

Acute Kidney Injury Requiring New Inpatient Dialysis Measure

Measure Justification Form

June 2019



Contents

1.0 Introduction	4
1.1 Project Title and Overview	4
1.2 Measure Name	4
1.3 Type of Measure	4
2.0 Importance.....	5
2.1 Evidence to Support the Measure Focus	5
2.1.1 Measure Description	5
2.1.2 Evidence for Measure Focus	5
2.2 Performance Gap	6
2.2.1 Rationale	6
2.2.2 Performance Scores.....	7
3.0 Scientific Acceptability	8
3.1 Data Sample Description	8
3.1.1 Type of Data Used for Testing.....	8
3.1.2 Specific Dataset Used for Testing	8
3.1.3 Dates of the Data Used in Testing.....	8
3.1.4 Levels of Analysis Tested.....	8
3.1.5 Entities Included in the Testing and Analysis.....	8
3.1.6 Patient Cohort Included in the Testing and Analysis.....	8
3.1.7 Sample Differences	10
3.1.8 Social Risk Factors Included in Analysis	10
3.2 Reliability Testing.....	10
3.2.1 Level of Reliability Testing	10
3.2.2 Method of Reliability Testing	10
3.2.3 Statistical Results from Reliability Testing	11
3.2.4 Interpretation	12
3.3 Validity Testing	12
3.3.1 Level of Validity Testing.....	12
3.3.2 Method of Validity Testing	12
3.3.3 Statistical Results from Validity Testing	14
3.3.4 Interpretation	15
3.4 Exclusions Analysis	15
3.4.1 Method of Testing Exclusions.....	15
3.4.2 Statistical Results from Testing Exclusions.....	16
3.4.3 Interpretation	17
3.5 Risk Adjustment or Stratification	18
3.5.1 Method of Controlling for Differences	18
3.5.2 Conceptual, Clinical, and Statistical Methods	20
3.5.3 Conceptual Model of Impact of Social Risks.....	20
3.5.4 Statistical Results	20
3.5.5 Analyses and Interpretation in Selection of Social Risk Factors.....	21
3.5.6 Method for Statistical Model or Stratification Development.....	22
3.5.7 Statistical Risk Model Discrimination Statistics	22
3.5.8 Statistical Risk Model Calibration Statistics	23
3.5.9 Statistical Risk Model Calibration – Risk Decile.....	23
3.5.10 Interpretation.....	23
3.6 Identification of Meaningful Differences in Performance.....	23
3.6.1 Method	23

3.6.2 Statistical Results	23
3.6.3 Interpretation	24
3.7 Missing Data Analysis and Minimizing Bias.....	24
3.7.1 Method	24
3.7.2 Missing Data Analysis	25
3.7.3 Interpretation	25
4.0 Feasibility.....	26
4.1 Data Elements Generated as Byproduct of Care Processes	26
4.2 Electronic Sources	26
4.3 Data Collection Strategy	26
4.3.1 Data Collection Strategy Difficulties.....	26
5.0 Usability and Use	27
5.1 Use	27
5.1.1 Current and Planned Use	27
5.1.2 Feedback on the Measure and Development Process	27
5.2 Usability	31
5.2.1 Improvement	31
5.2.2 Unexpected Findings.....	31
5.2.3 Unexpected Benefits	31
6.0 Related and Competing Measures	32
6.1 Relation to Other Cost Measures	32
6.2 Harmonization.....	32
6.3 Competing Measures	32
Contact Information	33

1.0 Introduction

This Measure Justification Form (MJF) provides results for the testing and evaluation of the Acute Kidney Injury Requiring New Inpatient Dialysis measure. The MJF is intended to provide detailed information about the testing conducted on this measure, and accompanies the Measure Methodology and Measure Codes List file, which, together, comprise the specifications for this cost measure.¹

1.1 Project Title and Overview

The Centers for Medicare & Medicaid Services (CMS) has contracted with Acumen, LLC to develop care episode and patient condition groups for use in cost measures to meet the requirements of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The contract name is “MACRA Episode Groups and Cost Measures.” The contract number is HHSM-500-2013-13002I, Task Order HHSM-500-T0002.

1.2 Measure Name

Acute Kidney Injury Requiring New Inpatient Dialysis Episode-Based Cost Measure

1.3 Type of Measure

Cost/Resource Use

¹ CMS, “Acute Kidney Injury (AKI) Requiring New Inpatient Dialysis Measure Methodology,” *MACRA Feedback Page*, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2019-revised-ebcm-measure-specs.zip>.
CMS, “Acute Kidney Injury (AKI) Requiring New Inpatient Dialysis Measure Codes List,” *MACRA Feedback Page*, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2019-revised-ebcm-measure-specs.zip>.

2.0 Importance

2.1 Evidence to Support the Measure Focus

2.1.1 Measure Description

The Acute Kidney Injury (AKI) Requiring New Inpatient Dialysis cost measure evaluates clinicians' risk-adjusted cost to Medicare for beneficiaries who receive their first inpatient (IP) dialysis service for AKI during the measurement period. The cost measure score is a clinician's average risk-adjusted cost for the episode group across all episodes attributed to the clinician. This procedural measure includes costs of services that are clinically related to the attributed clinician's role in managing care from the clinical event that opens or 'triggers' the episode, through 30 days after the trigger. Beneficiary populations eligible for the Acute Kidney Injury Requiring New Inpatient Dialysis measure include Medicare beneficiaries enrolled in Medicare Parts A and B during the performance period.

2.1.2 Evidence for Measure Focus

Policymakers contend that an estimated 80 percent of overall health care costs are attributable to decisions made by clinicians.² However, these same clinicians are often unaware of how their care decisions influence the overall costs of care. One of the goals for using cost measures is to help inform clinicians on the costs attributable to their decision-making, as well as the total cost of their patient's care. A cost measure offers opportunity for improvement if clinicians can exercise influence on a significant share of costs during the episode, or if lower spending and better care quality can be achieved through changes in clinical practice.

According to the literature and previous feedback received through stakeholder input activities, this measure represents an area where there are opportunities for improvement. These include mitigating the rates of adverse outcomes and AKI requiring dialysis readmissions, and improving early detection of AKI requiring dialysis.

Reducing the rates of adverse outcomes could have a substantial impact on patient health and their subsequent healthcare costs. Post discharge, AKI patients are still at high risk for adverse events and re-hospitalization. Patients 66 years and older have a 35 percent chance of recurrent AKI hospitalization within a year.³ Therefore, addressing hospital readmission related to AKI presents an opportunity to decrease health care spending. Approximately 20 percent of Medicare beneficiaries discharged from a hospital were readmitted within 30 days.⁴ AKI patients in particular have significantly higher 30-, 60-, and 90-day hospital readmission rates than patients without AKI.⁵ Spending for treatment can range anywhere from \$10,700 to \$44,335.^{6, 7} AKI requiring dialysis, the most severe form of AKI, results in an increase of \$42,077 in

² Fred, Herbert L. "Cutting the Cost of Health Care: The Physician's Role." *Texas Heart Institute Journal*, vol. 43, no. 1, 2016, pp. 4 – 6.

³ United States Renal Data System. 2017 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2017.

⁴ Koulouridis, Ioannis, Lori Lyn Price, Nicolaos E Madias, et al. "Hospital-Acquired Acute Kidney Injury and Hospital Readmission: A Cohort Study." *American Journal of Kidney Disease*, vol. 65, no. 2, 2014, pp. 275-282.

⁵ Ibid.

⁶ Silver, Samuel A, Jin Long, Yuanchao Zheng, et al. "Cost of Acute Kidney Injury in Hospitalized Patients." *Journal of Hospital Medicine*, vol. 12, no. 2, 2017, pp. 70-76.

⁷ Lysak, Nicholas, Azra Bihorac, and Charles Hobson. "Mortality and Cost of Acute and Chronic Kidney Disease after Cardiac Surgery." *Current Opinion in Anesthesiology*, vol. 30, no. 1, 2017, pp. 113-117.

hospitalization costs and an increase in length of stay by 11.5 days.⁸ However, USRDS reported only 1 out of every 7 Medicare patients hospitalized for AKI saw a kidney doctor after discharge. Improving follow-up protocols could potentially help prevent the onset of additional complications and readmission.

