

2025 Pre-Rulemaking Measure Review Preliminary Assessment

MUC ID	Title
MUC2025-047	Hospital Sepsis Program Core Elements Score
Measure Steward & Developer	Proposed CMS Programs
Centers for Disease Control and Prevention (CDC)	Hospital Inpatient Quality Reporting (IQR) Program Link: Hospital Inpatient Quality Reporting (IQR) Program

Measure Overview	
<p>Rationale: This measure will assess uptake of evidence-based sepsis program best practices described in the CDC Hospital Sepsis Program Core Elements and will provide guidance to acute care hospitals for monitoring and optimizing hospital management and outcomes of sepsis, leading to improved patient outcomes.</p>	
<p>CMS-provided program rationale: Sepsis is a leading cause of death in hospitals. Each year, according to the Centers for Disease Control and Prevention (CDC), at least 1.7 million adults in the U.S. develop sepsis, and at least 350,000 die as a result.</p>	
<p>Description: Annual, non-weighted score, assessing acute care hospitals on their leadership support, personnel resources, implementation of quality improvement tools and practices to improve the recognition and care of patients with sepsis. Measure score = Sum of Hospital Sepsis Program Priority Examples in use by hospital</p>	
<p>Measure background: New measure never reviewed by the Measure Applications Partnership (MAP) Workgroup or PRMR; never used in a Medicare program.</p>	
<p>Numerator: The measure is a series of attestations on overall program practices to improve the recognition and care of patients with sepsis. See appendix for full list of attestations.</p>	
<p>Exclusions: N/A</p>	
<p>Denominator: 28 Hospital Sepsis Program Priority Examples, as described in the CDC Core Elements document.</p>	
<p>Exclusions: N/A</p>	
<p>Exceptions: N/A</p>	
<p>Substantive changes from prior version (if applicable): N/A</p>	
<p>Measure type: Structure</p>	<p>Measure is a composite: No</p> <p>Measure is digital and/or an eCQM: No</p> <p>Measure is a paired or group measure: No</p>
<p>Level of analysis: Facility</p>	<p>Data source(s): Non-Digital-Other: Attestation by team that responds to National Healthcare Safety Network (NHSN) Annual Survey.</p>
<p>Care setting(s): Hospital inpatient acute care facility</p>	<p>Risk adjustment or stratification: No</p>

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Measure Overview	
CBE endorsement status: Not Endorsed	CBE endorsement history: Never Submitted
Is measure currently used in CMS programs? No	Measure addresses statutorily required area? No

MUC2025-047 Preliminary Assessment

Evaluation

Meaningfulness

Importance	
Type of evidence:	Clinical Guidelines or U.S. Preventive Services Task Force (USPSTF) Guidelines, Empirical data [MUC Entry/Review Information Tool (MERIT) submission form]
<p>Importance: Sepsis is a major contributor to hospital mortality and long-term disability, with over 1.7 million hospitalizations annually in the U.S. and 350,000 resulting in death or hospice discharge. As outlined in a literature review provided by the developer, effective hospital sepsis programs require strong leadership, multidisciplinary collaboration, and dedicated resources, including sepsis coordinators and structured protocols for early recognition and treatment. Programs benefit from standardized screening tools, care pathways, rapid response teams, and “Code Sepsis” protocols, all aimed at improving timely intervention and reducing mortality. Education for health care staff, patients, and caregivers is essential, especially given the high risk of post-sepsis complications and rehospitalization. Feedback from patients on the technical expert panel (TEP) for this measure indicated strong importance of this measure target to patients.</p>	
Rating: Met	

Conformance	
<p>Measure alignment with conceptual intent: The intent of this measure is to assess uptake of evidence-based sepsis program best practices described in the CDC Hospital Sepsis Program Core Elements and to provide guidance to acute care hospitals for monitoring and optimizing hospital management and outcomes of sepsis, leading to improved patient outcomes. This structure measure quantifies the number of “Yes” responses to 28 Hospital Sepsis Program Priority Examples that outline processes and practices that improve the recognition and care of patients with sepsis. This measure aligns with the Hospital IQR Program objective to improve the quality of care that hospitals provide and to distribute clearly defined and objective data about hospital performance.</p>	
Rating: Met	

