Public Comment Summary Report: Community-Onset Sepsis: 30-day Mortality

Project Title: Patient Safety Measure Development and Maintenance

Dates: The Call for Public Comment ran from **June 10, 2022** and closed on **July 8, 2022**.

Project Overview: The Centers for Medicare & Medicaid Services (CMS) has contracted with American Institutes for Research (AIR) (with subcontractor University of California, Davis) to develop, maintain, reevaluate, and implement patient safety measures for CMS' hospital-level quality reporting programs. The contract name is Patient Safety Measure Development and Maintenance. The contract number is 75FCMC18D0027. As part of its measure development process, the AIR-UC Davis Team requested interested parties to submit comments on the candidate measure that may be suitable for this project. The electronic clinical quality measure (eCQM), titled Community-Onset Sepsis: 30-day Mortality, is an outcome mortality measure that uses both claims and electronic health record (EHR) data to assess the proportion of inpatient hospitalizations for adult patients admitted with community-acquired sepsis who die within 30 days of presentation.

Information About the Comments Received: The measure developer solicited public comments by posting to the CMS Measure Management System (MMS) website, sending electronic communications to the MMS list-serv, eCQM Governance, MAT/Bonnie User Groups, and the HL7 CQI workgroup, electronic outreach to patient safety and other professional organizations, and through announcements to the Technical Expert Panel (TEP) and Technical Advisory Group (TAG). Respondents completed an online survey collecting both quantitative (5-point Likert scale questions ranging from agree to strongly disagree) and qualitative feedback (free-text boxes) on measure definitions, importance, implementation, unintended consequences, feasibility, risk-adjustment variables, required data elements, and clinical and eCQM workflows.

We received 19 responses on this topic.

Stakeholder Comments

General Stakeholder Comments:
This public comment period solicited feedback on the Community-Onset Sepsis: 30-day Mortality measure. No general comments were received. A summary of all the comments received is included below.

Measure-Specific Stakeholder Comments:
This section summarizes the public comments received for the Community-Onset Sepsis: 30-day Mortality measure and is categorized into the five major themes that emerged during the developer's review.

1. **Denominator**
    a. **Denominator inclusion criteria are appropriate.** 12 of 19 respondents agreed/strongly agreed that the denominator inclusion criteria are clear and

appropriate. Three respondents expressed concerns about the use of SIRS criteria and ICD-10-CM present-on-admission codes in the denominator and recommended exclusive use of the CDC's Adult Sepsis Event (ASE) definition. Two respondents suggested inclusion of additional variables (blood pressure changes, fluid resuscitation values, and lactate/repeat lactate) in the denominator. Three respondents expressed concerns that patients with certain acute conditions requiring emergency care may also meet SIRS criteria (e.g., trauma, burns, asthma attacks), which may introduce false-positive cases. One respondent suggested that the measure use different criteria for pregnant individuals. Three respondents suggested that the denominator population be expanded to include non-Medicare patient data.

b. **Denominator exclusion criteria are appropriate.** 10 of 19 respondents agreed that the denominator exclusion criteria are clear and appropriate. Two respondents expressed concerns regarding exclusion of patients with prior inpatient episodes for sepsis within a 30-day window. Three respondents suggested further refinements around the exclusions for transfers from outside emergency departments and patients currently on or transferred to hospice or comfort care. One respondent felt that the rationale for excluding influenza and COVID-19 was not clear.

2. Numerator

a. **Numerator inclusion criteria**. 11 of 19 respondents agreed that the numerator inclusion criteria are clear and appropriate.

b. **Attribution of Death to Sepsis.** Two respondents questioned how 30-day mortality could be accurately attributed to sepsis in a population that often has multiple comorbid conditions or pre-existing diseases.

c. **Evidence Supporting Numerator Design.** Two respondents questioned whether empirical data actually demonstrate a relationship between 30-day mortality and at least one process, intervention or service that could be attributed to an individual hospital.

3. Risk Adjustment

a. **Use of claims-based information for risk adjustment**. 12 of 19 respondents agreed with our recommendation to include claims-based demographic (age, sex), pre-existing comorbidity, and primary site/source of infection factors in risk-adjustment. One respondent suggested additional demographic variables and another suggested inclusion of social risk factors. One respondent also noted uncertainty around how site or source of infection can be reliably extracted from administrative data.

b. **Use of EHR-derived vital signs for risk adjustment.** 8 of 19 respondents agreed with using EHR-derived vital signs and treatment factors, supplemented by key SIRS-related or SOFA-related laboratory values in risk-adjustment. One respondent expressed concern about using SIRS criteria in the risk-adjustment model and questioned whether SIRS criteria have been shown to prognosticate mortality.

4. Feasibility

a. **Availability of data in structured fields.** 11 of 19 respondents agreed that required data elements are routinely captured as structured data rather than free text fields in the electronic health record used at their hospital. Three respondents noted that EHR-derived vital signs are often unreliable and may be lacking vital signs taken

outside of the inpatient setting (ED, ambulance). One respondent noted that site or source of infection may be difficult to capture, and another respondent observed that although many of the elements are available in structured data, the clinician notes also contain important information. One respondent also noted that reliance on EHR-derived structured data may lead to variability among hospitals because of differences in the structure, completeness, and interpretation of the data. Two respondents noted that the use of time-stamped data may be challenging for hospitals to implement, particularly those without sophisticated electronic health record (EHR) systems.

b. **DNR status.** 9 of 19 respondents indicated that DNR status at time of admission is captured in structured EHR data at their hospital. Two respondents noted that code status is not always accurate depending on the timeframe of interest.

c. **Mapping of home medications to RXNORM codes.** 8 of 19 respondents indicated that patient-reported home medications are mapped to RXNORM codes. The remaining respondents indicated uncertainty if home medications are mapped to RXNORM codes.

d. **Availability of the Medicare Beneficiary Identification (MBI).** 9 of 19 respondents indicated that the MBI is available in a structured field within the EHR used at their hospital. The remaining respondents indicated uncertainty as to whether the MBI is available in a structured field.

5. Implementation and Public Reporting

a. **Meaningful reporting.** 11 of 19 respondents agreed that the results of this measure can be easily interpreted and reported in a way that is useful and meaningful to various stakeholders. Two respondents noted that misalignment between this measure and other sepsis surveillance strategies (such as that used by the CDC or other chart-abstracted measures) may be a source of confusion for hospitals and other stakeholders. Another respondent noted the importance of addressing hospitals with very low denominators so that the results are not biased against hospitals taking care of large numbers of patients.

b. **Unintended consequences.** 9 of 19 respondents disagreed that the measure may result in unintended consequences.

Preliminary Recommendations

This section provides a summary of our analysis of the five major themes and final recommendations.

1. Denominator

a. Denominator Inclusion Criteria

i. **Align with ASE vs SIRS.** First, we do understand the need to harmonize with sepsis definitions and measures used by other federal agencies, such as the CDC ASE definition. However, existing CMS public reporting programs (i.e., Care Compare) are based on the sepsis and "severe sepsis" definitions used in the SEP-1 process bundle, which is the only NQF-endorsed measure in this space. Stakeholders have long experience with this measure and the definitions upon which it relies. The same definitions are used by the Veterans Health Administration, the Surviving Sepsis Campaign, and the current edition of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM), which is the official nosology maintained by the Centers for Disease

Control and Prevention on behalf of the Cooperating Parties. CMS must prioritize internal harmonization with existing quality improvement initiatives and specifications, but we will continue to follow developments in the field and adapt our measure specifications to remain consistent with evolving consensus. Second, the SIRS criteria are only one of three sets of criteria used to define sepsis in the proposed measure. The presence of the other two components - organ dysfunction and documentation of suspected infection (both of which are included in the CDC ASE measure) - will mitigate the risk of false-positives introduced by SIRS criteria. In fact, because the SIRS criteria are a necessary additional criterion (besides a diagnosis of infection and evidence of organ dysfunction), our definition is potentially more restrictive than the CDC ASE definition. Third, since we will be collecting SIRS criteria during testing, we will continue to evaluate alternative solutions and test the impact of removing the SIRS criteria from the denominator definition on the accuracy of the measure specification.

