Centers for Medicare & Medicaid Services

Center for Clinical Standards and Quality

CMS ESRD Measures Manual for the 2025 Performance Period

Proposed

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1.   Introduction

The *CMS ESRD Measures Manual* (*Manual*) Version10.0 represents an effort to respond to strong stakeholder interest in the detailed specifications that underwrite reporting and clinical performance measures in the Centers for Medicare & Medicaid Services (CMS) End Stage Renal Disease (ESRD) quality programs during the Calendar Year (CY) 2025 Performance Period. CMS, along with its external partners, recognizes that seemingly minor and esoteric aspects of the measure specifications may have a substantial impact on measure scores. Accordingly, the *Manual* provides a transparent and detailed description of how CMS ESRD measures are calculated, offering the public a comprehensive understanding of how CMS evaluates the quality of care provided by dialysis facilities.

CMS has designed the *Manual* to serve as a resource for improving the reliability and validity of CMS ESRD measures. CMS envisions the *Manual* will enhance dialysis facilities' quality improvement efforts. The *Manual* should enable dialysis facilities to more accurately track and predict their performance in CMS ESRD quality programs, such as the ESRD Quality Incentive Program (QIP) and Dialysis Facility Measures on https://data.cms.gov/quality-of-care/medicare-dialysis-facilities (Dialysis Facility Measures). CMS believes that providing facilities with the information needed to anticipate their scores on CMS ESRD measures will enable them to improve their performance in CMS quality improvement programs and will ultimately lead to better care for patients with ESRD.

With this context in mind, the *Manual* is divided into a series of sections. Sections pertaining to individual CMS ESRD measures are further broken down into standardized subsections covering clinical evidence that support measure concepts, numerator and denominator calculations and definitions, and high-level lists of facility- and patient-level exclusions. Subsequent sections describe the processes used to determine exclusion criteria and calculate intermediary variables, methods for mapping facilities and interpreting changes in ownership, as well as methods used to assess dialysis facilities' overall quality care in the various CMS ESRD quality programs. In sum, the *Manual* provides an end-to-end, detailed description of how CMS evaluates the quality of dialysis care, recognizing that additional details will need to be documented in future versions of the *Manual*.

The *Manual* represents CMS's best attempt to articulate calculations that underwrite measure scores. Nevertheless, it is subregulatory guidance, and does not carry the same force as regulations and statutes.

2. Measurement Information

2.1 Vascular Access Type Clinical Measure: Hemodialysis Vascular Access: Long-term Catheter Rate (ESRD QIP and Dialysis Facility Measures)

2.1.1 Measure Name

Hemodialysis Vascular Access: Long-term Catheter Rate

2.1.2 Measure Description

Percentage of adult hemodialysis (HD) patient-months using a catheter continuously for three months or longer for vascular access. (Consensus-Based Entity [CBE] ID 2978)

2.1.3 Measure Rationale

Based upon data from the CMS Fistula First/Catheter Last initiative, a gradual trend towards lower catheter use has been observed among prevalent maintenance HD patients in the United States (US), declining from approximately 28% in 2006 to approximately 17.4% by March 2017. Furthermore, the percentage of maintenance HD patients using a catheter for at least three months has declined as well over this time period from nearly 12% to 10.6%. Continued monitoring of chronic catheter use is needed to sustain this trend.

2.1.4 Measure Type

Intermediate Clinical Outcome

2.1.5 Improvement Noted as Higher or Lower Rate

A lower rate indicates better quality.

2.1.6 Numerator Statement

The number of adult patient-months in the denominator who were on maintenance HD using a catheter continuously for three months or longer as of the last HD session of the reporting month.

2.1.7 Facility Exclusions

- Facilities that treat fewer than 11 eligible patients during the calendar year.

- Calculations will exclude the months covered by a granted Extraordinary Circumstances Exception (ECE) (see Section 3.4).

2.1.8   Denominator Statement

All patient-months where the patient is at least 18 years old (see Section 3.1.3) as of the first day of the reporting month who are determined to be maintenance HD patients (in-center hemodialysis [ICHD] and home HD) for the complete reporting month at the same facility.

2.1.9   Denominator Exclusions

- Pediatric patients (<18 years old)
- Patient-months not on HD
- Patient-months with in-center or home HD for less than a complete reporting month at the same facility
- Patients not on ESRD treatment
- Patient-months in which a patient with limited life expectancy has a catheter in place. Limited life-expectancy is defined as:
  - Patients under hospice care in the current reporting month
  - Patients with metastatic cancer in the past 12 months
  - Patients with end stage liver disease in the past 12 months
  - Patients with coma or anoxic brain injury in the past 12 months

ESRD QIP Only:

For new facilities only, the month in which the CMS Certification Number (CCN) becomes effective and the following three months (see Section 3.5).

2.1.10   Denominator Details

Determination of patient assignment to the facility is derived from a combination of Medicare claims, the Medical Evidence Form (CMS-2728), and data from the EQRS. Determination of patient modality is derived from a combination of Medicare-paid dialysis claims, the Medical Evidence Form (CMS-2728), and data from EQRS (Dialysis Facility Measures only). See Section 3.1.1 for modality determination used in ESRD QIP calculations.

The patient's age is determined by subtracting the patient's date of birth from the first day of the reporting month. Patients that are <18 years old as of the first day of the reporting month are excluded from the reporting month. Months with vascular access type changes (e.g., fistula or graft to catheter) are not excluded from the denominator as long as patients are on HD and in the assigned facility for the entire month. In other words, if the patient was on HD and assigned to the facility the entire month, the patient-month would be included in the denominator regardless of their vascular access type during the month. In the month a patient changes modality or transfers, the patient-month is excluded from the denominator.

 For the exclusion of catheter patients with limited life expectancy, catheter use in the reporting month is defined as the EQRS "Access Type" having any of the following values: ("AV Fistula Combined with a Catheter", "AVFWCATHETER", "AV Graft Combined with a Catheter", "AVGWCATHETER", "Catheter Only", "CATHETERONLY", "Port Access Only", "PORTONLY", "Other/Unknown", "OTHERUNKNOWN", " " [missing]

Hospice information comes from CMS institutional Medicare Claims files that contain final action claims submitted by hospice providers (CLM_TYPE_CD=50). Once a beneficiary elects hospice, all hospice-related claims will be found in this file, regardless of whether the beneficiary is in Medicare fee-for-service or in a Medicare managed care plan.

Patients are identified as receiving hospice care if they have any final action claims submitted to Medicare by hospice providers in the current month.

Diagnoses of metastatic cancer, end stage liver disease, or coma in the past 12 months were determined from Medicare claims. Medicare claim types include inpatient admissions, outpatient claims (including dialysis claims), and physician services. Claims from providers, such as laboratories that report diagnosis codes when testing for the presence of a condition are excluded. Use the International Classification of Diseases (ICD) information related to this edition of the *Manual*, which can be found on the [Measuring Quality page](#) on the ESRD QIP section of CMS.gov for a detailed list of ICD-10 diagnostic codes used to identify these comorbidities.

2.1.11 Mapping Patients to Facilities

For each patient, we identify the dialysis provider in each month using a combination of Medicare claims, the Medical Evidence Form (CMS-2728), and data from EQRS. Patients are required to have been treated by the same facility for the complete month in order to be assigned to that facility for the reporting month.

To be included in the denominator for a particular reporting month, the patient must be receiving home or ICHD for the complete reporting month at the facility and be at least 18 years old as of the first day of the reporting month.

The monthly patient count at a facility includes all eligible prevalent and incident patients. The number of patient-months is determined by summing the number of months each patient is eligible for the measure during the reporting year. An individual patient may contribute up to 12 patient-months per year.

2.1.12 Calculating Numerators

The numerator is determined by calculating the facility-level number of patient-months with a long-term catheter in use. Long-term catheter use is defined as using a catheter, at the same facility, for at least three consecutive complete months as of the last HD session of the reporting month.

For a given month, if any of the following "Access Types" in EQRS are reported as "AV Fistula Combined with a Catheter", "AVFWCATHETER", "AV Graft Combined with a Catheter", "AVGWCATHETER", "Catheter Only", "CATHETERONLY", "Port Access Only", "PORTONLY", "Other/Unknown", "OTHERUNKNOWN", or " " (missing), a catheter is considered in use. If a catheter has been recorded for three consecutive months (i.e., in the reporting month and the immediate two preceding months) at the same facility, the reporting month is counted in the numerator. Therefore, a Catheter combined with any other access type,

missing, unknown, or port access are treated as Catheter if reported in current and prior two months. If multiple vascular access types for a patient were reported during a reporting month, the last vascular access type reported by the assigned facility is used in the calculation. If the vascular access type is missing from the assigned facility, we will substitute with the last vascular access type reported by other facilities.

If a patient changes dialysis facilities, the counting of the three consecutive complete months restarts at the new facility. Patients have to be treated with HD using a catheter for at least three complete months at the same facility to be included in the numerator. If a patient's first and second months fall into the reporting period, it is possible that these two months are included in the denominator (if eligible) but not in the numerator.

2.1.13   Data Elements and Data Source

EQRS, Medicare Claims and the CMS Medical Evidence Form (CMS 2728) are used as the data sources for establishing the denominator. EQRS is the data source for establishing the numerator. Medicare claims are used for the comorbidity conditions exclusion criteria.

Variable	Primary Data Source
Facility CCN	CMS data sources[1]
Reporting year and month	EQRS
Vascular access type	EQRS
Date of birth	CMS data sources[1]
Date of first ESRD service	Medical Evidence Form (CMS-2728)
Age at the first day of reporting month	CMS data sources[1]
Primary type of treatment ID (EQRS dialysis type)	EQRS
Hospice status in the current month[4]	Medicare Claims CMS Hospice file[2]
Metastatic cancer reported on Medicare Claims in past 12 months[4]	Medicare Claims[3]
End-Stage Liver Disease reported on Medicare Claims in past 12 months[4]	Medicare Claims[3]
Coma or anoxic brain damage reported on Medicare Claims in past 12 months[4]	Medicare Claims[3]

Table 1: Data Elements and Sources for the Vascular Access Type Clinical Measure: Hemodialysis Vascular Access: Long-term Catheter Rate (ESRD QIP and Dialysis Facility Measures)

1. This may include information from: EQRS, Medicare Enrollment Database (EDB), Medical Evidence Form (CMS 2728), Medicare Claims, and Organ Procurement and Transplantation Network Database (OPTN – Dialysis Facility Measures only)

2.   Hospice information comes from CMS institutional Medicare Claims files that contain final action claims submitted by hospice providers (CLM_TYPE_CD=50). Once a beneficiary elects hospice, all hospice related claims will be found in this file, regardless of whether the beneficiary is in Medicare fee-for-service or in a Medicare managed care plan.

3.   Medicare claims include Part A claims such as inpatient admissions and Part B claims such as outpatient claims (including dialysis claims), and physician services. Claims from providers, such as laboratories, that report diagnosis codes when testing for the presence of a condition are excluded.

4.   Exclusion factors: A detailed list of ICD-10 diagnostic codes used to identify exclusion comorbidities is included in this file (use the ICD information related to this edition of the *Manual*, which can be found on the Measuring Quality page on the ESRD QIP section of CMS.gov)

2.1.14   Flowchart

Figure 1 provides a flowchart that represents the processes used to calculate the Vascular Access Type (VAT) Clinical Measure: Hemodialysis Vascular Access: Long-term Catheter Rate.

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VAT Long Term Catheter Rate: Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access.

