Quality Payment
PROGRAM

Sepsis

Measure Testing Form

Summer 2020 Field Testing

Contents

1.0 Introduction

This Measure Testing Form provides results for the testing of the Sepsis measure that is being field tested between August 17 and September 18, 2020. Section 2 describes the scientific literature to support the measure as well as evidence of a performance gap among clinicians or clinician groups. Section 3 presents testing information and results for the measure.

The testing form accompanies the draft Measure Methodology document and draft Measure Codes List file posted on the MACRA Feedback Page,[1] which comprise the specifications for the Sepsis measure.

1.1 Field Testing

1.1.1 Overview

As a part of the measure development process, field testing is an opportunity for clinicians and other stakeholders to learn about episode-based cost measures and provide input on the draft measure specifications. During field testing, Field Test Reports are distributed on the Quality Payment Program website[2] for group practices (identified by Tax Identification Number [TIN]) and individual clinicians (identified by combination of TIN and National Provider Identifier [NPI]) who meet the minimum number of cases for each measure. A volume threshold of 10 episodes was used for procedural and acute inpatient medical condition episode groups (including Sepsis) and 20 episodes for chronic condition episode groups. Draft measure specifications and supplemental documentation are available on the MACRA Feedback Page.[3] Stakeholder feedback during field testing is collected on the draft specifications for each measure.

1.1.2 Providing Feedback

The feedback from field testing helps inform refinements to the measures before the Centers for Medicare & Medicaid Services (CMS) considers them for potential use in the Cost performance category of the Merit-based Incentive Payment System (MIPS). Acumen is collecting stakeholder feedback on the draft measure specifications of the 5 episode-based cost measures during the field testing period, between August 17 and September 18, 2020, through this online Field Testing Feedback Survey.[4]

Specific questions about the Sepsis measure specifications are available in the Questions for Field Testing Measure Specifications document,[5] which stakeholders can use as a reference while reviewing the field testing materials.

[1] CMS, MACRA Feedback Page, https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback.
[2] CMS, "QPP Account," Quality Payment Program, https://qpp.cms.gov/login.
[3] CMS, MACRA Feedback Page, https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback.
[4] The field testing online survey will be open beginning August 17, 2020 at this link: https://www.surveymonkey.com/r/2020-cost-measures-field-testing
[5] This document will be available on the MACRA Feedback Page once field testing begins. https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback.

2.0 Measure Testing: Importance

2.1 Evidence to Support the Measure Focus

2.1.1 Measure Description

The Sepsis cost measure evaluates clinicians' or clinician groups' risk-adjusted cost to Medicare for patients who receive inpatient medical treatment for sepsis. The measure score is a clinician's or clinician group's average risk-adjusted cost across all attributed episodes for the episode group. This acute inpatient medical condition measure includes services that are clinically related and under the reasonable influence of the attributed clinician or clinician group managing care during each episode, which extends from the date of admission which opens or "triggers" the episode to 45 days after the date of admission. Medicare beneficiaries enrolled in Medicare Parts A and B during the performance period are eligible for the measure.

2.1.2 Evidence for Measure Focus

A recent study indicates that clinician beliefs about treatment and the efficacy of particular therapies may be the most important factors explaining the variation in health care expenditures.[6] However, clinicians are often unaware of how their care decisions influence the overall costs of care. Cost measures are intended to help inform clinicians on the costs associated with their decision-making and to incentivize cost-effective, high-quality care. A cost measure offers opportunity for improvement if clinicians can exercise influence on the intensity or frequency of a significant share of costs during the episode, or if clinicians can achieve lower spending and better care quality through changes in clinical practice.

According to the literature and feedback received through stakeholder input activities to date, this measure's focus represents an area where there are opportunities for improvement. Primary opportunities for improvement are early recognition of the sepsis condition, prompt and appropriate administration of antibiotics and provision of resuscitation, and improved post-discharge care coordination. As discussed further throughout this section, these interventions may prevent progression of sepsis, thereby avoiding longer hospital stays, higher readmissions, and overall higher cost.

One opportunity to prevent more severe forms of sepsis (and related complications) is through improvement of early sepsis screening and recognition. The Surviving Sepsis Campaign's International Guidelines for Management of Sepsis and Septic Shock and other guidelines such as the sepsis 3-hour resuscitation bundle and the 6-hour septic shock bundle all stress the importance of early recognition for sepsis.[7,8] Various studies have found that delayed sepsis diagnosis and treatment has an adverse effect on sepsis outcomes, including progression to

[6] David Cutler et al., "Physician Beliefs and Patient Preferences: A New Look at Regional Variation in Health Care Spending," American Economic Journal: Economic Policy 11, no. 1 (February 1, 2019): 192–221, https://doi.org/10.1257/pol.20150421.
[7] A. Rhodes et al., "Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock: 2016," Crit Care Med 45, no. 3 (Mar 2017). https://doi.org/10.1097/CCM.0000000000002255.
[8] R. Kleinpell, L. Aitken, and C. A. Schorr, "Implications of the New International Sepsis Guidelines for Nursing Care," Am J Crit Care 22, no. 3 (May 2013). https://doi.org/10.4037/ajcc2013158.

severe sepsis and septic shock, which represents higher mortality and overall cost.[9,10,11] As an example, a 2020 study found that among all Medicare sepsis hospitalizations in 2018, the average total payment for septic shock cases was over $9,000 more than the average for sepsis hospitalizations.[12] The mean length of stay for septic shock is also substantially longer than for sepsis inpatient stays.[13] Early identification of sepsis may allow for earlier sepsis treatment, which may include fluid resuscitation, antimicrobial therapy, source control interventions, vasoactive medications, corticosteroids, blood products, and mechanical ventilation, when necessary.[14]

Along with early recognition of sepsis, adherence to treatment guidelines have been shown to be the primary means of improving sepsis outcomes. Several programs and emerging technologies focused on training clinical staff in early detection of sepsis and prompt administration of antibiotics have been associated with lower inpatient mortality rates and costs. For example, a 2015 study found that a sepsis intervention program yielded an over 8% reduction in the sepsis-associated mortality rate and a significant decrease in Medicare costs without a compensatory rise in post-acute care discharges.[15] These outcomes were attributed to the intervention program's design which included 4 components: (i) an intervention designed and refined by a multidisciplinary physician-chaired committee, (ii) a screening tool designed for integration with routine nursing care, (iii) data-driven revisions to screening and response protocols to target higher risk units and patients, and (iv) periodic education and training for all clinical staff on the epidemiology of sepsis along with the proper usage of the screening tool. Another 2016 study found that a sepsis intervention program yielded a lower mortality rate and a reduced length of stay for sepsis patients; its intervention program included parameters for emergent antibiotic therapy, intravenous antibiotics, antimicrobial treatment, source control, and periodic review of available information to appropriately modify the antibiotic treatment.[16]

In addition to staff training interventions, as technology progresses, there are improving software products and devices that can streamline patient monitoring, blood culture analysis,

[9] R. Ferrer et al., "Empiric Antibiotic Treatment Reduces Mortality in Severe Sepsis and Septic Shock from the First Hour: Results from a Guideline-Based Performance Improvement Program," Crit Care Med 42, no. 8 (Aug 2014). https://doi.org/10.1097/CCM.0000000000000330; M. R. Filbin et al., "Sepsis Visits and Antibiotic Utilization in U.S. Emergency Departments*," Crit Care Med 42, no. 3 (Mar 2014). https://doi.org/10.1097/CCM.0000000000000037; V. X. Liu et al., "The Timing of Early Antibiotics and Hospital Mortality in Sepsis," Am J Respir Crit Care Med 196, no. 7 (Oct 1 2017). https://doi.org/10.1164/rccm.201609-1848OC; B. B. Whiles, A. S. Deis, and S. Q. Simpson, "Increased Time to Initial Antimicrobial Administration Is Associated with Progression to Septic Shock in Severe Sepsis Patients," Crit Care Med 45, no. 4 (Apr 2017). https://doi.org/10.1097/CCM.0000000000002262; L. Pruinelli et al., "Delay within the 3-Hour Surviving Sepsis Campaign Guideline on Mortality for Patients with Severe Sepsis and Septic Shock," Crit Care Med 46, no. 4 (Apr 2018). https://doi.org/10.1097/CCM.0000000000002949.

[10] Whiles, Deis, and Simpson.

[11] G. S. Martin, "Sepsis, Severe Sepsis and Septic Shock: Changes in Incidence, Pathogens and Outcomes," Expert Rev Anti Infect Ther 10, no. 6 (Jun 2012). https://doi.org/10.1586/eri.12.50; AHRQ, "Hcup National Inpatient Sample (Nis): Healthcare Cost and Utilization Project (Hcup), 2013," (Rockville, MD).

[12] T. G. Buchman et al., "Sepsis among Medicare Beneficiaries: 1. The Burdens of Sepsis, 2012-2018," Crit Care Med 48, no. 3 (Mar 2020). https://doi.org/10.1097/CCM.0000000000004224.

[13] AHRQ, "Hcup National Inpatient Sample (Nis): Healthcare Cost and Utilization Project (Hcup), 2013."

[14] J. Hajj et al., "The "Centrality of Sepsis": A Review on Incidence, Mortality, and Cost of Care," Healthcare (Basel) 6, no. 3 (Jul 30 2018). https://doi.org/10.3390/healthcare6030090.

[15] S. L. Jones et al., "Reductions in Sepsis Mortality and Costs after Design and Implementation of a Nurse-Based Early Recognition and Response Program," Jt Comm J Qual Patient Saf 41, no. 11 (Nov 2015).

[16] S. B. Armen et al., "Improving Outcomes in Patients with Sepsis," Am J Med Qual 31, no. 1 (Jan-Feb 2016). https://doi.org/10.1177/1062860614551042.

alerts, and communication. In tandem with training-based interventions, technology solutions may improve the timeliness and subsequent outcomes of sepsis treatments.