ii. **Use of ICD-10-CM POA.** We recognize the concerns around ICD-10-CM coding guidelines and variability as they pertain to sepsis. This component of the "suspected infection" criterion provides an alternative pathway to the diagnosis of sepsis that doesn't require 4-days of antibiotic treatment, as the CDC ASE measure requires. Our measure aligns with many other quality measures (e.g., pneumonia, stroke, heart failure) in that it is defined based on the presence of a condition, not based on how the condition was treated. Basing the definition on how the condition of interest was treated (e.g., antibiotic administration) risks missing some instances of the condition because the treatment provided could have been divergent from clinical norms (e.g., clinicians failed to administer antibiotics, provided an inappropriate antibiotic, or continued antibiotic therapy for less than 4 days). Furthermore, such instances may be particularly informative in characterizing and differentiating hospital performance. Other states with statewide sepsis initiatives such as New York and Michigan use ICD-10-CM diagnosis codes as at least one component of the denominator definition. During the testing phase, we will explore the marginal impact of including ICD-10-CM codes in the denominator criteria, and whether these codes introduce false-positives.

iii. **Inclusion of additional criteria.**
    1) **Blood Pressure.** There is no mechanism to identify a patient's "usual" blood pressure from the inpatient electronic health record. The EHR only reflects those blood pressure values that are taken within the inpatient encounter.
    2) **Fluid Resuscitation.** Although fluid resuscitation is captured in the CMS process measure SEP-1 bundle, this measure is designed as a risk-adjusted outcome measure, not a process measure.
    3) **Lactate.** We will collect lactate values as part of our testing process.

iv. **False Positive Cases.** We recognize that patients with certain acute conditions requiring emergency care (e.g., trauma, burns, asthma attacks) will meet SIRS criteria. However, SIRS is only one of three sets of criteria used to define the measure population. The presence of the other two components - organ

dysfunction and documentation of suspected infection (both of which are included in the CDC ASE measure) - will mitigate the risk of false-positives introduced by SIRS criteria. We will continue to evaluate alternative solutions during pilot testing. Additionally, we have given thought to how best to differentiate new organ dysfunction from chronic illness. For example, we plan to incorporate diagnosis code-based logic and thresholds for creatinine levels that account for the possibility of end-stage renal disease. We will explore additional options to improve the specificity of the organ dysfunction criteria as we pilot test the indicator.

v. **Pregnant Individuals.** Our intent is to exclude pregnant individuals from this measure, as maternal sepsis is covered by The Joint Commission measure ePC-07: Severe Obstetric Complications, which CMS has proposed adopting for CY 2024 reporting period/FY 2026 payment determination and for subsequent years. For more information, please refer to the FY 2023 IPPS/LTCH Proposed Rule: https://public-inspection.federalregister.gov/2022-08268.pdf

vi. **Expanding the patient population.** While we understand the importance to expand the patient population beyond Medicare beneficiaries, we currently do not have the mechanism to capture all the required measure data elements across all payors at this time.

b. Denominator Exclusion Criteria

i. **30-day Prior Hospitalizations.** The primary reason that the measure excludes patients with a recent hospitalization for sepsis is to avoid problems with (1) the non-independence of overlapping 30-day periods for the same patient and (2) the need to attribute outcomes for each episode of sepsis to one hospital. In other words, the measure is focused on community-acquired sepsis because, given the current constraints of electronic health records, it would be very difficult to uniformly and precisely identify the onset of sepsis that develops during hospitalization (and thus measure hospitals' performance in treating it) within the complex milieu of events that occur during hospitalization. In comparison, it is relatively easy to define incident cases of sepsis (and when hospitals have the opportunity to treat it) when the sepsis is the original reason for hospitalization.

ii. **Influenza and Covid-19.** The intent of this measure is to focus on incident cases of de novo sepsis, and not cases that represent sequelae of a viral infection or reflect the subsequent outcomes of that viral infection. However, CMS will continue to monitor emerging knowledge regarding COVID-19 and consider including COVID-19 patients with sepsis as treatment approaches become more standardized and evidence-based.

iii. **Transfers.**

1) **Prior Emergency Department (ED) Visit.** The scope of this measure concerns only inpatient hospitalizations, and we are limited to using claims data (rather than the electronic health record) to identify prior ED encounters. For ED encounters that develop into an inpatient hospitalization, all of the necessary information is available. However,

not all ED encounters lead to an inpatient encounter and, for those that do not, the claims data lack timestamps, so we are unable to ascertain critical timing details that are key to our definition of sepsis.

2) **Hospice.** Given that this measure uses Medicare enrollment data, we can ascertain whether patients were enrolled in hospice at the time of the index hospitalization. Because patients occasionally discontinue hospice care (opting for curative treatment), ascertainment of hospice enrollment must be based on the date of the index hospitalization.
3) **Comfort Care.** Unfortunately, there is no satisfactory way to distinguish patients whose preferences shift to maximizing comfort early in the course of illness from those who consider this possibility but ultimately opt to continue with curative treatment. In such cases, there is considerable hazard that the quality of care provided can influence patient/surrogate preferences regarding comfort care, and we specifically do not want to exclude patients because they have received suboptimal care. Furthermore, electronic health records currently do not capture sufficient information to determine whether and when the focus of care shifted purely to maximizing comfort. In the absence of unequivocal information that the focus of care was on maximizing comfort, such as concurrent hospice enrollment, we do not have a valid means to exclude patients who refuse specific treatments.

2. Numerator

a. **Evidence Supporting Numerator Design.** We are aware of the National Quality Forum (NQF) evidentiary requirements and will be conducting a thorough analysis during testing to provide empirical evidence with supportive literature as part of our submission to NQF.
b. **Attribution of Death to Sepsis.** CMS has empirically examined the temporal pattern of sepsis outcomes and the 30-day window provides a reasonable balance wherein the majority of 30-day deaths appear to be linked to the index hospitalization. In addition, there is ample evidence from other clinical contexts and other risk-adjusted mortality measures that it is necessary to standardize the duration of follow-up to minimize bias in comparisons across hospitals. Similarly, experience with other mortality measures has demonstrated that all-cause 30-day mortality is the preferred outcome. Quality measures that use mortality as the outcome of interest predominantly, if not exclusively, focus on all-cause mortality because ascertainment of causation may be imprecise and because there may be unknown pathways by which the care provided results in death. Furthermore, most patients and their family members, along with their health care providers, care about mortality independent of the cause, not just "sepsis-related" mortality. Just as randomized trials typically focus on all-cause rather than disease-specific mortality, we feel that the most valid outcome is mortality within 30 days from any cause. We agree that risk factors for death that are present at baseline should be identified separate from the occurrence of sepsis and should factor into risk adjustment for this measure. We plan to ascertain baseline characteristics from initial vital signs, lab values, and comorbidities (ICD-10-CM diagnosis codes indicated as "present on admission").

3. Risk Adjustment

a. **Consider additional variables (e.g., demographic data, social risk factors).** We will

evaluate commenter feedback about risk adjustment and additional variables during data collection and analysis. However, risk adjustment modeling will require a larger data set than what is feasibly attainable during pilot testing and may not be feasible until after initial implementation of the measure.

b. **Reliability of site/source of infection in EHR.** We will consider the challenges associated with the varying documentation systems, workflows, and reliability of documentation as we conduct measure testing.

c. **Validity testing.** We concur with the need for pilot testing of the validity of this measure and are actively engaging candidate participating hospitals for such testing. We acknowledge, however, that full validation of risk adjustment methods will likely need to wait until measure implementation because of the large sample size that is necessary.