Legend

Process	Calculation	Excluded
Decision	Data Source	

Determine eligibility of patient-months

EQRS*

Is patient in a facility on home or in-center hemodialysis for the full reporting month of service AND At least 18 years old as of the first day of the reporting month? — **No** → Not in Patient Population

Yes

Are patient months with catheter use defined as EQRS Access Type** AND with limited life expectancy defined by one or more of the following: Patients under hospice care in the current reporting month; Patients with metastatic cancer in the past 12 months; Patients with end stage liver disease in the past 12 months; Patients with coma or anoxic brain injury in the past 12 months. — **Yes** → Not in Patient Population

No

Denominator

Has EQRS Access Type of catheter use** been recorded each month for at least three consecutive complete reporting months as of the last HD session of the reporting month? — **No** → Not in Numerator

Yes

Numerator → **Catheter rate = Numerator/ Denominator**

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**Figure 1: Vascular Access Type Clinical Measure: Hemodialysis Vascular Access: Long-term Catheter Rate Flowchart
(ESRD QIP and Dialysis Facility Measures)**

*   Multiple data sources included in EQRS are the CMS Annual Facility Survey (CMS-2744), Medicare dialysis and hospital payment records, and the CMS Medical Evidence Form (CMS-2728). Other sources include transplant data from the Organ Procurement and Transplant Network (OPTN) (Dialysis Facility Measures only), the Death Notification Form (CMS-2746), the Dialysis Facility Compare (Dialysis Facility Measures) and the Social Security Death Master File (Dialysis Facility Measures only).

**   For a given month, if any of the following "Access Types" in EQRS are reported as "AV Fistula Combined with a Catheter", "AVFWCATHETER", "AV Graft Combined with a Catheter", "AVGWCATHETER", "Catheter Only", "CATHETERONLY", "Port Access Only", "PORTONLY", "Other/Unknown", "OTHERUNKNOWN", or " " (missing), a catheter is considered in use.

2.1.15   Selected References

- National Kidney Foundation: DOQI Clinical Practice Guidelines for Vascular Access, http://www.kidney.org/professionals/KDOQI/guidelines_commentaries.

- Grubbs V, Wasse H, Vittinghoff E, Grimes BA, Johansen KL. Health status as a potential mediator of the association between hemodialysis vascular access and mortality. Nephrol Dial Transplant. 2014;29(4):892-8.

- ESRD Vascular Access Technical Expert Panel (TEP) Summary Report, https://dialysisdata.org/sites/default/files/content/ESRD_Measures/ESRD_Vascular_Access_TEP_Summary_Report.pdf.

2.2 Hemodialysis Vascular Access: Standardized Fistula Rate (Dialysis Facility Measures Only)

2.2.1 Measure Name

Hemodialysis Vascular Access: Standardized Fistula Rate (SFR)

2.2.2 Measure Description

Adjusted percentage of adult HD patient-months using an autogenous arteriovenous fistula (AVF) as the sole means of vascular access.

2.2.3 Measure Rationale

The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI) guidelines state the following: 1) AV fistulas have the lowest rate of thrombosis and require the fewest interventions, 2) cost of AV fistula use and maintenance is the lowest, 3) fistulas have the lowest rates of infection, and 4) fistulas are associated with the highest survival and lowest hospitalization rates. Indeed, a number of epidemiologic studies consistently demonstrate the reduced morbidity and mortality associated with greater use of AV fistulas for vascular access in maintenance HD.

As the accompanying literature review indicates, there are a growing number of studies reporting that creating AVF in some patients is less likely to be successful in the presence of certain comorbidities. In addition, certain patient groups may have less incremental benefit from an AV fistula relative to an AV graft. By adjusting the fistula rate for patient characteristics and comorbidities associated with low AV fistula success rates, this measure accounts for patients where a graft or even a catheter may be a more appropriate option.

Since the CY 2018 ESRD PPS final rule, there have been several changes to what many experts consider to be best practices with respect to vascular access in ESRD patients due to improvements in the care of ESRD patients overall, changes in patient demographics, and increasing patient longevity (88 FR 42500). Guidance published in 2019 by the NKF KDOQI reflects updated best practices. The KDOQI's 2019 guidance notes that prior guidelines and initiatives have emphasized a "fistula first" approach to vascular access choice due to the AV fistula's associations with better short-term results compared with other vascular access types. However, the 2019 guidance also notes that more recent data have challenged these associations because of the high complication rates of AV fistula maturation failure requiring intervention. Therefore, following re-evaluation of this Fistula First approach, the KDOQI's 2019 guidance concludes that the Fistula First approach should no longer be considered a clinical best practice. Instead, the KDOQI's 2019 guidance concludes that a patient-centered approach to HD vascular access that is based on a consideration of the patient's needs and dialysis access eligibility is preferred. Providers should consider what would be most appropriate for the individual patient, including that AV fistula may not always be most appropriate based on the individual patient's needs.

After considering these evolving best practices and the KDOQI's 2019 guidance, we have determined that the Standardized Fistula Rate Clinical Measure does not provide patients and their healthcare providers the necessary level of flexibility to choose the most suitable AV access (88 FR 42500). Patients, in consultation with their healthcare providers, should have the flexibility to choose AV access (either AV fistula or AV graft) where appropriate to their specific patient characteristics and treatment plans. This determination should be based on the healthcare provider's best clinical judgment that considers the vessel characteristics, patient comorbidities, health circumstances, and patient preference.

2.2.4   Measure Type

Intermediate Clinical Outcome

2.2.5   Improvement Noted as Higher or Lower Rate

A higher rate indicates better quality.

2.2.6   Risk Adjustment

Statistical risk model.

2.2.7   Numerator Statement

The numerator is the adjusted count of adult patient-months using an AVF as the sole means of vascular access as of the last HD treatment session of the month.

2.2.8   Facility Exclusions

- Facilities that treat fewer than 11 eligible patients during the calendar year.
- Calculations will exclude the months covered by a granted ECE (see Section 3.4).

2.2.9   Denominator Statement

All patient-months where the patient is at least 18 years old (see Section 3.1.3) as of the first day of the reporting month who are determined to be maintenance HD patients (in-center and home HD) for the entire reporting month at the same facility.

2.2.10   Denominator Exclusions

- Pediatric patients (<18 years old)
- Patient-months not on HD
- Patient-months with in-center or home HD for less than a complete reporting month at the same facility
- Patients not on ESRD treatment
- Patient-months in which a patient with limited life expectancy has a catheter in place. Limited life-expectancy is defined as:
  - o Patients under hospice care in the current reporting month
  - o Patients with metastatic cancer in the past 12 months

- o Patients with end stage liver disease in the past 12 months
- o Patients with coma or anoxic brain injury in the past 12 months

2.2.11 Denominator Details

Determination of patient assignment to the facility is derived from a combination of Medicare claims, the Medical Evidence Form (CMS-2728), and data from EQRS. Determination of patient modality is derived from a combination of Medicare-paid dialysis claims, the Medical Evidence Form (CMS-2728), and data from EQRS (Dialysis Facility Measures only). The patient's age is determined by subtracting the patient's date of birth from the first day of the reporting month. Patients that are <18 years old as of the first day of the reporting month are excluded.

For the exclusion of catheter patients with limited life expectancy, catheter use in the reporting month is defined as the EQRS "Access Type" having any of the following values: ("AV Fistula Combined with a Catheter", "AVFWCATHETER", "AV Graft Combined with a Catheter", "AVGWCATHETER", "Catheter Only", "CATHETERONLY", "Port Access Only", "PORTONLY", "Other/Unknown", "OTHERUNKNOWN", " " [missing]).

Hospice information comes from CMS institutional Medicare Claims files that contain final action claims submitted by hospice providers (CLM_TYPE_CD=50). Once a beneficiary elects hospice, all hospice-related claims will be found in this file, regardless of whether the beneficiary is in Medicare fee-for-service or in a Medicare managed care plan.

Patients are identified as receiving hospice care if they have any final action claims submitted to Medicare by hospice providers in the current month.

Diagnoses of metastatic cancer, end stage liver disease, or coma in the past 12 months were determined from Medicare claims. Medicare claim types include inpatient admissions, outpatient claims (including dialysis claims), and physician services. Claims from providers, such as laboratories that report diagnosis codes when testing for the presence of a condition are excluded. Use the ICD information related to this edition of the *Manual*, which can be found on the Measuring Quality page on the ESRD QIP section of CMS.gov for a detailed list of ICD-10 diagnostic codes used to identify these comorbidities.

2.2.12 Mapping Patients to Facilities

For each patient, we identify the dialysis provider at each month using a combination of Medicare claims, the Medical Evidence Form (CMS-2728), and data from EQRS. Patients are required to have been treated by the same facility for the complete month in order to be assigned to that facility for the reporting month.

To be included in the denominator for a particular reporting month, the patient must be receiving home or ICHD for the complete reporting month at the facility and be at least 18 years old as of the first day of the month.

The monthly patient count at a facility includes all eligible prevalent and incident patients. The number of patient-months is determined by summing the number of months each patient is

eligible for the measure during the reporting year. An individual patient may contribute up to 12 patient-months per year.

2.2.13   Calculating Numerators

The numerator is determined by number of patient-months using an AVF as the sole means of vascular access at a given facility, adjusted for patient-mix. An AVF is considered in use if the EQRS "Access Types" of "AV Fistula Only (with 2 Needles)", "AVFONLY", "AV Fistula single needle device", or "AVFSINGLE" has been recorded for a given month. If multiple vascular access types for a patient were reported during a reporting month, the last vascular access type reported by the assigned facility is used in the calculation. If the vascular access type is missing from the assigned facility, we will substitute with the last vascular access type reported by other facilities.

2.2.14   Statistical Risk Model and Variables

The SFR measure is a directly standardized percentage, in that each facility's percentage of AVF use is adjusted to the national distribution of covariates (risk factors) (with 'national' here referring to all facilities combined). The SFR for a facility is an estimate of what the facility's percentage of AVF would equal if the facility's patient mix was equal to that of the nation as a whole. The measure is adjusted for patient demographic and clinical characteristics based on a logistic regression model. This model is limited to ESRD facilities treating at least 11 eligible patients during the performance period and includes the facility indicators and assumes that the regression coefficients of risk factors are the same across all facilities. The common risk effects are assumed in order to improve computational stability in estimating facility-specific effects.

The patient characteristics included in the logistic regression model as covariates are:

- Age categories: 18-24, 25-59, 60-74, and 75+
- Body mass index (BMI) at incidence, calculated based on the height and weight provided on patient's Medical Evidence Form (CMS-2728). BMI is divided into the following categories: BMI < 18.5, $18.5 \leq$ BMI < 25, $25 \leq$ BMI < 30, or BMI $\geq$ 30. Missing and out-of-range BMIs are categorized into the mode group (i.e., $\geq$30).
- Nursing home status in prior 12 months
    - o   No nursing home care: 0 days
    - o   Short-term nursing home: 1-89 days
    - o   Long-term nursing home: >90 days
- Nephrologist's care prior to ESRD incidence reported on the Medical Evidence Form (CMS-2728).
- Duration of ESRD categories: 0-1 year, >1-5 years, >5-9 years, and >9 years.
- Inability to ambulate/transfer at ESRD incidence as reported on the Medical Evidence Form (CMS-2728) and combined into one indicator variable.
- Diabetes as primary cause of ESRD as reported on the Medical Evidence Form (CMS-2728).

- Comorbidities either at ESRD incidence as reported on the Medical Evidence Form (CMS-2728) or the Medicare eligible months (below) together with prevalent comorbidities based on Medicare claims filed in prior 12 months. Use the ICD information related to this edition of the *Manual*, which can be found on the Measuring Quality page on the ESRD QIP section of CMS.gov for list of codes used to identify these conditions.
    - Diabetes (NOT as primary cause of ESRD)
    - Heart diseases (i.e., coronary artery disease and congestive heart failure)
    - Peripheral vascular disease
    - Cerebrovascular disease
    - Chronic obstructive pulmonary disease
    - Anemia (unrelated to ESRD/chronic kidney disease [CKD])
    - Non-Vascular Access-Related Infections
    - Drug dependence
- Indicator for having at least one of the comorbid conditions listed above.
- Indicator for missing a CMS-2728 form.
- Indicator for Medicare coverage for at least 6 months or Medicare Advantage coverage at least 1 month during the past 12 months*.

