November 2, 2020

Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
CMS-1715-P, Room 445-G
200 Independence Ave, SW
Washington, DC 20201

RE: Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments, and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency [CMS-3401-IFC.]

Dear Administrator Verma:

On behalf of the American Society for Clinical Pathology (ASCP), I am writing to provide comment on, and ASCP's overall support for, the Interim Final Rule with Comment (IFC) amending the Clinical Laboratory Improvement Amendments (CLIA). This rule requires all clinical laboratories to report coronavirus (COVID-19) test results within 24 hours of test completion to state and local public health departments. Ultimately this data will be transmitted to the U.S. Department of Health and Human Services, via its surrogate, the Centers for Disease Control and Prevention (CDC).

ASCP represents the frontlines of laboratory diagnostics, and our membership of 100,000+ board certified pathologists, other physicians, and non-physician laboratory professionals lead the nation's efforts to diagnose and screen for COVID-19 and other diseases/conditions. ASCP is the world's largest organization representing the field of laboratory medicine and pathology. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP enhances the quality of the profession through comprehensive educational programs, publications, and self-assessment materials.

ASCP strongly supports the Agency's goals of securing timelier COVID-19 testing data and believes that this rule could provide a significant benefit to patient health and public health efforts to contain the COVID-19 pandemic. That said, we offer comments on several issues related to policies outlined in this rule. Our comments address the following issues:

- Requirements for Laboratories to Report SARS–CoV–2 Test Results During the PHE for COVID–19
- Hospital Staffing and Laboratory Supply Surveys
- Regulatory Impact Analysis

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

A. Background

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was signed into law. Section 18115 of the CARES Act requires that every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 must report the test results

to the Secretary until the conclusion of the Public Health Emergency (PHE) for COVID-19. These reporting requirements are detailed in a June 4 guidance document.

In this IFC, CMS has required all clinical laboratories, including certificate of waiver laboratories, to report coronavirus (COVID-19) test results to state or local public health departments within 24 hours of test completion. ASCP supports this. **Until an effective vaccine or treatment is available, the most important tool needed for a more effective pandemic response is robust laboratory testing capacity for COVID-19. Without quick turnaround times and prompt reporting to public health officials, the disease will likely go undetected longer and will spread to more people before infected individuals are identified.**

B. Definition of SARS-CoV-2 Testing

The IFC defines reportable tests as those "intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19." ASCP largely supports this definition, however, several points need to be discussed. Reverse transcriptase-polymerase chain reaction (PCR) tests rightly fit this definition and must be reported. These tests represent the gold standard for the purposes of diagnosing COVID-19 and represent the most reliable data on which the public health response and patient care can be based—at least in the near term. That said, we believe that antigen and antibody (serology) tests require discussion.

i. Antigen Tests

Given the rapid turnaround times and scalability for antigen testing, these tests promise to significantly increase national testing capability for COVID-19, which could help relieve some of the stress on clinical laboratories struggling with shortages of testing supplies. ASCP recognizes the potential benefit that reporting these test results could provide to the public health response; however, there are several issues that need to be resolved when relying on this data.

We note that the Kaiser Health News recently conducted a study[1] on antigen testing and observed that "unlike using tests run through labs, many providers who would use antigen tests don't have an easy way to send data electronically to public health authorities." Clearly there is a need for antigen test data. ASCP urges CMS to work with these non-traditional testing locations to ensure that they come into compliance with these reporting requirements.

The aforementioned KFF study found that there is "significant variation over whether people who test positive for COVID-19 with an antigen test are counted as cases and whether states even publicly report antigen data in their testing numbers (emphasis added):

- 21 states and D.C. do not report all antigen test results.
- 15 states and D.C. do not count positive results from antigen tests as COVID cases.
- Two states do not require antigen test providers to report results, and five others require only positive results to be reported.
- Nearly half of states believe their antigen test results are underreported."

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[1] Pradhan, R. et Al., September 16, 2020. Lack of Antigen Test Reporting Leaves Country 'Blind to the Pandemic', Kaiser Health News. Accessed 10/29/2020.

As a result, national totals as well as many state counts of infected individuals appear to be artificially low. The lack of antigen data could suggest that infection rates are declining — when in reality the increased reliance on antigen testing may be responsible for an under-reporting of COVID case data. Unless efforts are undertaken to properly factor in antigen testing data (and data quality), state reported testing data could undermine the integrity of the data used by public health officials to respond to the virus. Problems with the data could also mis-direct businesses, schools and other entities that are considering reopening.