4. **Feasibility**

a. **Structured fields.** The electronic data elements used in the measure (e.g., vital signs, lab test results) are a standard EHR requirement and are already captured in several eCQMs within CMS quality programs.

b. **Increased burden.** We agree this measure may necessitate EHR software changes, since all eCQMs require some level of effort to identify data sources, map value sets, and implement coding language. This measure does not divert from the standard of practice for eCQM implementation efforts. The burden is expected to be considerably less than that for measures that require human review of text information, such as clinician notes.

c. **Data validity.** We will evaluate these recommendations during data collection and analysis. However, risk adjustment modeling will require a larger data set than what is feasibly attainable during pilot testing and may not be feasible until after initial implementation of the measure.

d. **Vital Signs.** This measure is based on inpatient hospitalizations; therefore, only vital signs that are documented during the hospitalization are eligible to meet the measure criteria. While we agree that clinicians can collect and document vital signs in multiple places and ways, hospitals should consider these opportunities to improve hospital workflow and documentation practices to improve quality care. This ongoing improvement process is especially critical since these same data elements are used across other federal and state quality measures such as the New York State Department of Health (NYSDOH) sepsis measure. Efforts to collect these clinical findings from the EHR are synergistic and can enhance claims data to allow for a more robust measure.

e. **Chemotherapy.** As an eCQM, we have no mechanism to capture medications given in the ambulatory setting. We will collect blood test values, including white blood cell counts, and comorbid diagnoses (such as cancer) during pilot testing.

f. **DNR, Antibiotics, Source of Infection.** We will be collecting encoded data (e.g., RXNORM, ICD-10-CM, SNOMED-CT), clinical documentation, and clinical orders for these data elements during pilot testing for evaluation.

g. **MBI.** This data element is included in the Quality Reporting Data Architecture (QRDA) used for data submission and should be reported when an MBI number is available.

5. Implementation and Public Reporting

a. **Implementation.** We understand and respect the need to harmonize with sepsis definitions and measures used by other federal agencies, such as the CDC ASE definition.

Existing CMS public reporting programs (i.e., Care Compare) are based on the sepsis and "severe sepsis" definitions used in the SEP-1 process bundle, which is the only NQF-endorsed measure in this space. Stakeholders have long experience with this measure and the definitions upon which it relies. The same definitions are used by the Veterans Health Administration, the Surviving Sepsis Campaign, and the current edition of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM), which is the official nosology maintained by the Centers for Disease Control and Prevention on behalf of the Cooperating Parties. CMS must prioritize internal harmonization with existing quality improvement initiatives and specifications, but we will continue to follow developments in the field and adapt our measure specifications to remain consistent with evolving consensus.

b. **Reporting.** We will utilize standard approaches to handling hospitals with very low denominators, such as the use of minimum volume thresholds and smoothing of estimated hospital performance based on hospital volume. We and others have used similar approaches for other measures, such as the CMS Patient Safety and Adverse Events Composite (Patient Safety Indicator 90).

Overall Analysis of the Comments and Recommendations

The AIR-UC Davis Team highlights that sepsis is one of the most common conditions present in hospitalized patients and is the most expensive medical condition in hospitalized patients.[1,2,3] A measure of community-acquired sepsis mortality rate would enable hospitals to assess harm reduction efforts and modify their quality improvement efforts. The measure would also help to identify hospitals that have persistently high rates of community-acquired sepsis mortality. The proposed measure concept will ensure that these events are tracked and that hospitals are incentivized to reduce the incidence of community-acquired sepsis mortality. Adoption of this measure has the potential to improve the quality of care for patients, and, therefore, increase patient safety.

We acknowledge and thank commenters for their carefully considered feedback on key items such as the need to harmonize sepsis definitions, suggestions for additional or refined denominator inclusion criteria (blood pressure changes, fluid resuscitation values, and lactate/repeat lactate) and denominator exclusions (transfers from outside emergency departments and patients currently on or transferred to hospice or comfort care), expanding the patient population beyond Medicare beneficiaries, the importance of additional risk adjustment variables (demographic data, social risk factors), data element feasibility and implementation burden. During pilot testing and data analysis, we will consider commenter feedback and recommendations and determine where refinements may be appropriate.

[1] Rhee C, Dantes R, Epstein L, et al. Incidence and trends of sepsis in US hospitals using clinical vs claims data, 2009-2014. *JAMA - J Am Med Assoc*. 2017;318(13):1241-1249. doi:10.1001/jama.2017.13836

[2] Hajj J, Blaine N, Salavaci J, Jacoby D. The "Centrality of Sepsis": A Review on Incidence, Mortality, and Cost of Care. *Healthcare*. 2018;6(3):90. doi:10.3390/healthcare6030090

[3] Torio CM, Moore BJ. National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2013: Statistical Brief #204.; 2016.

Public Comment Verbatim Report

Date Posted/ Received	Name, Credentials, and Organization of Respondent	Type of Organization	Measure Set or Measure	Text of Comments	Response
7/8/2022	Angela Margaret Ingraham; Physician	Academic/ University	Denominator: False-positive cases	How are alternative explanations for organ dysfunction abnormalities defined and determined?	Thank you for your feedback about the denominator. We recognize that patients with certain acute conditions requiring emergency care (e.g., trauma, burns, asthma attacks) will meet SIRS criteria. However, SIRS is only one of three sets of criteria used to define the measure population. The presence of the other two components - organ dysfunction and documentation of suspected infection (both of which are included in the CDC ASE measure) - will mitigate the risk of false-positives introduced by SIRS criteria. We will continue to evaluate alternative solutions during pilot testing. We have given thought to how best to differentiate new organ dysfunction from chronic illness. For example, we plan to incorporate diagnosis code-based logic and thresholds for creatinine levels that account for the possibility of end-stage renal disease. We will explore additional options to improve the specificity of the organ dysfunction criteria as we pilot test the indicator.
7/8/2022	Angela Margaret Ingraham; Physician	Academic/ University	Denominator Exclusion: Transfers (ED/Hospice/Comfort Care)	Is there a way to capture patients who are admitted for sepsis but that are quickly transitioned to comfort care so that hospitals are not penalized for deaths when treatment of infection was not pursued?	We appreciate the commenter's suggestion. Unfortunately, there is no satisfactory way to distinguish patients whose preferences (or those of their surrogates) shift to maximizing comfort early in the course of illness from those who consider this possibility but ultimately opt to continue with curative treatment. In such cases, we believe there is considerable hazard that the quality of care provided can influence patient/surrogate preferences regarding comfort care, and we specifically do not want to exclude patients because they have received suboptimal care. Furthermore, electronic health records currently do not capture sufficient information to determine whether the focus of care shifted purely to maximizing comfort. Thus, unless there was unequivocal information that the focus was not on curative treatment, such as concurrent hospice status, we feel that we do not have a valid means to exclude patients on the basis of a shift to maximizing comfort.
7/8/2022	Angela Margaret Ingraham; Physician	Academic/ University	Data Elements: DNR	In our system, EPIC has a code status; however, it is not always accurate at time of admission.	We thank the commenter for their feedback on DNR status documentation. We will consider the validity and the feasibility of capturing this data element as we conduct measure testing.

Date Posted/ Received	Name, Credentials, and Organization of Respondent	Type of Organization	Measure Set or Measure	Text of Comments	Response
7/8/2022	Sepsis Task Force (IDSA, ACEP, PIDS, SIDP, SHEA, SHM)	Trade and Professional Association	Denominator: Use of ICD-10 POA codes	The undersigned medical societies would like to share concerns with the proposed denominator as well as concrete recommendations to help positively influence the development of this important measure. 2. Using present-on-admission ICD-10 codes for sepsis or bacterial infection to identify suspected infection adds unnecessary complexity, subjectivity, and variability to the measure. It is difficult to imagine ICD-10 codes will detect any meaningful cases of sepsis that will not be detected by the proposed culture and antibiotic criteria. Furthermore, prior studies have shown that: a. Diagnosis codes are unreliable for sepsis surveillance. This is because: i. Diagnosing sepsis is subjective and varies widely between clinicians and hospitals.4,5 ii. Coding practices for infection, organ dysfunction, and sepsis differ widely between clinicians and hospitals.6-8 b. Both diagnosis and coding practices for sepsis are changing over time and can be easily influenced by internal initiatives (such as quality improvement and awareness campaigns) and external pressures (such as changes in payment policies).9-14 c. Many of these above concerns are magnified for specific infections. This is especially the case for pneumonia (the most common cause of sepsis). The diagnosis is highly subjective, varies widely between clinicians, and coding practices are changing over time.15,16 d. Present-on-admission codes have variable accuracy and can be easily gamed by hospitals.17	Thank you for your comment. We recognize the concerns around ICD-10-CM coding guidelines and variability as they pertain to sepsis. This component of the "suspected infection" criterion provides an alternative pathway to the diagnosis of sepsis that doesn't require 4-days of antibiotic treatment, as the CDC ASE measure requires. Our measure aligns with many other quality measures in that it is defined based on the presence of a condition, not based on how the condition was treated. Basing the definition on how the condition of interest was treated (e.g., antibiotic administration) risks missing some instances of the condition because the treatment provided could have been extremely divergent from clinical norms (e.g., clinicians failed to administer antibiotics). Furthermore, such instances may be particularly informative in characterizing and differentiating hospital performance. Other states with statewide sepsis initiatives such as New York and Michigan use ICD-10-CM diagnosis codes as at least one component of the denominator definition. During the testing phase, we will explore the marginal impact of the denominator criteria based on ICD-10-CM codes and whether these codes introduce false-positives.