Improving awareness and early diagnosis of AKI requiring dialysis could also lead to improved patient outcomes. Early identification and effective assessment during hospitalization has been proposed as a way to prevent worse outcomes and reduce expenditures.⁹ AKI requiring dialysis is associated with several diagnoses ranging from septicemia to heart failure or even hypertension.¹⁰ AKI requiring dialysis also predisposes patients to chronic kidney disease (CKD) and is a strong predictor of stage 4 CKD progression.¹¹ Chawla et al. (2011) found age increases the odds of developing CKD by 2 percent each year, while a 1 unit (mg/dl) increase of serum creatinine concentration during AKI hospitalization increases the odds of developing stage 4 CKD by 44-50 percent and having acute tubular necrosis by 60 percent. This reveals an opportunity to improve care by identifying patients at risk prior to discharge to implement interventions strategies early.

2.2 Performance Gap

2.2.1 Rationale

The annual expenditure of hospital-based AKI exceeds \$10 billion, and each year there is approximately 600,000 cases of AKI.^{12, 13} In 2015, 4.3 percent of Medicare beneficiaries experienced a hospitalization complicated by AKI.¹⁴ More specifically, over a nine-year span, over 1.09 million hospitalizations involved AKI requiring dialysis.¹⁵ Spending for hospitalizations with AKI requiring dialysis showed an increase of \$42,077 in hospitalization costs and an increase in length of stay by 11.5 days.¹⁶ The Acute Kidney Injury Requiring New Inpatient Dialysis episode-based cost measure was recommended for development by an expert clinician committee – the Renal Disease Management Clinical Subcommittee – because of its high impact in terms of patient population and Medicare spending, and the opportunity for incentivizing cost-effective, high-quality clinical care in this area. Based on the initial

⁸ Silver, Samuel A, Jin Long, Yuanchao Zheng, et al. "Cost of Acute Kidney Injury in Hospitalized Patients." *Journal of Hospital Medicine*, vol. 12, no. 2, 2017, pp. 70-76.

⁹ Chawla, Lakhmir S, Richard L Amdur, Susan Amodeo, et al. "The Severity of Acute Kidney Injury Predicts Progression to Chronic Kidney Disease." *Kidney International*, vol. 79, no. 12, 2011, pp. 1361-1369.

¹⁰ Hsu, Raymond K, Charles E McCulloch, Michael Heung, et al. for the Centers for Disease Control and Prevention Chronic Kidney Disease Surveillance Team. "Exploring Potential Reasons for the Temporal Trend in Dialysis-Requiring AKI in the United States." *The Clinical Journal of the American Society of Nephrology*, vol. 11, no. 1, 2016, pp. 14-20.

¹¹ Coca, Steven G, Kerry C Cho, and Chi-yuan Hsu. "Acute Kidney Injury in the Elderly: Predisposition to Chronic Kidney Disease and Vice Versa." *Nephron Clinical Practice*, vol. 119, 2011, pp. c19-c24.

¹² Lysak, Nicholas, Azra Bihorac, and Charles Hobson. "Mortality and Cost of Acute and Chronic Kidney Disease after Cardiac Surgery." *Current Opinion in Anesthesiology*, vol. 30, no. 1, 2017, pp. 113-117

¹³ Chawla, Lakhmir S, Richard L Amdur, Susan Amodeo, et al. "The Severity of Acute Kidney Injury Predicts Progression to Chronic Kidney Disease." *Kidney International*, vol. 79, no. 12, 2011, pp. 1361-1369.

¹⁴ United States Renal Data System. 2017 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2017.

¹⁵ Hsu, Raymond K, Charles E McCulloch, R Adams Dudley, et al. "Temporal Changes in incidence of Dialysis-Requiring AKI." *Journal of the American Society of Nephrology*, vol. 24, no. 1, 2012, pp. 37-42.

¹⁶ Silver, Samuel A, Jin Long, Yuanchao Zheng, et al. "Cost of Acute Kidney Injury in Hospitalized Patients." *Journal of Hospital Medicine*, vol. 12, no. 2, 2017, pp. 70-76.

recommendations from the Clinical Subcommittee, the subsequent measure-specific workgroup provided extensive, detailed input on this measure.

2.2.2 Performance Scores

Performance scores are provided for 771 clinician group practices (identified by Tax Identification Number [TIN]) and 2,182 practitioners (identified by combination of TIN and National Provider Identifier [NPI]). These counts represent attributed clinicians and clinician groups billing Part B Physician/Supplier claims under a Merit-based Incentive Payment System (MIPS) eligible clinician specialty, and do not reflect other MIPS eligibility criteria (e.g., Advanced APM participation). This table uses a testing volume threshold of 10 episodes.

Table 1: Distribution of Performance Scores

Metric	TIN	TIN-NPI
Mean score	\$37,886	\$43,456
Standard deviation	\$6,734	\$8,258
Score IQR	\$8,061	\$10,310
Score percentile		
10 th	\$30,542	\$34,144
20 th	\$32,600	\$36,587
30 th	\$33,800	\$38,542
40 th	\$35,605	\$40,601
50 th	\$36,986	\$42,404
60 th	\$38,450	\$44,327
70 th	\$40,320	\$46,612
80 th	\$42,545	\$49,522
90 th	\$46,312	\$54,180

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), enrollment database (EDB), and Common Medicare Environment (CME)

3.1.2 Specific Dataset Used for Testing

The Acute Kidney Injury Requiring New Inpatient Dialysis measure uses Medicare Part A and Part B claims data maintained by CMS. Part A and B claims data are used to build episodes of care, calculate episode costs, and construct risk adjusters. Data from the EDB are used to determine beneficiary-level exclusions and supplemental risk adjusters, specifically Medicare Parts A, B, and C enrollment, primary payer, disability status, end-stage renal disease (ESRD), beneficiary birth dates, and beneficiary death dates. The risk adjustment model also accounts for expected differences in payment for services provided to beneficiaries in long-term care based on the 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 American Census, American Community Survey (ACS), and CME are used in analyses evaluating social risk factors in risk adjustment.

3.1.3 Dates of the Data Used in Testing

The measurement period includes Acute Kidney Injury Requiring New Inpatient Dialysis episodes ending from January 1, 2017 through December 31, 2017.

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

771 clinician group practices and 2,182 practitioners were included in the analyses. Clinicians and clinician groups were included in testing if they were attributed 10 or more Acute Kidney Injury Requiring New Inpatient Dialysis episodes during the measurement period. Episodes from all 50 States and D.C. in the following settings were included: acute IP hospitals.

3.1.6 Patient Cohort Included in the Testing and Analysis

17,759 Medicare beneficiaries (from 18,795 episodes) were included in TIN level testing and analysis, and 14,138 beneficiaries (from 14,898 episodes) were included in TIN-NPI level measure testing.

The beneficiary population eligible for the Acute Kidney Injury Requiring New Inpatient Dialysis measure calculation consists of Medicare beneficiaries enrolled in Medicare Parts A and B (but not Part C) who meet the triggering logic that identifies patients who receive their first IP dialysis service for AKI through information on Part B Physician/Supplier claims, including Current Procedural Terminology/Healthcare Common Procedure Coding System (CPT/HCPCS) codes. Beneficiaries and their episodes were included in the sample if they met a set of inclusion criteria (listed below) meant to ensure completeness of data and to focus the measure on a clinically homogeneous cohort of patients receiving their first IP dialysis service for AKI.

The inclusion criteria are:

- The beneficiary has 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 beneficiary was 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 beneficiary has a sufficient 120-day lookback period.
- The beneficiary date of birth is not missing.
- The beneficiary death date did not occur before episode end.
- The episode can be attributed to at least one main clinician.
- The episode trigger claim was in a short-term stay acute IP hospital as defined by subsection (d).¹⁷
- The episode is not an outlier case.
- The beneficiary's trigger event does not include an IP stay with a Medicare Severity Diagnosis-Related Group (MS-DRG) code for kidney transplant.
- The beneficiary has not received a prior kidney transplant.
- The beneficiary is not receiving dialysis for a drug overdose or poisoning on the trigger claim.
- The beneficiary is not receiving plasmapheresis during the trigger event.
- The beneficiary does not receive post-discharge dialysis for ESRD after the discharge date.
- The beneficiary has not received previous outpatient dialysis.
- The beneficiary's Medicare eligibility is not due to ESRD.

