Measure Information Form

1.	Measure Name/Title (CMS Consensus-Based Entity [CBE] Measure Submission Form Measure Specifications sp.01)
	Standardized Mortality Ratio for Dialysis Facilities
2.	Descriptive Information
2.1	Measure Type
	 □ process ☑ outcome □ PRO-PM □ cost /resource use □ efficiency □ structure □ intermediate outcome □ population health □ composite □ process □ outcome □ other □ other
2.2	Brief Description of Measure (CMS CBE Measure Submission Form, Measure Specifications sp.02 and sp.06) Standardized mortality ratio is defined to be the ratio of the number of deaths that occur for Medicare ESRD dialysis patients treated at a particular facility to the number of deaths that would be expected given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. This measure is calculated as a ratio but can also be expressed as a rate.
2.3	If Paired or Grouped (CMS CBE Measure Submission Form, Measure Specifications sp.03) N/A

3. Measure Specification

3.1 Measure-Specific Webpage (CMS CBE Measure Submission Form, Measure Specifications sp.09)

N/A

3.2 If this is an electronic clinical quality measure (eCQM) (CMS CBE Measure Submission Form, Measure Specifications sp.10)

N/A

3.3 Data Dictionary, Code Table, or Value Sets (CMS CBE Measure Submission Form, Measure Specifications sp.11)

Attachment : SMR_Code_List.xlsx

For an instrument-based measure (CMS CBE Measure Submission Form, Measure Specifications sp.23 and sp.24)

N/A

- 3.5 Updates since last submission (CMS CBE Measure Submission Form, Specifications: Maintenance Update spma.01 and spma.02)
 - Addition of COVID-19 adjustment in SMR model. New time periods for each patient begin at the start of a new COVID-19 diagnosis category and COVID-19 diagnosis is now included as a covariate in stage 1 of the SMR model. Proportion of time during the treatment period that the patient is enrolled in Medicare Advantage is also now included as a covariate in stage 1 of the SMR model.
- 3.6 Numerator Statement (CMS CBE Measure Submission Form, Measure Specifications sp.12)

Number of deaths among eligible patients at the facility during the time period.

3.7 Numerator Details (CMS CBE Measure Submission Form, Measure Specifications sp.13)

Information on death is obtained from several sources which include the CMS ESRD Program Medical Management Information System, the Death Notification Form (CMS Form 2746), and the Social Security Death Master File. The number of deaths that occurred among eligible dialysis patients during the time period is calculated. This count includes only Medicare patients, as detailed above. It does not include deaths from street drugs or accidents unrelated to treatment: Deaths from these causes varied by facility, with certain facilities (in particular, urban facilities that treated large numbers of male and young patients) reporting large numbers of deaths from these causes and others reporting extremely low numbers (Turenne, 1996). Since these deaths are unlikely to have been due to treatment facility characteristics, they are excluded from the calculations.

3.8 Denominator Statement (CMS CBE Measure Submission Form, Measure Specifications sp.14)

Number of deaths that would be expected among eligible dialysis patients at the facility during the time period, given the national average mortality rate and the patient mix at the facility.

3.9 Denominator Details (CMS CBE Measure Submission Form, Measure Specifications sp.15)

Assignment of Patients to Facilities

The treatment history file provides a complete history of the status, location, and dialysis treatment modality of an ESRD patient from the date of the first ESRD service until the patient dies or the data collection cutoff date is reached. For each patient, a new record is created each time he/she changes facility or treatment modality. Each record represents a time period associated with a specific modality and dialysis facility. EQRS is the primary basis for placing patients at dialysis facilities and dialysis claims are used as an additional source. Information regarding first ESRD service date, death and transplant is obtained from additional sources including the CMS Medical Evidence Form (CMS-2728), transplant data from the OPTN, the Death Notification Form (CMS-2746).

The denominator for SMR for a facility is the total number of expected deaths identified using all patient-records at the facility meeting inclusion criteria. The number of days at risk in each of these patient-records is used to calculate the expected number of deaths for that patient-record.

