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November 2, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-3401-IFC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protections 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 of American Medical Colleges (AAMC or the Association) welcomes the opportunity to comment on the interim final rule with comment period (IFC) entitled "Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protections and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency," 85 *Fed. Reg.* 54820 (September 2, 2020), issued by the Centers for Medicare & Medicaid Services (CMS or the Agency).

The AAMC is a not-for-profit association dedicated to transforming health through medical education, health care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; more than 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and their more than 179,000 full-time faculty members, 92,000 medical students, 140,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The AAMC appreciates CMS' efforts to reduce regulatory burden on hospitals during the public health emergency (PHE) by providing regulatory flexibilities offered during the PHE. These flexibilities have allowed AAMC member teaching hospitals and physicians to meet the needs of their communities during the PHE. We applaud CMS for acting so quickly during the initial phases of the pandemic to improve care delivery to patients. We believe that many of these flexibilities have led to improved access and opportunities for care delivery.

In March 2020, the Department of Health and Human Services (HHS) requested that hospitals report, on a daily basis, COVID-related data, including intensive care unit bed capacity, drug and personal protective equipment inventory and acquisition issues. While this reporting was not mandated, almost all hospitals complied with the request, even when reporting requirements frequently changed.

As hospitals continued to voluntarily report this data, the AAMC and its members were disappointed when CMS released the IFC announcing that hospital reporting of this data would be mandatory and linked to compliance with the Medicare Conditions of Participation (CoPs). We feel this is an unnecessary response by the Administration to compel hospitals to report, even though more than 90 percent of hospitals voluntarily report and strive for completeness in the data reported. Failure to report the enormous amount of information at the required frequency may be due to inadvertent or technical errors. CMS stated in an October 29 stakeholder call that under the new guidelines, reporting is viewed as "all or nothing." If a hospital fails to submit data on all fields, then CMS considers them to be non-compliant for each day that reporting is not viewed to be 100 percent. In other words, even if a hospital is reporting 99 percent of the required data, it would be considered non-compliant based on *one percent* of missing data. We feel this is extreme and unnecessarily punitive given the vast amount of data hospitals are required to report each day. As the majority of hospitals have been compliant with reporting requirements, we do not believe that CMS should have published this requirement as an IFC that was effective as of September 2, the date of publication in the Federal Register. Hospitals that do not report this information during the COVID-19 PHE will be considered non-compliant with the Medicare CoPs and subject to termination from the Medicare program. **We oppose making COVID-related hospital reporting a requirement for Medicare CoPs and ask that it be withdrawn.**

FREQUENCY OF REPORTING AND AMOUNT OF INFORMATION REQUIRED SHOULD BE REDUCED

On October 6, 2020, more than a month after the release of the IFC, CMS released sub-regulatory guidance outlining significantly more data points, including data on influenza, that hospitals are now required to report on. While we appreciate that the frequency of reporting for some items, such as personal protective equipment and supplies has been reduced to once a week, requiring hospitals to continue to report most data elements on a daily basis adds to hospitals' burden. **We urge CMS to decrease the amount and frequency of COVID-related data hospitals are required to report.**

The reporting requirements and the data elements to be reported have changed numerous times and the expansion of data points associated with each question has become increasingly time consuming for hospitals to gather and report. There are now 38 data points that contain multiple sub-elements that are required to be reported without a clear reason for the need for reporting. Complying with the daily reporting elements has required hospitals to redirect staff to source the data, format it, accommodate changes in reporting requirements and, finally, develop a report suitable for submission.

Currently, all hospitals must report on all data elements. We question the necessity for all hospitals to report and believe there would be sufficient data if only a cross-section of hospitals were required to report on a rolling basis. Instead of requiring mandatory reporting by all hospitals, the Administration should consider sampling hospitals to collect data to alleviate the burden on hospitals for daily reporting. This would allow hospitals to redirect scarce resources for use in other settings. Therefore, we urge the Administration to evaluate the need for all hospitals to collect and report this information on a daily basis.

These federal reporting requirements are in addition to reporting hospitals are required to do at the state and local levels. Increased reporting combined with inconsistent requirements adds to the confusion on what and to whom to report. This has resulted in hospitals reporting the same or similar information to the Centers for Disease Control and Prevention (CDC) and their state health departments to ensure compliance. The inclusion of the influenza questions illustrates increased data reporting for hospitals. For example, hospitals would ordinarily report flu cases to the state who in turn would report up to the CDC. Now, hospitals will be compelled to report these cases at both the state and federal levels to ensure compliance. These reporting obligations are further complicated for health systems that span more than one state.