To determine whether the Acute Kidney Injury Requiring New Inpatient Dialysis measure's inclusion 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) episodes with inclusion criteria, (ii) episodes without inclusion criteria, (iii) beneficiaries with inclusion criteria, and (iv) beneficiaries without inclusion criteria.

This analysis shows that the Acute Kidney Injury Requiring New Inpatient Dialysis measure's inclusion criteria have some effect on the percentage of beneficiaries of any particular demographic or patient characteristic. The greatest difference between beneficiaries being included or not included in the measure is less than 10 percentage points across each of the demographic characteristics in the analysis at TIN and TIN-NPI level testing. The percentage of beneficiaries aged 60 to 64 without applying the inclusion criteria is 7.6 percent, compared to 7.3 percent at TIN level testing and 7.1 percent TIN-NPI level testing. The difference for female beneficiaries when inclusion criteria are applied is 4.1 at the TIN level and 4.0 percent at the TIN-NPI level. The difference in race categories with and without inclusion criteria shows some changes, with the largest differences for black (5.2 and 6.0 percentage points at the TIN and TIN-NPI levels, respectively) and white (8.0 and 9.2 percentage points at the TIN and TIN-NPI levels, respectively). These results indicate that there is some shifting in patient characteristics as a result of using the inclusion criteria listed above at both TIN and TIN-NPI level testing.

¹⁷ 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](#).

3.1.7 Sample Differences

n/a

3.1.8 Social Risk Factors Included in Analysis

The social risk factors analyzed were variables from the ACS, EDB, and CME. All ACS variables are at the Census Block Group level. Social risk variables analyzed include the following:

- 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%
- Race (EDB)
 - Asian, Black, Hispanic, North American Native, White, and Other
- Sex (EDB)
 - Female, male
- Dual status (CME)
 - Full dual, partial dual, non-dual

3.2 Reliability Testing

3.2.1 Level of Reliability Testing

The following levels of reliability were tested: critical data elements used in the measure and performance measure score (e.g., signal-to-noise analysis).

3.2.2 Method of Reliability Testing

Data Element Reliability

The Acute Kidney Injury Requiring New Inpatient Dialysis measure is constructed using CMS claims data, as described in Section 3.1.2. CMS has implemented several auditing programs to assess overall claims code accuracy, ensure appropriate billing, and recoup any overpayments. CMS routinely conducts data analysis to identify potential problem areas and detect fraud, and audits important data fields used in this measure, including diagnosis and procedure codes and other elements that are consequential to payment. Specifically, CMS works with Zone Program Integrity Contractors, and formerly Program Safeguard Contractors, to ensure program integrity; the agency also uses Recovery Audit Contractors to identify and correct for underpayments and overpayments.

CMS also uses the Comprehensive Error Rate Testing (CERT) Program to ensure that Medicare payments are correct in accordance with coverage, coding, and billing rules. Between 2005 and 2017, CERT estimates that proper payment, which includes payments that met Medicare coverage, coding, and billing rules, ranged from 87.3 to 96.4 percent of total payments

each year.¹⁸ The FY 2018 Medicare FFS program proper payment rate was 91.9 percent.¹⁹ CMS continues to perform successful corrective actions and give providers additional education to ensure accurate billing.

To ensure claims completeness and inclusion of any corrections, the measure was developed and tested using data with a three month claims run-out from the end of the measurement period.

Measure Reliability

Measure reliability is the degree to which repeated measurements of the same entity agree with each other. For measures of clinician performance, the measured entity is the TIN or TIN-NPI, and reliability is the extent to which repeated measurements of the TIN or TIN-NPI give similar results. To estimate measure reliability, we used a signal-to-noise analysis.

This approach seeks to determine the extent to which variation in the measure is due to true, underlying clinician performance rather than random variation (i.e., statistical noise) within clinicians due to the sample of cases observed. To achieve this, we calculate reliability scores as:

$$R_j = \frac{\sigma_b^2}{\sigma_b^2 + \sigma_{w_j}^2}$$

Where:

$\sigma_{w_j}^2$ is the within-group variance of the mean measure score of clinician j

σ_b^2 is the between-group variance of clinicians within the episode group

That is, reliability is calculated as the ratio of between-group variance to the sum of between-group variance and within-group variance. Reliability closer to a value of one indicates that the between-group variance is relatively large compared to the within-group variance, which suggests that the measure is effectively capturing the systematic differences between the clinician and their peer cohort.

3.2.3 Statistical Results from Reliability Testing

Measure Reliability

At the 10, 20, and 30 episode thresholds, 100 percent of TINs have mean reliability greater than or equal to 0.4. For TIN-NPIs, 85 percent of clinicians have mean reliability greater than or equal to 0.4 at the 10 episode threshold, and this share rises to 100 percent at the 20 and 30 episode thresholds. At a volume threshold of at least 10 episodes, the mean reliability is 0.58 for TINs and is 0.48 for TIN-NPIs. The mean reliability continues to increase at the 20 and 30-episode volume thresholds.

Table 2: Reliability Results at Various Volume Thresholds

Volume Threshold (# episodes)	TIN		TIN-NPI	
	Mean Reliability	% ≥ 0.4	Mean Reliability	% ≥ 0.4
10	0.578	100%	0.483	85.29%

¹⁸ Comprehensive Error Rate Testing (CERT) Program. “Appendices Medicare Fee-for-Service 2018 Improper Payments Report”. Table A6. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/Downloads/2018MedicareFFSSupplementalImproperPaymentData.pdf>

¹⁹ Ibid.

Volume Threshold (# episodes)	TIN		TIN-NPI	
	Mean Reliability	% ≥ 0.4	Mean Reliability	% ≥ 0.4
20	0.689	100%	0.609	100%
30	0.748	100%	0.695	100%

3.2.4 Interpretation

Measure Reliability

Overall reliability of the Acute Kidney Injury Requiring New Inpatient Dialysis measure exceeds 0.4 at a volume threshold of 10 episodes or more for both TINs and TIN-NPIs due to the large number of episodes attributed to clinicians. CMS generally considers 0.4 as the threshold indicating ‘moderate’ reliability, which is supported by previous work into reliability.²⁰

While higher volume thresholds yield even higher reliability results, it is at the cost of further reducing the number of clinicians and clinician groups able to receive a measure score.

3.3 Validity Testing

3.3.1 Level of Validity Testing

We conducted performance measure score validity testing, which included systematic assessment of face validity and empirical validity testing.

3.3.2 Method of Validity Testing

Face Validity

The Acute Kidney Injury Requiring New Inpatient Dialysis measure was developed through a structured, iterative process for gathering detailed input from recognized clinician experts on the measure. These expert panels were convened to methodically assess the extent to which the measure: (i) captured what it was intended to capture, and (ii) differentiated between provider performance. Experts in this clinical area evaluated specifications in an iterative process 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 and refining this measure, Acumen incorporated input from (i) the Renal Disease Management Clinical Subcommittee, (ii) the Acute Kidney Injury Requiring New Inpatient Dialysis workgroup, (iii) a Technical Expert Panel (TEP), (iv) a Person and Family Committee (PFC), and (v) stakeholder feedback from national field testing.

The Clinical Subcommittee comprised 17 members with clinical experience in renal disease management, affiliated with 14 specialty societies. The Clinical Subcommittee provided input at an in-person meeting in April 2018 on which measure to develop, on the measure scope, and on the composition of a smaller, targeted workgroup to provide detailed input on each aspect of measure specifications. The Acute Kidney Injury Requiring New Inpatient Dialysis workgroup was composed of 11 members, affiliated with nine specialty societies, including Renal Physicians Association, American Society of Nephrology, and American College of Radiology. The workgroup considered empirical analyses and their clinical expertise to provide input during an in-person meeting and several webinars between June and December 2018. Input was

²⁰ Mathematica, Inc., “Memorandum: Reporting Period and Reliability of AHRQ, CMS 30-Day and HAC Quality Measures – Revised,” http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf.

gathered in a structured manner including the use of a polling process requiring greater than 60 percent consensus.

The TEP provided high-level guidance and input on the overall direction of measure development and the framework for episode-based cost measures, while the PFC provided a patient and family perspective. PFC input included concepts of healthcare quality and value, guiding principles and measure-specific topics to inform the workgroups such as pre- and post-trigger windows for selected episodes, and inclusion of services and costs for attributed clinicians. In addition, the national field testing feedback period in October and November 2018 offered all stakeholders an opportunity to review and provide input on draft measure specifications and measure feedback reports for attributed clinicians and clinician groups. During this period, 78,221 field test reports for TINs and TIN-NPIs were available for download and review for 11 episode-based cost measures developed throughout 2018.

