American College of Emergency Physicians®
ADVANCING EMERGENCY CARE

December 7, 2022

Charles Kahn, III, MPH and Misty Roberts, MSN
Co-Chairs, Measure Applications Partnership Coordinating Committee
c/o National Quality Forum
1030 15th St NW, Suite 800
Washington, DC 20005

Dear Mr. Kahn and Ms. Roberts,

On behalf of the nearly 40,000 members of the American College of Emergency Physicians (ACEP), we are writing to provide feedback on the Centers for Medicare and Medicaid Services (CMS) 2022-2023 Measures Under Consideration (MUC) list currently under review by the National Quality Forum's (NQF) Measures Application Partnership (MAP). ACEP is the national medical society representing emergency medicine. Through continuing education, research, public education, and advocacy, ACEP advances emergency care on behalf of its members and the more than 150 million patients they treat on an annual basis.

We submitted comments on multiple measures through the online portal, but want to re-emphasize our comments on two extremely important measures.

WASHINGTON, DC OFFICE
901 New York Ave, NW
Suite 515E
Washington DC 20001-4432

202-728-0610
800-320-0610
www.acep.org

<u>MUC2022-082: Severe Sepsis and Septic Shock: Management Bundle</u>

CMS, NQF, and the SEP-1 measure stewards deserve credit for bringing welcome attention to the need to improve sepsis care and outcomes. However, ACEP continues to have major concerns about the SEP-1 Severe Sepsis and Septic Shock: Early Management Bundle measure (MUC2022-082), which CMS is considering for adoption through future rulemaking under the Hospital Value-Based Purchasing (VBP) Program. If CMS adopts this measure under the VBP Program, it would represent a major shift in accountability from pay-for-reporting to pay-for-performance. We believe this shift will not enhance care and may create unintended threats to health of those with sepsis or other conditions that can mimic sepsis.

We summarize our major concerns about SEP-1, some of which we have previously outlined in a 2021 position paper and in public comments during the NQF re-endorsement process. We restate and update these concerns since the quality of evidence to support a pay-for-performance measure must be even higher than for pay-for-reporting. The evidence published to date is insufficient to support this change for SEP-1.

1. Despite massive investments by US hospitals to implement, assess compliance with, and report data on the SEP-1 core measure, rigorous analyses indicate that implementation of SEP-1 has not improved outcomes for patients.

- Careful analyses using interrupted time series models and clinical data from hundreds of hospitals demonstrate that implementation of SEP-1 led to changes in *processes* of care (including lactate checks, fluids, and, in some

studies, broad spectrum antibiotics) but *not* to improvements in sepsis-associated mortality.[2-5] These data support the concern that SEP-1 forces clinicians and hospitals to focus on a set of processes and interventions that have not been shown to lead to better outcomes for patients.

- The only study that suggest a possible benefit of SEP-1 is one that retrospectively compared outcomes for patients who received SEP-1 compliant vs non-compliant care.[6] Despite attempting to adjust for baseline risk using propensity matching, however, this study is at high risk for confounding because the patients who do not receive SEP-1 compliant care tend to be very different from those who do (including more severe illness, more ambiguous clinical presentations, higher rates of hospital vs community-onset sepsis, and higher rates of septic shock which requires more steps required to pass the measure).[7] When assessing compliance just among patients with septic shock (a fairer comparison than combining patients with sepsis and septic shock), mortality rates for SEP-1 compliant vs non-compliant care in this study were not statistically different (and in fact numerically higher for those who received compliant care, 38% vs 35%).[6]

2. **SEP-1's requirement to immediately administer antibiotic therapy to all patients with possible sepsis, regardless of severity-of-illness, risks increasing excessive and unwarranted antibiotic administration. This concern will be magnified if SEP-1 shifts from pay-for-reporting to pay-for-performance.**

