Herb B. Kuhn
President and CEO
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July 10, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Herbert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Ms. Verma:

On behalf of its 140 member hospitals, the Missouri Hospital Association would like to voice concern about the application of the Sepsis-3 definition by many payers as a tool to deny claims. Throughout the past year, numerous Missouri hospitals have expressed concerns regarding payment denials and downcoding practices from insurers who state claims do not meet the Sepsis-3 definition. MHA is concerned the Centers for Medicare & Medicaid Services eventually will subscribe to the definition change through modifications to IDC-10-CM related to sepsis, and it will have unintended consequences that undermine the recognition of work that occurs to identify and treat patients presenting with suspected sepsis.

The Sepsis-3 criteria formulated by the Sepsis Definitions Task Force are not consistent with the Sepsis-2 criteria that otherwise have been universally adopted, most notably by CMS. In fact, several national organizations, including CMS, reviewed the Sepsis-3 criteria and determined they have not gone through the real-world application testing needed to assess reliability, feasibility and usability. According to an article in the *Journal of the American Medical Association* in 2016, Sepsis-3 was designed as a research definition to help classify patients for academic study in mortality prediction and was created as a mortality measure tool for use in the delivery of ICU care. Our member hospitals and the physicians they employ follow Sepsis-2 criteria as they are aligned with CMS' core measure criteria, Surviving Sepsis Campaign initiative.

The use of sepsis definitions and criteria that do not align with accepted practice could lead to confusion, potential misdiagnoses and patient harm. The nationally recognized Sepsis-2 protocol is grounded in recognition of sepsis on systemic inflammatory response criteria, which empowers clinicians to engage a sepsis diagnosis earlier in the advancement of the disease. By prompting clinicians to initiate monitoring and treatment protocols, downstream challenges, such as organ failure, morbidity and mortality, can be avoided. Last year, the ICD-10 Coordination and Maintenance Committee through the Centers for Disease Control and Prevention proposed eliminating the Severe Sepsis diagnosis minimizing the accepted Sepsis-2 criteria. The Sepsis-3 criteria — although supporting the identification of patients with a likelihood for a poor outcome — fail to support the diagnostic work, collaboration and care that clinicians and providers

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employ for early identification and treatment of patients. While it does not appear the proposed ICD-10 changes were adopted by the CDC and CMS, commercial and Medicare Advantage payers are ramping up their denials of sepsis claims using the Spesis-3 criteria as the rationale for denial.

A group of Missouri physicians recently shared the following regarding the current use of the Sepsis-2 bundles and the challenges presented by adoption of the Sepsis-3 criteria.

> "The inherent goal [of using the Sepsis-2 definition] is to capture and prevent patient death in as broad a patient population as possible. A great deal of investment has been made by our system and others to respond appropriately to these guidelines. As a community, we are working diligently to achieve success. We are now being presented with new rules from private payers. They are using their influence to supplant the physician and define what sepsis is, forcing the medical experts to think two different ways about the same patient. This presents several problems and provides a great disservice to patients with sepsis."

Accurate measurement of outcomes is dependent upon reproducible documentation criteria and coding. The use of primary diagnosis codes for sepsis using ICD-10-CM classification and official CMS coding guidelines promotes standardization of information. Accurate documentation and care provided by physicians that is aimed at early recognition and treatment have resulted in improved outcomes for sepsis patients. The diagnosis codes used with Sepsis-3 criteria are not consistent with CMS requirements nor are they considered primary diagnosis codes. The introduction of another process to comply with billing and outcomes requirements would be acceptable if there was benefit to patient outcomes and utilization of health care resources, including the downstream impact of late diagnosis and delayed treatment. However, this is not the case. We believe that significant restricting of the diagnosis coding system would negatively impact the quality of data collection our members use to evaluate effective treatment modalities, including antibiotic selection, timeliness of recognition and intervention, and ultimately their ability to save lives where quality of life still can occur. The Sepsis-3 criteria may have a place in identifying those patients with the highest likelihood of poor outcomes; however, it has not been found to be reliable for diagnosis, coding, early detection of sepsis and improved patient outcomes.

Hospitals and clinicians seek and deserve as much certainty as possible when treating patients. This point is best articulated by the group of physicians referenced earlier. They stated that, "Providers are working every day to save the lives of sepsis patients only to be given an additional barrier that is not providing any benefit to the patients."

We must do all we can to eliminate barriers to the delivery of high-quality patient care. Payment for quality care and outcomes is a cornerstone principle, which stands to benefit patients, providers and payers, and for which we strive to have common ground. We urge CMS to consider the value of continued use of consistent and validated standards for identification and treatment of sepsis through continued advocacy for a sepsis policy with nationally recognized

and tested criteria. In addition, MHA urges CMS to ensure its Medicare Advantage contractors are using the same Sepsis DR.G assignment as the Medicare fee-for-service program.
If you have additional questions, please contact Andrew Wheeler at awheeler@mhanet.com or Sarah Willson at swillson@mhanet.com.

Sincerely,

Herb B. Kuhn
President and CEO

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c Jeff Kahrs
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