20 programs and activities of the National Insti-
21 tutes of Health and the Centers for Disease
22 Control and Prevention with respect to sci-
23 entific and clinical research on the cellular im-
24 mune response related to COVID–19;

1 (B) develop and implement a national
2 strategy to research the cellular immune re-
3 sponse to SARS-CoV-2, which shall include re-
4 search on—

5 (i) the type and duration of T-cell re-
6 sponses to COVID-19 vaccines and how
7 such responses confer immunity and con-
8 tribute to protection from infection with
9 SARS-CoV-2 variants of concern;

10 (ii) the type and duration of T-cell re-
11 sponses in patients who have recovered
12 from COVID-19 and how such responses
13 may confer immunity;

14 (iii) the type and duration of T-cell
15 immune responses in patients facing long-
16 term COVID-19 symptoms; and

17 (iv) the type and duration of T-cell re-
18 sponses to vaccination and natural infec-
19 tion in certain populations, such as chil-
20 dren, the elderly, and immunocompromised
21 individuals; and

22 (C) update the strategy under subpara-
23 graph (B) as appropriate; and

24 (2) subject to the availability of appropriations,
25 may make grants to States, political subdivisions,

1 public-private partnerships, academic institutions,
2 and other public entities to carry out scientific and
3 clinical research on the cellular immune response re-
4 lated to COVID–19 and to implement the strategy
5 under paragraph (2).

6 (b) CONSULTATION.—In carrying out subsection (a),
7 the Secretary shall consult with relevant individuals, as
8 appropriate, such as—

9 (1) clinicians, public health professionals, and
10 others with expertise in cellular immune response;

11 (2) representatives of patient advocacy and re-
12 search organizations with interest in cellular immune
13 research;

14 (3) researchers with expertise in cellular immu-
15 nology; and

16 (4) epidemiologists with experience in cellular
17 immune response.

18 (c) PUBLIC MEETING.—Not later than 3 months
19 after the date of the enactment of this Act, the Secretary,
20 acting through the Director of the National Institutes of
21 Health, shall convene a public meeting composed of sub-
22 ject matter experts and stakeholders to identify research
23 needs and opportunities.

24 (d) PUBLICATION OF STRATEGY.—The Secretary
25 shall make public the strategy under subsection (a)(1)(B),

- 1 including initial funding opportunity announcements,
- 2 within 6 months of the date of enactment of this Act.

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