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7/8/2022	Sepsis Task Force (IDSA, ACEP, PIDS, SIDP, SHEA, SHM)	Trade and Professional Association	Data Elements: Structured Fields	The undersigned medical societies would like to share concerns with the proposed denominator as well as concrete recommendations to help positively influence the development of this important measure. 3. The complexity of the proposed measure will impose a substantial burden on hospitals and will likely lead to additional variability between hospitals because of differences in the structure, completeness, and interpretation of the data they will extract use to apply the measure. a. The proposed measure requires granular time-stamped data from multiple data streams, including vital signs, medications, laboratory data, and potentially respiratory flowsheets. This will be a challenge for all hospitals but especially hospitals without sophisticated electronic health record (EHR) systems to pull and analyze in a consistent fashion. i. Many of these data elements are represented in different ways in the same EHR (e.g., separate fields for temperature by axilla, mouth, rectum, bladder, etc.) allowing for differences in the ways hospitals will pull the data and unintended errors. ii. Likewise, respiratory rates can be present in separate fields depending on how they are measured (manual counts vs electronic monitors), and hospitals will vary on whether unstructured data are included (e.g., comments) and on how outlier values are handled (included, discarded, flagged). iii. The more data elements required, the greater the probability that different analysts at different hospitals will make different decisions on what to pull and how to clean and organize it for analysis. iv. This creates both a burden on hospitals and a risk for non-comparable data for CMS even if CMS supplies hospitals with standardized analytic code. b. The need to anchor clinical data elements to very specific time intervals relative to hospital presentation introduces further complexity and potential for error. This contrasts with CDC NHSN measures that are anchored to calendar days for greater simplicity. c. Successful coding and implementation will require substantial IT expertise and resources for auditing and validation.	Thank you for your comment. The electronic data elements used in the measure (e.g., vital signs, lab test result) are a standard EHR requirement and are captured in several eCQMs within CMS quality programs. Since this measure is focused on inpatient encounters inclusive of time spent in ED and Observations, we will be able to capture timestamps to evaluate variables within a 6-hour window.

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7/8/2022	Sepsis Task Force (IDSA, ACEP, PIDS, SIDP, SHEA, SHM)	Trade and Professional Association	Feasibility: Increased burden	The undersigned medical societies would like to share concerns with the proposed denominator as well as concrete recommendations to help positively influence the development of this important measure. 3. The complexity of the proposed measure will impose a substantial burden on hospitals and will likely lead to additional variability between hospitals because of differences in the structure, completeness, and interpretation of the data they will extract use to apply the measure. a. The proposed measure requires granular time-stamped data from multiple data streams, including vital signs, medications, laboratory data, and potentially respiratory flowsheets. This will be a challenge for all hospitals but especially hospitals without sophisticated electronic health record (EHR) systems to pull and analyze in a consistent fashion. i. Many of these data elements are represented in different ways in the same EHR (e.g., separate fields for temperature by axilla, mouth, rectum, bladder, etc.) allowing for differences in the ways hospitals will pull the data and unintended errors. ii. Likewise, respiratory rates can be present in separate fields depending on how they are measured (manual counts vs electronic monitors), and hospitals will vary on whether unstructured data are included (e.g., comments) and on how outlier values are handled (included, discarded, flagged). iii. The more data elements required, the greater the probability that different analysts at different hospitals will make different decisions on what to pull and how to clean and organize it for analysis. iv. This creates both a burden on hospitals and a risk for non-comparable data for CMS even if CMS supplies hospitals with standardized analytic code. b. The need to anchor clinical data elements to very specific time intervals relative to hospital presentation introduces further complexity and potential for error. This contrasts with CDC NHSN measures that are anchored to calendar days for greater simplicity. c. Successful coding and implementation will require substantial IT expertise and resources for auditing and validation.	We thank the commenters for feedback regarding the increased burden of implementing and reporting this measure. While we agree this measure may necessitate some changes to electronic health record software, it should also drive standardization efforts in how this information is captured, stored, and shared to improve patient safety. Once any needed EHR changes are implemented, the additional burden on hospital staff should be minimal, given that staff are already expected to quickly identify and treat sepsis patients. We will work with CMS to provide adequate guidance for reporting and interpretation of the measure results.

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7/8/2022	Sepsis Task Force (IDSA, ACEP, PIDS, SIDP, SHEA, SHM)	Trade and Professional Association	Implementation: Concerns about misalignment between federal agencies	The undersigned medical societies would like to share concerns with the proposed denominator as well as concrete recommendations to help positively influence the development of this important measure. 4. The proposed measure is misaligned with sepsis surveillance strategies adopted by other federal agencies a. CDC has invested considerable effort into developing and validating the Adult Sepsis Event (ASE) definition, a surveillance metric modeled on Sepsis-3 criteria that uses clinical indicators alone to define sepsis without diagnosis codes or SIRS criteria. The clinical indicators include markers of suspected infection (blood culture draws and antibiotic administrations) and organ dysfunction (increased respiratory support, initiation of vasopressors, increases in creatinine or bilirubin, or decreases in platelets). Using clinical indicators rather than diagnosis codes for surveillance helps minimize artefactual variation between hospitals due to differences in coding practices rather than differences in sepsis rates. Misalignment between federal agencies will be a source of confusion for hospitals and other stakeholders.	We thank the commenters for feedback about measure implementation and public reporting. We understand and respect the need to harmonize with sepsis definitions and measures used by other federal agencies, such as the CDC ASE definition. Existing CMS public reporting programs (i.e., Care Compare) are based on the sepsis definition used in the SEP-1 process bundle, which is the only NQF-endorsed measure in this space. CMS must first prioritize internal harmonization but will continue the evaluation and harmonization efforts with other agency definitions for future consideration.

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7/8/2022	Sepsis Task Force (IDSA, ACEP, PIDS, SIDP, SHEA, SHM)	Trade and Professional Association	Denominator: Align with ASE vs SIRS	The undersigned medical societies would like to share concerns with the proposed denominator as well as concrete recommendations to help positively influence the development of this important measure. Concerns: 1. Using SIRS criteria and diagnosis codes to identify sepsis is out-of-step with current international consensus definitions and national surveillance strategy being pursued by the U.S. Centers for Disease Control and Prevention (CDC). a. SIRS is very common in hospitalized patients, yet it is neither sensitive nor specific. b. SIRS is present in up to 50% of patients but less than one in five have an infection. c. Despite its ubiquity SIRS still misses 1 in 8 patients with sepsis. d. For these reasons, the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3) published in 2016 removed SIRS from the definition of sepsis.3 Continuing to focus on SIRS as a cornerstone of this sepsis measure puts CMS at odds with the consensus international definition, professional societies, and most of the medical community who have moved past SIRS. e. CDC has invested considerable effort into developing and validating the Adult Sepsis Event (ASE) definition, a surveillance metric modeled on Sepsis-3 criteria that uses clinical indicators alone to define sepsis without diagnosis codes or SIRS criteria. The clinical indicators include markers of suspected infection (blood culture draws and antibiotic administrations) and organ dysfunction (increased respiratory support, initiation of vasopressors, increases in creatinine or bilirubin, or decreases in platelets). Using clinical indicators rather than diagnosis codes for surveillance helps minimize artifactual variation between hospitals due to differences in coding practices rather than differences in sepsis rates. Misalignment between federal agencies will be a source of confusion for hospitals and other stakeholders. … The undersigned medical societies recommend collaborating with CDC and NHSN to use the Adult Sepsis Event (ASE) definition as the basis for the sepsis outcome measure. Our rationale is as follows: 1. CDC's ASE definition does not rely on ICD-10 codes and instead uses only clinical data routinely available in EHR systems to identify patients with presumed serious infections and concurrent organ dysfunction. Prior data have demonstrated the following strengths of ASE: a. Greater sensitivity and similar positive predictive value vs sepsis discharge diagnosis codes relative to detailed medical record reviews11,18 b. More stable performance over time	We thank the commenters for feedback about the denominator. First, we do understand the need to harmonize with sepsis definitions and measures used by other federal agencies, such as the CDC ASE definition. However, existing CMS public reporting programs (i.e., Care Compare) are based on the sepsis definition used in the SEP-1 process bundle, which is the only NQF-endorsed measure in this space. CMS must prioritize internal harmonization before it can harmonize with other agencies. Second, the SIRS criteria are only one of three sets of criteria used to define sepsis. The presence of the other two components - organ dysfunction and documentation of suspected infection (both of which are included in the CDC ASE measure) - will mitigate the risk of false-positives introduced by SIRS criteria. In fact, because the SIRS criteria are a necessary additional criterion (besides a diagnosis of infection and evidence of organ dysfunction), our definition is actually more restrictive than the CDC ASE definition. Third, since we will be collecting SIRS criteria for risk-adjustment purposes during testing, we will continue to evaluate alternative solutions and test the impact of removing the SIRS criteria from the denominator definition on the accuracy of the measure specification.