Finally, as post-discharge mortality for sepsis hospitalizations has decreased in the past decade, there is an increasing number of patients surviving sepsis and, thus, an increased need for post-discharge care coordination. Patients surviving sepsis experience an increased risk for new or worsened functional and cognitive impairment as well as worsening of chronic health conditions, leading to increased risk of readmission.[17] A 2018 literature review on enhancing recovery from sepsis concluded that post-discharge management should focus on the following: (i) screening for common and treatable post-sepsis impairments (e.g., functional disability, swallowing impairment, mental health impairment) and referring to appropriate treatment, (ii) reviewing and adjusting long-term medication for appropriateness, and (iii) evaluating for treatable conditions that commonly result in readmission (e.g., infection, heart failure, and renal failure).[18]

2.2 Performance Gap

2.2.1 Rationale

Sepsis represents a significant share of hospitalizations and Medicare cost. A recent study indicated that from 2012 to 2018, the annual number of Medicare Parts A and B (fee-for-service) beneficiaries with a sepsis hospitalization (defined as having a sepsis diagnosis) rose from around 800,000 to over 1.1 million; annual total cost for these hospitalizations rose from $17.8 billion to over $22.4 billion.[19] Additionally, the total cost of skilled nursing facility care in the 90 days after the sepsis hospitalization discharge rose from $3.9 billion to over $5.6 billion over that same interval. An earlier study using a 2013 sample estimated that sepsis hospitalizations represented over 8% of Medicare costs.[20] Hospitalizations with sepsis have an average length of stay that is greater than other conditions, and it is longer for cases of septic shock.[21]

Sepsis hospitalizations also have a significant level of mortality. According to the Centers for Disease Control and Prevention, at least 1.7 million adults develop sepsis each year, and 1 in 3 patients who die in a hospital have sepsis (i.e., about 270,000 deaths annually).[22] A 2020 study found that the one-week, six-month, and one-year mortality rates for Medicare beneficiaries admitted for sepsis hospitalizations range from 7.2 – 40.6%, 26.5 – 60.1%, and 32.9 – 64.6%,

[17] H. Lee et al., "Detailed Cost Analysis of Care for Survivors of Severe Sepsis," Crit Care Med 32, no. 4 (Apr 2004). https://doi.org/10.1097/01.ccm.0000120053.98734.2c; T. J. Iwashyna et al., "Long-Term Cognitive Impairment and Functional Disability among Survivors of Severe Sepsis," JAMA 304, no. 16 (Oct 27 2010). https://doi.org/10.1001/jama.2010.1553; T. J. Iwashyna et al., "Population Burden of Long-Term Survivorship after Severe Sepsis in Older Americans," J Am Geriatr Soc 60, no. 6 (Jun 2012). https://doi.org/10.1111/j.1532-5415.2012.03989.x; S. Yende et al., "Risk of Cardiovascular Events in Survivors of Severe Sepsis," Am J Respir Crit Care Med 189, no. 9 (May 1 2014). https://doi.org/10.1164/rccm.201307-1321OC; H. C. Prescott and D. C. Angus, "Enhancing Recovery from Sepsis: A Review," JAMA 319, no. 1 (Jan 2 2018). https://doi.org/10.1001/jama.2017.17687.

[18] Prescott and Angus.

[19] T. G. Buchman et al., "Sepsis among Medicare Beneficiaries: 1. The Burdens of Sepsis, 2012-2018," Crit Care Med 48, no. 3 (Mar 2020). https://doi.org/10.1097/CCM.0000000000004224.

[20] AHRQ, "Hcup National Inpatient Sample (Nis): Healthcare Cost and Utilization Project (Hcup), 2013."

[21] C. J. Paoli et al., "Epidemiology and Costs of Sepsis in the United States-an Analysis Based on Timing of Diagnosis and Severity Level," Crit Care Med 46, no. 12 (Dec 2018). https://doi.org/10.1097/CCM.0000000000003342; M. J. Hall et al., "Inpatient Care for Septicemia or Sepsis: A Challenge for Patients and Hospitals," NCHS Data Brief, no. 62 (Jun 2011).

[22] "Data & Reports," 2016, accessed June 19, 2019, 2019, https://www.cdc.gov/sepsis/datareports/index.html.

respectively, based on severity.[23] Overall, hospital mortality rate is significantly higher for cases with septic shock.[24]

Given the high cost associated with providing care for sepsis and frequent use of post-acute care services following sepsis hospitalizations, sepsis cost measurement provides an opportunity for improvement on overall cost performance. According to the 2020 study of 2012-2018 Medicare sepsis hospitalizations, the average hospital cost in 2018 ranged from about $16,000 to over $29,000, based on severity, with significantly higher cost for cases where sepsis is not present on admission.[25] There are also substantial downstream costs associated with sepsis; for example, patients hospitalized for sepsis are more likely to be discharged to either a short-term care facility or long-term care institution compared to patients hospitalized for other conditions. The 2020 study also found that, within 6 months of discharge, patients hospitalized for sepsis relative to patients hospitalized for other conditions had: (i) 22.6% fewer discharges to the home, (ii) a more than two-fold increase in mortality, and (iii) a larger share of patients in skilled nursing facilities (or other nursing care), hospice care, or readmitted to an inpatient hospital.[26]

The Sepsis episode-based cost measure was recommended for development by an expert clinician committee—the Hospital Medicine Clinical Subcommittee. Based on the initial recommendations from the Clinical Subcommittee, the subsequent measure-specific Clinician Expert Workgroup provided extensive, detailed input on this measure.

2.2.2 Performance Scores

To demonstrate the performance gap captured in the measure, Table 1 below presents a distribution of performance scores for 6,490 clinician group practices and 51,298 practitioners attributed episodes in 2019. These counts represent attributed clinicians and clinician groups billing Part B Physician/Supplier claims under a MIPS eligible clinician specialty, and do not reflect other MIPS eligibility criteria (e.g., Advanced Alternative Payment Model participation). This table uses a testing volume threshold of 10 episodes.

Table 1. Distribution of Performance Scores

Metric	TIN	TIN-NPI
Mean score	$19,516	$22,682
Score Interquartile Range (IQR)	$2,764	$3,902
Score percentile		
10th	$16,685	$18,999
25th	$18,003	$20,577
50th	$19,253	$22,417
75th	$20,768	$24,479
90th	$22,686	$26,643

[23] Buchman et al.
[24] Paoli et al.
[25] Buchman et al.
[26] T. G. Buchman et al., "Sepsis among Medicare Beneficiaries: 2. The Trajectories of Sepsis, 2012-2018," Crit Care Med 48, no. 3 (Mar 2020). https://doi.org/10.1097/CCM.0000000000004226.

3.0 Scientific Acceptability

3.1 Data Sample Description

3.1.1 Type of Data Used for Testing

Medicare administrative claims, Long-Term Minimum Data Set (MDS), Medicare Enrollment Database (EDB), Common Medicare Environment (CME), and United States Census Bureau's American Community Survey (ACS).

3.1.2 Specific Dataset Used for Testing

The Sepsis measure uses Medicare Part A, Part B, and Part D claims data maintained by CMS. Part A, B, and D claims data are used to build episodes of care, calculate episode costs, and construct risk adjustors. To ensure that the measure accurately reflects Medicare costs, Part D branded drug costs were adjusted to account for drug rebates. More detailed information on the Part D payment standardization methodology and the Part D rebate adjustment methodology is available on the MACRA Feedback Page.[27]

Episode costs are payment standardized and risk adjusted to ensure accurate comparison of cost across clinicians. Payment standardization adjusts the allowed amount for a Medicare service to limit observed differences in costs to those that may result from health care delivery choices. Data from the EDB are used to determine beneficiary-level (or patient-level) exclusions and secondary risk adjustors, specifically Medicare Parts A, B, and C enrollment, primary payer, disability status, end-stage renal disease (ESRD), patient birth dates, and patient death dates. The risk adjustment model also accounts for expected differences in payment for services provided to patients in long-term care based on data from the MDS. Specifically, the MDS is used to create the long-term care indicator variable in risk adjustment.

For measure testing, data from the ACS and CME are used in analyses evaluating social risk factors in risk adjustment.

3.1.3 Dates of the Data Used in Testing

Sepsis episodes ending from January 1, 2019, through December 31, 2019.

3.1.4 Levels of Analysis Tested

Individual clinician (identified by combination of TIN and NPI) and clinician group/practice (identified by TIN).

3.1.5 Entities Included in the Testing and Analysis

The overall population used for testing includes 33,669 clinician group practices and 311,487 practitioners, which includes any clinician groups/practitioners who had at least one Sepsis episode in the measurement period. After applying exclusions and the case minimum, the final population for testing and analyses included 6,490 clinician group practices and 51,298 practitioners who were attributed 10 or more Sepsis episodes during the measurement period. Episodes from all 50 States and the District of Columbia triggered in the following setting(s) were included:

- Hospital inpatient acute care facility

[27] CMS, MACRA Feedback Page, https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback.

3.1.6 Patient Cohort Included in the Testing and Analysis

451,693 Medicare patients, with a mean age of 74.57, (from 518,677 episodes) were included in measure testing and analyses (where patient populations are not subject to any case minimum restrictions).

The patient population for the Sepsis measure calculation consists of Medicare beneficiaries enrolled in Medicare Parts A and B (but not Part C) who receive inpatient medical treatment for sepsis that triggers a Sepsis episode, as identified by trigger Medicare Severity Diagnosis-Related Group (MS-DRG) codes for sepsis on inpatient claims. For episodes triggered by non-sepsis MS-DRG codes (i.e., for other common sources of infection), an International Classification of Diseases, 10th Edition (ICD-10) diagnosis code indicating sepsis must accompany the MS-DRG trigger code on the trigger claim.

Patients and their episodes were excluded from the sample if they met a set of exclusion criteria (listed below) meant to ensure completeness of data and to focus the measure on a clinically homogeneous cohort of patients receiving inpatient medical treatment for sepsis.