One of the key roles of the measure-specific 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 providing the first IP dialysis for a beneficiary experiencing AKI, thus preventing inclusion of unrelated cost variation in this measure. Assigned services occurring in the outpatient (OP) and clinician service, IP medical, IP surgical, and emergency department (ED) settings were defined in the post-trigger window, and include the dialysis procedure, evaluation, testing, treatment, 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 Acute Kidney Injury Requiring New Inpatient Dialysis measure by examining the differences in risk-adjusted cost for known indicators of resource or service utilization based on a literature review, specifically complications related to the IP dialysis service for AKI. For this analysis, we compared the ratio of observed to expected cost (henceforth called the "O/E cost ratio") for Acute Kidney Injury Requiring New Inpatient Dialysis episodes with and without complications related to the IP dialysis service for AKI that occurs in the post-trigger period. This analysis sought to confirm the expectation that the Acute Kidney Injury Requiring New Inpatient Dialysis measure captures variation in service utilization.

In the second approach, we evaluated how different types of cost impact risk-adjusted measure scores. Certain services or costs included in the Acute Kidney Injury Requiring New Inpatient Dialysis measure were classified into clinically coherent groups of services, called "clinical themes." The Acute Kidney Injury Requiring New Inpatient Dialysis measure clinical themes are:

- **Dialysis:** Includes services and supplies associated with dialysis, such as diagnostic ultrasounds and catheters, to treat acute kidney failure, hypotension, anemias, hypertension, and other disorders of fluid, electrolyte, and acid-base balance.
- **Follow-Up for Kidney Disease:** Includes ED visits and critical care for hypertensive heart and/or CKD and its causes, such as diagnostic ultrasounds, tests, or procedures, and hospital care for the kidney disease.
- **Acute Kidney Injury (AKI):** Includes respiratory intubation and mechanical ventilation, hospital and physician care for the acute kidney injury, diagnostic procedures, laboratory testing, and medications.
- **Volume Overload:** Includes laboratory testing, respiratory intubation and mechanical ventilation for pulmonary edema and related conditions, hospital and physician care for diagnoses related to volume overload such as heart failure, and other diagnostic procedures.

- **Hypertensive Urgency / Emergency:** Includes respiratory intubation and mechanical ventilation, hospital and physician services to treat patients with related diagnoses, and other diagnostic procedures to address hypertensive crisis.
- **Hypotension:** Includes ED visits, hospital care, and critical care, such as respiratory intubation and mechanical ventilation, and other physician and diagnostic procedures, to address syncope and collapse, volume depletion, and hypotension.
- **Electrolyte Abnormalities:** Includes ED visits, hospital and physician services, and critical care, such as respiratory intubation and mechanical ventilation, laboratory testing, and other diagnostic procedures, to address disorders of mineral metabolism or fluid, electrolyte, and acid-base balance.
- **Dialysis Catheter Placement / Complications:** Includes insertion, replacement or removal of catheters.
- **Anemia, Non-Hemolytic and Non-Primary Marrow:** Includes blood transfusions, medications, and other diagnostic procedures.
- **Medication Side Effects:** Includes respiratory intubation, mechanical ventilation, and diagnostic procedures to address poisoning effects from drugs.

As with the first analysis for validity, the aim of this analysis was to determine whether the measure is capturing variation in provider 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 the Volume Overload theme would have the highest correlation with risk-adjusted episode cost, as this is an area where complications are likely, and complications are associated with high cost even after accounting for beneficiary characteristics.²¹ We would expect similar trends for the Hypertensive Urgency / Emergency theme as it contains services relating to complications, such as hypertensive crisis. By contrast, we expected that the Dialysis theme will be lower cost, as there are less possibilities for complications and all beneficiaries are experiencing their first dialysis. Risk adjustment should account for any variations in treatment plans based on beneficiary characteristics.

3.3.3 Statistical Results from Validity Testing

Table 3 presents an analysis of validity, showing the O/E cost ratio of episodes with or without downstream acute (re)admissions. The mean O/E cost ratio for all episodes is 1.04. The mean observed to expected cost for episodes with services relating to complications during the post-trigger period is 1.93, compared with 0.96 for episodes without services relating to complications during the post-trigger period.

Table 3: 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	1.04	0.61	0.36	0.46	0.57	0.71	0.89	1.19	1.65	2.03	3.43
Episodes with Downstream Acute (Re)admission	1.93	1.23	0.60	0.74	0.87	1.17	1.60	2.22	3.40	4.21	6.53
Episodes without Downstream Acute (Re)admission	0.96	0.43	0.35	0.45	0.56	0.70	0.87	1.12	1.47	1.75	2.52

²¹ Khan, N.A., Quan, H., Bugar, J.M. et al., "Association of postoperative complications with hospital costs and length of stay in a tertiary care center" J Gen Intern Med (2006) 21: 177.

The clinical themes analysis demonstrates that the Acute Kidney Injury (AKI) (correlation: 0.52) and Hypertensive Urgency / Emergency (correlation: 0.45) themes have the highest correlation between risk-adjusted cost. By contrast, the Dialysis (correlation: 0.07) and Hypotension (correlation: 0.05) themes had lower correlation with risk-adjusted cost.

3.3.4 Interpretation

As expected, the average O/E cost ratio for episodes with post-trigger complications is higher than for episodes without downstream acute (re)admission. This result demonstrates that the Acute Kidney Injury Requiring New Inpatient Dialysis measure is able to capture, accurately, higher resource use.

The clinical themes analysis demonstrates that high risk-adjusted cost is associated with themes related to complications. This indicates that the measure may penalize clinicians who have higher rates of complications, while not disincentivizing the provision of appropriate routine care, such as dialysis and catheter placements. Importantly, we see similar correlations with risk-adjusted cost for themes that have large differences in cost. For example, the Medication Side Effects theme (average cost: \$2,835.69) and Electrolyte Abnormalities theme (average cost: \$502.57) have 0.19 and 0.20 correlations with risk-adjusted cost, respectively. This indicates that the correlation does not come from a mechanical increase in episode costs from high-cost themes.

3.4 Exclusions Analysis

3.4.1 Method of Testing Exclusions

Exclusions are used in the Acute Kidney Injury Requiring New Inpatient Dialysis either to capture a homogenous patient population within the scope of the measure focus on the IP dialysis service for AKI and that episodes provide meaningful information to attributed clinicians or as part of data processing, to ensure that sufficient data are available to accurately determine episode spending and calculate risk adjustment for each episode. For the exclusions analysis, we focused on exclusions added to ensure a homogenous patient population. These exclusions, along with their rationales, are listed below:

- *Episodes where beneficiary death date occurred before the episode end date.*
 - These episodes were excluded for all measures due to the potential to inaccurately reflect a clinician's performance. Episodes where the beneficiary 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 where the beneficiary's inpatient stay is for a kidney transplant.*
 - Beneficiaries who receive a kidney transplant were excluded from this measure, as defined by the presence of MS-DRG 652 on the IP claims at the time of the trigger event. Patients with kidney transplants are much more complicated and are at higher risk for complications. These make up a small group of patients.
- *Episodes where the beneficiary has a prior kidney transplant.*
 - Beneficiaries who received a prior kidney transplant were excluded from this measure, as defined by ICD-10 codes and MS-DRG 652 on the Part B Physician/Supplier, OP, and IP claims during the 120 day lookback period. Kidney transplant patients are much more complicated and are at higher risk for complications. These make up a small group of patients.
- *Episodes where the beneficiary receives dialysis for a drug overdose or poisoning.*

