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Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3401-IFC  
P.O. Box 8016  
Baltimore, MD 21244-8016

To Whom It May Concern:

The Missouri Hospital Association, on behalf of its 141 member hospitals, would like to offer comment on the interim final rule (CMS-3401-IFC) that went into effect on Wednesday, September 2. The rule, which was unexpected and jarring, imposes a variety of new obligations on hospitals, nursing homes and other health care providers regarding COVID-19 data reporting and Medicare Conditions of Participation. Lack of compliance with the new obligations threatens regulatory penalties that include exclusion from the Medicare program. Missouri hospitals recognize the importance of driving decisions during and outside of a pandemic based on accurate data. However, the threats of exclusion from the Medicare program and stiff monetary penalties to drive compliance are misplaced. That type of heavy-handed approach especially is inappropriate given Missouri hospitals' past and recent engagement in, and compliance with, COVID-19 data collection expectations and the chaotic state of regulatory compliance communication by the Centers for Medicare & Medicaid Services.

Under the new rule, hospitals are required to report COVID-19 data as a Medicare CoP. Hospitals were provided with information on where to report the required data in the final rule. However, additional compliance details from CMS have been unstable, contradictory and insufficient creating a prolonged period of regulatory compliance chaos after a period of full compliance with reporting standards. According to U.S. Department of Health and Human Services data shared with MHA on September 10, Missouri hospitals were nearing full compliance with the daunting and rapidly evolving demands for submission of COVID-19 data. By mid-September, MHA was made aware that only 11 of its member hospitals were compliant with data submission guidelines. For more than a month, hospitals operated in the dark without formal communication from the agency on the guidelines for what data must be submitted and how compliance was being measured.

Hospitals finally received additional guidance on October 6. However, in the weeks since the document's release, there have been more questions than answers. For days after the guidance was released, the Guidance for Hospital Reporting and FAQ link within the document pointed to an old FAQ contradicting the new reporting frequency for freestanding psychiatric hospitals and Distinct Part Psychiatric Units. While MHA received an updated FAQ, the CMS Quality, Safety & Oversight Group's document still contained the wrong link creating confusion for members. There have been numerous questions surrounding reporting by facility versus by the Medicare

CCN. This is not addressed in the guidance. The data liaison instructed MHA to tell hospitals to report at the facility level regardless whether they share a certification number with another location. The liaison, when asked, is unclear as to how CMS came up with the list of hospitals that should be reporting. Hospitals reported in mid-October they still are seeking clarification from CMS. Hospitals have been instructed if they report by a single CCN to be sure to keep individual facility data in case down the road they have to prove their participation. In addition, the CMS list of facilities held by the liaison is inaccurate. In Missouri, there are four hospitals on the list that have not been in operation for years, and one hospital that has never shown up on the list but clearly is a Medicare-certified hospital surveyed under CMS and licensed by the state. These inaccuracies have existed for months. The guidance did little to align and clarify the process so that CMS, HHS and hospitals could operate from the same playbook.

Further compounding the chaos, information received from HHS and Teletracking staff is sometimes inconsistent, contradictory and delayed. One Missouri hospital is receiving HHS compliance reports under the correct hospital name; however, it is required to submit data under its cancer center into Teletracking. This issue persists despite being communicated to our HHS and CMS partners. In another example, hospitals have reached out to MHA explaining they have entered data into the Teletracking system; however, the compliance report shows multiple fields of missing data. Given the lack of a robust audit function in Teletracking, the hospital is unable to prove the entry of the data. While this has been communicated as an issue, soon this will result in enforcement letters being issued.

Everyone understands the need for accurate and timely data when making critical decisions. As evidenced by our current 90 percent compliance and the many public facing dashboards that MHA and hospitals in the state of Missouri support, we have and will continue to be willing and dependable partners. However, complex and stringent data requirements coupled with the feedback of inaccurate data and the lack of clear guidance could set hospitals up to fail. In addition, the data being submitted by hospitals is duplicative of data reporting requirements for other entities. For example, the state and local public health departments only recently have had access to the same communicable disease reporting data. Many LPHDs still are requiring hospitals to submit data that duplicates what is reported to the state. The LPHDs do not believe the reporting mechanisms of the state are reliable and timely enough to aid in contact tracing. In addition, the communicable disease reporting system infrastructure of the state does not accept electronic health record reporting. Hospitals are submitting Excel spreadsheets or faxing communicable disease reporting forms to the state and having to submit the same manually burdensome data to the LPHD and CMS using yet another format. The syndromic surveillance system for disease and laboratory reporting has largely gone unused given its limited capacity to provide meaningful information.

Based on the myriad challenges with this new reporting system and the chaotic state of federal communications about compliance expectations, MHA urges CMS to suspend its enforcement activities for these data reporting requirements or retool them to be an appropriate response to a clearly-explained, reasonable and efficient reporting system. We believe CMS should focus on planning for a prolonged response and future surveillance needs by setting criteria for state

reporting to CMS. Thought should be given to how the system would support health care providers easily reporting data to local, state and federal agencies such that the data is reported only once and distributed via systems that connect. The federal government offers matching funds for other data programs none of which are as critical to the decision-making needs during a pandemic where we know little about our viral attacker. Instead of spending time and resources on how to penalize nonreporting of fields or facilities that do not care for COVID patients, the federal government should utilize this opportunity to create a communication system to speed early detection and response among jurisdictions. This is not a sprint. Rather, we are in a marathon to ensure processes and expectations are well established with the current pandemic and challenges our health care system will face in the future.

Sincerely,

A handwritten signature in cursive script that reads "Sarah Willson".

Sarah Willson, BSN, MBA, FACHE  
Vice President Clinical and Regulatory Affairs

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