The exclusion criteria are:

- The patient does not have Medicare as their primary payer for the entire episode window, as well as the 120 days prior to the trigger day (the 120-day lookback period).
- The patient was not continuously enrolled in Medicare Parts A and B, and not enrolled in Part C, for the entirety of the episode window and the 120-day lookback period.
- The patient does not have a sufficient 120-day lookback period.
- The patient date of birth is missing.
- The patient death date occurred before the episode's end.
- The episode trigger claim was not in an inpatient (IP) setting.
- The IP facility is not a short-term stay acute hospital as defined by subsection (d).[28]
- The episode is an outlier case.
- The episode has no attributed clinician or clinician group.
- The episode has an overlapping admission day with another inpatient stay.
- The patient has neutropenia.
- The patient is a transplant patient.
- The patient left against medical advice.
- The patient is on a clinical trial.
- The patient is on hospice or comfort care on admission.
- The patient received extracorporeal membrane oxygenation (ECMO) during the hospitalization.
- The episode does not have either a sepsis MS-DRG and/or a diagnosis of sepsis on the trigger inpatient claim.

To determine whether the Sepsis measure's exclusion criteria distort patient characteristics on episodes, we produced and analyzed distributions of patient characteristics (age, race, sex, dual eligibility status, income, unemployment, hierarchical condition categories [HCCs]) for (i)

[28] Only stays at IP facilities that are paid under a short-term stay acute hospital as defined by subsection (d) will be included. Subsection (d) hospitals are hospitals in the 50 states and D.C. other than: psychiatric hospitals, rehabilitation hospitals, hospitals whose inpatients are predominantly under 18 years old, hospitals whose average inpatient length of stay exceeds 25 days, and hospitals involved extensively in treatment for or research on cancer. For details on the identification of these hospitals, please refer to the CCN definitions for Short-term (General and Specialty) Hospitals facility types in Chapter 2, Section 2779A1 of the CMS State Operation Manual.

episodes with exclusion criteria, (ii) episodes without exclusion criteria, (iii) patients with exclusion criteria, and (iv) patients without exclusion criteria.

This analysis shows that the Sepsis measure's exclusion criteria have a minimal effect on the percentage of patients in any particular demographic category. The difference between patients being excluded and included in the measure is less than 6.82 percentage points across each of the characteristics in the analysis at TIN level testing, and less than 6.85 percentage points at TIN-NPI level testing. To illustrate, the percentage of patients aged 65 to 69 is 14.37% without applying the exclusion criteria, compared to 13.86% after applying the exclusion criteria at the TIN level. Furthermore, the difference in the percentage of patients across race categories with and without the exclusion criteria is less than 2 percentage points at both TIN and TIN-NPI level testing. When it comes to gender, there is a difference of 2.72 or less percentage points between the included and excluded populations with regards to the share of male and female patients (for both TIN and TIN-NPI level testing). These results indicate that there is minimal shift in patient characteristics as a result of using the exclusion criteria listed above at both TIN and TIN-NPI level testing.

3.1.7 Social Risk Factors Included in Analysis

The social risk factors analyzed were variables from the ACS, EDB, and CME. ACS variables are either at the Census Block Group or Zone Improvement Plan (ZIP) Code level. Social risk variables analyzed include the following:

- Race (EDB)
    - Asian, Black, Hispanic, North American Native, White, and Other
- Sex (EDB)
    - Female, male
- Dual status (CME)
    - Full dual, partial dual, non-dual to indicate whether a patient is dually enrolled in Medicare and Medicaid
- Income (ACS)
    - Low Income: median income < 33rd percentile nationally
    - Medium Income: median income in the interval spanning the 33rd percentile to the 66th percentile nationally
    - High Income: median income > 66th percentile
- Education (ACS)
    - Education < High School: when % with < high school education is the highest for a given Census Block Group
    - Education = High School: when % with only high school is the highest
    - Education > High School: when % with > high school is the highest
- Employment (ACS)
    - Unemployment Rate > 10%
    - Unemployment Rate <= 10%
- Agency for Healthcare Research and Quality (AHRQ) Socioeconomic Status (SES) Index (ACS)
    - Continuous variable (composite score of multiple community-level metrics, such as property values, density of living spaces, and poverty level) that can theoretically range from 0 to 100[29]

[29] Refer to Section 3, page 42 of this AHRQ publication for the scoring algorithm used to calculate the AHRQ SES index variable.

3.2 Validity Testing

3.2.1 Level of Validity Testing

Our performance measure score validity testing included systematic assessment of both face validity and empirical validity testing.

3.2.2 Method of Validity Testing

Face Validity

The Sepsis measure was developed through a structured, iterative process for gathering detailed input from recognized clinician experts on the measure. Experts in this clinical area evaluated specifications to ensure that each aspect of the measure (e.g., assigned services) was intentionally capturing only the costs of care within the reasonable influence of the attributed clinician for a defined patient population (i.e., the ability of the measure score to differentiate good from poor performance).

In developing this measure, Acumen incorporated input from:

(i) a Hospital Medicine Clinical Subcommittee;
(ii) a Sepsis Clinician Expert Workgroup;
(iii) a Technical Expert Panel (TEP); and
(iv) the Person and Family Committee (PFC).

This process is detailed in the Episode-Based Cost Measures Development Process document posted on the MACRA Feedback Page.[30]

One of the key roles of the measure-specific Clinician Expert Workgroup was to develop service assignment rules for the cost measure. These service assignment rules are intended to ensure clinicians are evaluated on services and costs that are clinically related to the attributed clinician's role in the inpatient treatment for sepsis, thus limiting cost variation unrelated to clinician care for this measure. Assigned services occurring in durable medical equipment, emergency department, home health, inpatient medical, inpatient surgical, inpatient rehabilitation facility, and outpatient facility and clinician service settings were defined for the 45-day post-trigger (post-admission) window, and include initial sepsis admission, sepsis readmission, evaluation, testing, treatment, Part D prescription drugs, complications, and follow-up.

Empirical Validity Testing

We undertook two approaches to estimate the measure's validity. In the first approach, we evaluated the empirical validity of the Sepsis measure by examining correlation with known indicators of resource or service utilization based on a literature review, specifically complications related to the inpatient treatment of sepsis. For this analysis, we compared the ratio of observed over expected spending at the provider level for Sepsis episodes with and without complications occurring in the post-trigger period. This analysis sought to confirm the expectation that the Sepsis measure captures variation in service utilization. We expect episodes with downstream acute readmissions or post-acute care would have higher observed to expected (O/E) cost ratios since complications like these should yield higher cost, even after accounting for patient clinical characteristics via risk adjustment.

In the second approach, we evaluated how different types of cost impact measure scores. To define types of cost, services or costs included in the Sepsis measure were classified into

[30] CMS, "2020 Episode-Based Cost Measure Field Testing Wave 3 Measure Development Process," MACRA Feedback Page, https://www.cms.gov/files/document/macra-cmft-ebcm-process-2020.pdf.

clinically coherent groups of services, called “clinical themes.” The Sepsis measure clinical themes are:

- **Initial Sepsis Admission:** The inpatient admission that triggered the episode, including all Part B physician/supplier and durable medical equipment services occurring during the hospitalization.
- **Recurrent Sepsis:** Any readmission, observation visit, or emergency room admission for recurrent sepsis.
- **Home Health, Physical Therapy, Occupational Therapy, and Speech Language Pathology:** Use of rehabilitation (including physical therapy, occupational therapy, and speech language pathology) or home health services following the triggering inpatient admission for sepsis.
- **Other Post-Acute Care:** Use of skilled nursing, inpatient rehabilitation facilities, or long-term care hospitals for care following a triggering inpatient admission for sepsis.
- **Recurrent Respiratory Infection, Complication, or Subsequent Care:** Readmission, observation visits, or emergency room admission for non-sepsis respiratory infections or subsequent outpatient care and care for respiratory infection complications.
- **Recurrent Non-Hepatobiliary Gastrointestinal Infection, Complication, or Subsequent Care:** Readmission, observation visits, or emergency room admission for non-sepsis, non-hepatobiliary gastrointestinal (GI) infections or subsequent outpatient care and care for non-hepatobiliary GI infection complications.
- **Recurrent Skin and Soft Tissue Infection, Complication, or Subsequent Care:** Readmission, observation visits, or emergency room admission for non-sepsis skin and soft tissue infections or subsequent outpatient care and care for skin and soft tissue infection complications.
- **Recurrent Kidney and Urinary Tract Infection, Complication, or Subsequent Care:** Readmission, observation visits, or emergency room admission for non-sepsis kidney and urinary tract infections or subsequent outpatient care and care for kidney and urinary tract infection complications.
- **Cardiac and Central Nervous System Complications (including arrhythmia, syncope, and encephalopathy):** Care for cardiac or central nervous system (CNS) complications (inpatient and outpatient) arising from sepsis, including arrhythmia, syncope, and encephalopathy. This does not include stroke or myocardial infarction.
- **Acute Renal Failure and Medication Complications:** Care for renal failure and various medication complications (inpatient and outpatient) arising from sepsis.
- **Outpatient Follow-Up and Lab Work:** Outpatient care for sepsis following initial admission, including relevant lab work such as chemistry panels, liver function tests, and monitoring of antibiotic levels and complications.
- **Part B Antibiotics and Infusion Supplies:** Outpatient intravenous antibiotics billed under Part B Physician/Supplier claims and necessary infusion supplies. This does not include home health, visiting nurse costs, oral antibiotics, or antibiotics received at a post-acute care facility.
- **Follow-Up Imaging:** All follow-up imaging related to the initial sepsis admission including x-rays, computed tomography (CT) scans, and magnetic resonance imaging (MRIs).
- **Part D Intravenous Antibiotics:** Outpatient intravenous (IV) antibiotics for the treatment of sepsis billed through Part D.
- **Part D Oral Antibiotics:** Outpatient oral antibiotics for the treatment of sepsis billed through Part D.