    *Medicare and Medicare Advantage coverages defined as follows:

    - The patient had $1,200+ of Medicare-paid dialysis claims or at least one Medicare inpatient claim (hospital or Skilled Nursing Facility [SNF]) during that month or one of the two prior months.
    - The Medicare EDB indicates the patient was enrolled in Medicare Advantage during the month.

Let n_i be the number of patients treated at the ith facility (for $i = 1,\ldots,F$), x_{ijm} be a vector of the patient characteristics, and p_{ijm} be the probability of dialyzing with an AVF for the jth patient in the ith facility (for $j = 1,\ldots,n_i$) in the mth month. To estimate facility effects, we use the following logistic regression model:

$$\text{logit}(p_{ijm}) = \alpha_i + \beta'x_{ijm},$$

and denote the resulting estimates of facility effects $(\alpha_1,\ldots,\alpha_F)$ by $(a_1,\ldots,a_F)$ and the estimates of the risk effects β by b.

The model is fitted using Generalized Estimating Equations (GEE; Liang and Zeger, 1986) in order to account for the correlation within patients across months. With over 7,000 facilities, it is difficult to estimate all parameters (i.e., including the facility indicators) simultaneously. Therefore, we break the fitting process into two stages. At the first stage, we estimate the β vector by averaging 10 random subgroups of approximately 700 facilities each. At the second stage, we then estimate the α_i I1,..., 7,000) by fitting facility-specific intercept-only GEE models, with the linear predictor from the first stage, $\beta'x_{ijm,}$ serving as an offset. Per well-established GEE results (e.g., Liang and Zeger, 1986), the estimator of α_i is consistent for its target value and

follows a normal distribution with standard error given by the robust 'sandwich' estimator computed via GEE. We can then compute SFR_i for each facility i as follows:

$$SFR_k = \sum_i \sum_j \sum_m exp(a_k + b'x_{ijm}) / \{1 + exp(a_k + b'x_{ijm})\} / \text{n},$$

where n = total number of patient-months included in the overall population.

2.2.15   Data Elements and Data Sources

EQRS, Medicare Claims, and the CMS Medical Evidence Form 2728 are used as the data sources for establishing the denominator (Table 2). EQRS is the data source for establishing the numerator. Medicare claims and the CMS Medical Evidence Form 2728 are data sources for the risk adjustment factors. Medicare claims and EQRS are used for the exclusion criteria.

Variable	Primary Data Source
Facility CCN	CMS data sources[1]
Reporting year and month	EQRS
Vascular access type	EQRS
Date of birth	CMS data sources[1]
Date of first ESRD	Medical Evidence Form (CMS-2728) EQRS Patient Events Medicare Claims[3] OPTN Database
Age at the first day of reporting month	CMS data sources[1]
BMI at incidence	Medical Evidence Form (CMS-2728)
Nursing home status (in the previous CY)	CMS Minimum Data Set
Primary type of treatment ID (EQRS dialysis type)	EQRS
Nephrologist's care prior to ESRD	Medical Evidence Form (CMS-2728)
Diabetes - Primary cause of ESRD	Medical Evidence Form (CMS-2728) EQRS
Diabetes –Not as primary cause of ESRD [5]	Medicare Claims[3] Medical Evidence Form (CMS-2728)
Heart failure[5]	Medicare Claims[3] Medical Evidence Form (CMS-2728)

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Variable	Primary Data Source
Other heart diseases[5]	Medicare Claims[3] Medical Evidence Form (CMS-2728)
Peripheral vascular disease[5]	Medicare Claims[3] Medical Evidence Form (CMS-2728)
Cerebrovascular disease[5]	Medicare Claims[3] Medical Evidence Form (CMS-2728)
Chronic obstructive pulmonary disease[5]	Medicare Claims[3] Medical Evidence Form (CMS-2728)
Drug dependence[5]	Medicare Claims[3] Medical Evidence Form (CMS-2728)
Inability to ambulate/transfer	Medical Evidence Form (CMS-2728)
Anemia (unrelated to ESRD/CKD)[5]	Medicare Claims[3]
Non-vascular access-related infections: pneumonias/ hepatitis/HIV/AIDS/tuberculosis[5]	Medicare Claims[3]
Not having at least 6-month Medicare eligible in past 12 months	Medicare Claims[3]
Hospice status in the current month[4]	CMS Hospice file[2]
Metastatic cancer reported on Medicare Claims in past 12 months[4]	Medicare Claims[3]
End-stage liver disease reported on Medicare Claims in past 12 months[4]	Medicare Claims[3]
Coma or anoxic brain damage reported on Medicare Claims in past 12 months[4]	Medicare Claims[3]

Table 2: Data Elements and Sources for Hemodialysis Vascular Access: Standardized Fistula Rate (Dialysis Facility Measures Only)

1. This may include information from: EQRS, Medicare Enrollment Database (EDB), Medical Evidence Form (CMS 2728), Medicare Claims, and Organ Procurement and Transplantation Network Database– (OPTN - Dialysis Facility Measures only). For Dialysis Facility Measures only, unique patients are identified by using a combination of social security number (SSN), first name, surname, sex, Medicare Beneficiary ID, Patient Health Insurance Claim Number and birth date. Dialysis Facility Measures runs a matching process to ensure that minor typos and misspellings do not cause a patient record to fall out of their history. The matching process is able to successfully match 99.5% of patients. The remaining patients have incomplete or incorrect data that does not allow them to be matched.

2. Hospice information comes from CMS institutional Medicare Claims files that contain final action claims submitted by hospice providers (CLM_TYPE_CD=50). Once a beneficiary elects hospice, all hospice related claims will be found in this file, regardless of whether the beneficiary is in Medicare fee-for-service or in a Medicare managed care plan.

3. Medicare claims include Part A claims such as inpatient admissions and Part B claims such as outpatient claims (including dialysis claims) and physician services. Claims from providers, such as laboratories, that report diagnosis codes when testing for the presence of a condition are excluded.

4. Exclusion factors: A detailed list of ICD-10 diagnostic codes and Healthcare Common Procedure Coding System (HCPCS) current procedural terminology (CPT) codes used to identify comorbidities in this edition of the *Manual*, can be found on the Measuring Quality page on the ESRD QIP section of CMS.gov.

5. Comorbidities were identified by combining prevalent comorbidities reported on all Medicare Claims in the past 12 months and incident comorbidities reported on the Medical Evidence Form (CMS-2728). A detailed list of ICD-10 diagnostic codes and HCPCS CPT codes used to identify comorbidities from Medicare Claims related to this edition of the *Manual*, can be found on the Measuring Quality page on the ESRD QIP section of CMS.gov.

2.2.16   Flowchart

Figure 2 provides a flowchart that represents the processes used to calculate the Standardized Fistula Rate.

Standardized Fistula Rate: Adjusted percentage of adult hemodialysis patient-months using an autogenous arteriovenous fistula (AVF) as the sole means of vascular access.

EQRS*

Is patient in a facility on home or in-center hemodialysis for the full reporting month of service AND At least 18 years old as of the first day of the reporting month?

No → Not in Patient Population

Yes

Are patient months with catheter use defined as EQRS Access Type** AND with limited life expectancy defined by one or more of the following: Patients under hospice care in the current reporting month; Patients with metastatic cancer in the past 12 months; Patients with end stage liver disease in the past 12 months; Patients with coma or anoxic brain injury in the past 12 months.

Yes → Not in Patient Population

No

Denominator

Yes

An AVF is in use at the last treatment of the month where the EQRS "Access Types" of "AV Fistula Only (with 2 Needles)", "AVFONLY", "AV Fistula single needle device", or "AVFSINGLE" is reported

No → Not in Numerator

Yes

Adjusted for age, BMI, nursing home status, duration of ESRD, nephrologist care prior to ESRD, inability to ambulate/transfer, diabetes as primary cause of ESRD, incident and prevalent comorbidities (Diabetes NOT as primary cause of ESRD), Heart Failure, Other Heart Diseases, Peripheral Vascular Disease, Cerebrovascular Disease, Chronic Obstructive Pulmonary Disease, Drug Dependence, Anemia (unrelated to ESRD/CKD), Non-Vascular Access-Related Infections), Indicator for at least one of comorbid conditions above, Indicator for missing CMS 2728 form, and Indicator for Medicare coverage for at least 6 months during the past 12 months or Medicare Advantage coverage at least 1 month during the past 12 months.

Apply Model Adjustment

Numerator

Facility SFR = Numerator/Denominator

Legend

Exclusion

Decision

Calculation

Adjustment

Data Source

Figure 2: Hemodialysis Vascular Access: Standardized Fistula Rate (Dialysis Facility Measures Only)

*Multiple data sources include CMS EQRS (the CMS Annual Facility Survey (CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN) (Dialysis Facility Measures only), the Death Notification Form (CMS-2746), the Dialysis Facility Compare (Dialysis Facility Measures) and the Social Security Death Master File (Dialysis Facility Measures only).

**For a given month, if any of the following "Access Types" in EQRS are reported as "AV Fistula Combined with a Catheter", "AVFWCATHETER", "AV Graft Combined with a Catheter", "AVGWCATHETER", "Catheter Only", "CATHETERONLY", "Port Access Only", "PORTONLY", "Other/Unknown", "OTHERUNKNOWN", or " " (missing), a catheter is considered in use.

2.2.17   Selected References

- National Kidney Foundation K/DOQI Clinical Practice Guidelines and Clinical Practice Recommendations for 2006 Updates: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy and Vascular Access. Am J Kidney Dis 48:S1-S322, 2006 (suppl 1). http://www.kidney.org/professionals/KDOQI/guidelines_commentaries
- Liang KY, Zeger SL. Longitudinal Data Analysis Using Generalized Linear Models. Biometrika. 1986; 73:13–22.
- Lok CE, Huber TS, Lee T, et al; KDOQI Vascular Access Guideline Work Group. KDOQI clinical practice guideline for vascular access: 2019 update. Am J Kidney Dis. 2020;75(4)(suppl 2):S1-S164.
- KDOQI clinical practice guidelines for vascular access. Am J Kidney Dis. 2006;48:S176-S247.

2.3   Adult Hemodialysis Kt/V Adequacy Measure (ESRD QIP and Dialysis Facility Measures)

2.3.1   Measure Name

Delivered Dose of Hemodialysis Above Minimum

2.3.2   Measure Description

Percentage of all adult ($\geq$18 years old) patient-months in the sample for analysis who were on ESRD treatment for 91 days or more and dialyzed greater than 2 and less than 4 times weekly whose delivered dose of HD (calculated from the last measurements of the month using the Urea Kinetic Modeling (UKM) or Daugirdas II formula) was a single pool (sp)Kt/V $\geq$ 1.2 during the study period (CBE ID 0249).

2.3.3   Measure Rationale

The dose of dialysis is used to estimate the ability of HD to clear the blood of accumulated toxins. In the adult population, outcome studies, referenced below, have shown an association between dose of HD in terms of small solute removal and clinical outcomes. In addition, at least one prior study demonstrates that a change in dialysis dose is associated with a change in patient outcomes. Furthermore, the studies referenced below demonstrate an association between dialysis adequacy as measured by Kt/V and outcomes. Also, although higher dialysis dose is associated with improvement in clinical outcomes, analysis of EQRS data from January 2010 indicates that only 66% of facilities had 70% or more of their patients receiving a dialysis dose of spKt/V of 1.2.