The denominator is based on expected mortality calculated from a Cox model (Cox, 1972; SAS Institute Inc., 2004; Kalbfleisch and Prentice, 2002; Collett, 1994). The model used is fit in two stages. The stage 1 model is a Cox model stratified by facility and adjusted for patient age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities, calendar year, BMI at incidence, MA coverage, and COVID-19 diagnosis. This model allows the baseline survival probabilities to vary between strata (facilities) and assumes that the regression coefficients are the same across all strata. Stratification by facility at this stage avoids biases in estimating regression coefficients that can occur if the covariate distributions vary substantially

across centers. The results of this analysis are estimates of the regression coefficients in the Cox model and these provide an estimate of the relative risk for each patient. This is based on a linear predictor that arises from the Cox model and is then used as an offset in the stage 2 model, which is unstratified and includes an adjustment for the race-specific, age-adjusted state population death rates.

General Inclusion Criteria for Dialysis Patients

We only entered a patient's follow-up into the tabulations after that patient had ESRD for more than 90 days. This minimum 90-day period assures that most patients are eligible for Medicare insurance either as their primary or secondary insurer. It also excludes from analysis patients who died during the first 90 days of ESRD.

In order to exclude patients who only received temporary dialysis therapy, we assign patients to a facility only after they have been on dialysis there for the past 60 days. This 60-day period is used both for patients who started ESRD for the first time and for those who returned to dialysis after a transplant. That is, deaths and survival during the first 60 days of dialysis at a facility do not affect the SMR of that facility.

Identifying Facility Treatment Histories for Each Patient

For each patient, we identified the dialysis provider at each point in time using a combination of Medicare dialysis claims, the Medical Evidence Form (CMS-2728), and data from EQRS. Starting with day 91 of ESRD, we determined facility treatment histories for each patient, and then listed each patient with a facility only once the patient had been treated there for 60 days. When a patient transferred from a facility, the patient remained assigned to it in the database for 60 days. This continued tabulation of the time at risk for 60 days after transfer from a facility attributes to a facility the sequelae of treatment there, even when a patient was transferred to another facility (such as a hospital-based facility) after their condition worsened.

In particular, we placed patients in their initial facility on day 91 of ESRD once that facility had treated them for at least 60 days. If on day 91 a facility had treated a patient for fewer than 60 days, we waited until the patient reached day 60 of treatment at that facility before placing them there.

Using EQRS data and dialysis claims to determine whether a patient has transferred to another facility, we attributed patient outcomes to the patient's original facility for 60 days after transfer out. On day 61 after transfer from a facility, we placed the patient in the new facility once the patient had been treated at the new facility for 60 days. When a patient was not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we did not attribute that patient to any facility.

Patients were removed from facilities upon receiving transplants. Patients who withdrew from dialysis or recovered renal function remained assigned to their treatment facility for 60 days after withdrawal or recovery. Additionally, patients for whom the only evidence of dialysis

treatment is the existence of Medicare claims were considered lost to follow-up and removed from a facility's analysis one year following the last claim, if there was no earlier evidence of transfer, recovery, or death. In other words, if a period of one year passed with neither Medicare dialysis claims nor EQRS information to indicate that a patient was receiving dialysis treatment, the patient is designated lost to follow-up, and not included in the analysis. If evidence of dialysis re-appeared, the patient was re-entered into analysis after 60 days of continuous therapy at a single facility.

Finally, all EQRS records noting continuing dialysis were extended until the appearance of any evidence of recovery, transfer, or death. Periods lost to follow-up were not created in these cases.

Days at Risk for Each Patient-Record

After patient treatment histories are defined as described above, periods of follow-up time (or patient-records) are created for each patient. A patient-record begins each time the patient is determined to be at a different facility or at the start of each calendar year. The number of days at risk starts over at zero for each patient record so that the number of days at risk for any patient-record is always a number between 0 and 365 (or 366 for leap years). Therefore, a patient who is in one facility for all four years gives rise to four patient-records and is analyzed the same way as would be four separate patients in that facility for one year each.

This measure is limited to Medicare dialysis patients. We require that patients reach a certain level of Medicare-paid dialysis bills to be included in the mortality statistics, or that patients have Medicare-paid inpatient claims during the period, or that patients have record of MA coverage. Specifically, months within a given dialysis patient-period are used for SMR calculation when they meet the criterion of being within two months after a month with either: (a) \$1200+ of Medicare-paid dialysis claims OR (b) at least one Medicare inpatient claim Or (c) if the patient is covered by MA coverage during this month according to the Medicare EDB.