As with the first analysis for validity, the aim of this analysis was to determine whether the measure is capturing variation in clinician or clinician group cost in the manner intended and expected. To measure this, we calculated the Pearson correlation between the cost of each clinical theme and the overall risk-adjusted cost for an episode.

We expected that clinical themes related to complications (e.g., recurrent sepsis; all of the source of infection-based complication clinical themes) would have the highest correlations with risk-adjusted episode cost, as they ought to be associated with high cost even after accounting for patient clinical characteristics. We would also expected the clinical themes related to the types of services that are more preventative (e.g., outpatient follow-up and lab work; follow-up imaging) to have weaker correlations with risk-adjusted episode cost, as these should yield lower cost and/or a smaller impact on episode costs after accounting for patient characteristics.

3.2.3 Statistical Results from Validity Testing

Table 2 below presents the results from the first analysis of validity. The mean O/E cost ratio for all episodes is 0.99. The mean O/E cost ratio for episodes with downstream acute readmission during the post-trigger period is 1.47, compared with 0.91 for episodes without downstream acute readmission during the post-trigger period. The mean O/E cost ratio for episodes with post-acute care during the post-trigger period is 1.25, compared with 0.77 for episodes without post-acute care during the post-trigger period. Additionally, there is greater variation in the O/E cost ratio among episodes with downstream acute readmission and post-acute care.

Table 2: Distribution of Observed to Expected Ratios

Episode Type	Observed / Expected Ratio										
	Mean	Std. Dev.	Percentile								
			1st	5th	10th	25th	50th	75th	90th	95th	99th
All Final Episodes	0.99	0.50	0.40	0.51	0.57	0.66	0.79	1.21	1.69	2.00	2.74
Episodes with Downstream Acute Readmission	1.47	0.54	0.68	0.83	0.92	1.09	1.34	1.71	2.20	2.53	3.28
Episodes without Downstream Acute Readmission	0.91	0.45	0.40	0.50	0.55	0.64	0.75	1.01	1.55	1.85	2.54
Episodes with Post-Acute Care (IRF LTCH HH SN)	1.25	0.54	0.49	0.61	0.69	0.83	1.13	1.55	1.97	2.27	2.95
Episodes without Post-Acute Care (IRF LTCH HH SN)	0.77	0.32	0.38	0.48	0.53	0.61	0.69	0.79	1.09	1.38	2.18

Table 3 below presents a subset of results from the clinical themes analysis. These results demonstrate that there is a greater correlation between the recurrent sepsis (correlation: 0.59), recurrent respiratory infection, complication, or subsequent care (correlation: 0.51), recurrent non-hepatobiliary gastrointestinal infection, complication, or subsequent care (correlation: 0.46), recurrent kidney and urinary tract infection, complication, or subsequent care (correlation: 0.40), recurrent skin and soft tissue infection, complication, or subsequent care (correlation: 0.33), and other post-acute care (correlation: 0.58) themes and risk-adjusted cost. By contrast, the outpatient follow-up and lab work (correlation: 0.02) and follow-up imaging (correlation: 0.15) themes had lower correlation with risk-adjusted cost.

Table 3: Clinical Themes

Clinical Theme	Pearson Correlation With Risk-Adjusted Cost
Initial Sepsis Admission	0.17
Recurrent Sepsis	0.59
Home Health, Physical Therapy, Occupational Therapy, and Speech Language Pathology	-0.07
Other Post-Acute Care	0.58
Recurrent Respiratory Infection, Complication, or Subsequent Care	0.51
Recurrent Non-Hepatobiliary Gastrointestinal Infection, Complication, or Subsequent Care	0.46
Recurrent Skin and Soft Tissue Infection, Complication, or Subsequent Care	0.33
Recurrent Kidney and Urinary Tract Infection, Complication, or Subsequent Care	0.40
Outpatient Follow-Up and Lab Work	0.02
Part B Antibiotics and Infusion Supplies	0.15
Follow-Up Imaging	0.15

3.2.4 Interpretation

As expected, the average O/E cost ratio for episodes with post-trigger complications (i.e., downstream acute readmissions and post-acute care) is higher than for episodes without downstream complications. This result demonstrates that the Sepsis measure is able to accurately capture higher resource use, and suggests that episodes with complications (the frequency or severity of which could be reasonably expected to be influenced by the treatment of the attributed clinician or clinician group) will yield higher costs, even after risk adjustment.

The clinical themes analysis demonstrates that high risk-adjusted cost is more strongly associated with recurrent sepsis, each of the source of infection-based clinical themes, and post-acute care. These results indicate that utilization of preventative services (i.e., services intended to prevent complications after the initial hospitalization) is not playing a strong role in driving up episode costs, even after accounting for patient clinical risk factors. This suggests that the measure may disincentivize higher rates of costlier complications, while not disincentivizing the provision of appropriate preventative types of care, such as follow-up imaging and outpatient follow-up and lab work. Importantly, we see that correlation with risk-adjusted cost is moderate not only for high-cost themes such as the initial sepsis admission (average cost: $12,381), but also for lower cost themes such as Part B antibiotics and infusion supplies (conditional average cost:[31] $687). This indicates that the correlation does not come from a mechanical increase in episode costs from high-cost themes.

3.3 Exclusions Analysis

3.3.1 Method of Testing Exclusions

Exclusions are used in the Sepsis measure to ensure a comparable patient population within the scope of the measure's focus on the inpatient treatment of sepsis and that episodes provide meaningful information to attributed clinicians. Exclusions are also used as part of data

[31] Conditional average cost is the average observed cost of episodes only among episodes that do have at least one service for a given clinical theme.

processing so that sufficient data are available to accurately determine episode spending and calculate risk adjustment for each episode. For the exclusions analysis discussed in this section, we focused on exclusions added to ensure a homogenous patient population. These exclusions, along with their rationales, are listed below:

- Episodes where patient death date occurred before the episode end date.
    - These episodes were excluded as they may not accurately reflect a clinician's performance. Episodes where the patient died may be unusually high-cost, due to perimortem treatment costs, or unusually low-cost, due to the truncated episode window. Neither of these cases accurately reflects the efficiency of the clinician performing the treatment.
- Episodes without a sepsis hospitalization or a hospitalization for other sources of infection with a sepsis diagnosis.
    - These episodes were excluded since they indicate that the patient does not present to an acute inpatient setting with evidence of sepsis, which is the intended scope of this measure.
- Episodes where the patient has neutropenia.
    - These patients are immunocompromised, likely undergoing treatment for their neutropenic state, and are at greater risk for a larger range of infections. The variance in costs for this high-risk patient cohort is expected to be higher and would likely not be adequately accounted for by risk adjustment.
- Episodes where the patient has had a transplant.
    - These patients have constant immunosuppression due to a transplanted organ, and they are at greater risk for uncommon infections. The variance in costs for this high-risk patient cohort is also expected to be higher and would likely not be adequately accounted for by risk adjustment.
- Episodes where the patient elects to leave against medical advice.
    - Leaving against medical advice prevents the attributed clinician from completing appropriate care for the patient, which leaves the patient at high risk of further complications. Retaining such patients would put the attributed clinician at risk of being attributed a costly episode in which they did not have the chance to fully treat the patient.
- Episodes where the patient is on a clinical trial.
    - These episodes were excluded for measure alignment and harmonization with the Severe Sepsis and Septic Shock: Management Bundle.
- Episodes where the patient has hospice or comfort care on admission.
    - These patients are more ill and clinically complex with a different set of expectations for care trajectory/ sequelae relative to the overall patient cohort. These episodes were excluded for measure alignment and harmonization with the Severe Sepsis and Septic Shock: Management Bundle.
- Episodes where the patient received ECMO during the hospitalization.
    - These patients are more ill with higher costs and rates of complications. The variance in costs for this high-risk patient cohort is expected to be higher and would likely not be adequately accounted for by risk adjustment.
- Episodes classified as outlier cases.
    - To account for limitations of risk adjustment, episodes predicted to have expected costs that are substantially different from observed costs are excluded as outliers. Specifically, episodes with residuals from the risk adjustment model below the 1st percentile and above the 99th percentile are considered outliers and removed from measure calculation.

Given the rationales for these exclusions, we would expect these excluded episodes to have a different risk profile than the included episodes, such as a higher mean cost, or a different distribution of costs (e.g., a long tail of high-cost episodes). For the exclusions, we examined the number of episodes and patients affected, as well as the distributions of observed cost and ratio of observed over expected spending (calculated by applying existing risk factor coefficients to the excluded episodes) for excluded episodes. We then compared the cost characteristics of the excluded episodes to those of final episodes included in measure calculation to assess the distinctness between the two patient cohorts. A full list of the exclusions used for the Sepsis measure is provided in the draft Measure Codes List.[32]

3.3.2 Statistical Results from Testing Exclusions

Table 4 below presents observed cost statistics and O/E cost ratios for the Sepsis measure exclusions. Cost statistics are also provided for the set of final episodes included in the Sepsis measure for comparison, with a testing volume threshold of 10 episodes at the TIN and TIN-NPI levels. For the standard exclusions in the table below (i.e., not an inpatient prospective payment system, or IPPS, acute hospital or psychiatric facility, no attributed clinician group, overlapping inpatient admission days), these patient cohorts are excluded from the measure in order to assess episodes in the intended setting and by the measure's intended attribution approach.