Date Posted/ Received	Name, Credentials, and Organization of Respondent	Type of Organization	Measure Set or Measure	Text of Comments	Response
(cont'd)	(cont'd)	(cont'd)	(cont'd)	compared to diagnosis codes18 c. Ability to accurately distinguish hospital-onset vs present-on-admission sepsis19 d. Ability to be applied to diverse EHR systems to generate comparable estimates of sepsis burden11 e. High prognostic significance among hospitalized patients. 2. The ASE definition is optimized for consistent application across diverse EHR systems. a. ASE has already been applied across diverse EHR systems and shown to generate consistent and reliable estimates of sepsis burden. 11 b. Building on ASE would leverage the considerable investment CDC has already made in developing and piloting an objective, automatable, electronic surveillance measure for sepsis. 3. Using ASE as the starting point for the CMS outcome measure would align the two major U.S. federal health agencies (CDC and CMS) in their approach to defining sepsis hospitalizations. In contrast, using a different definition risks sowing further confusion in the field. a. Collaborating with CDC would also allow CMS to leverage the NHSN infrastructure, as it has done with other healthcare associated infection (HAI) quality measures such as central line-associated bloodstream infection, catheter associated urinary tract infection, C. difficile, methicillin-resistant Staphylococcus aureus bacteremia, and selected surgical site infections. Suggested Path Forward: The ASE was designed as a tool to facilitate objective and consistent retrospective surveillance across diverse hospitals to better track sepsis rates and outcomes. While these properties make it ideal in many ways to serve as the basis for a quality outcome measure, we appreciate that modifications to the definition may be needed to optimize it for the purpose of an outcome measure. Furthermore, although ASE is simpler than the proposed CMS sepsis measure, we recognize there are important practical considerations regarding the complexity of coding for ASE and the associated reporting burden. We believe that these challenges can be addressed through close collaborations between CMS, AIR, UCD, CDC, and other stakeholders.	(cont'd)
7/8/2022	Denise Bartosz; Catholic Health System	Hospital	Reporting: Hospitals with low denominators	You will need to consider how to handle hospitals with very low denominators. This is often due to the fact that they are small facilities and transfer the sickest patients. This then results in very low mortality rates which skews the data in a unfavorable manner for hospitals taking care of large number of patients.	Thank you for your comment. We will utilize standard approaches to handling hospitals with very low denominators, such as the use of minimum volume thresholds and smoothing of estimated hospital performance based on hospital volume. We and others have used similar approaches for other measures, such as the CMS Patient Safety and Adverse Events Composite (Patient Safety Indicator 90).

Date Posted/ Received	Name, Credentials, and Organization of Respondent	Type of Organization	Measure Set or Measure	Text of Comments	Response
7/8/2022	Denise Bartosz; Catholic Health System	Hospital	Feasibility: Vital signs	At times there may be relevant clinical data that does not appear immediately in the EMR. Vital signs taken in route via ambulance. Issues related to the recent overcrowding in many of the ED's across the country. There would need to be significant study related to this data collection methodology.	Thank you for your comment. This measure only considers documentation that was done during the inpatient hospitalization and does not evaluate for documentation completed in the ambulance.
7/8/2022	Denise Bartosz; Catholic Health System	Hospital	Data Elements: Structured fields	I would say in general many of the elements are structured data but often the clear picture of the patient is really in clinician notes	Thank you for your comment. The electronic data elements used in the measure (e.g., vital signs, lab test result) are a standard EHR requirement and are captured in several eCQMs within CMS quality programs. Since this measure is focused on inpatient encounters inclusive of time spent in ED and Observations, we will be able to capture timestamps to evaluate variables within a 6-hour window.
7/7/2022	Wesley McFee/Nathan Littauer Hospital	Hospital	Denominator: Expand beyond Medicare patient population	Because of the clinical research implications of this data set, as well as the fact that Medicare patients may not be truly representative of the U.S. population, it is recommended to remove "Medicare beneficiaries" from the initial population statement. Instead, create an attribute to identify Medicare beneficiaries. Nothing precludes CMS from collecting this data, as it has done in the past by way of Press-Ganey's Quality Performer, and the value in doing so can be substantial.	Thank you for your comment. While we understand the importance to expand the patient population beyond Medicare beneficiaries, we currently do not have the mechanism to capture all the required measure data elements across all payors at this time.
7/7/2022	Wesley McFee/Nathan Littauer Hospital	Hospital	Denominator: Expand beyond Medicare patient population	Yes, although see note regarding removing Medicare from exclusion criteria. Hospitals gain from knowing mortality data from their patient population, not just their Medicare patients. The NYSDOH model for sepsis data attributes should be more of a model for CMS than it currently is.	Thank you for your comment. While we understand the importance to expand the patient population beyond Medicare beneficiaries, we currently do not have the mechanism to capture all the required measure data elements across all payors at this time.
7/7/2022	Wesley McFee/Nathan Littauer Hospital	Hospital	Denominator: Expand beyond Medicare patient population	Agree, albeit with the caveat that completely excluding non-Medicare patient data would not make this useful and meaningful to hospitals, who treat all persons, irrespective of their insurance card. This would be particularly true in small hospitals, whereby the n-size of Medicare only patients would be too small to have any value whatsoever.	Thank you for your comment. While we understand the importance to expand the patient population beyond Medicare beneficiaries, we currently do not have the mechanism to capture all the required measure data elements across all payors at this time.
7/7/2022	Wesley McFee/Nathan Littauer Hospital	Hospital	Feasibility: Vital signs	Mixed agreement: Capturing vital signs and other clinical findings is necessary and applauded for substantive data collection and analysis. In fact, I might suggest that data collection in this regard would benefit from being more robust, like the NYSDOH sepsis data model.	Thank you for your comment. We are aware of the NYSDOH sepsis initiative and agree that collecting vital signs and other clinical findings from the EHR are synergistic and can enhance claims data for a more robust measure.