2.3.4   Measure Type

Intermediate outcome

2.3.5   Improvement Noted as Higher or Lower Rate

A higher rate indicates better quality.

2.3.6   Risk Adjustment

None.

2.3.7   Numerator Statement

Number of patient-months in denominator whose delivered dose of HD (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V $\geq$ 1.2 and also in range (spKt/V $\leq$ 5.0).

2.3.8　Facility Exclusions

Results from facilities that treat fewer than 11 eligible patients during the performance period are not reported on Dialysis Facility Care Compare and are not included in ESRD QIP calculations.

2.3.9　Denominator Statement

All patient-months for adult ($\geq$18 years old, see Section 3.1.3) patients in the sample for analysis who have had ESRD for 91 days or more, and dialyzing greater than 2 and less than 4 times weekly the entire month.

2.3.10　Denominator Exclusions

- Patient-months where the patient is not assigned to the same facility for the entire month.
- Patients younger than 18 years old as of the first day of the reporting month if EQRS data are used or as of the claim from date if claims data are used (see Section 3.1.3).
- Patient-months where the patient is not on HD the entire month.
- Patient-months for patients who were on ESRD treatment (see Section 3.1.2) for less than 91 days as of the first day of the reporting month.
- Patients-months where patients are not dialyzing greater than 2 and less than 4 times weekly (see Section 3.1.4).

ESRD QIP Only:

- Calculations will exclude the months covered by a granted ECE (see Section 3.4).
- For new facilities only, the month in which the CMS Certification Number (CCN) becomes effective and the following three months are excluded (see Section 3.5).

2.3.11　Mapping Patients to Facilities

A patient may only be assigned to **one** dialysis facility each month. For each patient, the dialysis provider at each point in time are identified primarily using data from EQRS, the Medical Evidence Form CMS-2728, and Medicare dialysis claims. Patient assignment to provider and modality (either HD or peritoneal dialysis [PD]) are both determined according to the information reported in the above-mentioned data sources.

For each reporting month, patients are required to have been indicated as treated by the facility for the complete month in order to be included in the denominator. If a patient transfers in or out of the facility, discontinues dialysis, recovers renal function, or dies anytime during the month, the entire patient-month is excluded. The number of sessions is not considered and the patient may not have received treatment at the facility for the entire month to be included. For example, if a patient is hospitalized or travels during the month, the patient may still be included in the facility's measure if they are indicated as the facility's patient that month according to the data as described above. Additionally, patients for whom the only evidence of dialysis treatment is the existence of Medicare claims are considered lost to follow-up and removed from a facility's analysis one year following the last claim, if there is no earlier evidence of transfer, recovery, or death. In other words, if a period of one year passes with neither Medicare dialysis claims nor

EQRS information to indicate that a patient is receiving dialysis treatment, we consider the patient lost to follow-up, and do not include the patient in the calculations.

2.3.12 Calculating Numerators

Number of patient-months in denominator whose delivered dose of HD (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a Kt/V $\geq$ 1.2 and Kt/V $\leq$ 5.0.

- If a patient has multiple in-range Kt/V values in EQRS during a month, then the last non-missing reported value is selected.
- If an in-range value was not found in EQRS for the patient during the month then the last reported non-missing value reported on the last eligible Medicare claim for the patient during the month is selected (when available). When Medicare claims are used, Kt/V values can be from any facility for Dialysis Facility Care Compare, and from assigned facility only for ESRD QIP.
  - A claim is considered eligible if it is from a HD patient who has ESRD for at least 91 days and is at least 18 years old (as of the claim-from date), and the claim is neither a "frequent" dialysis claim nor an "infrequent" dialysis claim as described in Section 3.1.4.
  - When there are multiple claims in a month, the Kt/V value from the last eligible claim with an in-range (less than or equal to 5.0) and not expired Kt/V value is selected. For ICHD patients, a Kt/V with an occurrence date from a previous month is defined as expired. For home HD patients, a Kt/V with an occurrence date more than four months prior to the claim through date is defined as expired.

2.3.13 Assigning Patient-Months to Numerators and Denominators

Once a Kt/V value for the patient-month has been selected, the following decision rules are used when considering whether to assign the patient-month to the numerator, denominator, or both:

- If selected Kt/V value is missing or not in the valid range (>5.0), include patient-month in the denominator but not the numerator.
- If selected Kt/V value is in the valid range ($\leq$ 5.0) and meets the Kt/V value threshold ($\geq$ 1.2), then include patient month in denominator and numerator.

2.3.14 Data Elements and Data Sources

The data elements used for this measure are listed below. A complete description of the data elements can be found at the ESRD section of QualityNet.gov.

EQRS Data Elements:

- Unique Patient Identifier (UPI)
- Facility CCN
- Patient date of birth
- Patient date of death

- Primary type of treatment ID (EQRS dialysis type)
- Number of dialysis sessions per week
- Medicare certified services offered
- Additional services offered (non-Medicare)
- Kt/V method
- Kt/V value
- Modality
- First date of ESRD (see Section 3.1.2)

Claims Based Data Elements:

Note: Only Type of Bill (TOB) 72x claims are considered in the measure calculation.

- Patient health insurance claim number
- Patient date of birth
- Patient date of death
- Claim related condition code
- Claim control number
- Claim-from date
- Claim through date
- Claim National Claims History (NCH) database daily process date
- Claim link number
- Claim occurrence date
- Claim occurrence code
- Claim CCN
- Claim value code D5
- Claim value amount
- Claim value sequence number
- Claim line institutional revenue center codes
- Claim line institutional revenue center date

2.3.15   Flowchart

Figure 3 provides a flowchart that represents the processes used to calculate the Adult HD Kt/V measure.

Centers for Medicare & Medicaid Services

Adult Hemodialysis (HD) Kt/V Dialysis Adequacy: Percent of all adult hemodialysis patient months for patients whose delivered dose of dialysis was greater than or equal to 1.2 during the reporting period.

Based on patients on ESRD treatment at the beginning of the reporting month when using EQRS; if claims are used, the 91 days is determined based on the claim-from date (first service date determined from CMS 2728, EQRS, claims, or transplant data).

Note: DOB is based on EQRS supplemented by claims. Age is calculated as of the beginning of the reporting month if EQRS is used, and the claim-from-date if claims are used.

Note for ESRD QIP only:
1. ECE months are not eligible, regardless of whether or not data are reported;
2. For new facilities only, the month in which the CCN becomes effective and the following three months are excluded.

Note: Kt/V values from EQRS can be obtained from any facility.

Missing Kt/V values or Kt/V =9.99 on claims (not reported) are excluded from numerator.

Facility must have at least 11 eligible patients to be scored on the measure or reported on DFCC.

For adult Home HD patients, if claims are used to determine Kt/V, the Kt/V does not have to be in the reporting month. The Kt/V reported on the claim must be within 4 months prior to the claim thru date.

Figure 3: Adult Hemodialysis (HD) Kt/V Dialysis Adequacy

2.3.16   Selected References

- Wolfe RA, Hulbert-Shearon TE, Ashby VB, Mahavadevan S, Port FK. Improvements in dialysis patient mortality are associated with Urea Reduction Ratio and Hematocrit, 1999 to 2002. Am J Kidney Dis 45(1):127-135, 2005.
- Wolfe RA, Ashby VB, Daugirdas JT, Agodoa LY, Jones CA, Port FK. Body size, dose of hemodialysis, and mortality. Am J Kidney Dis 35:80-88, 2000.
- Port FK, Ashby VB, Dhingra RK, Roys EC, Wolfe RA. Dialysis dose and body mass index are strongly associated with survival in hemodialysis patients. J Am Soc Nephrol 13:1061-1066, 2002.
- Port FK, Wolfe RA, Hulbert-Shearon TE, McCullough KP, Ashby VB, Held PJ. High dialysis dose is associated with lower mortality among women but not among men. Am J Kidney Dis 43:1014-1023, 2004.
- Daugirdas JT, Greene T, Chertow GM, Depner TA. Can Rescaling Dose of Dialysis to Body Surface Area in the HEMO Study Explain the Different Responses to Dose in Women versus Men? Clin J Am Soc Nephrol. 2010 Sep;5(9):1628-36.
- Daugirdas JT, Hanna MG, Becker-Cohen R, Langman CB. Dose of dialysis based on body surface area is markedly less in younger children than in older adolescents. Clin J Am Soc Nephrol. 2010 May;5(5):821-7.
- Lowrie EG, Li Z, Ofsthun NJ, Lazarus JM. Evaluating a new method to judge dialysis treatment using online measurements of ionic clearance. Kidney Int. 2006 Jul;70(1):211-7.

2.4 Adult Peritoneal Dialysis Kt/V Adequacy Measure (ESRD QIP and Dialysis Facility Measures)

2.4.1 Measure Name

Delivered Dose of PD Above Minimum

2.4.2 Measure Description

Percent of PD patient-months with Kt/V greater than or equal to 1.7 (dialytic + residual) during the four-month study period (CBE ID 0318).

2.4.3 Measure Rationale

Evaluation of PD adequacy every four months for adults is critical to ensure timely dose adjustment as needed, and adequate dialysis doses (Kt/V urea $\geq$ 1.7 for adult patients and Kt/V urea $\geq$ 1.8 for pediatric patients) have been linked to improved patient outcomes. Therefore, continued implementation of this measure is needed to ensure frequent adequacy measurement and adequate dialysis dosing. The studies referenced below have shown a Kt/V of 1.8/week or greater in adult PD patients was associated with better serum albumin levels and improved survival. The Adequacy of Peritoneal Dialysis in Mexico (ADEMEX) study did not show clinical benefit within weekly Kt/V doses exceeding 1.7/week in adult continuous ambulatory PD (CAPD) patients.

2.4.4 Measure Type

Intermediate Outcome

2.4.5 Improvement Noted as Higher or Lower Rate

A higher rate indicates better quality.

2.4.6 Risk Adjustment

None.

2.4.7 Numerator Statement

Patient-months in the denominator for patients whose delivered dose of PD was equal to or greater than 1.7 Kt/V (dialytic + residual, measured in the last 4 months) and also in range (Kt/V $\leq$ 8.5).

2.4.8 Facility Exclusions

Results from facilities that treat fewer than 11 eligible patients during the performance period are not reported on Dialysis Facility Care Compare and are not included in ESRD QIP calculations.

2.4.9   Denominator Statement

All patient-months for adult ($\geq$ 18 years old) patients in the sample for analysis who have had ESRD for 91 days and receiving PD the entire month.

2.4.10   Denominator Exclusions

- Patients-months where the patient is not assigned to the same facility for the entire month.

- Patients younger than age 18 years old as of the first day of the reporting month if EQRS data are used or as of the claim from date if claims data are used (Section 3.1.3).

- Patients-months where the patient is not on PD the entire month.

- Patients-months where the patient was on ESRD treatment (see Section 3.1.2) for less than 91 days as of the first day of the reporting month.

   ESRD QIP Only:
   - Calculations will exclude the months covered by a granted ECE (see Section 3.4).
   - For new facilities only, the month in which the CMS Certification Number (CCN) becomes effective and the following three months (see Section 3.5).

2.4.11   Mapping Patients to Facilities

See Section 2.3.11.

2.4.12   Calculating Numerators

Number of patients in denominator whose delivered dose of PD (dialytic + residual, calculated from the last measurements of the four-month study period) was a Kt/V $\geq$ 1.7 and Kt/V $\leq$ 8.5.

- If a patient has multiple in-range Kt/V values in EQRS during a month, then the last reported value is selected.