We use the number of days at risk in each of these patient-records to calculate the expected number of deaths for that patient-record and sum the total number of expected deaths during all patient-records at the facility as the expected number of deaths for that facility.

3.10 Denominator Exclusions (CMS CBE Includes "Exception" in the "Exclusion" Field) (CMS CBE Measure Submission Form, Measure Specifications sp.16)

N/A

3.11 Denominator Exclusion Details (CMS CBE Includes "Exception" in the "Exclusion" Field) (CMS CBE Measure Submission Form, Measure Specifications sp.17)

N/A

	sp.18)
	N/A
3.13	Risk Adjustment Type (CMS CBE Measure Submission Form, Measure Specifications sp.19)
	 □ no risk adjustment or risk stratification □ stratification by risk category/subgroup ☑ statistical risk model □ other
	The patient characteristics included in the stage 1 model as covariates are:
	Age: Determine each patient's age for the birth date provided in the EQRS, Medicare Claims, and the Medical Evidence Form (CMS-2728). Age is included as a piecewise continuous variable with different coefficients based on whether the patient is aged 0-13 years old, 14-60 years old, or 61+ years old.
	Sex: Determine each patient's sex from EQRS.
	Race (White, Black, Asian/Pacific Islander (API), Native American or other): We determine race from EQRS, Medical Evidence Form (CMS-2728), and the CMS Medicare EDB file.
	Ethnicity (Hispanic, non-Hispanic or unknown): Determine ethnicity from EQRS, patient's CMS-2728, and the CMS Medicare Enrollment Database File.
	Diabetes as cause of ESRD: Determine each patient's primary cause of ESRD from patient's CMS 2728, and EQRS.

Stratification Details/Variables (CMS CBE Measure Submission Form, Measure Specifications

3.12

Duration of ESRD: Determine each patient's length of time on dialysis using the first service date from patient's CMS-2728, EQRS, Medicare claims history (all claim types), OPTN data (Dialysis Facility Measures only). The data is categorized as less than one year, 1-2 years, 2-3 years, or 3+ years as of the period start date.

Nursing home status: Uses multiple sources* including the CMS Nursing Home MDS. Determine each patient's nursing home status in previous 365 days and categorize as none (0 days), short-term nursing home (0-89 days), or long-term nursing home (>=90 days).

BMI at incidence: Calculate each patient's BMI as the height and weight provided on patient's CMS-2728. BMI is categorized as less than 18.5%, 18.5-24.9%, 25-29.9%, and greater than 30%. Patient BMI is grouped as greater than 30% when either missing, or outside the range of 10 to 70 for adults or 5 to 70 for children.

Comorbidities at incidence: Determine each patient's comorbidities at incidence from patient's CMS-2728 namely, alcohol dependence, atherosclerotic heart disease, cerebrovascular disease,

chronic obstructive pulmonary disease, congestive heart failure, diabetes (includes currently on insulin, on oral medications, without medications, and diabetic retinopathy), drug dependence, inability to ambulate, inability to transfer, malignant neoplasm, cancer, other cardiac disease, peripheral vascular disease, and tobacco use (current smoker). Each comorbidity is included as a separate indicator in the model, having a value of 1 if the patient has that comorbidity, and a value of 0 otherwise. Another categorical indicator variable is included as a covariate in the stage 1 model to flag records where patients have at least one comorbidity. This variable has a value of 1 if the patient has at least one comorbidity and a value of 0 otherwise.

Prevalent comorbidities: We identify a patient's prevalent comorbidities based on claims from the previous calendar year. The specific list of ICD codes used for adjustment related to this edition of the Manual, can be found on the ESRD QIP section of CMS.gov. These ICD codes are then grouped using comorbidity groups defined by the 2019.1 version of the AHRQ CCS. See https://dialysisdata.org/content/dfccmethodology for a full list of the AHRQ categories used in the model adjustment.

Calendar year

MA coverage: Calculate the proportion of time during the treatment period that the patient is enrolled in Medicare Advantage from Medicare EDB.

