AMERICAN CLINICAL LABORATORY ASSOCIATION

January 30, 2023

The Honorable Brian Schatz
United States Senate
Washington, DC 20510

The Honorable Mike Thompson
United States House of Representatives
Washington, DC 20510

DELIVERED VIA ELECTRONIC DELIVERY

RE: Updating the *CONNECT for Health Act of 2021* (S. 1512/H.R. 2903)

Dear Senator Schatz, Congressman Thompson and Members of the Senate Telehealth Working Group and House Telehealth Caucus:

The American Clinical Laboratory Association (ACLA) appreciates the opportunity to share recommendations for updating the *CONNECT for Health Act of 2021* as you seek its reintroduction in the 118th Congress. ACLA is the not-for-profit association representing the nation's leading clinical and anatomic pathologic laboratories, including national, regional, specialty, end-stage renal disease, and nursing home laboratories. Tests performed by clinical laboratories are critical for the diagnosis and management of an extensive range of acute, chronic, and infectious health conditions including but not limited to: cancers; pneumonia; diabetes; heart, liver, and kidney disease; anemia; infections, and opioid dependency. ACLA member laboratories advocate for unimpeded patient access to telehealth services as well as access to telehealth-ordered clinical laboratory tests. We write to share proposals that aim to improve program integrity while retaining strong patient access.

ACLA supports the aims of the *CONNECT for Health Act* in expanding access to telehealth services permanently and removing barriers to coverage. Allowing clinicians to order laboratory tests via telehealth helps ensure patient access to essential diagnostic and screening services which can be vital to delivering timely health care. Furthermore, the use of telehealth to order laboratory tests helps protect immunocompromised patients from the risk of exposure to infectious diseases; helps ease the stigma associated with certain medical conditions; and improves access for patients who live a significant traveling distance from their providers.

Increased utilization of telehealth has, understandably, led to federal government monitoring of fraud, waste, and abuse in telehealth. Despite the increased use of telehealth during the COVID-19 public health emergency (PHE), the HHS' Office of Inspector General (OIG) recently reported only a small number of providers whose telehealth billing practices were considered to be "high risk"[1]. These findings suggest that any efforts to address rare instances of fraud and abuse and maintain program integrity should be appropriately targeted.

[1] https://oig.hhs.gov/oei/reports/OEI-02-20-00720.asp

Consistent with the Bipartisan Policy Center's recommendations[2] to protect Medicare program integrity, ordering of fraudulent laboratory tests may be easily identified through scrutiny of specific codes of concern or outlier physician ordering practices in certain Medicare Administrative Contractor (MAC) jurisdictions. Importantly, the recently passed *Consolidated Appropriations Act, 2023*, requires a program integrity study by the HHS Office of Inspector General auditing Medicare claims to assess potential fraud in telehealth. The results of this study should guide Congress in consideration of additional program integrity measures.

Additionally, the Centers of Medicare and Medicaid Services (CMS) should require registration of technology vendors who offer and maintain telehealth platforms for use by Medicare providers. Registration would provide CMS with a transparent view of the telehealth technology marketplace, creating accountability for the technology vendors. For example, vendors could be required to attest that they will not solicit, induce, nor facilitate fraudulent billing of the Medicare program as well as accept consequences for noncompliance.

Both auditing of ordering practices and registration of technology vendors are appropriate integrity policies that help create reasonable accountability from providers and vendors who leverage telehealth technology. These measures are much more targeted than an across-the-board requirement of in-person, face-to-face visits and would better address any program integrity concerns while not creating barriers to patients who benefit from telehealth access.

As a final point, while the *CONNECT for Health Act* removes geographic and originating site restrictions, ACLA recommends including clarifying language that in-person, face-to-face visits would not be required for ordering clinical laboratory tests. First, the requirement of a face-to-face visit has the potential to block legitimate and clinically appropriate patient access to medically necessary laboratory tests, such as those ordered in preparation for an in-person appointment or a visit outside a one-year window of last seeing the provider. Second, requirements for an in-person visit do not reflect how clinical laboratory tests are ordered and performed. Clinical laboratories do not have direct contact with patients in advance of lab work to ascertain if the patient had an in-person visit with an ordering clinician. Clinical laboratories also lack the capability to reliably confirm this information in a timely manner, therefore delaying the administration of the ordered tests. Laboratories have a clinical and ethical obligation to report test results as soon as possible. Therein lies the distinct risk that laboratories will have already delivered results for a legitimately ordered test, only to have the claim later denied. Such broad restrictions on clinical laboratory test ordering should be excluded in any future proposals, particularly as an attempt to address fraud and abuse or program integrity concerns.

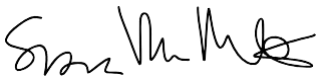
ACLA believes telehealth has the potential to continue broadening access to care for patients and improving their health outcomes. The responsibility for Medicare program integrity should be appropriately distributed across vendors and providers who generate test orders for Medicare beneficiaries; clinical laboratories who receive test orders from authorized providers and perform the tests should not be penalized for actions over which they have no control while those who

[2] Bipartisan Policy Center, The Future of Telehealth After COVID-19: New Opportunities and Challenges (October 2022). Accessed at: https://bipartisanpolicy.org/download/?file=/wp-content/uploads/2022/09/BPC-The-Future-of-Telehealth-After-COVID-19-October-2022.pdf.

control utilization are exempted from accountability. ACLA stands ready to engage with lawmakers on re-introduction of the *CONNECT for Health Act* to recognize the importance of telehealth for ordering clinical laboratory tests and reducing barriers such as requiring face-to-face visits that would very likely impede patient access to critical tests.

Thank you for your consideration of these comments. If ACLA may be of further assistance, please contact Tom Sparkman at tsparkman@acla.com or Holly Grosholz at hgrosholz@acla.com.

Sincerely,



Susan Van Meter, President
American Clinical Laboratory Association