ASSOCIATION FOR MOLECULAR PATHOLOGY
Providing global expertise in molecular testing that drives patient care
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November 2, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
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 (CMS-3401-IFC)

Dear Administrator Verma:

The Association for Molecular Pathology (AMP) appreciates the actions that the Centers for Medicare & Medicaid Services (CMS) has taken to expand access to testing to address the COVID-19 public health emergency (PHE). We respectfully submit the following comments on the third interim final rule with comment period (IFC) related to the requirements for laboratories to report SARS-CoV-2 test results during the PHE.

AMP is an international medical and professional association representing approximately 2,500 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

CMS is revising the Clinical Laboratory Improvement Amendments (CLIA) regulations to require all laboratories, including those with a Certificate of Waiver, to report SARS-CoV-2 test results during the PHE. AMP understands and supports the effort of the administration to comprehensively collect important data in order properly respond to the pandemic. Moreover, we support the efforts of CMS via the CLIA program to ensure that laboratories are performing accurate and reliable testing and understand that more information needs to be provided to the CMA CLIA program for these purposes.

However, AMP is concerned about the undue burden compounding reporting requirements place on laboratories. For example, AMP recently conducted a survey of its membership and specifically asked questions regarding data reporting required under the June 4 Department of Health and Human Services' (HHS) guidance[1]. Raw data results are provided in Appendix A. Nearly half of respondents reported one or more issues with reporting. Based on these survey responses, we are concerned with this requirement due to the challenges that our members have faced implementing the HHS June 4 guidance on lab reporting (see page 26 of the survey or full results in Appendix A). Under the guidance, laboratories were required to comply by August 1; however,

[1] https://www.amp.org/AMP/assets/File/advocacy/Survey_Report_August_2020_AMP_SARSCoV2_FINAL.pdf?pass=2

reporting specifications were not released in time for state and public health departments to be ready to accept data on this date. Another barrier to implementation is that laboratories did not have the resources to be able to meet the requirements to report to a new state department of health not previously reported to within a 24-hour period.

Our members' laboratories have had challenges accessing the data that HHS required to be reported in the guidance. The guidance required demographic data elements that is often not available to laboratories, and additionally, laboratories also report that ask on order entry (AOE) responses are not available, or are difficult to implement in all orders.

There are also patient data systems limitations that have made compliance with the HHS guidance challenging for laboratories. Common problems that we have heard from members include that device identifiers have not been previously required; that the laboratory information system (LIS) does not have a place to assign these identifiers in its database; AOE questions requiring the Logical Observation Identifiers Names and Codes (LOINC) and the Systematic Nomenclature of Medicine (SNOMED) coding that are not available in the electronic health record (EHR); HL7 electronic reporting is not available; and that LOINC/SNOMED have not been previously required and the LIS does not have a place to assign these in its' database.

AMP is concerned that these problems with implementing HHS' data reporting guidance will only be exacerbated by CMS' proposed changes to the CLIA regulations. Laboratories continue to seek clarification on the parameters of these reporting requirements and to date do not have a clear understanding of the requirements; evidence of this is seen in transcripts from the regularly scheduled Clinical Laboratory COVID-19 Response Calls organized by CDC[2,3]. We request that CMS delay this reporting requirement until HHS, working with the laboratory community, resolves the barriers preventing laboratories from being able to report the data necessary to address the PHE. To accomplish this, the existing reporting requirements should be amended to reflect the currently available infrastructure and technology available across laboratories. Additionally, we recommend that CMS work with HHS to ensure coordination amongst all reporting requirements with the HHS agencies and, to the extent possible, streamline reporting requirements in order to reduce the burden on laboratories. Additionally, clear, comprehensive instructions should be made available to ensure that all laboratories are able to comply. As the agency knows, the laboratory community continues to be a vital part of the nation's response to the COVID-19 pandemic and adding burdensome regulations will not benefit these efforts.

Thank you for the opportunity to submit these comments on CMS' third IFC related to the requirements for laboratories to report SARS-CoV-2 test results during the PHE. We are happy to answer any questions about our recommendations and provide further information. Please direct your correspondence to Tara Burke, PhD, AMP Senior Director of Public Policy and Advocacy, at tburke@amp.org.

Sincerely,

Karen E. Weck, MD FCAP
President, Association for Molecular Pathology

[2] https://www.cdc.gov/csels/dls/preparedlabs/documents/covid-19-response-calls/09_14_2020_transcript.pdf
[3] https://www.cdc.gov/csels/dls/preparedlabs/covid-19-clinical-calls/2020-september.html#09_28_2020

Appendix A: Raw Data Results from AMP August Survey Question 92 "In June 2020 HHS announced new laboratory data reporting guidance for COVID-19 testing. Did your laboratory / institution experience challenges implementing the new reporting requirements prior to the August 1 deadline? Select all that apply."

Answer Choices	Responses	
No	35.24%	37
Yes, the federal government required laboratories to comply by August 1, but state and local public health departments did not receive the exact specifications from the federal government until July 31 (one day before the deadline), so state and public health departments could not accept the data.	20.00%	21
Yes, the federal government requires that laboratories report data to the state department of public health of the patient's residence within 24 hours of the result being verified. This requires a single laboratory to report to multiple state departments of public health, all of which have different reporting requirements, and for a patient from a state not previously reported to, the expectation of reporting within 24 hours to a new state with a different format cannot be supported by existing resources.	15.24%	16
Yes, required demographic data elements were not available to the testing laboratory	19.05%	20
Yes, recommended additional demographic data elements were not available to the testing laboratory	17.14%	18
Yes, "ask on order entry" (AOE) question responses were not available to the testing laboratory	20.00%	21
Yes, the AOE questions were difficult to implement in all test orders	17.14%	18
Yes, the answers to the AOE questions require LOINC and SNOMED coding, which is not available in the EHR or laboratory system	6.67%	7
Yes, HL7 electronic laboratory reporting was not available	7.62%	8
Yes, available LOINC and SNOMED-CT codes were not applicable to our testing methodologies	2.86%	3
Yes, LOINC codes on orders have not been previously asked for, and LOINC codes could not be assigned to orders in the laboratory system	3.81%	4
Yes, LOINC and SNOMED codes have not been previously required on actual result observations (e.g., Positive, Negative), and the laboratory system does not have a place to assign these in its database	3.81%	4
Yes, LOINC and SNOMED codes have not been previously required on specimen types, so the laboratory system does not have a place to assign these in its database	3.81%	4
Yes, Device identifiers (e.g., FDA Unique Device Identifiers) have not been previously required, and the laboratory system does not have a place to assign these in its database	5.71%	6
Yes, other (please specify below)	6.67%	7
N/A, we are in the process of validating	10.48%	11
	Answered	**105**
	Skipped	**8**