



# COLLEGE of AMERICAN PATHOLOGISTS

November 2, 2020

Seema Verma Administrator  
Administrator  
Centers for Medicare and Medicaid Services (CMS)  
7500 Security Boulevard,  
Baltimore, MD 21244

Re: Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency [Docket No. CMS-3401-IFC]

Dear Administrator Verma:

The College of American Pathologists (CAP) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. Pathologists are physicians who specialize in the diagnosis of disease through laboratory methods, and their primary mission is the delivery of high-quality diagnostic services to patients and other physicians.

The CAP will provide specific comments on the following provisions:

C. Requirements for Laboratories to Report SARS-CoV-2 Test Results During the PHE for COVID-19

F. Limits on COVID-19 and Related Testing Without an Order and Expansion of Testing Order Authority

J. Requirement for Long-Term Care (LTC) Facilities to Test Facility Residents and Staff for COVID-19

**C. Requirements for Laboratories to Report SARS-CoV-2 Test Results During the PHE for COVID-19**

The CLIA program proposes modifying the CLIA regulations to add new requirements on laboratories for reporting SARS-CoV-2/COVID-19 test results to agencies for public health purposes. CMS plans to impose civil monetary penalties for laboratories that fail to report in accordance with the new and additional requirements. CMS will also require deemed



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accreditation organizations to institute requirements equivalent or more stringent those being added to CLIA. Specifically, during the public health emergency (PHE) for COVID-19, each laboratory that performs a SARS-CoV-2 test (whether molecular, antigen, and serologic tests) must report SARS-CoV-2 test results in such form and manner, and at such timing and frequency, as the Secretary may prescribe in the interim final rule. The CAP supports clinical laboratory reporting SARS-CoV-2 results as codified in the Coronavirus Aid, Relief, and Economic Security (CARES) Act, which requires every laboratory performing SARS-CoV-2 report positive and negative results to the Secretary; however, we oppose reporting in the manner specified by the Secretary in the requirements released on June 4, 2020. This guidance required clinical laboratory reporting to HHS of COVID-19 test results along with other clinical data elements. Following release of the HHS COVID-19 data reporting requirements on June 4th, HHS, CDC, and (state?) public health officials have issued multiple, complicated guidance documents that at times have contained conflicting information. Consequently, clinical laboratories have encountered great difficulties when attempting to comply with the HHS mandate.

The release of the interim final rule has provided some clarity on reporting obligations for clinical laboratories, but the regulatory burden and confusion remains for laboratories to comply with the HHS guidance. For example, the HHS guidance specifies that clinical laboratories report to the patients' state of residence. For many clinical laboratories this will require clinical laboratories to establish multiple system interfaces, which are costly and laborious. Given these difficulties, the **CAP recommends the Administration rescind June 4th HHS guidance with the unworkable COVID-19 reporting requirements until a workable set of requirements has been developed; reduce the required number of data elements for COVID-19 reporting to those within the purview of the clinical laboratory and simplify reporting to a phased-in approach where HHS focuses on the public health laboratories ability to collect data from clinical laboratories then moved to clinical laboratories reporting COVID-19 data elements more broadly.**

CMS proposes civil monetary penalties (CMPs) as condition-level penalties of \$1000 for the first day of noncompliance with the new reporting requirements, and \$500 for each subsequent day the laboratory fails to report SARS-CoV-2 test results. While we understand the intent of imposing CMP to ensure compliance with SARS-CoV-2 reporting, clinical laboratories have spent significant time as required to meet testing needs amid shortages of swabs, reagents, and testing platforms while experiencing significant financial pressure. Alternative mechanisms have been created to help clinical laboratories with reporting, but the cost to implement these systems is approximately \$100,000 to implement. At a time when resources are scarce, employing new systems have further strain clinical laboratories' resources. **CMS should not be imposing civil monetary penalties during the PHE on clinical laboratories given the unfunded mandate with its complex and conflicting messages from the administration, agency, and local public health officials. If CMS elects to move forward on CMPs, the agency should impose penalties on a daily basis for each day of substantial incompliance and consider the range**



of penalty amount to correspond with condition level deficiencies that do not pose immediate jeopardy and in an amount not to exceed \$10,000.