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7/7/2022	Wesley McFee/Nathan Littauer Hospital	Hospital	Risk Adjustment: Adjusting for SIRS criteria	However, the method of risk-adjustment vis-à-vis findings is not clear. Using a mortality prognostication method like SOFA in risk adjustment is reasonable, of course. How to risk-adjust for a SIRS element, or SIRS criteria in aggregate, would require more information; SIRS criteria has not been shown to prognosticate mortality, yes?	We thank the commenters for feedback about risk adjustment and potential risk-adjustment variables. We will evaluate these recommendations during data collection and analysis. However, risk adjustment modeling will require a larger data set than what is feasibly attainable during pilot testing and may not be feasible until after initial implementation of the measure.
7/7/2022	American Medical Association	Trade and Professional Association	Risk Adjustment: Inclusion of social risk factors	The AMA also urges CMS to ensure that the measure is adequately risk adjusted both for clinical and social risk factors and that the measure as specified produces valid results. We note that this testing should not solely rely on a face validity assessment, rather CMS must also provide results on empiric validity at the measure score level. Demonstration of the validity of the underlying data elements across a wide set of electronic health record system vendors will also be critical to ensure that the data are accurately measuring the denominator specifications, particularly given the number and complexity of data elements that must be collected.	Thank you for your comment. We concur with the need for pilot testing of the validity of this measure and are actively engaging candidate participating hospitals for such testing. We acknowledge, however, that full validation of risk adjustment methods will likely need to wait until measure implementation because of the large sample size that is necessary.
7/7/2022	American Medical Association	Trade and Professional Association	Numerator: Evidence supporting numerator design	The AMA believes that attribution must be determined based on evidence that the accountable unit is able to meaningfully influence the outcome, which aligns with the National Quality Forum (NQF) report, Improving Attribution Models (NQF, 2018). This principle is also supported by the evidence requirements for outcome measures in CMS's Blueprint, which requires that there be at least one structure or process that can influence the outcome and this relationship must be demonstrated through empirical evidence. Specifically, CMS must demonstrate that facilities can meaningfully influence mortality beyond the inpatient stay. None of the evidence included in the public comment documents specifically addressed how a facility could reduce mortality rates beyond the inpatient stay and, as a result, we do not believe that CMS has adequately demonstrated this link for this measure.	Thank you for your comment. We are aware of the National Quality Forum (NQF) evidentiary requirements and will be conducting a thorough analysis during testing to provide empirical evidence with supportive literature as part of our submission to NQF.

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7/7/2022	American Medical Association	Trade and Professional Association	Feasibility: Data validity	The AMA also urges CMS to ensure that the measure is adequately risk adjusted both for clinical and social risk factors and that the measure as specified produces valid results. We note that this testing should not solely rely on a face validity assessment, rather CMS must also provide results on empiric validity at the measure score level. Demonstration of the validity of the underlying data elements across a wide set of electronic health record system vendors will also be critical to ensure that the data are accurately measuring the denominator specifications, particularly given the number and complexity of data elements that must be collected.	Thank you for your comment. We will evaluate these recommendations during data collection and analysis. However, risk adjustment modeling will require a larger data set than what is feasibly attainable during pilot testing and may not be feasible until after initial implementation of the measure.
7/7/2022	American Medical Association	Trade and Professional Association	Denominator: Align with ASE vs. SIRS	In addition, we urge CMS to simplify and align the denominator criteria with the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) Adult Sepsis Event criteria (CDC, 2018). These criteria are well validated without requiring additional diagnosis codes or systemic inflammatory response syndrome (SIRS) criteria. Facilities and other stakeholders already have experience collecting and using these criteria and it is less than optimal to have another federal agency set different requirements for the same clinical concept.	We thank the commenters for feedback about the denominator. First, we do understand the need to harmonize with sepsis definitions and measures used by other federal agencies, such as the CDC ASE definition. However, existing CMS public reporting programs (i.e., Care Compare) are based on the sepsis definition used in the SEP-1 process bundle, which is the only NQF-endorsed measure in this space. CMS must prioritize internal harmonization before it can harmonize with other agencies. Second, the SIRS criteria are only one of three sets of criteria used to define sepsis. The presence of the other two components - organ dysfunction and documentation of suspected infection (both of which are included in the CDC ASE measure) - will mitigate the risk of false-positives introduced by SIRS criteria. In fact, because the SIRS criteria are a necessary additional criterion (besides a diagnosis of infection and evidence of organ dysfunction), our definition is actually more restrictive than the CDC ASE definition. Third, since we will be collecting SIRS criteria for risk-adjustment purposes during testing, we will continue to evaluate alternative solutions and test the impact of removing the SIRS criteria from the denominator definition on the accuracy of the measure specification.
7/5/2022	Cerner Corporation	Electronic health record vendor	Feasibility: Structured fields	Agree, but there is no enough information in the shared document to determine feasibility of identification of the 'definition for severe sepsis' as it could be challenging to evaluate all the clinical data within the proper timeframe (within 6 hours of 'presentation')	Thank you for your comment. The electronic data elements used in the measure (e.g., vital signs, lab test result) are a standard EHR requirement and are captured in several eCQMs within CMS quality programs.

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7/5/2022	Cerner Corporation	Electronic health record vendor	Data Elements: Sepsis timeframes	Capturing the clinical data should be feasible for EHR systems as it is expected to be codified data. However, if the measure logic expects to consider some of the complicated timeframes required for Sepsis presentation identification (similar to Sepsis bundle - chart abstracted measure), the feedback would be different.	We thank the commenters for insights into the feasibility of capturing the necessary data to define severe sepsis within the proper timeframe and will consider these challenges as we conduct measure testing.
7/5/2022	Krista Kaups, MD, MS; CRMC Fresno	Academic/ University	Measure Title: Changing measure title to "community-onset severe sepsis"	Overall agree, however the measure is titled "community-onset sepsis" and description is of severe sepsis, and this should be reconciled since the primary outcome is death rate (and death rate varies considerably from sepsis to septic shock)	Thank you for your feedback regarding the use of the term "severe sepsis." Over time, the nomenclature for sepsis has evolved according to how experts in this field think about the defining features of sepsis. While the ICD-10-CM coding classification uses the term "severe sepsis," the newer ICD-11-CM classification (the parent classification that precedes development of the U.S. "Clinical Modification" derivation) and the Third International Consensus definition (Sepsis-3) both abandon the term "severe sepsis" and only differentiate between "sepsis" and "septic shock." The basis for this change was that experts considered sepsis, which is recognized to have a mortality rate of 10%, to be sufficiently severe that there was little utility in differentiating "sepsis" from "severe sepsis" (https://www.sccm.org/Research/Quality/Sepsis-Definitions). While we intend for this proposed measure to reflect the most current conceptualization of sepsis, we acknowledge that there are aspects of how the denominator (patients with sepsis) is defined that are rooted in the sepsis bundle process measure, "SEP-1," that incorporates the ICD-1-CM code for "severe sepsis." We carefully chose the definition we use in part because CMS currently maintains the SEP-1 bundle as a measure and thus it is desirable for there to be some consistency in how CMS' sepsis-related measures define the concept.
7/5/2022	Krista Kaups, MD, MS; CRMC Fresno	Academic/ University	Denominator: Blood pressure changes	For BP criteria, in addition to systolic BP less than 90 mmHg, consider adding: 'or BP decreased more than 40 mmHg from usual' to adequately account for patients who have baseline, untreated/ uncontrolled hypertension.	Thank you for your comment. There is no mechanism to identify a patient's "usual" blood pressure from the inpatient electronic health record. The EHR only reflects those blood pressure values that are taken within the inpatient encounter.
7/5/2022	Krista Kaups, MD, MS; CRMC Fresno	Academic/ University	Numerator: Attribution of death to sepsis	Although death is a clear criteria, the challenge will be identifying patients who die from conditions unrelated to the septic episode	Thank you for your comment. Quality measures that use mortality as the outcome of interest predominantly if not exclusively focus on all-cause mortality because ascertainment of causation may be imprecise and because there may be unknown pathways by which the care provided results in death. Furthermore, we presume that most patients and their loved ones care most about mortality independent of the cause, and not just "sepsis-related" mortality. Just as randomized trials typically focus on all-cause rather than disease-specific mortality, we feel that the most valid outcome is mortality within 30 days from any cause.