- SEP-1 stipulates the same time-to-antibiotic goals (3 hours) for sepsis and septic shock, but the association between time-to-antibiotics and mortality in the largest and highest-quality observational studies is much stronger for septic shock than for sepsis.[8,9] The only randomized controlled trial to compare differential timing of antibiotics in patients with suspected sepsis (the vast majority of whom did not have septic shock) did not show any differences in 28-day mortality despite antibiotics being administered a median of 96 minutes earlier in the intervention arm.[10]

- The signs and symptoms of sepsis are non-specific and mimicked by many non-infectious conditions. At least one third of patients treated with antibiotics for possible sepsis turn out to have viral infections or non-infectious conditions.[11,12] The impact of the SEP-1 implementation on others who seem initially to have sepsis but later discovered *not* to have this was unassessed in the supportive trial;[9] this is not a trivial issue as sepsis care steps may not help and can harm those without sepsis, something seen decades earlier with a community acquire pneumonia measure.

- Immediate empiric antibiotics are appropriate in patients with suspected septic shock, but the perception that any delays in antibiotic therapy led to worse outcomes for patients with suspected sepsis, regardless of severity-of-illness, leads to inappropriate antibiotic prescribing and is the wrong message for clinicians.

- External pressures to rush to treatment will further expose many patients without infection or with very low likelihood of infection to the risk of antibiotics (including direct toxicities, *C. difficile* infection, and development of antibiotic resistance) without benefit and potentially exacerbate the public health crisis of antibiotic resistance.[13]

3. **There are no high-quality data supporting the 3-hour 30 cc/kg threshold for crystalloid fluids in patients with sepsis-induced hypotension or repeat lactate measurements as an approach to reduce sepsis mortality, yet both are common causes of SEP-1 failure.[14] Hospitals should not be denied payment for not complying with these bundle elements that have both been labeled as "weak recommendations with low quality of evidence" in the latest version of the Surviving Sepsis Campaign Guidelines.[17]**

- The largest observational study of sepsis bundle compliance (almost 50,000 patients treated in New York hospitals under the state health department's sepsis regulatory requirements) did not find an association between completion of the 30 cc/kg fluid bundle component and mortality.[5]

- The recent cessation of the CLOVERS trial which aimed to compare aggressive early fluid resuscitation vs earlier initiation of vasopressors in septic shock was stopped early for futility (https://clinicaltrials.gov/ct2/show/NCT03434028). This underscores the lack of data to support a one-size fit-all approach to fluid management.

- The lack of benefit of serial lactates is further supported by a recent randomized controlled trial of patients with septic shock that showed no difference in mortality between fluid resuscitation based on physical exam (capillary refill time) versus serial lactate measurements.[9]

4. **The current SEP-1 time-zero is complex, subjective, and not evidence based.**

    - The SEP-1 time zero definition requires documentation of suspected infection, SIRS criteria, and one of more than 8 potential organ dysfunction criteria within a limited time window. The complexity of the current time zero definition contributes to variability in abstraction and undermines the validity of the measure.[16]

5. **Pay-for-performance based on a flawed measure is likely to negatively and disproportionally affect safety-net healthcare systems.**

    - Hospitals caring for a high percentage of medically underserved patients have been shown to bear the brunt of financial penalties associated with CMS value-based purchasing programs.[17] Before implementing a new measure in CMS's Hospital Value-Based Purchasing Program, or any other pay-for- performance program, its impact on the poorest hospital systems must be considered.

We would like to reiterate the concrete suggestions we have previously made to improve SEP-1, which include the following:

1. Focus the bundle on the subset of patients most likely to benefit from rapid and aggressive interventions, which are those with septic shock.

2. Minimize antibiotic overuse and adverse effects by eliminating patients with possible but unconfirmed sepsis who do not have shock from the bundle since many of these patients do not have infections and the data supporting immediate antibiotics for this population are weak.

3. Eliminate bundle elements that do not contribute to improved patient outcomes, such as measuring serial lactates and 30 cc/kg of fluids for hypotension.

4. Streamline the reporting process to focus on clinical outcomes rather than process measures.

5. Make reporting electronic with data that is easily extractable from the electronic health record.

6. Get input and support for intended changes from all stakeholders, including the full array of professional organizations that routinely manage patients with possible sepsis.