- Beneficiaries who receive dialysis for a drug overdose or poisoning were excluded from this measure, as defined by the presence of ICD-10 codes on Part B Physician/Supplier claims at the time of the trigger. These dialysis procedures are not for an acute kidney injury.
- *Episodes where the beneficiary receives plasmapheresis.*
 - Beneficiaries who receive plasmapheresis were excluded from this measure, as defined by ICD-10 or CPT/HCPCS codes on Part B Physician/Supplier, OP, or IP claims at the time of the trigger. These procedures are more complex than dialysis, make up a small portion of patients, and are very different in follow-up care.
- *Episodes where the beneficiary receives post-discharge dialysis for ESRD.*
 - Beneficiaries who receive post-discharge dialysis for ESRD were excluded from this measure, as defined by any condition code other than 84 billed on the OP claims during a 14 day lookforward period. This indicates that the patient received dialysis for ESRD and not for AKI.
- *Episodes where the beneficiary has previous OP dialysis.*
 - Beneficiaries who received previous OP dialysis were excluded from the measure, as defined by code 72 on the OP claims during the 120 day lookback period from the IP start date. This indicates that the patient previously received dialysis and thus, this is not a new AKI-dialysis episode.
- *Episodes where the beneficiary receives Medicare eligibility because of ESRD.*
 - Beneficiaries who receive Medicare eligibility because of ESRD were excluded from this measure, as defined by enrollment information in the EDB, as this suggests the patient has ESRD.
- *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 were 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 substantially higher or lower 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 beneficiaries affected, as well as the distributions of observed cost and ratio of observed to expected cost (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 and details used for the Acute Kidney Injury Requiring New Inpatient Dialysis measure is provided in the Measure Codes List.²²

3.4.2 Statistical Results from Testing Exclusions

Table 4 below presents observed cost statistics and observed to expected cost ratios for the Acute Kidney Injury Requiring New Inpatient Dialysis measure exclusions. Cost statistics are also provided for the set of final episodes included in the Acute Kidney Injury Requiring New

²² CMS, “Acute Kidney Injury (AKI) Requiring New Inpatient Dialysis Measure Codes List,” *MACRA Feedback Page*, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2019-revised-ebcm-measure-specs.zip>

Inpatient Dialysis measure for comparison, with a testing volume threshold of 10 episodes at the TIN and TIN-NPI levels.

Table 4: Cost Statistics for Measure Exclusions

Exclusion	Episodes		Observed Cost			O/E		
	#	%	Mean	Percentile		Mean	Percentile	
				10 th	90 th		10 th	90 th
All Episodes Meeting Triggering Logic	1,197,195	100.00%	\$17,905	\$6,207	\$33,420	1.07	0.57	1.81
Death in Episode	183,568	15.33%	\$22,874	\$7,721	\$45,153	1.09	0.55	1.64
Post-Discharge Dialysis for ESRD	384,428	32.11%	\$17,995	\$9,789	\$31,555	1.33	0.73	2.09
Previous Outpatient Dialysis	431,013	36.00%	\$18,567	\$9,544	\$32,340	1.31	0.70	2.05
Indicator: ESRD	471,262	39.36%	\$18,562	\$9,336	\$32,426	1.29	0.67	2.03
Kidney Transplant	7,775	0.65%	\$24,307	\$19,806	\$30,864	0.96	0.74	1.20
Prior Kidney Transplant	70,134	5.86%	\$16,252	\$5,849	\$31,128	0.91	0.45	1.46
Drug Overdose/Poisoning	4,146	0.35%	\$16,217	\$4,948	\$32,071	0.92	0.48	1.45
Plasmapheresis	2,088	0.17%	\$34,529	\$6,944	\$77,296	1.12	0.53	2.05
Outlier Cases	460	0.04%	\$136,274	\$53,988	\$244,431	1.89	0.51	3.97
<i>Final Episodes (TIN)</i>	18,795	1.57%	\$36,388	\$9,666	\$83,962	1.03	0.56	1.62
<i>Final Episodes (TIN-NPI)</i>	14,898	1.24%	\$36,588	\$9,747	\$84,312	1.02	0.56	1.60

3.4.3 Interpretation

The statistical results indicate that the excluded episodes have fairly different results to the final set of episodes and these episodes were excluded due to clinical considerations to ensure a comparable patient cohort that will yield meaningful information to attributed clinicians. Further discussion of the results for each exclusion is provided below.

Episodes ending in death: There is a marked difference in observed cost for episodes ending in death and the final set of episodes: episodes ending in death have a mean observed cost that is approximately \$14,000 less than that of the final set of episodes at the TIN and TIN-NPI level. At the 90th percentile, the observed for episodes ending in death is \$45,153, almost half of the observed cost for the final set of episodes at approximately \$84,000. This suggests that episodes ending in death have lower cost due to the truncated window, so are excluded to avoid problematic incentives that could arise where patients who die have lower costs.

Episodes where the beneficiary received post-discharge dialysis for ESRD: These episodes are outside of the scope of the measure intent as patients with ESRD are a different patient cohort, and the episodes appear systematically less costly than the final set of episodes - the mean observed cost of these episodes is approximately half that of the final set of episodes.

Episodes where the beneficiary had previous OP dialysis: These episodes are outside of the scope of the measure intent because this indicates the patient previously received dialysis and thus, this is not a new AKI-dialysis episode. The episodes also appear systematically less costly than the final set of episodes - the mean observed cost of these episodes is approximately half that of the final set of episodes.

Episodes where there is an ESRD indicator: These episodes are outside of the scope of the measure intent as this indicates a patient has ESRD, which is a different patient cohort. The episodes appear systematically less costly than the final set of episodes - the mean observed cost of these episodes is approximately half that of the final set of episodes.

Episodes where the beneficiary is receiving a kidney transplant: These episodes are outside of the scope of the measure intent, as patients with kidney transplants typically do not receive dialysis unless the kidney has started to fail, and are therefore a different patient cohort. The episodes appear systematically less costly than the final set of episodes - the mean observed cost of these episodes is approximately \$12,000 less. As such, these cases are not included in the measure to ensure a clinically comparable patient cohort.

Episodes where the beneficiary had a prior kidney transplant: These episodes are outside of the scope of the measure intent, and appear systematically less costly than the final set of episodes - the mean observed cost of these episodes is less than half (approximately \$20,000) the final set of episodes. As such, these cases are not included in the measure to ensure a clinically comparable patient cohort.

Episodes where the beneficiary received dialysis for a drug overdose or poisoning: These episodes are outside of the scope of the measure intent, and appear systematically less costly than the final set of episodes - the mean observed cost of these episodes is less than half that of the final set of episodes.

Episodes where the beneficiary received plasmapheresis: The mean observed cost of these episodes is approximately \$2,000 less than for the final set of episodes. Although the mean cost is similar, these procedures have very different follow-up care and outside of the scope of the measure.

Outlier cases: The O/E cost ratio is 1.89 at the mean and is 3.97 at the 90th percentile, compared to 1.03 and 1.62 for the corresponding percentile values for the final set of episodes at the TIN level. This indicates 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.

3.5 Risk Adjustment or Stratification

3.5.1 Method of Controlling for Differences

Differences in case mix are controlled for using a statistical risk model with 117 risk factors. This measure's risk adjustment model is not stratified by risk categories.

The risk adjustment model for the Acute Kidney Injury Requiring New Inpatient Dialysis 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. Although the MA risk adjustment model includes 24 age/sex variables, this risk adjustment model does not adjust for sex and so only includes 12 age categorical 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 expert clinician workgroup as affecting resource use.

The model includes 79 HCC indicators derived from the beneficiary'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 beneficiaries without a full 120-day lookback period are excluded from the measure. This 120-day period is used to measure beneficiary health status and ensures that each beneficiary'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 beneficiary qualifies for Medicare through Disability or ESRD. The model also includes an indicator of whether the beneficiary recently required long-term care, defined as 90 days in a long-term care facility without being discharged to community for 14 days. Beneficiaries who need to reside in long-term care facilities typically require more intensive care than beneficiaries 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 beneficiary has stage 3 CKD because the HCC model does not include stage 3 CKD patients who are more vulnerable to kidney injury;
- whether the beneficiary has a length of hospital stay from 1-2 days, 3-7 days, 8-14 days, or more than 14 days, as these are proxies for the severity of underlying illness and the nephrologist may have limited influence over length of stay or the underlying disease process that caused AKI;
- whether the beneficiary has an Intensive Care Unit/ Coronary Care Unit stay for 1-2 days, 3-7 days, 8-14 days, or more than 14 days, as these are proxies for the severity of underlying illness and the nephrologist may have limited influence over length of stay or the underlying disease process that caused AKI;
- whether the beneficiary has a prior fistula or graft placement, as this is an indication that the patient has severe CKD and is close to needing dialysis;
- whether the beneficiary has vein mapping, as this is an indication that the patient has severe CKD and is close to needing dialysis;
- whether the beneficiary has glomerular disease because these patients often require additional treatments above and beyond dialysis, including immunosuppression, and have cost of care differences between typical AKI patients;
- whether the beneficiary has frailty indicators (e.g., dementia, a skilled nursing facility visit, and home hospital bed) as these are risk factors for additional downstream complications; and
- whether the beneficiary received post-acute care (e.g., recent admission to an inpatient rehabilitation facility [IRF], skilled nursing facility [SNF], or long-term care hospital [LTCH], or recent receipt of home health [HH]) prior to the episode), as this is an indicator for a higher risk patient.