**F. Limits on COVID-19 and Related Testing without an Order and Expansion of Testing Order Authority**

1. The CAP remains concerned that the CMS's revised policy that allows for one COVID-19 diagnostic test and one other related test without an order from a physician or other practitioner, as described in the preamble of the IFC, includes language allowing for a local coverage determination (LCD) to override the policy. While we appreciate CMS' attempt to develop a policy that strikes an appropriate balance in providing the flexibility necessary to ensure beneficiaries have prompt and equal access to important COVID-19 and related diagnostic testing during the public health emergency, while simultaneously preventing unnecessary add-on testing, the inclusion of the caveat allowing a LCD to override the policy represents a serious flaw in ensuring beneficiaries have equal access to this important diagnostic testing.

The CMS list of "COVID-19, Influenza, and RSV Clinical Diagnostic Laboratory Tests for which Medicare Does Not Require a Practitioner Order During the PHE"<sup>1</sup> includes a caveat that "*Other Medicare conditions of coverage and payment continue to apply, including any applicable local coverage determinations.*" What appeared as a regulatory flexibility for improving access to and coverage for diagnostic testing while also reducing provider burden, is effectively negated by CMS's deference to local coverage policy. In fact, CMS's policy hinders comprehensive testing for beneficiaries in regions where the local policy is more restrictive than allowed under the aforementioned IFC<sup>2</sup>, impeding providers' ability to rapidly diagnose and manage patients with COVID-like symptoms and creating gross inequities for seniors. Further, CMS policy is in direct contrast with this Administration's *Testing Blueprint: Opening Up America Again*, which states:

*"Finally, the Administration will update diagnostic testing algorithms and protocols in order to account for seasonality of influenza and other diseases that may occur concurrently. This effort is needed because, in Fall 2020, COVID-19 could co-circulate with influenza or other respiratory viruses. **Under this scenario, anyone with an influenza-like illness may be recommended to undergo a testing sequence, a dual***

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<sup>1</sup> <https://www.cms.gov/files/document/covid-ifc-2-flu-rsv-codes.pdf>

<sup>2</sup> The Palmetto GBA Molecular Diagnostic Services Program (MoIDX) established the Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (RVPs) local coverage determination (LCD), which has been adopted by Medicare Administrative Contractors (MACs) covering 28 states, as well as American Samoa, Guam and the Northern Mariana Islands. This LCD was established prior to the COVID-19 pandemic and is based on clinical assumptions that are superseded by the clinical circumstances of our public health emergency.

<sup>3</sup> <https://www.whitehouse.gov/wp-content/uploads/2020/04/Testing-Blueprint.pdf>



**antigen test, or a dual nucleic acid test to enable effective diagnoses of COVID-19 even in the context of a co-circulating disease.** [emphasis added]<sup>3</sup>

The CAP contends that uniform national coverage of COVID-19 and other related diagnostic tests are essential to providing appropriate patient care and is consistent with direction from this Administration, guidance from this agency<sup>4</sup>, the Centers for Disease Control and Prevention (CDC)<sup>5</sup>, and other leading organizations<sup>6</sup> during this national emergency. State health departments have also encouraged testing algorithms that include respiratory viral panel (RVPs) and COVID-19 testing. For example, the Nebraska Department of Health and Human Services issued an Advisory through its Health Alert Network explaining that,

- *“Clinicians should consider and test for infectious agents known to be circulating for which testing is readily available:*
  - *rapid influenza tests*
  - *multiplex PCR respiratory viral panels.*
- *Anyone with a severe respiratory disease of unclear etiology, especially with a negative flu and respiratory viral panel multiplex PCR test (RVP) (e.g., BioFire respiratory panel) should be tested for COVID-19.”*<sup>7</sup>

The Maryland Department of Health also encourages simultaneously testing as part of its guidance to nursing homes and assisted living facilities<sup>8</sup>.

Given how easily COVID-19 spreads, it is imperative to ensure that providers cohort patients appropriately and are confident in the COVID test results. The many COVID tests that have been created have varying degrees of specificity and sensitivity and there have been numerous cases where clinical suspicion for a false negative test is high in a patient with a COVID-like illness. In this scenario, providers need the ability to rapidly identify the pathogen causing the patient's symptoms to ensure they are in fact COVID negative, and then appropriately isolate or cohort a patient accordingly. As an example, respiratory virus panels are a critical tool for clinicians during this pandemic. They provide a crucial adjunct in determining the etiology of patients' symptoms who present with flu-like illnesses. Many respiratory pathogens present similarly in patients and it is difficult to delineate between influenza, coronavirus, rhinoviruses, and many other pathogens without accurate testing. Individual tests take too long to process and once COVID and influenza

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<sup>4</sup> Centers for Medicare & Medicaid Services FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 42, available at <https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf>.