Feasibility	
eCQM feasibility testing/analysis conducted:	No, not an eCQM.
<p>Feasibility: For this measure, no data elements are captured in defined fields within electronic sources. Instead, data are collected through the</p>	

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MUC2025-047 Preliminary Assessment

Feasibility	
<p>NHSN Annual Survey and submitted via a web interface. Measure scores are calculated by assessing information submitted to NHSN via the NHSN Patient Safety Annual Survey. The information is submitted by measured entities once and used for multiple purposes. Although this workflow may require effort from administrative staff and leadership, it aligns with existing survey processes, thereby minimizing the additional burden associated with implementing the measure.</p>	
Rating: Met	

Validity	
Validity testing method(s):	Face Validity, Empiric Validity [MERIT Submission Form]
Testing level(s)	Facility
Was this measure tested in the same target population as the CMS program?	Yes
<p>Validity: Face validity was established through stakeholder feedback and three patient/caregiver meetings, where participants consistently supported the measure and its ability to distinguish between hospitals providing high- versus low-quality sepsis care. Respondents also offered constructive suggestions to improve data collection, transparency, and accuracy, with no participants expressing opposition to the measure.</p> <p>Empiric validity of the Core Elements Measure was evaluated by comparing 2023 scores to external benchmarks from the Michigan Hospital Medicine Safety Consortium (HMS) and CMS's SEP-1 measure. Among 65 Michigan hospitals, the Core Elements Measure showed a moderate positive correlation with Early Sepsis Bundle scores ($r = 0.422, p < 0.001$) and a weaker but significant correlation with risk-adjusted 30-day mortality ($r = 0.261, p = 0.03$). Nationally, among 2,819 hospitals, the Core Elements Measure demonstrated a weak but statistically significant positive correlation with SEP-1 scores (Spearman $r = 0.219, 95\% \text{ CI: } 0.183\text{--}0.255, p < 0.0001$). These findings support the empirical validity of the measure, indicating it is meaningfully associated with established indicators of sepsis care quality and outcomes.</p>	
<p>Threats to validity: Risk adjustment or stratification is not recommended for structure measures. The developer did not discuss the potential for threats to measure validity in the submission materials.</p>	
<p>Considerations for committee members: Committee members should consider if there are facility-level or external factors that may impact validity of this measure within the Hospital IQR Program.</p>	
Rating: Met	

MUC2025-047 Preliminary Assessment

Reliability	
Reliability testing method(s):	This is a structure measure; accountable-entity level reliability testing is not applicable.
Testing level:	N/A
Reliability discussion: N/A	
Rating: N/A	

Usability	
Usability considered in application:	Yes, the submission materials briefly discuss the measure's usability within the Hospital IQR Program.
Usability discussion: This measure is highly usable within a hospital inpatient quality program due to its alignment with existing data collection workflows and its focus on actionable components of sepsis care. It leverages the NHSN Annual Survey for data reporting and minimizes additional burden by integrating into established administrative processes. The measure supports performance improvement by identifying specific elements of sepsis care that are present or missing, enabling targeted interventions. The developer noted that this measure may result in increased cost due to additional resources required to staff sepsis programs to improve the measure score after implementation.	
Rating: Met	

Appropriateness of Scale

Appropriateness of Scale	
Similar or related measures in program(s):	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure) in Hospital IQR
Measure balance, burden, and value across target populations/measured entities: Improvements in sepsis care is an established target of the Hospital IQR Program, as evidenced by the related Severe Sepsis and Septic Shock: Management Bundle measure. Variation in hospital resources, infrastructure, and program maturity may influence how easily this structure measure can be implemented and the extent to which hospitals benefit from it. Hospitals with more developed data systems and established sepsis programs may find it easier to leverage the measure for quality improvement, while others may require additional support to fully realize its potential. The measure's emphasis on transparency and detailed reporting may present greater demands for some facilities but also offers opportunities to enhance accountability and drive meaningful improvements in sepsis care.	