In its current state, however, we do not believe that SEP-1 is appropriate for pay-for-reporting or pay-for-performance.

MUC2022-100: Emergency Medicine

The Emergency Medicine (EM) episode-based cost measure (MUC2022-100), which is under consideration for the Merit-based Incentive Payment System (MIPS), evaluates a clinician's risk-adjusted cost to Medicare for patients who have an emergency department (ED) visit during the performance period. This measure includes costs of Part A and B services during each episode from the start of the ED visit that triggers the episode through 14 days after the trigger, excluding a defined list of services for each ED visit type that are unrelated to the ED care. The measure is also stratified into 28 different high-volume ED conditions. The measure score is the clinician's risk-adjusted cost for the episode group averaged across all episodes attributed to the clinician.

ACEP supports this measure but has some recommended modifications. ACEP members participated in the Acumen workgroup to help develop the measure, and we also submitted detailed comments during the field testing process.

We appreciate that, following field testing, Acumen revised the measure to exclude some additional services that are not clinically related to the initial emergency department (ED) visit or that cannot be influenced by the emergency physician who triggered the episode, including: radiation oncology services, ambulance services, and Medicare Part B drugs. Including the costs of these services in the measure would have caused the measure to be an inaccurate reflection of the cost of emergency care.

ACEP also has concerns about the length of the episode that is captured under this measure. Although we appreciate that Acumen shortened the length from 30 days to 14 days following the field testing period, we strongly urge the measure developer to further reduce the length of the episode to 10 days.

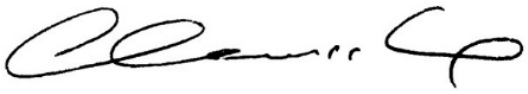
Shortening this period would further reduce the chance of the measure including services and costs that are beyond the score of the initial emergency visit and increase the likelihood that this cost measure is accurately attributable to emergency physicians. In fact, an even shorter window (i.e., a 7-day cutoff) is consistent with published work which demonstrates that only 1 in 5 ED revisits within 30 days are related to the initial ED visit (specifically, that 77% should be classified as new index episodes), and that a majority of related ED revisits occur within seven days. Decreasing the length of the episode would also negate the need for so many exclusions in the measure. A large component of the variation in the cost of episodes is driven by spending for post-acute care services among patients who are admitted, which, as noted earlier, are not controlled by emergency physicians. An episode period of 10 days or shorter would help to ensure that these services are not even included in the measure to begin with.

Finally, ACEP recommends that the measure developer also stratify the measure based on the size of the hospital, hospital type (critical access hospital or traditional hospital), and ED volume. These factors can significantly impact the total cost of care. For example, some smaller, rural hospitals cannot handle all inpatient cases and may transfer admitted patients in need of inpatient services to other facilities on a routine basis. Therefore, these hospitals' cost profiles would be biased and vary significantly from other hospitals, and the measure must take that into account.

We urge the measure developer to attribute costs to physicians on a facility basis using the attribution methodology included in the Acute Unscheduled Care Model (AUCM). The AUCM was reviewed and recommended for implementation by the Physician-Focused Payment Model Technical Advisory Committee (PTAC) in 2018, and the former Secretary of Health and Human Services, Alex Azar, subsequently expressed interest in testing the model through CMS's Center for Medicare and Medicaid Innovation (CMMI).

ACEP appreciates the opportunity to provide feedback during this pre-rulemaking process. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory and External Affairs, at jdavis@acep.org.