- If an in-range value was not found in EQRS for the patient during the month then the last reported non-missing value reported on the last eligible Medicare claim for the patient during the month is selected (when available). When Medicare claims are used, Kt/V values can be from any facility for Dialysis Facility Care Compare, and from assigned facility only for ESRD QIP.
   - A claim is considered eligible if it was from a PD patient who has ESRD for at least 91 days and is at least 18 years old (as of the claim-from date).
   - The last eligible claim with an in-range (less than or equal to 8.5) and not expired (Kt/V occurrence date more than four months prior to the claim through date) Kt/V value reported is selected when there were multiple claims reported in a month.

2.4.13   Assigning Patient-Months to Numerators and Denominators

Once a Kt/V value for the patient-month has been selected, the following decision rules are used when considering whether to assign the patient-month to the numerator, denominator, or both:

- If the selected Kt/V value is missing or not in the valid range (>8.5), include patient-month in the denominator but not the numerator.

- If selected Kt/V value is in valid range (≤8.5) and meets the Kt/V value threshold (≥1.7), then include the patient-month in denominator and the numerator.

2.4.14   Data Elements and Data Sources

The data elements used for this measure are listed below. A complete description of the data elements can be found at the ESRD section of QualityNet.gov.

EQRS Data Elements:

- UPI
- Facility CCN
- Patient date of birth
- Patient date of death
- Primary type of treatment ID (EQRS dialysis type)
- Medicare certified services offered as of 12/31 of the performance period
- Additional services offered (Non-Medicare) as of 12/31 of the performance period
- Kt/V value
- Modality
- First date of ESRD (see Section 3.1.2)

Claims Based Data Elements:

Note: Only Type of Bill (TOB) 72x claims are considered in the measure calculation.

- Claim related condition code
- Claim control number
- Claim-from date
- Claim through date
- Claim NCH daily process date
- Claim link number
- Claim occurrence code
- Claim occurrence date
- Claim CCN
- Claim value code D5

- Claim value amount
- Claim value sequence number
- Claim line institutional revenue center codes
- Claim line institutional revenue center date
- Patient health insurance claim number
- Patient date of death
- Patient date of birth

2.4.15   Flowchart

Figure 4 provides a flowchart that represents the processes used to calculate the Adult PD Kt/V measure.

Centers for Medicare & Medicaid Services

Adult Peritoneal Dialysis (PD) Kt/V Dialysis Adequacy: Percent of all adult peritoneal dialysis patient months for patients whose delivered dose of dialysis was greater than or equal to 1.7 during the reporting period.

Based on patients on ESRD treatment at the beginning of the reporting month when using EQRS; if claims are used, the 91 days is determined based on the claim-from date (first service date determined from CMS 2728, EQRS, claims, or transplant data).

Note: DOB is based on EQRS supplemented by claims. Age is calculated as of the beginning of the reporting month if EQRS is used, and the claim-from-date if claims are used.

Note for ESRD QIP only:
1. ECE months are not eligible, regardless of whether or not data are reported;
2. For new facilities only, the month in which the CCN becomes effective and the following three months are excluded.

Facility must have at least 11 eligible patients to be scored on the measure or reported on DFCC.

Note: Kt/V values from EQRS can be obtained from any facility.

Missing Kt/V values or Kt/V =9.99 on claims (not reported) are excluded from numerator.

Figure 4: Adult Peritoneal Dialysis (PD) Kt/V Dialysis Adequacy

2.4.16   Selected References

- Paniagua R, Amato D, Vonesh E, et al. Effects of increased peritoneal clearances on mortality rates in peritoneal dialysis: ADEMEX, a prospective, randomized, controlled trial." JASN.2002 13:1307-20.

- Lo WK, Lui SL, Chan TM, Li FK, Lam MF, Tse KC, Tang SC, Choy CB, Lai KN. Minimal and optimal peritoneal Kt/V targets: Results of an anuric peritoneal dialysis patient´s survival analysis. Kidney Int. 2005; 67:2032-8.

2.5 Pediatric Hemodialysis Kt/V Adequacy Measure (ESRD QIP and Dialysis Facility Measures)

2.5.1 Measure Name

Minimum spKt/V for Pediatric Hemodialysis Patients

2.5.2 Measure Description

Percentage of all pediatric ($\leq$ 18 years old) patient-months in the sample for analysis who were on ESRD treatment for 91 days or more and dialyzing greater than two and less than four times weekly whose delivered dose of HD (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V $\geq$ 1.2 during the study period (CBE ID 1423).

2.5.3 Measure Rationale

In considering target spKt/V, the pediatric HD population should receive at least a spKt/V of 1.2, which is the minimum requirement for the adult population in order to allow for the increased nutritional needs of children. Analysis of clinical process measure data further support this cutoff since adolescents with spKt/V below 1.2 were found to have significantly increased risk of hospitalization as compared to those with spKt/V of 1.2-1.4.

2.5.4 Measure Type

Intermediate Outcome

2.5.5 Improvement Noted as Higher or Lower Rate

A higher rate indicates better quality.

2.5.6 Risk Adjustment

None.

2.5.7 Numerator Statement

Number of patient-months in denominator whose delivered dose of HD (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V $\geq$ 1.2. Kt/V must also be in range (spKt/V $\leq$ 5.0).

2.5.8 Facility Exclusions

Results from facilities that treat fewer than 11 eligible patients during the performance period are not reported on Dialysis Facility Care Compare and are not included in ESRD QIP calculations.

2.5.9 Denominator Statement

All pediatric (<18 years old) patient-months in the sample for analysis who have had ESRD for 91 days or more and dialyzing greater than two and less than four times weekly the entire month.

2.5.10 Denominator Exclusions

- Patient-months for patients not assigned to the same facility for the entire month.
- Patients 18 years and older as of the first day of the reporting month if EQRS data are used or as of the claim from date if claims data are used (see Section 3.1.3).
- Patient-months for patients not on ICHD the entire month.
- Patient-months for patients who are on ESRD treatment (see Section 3.1.2) for less than 91 days as of the first of the month.
- Patient-months for patients not dialyzing greater than two and less than four times weekly (see Section 3.1.4).

ESRD QIP Only:

- Calculations will exclude the months covered by a granted ECE (see Section 3.4).
- For new facilities only, the month in which the CMS Certification Number (CCN) becomes effective and the following three months (see Section 3.5).

2.5.11 Mapping Patients to Facilities

See Section 2.3.11.

2.5.12 Calculating Numerators

Number of patient-months in denominator whose delivered dose of HD (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V $\geq$ 1.2 and spKt/V $\leq$ 5.0.

- If a patient has multiple in-range Kt/V values in EQRS during a month, then the last reported value is selected.
- If an in-range value was not found in EQRS for the patient during the month then the last reported non-missing value reported on the last eligible Medicare claim for the patient during the month is selected (when available). When Medicare claims are used, Kt/V values can be from any facility for Dialysis Facility Care Compare, and from assigned facility only for ESRD QIP.
  - A claim is considered eligible if it was from an HD (in-center) patient who has ESRD for at least 91 days and is under 18 years old (as of the claim-from date), and the claim is neither a "frequent" dialysis claim nor an "infrequent" dialysis claim as described in Section 3.1.4.
  - When there were multiple claims in a month, the Kt/V value from the last eligible claim with an in-range (less than or equal to 5.0) and not expired Kt/V value is selected. A Kt/V with an occurrence date from a previous month is defined as expired.

2.5.13   Assigning Patient-Months to Numerators and Denominators

Once a Kt/V value for the patient-month has been selected, the following decision rules are used when considering whether to assign the patient-month to the numerator, denominator, or both:

- If selected Kt/V value is missing or not in the valid range (>5.0), include patient-month in the denominator but not the numerator.

- If selected Kt/V value is in the valid range (≤ 5.0) and meets the Kt/V value threshold (≥ 1.2), then include patient month in denominator and numerator.

2.5.14   Data Elements and Data Sources

The data elements used for this measure are listed below. A complete description of the data elements can be found at the ESRD section of QualityNet.gov.

EQRS Data Elements:

- UPI
- Facility CCN
- Patient Date of birth
- Patient date of death
- Primary type of treatment ID (EQRS dialysis type)
- Number of dialysis sessions per week
- Medicare certified services offered as of 12/31 of the performance period
- Additional services offered (non-Medicare) as of 12/31 of the performance period
- Kt/V value
- Kt/V method
- Modality
- First date of ESRD (see Section 3.1.2)

Claims Based Data Elements:

Note: Only Type of Bill (TOB) 72x claims are considered in the measure calculation.

- Claim related condition code
- Claim control number
- Claim-from date
- Claim through date
- Claim NCH daily process date
- Claim link number
- Claim occurrence date
- Claim occurrence code

- Claim CCN
- Claim value code D5
- Claim value amount
- Claim value sequence number
- Claim line institutional revenue center codes
- Claim line institutional revenue center date
- Patient health insurance claim number
- Patient date of death
- Patient date of birth

2.5.15   Flowchart

Figure 5 provides a flowchart that represents the processes used to calculate the Pediatric HD Kt/V measure

Pediatric Hemodialysis (HD) Kt/V Dialysis Adequacy: Percent of all pediatric in-center hemodialysis patient months for patients whose delivered dose of dialysis was greater than or equal to 1.2 during the reporting period.

Based on patients on ESRD treatment at the beginning of the reporting month when using EQRS; if claims are used, the 91 days is determined based on the claim-from date (first service date determined from CMS 2728, EQRS, claims, or transplant data).

Note: DOB is based on EQRS supplemented by claims. Age is calculated as of the beginning of the reporting month if EQRS is used, and the claim-from-date if claims are used.

Note for ESRD QIP only:
1. ECE months are not eligible, regardless of whether or not data are reported;
2. For new facilities only, the month in which the CCN becomes effective and the following three months are excluded.

Note: Kt/V values from EQRS can be obtained from any facility.

Missing Kt/V values or Kt/V =9.99 on claims (not reported) are excluded from numerator.

Facility must have at least 11 eligible patients to be scored on the measure or reported on DFCC.

Figure 5: Pediatric Hemodialysis (HD) Kt/V Dialysis Adequacy

2.5.16   Selected References

- Frankenfield DL, Neu AM, Warady BA, Watkins SL, Friedman AL, Fivush BA. Adolescent hemodialysis: results of the 2000 ESRD Clinical Performance Measures Project. Pediatr Nephrol 2002; 17:10-15.

- Leonard MB, Stablein DM, Ho M, Jabs K, Feldman HI. Racial and center differences in hemodialysis adequacy in children treated at pediatric centers: a North American Pediatric Renal Transplant Cooperative Study (NAPRTCS) report. J Am Soc Nephrol. 2004 Nov;15(11):2923-32.

2.6 Pediatric Peritoneal Dialysis Kt/V Adequacy Measure (ESRD QIP and Dialysis Facility Measures)

2.6.1 Measure Name

Delivered Dose of Pediatric Peritoneal Dialysis Above Minimum

2.6.2 Measure Description

Percent of pediatric PD patient-months with Kt/V greater than or equal to 1.8 Kt/V (dialytic + residual) during the six-month study period.

2.6.3 Measure Rationale

Dialysis dose is an intermediate clinical outcome. The dose of dialysis is used to estimate the ability of PD to clear the blood of accumulated toxins. In the adult population, clinical practice guidelines have established an association between dose of PD in terms of small solute removal and clinical outcomes. These studies have shown a Kt/V of 1.8/week or greater in adult PD patients was associated with better serum albumin levels and improved survival.

Pediatric PD adequacy targets should be no lower than existing adult PD adequacy targets since generally, pediatric patients' greater metabolic demands require higher adequacy targets in terms of small solute clearance. No equivalent large scale clinical trials have been conducted in the pediatric PD population, but smaller scale observational studies support the association between delivered PD dose and patient outcomes including the potential for improved growth.

