United States Senate
WASHINGTON, DC 20510

April 8, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington D.C. 20201

Dear Secretary Azar:

We write to make clear that tests for antibodies of COVID-19 or SARS-CoV-2 are required to be covered at no cost to patients in accordance with the Families First Coronavirus Response Act (P.L. 116-127) and the Coronavirus Aid, Relief, and Economic Security Act (P.L. 116-136).

Increasing the availability of testing is one of Congress' primary goals as we combat this disease. Increasing diagnosing testing is vital to slowing the spread of the virus, and our country's economic and educational well-being is dependent on Americans having confidence in being able to go back to school, work, and out to eat.

It is critical that the federal government incentivize the development of tests that can detect COVID-19 antibodies, which will help better inform Americans about their short, and potentially long, term immunity to COVID-19.

To achieve this goal, Congress included provisions guaranteeing coverage at no cost to the patient for COVID-19 testing in the Families First Coronavirus Response Act (P.L. 116-127) and the Coronavirus Aid, Relief, and Economic Security Act (P.L. 116-136).

Specifically, the laws provide that, "…the detection of SARS–CoV–2 or the diagnosis of the virus that causes COVID–19…" must be covered for all patients, regardless of their source or status of health care coverage. This provision applies to a current or future diagnostic test, that:

"(A) is approved, cleared, or authorized under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c, 360e, 360bbb–3);
"(B) the developer has requested, or intends to request, emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), unless and until the emergency use authorization request under such section 564 has been denied or the developer of such test does not submit a request under such section within a reasonable timeframe;
"(C) is developed in and authorized by a State that has notified the Secretary of Health and Human Services of its intention to review tests intended to diagnose COVID–19; or
"(D) other test that the Secretary determines appropriate in guidance.''

It is the express intent of Congress that this statutory provision applies to both the diagnosis of COVID-19 or SARS-CoV-2 and the detection of antibodies to SARS–CoV–2 that indicate a person may be immune to future infection, at least for the short term.

Thank you for your attention to this matter.

Sincerely,

Lamar Alexander
U.S. Senator

Roy Blunt
U.S. Senator