AMERICAN CLINICAL LABORATORY ASSOCIATION

September 13, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Becerra,

The American Clinical Laboratory Association (ACLA), representing the nation's leading clinical and anatomic pathology laboratories, appreciates the Biden Administration's and Department of Health & Human Services' (HHS) leadership in our nation's continuing COVID-19 pandemic response efforts, including the recognition of the important role of laboratory testing in a comprehensive public health emergency response. During the pandemic, numerous policies were put in place to facilitate and bolster the nation's response, including by improving patient access to services. ACLA appreciates that HHS has begun to contemplate the eventual end of the COVID-19 public health emergency (PHE), as evidenced by the recent post from the Centers for Medicare & Medicaid Services (CMS) outlining a post-PHE Roadmap.[1] ACLA urges you to consider extending several COVID-19 testing-related policies and flexibilities beyond the expiration of the PHE and to commit to working with ACLA on future preparedness matters, including through consideration of a proposal being developed in collaboration with the Johns Hopkins Center for Public Health Services for an immediate response diagnostics action plan.

Since the earliest days of the pandemic, in collaboration with the U.S. Government, ACLA member labs have been an essential component of the nation's pandemic response. The earliest development, validation, and nationwide scaling of COVID-19 tests was achieved by ACLA members. Since March 2020, ACLA members collectively have performed more than 200 million tests while working around the clock to scale a range of diagnostic tools as part of a comprehensive public health response, including at-home specimen collection kits, specimen pooling, multiplex testing, and the launch of novel RNA extraction methods. Several policies established or extended during the PHE have been essential to the response and should be continued for the betterment of preparedness and patient access post-PHE.

1. Continuation of COVID-19 Testing-Related Policies and Flexibilities

ACLA members remain committed to providing accurate and reliable COVID-19 tests as the virus continues to circulate in our communities. Extending certain testing-related policies and flexibilities will help ensure that ACLA members can continue to support patient and public health in the context of the current pandemic, as they have for almost three years.

[1] Centers for Medicare & Medicaid Services (CMS). Creating a Roadmap for the End of the COVID-19 Public Health Emergency, August 18, 2022. Retrieved on August 24, 2022 from: https://www.cms.gov/blog/creating-roadmap-end-covid-19-public-health-emergency

A. Flexibility For Digital Pathology and Laboratory Data Remote Review

ACLA encourages permanent policy revisions to allow laboratory professionals to review digital images and data from a remote site, including from their home offices, without needing to obtain a separate Clinical Laboratory Improvement Amendments (CLIA) certificate for the remote site. ACLA is encouraged by the language in the CMS Roadmap that the agency plans to continue to evaluate the flexibility to continue enforcement discretion beyond the end of the PHE to allow remote review of laboratory images and data without a separate CLIA certificate for the remote location under the primary site that houses the certificate.**Error! Bookmark not defined.** ACLA believes that CMS should revise the current CLIA regulations[2] to formalize such a policy for the benefit of laboratory professionals and the patients they serve.

Early in the course of the COVID-19 pandemic, the Center for Clinical Standards and Quality within CMS issued guidance to State Survey Agency Directors for the CLIA program to "exercise enforcement discretion to ensure pathologists may review pathology slides remotely" at a temporary testing site such as a pathologist's home.[3] Not long afterwards, the Food and Drug Administration (FDA) issued an enforcement discretion policy to help expand the availability of devices for remote reviewing and reporting of scanned digital images of pathology slides and to allow modifications to FDA-cleared indications, functionality, and hardware and software of digital pathology devices, without compliance with certain device regulations.[4] When issuing these policies, each of the agencies stated they were intended to stay in place for the duration of the PHE.

Additionally, months before the start of the pandemic, the Clinical Laboratory Improvement Advisory Committee (CLIAC) recommended that the CLIA program "consider that, when laboratory professionals are providing patient care through selection, interpretation, and reporting of patient results by accessing data remotely in a secure environment, they shall be deemed as performing those services at the primary site that houses the CLIA Certificate."[5] In other words, CLIAC recognized that access to a laboratory information system in a secure environment is the same whether the access is via a monitor inside of a CLIA-certified facility or the access is via a monitor located elsewhere. ACLA has advocated for this flexibility for many years as digital pathology and laboratory information systems have long allowed viewing digital cases from any location within an appropriately secure and clinically validated system inside a laboratory, at another on-campus location, or in another remote location such as the home office. Thus, "remote digital pathology" can be indistinguishable from on-location digital pathology, but for the physical location of the pathologist and laboratory professional. The professional service is furnished in the same way, regardless of whether it is in the laboratory or home office.