2.6.4 Measure Type

Intermediate outcome

2.6.5 Improvement Noted as Higher or Lower Rate

A higher rate indicates better quality.

2.6.6 Risk Adjustment

None.

2.6.7 Numerator Statement

Patient-months in the denominator for patients whose delivered dose of PD was equal to or greater than 1.8 Kt/V (dialytic+ residual, measured in the last six months). Kt/V must also be in range (Kt/V$\leq$ 8.5).

2.6.8 Facility Exclusions

Results from facilities that treat fewer than 11 eligible patients during the performance period are not reported on Dialysis Facility Care Compare and are not included in ESRD QIP calculations.

2.6.9   Denominator Statement

All pediatric (< 18 years old) patient-months in the sample for analysis who have had ESRD for 91 days and receiving PD the entire month.

2.6.10   Denominator Exclusions

- Patient-months for patients not assigned to the same facility for the entire month.
- Patients aged 18 years and older as of the first day of the reporting month if EQRS data are used or as of the claim from date if claims data are used (see Section 3.1.3).
- Patient-months for patients not on PD the entire month.
- Patient-months for patients who were on ESRD treatment (see Section 3.1.2) for less than 91 days as of the first of the month.

    ESRD QIP Only:

- Calculations will exclude the months covered by a granted ECE (see Section 3.4).
- For new facilities only, the month in which the CMS Certification Number (CCN) becomes effective and the following three months (see Section 3.5).

2.6.11   Mapping Patients to Facilities

See Section 2.3.11.

2.6.12   Calculating Numerators

Number of patients in denominator whose delivered dose of PD (dialytic + residual, calculated from the last measurements of the six-month study period) was a Kt/V ≥ 1.8 and Kt/V ≤ 8.5.

- If a patient has multiple in-range Kt/V values in EQRS during a month, then the last reported value is selected.
- If an in-range value was not found in EQRS for the patient during the month then the last reported non-missing value reported on the last eligible Medicare claim for the patient during the month is selected (when available). When Medicare claims are used, Kt/V values can be from any facility for Dialysis Facility Care Compare, and from assigned facility only for ESRD QIP.
  - A claim is considered eligible if it was from a PD patient who had ESRD for at least 91 days and was under 18 years old (as of the claim-from date).
  - The last eligible claim with an in-range (less than or equal to 8.5) and not expired (Kt/V occurrence date more than six months prior to the claim through date) Kt/V value reported is selected when there were multiple claims reported in a month.

2.6.13   Assigning Patient-Months to Numerators and Denominators

Once a Kt/V value for the patient-month has been selected, the following decision rules are used when considering whether to assign the patient-month to the numerator, denominator, or both:

- If the selected Kt/V value is missing or not in the valid range ($>$ 8.5), include patient-month in the denominator but not the numerator.

- If selected Kt/V value is in valid range ($\leq$ 8.5) and meets the Kt/V value threshold ($\geq$ 1.8), then include the patient-month in denominator and the numerator.

2.6.14   Data Elements and Data Sources

The data elements used for this measure are listed below. A complete description of the data elements can be found at the ESRD section of QualityNet.gov.

EQRS Data Elements:

- UPI
- Facility CCN
- Patient date of birth
- Patient date of death
- Primary type of treatment ID (EQRS dialysis type)
- Medicare certified services offered as of 12/31 of the performance period
- Additional services offered (Non-Medicare) as of 12/31 of the performance period
- Kt/V
- First date of ESRD (see Section 3.1.2)

Claims Based Data Elements:

Note: Only Type of Bill (TOB) 72x claims are considered in the measure calculation.

- Claim related condition code
- Claim control number
- Claim from date
- Claim through date
- Claim NCH daily process date
- Claim link number
- Claim occurrence date
- Claim occurrence code
- Claim CCN
- Claim value code D5
- Claim value amount

- Claim value sequence number

- Claim line institutional revenue center codes

- Claim line institutional revenue center date

- Patient health insurance claim number

- Patient date of death

- Patient date of birth

2.6.15   Flowchart

Figure 6 provides a flowchart that represents the processes used to calculate the Pediatric PD Kt/V measure.

Pediatric Peritoneal Dialysis (PD) Kt/V Dialysis Adequacy:
Percent of all pediatric peritoneal dialysis patient months for patients whose delivered dose of dialysis was greater than or equal to 1.8 during the reporting period.

Based on patients on ESRD treatment at the beginning of the reporting month when using EQRS; if claims are used, the 91 days is determined based on the claim-from date (first service date determined from CMS 2728, EQRS, claims, or transplant data).

Note: DOB is based on EQRS supplemented by claims. Age is calculated as of the beginning of the reporting month if EQRS is used, and the claim-from-date if claims are used.

Note for ESRD QIP only:
1. ECE months are not eligible, regardless of whether or not data are reported;
2. For new facilities only, the month in which the CCN becomes effective and the following three months are excluded.

Note: Kt/V values from EQRS can be obtained from any facility.

Missing Kt/V values or Kt/V =9.99 on claims (not reported) are excluded from numerator.

Facility must have at least 11 eligible patients to be scored on the measure or reported on DFCC.

Figure 6: Pediatric Peritoneal Dialysis (PD) Kt/V Dialysis Adequacy

2.6.16 Selected References

- National Kidney Foundation. K/DOQI Clinical Practice Guidelines and Clinical Practice Recommendations for 2006 Updates: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy and Vascular Access. Am J Kidney Dis. 2006; 48:S1-S322, (suppl 1).

2.7 nPCR for Pediatric Hemodialysis Patients (Dialysis Facility Measures Only)

2.7.1 Measure Name

Measurement of normalized protein catabolic rate (nPCR) for Pediatric Hemodialysis Patients.

2.7.2 Measure Description

Percentage of patient months of pediatric (less than 18 years old) ICHD patients (irrespective of frequency of dialysis) with documented monthly nPCR measurements.

2.7.3 Measure Rationale

nPCR provides an estimate of dietary protein intake and has been shown to provide additional information to spKt/V. Studies have shown that in adolescent patients who achieved target spKt/V levels, nPCR was associated with nutritional status. Furthermore, there is evidence that nPCR < 1 gram/kg/day is predictive of malnutrition and sustained weight loss among adolescent patients.

2.7.4 Measure Type

Process

2.7.5 Improvement Noted as Higher or Lower Rate

A higher number indicates better quality.

2.7.6 Risk Adjustment

None.

2.7.7 Numerator Statement

Number of patient months in the denominator with monthly nPCR measurements.

2.7.8 Facility Exclusions

Facilities that treat fewer than 11 eligible patients during the performance period are excluded from the measure.

2.7.9 Denominator Statement

Number of all patient months for pediatric (less than 18 years old) ICHD patients (irrespective of frequency of dialysis).

2.7.10 Denominator Exclusions

Exclusions that are implicit in the denominator definition include:

- Adult patients (>= 18 years old) (see Section 3.1.3)
- Patients not assigned to the facility for the entire month
- Home HD patients

2.7.11   Mapping Patients to Facilities

See Section 2.3.11

2.7.12   Calculating Numerators

The number of patients in the study month where (1) nPCR value and the date the nPCR was collected were known or (2) the components that make up nPCR (blood urea nitrogen [BUN] pre-dialysis, BUN post-dialysis, pre-dialysis weight, pre-dialysis weight unit of measure, post-dialysis weight, post-dialysis weight unit of measure, and delivered minutes of BUN HD session) and the date of collection are all known.

2.7.13   Data Elements and Data Sources

EQRS Data Elements:

- UPI
- Facility CCN
- Patient date of birth
- Patient date of death
- Primary type of treatment ID (EQRS dialysis type)
- Number of dialysis sessions per week
- Medicare certified services offered as of 12/31 of the performance period
- Additional services offered (non-Medicare) as of 12/31 of the performance period
- BUN pre-dialysis
- BUN post-dialysis
- Pre-dialysis weight
- Pre-dialysis weight unit of measure
- Post-dialysis weight
- Post-dialysis weight unit of measure
- Delivered minutes of BUN HD session
- First date of ESRD (see Section 3.1.2)

Claims Based Data Elements:

Note: Only Type of Bill (TOB) 72x claims are considered in the measure calculation.

- Claim control number
- Claim-from date

- Claim through date
- Claim CCN
- Patient health insurance claim number
- Patient date of death
- Patient date of birth

2.7.14 Flowchart

Figure 7 provides a flowchart that represents the processes used to calculate the nPCR for Pediatric Hemodialysis Patients Rate.
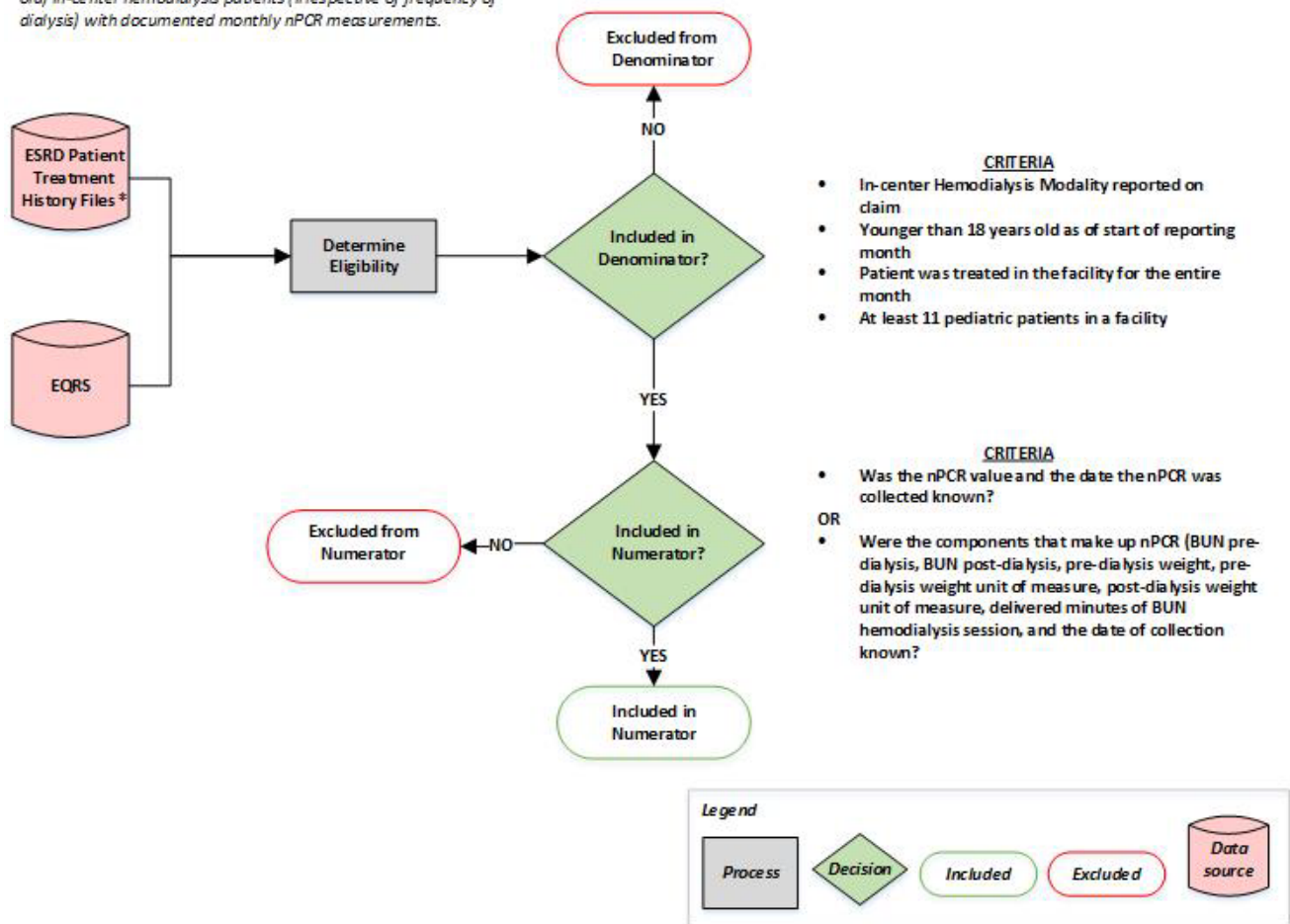
Figure 7: nPCR for Pediatric Hemodialysis Patients Flowchart (Dialysis Facility Measures Only)

*Multiple data sources from EQRS include the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (CMS-2728). Other data sources include transplant data from the Organ Procurement and Transplant Network (OPTN) the Death Notification Form (CMS-2746), the Dialysis Facility Compare (Dialysis Facility Measures) and the Social Security Death Master File.