This problem will only get worse as antigen testing takes on a larger role in efforts to test for the SARS-CoV-2 virus. In order to ensure that the federal government has robust data on which to base its containment efforts, the federal government must require states to report antigen data. Otherwise, we see little value and significant burden with tasking clinical laboratories to report this information.

The KFF study also noted that guidance from the Centers for Disease Control and Prevention defines a "confirmed" COVID case as one based on PCR testing. Positive results from antigen tests are considered "probable" cases because the tests can be less accurate. One of the issues with antigen test accuracy concerns the potential for high rates of "false positive" and/or "false negative" results. ASCP is likewise concerned about this issue, as outlined in the attached letter, and concurs on the need for confirmatory testing.

We note that according to the June 4 guidance from the U.S. Department of Health and Human Services (HHS), the Department is requiring the submission of data on whether patient are symptomatic. This is appropriate and necessary. When test results do not correlate with the presence of symptoms, there is an elevated risk of "false positive" or "false negative" results. However, **ASCP believes that when positive antigen test results are obtained on *symptomatic* patients, these results *should* be reported as positives**. **If positive antigen results are obtained from *asymptomatic* patients, the results should be classified as *presumptive positives* and the confirmatory test reported as positive or negative.**

ii. Serology (Antibody) Testing

Serology tests do not detect SARS-CoV-2, nor should they be used to diagnose SARS-CoV-2 infection. From our perspective, the definition of a reportable test would not suggest that these tests are intended to be reported. Agency officials, however, have commented that serology test results *must* be reported. We strongly urge the Agency to clarify this in a subsequent rule, as this is not clear. Given the language of the regulation, it would be inappropriate for the Agency to impose any penalties on any clinical laboratories for not reporting serology test results until the Agency has adequately informed clinical laboratories of its expectations. As we stated for antigen testing, if clinical laboratories are going to be required to report this data, then state and local public health departments as well as the federal government *must* report this data. That said, this data should be distinguishable from data for confirmed and presumptive test results.

C. Data Receiving Entity

CMS states in the IFC that the June 4, 2020 guidance states that "all laboratories…shall report data…to the appropriate state or local public health department *based on the individual's residence* (emphasis added)." In apparent conflict with the regulation, CMS staff have indicated that clinical laboratories can report this data to the state or local public health department serving the state/locality in which the laboratory is located.

To ensure an informed public health response, ASCP believes that test results should be reported to the state or local public health department representing the city or locality *where the patient is currently located (presumably the site where the specimen was collected)*, even if their state of residence is elsewhere. For states and local public health agencies to respond appropriately, they need data on infectious individuals in their area of responsibility.

We are concerned that requiring testing data to be referred to the state or local public health department based on the tested individual's residence could add to the cost of compliance with this rule, particularly for smaller clinical laboratories that lack the sophisticated information systems and support staff of larger, more technology-forward clinical laboratories. Focusing on the site of collection should aid the public response and lower the expected compliance challenges and cost for some clinical laboratories.

If CMS intends to retain the state of residence requirement, ASCP believes that it the Agency should identify a single reporting entity that laboratories can rely on to route data to the appropriate location, such as the state or local public health department perhaps. Alternatively, we are aware that the Association of Public Health Laboratories' (APHL) AIM platform could route reported data to the appropriate site. Unfortunately, there is a cost associated with the platform. In the interests of reducing the financial burden of this rule and improving the appropriate transfer of the data we recommend that CMS engage with APHL so that laboratories are not charged for reporting these results during the PHE.

D. Transparency of Received Data

ASCP believes that most, if not all, de-identified data received by the federal, state and local governments, such as number of positive test results, presumed positive test results, total tests performed, etc., should be publicly reportable based on the location where the specimen was obtained. To better manage the COVID-19 pandemic response, the public deserves accurate and reliable data on where infectious individuals are located when the specimen was collected. ASCP strongly urges that all government public health agencies should be required to publicly make this data available within 24 hours of it being approved or deemed complete. If clinical laboratories should be expected to provide this data within this timeframe, so too should government agencies.

E. MIPS Provisions: Improvement Activities Performance Category: Improvement Activities Inventory Update: Clinical Trials

In the March 31st IFC for COVID-19, CMS added a new improvement activity to the Improvement Activities Inventory for the CY 2020 performance period in response to the PHE titled "COVID-19 Clinical Trials." The new activity promotes clinician participation in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection.