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7/5/2022	Krista Kaups, MD, MS; CRMC Fresno	Academic/ University	Numerator: Attribution of death to sepsis	The concern will be ensuring adequate identification and inclusion of pre-existing disease/co-morbidities to ensure that deaths from causes other than sepsis are excluded.	Thank you for your comment. As described above, we believe there is valid reason to use all-cause 30-day mortality as the outcome. As such, we do not believe it is desirable to exclude deaths from causes other than sepsis. We agree that identification of risk factors for death that are present at baseline (at the time of sepsis determination) and separate from the occurrence of sepsis is important and should factor into risk adjustment for this measure. We plan to ascertain baseline characteristics from initial vital signs, lab values, and comorbidities (ICD-10-CM diagnosis codes indicated as "present on admission").
7/1/2022	Carol Sheridan, RN, MSN; Montefiore Medical Center	Hospital	Denominator Exclusion: 30-day prior hospitalizations	On p. 10 if references excluding sepsis within 30 day window. I recommend you don't exclude this pt population, this data would be helpful to health systems providers to more aggressively refer pts to hospice. Many of these patients "frequent flyers" have 3+ comorbidities and frequently represent significant amount of both HAI's (CLABSI, CAUTI, C DIFF, and MRSA) as well as HAC's (HAPU's and falls w injuries). We need a new model of care for these pt's who utilizers of services/care with no improved outcomes.	Thank you for your comment. The approach to measure construction - requiring that each sepsis episode be uniquely attributed to a single hospital, thus requiring exclusion of subsequent episodes within a 30-day window from the index episode - aligns with the construction of other risk-adjusted 30-day mortality measures used in CMS public reporting programs.
7/1/2022	Carol Sheridan, RN, MSN; Montefiore Medical Center	Hospital	Data Elements: Chemotherapy	Although you list immunomodulatory drugs, (would capture organ tx pt's, Rheumatology and other Immune related disease. Please be sure this would also capture the administration of chemotherapy in the past 30 days. 80-90% of chemotherapy is given in the ambulatory setting, with pt. returning home or to SNF. The effective use of Growth Factors to prevent neutropenia remains a challenge in Oncology Practice, (despite national guidelines NCCN). As a result, it is not uncommon to see Oncology pt.'s referred to ED's for fever, other dx's ultimately septic. You have WBC count as one of the data points you're planning to collect.	Thank you for your comment. As an eCQM, we have no mechanism to capture medications given in the ambulatory setting. We will collect blood values, white blood cell count and comorbid diagnoses (such as cancer) during pilot testing.
6/30/2022	Press Ganey Associates	Performance Measurement System Vendor	Denominator: Pregnant individuals	The numbers of pregnant individuals with severe sepsis is low but would be very impactful to include in the population. Lab values and vital signs are different for the pregnant patient vs non-pregnant patient with severe sepsis.	Thank you for your comment. Our intent is to exclude pregnant individuals from this measure, as maternal sepsis is covered by The Joint Commission measure ePC-07: Maternal Complications or Severe Maternal Morbidity (SMM), which CMS has proposed adopting for CY 2024 reporting period/FY 2026 payment determination and for subsequent years. For more information, please refer to the FY 2023 IPPS/LTCH Proposed Rule: https://public-inspection.federalregister.gov/2022-08268.pdf

Date Posted/ Received	Name, Credentials, and Organization of Respondent	Type of Organization	Measure Set or Measure	Text of Comments	Response
6/30/2022	Press Ganey Associates	Performance Measurement System Vendor	Denominator Exclusion: Transfers (ED/Hospice/ Comfort Care)	Second, it would be helpful to expand the exclusion of "prior enrollment in hospice" to include a specific timeframe (i.e., excluded if enrolled in hospice in last two years, 6 months, etc.).	Thank you for your comment. Given that this measure uses Medicare enrollment data, we can ascertain whether they were enrolled in hospice during the index hospitalization. Because patients occasionally discontinue hospice care (opting for curative treatment), ascertainment of hospice status ideally should coincide with the index hospitalization. This approach is consistent with other risk-adjusted 30-day mortality measures used in CMS public reporting programs.
6/30/2022	Press Ganey Associates	Performance Measurement System Vendor	Denominator: Expand beyond Medicare patient population	It would be helpful to look at all payor sources.	Thank you for your comment. While we understand the importance to expand the patient population beyond Medicare beneficiaries, we currently do not have the mechanism to capture all the required measure data elements across all payors at this time.
6/30/2022	Press Ganey Associates	Performance Measurement System Vendor	Risk Adjustment: Inclusion of demographic data	Yes, these factors should be included. However, CMS should also include race, ethnicity, and other demographic data, such as gender identity and sexual orientation.	Thank you for your feedback on risk adjustment and potential risk-adjustment variables. We will evaluate these recommendations during data collection and analysis. However, risk adjustment modeling will require a larger data set than what is feasibly attainable during pilot testing and may not be feasible until after initial implementation of the measure.
6/30/2022	Press Ganey Associates	Performance Measurement System Vendor	Denominator: Pregnant individuals	Pregnant patients have different criteria for severe sepsis than non-pregnant patients, so that distinction should be addressed and made clearer within the measure specifications.	Thank you for your comment. Our intent is to exclude pregnant individuals from this measure, as maternal sepsis is covered by The Joint Commission measure ePC-07: Maternal Complications or Severe Maternal Morbidity (SMM), which CMS has proposed adopting for CY 2024 reporting period/FY 2026 payment determination and for subsequent years. For more information, please refer to the FY 2023 IPPS/LTCH Proposed Rule: https://public-inspection.federalregister.gov/2022-08268.pdf
6/30/2022	Press Ganey Associates	Performance Measurement System Vendor	Denominator: Inclusion of lactate/ repeat lactate values	Second, lactate/repeat lactate would also be helpful to measure as they are important in the diagnosis of severe sepsis / septic shock.	Thank you for your comment. We will collect lactate values as part of our testing process.
6/30/2022	Press Ganey Associates	Performance Measurement System Vendor	Denominator: Inclusion of fluid resuscitation values	Similarly, fluid resuscitation would also be helpful if EHRs have discreet fields to capture that.	Thank you for your comment. Although fluid resuscitation is captured in the CMS process measure SEP-1 bundle, this measure is designed as a risk-adjusted outcome measure, not a process measure.

Date Posted/ Received	Name, Credentials, and Organization of Respondent	Type of Organization	Measure Set or Measure	Text of Comments	Response
6/30/2022	Press Ganey Associates	Performance Measurement System Vendor	Implementation: Concerns about misalignment between sepsis definitions	Lastly, the differences in the chart-abstracted measure versus this measure may lead to confusion because of the differences in criteria for severe sepsis.	Thank you for your feedback regarding measure implementation and public reporting. We understand and respect the need to harmonize with sepsis definitions and measures used by other federal agencies, such as the CDC ASE definition. Existing CMS public reporting programs (i.e., Care Compare) are based on the sepsis definition used in the SEP-1 process bundle, which is the only NQF-endorsed measure in this space. CMS must first prioritize internal harmonization but will continue the evaluation and harmonization efforts with other agency definitions for future consideration.
6/30/2022	Brenda Carlson; Strong Memorial/URMC	Hospital	Numerator: Attribution of death to sepsis	There are often multiple comorbid conditions present in this population of Medicare patients. It would be difficult to determine if the presence of sepsis had the highest impact mortality.	Thank you for your comment regarding the numerator. Our team empirically examined the temporal pattern of sepsis outcomes, and the 30-day window provides a reasonable balance wherein the majority of 30-day outcomes appear to be linked to the index hospitalization. In addition, there is ample evidence from other clinical contexts and other risk-adjusted mortality measures that it is necessary to standardize the duration of follow-up to minimize bias in comparisons across hospitals. We will continue to evaluate alternative solutions during pilot testing.
6/26/2022	Christine S Cocanour; UC Davis Health	Academic/ University	Denominator: Patients with trauma or burns	Patients with trauma or burns will have a SIRS response and will not have an infection source. This will confound the data.	Thank you for your comment. We recognize that patients with certain acute conditions requiring emergency care (e.g., trauma, burns, asthma attacks) will meet SIRS criteria. However, SIRS is only one of three sets of criteria used to define the measure population. The presence of the other two components - organ dysfunction and documentation of suspected infection (both of which are included in the CDC ASE measure) - will mitigate the risk of false-positives introduced by SIRS criteria. We will continue to evaluate alternative solutions during pilot testing. We have given thought to how best to differentiate new organ dysfunction from chronic illness. For example, we plan to incorporate diagnosis code-based logic and thresholds for creatinine levels that account for the possibility of end-stage renal disease. We will explore additional options to improve the specificity of the organ dysfunction criteria as we pilot test the indicator.