Table 4: Cost Statistics for Measure Exclusions

Exclusion	Episodes		Observed Cost			O/E Cost Ratio		
			Mean	Percentile		Mean	Percentile	
	#	%		10th	90th		10th	90th
All Episodes Meeting Triggering Logic	762,434	100.00%	$20,889	$8,160	$38,874	0.97	0.51	1.68
Episodes not triggered in an IPPS acute hospital or psychiatric facility	33,601	4.41%	$33,650	$8,313	$81,023	1.34	0.53	2.45
Episodes with no attributed clinician group	45,020	5.90%	$32,193	$13,075	$62,255	1.12	0.52	2.01
Episodes with an overlapping inpatient admission day	3,481	0.46%	$26,649	$7,545	$50,030	1.25	0.43	2.30
Episodes where patient death date occurred before the episode end date	174,293	22.86%	$21,032	$10,211	$42,748	0.78	0.43	1.33
Episodes where the patient has neutropenia	31,786	4.17%	$22,656	$9,970	$42,932	1.01	0.53	1.73
Episodes where the patient had a transplant	19,173	2.51%	$22,185	$8,066	$42,187	1.04	0.54	1.78
Episodes where the patient elects to leave against medical advice	4,993	0.65%	$17,293	$7,348	$30,427	0.94	0.56	1.52
Episodes where the patient is on a clinical trial	5,525	0.72%	$21,344	$8,365	$39,657	0.98	0.50	1.68

[32] CMS, MACRA Feedback Page, https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback.

Exclusion	Episodes		Observed Cost			O/E Cost Ratio		
			Mean	Percentile		Mean	Percentile	
	#	%		10th	90th		10th	90th
Episodes where the patient has hospice or comfort care on admission	1,044	0.14%	$8,508	$4,830	$13,931	0.38	0.19	0.69
Episodes the patient received ECMO during the hospitalization	73	0.01%	$78,082	$33,913	$162,189	1.26	0.60	2.55
Episodes classified as outlier cases	10,372	1.36%	$53,252	$7,901	$115,533	2.24	0.30	4.92
Final Episodes (TIN)	460,458	60.39%	$19,078	$7,841	$35,071	0.96	0.55	1.64
Final Episodes (TIN-NPI)	358,342	47.00%	$19,307	$7,972	$35,307	0.97	0.56	1.65

*This table does not include all measure exclusions.

3.3.3 Interpretation

The statistical results indicate that most excluded episodes differ substantially in either mean observed cost, mean O/E cost ratio, or variation in cost (or O/E cost ratio) compared to the final set of episodes. These results support the exclusion of these episodes to ensure a comparable patient cohort that will yield meaningful information to attributed clinicians. Further discussion of the results for exclusions applied based on the clinical validity of the study population are provided below.

Episodes where patient death date occurred before the episode end date: The mean O/E cost ratio for these episodes (0.78) is lower than the mean O/E cost ratio for final episodes at both TIN level testing (0.96) and TIN-NPI level testing (0.97). At the same time, the mean observed cost for these episodes is $21,032, compared to $19,078 for final episodes at the TIN level (and $19,307 at the TIN-NPI level). These results indicate that this patient cohort is distinct in both observed cost and risk profile, and excluding these episodes ensures a fairer cost comparison.

Episodes where the patient has neutropenia: As expected, these episodes present more cost and have a higher O/E cost ratio than the final set of episodes. The mean observed cost for these episodes is $22,656, compared to $19,078 for final episodes at the TIN level (and $19,307 at the TIN-NPI level). The mean O/E cost ratio for these episodes is 1.01, compared to 0.96 for final episodes at the TIN level (and 0.97 at the TIN-NPI level). This aligns with the clinical rationale to exclude this clinically distinct population, who may be at greater risk for a larger range of infections.

Episodes where the patient has had a transplant: As expected, these episodes present more variation and have a higher O/E cost ratio than the final set of episodes. The mean observed cost for these episodes is $22,185, compared to $19,078 for final episodes at the TIN level (and $19,307 at the TIN-NPI level). The mean O/E cost ratio for these episodes is 1.04, compared to 0.96 for final episodes at the TIN level (and 0.97 at the TIN-NPI level). This aligns with the clinical rationale to exclude this clinically distinct population, which may be more likely to develop uncommon infections.

Episodes where the patient elects to leave against medical advice: This measure is intended to incentivize clinicians to change their behavior and treatment patterns to increase cost-effectiveness. However, the ability of the measure to accurately reflect such improvements is limited if attributed clinicians are held accountable for patients who do not take advantage of the

offered care. Though the cost and O/E cost ratios for these episodes are slightly lower than the final episodes, these patients are excluded to allow the measure to capture the outcomes of clinicians' decisions.

Episodes where the patient is on a clinical trial: Though the observed cost and O/E cost ratios for these episodes are relatively within the same range as the final episodes, these patients are excluded to align and harmonize with the Severe Sepsis and Septic Shock: Management Bundle, which also excludes patients participating in clinical trials. This population also represents a very small and potentially clinically distinct patient cohort.

Episodes where the patient has hospice or comfort care on admission: The mean observed cost for these episodes ($8,508) is substantially lower than it is for final episodes at over $19,000. The O/E cost ratio ranges from 0.19 at the 10th percentile to 0.69 at the 90th percentile for these episodes, compared to 0.55 at the 10th percentile and 1.64 at the 90th percentile for final episodes at the TIN level (and compared to 0.56 at the 10th percentile and 1.65 at the 90th percentile at the TIN-NPI level). Beyond the discrepancies in cost and cost variation, these episodes are excluded to align and harmonize with the Severe Sepsis and Septic Shock: Management Bundle, which also excludes these patients. Also, this population represents a very small patient cohort.

Episodes where the patient received ECMO during the hospitalization: The mean observed cost ($78,082) and mean O/E cost ratio (1.26) for these episodes (along with their distributions) are substantially larger than for final episodes. The mean observed cost is more than 4 times larger for episodes with ECMO relative to the final episodes. The difference in patient cohort becomes more pronounced at the 90th percentile, where episodes with ECMO have an O/E cost ratio of 2.55 compared to 1.64 or 1.65 for final episodes. Also, episodes with ECMO represent a very small patient cohort.

Episodes classified as outlier cases: The mean observed cost of these episodes is approximately three times greater than for the final set of episodes. The O/E cost ratio for outlier cases ranges from 0.30 at the 10th percentile to 4.92 at the 90th percentile, indicating that the risk adjustment model is currently unable to account for the patient characteristics associated with these high- and low-cost outlier episodes. Excluding outliers based on risk-adjusted cost eliminates the episodes that deviate most from expected spending levels based on patient characteristics.

3.4 Risk Adjustment or Stratification

3.4.1 Method of Controlling for Differences

Differences in case mix are controlled for using a statistical risk model with 139 risk factors and stratification by 2 risk categories.

The risk adjustment model for the Sepsis measure broadly follows the CMS-HCC risk adjustment methodology, which is derived from Medicare Parts A and B claims and is used in the Medicare Advantage (MA) program. Patient age is included via 12 age categorical variables derived from the MA risk adjustment model's age/sex variables. Severity of illness is measured using HCCs, indicators of enrollment and long-term care status, and disease interactions. The risk adjustment model also includes variables for factors identified by the Clinician Expert Workgroup as affecting resource use.

The model includes 79 HCC indicators derived from the patient's Parts A and B claims during the period 120 days prior to the episode trigger and are specified in the CMS-HCC Version 22

(V22) 2016 model. Episodes for patients without a full 120-day lookback period are excluded from the measure. This 120-day period is used to measure patient health status and ensures that each patient's claims record contains sufficient fee-for-service data both for measuring spending levels and for risk adjustment purposes.

In addition, the risk adjustment model includes status indicator variables for whether the patient qualifies for Medicare through Disability or ESRD. The model also includes an indicator of whether the patient recently required long-term care, defined as 90 days in a long-term care facility without being discharged to community for 14 days. Patients who need to reside in long-term care facilities typically require more intensive care than patients who live in the community. These enrollment and long-term care status variables are non-diagnostic indicators of severity of illness.

The model also accounts for disease interactions between HCCs and/or enrollment status variables included in the MA model. These interactions are included because certain combinations of comorbidities increase costs more than is predicted by the HCC indicators alone.

Furthermore, the risk adjustment model includes measure-specific factors intended to further isolate costs that attributed clinicians can reasonably influence, informed by expert clinician input and empirical analyses. The following variables were added to avoid potential unintended consequences:

- Whether the patient:
    - Had a diagnosis for bacteremia during the trigger inpatient stay.
    - Had a diagnosis for central nervous system infection during the trigger inpatient stay.
    - Had a diagnosis for endocarditis infection during the trigger inpatient stay.
    - Had a hospitalization or diagnosis for non-hepatobiliary gastrointestinal infection for their trigger inpatient stay.
    - Had a hospitalization or diagnosis for respiratory infection for their trigger inpatient stay.
    - Had a hospitalization or diagnosis for kidney and urinary tract infection for their trigger inpatient stay.
    - Had a hospitalization or diagnosis for cellulitis infection for their trigger inpatient stay.
    - Received hospice services in the 120 days prior to the episode trigger.
    - Was transferred from an inpatient rehabilitation facility.
    - Was transferred from a long-term care hospital.
    - Had a long-term care hospital stay in the 120 days prior to the episode trigger.
    - Was transferred from a hospital.
    - Was transferred from a skilled nursing facility.
    - Was enrolled in Medicare Part D.

As with the CMS-HCC model, the risk adjustment approach for this measure uses an ordinary least squares linear regression model. The predicted, or expected, cost is winsorized at the 0.5th percentile to make sure episodes with unusually small predicted cost, which would lead to abnormally large O/E cost ratios, do not dominate certain clinicians' final score. The winsorized expected costs are renormalized to ensure the average expected episode cost is the same before and after winsorizing. Then, as presented in the exclusions analysis above, extremely low- or high-cost outlier episodes with residuals below the 1st percentile or above the 99th percentile are excluded to reduce the effect of episodes that deviate the most from their

expected values in absolute terms. The expected cost after excluding these outliers is again renormalized to ensure that average expected costs are the same after outlier removal.

Finally, the risk adjustment model outlined above is stratified for each of the two Sepsis measure sub-groups below, which are based on the presence of septic shock during the hospitalization.

