2025 Pre-Rulemaking Measure Review Preliminary Assessment

MUC ID	Title
MUC2025-045	Adult Community-Onset (CO) Sepsis Standardized Mortality Ratio (SMR)
Measure Steward & Developer	**Proposed CMS Programs**
Centers for Disease Control and Prevention	Hospital Inpatient Quality Reporting (IQR) Program Link: Hospital Inpatient Quality Reporting (IQR) Program Hospital Value-Based Purchasing (HVP) Program Link: Hospital Value-Based Purchasing (VBP) Program

Measure Overview
Rationale: To provide facilities with a nationally benchmarked metric of community-onset sepsis mortality outcomes, which can be used to measure their progress to improving the care of patients with sepsis.
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. It is also one of the main causes of hospital readmissions.
Description: Annual risk-adjusted standardized mortality ratio (SMR) of adult inpatients with community-onset sepsis who died during their hospitalization or were discharged to hospice. SMR is reported annually and is calculated by dividing the number of observed community-onset sepsis deaths by the number of predicted community-onset sepsis deaths.
Measure background: New measure never reviewed by the Measure Applications Partnership (MAP) Workgroup or PRMR; never used in a Medicare program.
Numerator: Number of annually observed adults with community-onset sepsis who died during hospitalization or were discharged to hospice. **Exclusions:** • Patients <18 years of age • Length of hospitalization >120 days • Patients with prior enrollment in hospice • Patients that transferred to another acute care hospital
Denominator: Number of annually predicted adults with community-onset sepsis who died during hospitalization or were discharged to hospice. **Exclusions:** • Patients <18 years of age • Length of hospitalization >120 days • Patients with prior enrollment in hospice

Measure Overview	
• Patients that transferred to another acute care hospital **Exceptions:** N/A	
Substantive changes from prior version (if applicable): N/A	
Measure type: Outcome	**Measure is a composite:** No **Measure is digital and/or an eCQM:** No **Measure is a paired or group measure:** No
Level of analysis: Facility	**Data source(s):** Digital-Administrative systems: Claims Data Digital-Electronic Health Record (EHR) Data
Care setting(s): Hospital Inpatient Acute Care Facility	**Risk adjustment or stratification:** Yes, risk adjusted.
CBE endorsement status: Not Endorsed	**CBE endorsement history:** Never submitted
Is measure currently used in CMS programs? No	**Measure addresses statutorily required area?** No

Evaluation

Meaningfulness

Importance	
Type of evidence:	Clinical Guidelines or U.S. Preventive Services Task Force (USPSTF) Guidelines; Empirical data
Importance: As outlined in the evidence provided by the developer, sepsis is a major global health concern, causing severe illness and death, with 1.7 million adult cases and 265,000 deaths annually in the U.S. Accurate tracking of sepsis incidence and outcomes is challenging due to the lack of a definitive diagnostic test and wide variation in diagnosis and coding practices. Reliance on administrative data and death certificates leads to inconsistent estimates and limits meaningful hospital comparisons. Increased screening and coding for sepsis have led to more cases being identified, often inflating case counts and lowering reported mortality rates. Studies show that claims data only moderately correlate with clinical data for sepsis incidence and mortality, and using objective clinical data provides more reliable hospital comparisons. Thirty-day mortality is commonly used to measure hospital performance but is limited by reporting delays and incomplete data for non-Medicare/Medicaid patients. A combined outcome of in-hospital mortality and discharge to hospice is a faster, more universally applicable measure. A measure assessing the community-onset sepsis standardized mortality ratio is essential for producing timely, consistent, and clinically meaningful comparisons across hospitals.	
Rating: Met	

Conformance
Measure alignment with conceptual intent: The goal of this measure is to provide facilities with a nationally benchmarked metric of community-onset sepsis mortality outcomes, which can be used to measure their progress to improving the care of patients with sepsis. The measure's numerator, denominator, and exclusions are clearly defined and directly support the intent of this measure. The numerator is the observed number of adults with community-onset sepsis who died or were discharged to hospice, and the denominator is the predicted number, both excluding minors, long hospital stays, prior hospice enrollment, and hospital transfers. This measure aligns with the Hospital IQR objective to improve the quality of care that hospitals provide and to distribute clearly defined and objective data about hospital performance as well as the Hospital VBP Program encourages hospitals to improve the quality, efficiency, patient experience, and safety of care.
Rating: Met

Feasibility	
eCQM feasibility testing/analysis conducted: N/A	No, not an eCQM
Feasibility: All data elements are in defined fields in electronic sources and align with United States Core Data for Interoperability (USCDI)/USCDI+ Quality standards, making the measure highly feasible. Claims data are widely available, standardized, and cost effective, as they are routinely collected for billing purposes. They also allow for large-scale and longitudinal analysis across diverse patient populations and care settings.	
Rating: Met	