ACLA encourages CMS to revise current CLIA regulations to formalize allowing remote review of laboratory images and data without a separate CLIA certificate for the remote location

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[2] 42 CFR §493

[3] Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency (March 26, 2020), *available at* https://www.cms.gov/files/document/qso-20-21-clia.pdf-0.

[4] Enforcement Policy for Remote Digital Pathology Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (April 24, 2020), *available at* https://www.fda.gov/media/137307/download.

[5] CLIAC Summary Report (Nov. 6-7, 2019) at 16, *available at* https://www.cdc.gov/cliac/docs/summary/cliac0919_summary.pdf.

after the expiration of the PHE. ACLA also recommends that CMS should extend this policy to laboratory technologists, cytogeneticists, cytotechnologists, and other authorized laboratory personnel who utilize digital images to perform analysis and interpretation on computers so that their remote offices are a fully functional extension of the laboratory. Each is qualified based on state and federal personnel requirements, undergoes standard competence assessments, and must adhere to strict policies and procedures. They are critical members of the laboratory workforce who provide patient care through selection, interpretation, and reporting of patient results by accessing data remotely in a secure environment.

B. Medicare Reimbursement for COVID-19 Molecular Testing

ACLA recommends continuation of the current reimbursement rate for COVID-19 high-throughput molecular testing beyond the expiration of the PHE. The CMS Administrator decision in April 2020 to create Healthcare Common Procedure Coding System (HCPCS) codes U0003[6] and U0004[7] and increase reimbursement to $100 for high-throughput COVID-19 molecular testing, such as polymerase chain reaction (PCR) tests, was instrumental in supporting ACLA members in dramatically scaling up high-throughput testing and maintaining ample capacity to meet the nation's unprecedented testing needs.[8] Later, the agency's decision to maintain that reimbursement rate for COVID-19 PCR tests when results are returned within two calendar days of specimen collection served to ensure that physicians and patients received timely and actionable results for the testing.[9]

COVID-19 will continue to circulate beyond the conclusion of the PHE, with periodic increases in case counts as new, highly transmissible variants surface. ACLA recommends HHS ensure the nation continues to have adequate COVID-19 diagnostic testing capabilities and that laboratories capable of performing the testing maintain ample capacity to scale up beyond the PHE. While rapid, home-based tests have been an important tool in the response, their availability has fluctuated, and their precision does not meet that of a laboratory-based molecular tests. Widely available laboratory-based testing will remain essential during future outbreaks. Congress has not replenished the fund administered by the Health Resources & Services Administration (HRSA) to pay for COVID-19 testing and treatment for the uninsured, making it especially important that reimbursement is adequate to cover laboratory testing and equipment maintenance costs so they can continue to meet the nation's COVID testing needs.

CMS indicates in the Roadmap document that the agency intends to end these payment amounts upon the expiration of the PHE and revert to the rates established under the clinical laboratory fee schedule.**Error! Bookmark not defined.** To effectuate continuation of this important policy, ACLA recommends that CMS consider maintaining the payment rate established in the Administrator's Rulings for high-throughput COVID-19 testing. Specifically, ACLA recommends revisions to the October 2020 Administrator's Ruling to remove the following verbiage from the

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[6] Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, making use of high throughput technologies.

[7] 2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies.

[8] CMS-2020-1-R (Apr. 14, 2020), *available at* https://www.cms.gov/files/document/cms-2020-01-r.pdf.

[9] CMS-2020-1-R2 (Oct. 15, 2020), *available at* https://www.cms.gov/files/document/cms-ruling-2020-1-r2.pdf.

ruling: "This Ruling expires upon the expiration of the ongoing emergency period defined in paragraph (1)(B) of section 1135(g) of the Act beginning on or after March 18, 2020."[Error! Bookmark not defined.] CMS also should provide guidance to Medicare Administrative Contractors (MACs) that COVID-19 diagnostic testing (molecular and antigen) will continue to be covered indefinitely after the expiration of the PHE.