<sup>5</sup> Centers for Disease Control and Prevention, Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19), available at <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html>.

<sup>6</sup> In addition to this guidance, the Society for Post-Acute and Long-Term Care Medicine and State health departments strongly encourage the use of molecular RVP same-day testing for other causes of respiratory illness, including infections such as influenza and pneumonia.

<sup>7</sup> <http://dhhs.ne.gov/han%20Documents/ADVISORY03112020.pdf>

<sup>8</sup> [https://phpa.health.maryland.gov/IDEHASharedDocuments/Preparing-for-and-Responding-to-COVID-19-in-LTC\\_final.pdf](https://phpa.health.maryland.gov/IDEHASharedDocuments/Preparing-for-and-Responding-to-COVID-19-in-LTC_final.pdf)



have been eliminated, there are too many options to individually test each pathogen. Ensuring rapid results is essential to triaging patients and minimizing disease transmission.

Access to and coverage for appropriate tests is essential to diagnose and manage patients with acute respiratory illness rapidly and effectively. The coverage caveat would seem to imply that the availability of the additional add-on testing deemed to be appropriate by the CDC might be available in some MAC jurisdictions but not in others as some LCDs limit the availability of testing based on pre-pandemic circumstances. The CAP requests that CMS recognize the potential for inconsistent LCDs to be out of step with current treatment approaches and that the IFC language, as implied, override Medicare coverage policy with regard to COVID-19 and related tests. **Based on this information, the CAP recommends that CMS provide uniform coverage for the clinical diagnostic laboratory tests that may be performed without a practitioner order, by removing the local coverage barrier during the COVID-19 public health emergency.**

2. The IFC language states that *“In addition to our concerns about previous laboratory schemes being applied to COVID-19 testing itself, the risk is exacerbated by the ability of the laboratory to perform add-on tests, such as to confirm or rule-out diagnoses other than COVID-19.”*

There are two sorts of “add-on” testing - laboratory-initiated reflex testing that does not require a specific request by a treating provider, and “add-on” tests initiated by the treating provider “adding-on” an order for additional testing on a previously submitted specimen which was deemed necessary for patient management subsequent to the original request for testing. We believe that, in keeping with the intent of the IFC, the language is referring to laboratory-initiated reflex testing. **However, to avoid confusion we request that CMS clarify the type of add-on tests referenced in the IFC.**

3. The IFC language also states that, *“...if a beneficiary received a test or multiple tests without an order before the effective date of this rule, these tests would not count toward the limit of one test without a physician or other practitioner order under this rule. We believe that this approach will provide **sufficient notice for laboratories to set up the systems and processes necessary to require an order beyond one test. For the COVID-19 and other related diagnostic tests for which an order is required,** we are also establishing a policy whereby the tests can be covered when ordered by a pharmacist or other healthcare professional who is authorized to order diagnostic laboratory tests in accordance with state scope of practice and other pertinent laws.....”*

When a laboratory receives a specimen for testing, it is unlikely to know if such an earlier test on a beneficiary has already been performed by another laboratory. In this scenario, prior testing cannot be reasonably ascertained and therefore, a laboratory should not be held responsible for any subsequent tests it receives without a physician order. **The CAP requests that CMS adjust its language to reflect our concerns.**



**J. Requirement for Long-Term Care (LTC) Facilities to Test Facility Residents and Staff for COVID-19**

In an effort to “strengthen the requirements for LTC facilities to better protect residents, members of a high-risk population,” CMS is establishing a “new requirement for LTC facilities to test their facility residents and staff, including individuals providing services under arrangement and volunteers.” While we agree with CMS and the Centers for Disease Control and Prevention (CDC) that testing is an “important addition to other infection prevention and control recommendations aimed at preventing [COVID-19] from entering nursing homes, detecting cases quickly, and stopping transmission,” we are concerned that these kinds of blanket requirements without the required support/supplies/resources will further strain testing services for COVID-19 and impact our ability to ensure patients receive the testing and treatment they need.

In the IFC, CMS admits these requirements will result in significant resource use and costs incurred by facilities, but the agency does not address issues including lack of supplies, inadequate reimbursement, and continued stress on laboratories and health systems. Further, while some criteria for testing frequency, such as “the identification of any facility resident or staff diagnosed with COVID-19 in the facility,” are important parameters for COVID-19 testing, other criteria, such as the county positivity rates, are less helpful or relevant for the individual facility. For example, staff is required to undergo testing depending on the county’s positivity rates for the facility, regardless of the positivity rates of the location where staff actually resides. This can result in overutilizing tests that are already in short supply and needed for clinical use. To be clear, the CAP recognizes the importance of testing as part of a public health surveillance and we support increased testing with appropriately managed resources/supplies, but these requirements and related guidance risk unnecessarily overburdening our health care systems.