- Sepsis with Septic Shock
- Sepsis without Septic Shock

Full details of the risk adjustment model are in the draft Measure Codes List file.[33]

3.4.2 Conceptual, Clinical, and Statistical Methods

We selected the CMS-HCC model based on previous studies evaluating its appropriateness for use in risk adjusting Medicare claims data. This model was developed specifically for use in the Medicare population, meaning that it accounts for conditions found in the Medicare population and is calibrated on Medicare fee-for-service beneficiaries. In addition, the CMS-HCC model is routinely updated for changes in coding practices (e.g., the transition from the 9th revision of the International Statistical Classification of Diseases and Related Health Problems, or ICD-9, to ICD-10 codes) and is exhaustive on these code sets. Because the CMS-HCC model has already been extensively tested, we focus our testing on how the CMS-HCC model was adapted to the Sepsis measure methodology.

The workgroup provided input on measure-specific risk adjustors after reviewing empirical analyses on subpopulations of interest to assess whether and if so, how, particular factors should be accounted for in the model. These could include patient characteristics, factors outside of the reasonable influence of the clinician, or any other factors that would help prevent unintended consequences. These additional risk adjustors are listed in the section above.

As previously noted, the risk adjustment model is run on episodes stratified into sub-groups, which may qualify as "ordering" of risk factors. Sub-groups were also determined based on the workgroup's input, with the goal of ensuring clinical comparability among episodes so that the cost measure fairly compares clinicians with similar patient case-mix. The sub-groups are listed in the above section. Hospitalizations with and without septic shock identified during the inpatient stay were separated into sub-groups to apply the risk adjustment model to similar hospitalizations and to avoid unfair comparisons among the populations solely based on cost. Per expert clinical input, septic shock hospitalizations are often more severe in terms of expected outcomes (e.g., mortality), including episode cost; thus, sub-grouping is recommended to ensure fair clinical comparability among cases with and without septic shock.

3.4.3 Conceptual Model of Impact of Social Risks

Our conceptual model of the impact of social risk factors is informed by both published external research and our own data analysis.[34,35,36]

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[33] CMS, MACRA Feedback Page, https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback.

[34] Assistant Secretary of Health and Human Services for Planning and Evaluation. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Washington, D.C. December 2016.

[35] Chen LM, Epstein AM, Orav EJ, Filice CE, Samson LW, Joynt Maddox KE. Association of Practice-Level Social and Medical Risk With Performance in the Medicare Physician Value-Based Payment Modifier Program. JAMA. 2017;318(5):453-461

[36] Medicare Payment Advisory Commission. Beneficiaries Dually Eligible for Medicare and Medicaid. 2018; https://www.macpac.gov/publication/data-book-beneficiaries-dually-eligible-for-medicare-and-medicaid-3/.

3.4.4 Statistical Results

The literature has extensively tested the use of the HCC model as applied to Medicare claims data. Although the variables in the HCC model were chosen to predict annual cost, CMS has also used this risk adjustment model in a number of other settings (e.g., accountable care organizations, or ACOs, previous physician Quality and Resource Use Reports, or QRUR programs, and other measures such as NQF #3512: Knee Arthroplasty, NQF #3509: Routine Cataract Removal with Intraocular Lens (IOL) Implantation, NQF #3510: Screening/Surveillance Colonoscopy, and NQF #2158: MSPB-Hospital cost measure). Recalling that the risk model relies on the existing CMS-HCC model, testing results for factors included in the CMS-HCC V22 2016 model can be found in the Evaluation of the CMS-HCC Risk-Adjustment Model report[37] and the Report to Congress: Risk Adjustment in Medicare Advantage.[38] For measure-specific factors not included in the CMS-HCC model, we sought expert clinician input through the workgroup, which provided recommendations on additional risk adjustors and sub-groups.

3.4.5 Analyses and Interpretation in Selection of Social Risk Factors

Acumen analyzed gender, dual status, income, education, and unemployment as social risk factors (more information on these variables can be found in Section 3.1.7). Patient gender and dual status were obtained from the EDB and CME. Information on income, education, and unemployment was obtained from ACS data and linked to episodes by census block group where possible to provide a more granular level of analysis than ZIP code. Patients without geographic information necessary to obtain ACS data were excluded, representing approximately 2% of episodes.

The percentage of female patients range from 49.85% to 52.19% across the two sub-groups in this measure. The majority of the patients (56.99% - 67.18%) have non-dual status. Income level is categorized into high, medium, and low from the continuous average income variable in ACS; therefore, each category has 33% of observations. While 3.54% to 4.22% of patients are classified as having below a high school education level, the overwhelming majority of episodes are classified at a high school level or greater. Finally, 19.78% to 21.75% of patients have high unemployment designation (>10%).

Acumen examined the impact of including social risk factors into our risk adjustment model by running goodness of fit tests when different risk factors are added and compared to the base risk adjustment model, where the base risk adjustment model refers to the full standard set of risk adjustment variables from the CMS-HCC V22 2016 model, disability status, ESRD status, interaction variables, recent long-term care use, and measure-specific clinical risk adjustors. Acumen ran a step-wise regression to include the following additional social risk factors on top of the adapted CMS-HCC model:

- Gender
- Dual status
- Gender + dual status
- Gender + dual status + race
- Gender + dual status + income + education + unemployment
- Gender + dual status + AHRQ SES index score
- Gender + dual status + race + income + education + unemployment
- Gender + dual status + race + AHRQ SES index score

[37] Pope, Gregory C., John Kautter, et al., “Evaluation of the CMS-HCC Risk-Adjustment Model: Final Report.” RTI International: March 2011.
[38] CMS, “Report to Congress: Risk Adjustment in Medicare Advantage,” https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/RTC-Dec2018.pdf.

The step-wise regressions help evaluate individual as well as joint significance of the social risk factors. We examined the impact of including social risk factors into our risk adjustment model with T-test of individual significance and F-test of joint significance.

First, we analyzed the model coefficients and p-values for each of the base and social risk factor models to understand whether any of the social risk factor covariates are predictive of episode cost. The T-test and F-test revealed many significant p-values, indicating that social risk factors may be predictive factors for determining resource use among patients for the relevant characteristic. However, the analysis also shows that the significance of the effects of social risk factors is not consistent. For example, Asian patient episodes may display lower expected spending for the Sepsis without Septic Shock sub-group but higher expected spending for the Sepsis with Septic Shock sub-group. There are also differences in significance between the sub-groups; for instance, the female patient episodes coefficient is statistically significant for the Sepsis with Septic Shock sub-group, but not for the Sepsis without Septic Shock sub-group.

Second, we analyzed the impact of adding social risk variables on overall model performance by looking at the differences in the ratio of observed to expected episode cost (O/E) with and without social factors in the risk adjustment model. When including social risk factors in our risk adjustment regression, the minor differences in the O/E cost ratios, even for clinicians at high or low extremes of risk, indicates that social risk factor effects on the model performance are likely captured through existing risk adjustment variables. Overall, the measure scores for 96.37% of TINs and 97.90% of TIN-NPIs did not change or changed by 5 percentiles or less.

Finally, we analyzed the correlation between measure scores calculated with and without the social risk factors. The measure scores calculated with and without these social factors were highly correlated at both the TIN level, with a Spearman correlation coefficient of 0.997, and the TIN-NPI level with a correlation coefficient of 0.998. These results indicate that the inclusion of social risk factors in the current risk adjustment model would have a limited effect on measure scores.

Due to the inconsistent direction and limited impact of social risk factor effects under the current risk adjustment model, we believe the Sepsis measure risk adjustment model sufficiently accounts for the effects of social risk factors on clinician measure scores.

3.4.6 Method for Statistical Model or Stratification Development

To analyze the validity of the current risk adjustment model, we examined 2 analyses: (1) R-squared and adjusted R-squared for the regression models, and (2) predictive ratios and O/E cost ratios to examine the fit of the models at different levels of patient complexity.

1) R-squared and adjusted R-squared were calculated for the measure. These results should be evaluated in the context of the measure's service assignment rules which are intended to ensure only clinically associated costs are grouped to episodes. This is an important distinction from all-cost measures as service assignment leaves less variation for the risk adjustment model to explain. In this context, a low R-squared may indicate the effectiveness of the service assignment rules. These results are provided in Section 3.4.7.
2) Predictive ratios and O/E cost ratios were calculated for each "risk decile" for the episode group. A "risk decile" is based on the risk scores, which indicate how costly episodes are expected to be, as predicted through risk adjustment. After arranging episodes into deciles based on their risk score, we calculated the predictive ratios and average O/E cost ratios for each decile. The predictive ratio aims to examine the fit of the model at different levels of patient complexity to examine the model's ability to predict both very low and high cost episodes, and is calculated using the formula of average (expected cost)/average (observed cost) for all episodes in each decile. Similarly, the O/E cost ratio demonstrates the model's

prediction accuracy, and is calculated using the formula of average (observed cost/expected cost) for all episodes in each decile. These are discussed in Sections 3.4.8 and 3.4.9.

