June 1, 2021

To whom it may concern,

On behalf of Sepsis Alliance, the nation's first and leading sepsis organization, and on behalf of the many millions of sepsis patients and survivors we represent, I write to express strong support of the continued measure of hospitals' compliance with the Severe Sepsis and Septic Shock Management Bundle (NQF # 0500, or SEP-1), with modifications as research continues to advance in the field.

Sepsis Alliance's mission is simple: to save lives and reduce the suffering caused by sepsis. Sepsis is the leading cause of death in U.S. hospitals[1] and claims over 270,000 American lives each year[1]. Another 1.4 million American survive sepsis every year[1], many of them with lingering costs and complications—including approximately 14,000 amputations[1] annually.

SEP-1 focuses on timely recognition of sepsis and early intervention with life-saving therapies. We know that saving lives and limbs from sepsis is about *time*: 12% of septic emergency department patients develop shock within 48 hours of presentation[1] and each hour of delay until initial antimicrobials are administered is associated with an 8.0% increase in progression to septic shock[1]. By emphasizing the screening of every patient in an effort to catch sepsis early, SEP-1 helps prevent the progression of sepsis to septic shock and ultimately saves lives.

Moreover, studies have shown the association between performance metrics and patient outcomes[1] and that decreased risk-adjusted sepsis mortality is associated with increased hospital-level compliance with mandated public reporting[1]. The mandate that hospitals gather and report sepsis-relevant performance data is part of what makes SEP-1 a life-saving measure.

The effectiveness and widespread approval of the SEP-1 measure led to its incorporation into the CMS Hospital IQR program in 2015. Today, there are sepsis screening programs at every hospital in the U.S., which has brought every community hospital in America up to the level of an academic facility on diagnosing and treating this challenging syndrome.

We respectfully disagree with those who urge removal of this measure. We understand that care is nuanced and that no single test can (yet) accurately or reliably establish a diagnosis of sepsis. In fact, this lack of a precise test is exactly why we should maintain a

measure meant to focus on improving the quality of care for the sepsis patient. Based on continued insights from analysis of the SEP-1 measure and associated outcomes, we support its continued improvement—there are, in fact, ongoing efforts to modify the measure in response to updated evidence and provider feedback.

Furthermore, we understand and wholeheartedly agree with the widespread concern about the immense problem of antimicrobial resistance (AMR). In fact, because AMR is a growing threat to sepsis prevention and treatment, and because sepsis patients are at the greatest risk if we lose access to a wide range of antimicrobials, we believe efforts to combat AMR are crucial,

Sepsis Alliance embraces the dual responsibility to diagnose and treat sepsis patients in a timely way, and to manage our antimicrobial medicine chest . At this time, the SEP-1 measure's stewards have proposed modifications meant to promote both decreased time to sepsis treatment *and* appropriate antibiotic usage; we also recognize the judicious use of IV fluids in the resuscitation of the sepsis patient and continue to encourage better multidisciplinary clinician engagement in the care of septic patients throughout their illness and recovery. Importantly, that standard of care includes stewardship considerations.

Continuing the SEP-1 measure would assure that hospitals maintain their focus on the number one cause of death in U.S. hospitals: sepsis. With modification, the SEP-1 measure will support the continued necessary education, screening, early recognition, and management of sepsis that improves care and saves lives in every community. Sepsis Alliance joins its organizational voice with the many leaders in the field who strongly support the maintenance and continued development of the SEP-1 measure.

Sincerely,

Thomas Heymann
President & CEO
Sepsis Alliance

[1] Liu V, et al. JAMA. 2014;312(1):90-92. http://jama.jamanetwork.com/article.aspx?articleid=1873131&resultClick=3

[1] Rhee C, et al. JAMA. 2017;318(13):1241-1249. http://jamanetwork.com/journals/jama/fullarticle/2654187

[1] Rhee C, et al. JAMA. 2017;318(13):1241-1249. http://jamanetwork.com/journals/jama/fullarticle/2654187

[1] Healthcare Cost and Utilization Project, Nationwide Inpatient Sample, 2012. Accessed April 6,2016

[1] Capp R, Horton CL, Takhar SS, Ginde AA, Peak DA, Zane R, Marill KA. Predictors of patients who present to the emergency department with sepsis and progress to septic shock between 4 and 48 hours of emergency department arrival. Crit Care Med. 2015 May;43(5):983-8. doi: 10.1097/CCM.0000000000000861. PMID: 25668750.

[1] Whiles BB, Deis AS, Simpson SQ. Increased Time to Initial Antimicrobial Administration Is Associated With Progression to Septic Shock in Severe Sepsis Patients. Crit Care Med. 2017 Apr;45(4):623-629. doi: 10.1097/CCM.0000000000002262. PMID: 28169944; PMCID: PMC5374449.

[1] Levy MM, Rhodes A, Phillips GS, Townsend SR, Schorr CA, Beale R, Osborn T, Lemeshow S, Chiche JD, Artigas A, Dellinger RP. Surviving Sepsis Campaign: association between performance metrics and outcomes in a 7.5-year study. Crit Care Med. 2015 Jan;43(1):3-12. doi: 10.1097/CCM.0000000000000723. PMID: 25275252.

[1] Levy MM, Gesten FC, Phillips GS, Terry KM, Seymour CW, Prescott HC, Friedrich M, Iwashyna TJ, Osborn T, Lemeshow S. Mortality Changes Associated with Mandated Public Reporting for Sepsis. The Results of the New York State Initiative. Am J Respir Crit Care Med. 2018 Dec 1;198(11):1406-1412. doi: 10.1164/rccm.201712-2545OC. PMID: 30189749; PMCID: PMC6290949.