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 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 noted 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.

Full details of the risk adjustment model are in the Measure Codes List File.²³ The National Summary Data Report (NSDR) Addendum includes regression coefficients and standard errors for each of the covariates used in the risk adjustment model.²⁴

3.5.2 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 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 Acute Kidney Injury Requiring New Inpatient Dialysis measure methodology.

The workgroup provided input on measure-specific risk adjusters 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 the influence of the attributed clinician, or any other factors that would help prevent unintended consequences. These additional risk adjusters are listed in the section above.

3.5.3 Conceptual Model of Impact of Social Risks

Our conceptual model of the impact of social risk factors is informed by both published, peer-reviewed literature and data analysis.

3.5.4 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., ACOs, previous physician QRUR programs, and other measures such as 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 Pope et al (2011) report.²⁵ 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 adjusters.

The results of the statistical analysis used to characterize our risk adjustment model can be found in the NSDR Addendum, which includes regression coefficients and standard errors for each of the covariates used in the risk adjustment model.

²³ CMS, “Acute Kidney Injury (AKI) Requiring New Inpatient Dialysis Measure Codes List,” *MACRA Feedback Page*, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2019-revised-ebcm-measure-specs.zip>.

²⁴ CMS, “National Summary Data Report Addendum: 11 Episode-Based Cost Measures and Revised MSPB Clinician Measure,” *MACRA Feedback Page*, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html>.

²⁵ 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.

3.5.5 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 3.1.8). Beneficiary 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.

44.2 percent of beneficiaries in this measure are female. The majority of the beneficiaries (68.4%) 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 percent of observations. While 4.29 percent of beneficiaries are classified below a high school education level, the 95.71 of episodes are classified at a high school level or greater. Finally, 28.36 percent of beneficiaries 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 adjusters. Acumen ran a step-wise regression to include gender, dual status, gender + dual status, and gender + dual + income + education + unemployment + race, on top of the adapted CMS-HCC model. 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 are likely predictive factors for determining resource use among beneficiaries for the relevant characteristic.

Secondly, we analyzed the impact of adding social risk variables on overall model performance by looking at the differences in the O/E cost ratios 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 providers 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. When including the social risk factors in risk adjustment, the O/E cost ratio for 92.98 percent of TINs and 95.77 percent of TIN-NPIs changed by ± 0.1 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 and TIN-NPI level, with a Spearman correlation coefficient of 0.947 at the TIN level and 0.961 at the TIN-NPI level. 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 Acute Kidney Injury Requiring New Inpatient Dialysis measure risk adjustment model sufficiently accounts for the effects of social risk factor on clinician measure scores.

3.5.6 Method for Statistical Model or Stratification Development

To analyze the validity of current risk adjustment model, we examined three analyses: (1) R-squared and adjusted R-squared for the regression models, (2) predictive ratios and O/E cost ratios to examine the fit of the models at different levels of patient complexity, and (3) coefficient estimates, standard errors, and p-values.

- 1) *R-squared and adjusted R-squared* were calculated for the measure overall. The results should be evaluated in the context of the service assignment rules, which indicate which costs are counted in the measures and which costs are not counted. This is an important distinction from all-cost measures, as a low R-squared does not necessarily indicate that a measure reflects variation unrelated to clinical care, while a high R-squared does not necessarily indicate the opposite; instead, the risk adjustment models must be evaluated in concert with the service assignment rules. These results are provided in Section 3.5.7.
- 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 3.5.8 and 3.5.9.
- 3) *Coefficient estimates, standard errors, and p-values* were run for the measure to consider the extent to which the coefficients for the risk factor covariates are predictive of episode cost. Results for individual risk adjustment variables should be viewed in the context of the entire model, rather than being analyzed individually. For instance, coefficients indicate the incremental effect of a model variable, holding all other variables fixed. As another example, interactions between model variables must be interpreted in concert with the effects of those variables in isolation.

The results of these analyses are presented in the NSDR Addendum to aid in the overall assessment of the predictive ability of the risk adjustment models.²⁶

3.5.7 Statistical Risk Model Discrimination Statistics

The overall R-squared for the Acute Kidney Injury Requiring New Inpatient Dialysis cost measure, calculated by dividing explained sum of squares by total sum of squares is 0.72. The adjusted R-squared is 0.72.

The NSDR Addendum also includes regression coefficients and standard errors for each of the covariates used in the risk adjustment model. More information on discrimination testing for the CMS-HCC model can be found at Pope et al. 2011.²⁷

²⁶ CMS, “National Summary Data Report Addendum: 11 Episode-Based Cost Measures and Revised MSPB Clinician Measure,” *MACRA Feedback Page*, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html>.

²⁷ 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.

3.5.8 Statistical Risk Model Calibration Statistics

We interpret calibration as how accurately the risk model's predictions 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 ranges from 0.93 to 1.50 across risk deciles and averages at 1.06. This indicates that on average the model is accurately predicting actual episode cost for episodes in the majority of risk deciles, though it underpredicts cost for episodes in the lowest cost decile. Full results are presented in the NSDR Addendum.²⁸

3.5.9 Statistical Risk Model Calibration – Risk Decile

Analysis of predictive ratios by risk decile for the measure shows that the model has moderately consistent predictive ratios across risk deciles, with each decile having a mean predictive ratio between 0.71 and 1.10. The mean predictive ratio for all risk deciles is 1.00. As shown above, the model accurately predicts cost for episodes at most risk levels, but underpredicts for episodes in the lowest cost decile.

3.5.10 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.²⁹ As noted in Section 3.5.6, 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 Section 3.5.8 and 3.5.9, the average O/E cost ratios and the predictive ratios for most risk deciles are close to one. Predictive ratios close to one indicate that expected spending is accurately predicting observed spending. Overall, the results show that the model is accurately predicting observed spending, regardless of overall risk level.

3.6 Identification of Meaningful Differences in Performance

3.6.1 Method

Our method of determining clinically meaningful differences in episode-based cost measure scores consists of stratifying the clinician measure scores by meaningful characteristics and investigating the clinician score distribution by percentile. 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. We analyze the distribution of measure scores for clinicians defined by these characteristics, as well as for the overall episode group.

The purpose of this analysis is to ensure that there is a sufficiently large difference in measure scores 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.

3.6.2 Statistical Results

Key findings show that, generally, there is a large performance difference among clinicians in the Acute Kidney Injury Requiring New Inpatient Dialysis measure:

- (i) the 99th percentile of the measure score is nearly 1.7 times the 1st percentile at the TIN level; and

²⁸ Ibid, 25.

²⁹ 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.

- (ii) the 99th percentile of the measure score is nearly 2.4 times the 1st percentile at the TIN level. These results indicate there is large potential for saving Medicare spending.

The results also show there are no large systemic regional difference in clinician score. The mean scores for clinicians across four census regions (excluding 'Unknown') are within a less than \$4,000 range (i.e., \$36,469-\$40,375 at the TIN level and \$42,134-\$45,539 at the TIN-NPI level). Similarly, clinicians in urban areas seem to perform comparably to those in rural areas, with a difference of \$718 at the TIN level and \$1,939 at the TIN-NPI level.

In terms of other clinician characteristics, analysis of clinicians by number of episodes indicates that clinicians with more episodes perform similarly to those who perform fewer IP dialysis services for AKI. 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. Results indicate little variation in measure score by risk score decile, with a range in mean TIN score of \$36,750 to \$42,323 and a range in mean TIN-NPI score of \$41,979 to \$48,938, indicating that the risk adjustment model is overall functioning as intended. Full results can be seen in the NSDR.³⁰

3.6.3 Interpretation

There is clinically and practically significant variation in Acute Kidney Injury Requiring New Inpatient Dialysis measure scores, indicating the measure's ability to capture differences in performance. There is relatively small ranges of scores across regions and across rural or urban care settings. The risk score deciles also has a relatively small range of cost. Overall, as expected, results show that clinicians are not being systematically penalized or rewarded due to risk score decile given the current Acute Kidney Injury Requiring New Inpatient Dialysis measure design (i.e., the differences in cost measure scores are not as a result of the risk profile of the patient cohort).