The testing supply chain has been under tremendous strain from overwhelming global demand, and this issue will persist with increased surveillance testing, calls to expand testing capacity, and necessary non-COVID-19 testing. As we have expressed earlier, the country continues to struggle to provide laboratories with a consistent supply of reagents, viral transport media, plastics (such as a pipette tips), and other items essential to providing both COVID-19 and non-COVID-19 testing.<sup>9</sup> For example, 64 percent of laboratory directors responding to a recent CAP survey reported difficulty in acquiring reagents for platforms/test kits to conduct COVID-19 testing.<sup>10</sup> 60 percent reported difficulty in acquiring flocked nasopharyngeal swabs to collect and transport patient samples, and 55 percent reported difficulty in acquiring viral transport media/universal transport media to conduct the tests. Further, while the IFC states that point-of-care antigen testing devices are being shipped to every facility, the real world clinical performance of antigen testing for SARS-CoV-2 in asymptomatic surveillance populations has not

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<sup>9</sup> <https://documents.cap.org/documents/testing-prioritization-letter.pdf>

<sup>10</sup> <https://www.cap.org/news/2020/in-follow-up-cap-survey-laboratories-report-more-patient-testing-capability-for-covid-19-despite-persistent-challenges>



been clearly described in rigorous studies as of August 2020<sup>11</sup> and CMS admits that facilities may choose to verify negative results with lab testing. State restrictions and requirements related to antigen or other surveillance testing may also result in increased burden on lab-based testing.

In addition to supply chain and resource issues, reimbursement for testing continues to be inadequate and we have concerns with unfunded mandates for surveillance testing. As the agency knows, CMS announced approximated payment rates of about \$36 for CDC developed coronavirus (SARS-CoV-2) NAT procedures, approximately \$51 for laboratories performing non-CDC tests, and \$100 for tests making use of high throughput technologies. Based on our review of costs from our members providing or seeking to offer these tests in their laboratory, a SARS-CoV-2/COVID-19 survey of directors of CAP accredited laboratories, a study of hospital charges across the country, and in depth interviews with laboratory cost managers, it is clear that the lower payment amounts set for these tests by the CMS are woefully inadequate to cover the costs in the typical laboratory performing SARS-CoV-2 nucleic acid testing. We remain greatly concerned that provider laboratories cannot sustain these underpayments indefinitely, along with the other overall increased costs associated with doing business during the national public health emergency. Further, CMS explains that costs incurred by LTC facilities “have potential to vary drastically depending on the extent of outbreaks in their respective communities, whether the facility has point-of-care testing, and the size of each facility.” If LTC facilities lack the financial ability to incur these costs, we are concerned further financial burden may land on laboratories.

Laboratories and health systems remain stressed, spending significant time as required to meet testing needs amid shortages of swabs, reagents, and testing platforms. Pathologists in hospitals and laboratories around the country have been responsible for developing and/or selecting new test methodologies, validating and approving testing for patient use, and expanding the testing capabilities of the communities they serve to meet emergent needs. As surveillance and other testing efforts increase, these responsibilities will only grow, and add to the stress of our pathology and laboratory community. Certainly, “a strong infection control program is critical to protect the health and safety of both residents and healthcare personnel of LTC facilities,” but decisions on when to employ surveillance testing must be made locally, taking numerous variables into consideration such as the local disease prevalence (or positivity rate in symptomatic individuals), availability of testing supplies, and the presence of a well-rationed plan for acting upon test results (including plans for quarantine, isolation, and contact tracing). We urge CMS to work with us and other stakeholders to revise these requirements and allow for more local decision-making that won’t unnecessarily strain testing services for COVID-19, overburden laboratories and health systems, and impact our ability to ensure patients receive the testing and treatment they need.

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<sup>11</sup> <https://documents.cap.org/documents/Screening-and-Surveillance-Testing-for-COVID-19-Questions-and-Answers.pdf>



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The CAP welcomes the opportunity to discuss our concerns and recommendations for implementation at your earliest. Please contact Helena Duncan at [hduncan@cap.org](mailto:hduncan@cap.org) or 202.354.7131.

Closing,

*The College of American Pathologists*

***Sent via regulation.gov***