MUC2025-047 Preliminary Assessment

Appropriateness of Scale

Considerations for the committee: Based on clinical and professional experience, the committee should consider the distribution of benefits and risks/burdens of the measure within the proposed program population.

Time-to-Value Realization

Time-to-Value Realization

Plan for near- and long-term impacts after implementation:

None specified

Measure implementation impacts over time: While the measure developer briefly mentions potential outcomes for their measure in the long-term, there may be need for further examination of near- and long-term impacts of this measure after implementation across hospitals.

Considerations for the committee:

- What are the potential near- and long-term impacts of this measure on measured entities, proposed CMS programs, and patient populations?
- Will benefits and burdens associated with this measure be realized within an appropriate implementation time frame?
- How will this measure mature through revisions in the future if added to these programs' measure sets?

Appendix

Hospital Sepsis Program Priority Examples with mapping to 2024 NHSN Annual Survey Items

Hospital Leadership Commitment - 1

1. Our sepsis program leader(s) are given sufficient specified time to manage the hospital sepsis program

Q54: EITHER APP, Nurse, OR Physician with non-0% effort (EITHER 1-10%, 11-25%, 26-50%, OR More than 50%). -AND- Q55. “providing sepsis program leaders with sufficient specified time”

Hospital Leadership Commitment - 2

2. Our sepsis program is provided sufficient resources, including data analytics and information technology support, to operate the program effectively

Q55. “Providing sufficient resources, including data analytics and information technology support, to operate the program effectively.”

Hospital Leadership Commitment - 3

3. Relevant staff from key clinical groups and support departments in our hospital have sufficient time to contribute to sepsis activities.

Q55. “Ensuring that relevant staff from key clinical groups and support departments have sufficient time to contribute to sepsis activities.”

Hospital Leadership Commitment - 4

4. Our hospital has a senior leader (e.g., Chief Clinical Officer, Chief Medical Officer, or Chief Nursing Officer) who serves as an executive sponsor for the sepsis program.

Q55. “Appointing a senior leader to serve as an executive sponsor for the sepsis program”

Hospital Leadership Commitment - 5

5. Sepsis has been identified as a hospital priority by hospital leadership and this priority has been communicated to hospital staff.

Q55. “Identifying sepsis as a facility priority and communicating this priority to hospital staff”

Accountability - 1

14. Our hospital has a program or committee charged with monitoring/improving outcomes.

Q53. “yes”

Accountability - 2

15. Our hospital has one leader or two co-leaders responsible for sepsis program or committee management and outcomes.

Q54. “yes”

Accountability - 3

16. Our hospital sets ambitious but achievable goals at regular intervals and updates goals periodically to promote continuous improvement

Q53a. “Setting annual goals for sepsis management and/or outcomes”

MUC2025-047 Preliminary Assessment

Accountability - 4

17. Our hospital assesses progress towards hospital sepsis goals at regular intervals and updates goals periodically (e.g., annually) to promote continual improvement.

Q62. BOTH “Progress towards achieving hospital goals for sepsis treatment and/or outcomes”, AND Q53a. “Setting annual goals for sepsis management and/or outcomes”

Accountability - 5

18. Our hospital has one physician and one nurse lead or champion to ensure physician and nursing engagement in the sepsis program.

Q54a: BOTH "Nurse" AND "Physician" are selected (at a minimum).

Multi-professional expertise - 1

22. Our hospital has a sepsis coordinator, who oversees day-to-day implementation of sepsis program activities.

Q55 - Facility leadership has demonstrated commitment to improving sepsis care by: “Having a sepsis coordinator who oversees day-to-day implementation of sepsis program activities”

Multi-professional expertise - 2

23. Clinicians and leaders from the emergency department, inpatient wards, and intensive care units are fully engaged in our hospital sepsis program activities.

Q53c. “critical care” selected if hospital has indicated =10 ICU beds in annual survey.