Validity	
Validity testing method(s):	Face validity, Empiric validity [MUC Entry/Review Information Tool (MERIT) Submission Materials]
Testing level(s):	Facility
Was this measure tested in the same target population as the CMS program?	Yes
Validity: Both the patient/caregiver panel and the technical expert panel (TEP) believed that this measure has good face validity. All nine members who attended the final TEP meeting indicated that the measure could be used to differentiate between hospitals providing good-quality sepsis care and those providing poor-quality sepsis care. Both patients and caregivers provided feedback that this measure will help identify trends and evaluate the success of sepsis programs at different facilities. Empiric validity was tested by comparing hospital-level adult community-onset sepsis standardized mortality ratios (SMR) to hospital-level process measures that are typically thought to reflect best practices for sepsis care. Researchers calculated hospital-level process metrics for community-onset sepsis care using detailed, time-stamped data from two hospital networks. These metrics included timely blood culture collection, time to first IV antibiotic, initial lactate measurement within 6 hours, and repeat lactate testing when indicated. They then analyzed the correlation between these metrics and hospitals' SMRs, as well as SEP-1 compliance scores, to determine whether adherence to early care practices aligned with better sepsis outcomes. Most metrics showed weak or no significant correlation with SMRs, except for timely lactate measurement within 6 hours, which had a modest but statistically significant association (r= 0.174, p = 0.044). The results underscore the rationale for the proposed sepsis mortality measure that encourages hospitals to focus on the full breadth of sepsis care, from presentation through discharge, and to foster innovation in identifying additional process measures that meaningfully impact outcomes.	
Threats to validity: This measure utilizes a risk-adjustment model incorporating baseline characteristics (age, sex), comorbidities, and detailed clinical data (including vital signs, laboratory values, positive blood cultures and COVID-19 tests, body mass index, and infection source per	

Validity
ICD-10 codes). The model is appropriate to address threats to validity of this measure.
Rating: Met

Reliability	
Reliability testing method(s):	Signal-to-noise [MERIT Submission Materials]
Testing level:	Facility
Reliability discussion: The developer calculated signal-to-noise reliability across 433,065 persons from 265 facilities. The developer reported a median reliability of 0.921. When at least 70% of the entities have a reliability >0.6, a measure is considered capable of differentiating entities by quality of performance. During collaboration on this PA, the developer provided additional examination of reliability by deciles, as shown in Table 1. In the table, greater than 70% of entities have reliability above 0.6, which indicates acceptable reliability for this measure during testing.	
Additional reliability analyses: Battelle was not able to estimate how many entities had reliability above 0.6 during testing. The timeframe for reliability testing was not specified in submitted materials to assess alignment with annual reporting cycles.	
Rating: Met	

Reliability Tables

The developer provided information by decile for performance scores and calculated reliability for the 268 entities described in the testing submission. Table 1 shows signal-to-noise ratio by reliability decile. The measure developer created this table to provide reviewers with a standardized format to assess reliability.

Table 1. MUC2025-045 Mean Reliability (by Reliability Decile)

-	Overall	Min	Decile 1	Decile 2	Decile 3	Decile 4	Decile 5	Decile 6	Decile 7	Decile 8	Decile 9	Decile 10	Max
Reliability (SNR)	0.834	0.081	0.302	0.648	0.811	0.878	0.909	0.933	0.951	0.963	0.971	0.981	0.991
Number of Entities	268	-	27	27	27	27	27	27	27	27	26	26	-
Number of Persons /Encounters/Episodes	433,065	11	1,834	6,258	12,448	20,962	25,873	39,170	50,249	70,052	81,016	125,203	9,308

Usability	
Usability considered in application:	Yes, the submission materials briefly discuss the measure's usability within relevant programs.
Usability discussion: This measure, which combines in-hospital mortality and discharge to hospice among adults with community-onset sepsis, offers strong usability within Hospital IQR and Hospital VBP programs. Unlike 30-day mortality, which is often limited to Medicare and Medicaid populations, this measure can be applied to all patients regardless of insurance status, making it more inclusive and representative of hospital performance. Its outcomes are readily available and can be tracked in near real time, supporting timely quality improvement efforts and resource allocation. Additionally, the measure aligns with the developer's emphasis on consistent surveillance methods, helping hospitals interpret trends in sepsis outcomes more accurately. By capturing both mortality and discharge to hospice, it reflects critical aspects of patient care and end-of-life decision-making, making it a meaningful metric for VBP programs focused on improving care quality and efficiency.	
Rating: Met	

Appropriateness of Scale

Appropriateness of Scale	
Similar or related measures in program(s):	None specified
Measure balance, burden and value across target populations/measured entities: This measure offers strong value with minimal burden across hospitals and patient populations. It uses readily available data to assess sepsis outcomes for all patients, regardless of insurance status, making it broadly applicable and equitable. Its simplicity supports consistent implementation across facilities, while its relevance to mortality and end-of-life care provides meaningful insights for quality improvement and value-based purchasing programs. Regarding balance of this measure's performance, burden, and benefit across populations, the developer's literature review and analysis do not indicate a potential for differential benefit or harm to specific subgroups of participating entities or their patient populations **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: The developer briefly mentions long- and near-term impacts of the measure in a patient population; there may be need for further examination of near- and long-term impacts of this measure after implementation across provider and patient populations.

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 the Hospital IQR and Hospital VBP measure sets?