**When there are multiple values for a patient during the month, the last is selected.

2.7.15   Selected References

- Clinical Practice Guidelines for Hemodialysis Adequacy: K/DOQI Guideline 8. Pediatric Hemodialysis Prescription and Adequacy: 2006.
- Clinical Practice Guideline for Nutrition in Children with CKD: 2008 Update, Recommendation 1.
- Goldstein SL, Baronette S, Gambrell TV, Currier H, Brewer ED. nPCR assessment and IDPN treatment of malnutrition in pediatric hemodialysis patients. Pediatr Nephrol. 2002; 17:531-534.
- Orellana P, Juarez-Congelosi M, Goldstein SL. Intradialytic parenteral nutrition treatment and biochemical marker assessment for malnutrition in adolescent maintenance hemodialysis patients. J Ren Nutr. 2005; Jul;15(3):312-7.
- Juarez-Congelosi M, Orellana P, Goldstein SL. Normalized protein catabolic rate versus serum albumin as a nutrition status marker in pediatric patients receiving hemodialysis. J Ren Nutr. 2007; 17:269-274.

2.8 Hypercalcemia Clinical (Dialysis Facility Measure Only) Reporting (ESRD QIP Only) Measures

2.8.1 Measure Name

Proportion of Patients with Hypercalcemia

2.8.2 Measure Description

Dialysis Facilities Measure Only:

Proportion of all adult patient-months (Medicare and non-Medicare patients) with three-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL or missing (CBE ID 1454).

ESRD QIP Only:

Percentage of all adult patient-months where total uncorrected serum or plasma calcium lab values were reported in EQRS during the performance period.

2.8.3 Measure Rationale

The Hypercalcemia Clinical Measure was developed in 2010 based on the recommendations of a clinical technical expert panel's (TEP) consideration of the multiple large, risk-adjusted observational studies (referenced below) demonstrating a consistent relationship between presence of hypercalcemia and patient mortality. TEP members felt that while small, the population of patients with hypercalcemia was at increased risk of cardiovascular events and therefore the condition needed to be identified and appropriately treated. The TEP agreed that therapy should be focused on preventing the development of a sustained serum calcium greater than 10.2 mg/dL. The measure was re-evaluated by a second clinical TEP in 2013. The 2013 TEP identified additional observational studies (referenced below) supporting the measure and affirmed their agreement with the measure's focus as a safety measure, emphasizing avoidance of hypercalcemia to prevent adverse clinical consequences.

Given both the 2010 TEP and 2013 TEP recommendations, and the additional evidence cited in the current consensus-based entity (CBE) submission, the measure remains an important intermediate outcome and patient safety measure, even in light of the lack of interventional trials supporting a specific threshold. Nevertheless, the number of large, risk-adjusted observational studies (referenced below) with consistent direction of association between hypercalcemia and mortality cannot be ignored.

Given this, several CBE standing committee reviewers agreed with the prior TEPs' opinions that the measure represented an appropriate safety-net. As an additional concern, the Protecting Access to Medicare Act of 2014 mandated the implementation of conditions treated through

oral-only medications in the ESRD QIP as a safety measure against over-use of oral-only medications following changes to the ESRD prospective payment system (PPS) bundle payment. Congress likely recognized the need for more safety measures in the ESRD program, particularly in the area of drug overuse, following similar concerns for the use of erythropoiesis stimulating agents (ESAs) in treating anemia in the same population.

2.8.4 Measure Type

Dialysis Facilities Measure Only:

Intermediate Outcome

ESRD QIP Only:

Process

2.8.5 Improvement Noted as Higher or Lower Rate

Dialysis Facilities Measure Only:

A lower rate indicates better quality.

ESRD QIP Only:

A higher rate indicates better reporting.

2.8.6 Risk Adjustment

None.

2.8.7 Numerator Statement

Dialysis Facilities Measure Only:

Number of patient-months in the denominator with three-month rolling average of total uncorrected (indicates that albumin is not considered in the calculation) serum or plasma calcium greater than 10.2 mg/dL or missing. Patient-months with missing values in the reporting month and the two months prior are included in the numerator to minimize any incentive favoring non-measurement of serum calcium during the preceding three months.

ESRD QIP Only:

Number of patient-months in the denominator with total uncorrected serum or plasma calcium lab value reported in EQRS.

2.8.8 Facility Exclusions

Facilities with fewer than eleven patients (< 11) who meet the measure's specifications during the period for which the rate is being calculated.

ESRD QIP Only:

- Calculations will exclude the months covered by a granted ECE (see Section 3.4).

- CCN certification date on or after September 1 of performance period.

- For new facilities only, the month in which the CCN becomes effective and the following three months (see Section 3.5).

2.8.9 Denominator Statement

Number of patient-months at the facility during the measurement period. Includes all patients, both Medicare and non-Medicare patients.

2.8.10 Denominator Exclusions

- Patient-months for patients who are on ESRD treatment (see Section 3.1.2) for less than 90 days as of the first day of the reporting month.

- Patients who died prior to the last day of the reporting month.

- Patient-months for patients not assigned to the same facility for the entire reporting month.

Dialysis Facility Measures Only:

- Patient younger than age 18 years, two months prior to the first of the reporting month (see Section 3.1.3).

ESRD QIP Only:

- Patient was not on ESRD treatment during the reporting month.
- Patient younger than age 18 years, as of the first day of the reporting month (see Section 3.1.3).
- Patients with other treatment modality.
- Calculations will exclude the months covered by a granted ECE (see Section 3.4).

2.8.11 Mapping Patients to Facilities

ESRD QIP:
- A patient is assigned to a facility based on admit and discharge dates from EQRS.
- Patients can be attributed to multiple facilities within the same month.

Dialysis Facility Measures:
- Patients can be attributed to only one facility per month.
- For each patient, the dialysis provider at each point in time was identified primarily using data from EQRS, the Medical Evidence Form (CMS-2728) and Medicare dialysis claims. Both patient assignment to the provider and modality (either HD or PD) were determined according to the information reported in the above-mentioned data sources. For each

reporting month, patients were required to have been indicated as treated by the facility for the complete month in order to be included in the denominator. If a patient transferred in or out of the facility, discontinued dialysis, recovered renal function, or died anytime during the month, the entire patient-month is excluded. Please note that the number of dialysis sessions is not considered, and the patient may not have received treatment at the facility for the entire month to be included. For example, if a patient is hospitalized or travels during the month, the patient may still be included in the facility's measure if they are indicated as the facility's patient that month according to the data as described above. 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, we considered the patient lost to follow-up and did not use them in the calculation.

2.8.12   Calculating Numerators

Dialysis Facilities Measures Only:
A patient-month is included in the numerator if the average calcium level is greater than 10.2 mg/dL or missing. Any value reported during the two months prior to the reporting month will only be used to calculate the three-month rolling average if applicable.

- The last calcium value reported in the month is used for calculation.

- No interpolation between calcium values for PD patients.

- "Uncorrected" indicates albumin is not considered in the calculation.

- A one-, two-, or three-month average can be calculated as long as there is a calcium value reported during the three-month window.

- Patient-months with missing values in the reporting month and the two months prior are included in the denominator and the numerator to minimize any incentive favoring non-measurement of serum or plasma calcium in the preceding three months.

- Out of range uncorrected serum calcium or plasma value (values < 0.1 and value > 20) are considered as missing.

ESRD QIP Only:
A patient-month is included in the numerator if a non-missing uncorrected serum or plasma calcium lab value is reported.

- The calcium value reported by the facility is used. The facility may obtain this value from an external source.

- "Uncorrected" indicates albumin is not considered in the calculation.

  o For new facilities only, calcium values reported during the calendar month of the facility's initial certification date and the following three months will not be used (see Section 3.5).

2.8.13   Calculation of ESRD QIP Hypercalcemia Score

The Hypercalcemia measure will be scored as a reporting measure. An eligible facility's score is calculated according to the following equation:

$$\left[\frac{\text{\# patient} - \text{months facility reported uncorrected serum calcium in EQRS}}{\text{\# eligible patient} - \text{months assigned to facility in the performance period}} \times 12\right] - 2$$

2.8.14   Data Elements and Data Sources

The data elements used for this measure are listed below. A complete description of the data elements can be found at the ESRD section of QualityNet.gov.

EQRS Data Elements:

- Facility CCN
- Initial certification date
- Patient date of birth
- Patient date of death
- UPI
- Admit date
- Discharge date
- Date of month/year associated with clinical record
- Uncorrected serum or plasma calcium reading amount
- Date of last uncorrected serum calcium reading
- First date of ESRD (see Section 3.1.2)

Claims Based Data Elements:

Note: Only Type of Bill (TOB) 72x claims are considered in the measure calculation.

- Claim control number
- Claim-from date
- Claim through date
- Patient health insurance claim number
- Patient date of birth
- Patient date of death
- Claim CCN

2.8.15   Flowchart for ESRD QIP

Figure 8 provides a flowchart that represents the processes used to calculate the Hypercalcemia Reporting Measure Rate for ESRD QIP.