3.7 Missing Data Analysis and Minimizing Bias

3.7.1 Method

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

The Acute Kidney Injury Requiring New Inpatient Dialysis measure also excludes episodes where the beneficiary 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 beneficiary needed to capture the clinical risk of the beneficiary in risk adjustment. Furthermore, Parts A and B claims data may not capture all Medicare resource use if some portion of the beneficiary's care is covered under Medicare Part C.

³⁰ CMS, "National Summary Data Report: 11 Episode-Based Cost Measures and Two Revised Cost Measures, Updated Following Field Testing (Oct-Nov 2018)," *MACRA Feedback Page*, <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/macra-mips-and-apms/macra-feedback.html>.

3.7.2 Missing Data Analysis

The table below presents the frequency of missing data across the four categories of missing data that caused episodes to be excluded from the Acute Kidney Injury Requiring New Inpatient Dialysis 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:

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

Table 5: Missing Data Categories for the Acute Kidney Injury Requiring New Inpatient Dialysis Measure

Exclusion	# Episodes	# TINs	# TIN-NPIs
Missing birth date	0	0	0
Death before trigger	1,631	827	1,363
Other primary payer	126,579	2,760	10,046
Not continuously enrolled	48,605	2,587	9,300

3.7.3 Interpretation

As the Acute Kidney Injury Requiring New Inpatient Dialysis measure is calculated with Medicare claims data, Acumen expects a high degree of data completeness, which is supported by the limited frequency of missing data as noted above. Acumen takes measures to address cases of missing or inaccurate information in claims data.

4.0 Feasibility

4.1 Data Elements Generated as Byproduct of Care Processes

The data elements used in this measure are generated, collected and/or used by healthcare personnel during the provision of care (e.g., blood pressure, laboratory values, diagnosis, depression score). The data collected during care provision are then translated into the appropriate coding system (e.g. ICD-10 diagnoses, MS-DRGs) for use in Medicare claims.

4.2 Electronic Sources

All data elements are in defined fields in electronic claims.

4.3 Data Collection Strategy

4.3.1 Data Collection Strategy Difficulties

Lessons and associated modifications may be categorized into three types: data collection procedures, handling of missing data, and sampling data associated with beneficiaries who died during an episode of care.

4.3.1.1 Data Collection

Acumen receives claims data directly from the Common Working File (CWF) maintained at the CMS Baltimore Data Center. Medicare claims are submitted by healthcare providers to a Medicare Administrative Contractor (MAC), and are subsequently added to the CWF. However, these claims may be denied or disputed by the MAC, leading to changes to historical CWF data. In rare circumstances, finalizing claims may take many months, or even years. As a result, it is not practical to wait until all claims for a given month are finalized before calculating this measure. As such, there is a trade-off between efficiency (accessing the data in a timely manner) and accuracy (waiting until most claims are finalized) when determining the length of the time (i.e., the “claims run-out” period) after which to pull claims data. To determine the appropriate claims run-out period, Acumen has performed testing on the delay between claim service dates and claims data finalization. Based on this analysis, Acumen uses a run-out period of three months after the end of the calendar year to collect data for development and testing purposes. If this measure is used in a CMS program, calculation and reporting would be done in line with that program’s reporting practices.

4.3.1.2 Missing Data

This measure requires complete beneficiary information, and a small number of episodes with missing data are excluded to ensure completeness of data and accurate comparability across episodes. For example, episodes where the beneficiary was not enrolled in Medicare Parts A and B for the 120 days prior to the episode start date are not included in this measure. This enables the risk adjustment model to accurately adjust for the beneficiary’s comorbidities using data from the previous 120 days of Medicare claims. Additionally, the risk adjustment model includes a categorical variable for beneficiary age bracket, so episodes for which the beneficiary’s date of birth cannot be located are not included in this measure.

4.3.1.3 Sampling

During measure testing, Acumen noted that episodes in which the beneficiary died prior to the episode end date exhibited different cost distributions compared to other episodes. To avoid this effect’s potential impact on clinician scores, this measure does not include episodes for which the beneficiary’s date of death occurs prior to the end of the episode window.

5.0 Usability and Use

5.1 Use

5.1.1 Current and Planned Use

The measure was developed for potential use in the Merit-based Incentive Program (MIPS), under a contract with CMS.

5.1.2 Feedback on the Measure and Development Process

5.1.2.1 Technical Assistance Provided During Development or Implementation

Development: Field Testing

Acumen and CMS conducted a national field test of 11 episode-based cost measures developed during 2018, including the Acute Kidney Injury Requiring New Inpatient Dialysis measure, for a 35-day comment period (October 3 to November 5, 2018). We provided field test reports to a sample of clinician groups and clinicians.³¹ Each report included information for all measures for which the clinician or clinician group was attributed 10 or more episodes. The testing sample was selected to balance coverage and reliability, since a key goal of field testing was to test the measures with as many stakeholders as possible. This sampling technique was used for field testing only and does not determine case minimums used for any potential program implementation.

- Total testing sample across all 11 episode-based cost measures: 14,237 TINs; 63,984 TIN-NPIs
- Testing sample for Acute Kidney Injury Requiring New Inpatient Dialysis: 853 TINs; 2,493 TIN-NPIs

All stakeholders, including those who did not receive a field test report, could review a mock field test report that was posted on the CMS website. Other public documentation posted during field testing included: measure specifications for each measure (comprising a Draft Cost Measure Methodology document and a Draft Measure Codes List file), a Measure Development Process document, a Frequently Asked Questions document, and a Fact Sheet.³² During field testing, Acumen conducted education and outreach activities including a national webinar, office hours with specialty societies, and Help Desk support.

5.1.2.2 Technical Assistance with Results

Field Testing

During the feedback period, 2,388 field test reports for episode-based cost measures were downloaded by 403 clinician groups (TINs) and 1,985 clinicians (TIN-NPIs). Stakeholder comments from field testing were summarized for the workgroup to consider in recommending refinements to the measures based on the testing data and feedback.

The following sections offer more details on the contents of each report and describe the education and outreach efforts associated with the field testing feedback period.

Data Provided During Field Testing

Each field test report contained the following sheets:

- High-level summary results across all episode-based cost measures being field tested

³¹ The field test reports were available for download from the CMS Enterprise Portal: <https://portal.cms.gov/wps/portal/unauthportal/home/>.

³² The Measure Development Process, Frequently Asked Questions, and Fact Sheet documents are posted on the MACRA Feedback Page: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html>.

- Results for each measure including cost measure score and breakdown of episode cost compared to the national average and TIN/TIN-NPIs with a similar patient case mix (or risk profile)
- Drill-down detail for each measure, including more detailed information on potential cost drivers in the TIN/TIN-NPI's episodes. For example:
 - Analysis of utilization and cost for the measure by specific service categories (e.g., OP evaluation and management services, procedures, and therapy, hospital IP services, emergency room services, post-acute services)
 - Breakdown of costs for Physician/Supplier Part B and IP claims (e.g., top 5 most billed services and by risk bracket)
- Episode-level table with detailed information for all episodes attributed to the TIN/TIN-NPI across all measures in the report
 - Data across six major categories: (i) episode costs, (ii) beneficiary information, (iii) attributed clinician(s), (iv) evaluation and management visits performed during episode, (v) Physician Fee Schedule costs to Medicare billed during episode, and (vi) other providers rendering care.

A mock field test report can be viewed on the CMS MACRA Feedback webpage.³³

Education and Outreach

Acumen directly conducted outreach via email to tens of thousands of stakeholders using the stakeholder contact list developed through previous education and outreach and clinician engagement efforts, as well as CMS, Quality Payment Program, and other available listservs. More detail on this outreach can be found in the Field Test Summary Report on the CMS MACRA Feedback webpage.

Acumen and CMS hosted two office hour sessions in October 2018, to provide an overview of field testing to specialty societies, discuss what information their members would be particularly interested in, and answer any questions. Acumen also hosted two office hour sessions with members of Clinical Subcommittees and workgroups to provide an update on development and field testing. Across all four office hours sessions, there were over 100 attendees.