C. Medicare Coverage of Serology Testing

ACLA recommends that CMS extend Medicare coverage of COVID-19 serology, or antibody, testing beyond the expiration of the PHE. The immunological benefits conferred by a past COVID-19 infection or vaccination are well-characterized, which makes continued Medicare coverage of COVID-19 serology testing an important tool for medical management in the Medicare population.

In a 2020 interim final rule, CMS added paragraph (a)(3) to 42 C.F.R. § 410.32, stating that "FDA-authorized COVID-19 serology tests are included as covered tests during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID-19 pandemic, as they are reasonable and necessary under section 1862(a)(1)(A) of the Act for beneficiaries with known current or known prior COVID-19 infection or suspected current or suspected prior COVID-19 infection."[10] ACLA agrees with the statement in the CMS Roadmap document, which indicates that, *"FDA-authorized COVID-19 serology testing is a Medicare covered diagnostic test for patients with known current or known prior COVID-19 infection or suspected current or suspected past COVID-19 infection. The outcome of the serology test may change the health care decisions made by a patient and their practitioner."*[Error! Bookmark not defined.]

D. Increased Reimbursement for COVID Testing Specimen Collection

ACLA recommends that CMS maintain the COVID-19 specimen collection codes (HCPCS codes G2023 and G2024) and their corresponding payment amounts beyond the termination of the PHE. As the association shared with the agency in comments to the Calendar Year (CY) 2021, 2022, and 2023 Physician Fee Schedule proposed rules, COVID-19 may continue to circulate indefinitely in congregate living facilities, such as skilled nursing facilities (SNFs) and assisted living facilities, and in the community. While the overwhelming majority of those who collect COVID-19 specimens on behalf of ACLA member labs are vaccinated, the duration of a vaccine's protective immunity appears limited and likely varies from person-to-person. Even after the end of the PHE, the risks to those collecting specimens will remain, as will the costs that are associated with mitigating those risks (*e.g.*, personal protective equipment, testing for specimen collectors themselves). For these reasons, the codes and the associated reimbursement rates should remain in place until the risks to specimen collectors of contracting COVID-19 have been reduced significantly, regardless of the timing of the PHE's termination.

Our nation's experience with "breakthrough infections" of vaccinated individuals has demonstrated that even those who have been vaccinated and boosted, and who exercise reasonable precautions such as masking and good hand hygiene, remain vulnerable. It is not possible to predict how easily transmissible or dangerous future variants will be, how effective available

[10] 85 Fed. Reg. 27550, 27598 (May 8, 2020).

vaccines will be against them, or how long we will have to exercise extreme caution about COVID-19 infection.

CMS has indicated in the Roadmap document that it intends to end these payment amounts upon the expiration of the PHE. ACLA urges CMS to maintain current payment rates for specimen collection codes G2023 and G2024 on the clinical laboratory fee schedule for the foreseeable future.

2. <u>Preparedness Recommendations: Immediate Response Diagnostics (IRDx) Action Plan</u>

Diagnostic testing is an essential tool in understanding and responding to pathogens of concern as they emerge. Recent responses to COVID-19 and monkeypox demonstrate the necessity of coordinated public and private sector efforts for a fulsome testing response. These recent examples suggest a need to establish a clear, predictable, and coordinated public-private sector model for launching testing in the earliest stages of a public health concern.

ACLA is working with the Johns Hopkins Center for Public Health Security (the Center) on a project to develop policy recommendations aimed at improving the nation's ability to develop and scale up diagnostic testing rapidly in response to a pathogen of concern, before it becomes a public health emergency. After conducting detailed interviews with current and former public and private sector leaders in the diagnostic testing ecosystem, the Center will produce a report this fall outlining an Immediate Response Diagnostics Action Plan (IRDx Plan) that will be shared broadly, including with the Administration and Congress. The plan outline will include actionable recommendations to strengthen public-private collaboration to scale up diagnostic testing rapidly when a pathogen of concern is identified. We encourage HHS to commit to convening with ACLA and the Center to discuss recommendations for an IRDx Plan upon completion of the study.

Thank you for your consideration of ACLA's recommendations on these important policy issues. Please do not hesitate to reach out to me with any questions or to discuss further.

Sincerely,

Susan Van Meter, President
American Clinical Laboratory Association

CC: Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services
Dawn O'Connell, Assistant Secretary for Preparedness and Response