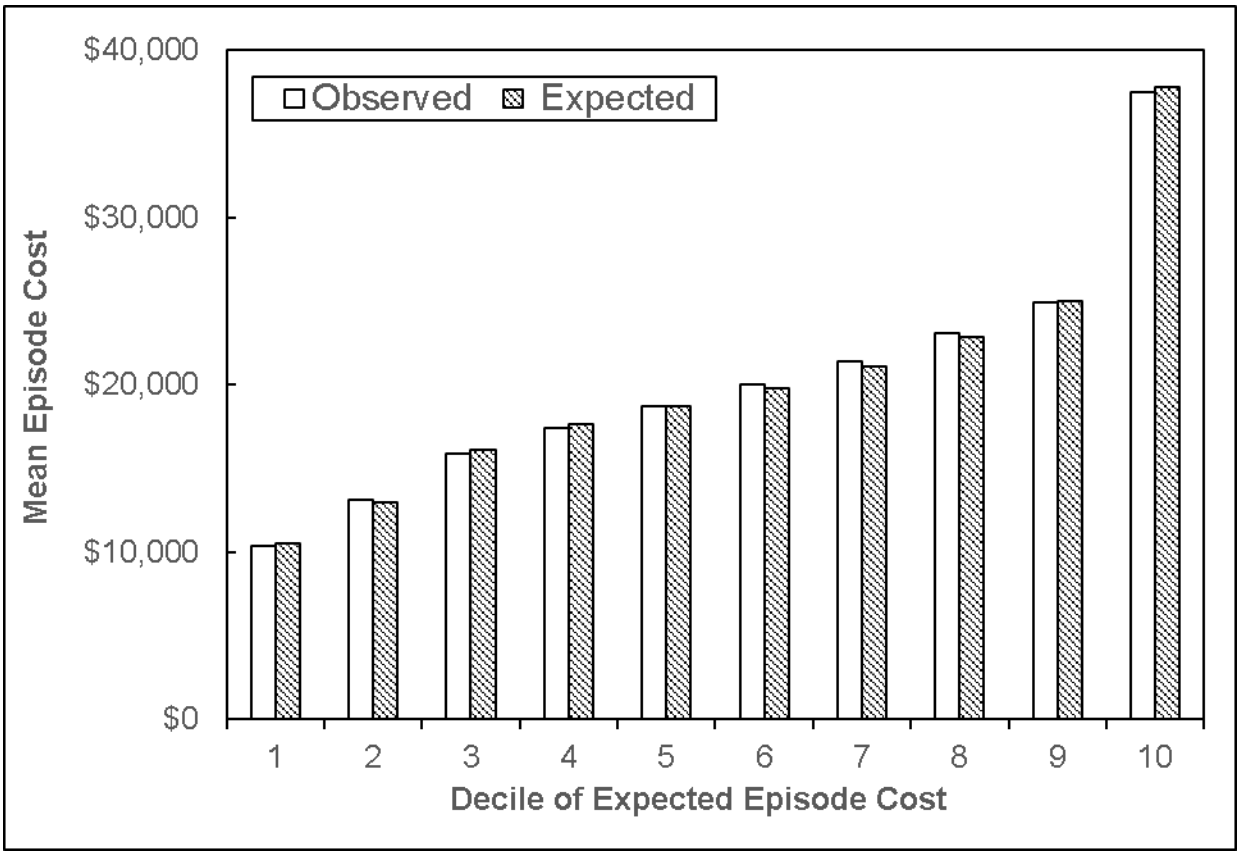
3.4.7 Statistical Risk Model Discrimination Statistics

The overall R-squared for the Sepsis cost measure, calculated by dividing explained sum of squares by total sum of squares is 0.31. The adjusted R-squared is 0.31. More information on discrimination testing for the CMS-HCC model can be found at Pope et al. 2011.[39]

3.4.8 Statistical Risk Model Calibration Statistics

We interpret calibration as how accurately the risk model's predictions/expectations match the actual episode cost. We calculate the average O/E cost ratio for each risk decile to demonstrate the model's prediction accuracy. The average O/E cost ratio is generally close to one across risk deciles, indicating that the model is accurately predicting actual episode cost. Full results are presented in Figure 1 below.

Figure 1. Risk Adjustment Model Diagnostics: Comparison of Observed and Expected Cost by Expected Cost Risk Deciles



Statistical Risk Model Calibration – Risk Decile

Analysis of predictive ratios by risk decile for the measure shows that the model has consistent predictive ratios across risk score deciles, with each decile having a predictive ratio between 0.99 and 1.02.

[39] Pope, Gregory C., John Kautter, et al., "Evaluation of the CMS-HCC Risk-Adjustment Model: Final Report." RTI International: March 2011.

3.4.9 Interpretation

The R-squared values for the model, which measure the percentage of variation in results predicted by the model, are higher than the values presented in similar analyses of risk adjustment models.[40] As noted in Section 3.4.6, these results should be interpreted alongside service assignment rules, which remove clinically unrelated services, so the resulting variation is reflective of variation related to factors within a clinician's reasonable influence.

As demonstrated in Sections 3.4.8 and 3.4.9, the average O/E cost ratios and the predictive ratios for all risk deciles are close to one. Predictive ratios close to one indicate that expected cost is accurately predicting observed cost. Overall, the results show that the model is accurately predicting observed cost, regardless of overall risk level.

3.5 Identification of Meaningful Differences in Performance

3.5.1 Method

Our method of determining clinically meaningful differences in episode-based cost measure performance consists of stratifying clinician measure O/E cost ratios by meaningful characteristics and investigating the clinician O/E cost ratio distribution by percentile. The cost measure score numerator is the sum of the O/E cost ratio for all episodes attributed to a clinician. This sum is then multiplied by the national average observed episode cost to generate a dollar figure. The denominator is the total number of episodes from the attributed to a clinician. Using O/E cost ratios allows for direct comparisons of performance at the sub-group level since a dollar figure cannot be calculated for those episodes using the national average observed episode cost. Stratification is performed for each of the following characteristics: urban/rural, census division, census region, risk score, and the number of episodes attributed to the clinician or clinician group. We analyze the distribution of measure O/E cost ratios for clinicians defined by these characteristics.

The purpose of this analysis is to ensure that there is a sufficiently large difference in measure O/E cost ratios among clinicians to determine a meaningful difference in performance. In addition, this analysis looks to confirm that the measure behaves as expected with respect to meaningful clinician characteristics.

3.5.2 Statistical Results

Key findings show that, generally, there is a large performance difference among clinicians in the Sepsis measure:

(i) The 99th percentile of the measure O/E cost ratio is nearly twice the measure O/E cost ratio at the 1st percentile for both the TIN and TIN-NPI levels; and
(ii) The Sepsis measure O/E cost ratio at the 90th percentile is approximately 37% and 40% greater than the O/E cost ratio at the 10th percentile at the TIN and TIN-NPI levels, respectively.

These results indicate there is a large potential for reducing Medicare costs.

The results also show that there is not a systemic regional difference in clinician O/E cost ratios. For instance, the mean O/E cost ratios for clinicians across nine census divisions are within a 0.08 or less range (i.e., 0.96 – 1.04 at the TIN level and 1.01 – 1.07 at the TIN-NPI level). Similarly, clinicians in urban areas seem to perform comparably to those in rural areas.

[40] Pope, Gregory C., John Kautter, Melvin J. Ingber, Sara Freeman, Rishi Sekar, and Cordon Newhart. "Evaluation of the CMS-HCC Risk-Adjustment Model: Final Report." RTI International: March 2011.

In terms of other clinician characteristics, analysis of clinicians by number of episodes indicates that clinicians with more episodes perform relatively similar to those with fewer episodes. We also analyzed clinicians by risk score decile, as variation by risk score decile could indicate that the risk adjustment model is over- or under-correcting for clinicians with systematically riskier patients. Measure O/E cost ratios also show little variation by risk score decile, with a range in median TIN O/E cost ratio of 0.96 to 1.04 and a range in median TIN-NPI O/E cost ratio of 1.00 to 1.08, indicating that the risk adjustment model is overall functioning as intended.

Tables 5-A and 5-B below present the distribution of cost measure O/E cost ratios by a range of clinician/clinician group characteristics, allowing a comparison of O/E cost ratio distributions for these breakdowns. The cost measure O/E cost ratios are presented at the TIN level and the TIN-NPI level.

Table 5-A: Sepsis TIN Level Cost Measure O/E Ratios

Characteristic	# of TIN-NPIs	Mean O/E Ratio	O/E Ratio Percentile						
			1st	10th	25th	50th	75th	90th	99th
All TINs	6,490	1.01	0.73	0.86	0.93	1.00	1.08	1.18	1.42
Sub-group									
Sepsis with Septic Shock	5,905	0.97	0.47	0.66	0.81	0.94	1.09	1.29	1.97
Sepsis without Septic Shock	6,489	1.02	0.72	0.86	0.93	1.00	1.09	1.19	1.47
Urban/Rural									
Urban	5,369	1.02	0.74	0.87	0.94	1.00	1.08	1.18	1.42
Rural	1,032	0.97	0.71	0.83	0.90	0.96	1.03	1.11	1.38
Unknown	29	1.02	0.82	0.87	0.95	1.00	1.06	1.19	1.40
No Data									
Census Region									
Northeast	1,041	1.03	0.77	0.90	0.96	1.02	1.09	1.18	1.36
Midwest	1,317	0.99	0.73	0.86	0.93	0.99	1.05	1.12	1.28
South	2,712	1.00	0.73	0.86	0.93	0.99	1.07	1.16	1.38
West	1,325	1.03	0.71	0.85	0.93	1.00	1.11	1.24	1.58
Unknown	95	1.00	0.68	0.85	0.91	0.99	1.07	1.20	1.54
Census Division									
New England	208	1.00	0.77	0.90	0.95	0.99	1.05	1.12	1.24
Middle Atlantic	833	1.04	0.78	0.90	0.96	1.03	1.10	1.21	1.40
East North Central	951	1.01	0.74	0.87	0.94	1.00	1.07	1.14	1.33
West North Central	366	0.96	0.73	0.85	0.91	0.96	1.01	1.07	1.24
South Atlantic	1,282	1.01	0.74	0.87	0.93	1.00	1.07	1.16	1.33
East South Central	497	1.00	0.74	0.86	0.93	0.99	1.06	1.15	1.44
West South Central	933	1.00	0.73	0.85	0.92	0.99	1.06	1.17	1.40
Mountain	346	0.96	0.68	0.82	0.90	0.96	1.01	1.11	1.31
Pacific	979	1.06	0.72	0.87	0.95	1.03	1.15	1.26	1.60
Unknown	95	1.00	0.68	0.85	0.91	0.99	1.07	1.20	1.54
TIN risk score decile									
1st	649	0.97	0.68	0.79	0.87	0.96	1.06	1.16	1.42
2nd	649	0.99	0.72	0.84	0.91	0.98	1.05	1.15	1.32
3rd	649	0.99	0.75	0.85	0.92	0.98	1.05	1.12	1.33
4th	649	0.99	0.72	0.87	0.93	0.98	1.04	1.13	1.31
5th	649	1.01	0.77	0.89	0.94	0.99	1.05	1.16	1.40
6th	649	1.01	0.77	0.88	0.94	0.99	1.06	1.15	1.33
7th	649	1.02	0.75	0.87	0.94	1.00	1.08	1.17	1.42
8th	649	1.03	0.74	0.87	0.96	1.02	1.09	1.20	1.45
9th	649	1.04	0.80	0.90	0.96	1.03	1.11	1.22	1.41
10th	649	1.07	0.77	0.89	0.96	1.04	1.15	1.26	1.59
Number of episodes									
10-19 Episodes	2,329	1.02	0.70	0.81	0.90	1.00	1.12	1.24	1.50
20-39 Episodes	1,563	1.02	0.77	0.87	0.93	1.01	1.09	1.18	1.41
40-59 Episodes	625	1.01	0.81	0.89	0.94	1.00	1.08	1.15	1.33
60-79 Episodes	366	1.01	0.78	0.90	0.94	1.01	1.08	1.13	1.24
80-99 Episodes	258	1.00	0.80	0.91	0.95	0.99	1.04	1.10	1.24
100-199 Episodes	670	0.99	0.85	0.91	0.94	0.99	1.03	1.08	1.22
200-299 Episodes	238	0.99	0.88	0.92	0.95	0.98	1.03	1.08	1.14
300+ Episodes	441	0.99	0.88	0.92	0.96	0.99	1.02	1.05	1.10

