



September 6, 2019

Dear XXXX:

As organizations representing both physicians and hospitals that support and treat patients with sepsis, we write to express concern about your organization's use of the Sepsis-3 criteria for validating and paying hospital claims.

The Sepsis-3 criteria formulated by the Sepsis Definitions Task Force is not consistent with the Sepsis-2 criteria that otherwise have been universally adopted, most notably by the Centers for Medicare & Medicaid Services. In fact, several national organizations,<sup>1</sup> 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. Our organizations respectfully request that you realign with the Sepsis-2 criteria. This would ensure payment practices are based on evidence and align with federal quality and payment standards.

The use of sepsis definitions and criteria that do not align with accepted practice leads 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. The Sepsis-3 criteria – although supporting the identification of patients with a likelihood for a poor outcome – fails to provide for early identification of patients. This criteria ultimately could lead to delays in diagnoses.

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 goals [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."*

<sup>1</sup> American College of Emergency Physicians, Society for Academic Emergency Medicine, Infectious Disease Society of America

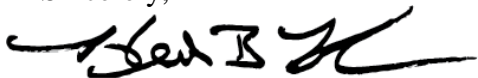
CMS repeatedly evaluated the possible transition to Sepsis-3 and found insufficient compelling evidence to change. The Sepsis-3 criteria has not been clinically validated or endorsed by numerous groups.<sup>1</sup> This primarily is due to the definition itself, which relies on use of the Sequential Organ Function Assessment to identify and quantify host organ dysregulation. Per the aforementioned statement, we believe the Sepsis-2 criteria supports early diagnosis and treatment, and reduces the risk of debilitating effects and downstream costs of undiagnosed or late-diagnosed sepsis.

Your action prompts further challenges. CMS publicly reports metrics and aligns payment programs according to their SEP-1 defined standards. 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 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. However, this is not the case. 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 your organization to consider the value of using consistent and validated standards for identification and treatment of sepsis by aligning your policy with nationally recognized and tested criteria.

Sincerely,



Herb B. Kuhn  
President and CEO



Steve Brushwood, D.O., FAAFP  
President  
Missouri Association of Osteopathic  
Physicians & Surgeons



Patrick Mills  
Executive Vice President  
Missouri State Medical Association



Evan Schwartz, M.D.  
President  
Missouri College of Emergency Physicians



September 6, 2019

Frank D'Antonio  
Coventry Health Care Of Missouri Inc  
1286 Fern Ridge Parkway, Suite 200  
St. Louis, MO 63141

Dear Mr. D'Antonio:

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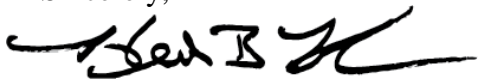
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September 6, 2019

Bruce Broussard  
Humana Regional Health Plan Inc  
500 W. Main Street  
Louisville, KY 40202

Dear Mr. Broussard:

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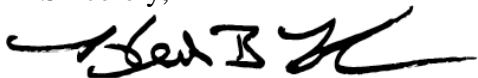
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September 6, 2019

Amadou Yattassaye  
Healthy Alliance Life Insurance Company  
1831 Chestnut Street  
St. Louis, MO 63103-2275

Dear Yattassaye:

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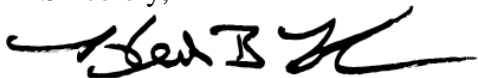
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Hmo Missouri Inc  
1832 Chestnut Street  
St. Louis, MO 63103-2275

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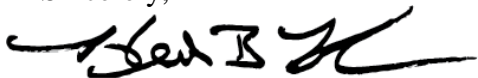
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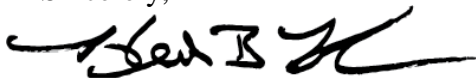
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September 6, 2019

Kevin Sparks  
Unitedhealthcare Of The Midwest Inc  
13655 Riverport Drive, MO050-1000  
Maryland Heights, MO 63043

Dear Mr. Sparks:

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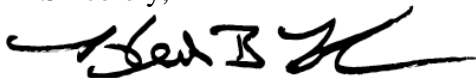
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We must do all we can to eliminate barriers to the delivery of high-quality patient care. Payment for quality care and outcomes is a cornerstone principle, which stands to benefit patients, providers and payers, and for which we strive to have common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

Sincerely,



Herb B. Kuhn  
President and CEO



Patrick Mills  
Executive Vice President  
Missouri State Medical Association



Steve Brushwood, D.O., FAAFP  
President  
Missouri Association of Osteopathic  
Physicians & Surgeons



Evan Schwartz, M.D.  
President  
Missouri College of Emergency Physicians



September 6, 2019

Frank Monical  
Cigna Healthcare Of St Louis Inc  
900 Cottage Grove Road  
Bloomfield, CT 6002

Dear Mr. Monical:

As organizations representing both physicians and hospitals that support and treat patients with sepsis, we write to express concern about your organization's use of the Sepsis-3 criteria for validating and paying hospital claims.

The Sepsis-3 criteria formulated by the Sepsis Definitions Task Force is not consistent with the Sepsis-2 criteria that otherwise have been universally adopted, most notably by the Centers for Medicare & Medicaid Services. In fact, several national organizations,<sup>1</sup> 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. Our organizations respectfully request that you realign with the Sepsis-2 criteria. This would ensure payment practices are based on evidence and align with federal quality and payment standards.

The use of sepsis definitions and criteria that do not align with accepted practice leads 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. The Sepsis-3 criteria – although supporting the identification of patients with a likelihood for a poor outcome – fails to provide for early identification of patients. This criteria ultimately could lead to delays in diagnoses.

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 goals [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."*

<sup>1</sup> American College of Emergency Physicians, Society for Academic Emergency Medicine, Infectious Disease Society of America

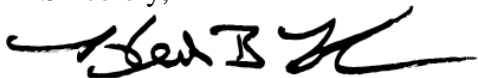
CMS repeatedly evaluated the possible transition to Sepsis-3 and found insufficient compelling evidence to change. The Sepsis-3 criteria has not been clinically validated or endorsed by numerous groups.<sup>1</sup> This primarily is due to the definition itself, which relies on use of the Sequential Organ Function Assessment to identify and quantify host organ dysregulation. Per the aforementioned statement, we believe the Sepsis-2 criteria supports early diagnosis and treatment, and reduces the risk of debilitating effects and downstream costs of undiagnosed or late-diagnosed sepsis.

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President  
Missouri College of Emergency Physicians



September 6, 2019

Erin Stucky  
Blue Cross Blue Shield of Kansas City  
2301 Main Street  
Kansas City, MO 64108

Dear Ms. Stucky:

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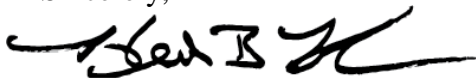
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Evan Schwartz, M.D.  
President  
Missouri College of Emergency Physicians





September 6, 2019

President  
Essence  
13900 Riverport Dr.  
Maryland Heights, MO 63043

Dear President:

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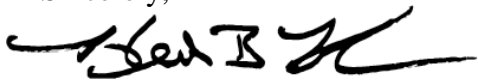
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