• COVID-19 diagnosis: Determines each patient's COVID-19 status based on inpatient Medicare claims. A claim record confirms a COVID-19 diagnosis if any COVID-19 diagnosis codes (ICD-10-CM: U071, B9729, J1282) are included as primary or secondary diagnoses. Secondary diagnoses include 2nd through 25th ordered diagnoses. Patients with an inpatient COVID-19 event on February 20, 2020 or later (including during the ECE period of March-June 2020) are identified as COVID-19 patients. To account for the time-dependent impact of COVID-19, patients are classified as being in a COVID-19 period immediately following an inpatient COVID-19 diagnosis, until death or until they survive 90 days post-infection. After 90 days, the COVID-19 indicator resets after the period of heightened risk for mortality due to COVID-19, and the patient is no longer classified as having COVID-19.

Categorical indicator variables are included as covariates in the stage 1 model to account for records with missing values for cause of ESRD, comorbidity at incidence (missing Medical Evidence Form (CMS-2728)), prevalent comorbidities, and BMI. These variables have a value of 1 if the patient is missing the corresponding variable and a value of 0 otherwise.

Beside main effects, two-way interaction terms between age, race, ethnicity, sex, duration of ESRD, and diabetes as cause of ESRD are also included:

- Age and Race: Black.
- Ethnicity and Race: Non-White.
- Diabetes as cause of ESRD and Race.
- Diabetes as cause of ESRD and Vintage.
- Duration of ESRD: less than or equal to 1 year and Race.
- Sex and Race: Black.

3.14	Type of Score (CMS CBE Measure Submission Form, Measure Specifications sp.20)
	 □ count □ rate/proportion ⋈ ratio □ categorical (e.g., yes or no) □ continuous variable (CV) (e.g., an average) □ composite/scale □ other (specify) Click or tap here to enter text.
3.15	Interpretation of Score (CMS CBE Measure Submission Form, Measure Specifications sp.21)
	Better quality = Lower score
3.16	Calculation Algorithm/Measure Logic (CMS CBE Measure Submission Form, Measure Specifications sp.22)
	See flowchart in Appendix.
3.17	Sampling (CMS CBE Measure Submission Form, Measure Specifications sp.25 and sp.26)
	N/A
3.18	Survey/Patient-Reported Data (CMS CBE Measure Submission Form, Measure Specifications
	sp.27)
	N/A
3.19	Data Source (CMS CBE Measure Submission Form, Measure Specifications sp.28)
	 □ administrative data □ claims data □ paper patient medical records □ electronic patient medical records □ electronic clinical data ☑ registries □ standardized patient assessments □ patient-reported data and surveys □ non-medical data

	\square other—describe in 3.20 (CMS CBE Measure Submission Form, Measure Specifications sp.29)
3.20	Data Source or Collection Instrument (CMS CBE Measure Submission Form, Measure Specifications sp.29)
	Multiple data sources are used for the calculation of this measure, including EQRS and Medicare claims. See attached data dictionary for more details.
3.21	Data Source or Collection Instrument (Reference) (CMS CBE Measure Submission Form, Measure Specifications sp.30)
	No data collection instrument provided
3.22	Level of Analysis (CMS CBE Measure Submission Form, Measure Specifications sp.07)
	individual clinician
	☐ group/practice
	☐ health plan☐ accountable care organization
	☐ geographic population
	☐ other (specify) Click or tap here to enter text.
3.23	Care Setting (CMS CBE Measure Submission Form, Measure Specifications sp.08)
	☐ ambulatory surgery center
	☐ clinician office/clinic
	\square outpatient rehabilitation
	\square urgent care – ambulatory
	☐ behavioral health: inpatient
	☐ behavioral health: outpatient
	☐ dialysis facility
	☐ emergency medical services/ambulance☐ emergency department
	□ home health
	□ hospice
	□ hospital
	☐ hospital: critical care
	\square hospital: acute care facility
	\square imaging facility
	☐ laboratory
	pharmacy
	nursing home/skilled nursing facility (SNF)
	☐ inpatient rehabilitation facility (IRF)
	☐ long-term acute care

	\square birthing center
	\square no applicable care setting
	\square other (specify) Click or tap here to enter text.
3.24	Composite Measure (CMS CBE Composite Measure Submission Form , Measure Specifications sp.30)
	N/A

REFERENCES