LACK OF TRANSPARENCY OF DATA USE

Hospitals agree with the need for transparency in COVID-19 data reporting. However, despite multiple inquiries as to the purpose and use of this data collection, the Administration has yet to communicate how it is using the data to guide the federal government's response to the pandemic. Further, data was no longer made public after reporting was redirected from the CDC in July. **We call on the Administration to be more transparent on the reasons for collecting this massive amount of information and how the data is currently being used as well as future plans for use of the data.**

DEVELOPMENT AND INCLUSION OF NEW REQUIRED DATA POINTS

As noted above, the October 6 reporting guidance includes new reporting questions pertaining to influenza. While currently voluntary, the guidance makes clear the intention to make reporting mandatory. It is unclear, however, the purpose for inclusion of these questions and whether these six questions on flu are the best ones to ask hospitals to report. Stakeholder input in developing data metrics to ensure meaningful data capture and to evaluate the need for inclusion in hospitals reporting requirements is vital. CMS has historically allowed for stakeholder input in sub-regulatory guidance. **We urge CMS to not finalize the influenza questions but to instead seek stakeholder input in an open and transparent format to ensure accurate and valuable data is captured and to decrease hospital burden.**

ENFORCEMENT PROCESS FOR NON-COMPLIANCE

The October 6 guidance also includes CMS' process to inform hospitals of non-compliance with the reporting requirements. We believe that the rollout of the process is confusing and will result in inaccurately communicating a hospital's non-compliance. On an October 22 call with stakeholders, CMS acknowledged it has encountered system challenges to accurately identify whether a hospital is in compliance. **If CMS does not withdraw the IFC, we request that the Agency suspend enforcement for non-compliance until system challenges are resolved.**

We appreciate CMS' response to stakeholder feedback and its work to provide sufficient notification to hospitals about compliance status and actions hospitals can take to correct deficiencies. However, we continue to have concerns about the process. The guidance initially stated that only hospitals that are considered non-compliant with reporting would receive a letter alerting them of the status. CMS also stated on the call that enforcement will begin in November, while at the same time acknowledging concerns with the system. As we stated previously, acting in good faith, hospitals voluntarily committed to reporting COVID-related data, even as reporting requirements changed. We do not feel hospitals should be penalized as CMS works out the problems with its enforcement process.

Further, CMS stated the letters are being sent to Chief Executive Officers, rather than a hospital-designated points of contact. The emails are being sent from a non-CMS email address and often are being mis-identified as spam or junk mail by hospitals' IT systems. CMS acknowledges being overwhelmed by hospitals' requests to change the points of contact and have asked stakeholders to allow for a 48-hour response. **We believe CMS should suspend the enforcement process until the confusion created by the roll-out is addressed by the issuance of clear and consistent information.**

HOSPITAL IN-HOUSE LABORATORY REPORTING

The IFC refers to the COVID FAQs[1] as the data items that hospitals are required to report as part of the CoPs. CMS notes that labs are currently required to report testing to state and local public health authorities in accordance with state or local law. Beginning August 1, 2020, COVID testing data should be sent to state health departments who in turn deidentify the data and report them to CDC. However, because some labs may not be reporting all testing data to the state health department or whose local jurisdiction has not converted to COVID-19 electronic lab reporting to CDC, these labs must report data to both the state and HHS. The HHS reporting must continue until the lab has confirmed that the CDC is receiving the information. All hospitals that perform in-house COVID-19 testing must report aggregate data to HHS through

[1] COVID-19 Guidance for Hospital Reporting and FAQs for Hospitals, Hospital Laboratory, and Acute Care Facility Data Reporting. Updated October 6, 2020. https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf

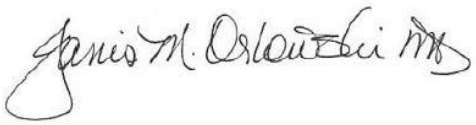
the HHS protect system until they have confirmed that the CDC is receiving their information through their state.[2]

Tying lab data reporting to hospital CoPs further jeopardizes hospital compliance. Moreover, as noted previously, requiring hospitals to double report data and the changing reporting requirements adds to hospitals' burden while increasing chances of double-counted or inconsistent data in the system. This is on top of CMS' recent announcement that it will reduce reimbursement for COVID-19 testing if results are not available within 2 days.[3] The potential for hospitals to be out of compliance, coupled with the reduced reimbursement, could disincentivize hospitals from processing COVID-19 tests in-house. Given the urgent need to increase COVID-19 testing across the country at this time of rapidly increasing infection rates[4], we must ensure that no laboratory is disincentivized to do COVID-19 testing for fear of jeopardizing the hospital's participation in federal health care programs. **We urge CMS not to include in-house lab data reporting as a CoP requirement for a hospital.**

CONCLUSION

Thank you for the opportunity to comment on this interim final rule with comment. We would be happy to work with CMS on any of the issues discussed above or other topics that involve the academic medical community. If you have questions regarding our comments, please feel free to contact Mary Mullaney at 202.909.2084 or mmullaney@aamc.org.

Sincerely,



Janis M. Orlowski, M.D., M.A.C.P.
Chief Health Care Officer

cc: Ivy Baer

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[2] *Ibid.*
[3] CMS Changes Medicare Payment to Support Faster COVID-19 Diagnostic Testing. October 15, 2020. https://www.cms.gov/newsroom/press-releases/cms-changes-medicare-payment-support-faster-covid-19-diagnostic-testing
[4] AAMC Recommendations for COVID-19 Testing: The Current State and The Way Forward. October 22, 2020. https://www.aamc.org/covidroadmap/testing