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6/24/2022	Christopher P. Michetti	Hospital	Denominator Exclusion: 30-day prior hospitalizations	Inclusion of patients with ANY hospitalization within the prior 30 days, regardless of that hospitalization being related to sepsis or not, risks confounding of the community-acquired conditions with those acquired from the hospital stay. For example, a perforated gastric ulcer that is due to steroids started during a recent hospital stay is not a community-acquired disease.	Thank you for your feedback regarding the denominator exclusions. The primary reason that the measure excludes patients with a recent hospitalization for sepsis is to avoid problems with (1) the non-independence of overlapping 30-day periods for the same patient and (2) how to attribute outcomes for such overlapping periods to more than one hospital. In other words, we do not consider it particularly important for the denominator to purely distinguish sepsis acquired as a result of interaction with the delivery of health care from sepsis that occurs de novo. The reason the measure is focused on community-acquired sepsis is simply because, given the current constraints of electronic health records, it would be very difficult to uniformly and precisely identify the onset of sepsis that develops during hospitalization (and thus measure hospitals' performance in treating it) within the complex milieu of events that occur during hospitalization. In comparison, it is relatively easy to define incident cases of sepsis (and when hospitals have the opportunity to treat it) when the sepsis is the original reason for hospitalization.
6/24/2022	Christopher P. Michetti	Hospital	Denominator Exclusion: Transfers (ED/Hospice/ Comfort Care)	Also, it is unclear why transfers from another ED would be excluded, provided they presented recently and are directly transferred to the receiving hospital.	We thank the commenter for the feedback about the denominator exclusions. The scope of this measure concerns only inpatient hospitalizations, and we are limited to using claims data (rather than the electronic health record) to identify prior emergency department (ED) encounters. For ED encounters that develop into an inpatient hospitalization, all of the necessary information for this electronic clinical quality measure is available. However, not all ED encounters lead to an inpatient encounter and, for those that do not, the claims data lack timestamps, so we are unable to ascertain critical timing details that are key to our definition of sepsis.
6/24/2022	Christopher P. Michetti	Hospital	Feasibility: Vital signs	EHR-derived vital signs are known to be extremely unreliable, often record erroneous values, and should be avoided. Other factors may be recorded.	Thank you for your comment. While we agree that there can be multiple places clinicians can document vital signs, which may conflict, hospitals should consider these opportunities to improve hospital workflow and documentation practices to improve quality of care.
6/24/2022	Christopher P. Michetti	Hospital	Data Elements: DNR	If "at the time of admission" means existing prior to admission, this often has missing data. If it means, for example, a DNR order placed within 24 hours of admission, then it would be reliable.	Thank you for the feedback on DNR status documentation. We will consider the validity and the feasibility of capturing this data element as we conduct measure testing.
6/17/2022	Hallie Prescott; Michigan Medicine	Hospital	Denominator Exclusion: Influenza and COVID	Unclear why influenza and COVID are excluded.	Thank you for the feedback regarding the denominator exclusions. However, the intent of this measure is to focus on incident cases of de novo sepsis, and not cases that represent sequelae of a viral infection or reflect the subsequent outcomes of that viral infection.
6/17/2022	Hallie Prescott; Michigan Medicine	Hospital	Risk Adjustment: Feasibility	These are reasonable insufficient for risk-adjustment. Unclear how site/source of infection will be extracted from EHR/admin data in a reliable fashion.	We thank the commenters for feedback about risk adjustment and the feasibility of capturing the necessary data for site/source of infection and will consider the challenges associated with the varying documentation systems and workflows across hospitals as we conduct measure testing.

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6/17/2022	Hallie Prescott; Michigan Medicine	Hospital	Data Elements: Source of Infection	Site/source of infection may be tricky to capture. The other stuff should be okay.	Thank you for your comment. We will be collecting ICD10 coding and other clinical documentation during testing.
6/17/2022	Hallie Prescott; Michigan Medicine	Hospital	Data Elements: Antibiotics	Will need to make sure antibiotics are systemic (IV/enteral).	Thank you for your feedback. We will collect antibiotic information (including the route of administration) as part of our testing process.
6/13/2022	Joseph Galante, MD; UC Davis Health	Academic/ University	Denominator: False-positive cases	I am trying to determine how a patient with an asthma attack for example would not be included: elevated heart rate and respiratory rate, may have some collapse on CXR for which given antibiotics and eventually intubated.	Thank you for your feedback regarding the denominator. We recognize that patients with certain acute conditions requiring emergency care (e.g., trauma, burns, asthma attacks) will meet SIRS criteria. However, SIRS is only one of three sets of criteria used to define the measure population. The presence of the other two components - organ dysfunction and documentation of suspected infection (both of which are included in the CDC ASE measure) - will mitigate the risk of false-positives introduced by SIRS criteria. We will continue to evaluate alternative solutions during pilot testing. We have given thought to how best to differentiate new organ dysfunction from chronic illness. For example, we plan to incorporate diagnosis code-based logic and thresholds for creatinine levels that account for the possibility of end-stage renal disease. We will explore additional options to improve the specificity of the organ dysfunction criteria as we pilot test the indicator.
7/7/2022	Federation of American Hospitals	Trade and Professional Association	Numerator: Evidence supporting numerator design	FAH does not believe that the rationale and underlying research for this measure provides sufficient evidence that a death in the 30 days following an inpatient admission for a patient with sepsis is a predictor of the quality of care provided by a hospital and may well be due to other factors outside of a hospital's control. In fact, we were unable to identify any information in the materials provided that outlined the empirical data that demonstrates a relationship between 30-day mortality and at least one process, intervention or service that could be attributed to an individual hospital. The FAH asks that the Centers for Medicare & Medicaid Services (CMS) complete a comprehensive review of published literature and research to determine the appropriate timeframe during which a death related to a diagnosis of sepsis should be attributed to a hospital.	Thank you for your comment. We are aware of the National Quality Forum (NQF) evidentiary requirements and will be conducting a thorough analysis during testing to provide empirical evidence with supportive literature as part of our submission to NQF.

Date Posted/ Received	Name, Credentials, and Organization of Respondent	Type of Organization	Measure Set or Measure	Text of Comments	Response
7/7/2022	Federation of American Hospitals	Trade and Professional Association	Feasibility: Data validity	In addition, the FAH believes that testing in just a handful of facilities is not sufficient to provide information on the feasibility of data capture and reporting for this measure. FAH is concerned that the complexity of the measure with its risk adjustment approach may significantly impact a hospital's ability to successfully collect and report on this measure. Thorough assessments of each data element and the required calculations and logic must be vetted across multiple facilities and vendor systems to truly understand whether the measure is ready to be implemented in electronic health record systems (EHRs). If it is not determined to be feasible in the majority of vendor systems currently used, then it would be prudent for CMS to delay further testing and implementation of the measure until these gaps in EHRs' data capture and reporting can be addressed.	Thank you for your comment. We will evaluate these recommendations during data collection and analysis. However, risk adjustment modeling will require a larger data set than what is feasibly attainable during pilot testing and may not be feasible until after initial implementation of the measure.
7/7/2022	Federation of American Hospitals	Trade and Professional Association	Denominator: Align with ASE vs SIRS	We also encourage CMS to simplify and align the denominator criteria with the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) Adult Sepsis Event criteria (CDC, 2018). These criteria are well validated without requiring additional diagnosis codes or systemic inflammatory response syndrome (SIRS) criteria. Facilities and other stakeholders already have experience collecting and using these criteria and it would be preferable to avoid having different requirements for the same clinical concept.	Thank you for your feedback regarding the denominator. First, we do understand the need to harmonize with sepsis definitions and measures used by other federal agencies, such as the CDC ASE definition. However, existing CMS public reporting programs (i.e., Care Compare) are based on the sepsis definition used in the SEP-1 process bundle, which is the only NQF-endorsed measure in this space. CMS must prioritize internal harmonization before it can harmonize with other agencies. Second, the SIRS criteria are only one of three sets of criteria used to define sepsis. The presence of the other two components - organ dysfunction and documentation of suspected infection (both of which are included in the CDC ASE measure) - will mitigate the risk of false-positives introduced by SIRS criteria. In fact, because the SIRS criteria are a necessary additional criterion (besides a diagnosis of infection and evidence of organ dysfunction), our definition is actually more restrictive than the CDC ASE definition. Third, since we will be collecting SIRS criteria for risk-adjustment purposes during testing, we will continue to evaluate alternative solutions and test the impact of removing the SIRS criteria from the denominator definition on the accuracy of the measure specification.