Acumen also worked with the Physician Value helpdesk and QPP Service Center to answer stakeholder questions during field testing and continued to answer questions after the feedback period ended.

Acumen and CMS hosted a national field testing webinar on October 9, 2018 to provide an overview of the measures being field tested and the information available for public comment. The webinar consisted of an hour-long presentation, outlining (i) the cost measure development activities, (ii) field testing activities, (iii) how to access and understand the confidential field test reports, and (iv) the contents of the reports. The presentation was followed by a 30-minute Q&A session. Around 85 comments and questions were received via webinar chat and on the phone.

A post-field testing webinar was held on March 27, 2019 to provide an update on the measures following field testing. The webinar consisted of a 60 minute presentation providing an overview of the basics of measure construction, highlighting refinements made after field testing, and

³³ CMS, "Episode-based Cost Measures Mock Field Test Report," *MACRA Feedback Page*, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2018-Mock-report-for-Episode-Based-Cost-Measures.xlsx>.

summarizing the testing done on the measures. This presentation was followed by a Q&A session.³⁴

5.1.2.3 Feedback on Measure Performance and Implementation

Field Testing

In total, Acumen received 67 survey responses and 25 comment letters, including many from specialty societies representing large numbers of potentially attributed clinicians.

Survey responses and comment letters were collected via an online survey, which contained general and detailed questions on the reports themselves, questions on the supplemental documentation, and questions on the measure specifications.

Pre-Rulemaking

CMS received 37 comments on the 11 episode-based cost measures included in the Measures Under Consideration List released in December 2018. This included four comments for the Acute Kidney Injury Requiring New Inpatient Dialysis cost measure. After the MAP Clinician Workgroup meeting in December 2018, there was another public comment period on their preliminary recommendations, which received 23 comments across the 11 measures, with three comments specific to the Acute Kidney Injury Requiring New Inpatient Dialysis cost measure.³⁵ These public comment periods were facilitated by NQF. Stakeholders were able to submit their comments via the NQF website.

5.1.2.4 Feedback from Providers being Measured

Field Testing

The Field Testing Feedback Summary Report presents all feedback gathered during the field testing period. The following list synthesizes some of the key points that were raised through the field testing feedback period:

- *Stakeholder engagement and involvement remains an important aspect of the measure development process.* Stakeholders expressed appreciation for the opportunity to provide feedback during field testing and for CMS' continued efforts to involve them in the measure development process. Commenters also valued the decision to operationalize previously collected feedback, as demonstrated through the addition of measure-specific workgroups to the development process.
- *Field test reports present useful information for understanding clinician performance, though reduced complexity could encourage more clinician participation.* Stakeholders praised the presentation and content of the field test reports. However, the complexity of the information presented in the reports was a challenge for some stakeholders.
- *Improved supplemental field testing materials are helpful but can be further refined.* Some stakeholders found the supplemental field testing materials to be informative and thorough, providing useful information on field testing and the specifications of the cost measures. However, many noted that although the materials are comprehensive, they remain lengthy and complex, and they believe the amount of information provided is too overwhelming to be useful.
- *Ample time for review of field testing reports and materials is vital to collecting meaningful stakeholder feedback.* Some stakeholders suggested the field testing period be extended or kept open, given the large amount and complexity of the information that was presented.

³⁴ CMS, Webinar Recordings, Slides and Transcripts, *QPP Webinar Library*
<https://qpp.cms.gov/about/webinars>.

³⁵ Measure Applications Partnership, *National Quality Forum*.
https://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx.

- *Transparent Clinical Subcommittee and measure-specific workgroup selection and voting encourages buy-in from stakeholders.* Some stakeholders expressed concern with the selection and voting processes for the Clinical Subcommittees and workgroups, highlighting that a transparent approach to member selection would ensure an appropriate mix of specialties and clinician types.
- *Field test report access continues to present challenges for stakeholders.* Some stakeholders noted that they faced difficulties creating accounts and downloading their field test reports from the CMS Enterprise Portal and these challenges may have negatively impacted the number of clinicians that were able to participate in field testing. Stakeholders urged CMS to communicate directly with clinicians receiving field test reports and to find an alternative for delivering and accessing the reports.

This feedback was used as the basis for the post-field testing refinements that were made to the measures, summarized below:

- Refinements to trigger codes, attribution, sub-groups, episode windows, assigned services, risk adjustment variables, exclusions, and alignment of cost with quality
- Adding/removing certain trigger codes and assigned services, removing sub-grouping, and revising the attribution methodology
- Stakeholders also noted that the level of clinician engagement in the development of these episode-based cost measures is a significant improvement over the development process for earlier cost measures.

5.1.2.5 Feedback from Other Users

Pre-Rulemaking

The MAP recognized the importance of cost measures to the MIPS program and conditionally supported the Acute Kidney Injury Requiring New Inpatient Dialysis cost measure pending NQF endorsement. Specifically, the MAP encouraged the NQF endorsement Cost and Efficiency Standing Committee to consider the appropriateness of the risk adjustment model to ensure clinical and social risk factors are reviewed and included when appropriate. MAP cautioned about the potential stinting of care and noted that appropriate risk adjustment could help safe guard against this practice. The MAP also encouraged the Standing Committee to examine the exclusions in this measure to ensure appropriate attribution.

5.1.2.6 Consideration of Feedback

Field Testing

Careful consideration was given to all feedback gathered during field testing, and several updates were made to the measure based on the recommendations of field testing commenters and an expert clinician workgroup comprised of subject matter and measure-development experts.

After completing field testing, Acumen compiled the feedback provided through the survey and comment letters into a measure-specific report, which was then provided to the expert clinician workgroup, along with empirical analyses to inform their discussion and evaluation of any refinements needed to ensure that the measure is capturing what it was intended to capture.

The changes to the Acute Kidney Injury Requiring New Inpatient Dialysis measure made after consideration of field testing analyses and stakeholder feedback are:

- **Risk Adjustment:** Added risk adjustors for:
 - Glomerular Disease
 - Frailty (e.g., dementia, skilled nursing facility visit, and home hospital bed)

- Use of post-acute care facilities prior to an episode (e.g., recent admission to an IRF, a SNF, or LTCH, or recent receipt of HH)
- **Exclusions:** Added exclusion for patients who have Medicare eligibility for ESRD

5.2 Usability

5.2.1 Improvement

n/a. The measures have not yet been implemented, and as such have not had influence over performance.

5.2.2 Unexpected Findings

n/a. There were no unexpected findings during the development and testing of this measure

5.2.3 Unexpected Benefits

n/a. There were no unexpected benefits during the development and testing of this measure.

6.0 Related and Competing Measures

6.1 Relation to Other Cost Measures

There are currently no related NQF-endorsed or non-NQF-endorsed cost measures that address this same measure focus or target population. There are no competing NQF-endorsed or non-endorsed cost measures that address both this same measure focus *and* at this same target population.

6.2 Harmonization

n/a

6.3 Competing Measures

n/a

Contact Information

Measure Steward Point of Contact

Organization: Centers for Medicare & Medicaid Services

Name: Joel Andress

Email Address: joel.andress@cms.hhs.gov

Phone Number: (410) 786-5237

Developer Point of Contact

Organization: Acumen, LLC

Email Address: macra-cost-measures-info@acumenllc.com

Phone Number: (650) 558-8882

Other Additional Information

Acute Kidney Injury Requiring New Inpatient Dialysis Workgroup Members:

David Roer, Renal Physicians Association

Devika Nair, American Society of Nephrology

Eileen Brewer, American Academy of Pediatrics

Geoffrey Teehan, American Society of Nephrology

Jane Schell, American Academy of Hospice and Palliative Medicine

Jennifer Scherer, American Academy of Hospice and Palliative Medicine

Namirah Jamshed, The American Geriatrics Society

Prasad Shankar, American College of Radiology

Salomao Faintuch, Society of Interventional Radiology

Scott Bieber, American Society of Nephrology

Terry Ketchersid, Renal Physicians Association

The Acute Kidney Injury Requiring New Inpatient Dialysis workgroup is composed from the larger Renal Disease Management Clinical Subcommittee. The composition list of the Clinical Subcommittee is included in the [Episode-Based Cost Measures Development Process document](#).³⁶

³⁶ CMS, "Episode-Based Cost Measure Field Testing Measure Development Process," *MACRA Feedback Page*, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2018-measure-development-process.pdf>.