Table 5-B: Sepsis TIN-NPI Cost Measure O/E Ratios

Characteristic	# of TIN-NPIs	Mean O/E Ratio	O/E Ratio Percentile						
			1st	10th	25th	50th	75th	90th	99th
All TIN-NPIs	51,298	1.04	0.75	0.87	0.95	1.03	1.13	1.22	1.45
Sub-group									
Sepsis with Septic Shock	47,540	1.03	0.50	0.67	0.82	0.99	1.18	1.42	2.16
Sepsis without Septic Shock	51,227	1.05	0.72	0.86	0.94	1.03	1.14	1.26	1.55
Urban/Rural									
Urban	41,656	1.05	0.76	0.88	0.95	1.04	1.13	1.23	1.45
Rural	5,822	1.01	0.73	0.85	0.92	1.00	1.09	1.19	1.41
Unknown	11	1.01	0.93	0.94	0.95	0.99	1.04	1.13	1.17
Census Region									
Northeast	9,767	1.07	0.78	0.90	0.97	1.05	1.15	1.24	1.45
Midwest	10,816	1.04	0.75	0.87	0.95	1.03	1.12	1.23	1.44
South	18,348	1.04	0.76	0.87	0.94	1.03	1.12	1.22	1.44
West	8,545	1.03	0.74	0.86	0.93	1.02	1.12	1.22	1.47
Unknown	3,822	1.03	0.74	0.86	0.93	1.02	1.12	1.22	1.44
Census Division									
New England	3,082	1.05	0.78	0.90	0.97	1.04	1.13	1.22	1.41
Middle Atlantic	6,685	1.07	0.77	0.90	0.97	1.06	1.16	1.25	1.47
East North Central	7,306	1.05	0.75	0.88	0.95	1.04	1.13	1.23	1.45
West North Central	3,510	1.03	0.74	0.86	0.93	1.01	1.10	1.21	1.42
South Atlantic	10,285	1.04	0.77	0.88	0.95	1.03	1.12	1.22	1.44
East South Central	3,327	1.04	0.77	0.88	0.95	1.03	1.11	1.21	1.41
West South Central	4,736	1.03	0.75	0.86	0.93	1.01	1.11	1.21	1.46
Mountain	2,749	1.01	0.72	0.85	0.92	1.00	1.08	1.18	1.44
Pacific	5,796	1.05	0.74	0.86	0.94	1.03	1.14	1.24	1.48
Unknown	3,822	1.03	0.74	0.86	0.93	1.02	1.12	1.22	1.44
TIN-NPI risk score decile									
1st	5,129	1.01	0.72	0.84	0.91	1.00	1.09	1.19	1.43
2nd	5,130	1.01	0.74	0.85	0.92	1.00	1.09	1.18	1.39
3rd	5,130	1.02	0.75	0.86	0.93	1.01	1.10	1.19	1.38
4th	5,130	1.03	0.75	0.87	0.94	1.02	1.11	1.20	1.40
5th	5,130	1.03	0.76	0.87	0.94	1.02	1.11	1.21	1.42
6th	5,130	1.05	0.77	0.89	0.95	1.04	1.12	1.22	1.41
7th	5,130	1.05	0.77	0.88	0.96	1.04	1.13	1.23	1.44
8th	5,130	1.06	0.77	0.88	0.96	1.05	1.15	1.24	1.46
9th	5,130	1.08	0.78	0.90	0.98	1.07	1.17	1.27	1.52
10th	5,129	1.09	0.78	0.90	0.98	1.08	1.18	1.28	1.53
Number of episodes									
10-19 Episodes	27,948	1.05	0.73	0.85	0.93	1.03	1.15	1.26	1.49
20-39 Episodes	18,144	1.04	0.80	0.89	0.95	1.03	1.11	1.19	1.36
40-59 Episodes	3,870	1.03	0.83	0.91	0.96	1.03	1.10	1.16	1.30
60-79 Episodes	916	1.03	0.84	0.91	0.97	1.02	1.09	1.15	1.27
80-99 Episodes	260	1.04	0.85	0.94	0.98	1.04	1.09	1.15	1.27
100-199 Episodes	152	1.04	0.85	0.93	0.98	1.03	1.10	1.15	1.23
200-299 Episodes	5	0.99	0.95	0.95	0.97	0.99	1.00	1.02	1.02
300+ Episodes	3	0.97	0.94	0.94	0.94	0.95	1.02	1.02	1.02

3.5.3 Interpretation

The results in Tables 5-A and 5-B above indicate that there is limited overall variation in the mean cost measure O/E cost ratios across episode sub-groups, the urban/rural divide, census regions, census divisions, TIN or TIN-NPI risk score decile, or episode volume at both the TIN

and TIN-NPI levels. For each characteristic, the largest difference in the mean O/E cost ratio across categories was 0.10 or less. This indicates that the risk adjustment model is overall functioning as intended; it is adjusting cost performance such that there are no substantive differences across the categories for these characteristics. For sub-groups, the model is run separately for each sub-group to account for the greater severity of septic shock cases and enable a more fair comparison across episodes. These results also support that there is meaningful variation in cost performance, even after risk adjustment, across these characteristics. For each sub-group (and at both reporting levels), there is a more than two-fold increase in measure score performance from the 1st to 99th percentiles. These results indicate that there is large potential for saving Medicare spending and that there are no systemic differences across geographic region, level of provider risk, and case volume.

3.6 Missing Data Analysis and Minimizing Bias

3.6.1 Method

Since CMS uses Medicare claims data to calculate the Sepsis measure, Acumen expects a high degree of data completeness. To further ensure that we have complete and accurate data for each patient who opens an episode, Acumen excludes episodes where patient date of birth information (an input to the risk adjustment model) cannot be found in the EDB, the patient does not appear in the EDB, or the patient death date occurs before the episode trigger date.

The Sepsis measure also excludes episodes where the patient is enrolled in Medicare Part C or has a primary payer other than Medicare in the 120-day lookback period and episode window. In such situations, Medicare Parts A and B claims data may not capture the complete clinical profile for the patient needed to capture the clinical risk of the patient in risk adjustment. Furthermore, Parts A and B claims data may not capture all Medicare resource use if some portion of the patient's care is covered under Medicare Part C.

3.6.2 Missing Data Analysis

The table below presents the frequency of missing data across the four categories of missing data which caused episodes to be excluded from the Sepsis measure. Frequency is presented in terms of the number of episodes excluded due to missing data, as well as the number of TINs and TIN-NPIs who had at least one episode excluded due to missing data. The missing data categories are:

- Patient date of birth is missing
- Patient death date occurred before the trigger date
- Patient has a primary payer other than Medicare during the episode window or in the 120-day lookback period
- Patient was not enrolled in Medicare Parts A and B, or was enrolled in Part C, during the 120-day lookback period and episode window

As a note, the episode and clinician counts below reflect exclusion from the initial population of triggered episodes, which consists of over 1.71 million Medicare Parts A and B beneficiaries who receive inpatient medical treatment for sepsis that triggers a Sepsis episode. Specifically, this includes over 2.22 million episodes with a MS-DRGs for sepsis or common sources of infection. After the missing data exclusions are applied, we then apply additional trigger logic to this patient cohort to narrow the population to only episodes with a diagnosis of sepsis for the non-sepsis MS-DRG cases. After applying this additional trigger logic and upstream measure exclusions for data completeness, there are 762,434 episodes for 646,592 patients.

Table 6: Missing Data Categories for the Sepsis Measure

Exclusion	# Episodes	# TINs	# TIN-NPIs
Missing birth date	*	*	*
Death before trigger	12,877	5,434	18,226
Other primary payer	210,886	18,504	153,304
Not continuously enrolled	167,320	14,140	108,563

* indicates that there were fewer than 11 episodes

3.6.3 Interpretation

As the Sepsis measure is calculated with Medicare claims data, Acumen expects a high degree of data completeness, which is supported by the limited frequency (relative to the overall scale of this measure) of missing data, as noted above. Acumen takes measures to ensure that missing or inaccurate information in claims data is not included in the cost measure.

Other Additional Information

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The Sepsis Clinician Expert Workgroup is composed from the larger Hospital Medicine Clinical Subcommittee. The composition list of the Clinical Subcommittee is included in the Episode-Based Cost Measures Development Process document.[41]

[41] CMS, "2020 Episode-Based Cost Measure Field Testing Wave 3 Measure Development Process," MACRA Feedback Page, https://www.cms.gov/files/document/macra-cmft-ebcm-process-2020.pdf.