Sincerely,



Christopher S. Kang, MD, FACEP
ACEP President

REFERENCES

1. Rhee C, Chiotos K, Cosgrove SE, et al. Infectious Diseases Society of America Position Paper: Recommended Revisions to the National Severe Sepsis and Septic Shock Early Management Bundle (Sep-1) Sepsis Quality Measure. *Clin Infect Dis.* 2021;72(4):541-552.
2. Barbash IJ, Davis BS, Yabes JG, Seymour CW, Angus DC, Kahn JM. Treatment Patterns and Clinical Outcomes after the Introduction of the Medicare Sepsis Performance Measure (Sep-1). *Ann Intern Med.* 2021.
3. Rhee C, Yu T, Wang R, et al. Association between Implementation of the Severe Sepsis and Septic Shock Early Management Bundle Performance Measure and Outcomes in Patients with Suspected Sepsis in Us Hospitals. *JAMA Netw Open.* 2021;4(12):e2138596.
4. Anderson DJ, Moehring RW, Parish A, et al. The Impact of Centers for Medicare & Medicaid Services Sep-1 Core Measure Implementation on Antibacterial Utilization: A Retrospective Multicenter Longitudinal Cohort Study with Interrupted Time-Series Analysis. *Clin Infect Dis.* 2022;75(3):503-511.
5. Pakyz AL, Orndahl CM, Johns A, et al. Impact of the Centers for Medicare and Medicaid Services Sepsis Core Measure on Antibiotic Use. *Clin Infect Dis.* 2021;72(4):556-565.
6. Townsend SR, Phillips GS, Duseja R, et al. Effects of Compliance with the Early Management Bundle (Sep-1) on Mortality Changes among Medicare Beneficiaries with Sepsis: A Propensity Score Matched Cohort Study. *Chest.* 2022;161(2):392-406.
7. Rhee C, Filbin MR, Massaro AF, et al. Compliance with the National Sep-1 Quality Measure and Association with Sepsis Outcomes: A Multicenter Retrospective Cohort Study. *Crit Care Med.* 2018;46(10):1585-1591.
8. Weinberger J, Rhee C, Klompas M. A Critical Analysis of the Literature on Time-to-Antibiotics in Suspected Sepsis. *J Infect Dis.* 2020;222(Suppl 2):S110-S118.
9. Im Y, Kang D, Ko RE, et al. Time-to-Antibiotics and Clinical Outcomes in Patients with Sepsis and Septic Shock: A Prospective Nationwide Multicenter Cohort Study. *Crit Care.* 2022;26:19.
10. Alam N, Oskam E, Stassen PM, et al. Prehospital Antibiotics in the Ambulance for Sepsis: A Multicentre, Open Label, Randomised Trial. *Lancet Respir Med.* 2018;6(1):40-50.
11. Klein Klouwenberg PM, Cremer OL, van Vught LA, et al. Likelihood of Infection in Patients with Presumed Sepsis at the Time of Intensive Care Unit Admission: A Cohort Study. *Crit Care.* 2015;19:319.
12. Shappell CN, Klompas M, Ochoa A, Rhee C, Program CDCPE. Likelihood of Bacterial Infection in Patients Treated with Broad-Spectrum Iv Antibiotics in the Emergency Department. *Crit Care Med.* 2021;49(11):e1144-e1150.
13. Carignan A, Allard C, Pepin J, et al. Risk of Clostridium difficile infection after perioperative antibaterial prophylaxis before and during an outbrak of infection due to a hypervirulent strain. Clin Inf Dis 2008;46:
14. Pepper DJ, Jaswal D, Sun J, Welsh J, Natanson C, Eichacker PQ. Evidence Underpinning the Centers for Medicare & Medicaid Services' Severe Sepsis and Septic Shock Management Bundle (Sep-1): A Systematic Review. *Ann Intern Med.* 2018;168(8):558-568.

15. Seymour CW, Gesten F, Prescott HC, et al. Time to Treatment and Mortality During Mandated Emergency Care for Sepsis. *N Engl J Med.* 2017;376(23):2235-2244.
16. Rhee C, Brown SR, Jones TM, et al. Variability in Determining Sepsis Time Zero and Bundle Compliance Rates for the Centers for Medicare and Medicaid Services Sep-1 Measure. *Infect Control Hosp Epidemiol.* 2018:1-3.
17. Rosenbaum L. Reassessing Quality Assessment - the Flawed System for Fixing a Flawed System. *N Engl J Med.* 2022;386(17):1663-1667.