Multi-professional expertise - 3

24. Our hospital sepsis program includes diverse multi-disciplinary representation (e.g., antimicrobial stewardship, critical care, emergency medicine, hospital medicine, infectious diseases, nursing, other primary services [e.g., surgery, oncology, obstetrics, pediatrics], pharmacy, and social work).

Q53b.BOTH =4 options selected, AND 53c=4 options selected

Multi-professional expertise - 4

25. Our hospital sepsis program has ongoing support from individuals with expertise and formal training in data management and analytics, information technology, and quality improvement and patient safety.

Q53c BOTH “data analytics” AND “information technology” selected.

Action - 1

27. Our hospital has implemented a standard process to screen for sepsis on presentation and throughout hospitalization.

Q56 – “Our facility uses the following approaches to assist in the rapid identification of patients with sepsis upon presentation to the facility.” AND Q57 “Our facility uses the following approaches to assist in identification of sepsis throughout hospitalization”

Action - 2

28. Our hospital has a hospital guideline or a standardized care pathway for management of sepsis that addresses

Q58. “Hospital guideline or care pathway for management of sepsis”

MUC2025-047 Preliminary Assessment

Action - 3

29. Our hospital has order sets for the management of sepsis tailored to the patient populations served.

Q58. "Hospital order set for management of sepsis"

Action - 4

30. Our hospital has structures and processes in place to facilitate prompt delivery of antimicrobials.

Q59.=2 options selected (EXCEPT "None of the above").

Action - 5

31. Our hospital has structures and processes in place to support effective hand-offs of patients with sepsis, such as templated notes to document sepsis diagnosis and treatment information.

Q58. EITHER "Structured template for documentation of sepsis treatment" OR "Standardized process for verbal hand-off of sepsis treatment"

Tracking - 1

37. Our hospital monitors hospital sepsis epidemiology, such as number of hospitalizations with community-onset sepsis, hospital-onset sepsis and septic shock.

Q62. "hospital sepsis epidemiology"

Tracking - 2

38. Our hospital monitors hospital sepsis management, such as time to antibiotic delivery and time from antibiotic order to antibiotic delivery

Q62. "hospital sepsis treatment"

Tracking - 3

39. Our hospital monitors sepsis outcomes, such as in-hospital mortality, length of hospitalization, and new discharge to a healthcare facility

Q62. "hospital sepsis outcomes"

Tracking - 4

40. Our hospital assesses use, usability, and impact of hospital sepsis tools to inform their ongoing improvement, such as use of sepsis order sets.

Q62. ALL the following: "use of hospital sepsis tools" AND "usability or acceptability of hospital sepsis tools" AND "impact of hospital sepsis tools"

Tracking - 5

41. Our hospital monitors progress towards achieving hospital goals for sepsis management and/or outcomes

Q62. "Progress towards achieving hospital goals for sepsis treatment and/or outcomes"

Reporting - 1

44. Our hospital reports sepsis treatment and outcome data to nursing, physician, unit-based, and hospital leadership at routine intervals (e.g., monthly or quarterly), which include: unit-level data, trends over time, and comparative or benchmarking data (e.g., comparison to other similar units or hospitals)

MUC2025-047 Preliminary Assessment

Q64a. ALL OF THE FOLLOWING: “unit-specific or service-specific” AND “benchmarking or comparative data” AND “temporal trends”

Education - 1

47. Our hospital provides sepsis-specific training and education in the hiring or on-boarding process for healthcare staff and trainees.

IF “YES” to Teaching hospital (from page 1 of survey): Q65: BOTH “trainees” AND at least 2 non-trainee categories. IF “NO” to Teaching hospital (from page 1 of survey) Q65: ANY two non-trainee categories.

Education - 2

48. Our hospital provides annual sepsis education to clinical staff.

Q66: =2 categories selected (except “None of the above”)

Education - 3

49. Our hospital provides written and verbal sepsis education to patients, families, and/or caregivers prior to discharge.

Q61. BOTH “Written educational material about sepsis” AND EITHER “Direct 1:1 education on sepsis from a healthcare personnel” OR “Pre-recorded video material about sepsis”