

April 2, 2020

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201



DELIVERED ELECTRONICALLY

RE: \$100 Billion CARES Act Fund for Eligible Health Care Providers

Dear Secretary Azar:

The American Clinical Laboratory Association (ACLA) is the voice of clinical laboratories on the front lines of the COVID-19 response, including Quest Diagnostics, LabCorp, BioReference Laboratories, Sonic Healthcare USA, ARUP, Mayo Clinic Laboratories, and others that have risen to the challenge of providing the COVID-19 tests that are so critical to combatting the pandemic in this country. Despite representing a very small share of health care spending, laboratory services are an essential tool for identifying and responding to infectious disease outbreaks and protecting the public.

ACLA and its members have coordinated closely with the White House, federal agencies such as HHS, the CDC and FDA, and state and local public health labs, hospitals and academic medical centers to rapidly expand testing capacity for COVID-19. To date, ACLA members alone have reported out *almost one million COVID-19 tests* since they began testing at the beginning of March.

ACLA urges the Administration to begin accepting applications from clinical laboratories immediately so they may access funds that Congress appropriated to the Public Health and Social Services Emergency Fund (PHSSEF) under Public Law 116-136, the Coronavirus Aid, Relief, and Economic Security (CARES) Act, for “eligible health care providers”, including clinical laboratories for “health care related expenses or lost revenues that are attributable to coronavirus.” Laboratories need this funding to build the capacity our nation needs to ensure access to testing for every patient that needs one.

Following the FDA’s February 29, 2020 guidance allowing commercial clinical laboratories to begin offering laboratory developed tests (LDTs) for COVID-19, ACLA members and other laboratories acted immediately and, within a week, began accepting patient specimens to test for COVID-19. ACLA members and others in the laboratory community are creating even more testing capacity and developing new types of tests to help combat the pandemic and save American lives.

ACLA fully supports the Administration's commitment to ensure patients can access COVID-19 tests and treatments without out-of-pocket costs. But, today, hundreds of thousands of Americans are still in need of a COVID-19 test, and commercial labs are using every available resource to scale capacity as quickly as possible. The increasing costs of testing components, such as specimen collection swabs, reagents, and personal protective equipment, combined with a decrease in revenues for routine lab services, have made it increasingly difficult to achieve the critical public health goal of developing and performing tens of thousands of COVID-19 tests each day. Financial support for laboratories is critical now so that every American that needs a test can get a test.

ACLA urges the Administration to make funding available to clinical laboratories for the following purposes, among others:

- Costs related to uncompensated COVID-19 testing services
- Support for laboratory personnel, including child and dependent care, training, temporary staff, and overtime pay
- Capital and supplies acquisition, including testing platforms, reagents, components, and specimen collection swabs; personal protective equipment; laboratory equipment; cybersecurity; and IT software and hardware
- Lost revenues due to lower test volume as a result of social distancing and a decrease in routine physician visits and surgeries
- Support for research and development COVID-19 testing

ACLA and its member laboratories are committed to working with the White House, HHS, CDC, FDA, Congress, and public health partners across the country to ensure that Americans receive the testing they need. Maintaining the full force of the commercial laboratory industry is essential to combat this pandemic. We greatly appreciate the Administration's support of clinical laboratories, particularly through distribution of these funds through the PHSSEF.

Sincerely,

A handwritten signature in black ink, appearing to read 'Julie Khani', written in a cursive style.

Julie Khani, President
American Clinical Laboratory Association