This expansion recognizes clinicians for participating in the care of a patient diagnosed with COVID-19 who submit patient data to a clinical data registry for research. To receive credit for this activity, a MIPS eligible clinician or group must: (1) Participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or (2) *participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research* (italics represent the IFC's new improvement activity).

ASCP supports the expansion of this improvement activity to incentivize pathologists who may not be directly participating in a clinical trial but through their work are supporting the clinical trial and improvements in patient care. This expansion is helpful for pathologists as they have long faced challenges in participating in the MIPS program. Additionally, ASCP suggests that CMS consider adding other research targets beyond therapeutics to this activity. From our perspective, targeting research related to diagnostic and other medical devices may prove advantageous to quality patient care.

II. Hospital Staffing and Laboratory Supply Surveys

ASCP supports the Agency's efforts to determine whether hospital staffing levels, including clinical laboratories, are sufficient and whether hospital laboratories have a 3-day supply of such items as personal protective equipment, swabs, and viral transport media. As for staffing, we have heard that testing volumes are returning to near normal levels for non-COVID-19 testing. It is our understanding that staffing shortages, coupled with high workload, are creating stressful workout conditions and resulting in increased levels of burnout.

Some of the supplies outlined in the October 6 HHS guidance document, such as personal protective equipment (PPE), swabs, and viral transport media, relate to specimen collection and the pre-analytic phase of laboratory testing. As a result, with the exception of PPE, these data points will not provide useful to assessing the extent to which hospital laboratories are encountering a shortage of the supplies necessary to the analytical phase of laboratory testing, for COVID-19 and/or other tests.

That said, we note that CMS's recent change in payment policy for high-throughput COVID-19 laboratory tests creates a $25 add-on code, for certain tests performed within 48 hours of specimen collection. To a certain degree, the data CMS receives for this code could serve as a proxy for whether laboratories are able to secure the supplies necessary for rapid performance of these tests. We urge public transparency for these data points.

III. Regulatory Impact Analysis

ASCP is concerned about the financial impact that CMS estimates this Interim Final Rule (IFR) will impose on clinical laboratories. In section IV.D of the IFR, CMS outlines its estimated compliance costs. Priced over a one-year timeframe, these costs fall somewhere between $1.4 billion and $7.8 billion annually (See spreadsheet 1 (attached)). As a reference point, the aggregate Medicare Part B reimbursements for services payable under the Clinical Laboratory Fee Schedule (CLFS) is estimated at $8.14 billion for 2020, according to the Medicare Trustees Report[2] — and this estimate was provided prior to the loss of laboratory referrals attributable to the COVID pandemic.

When examining CMS's cost estimates on a per test basis, the cost of this regulation is revealing. According to CDC, approximately 130 million COVID-19 tests[3] (the vast majority of which is PCR testing) have been performed since the beginning of the coronavirus pandemic. If we assume that four times as

[2] The Boards of Trustees of the Federal Hospital Insurance and Federal Supplemental Medical Insurance Trust Funds, 2019 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplemental Medical Insurance Trust Funds, Table IV.B6.—Aggregate Part B Reimbursement Amounts on an Incurred Basis, p. 134. April 29, 2019.
[3] Data obtained from the CDC COVID Data Tracker, updated October 15, 2019. See: https://covid.cdc.gov/covid-data-tracker/#testing_testsperformed

many tests are performed over the next year that places the cost of this regulation at between $2.50 to $15 per test, with a midpoint cost of $8.75 per test.

These costs, coupled with other financial challenges for clinical laboratories, such as the recently finalized $25 payment reduction for COVID-19 tests not performed within 48 hours; the Medicare Physician Fee Schedule's proposed 9 and 4 percent cuts in pathology and laboratory reimbursements, and planned reductions in the CLFS for 2021 caused by section 216 of the Protecting Access to Medicare Act's, and the massive reduction in testing referrals caused by the COVID-19 pandemic, will complicate the ability of some clinical laboratories, particularly smaller and/or rural laboratories, to meet the nation's COVID-19 testing and reporting demands.

ASCP strongly supports the Agency's efforts to secure timely reporting of robust COVID-19 testing data. That said, ASCP urges CMS to reexamine this rule with the goal of developing less burdensome approaches to reporting and to provide additional funding to help those clinical laboratories toward compliance.

We appreciate the opportunity to provide these comments. If we can be of any assistance in developing guidance on this matter or anything else, please do not hesitate to contact me or Matthew Schulze, Director of the ASCP Center for Public Policy, at (202) 735-2285.

Sincerely,

Kimberly Sanford, MD, MASCP, MT(ASCP)
President, American Society for Clinical Pathology

Attachment