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Association of
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February 2, 2021

Ms. Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1736-IFC
P.O. Box 8010
Baltimore, MD 21244-1850

RE: Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) To Report COVID–19 Therapeutic Inventory and Usage and To Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID–19), (RIN 0938-AU12)

Dear Ms. Richter:

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 "Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) To Report COVID–19 Therapeutic Inventory and Usage and To Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID-19)," 85 *Fed. Reg.* 86264 (December 29, 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 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.

The Association agrees that data collection and reporting during the PHE is important and supports the Administration's efforts to bolster data systems and transparency for vaccinations.[1] However, there continues to be a lack of transparency as to how the data is being use. As hospitals continue to report COVID-19 related information, the AAMC urges the Administration to increase transparency as to why this data is being collected and how it is being used. If the Administration seeks to collect more information in the future, we ask that there is greater stakeholder engagement in order to ensure that the data being collected is meaningful and can be fully utilized. The AAMC and its members stand ready to assist the Administration in this effort.

As noted in our previous comment letter[2] to the Agency on required hospital reporting during the PHE, the AAMC continues to be concerned about the burden on hospitals as a result of increased reporting requirements. We do not believe that these reporting requirements should be tied to compliance with Medicare Conditions of Participation (CoPs). The IFC says that this added reporting is required to "support broad surveillance of COVID-19 in conjunction with other acute respiratory disease that *may further burden and strain hospital resources* [emphasis added]." (p. 86265). Increased mandatory reporting requirements also adds burden and strains hospital resources. Therefore, we ask CMS to withdraw this IFC and not increase hospital reporting requirements.

The Agency also waived formal notice and comment rulemaking for these requirements, claiming that it is in the "public interest" to track the incidence of COVID-19 and other acute respiratory illnesses in hospitals. (p. 86265). The Association does not believe that rulemaking should be waived in favor of "public interest" in this instance because the CDC tracks influenza data year-round. Additionally, stakeholder input in developing data metrics to ensure meaningful data capture and to evaluate the need for inclusion in hospital reporting requirements is vital; without it, the questions may not adequately capture the sought-after information. Lastly, as is always true, the value of formal notice and comment rulemaking is that it helps to better inform the Agency before it finalizes a rule.

Greater Transparency of Data Use is Required

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, it is still unclear how this data is being used to guide the federal government's response to the pandemic. Throughout the PHE, hospitals have provided an overwhelming amount of information with no transparency to its usefulness and with little public reporting its use. We call on the Administration to be more transparent on the reasons for collecting the current extensive amount of information and how the data is currently being used as well as future plans for use of the data before adding on additional data requirements.

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[1] National Strategy for the COVID-19 Response and Pandemic Preparedness. January 2020. https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf#page=50

[2] AAMC comment letter to CMS-3401-IFC. November 2, 2020. https://www.aamc.org/media/49161/download

Additional Data Reporting Should Not Be Required

Beginning December 18, 2020, the Agency required mandatory daily reporting to track Acute Respiratory Illness, including seasonal influenza, influenza-like symptoms and severe acute respiratory infection during the PHE. Data elements include diagnoses, admissions, and counts of patients currently hospitalized with this condition. (p. 86264-86265). CMS states that this reporting is required for "essential planning, monitoring, and resource allocation during the PHE" and "will be an important tool for supporting surveillance of COVID-19." (p. 86265). In addition to the increased burden on hospitals, the AAMC does not believe that hospital reporting of influenza cases during the PHE is needed because the federal government collects this data through other avenues.

The Centers for Disease Control and Prevention collects, compiles and analyzes information on influenza activity year-round in the U.S. FluView[3] is a weekly influenza report that tracks seasonal influenza activity in the U.S. The Influenza Hospitalization Surveillance Network[4] (FluSurv-NET) collects laboratory-confirmed influenza-associated hospitalizations among children and adults from a network of acute care hospitals to track influenza infections. Therefore, requiring hospitals to also report this information as part of the PHE data requirements is unnecessary.

CMS also is requiring hospitals to track inventory supplies and usage rates for COVID-19-related therapeutics that have been distributed and delivered to the hospital by the Department of Health and Human Services; weekly mandatory hospital reporting began January 8, 2021. The weekly reporting includes the number of doses the hospital has on hand and administered the previous week. The IFC states that this reporting is necessary to provide public health officials "a more robust and accurate database in order to efficiently and effectively manage the distribution and delivery of these therapeutics." (p. 86264). Hospitals receive COVID-related supplies and therapeutics from a variety of sources. Daily accounting of doses is burdensome for hospitals and it is unclear as to goal of reporting this information. Understanding the goal of data collection would assist hospitals in providing key information to CMS and others. We urge CMS to rescind this requirement.

Reporting Requirements Should Not Part of the Hospital Conditions of Participation

CMS is tying COVID-19 data reporting to compliance with hospital CoPs. The IFC notes that hospitals that do not report these data elements will be in violation of the Medicare CoP reporting requirements and subject to termination from Medicare and Medicaid. CMS acknowledges that it lacks the statutory authority to impose civil monetary penalties against hospitals for non-compliance, but "will continue to utilize all enforcement and payment authorities available to incentivize and promote compliance with all health and safety requirements, as allowed by statute and regulation." (p. 86265). The AAMC believes that requiring hospitals to report this information or be removed from the Medicare and Medicaid

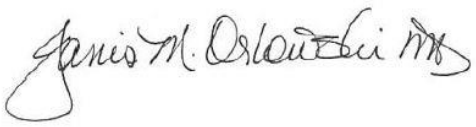
[3] https://www.cdc.gov/flu/weekly/overview.htm
[4] https://www.cdc.gov/flu/weekly/influenza-hospitalization-surveillance.htm

programs is extreme. Throughout the PHE, hospitals have worked with federal and state governments to assist with surveillance by voluntarily reporting COVID-19-related information. Requiring duplicative reporting does not improve the data that is collected; it just adds to the burden of those required to report it. We call on CMS to not incorporate COVID-19 reporting requirements into hospital CoPs.

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 mmullaney@aamc.org.

Sincerely,



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

cc: Ivy Baer