Centers for Medicare & Medicaid Services

Hypercalcemia: Percent of eligible patient-months with an uncorrected serum calcium lab value reported in EQRS

Process

Decision

Calculation

Excluded

Data Source

- The result of the formula should be rounded with half (0.5) rounded up.
- If the result of the formula is negative, round the result to zero (0).
- If there are NO eligible months, the facility receives No Score on the measure.

$$\left[\frac{\text{\# patient} - \text{months facility reported uncorrected serum calcium in EQRS}}{\text{\# eligible patient} - \text{months assigned to facility in the performance period}} \times 12 \right] - 2$$

Calculate facility measure score

Calculate facility numerator: number of eligible patient-months with an uncorrected serum calcium lab value reported in EQRS

The month in which a facility CCN is first certified and the following three months are not eligible

Months covered by an ECE are not eligible

Calculate facility denominator: Number of eligible patient-months

Map EQRS patient records to facilities

EQRS data

System determines if facility is eligible for measure

Was facility CCN certification date before Sept 1 of performance year? —No→ Facility excluded from measure calculation

Yes

System determines eligible patients within facility

Does patient have valid 2728 form or EQRS record? —No→

Yes

Is patient at least 18 years old as of the first day of the reporting month? —No→

Yes

Is patient on ESRD treatment for at least 90 days? —No→

Yes

Was the patient on ESRD treatment during the reporting month? —No→ Patient excluded from measure calculation

Yes

Was the patient's treatment modality in-center hemodialysis, home hemodialysis, or peritoneal dialysis? —No→

Yes

Did the patient die prior to the last day of the reporting month? —Yes→

No

Was the patient assigned to the same facility for the entire reporting month? —No→

Yes

Did the facility treat eleven (11) or more eligible patients? —Yes→ Calculate facility denominator: Number of eligible patient-months

—No→

Figure 8: Hypercalcemia Reporting Measure Rate Flowchart (ESRD QIP Only)

2.8.16 Flowchart for Dialysis Facility Measures

Figure 9 provides a flowchart that represents the processes used to calculate the Hypercalcemia Clinical Measure Rate for Dialysis Facility Measures.
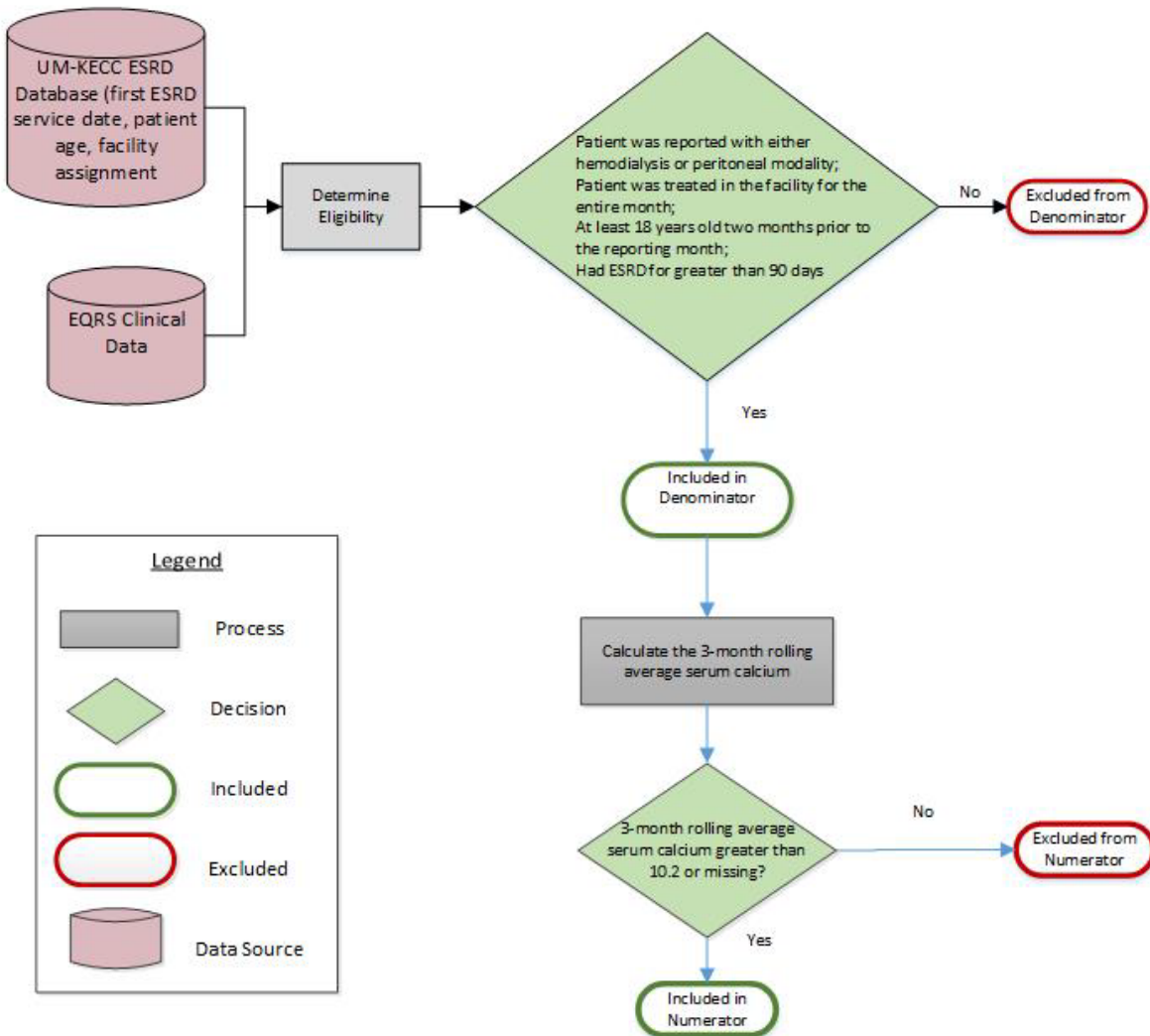
Figure 9: Hypercalcemia Clinical Measure Rate Flowchart (Dialysis Facility Measures Only)

2.8.17   Selected References

- National Kidney Foundation: K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. Am J Kid Disease. 2003; 42:S1-S202 (suppl 3).

- Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Work Group: KDIGO Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD). Kidney Int. 2009; 76 (Suppl 113): S1-S130.

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- Kalantar-Zadeh K, Kuwae N, Regidor DL, Kovesdy CP, Kilpatrick RD, Shinaberger CS, McAllister CJ, Budoff MJ, Salusky IB, Kopple JD. Survival predictability of time-varying indicators of bone disease in maintenance hemodialysis patients. Kidney Int. 2006; 70:771-80.

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- Chertow GM, Raggi P, Chasan-Taber S, Bommer J, Holzer H, Burke SK. Determinants of progressive vascular calcification in hemodialysis patients. Nephrol Dial Transplant. 2004; 19(6):1489-1496.

- Dhingra R, Sullivan LM, Fox CS, Wang TJ, D´Agostino RB Sr, Gaziano JM, Vasan RS. Relations of serum phosphorus and calcium levels to the incidence of cardiovascular disease in the community. Arch Intern Med. 2007;167: 879–885.

- Wang AY, Lam CW, Wang M, Chan IH, Lui SF, Sanderson JE. Is valvular calcification a part of the missing link between residual kidney function and cardiac hypertrophy in peritoneal dialysis patients? Clin J Am Soc Nephrol. 2009; 4:1629-36.

- Ketteler M, Schlieper G, Floege J. Calcification and cardiovascular health: new insights into an old phenomenon. Hypertension. 2006; 47:1027–1034.

- Giachelli CM. Vascular calcification mechanisms. Journal of the American Society of Nephrology: J Am Soc Nephrol. 2004; 15:2959–2964.

- Yang H, Curinga G, Giachelli CM. Elevated extracellular calcium levels induce smooth muscle cell matrix mineralization in vitro. Kidney Int. 2004;66(6):2293–2299.

- US Renal Data System, USRDS 2013 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2013.

2.9   Clinical Depression Screening and Follow-Up Clinical Measure (ESRD QIP Only)

2.9.1   Measure Name

Screening for Clinical Depression and Follow-Up Clinical Measure

2.9.2   Measure Description

Facility reports in EQRS one of the four conditions below (condition 1, 2, 4 and 5) for each qualifying patient once before the close of the December clinical month. **Note:** the bold terms are defined below.

1. **Screening for clinical depression** is documented as being **positive** and a **follow-up plan** is documented.

2. Screening for clinical depression documented as **positive**, a follow-up plan is not documented, and the facility possesses documentation that the patient is **not eligible.**

3. Screening for clinical depression documented as **positive**, the facility possesses no documentation of a follow-up plan, and no reason is given.

4. Screening for clinical depression documented as negative and no follow-up plan required.

5. Screening for clinical depression not documented, but the facility possesses documentation stating the patient is **not eligible**.

6. Clinical depression screening not documented, and no reason is given.

Note: the following terms in bold above are defined as follows:

- **Screening for clinical depression** – Completion of a clinical or diagnostic standardized tool used to identify people at risk of developing or having a certain disease or condition, even in the absence of symptoms. A standardized tool is an assessment tool that has been appropriately normalized and validated for the population in which it is used. Facilities are not required to use a particular tool but should choose one that is appropriate for their patient population. **The name of the standardized assessment tool used must be documented in the medical record.**

- **Positive** – Based on the scoring and interpretation of the specific standardized tool used, and through discussion during the patient visit, the provider should determine if the patient is deemed positive for signs of depression. **Justification for or against a positive screening should be documented in the medical record.**

- **Follow-up plan** – A documented outline of care for a positive depression screening.

- **Not eligible (condition 2)** – A patient may not be eligible for follow-up plan, or it may not be appropriate for a patient to undergo treatment or therapy for depression because such treatments are medically contraindicated. **Justification for a patient's ineligibility for follow-up treatment should be documented in the patients' medical record.**

- **Not eligible (condition 5)** – A patient is not eligible for Depression Screening if one or more of the following reasons are documented in the patient's <u>medical record</u>:

  - Patient refuses to participate.

  - Patient is in an urgent or emergent situation where time is of the essence and to delay treatment would jeopardize the patient's health status.

  - Situations where the patient's motivation to improve may impact the accuracy of results of nationally recognized standardized depression assessment tools. For example: certain court appointed cases.

  - Patient was referred with a diagnosis of depression.

  - Patient has been participating in on-going treatment with screening of clinical depression in a preceding reporting period.

  - Severe mental and/or physical incapacity where the person is unable to express himself/herself in a manner understood by others. For example: cases such as delirium or severe cognitive impairment, where depression cannot be accurately assessed through use of nationally recognized standardized depression assessment tools.

2.9.3   Measure Type

Process

2.9.4   Facility Exclusions

- Facilities with fewer than 11 eligible patients during the performance period (see Section 2.9.7 below).

- Facilities with a CCN certification date on or after September 1 of the performance period.

- Calculations will exclude the months covered by a granted ECE.

- .

2.9.5   Numerator Statement

Number of eligible patients in the performance period for whom a facility successfully reports one of four conditions related to clinical depression screening and follow-up.

2.9.6   Denominator Statement

Number of eligible patients in the performance period.

2.9.7   Patient Exclusions

- Patients who are younger than 12 years old (see Section 3.1.3) as of October 31 of the performance period.

- Patients who are treated at the facility for fewer than 90 days (days do not have to be consecutive) during the performance period (see Section 3.1.5).

- Patients not on ESRD treatment as defined by a completed 2728 form, an EQRS record, or a sufficient amount of dialysis reported on dialysis facility claims.

- Patients with other treatment modality.

2.9.8 Determining Successful Reporting for a Patient

If a patient is eligible at more than one facility, then each facility must report for the patient in order to receive credit on the measure. Facilities are not required to report for patients if one or more of the following are documented during the encounter of the measurement period:

1. Patient has an active diagnosis of depression prior to any encounter during the measurement period.
2. Patient has a diagnosed bipolar disorder prior to any encounter during the measurement period.

Facilities can select one of six conditions in EQRS. A facility is considered to have successfully reported for a patient if it reports condition 1, 2, 4, or 5 in EQRS for the patient once before the close of the December clinical month (See Section 2.9.2 for definitions of bold terms):

1. **Screening for clinical depression** is documented as being **positive** and a **follow-up plan** is documented.
2. Screening for clinical depression documented as **positive**, a follow-up plan is not documented, and the facility possesses documentation that the patient is **not eligible**.
3. Screening for clinical depression documented as **positive**, the facility possesses no documentation of a follow-up plan, and no reason is given.
4. Screening for clinical depression documented as negative and no follow-up plan required.
5. Screening for clinical depression not documented, but the facility possesses documentation stating the patient is **not eligible**.
6. Clinical depression screening not documented, and no reason is given.

2.9.9 Data Elements and Data Sources

The data elements used for this measure are listed below. A complete description of the data elements can be found at the [ESRD section of QualityNet.gov](#).

EQRS Data Elements:

- Facility CCN
- Initial certification date
- Patient date of birth
- UPI
- Admit date
- Discharge date
- Patient reporting measure type

- Patient reporting option info
- Patient reporting time period assessment

2.9.10 Flowchart

Figure 10 provides a flowchart that represents the processes used to calculate the Screening for Clinical Depression and Follow-Up Clinical Measure Rate.

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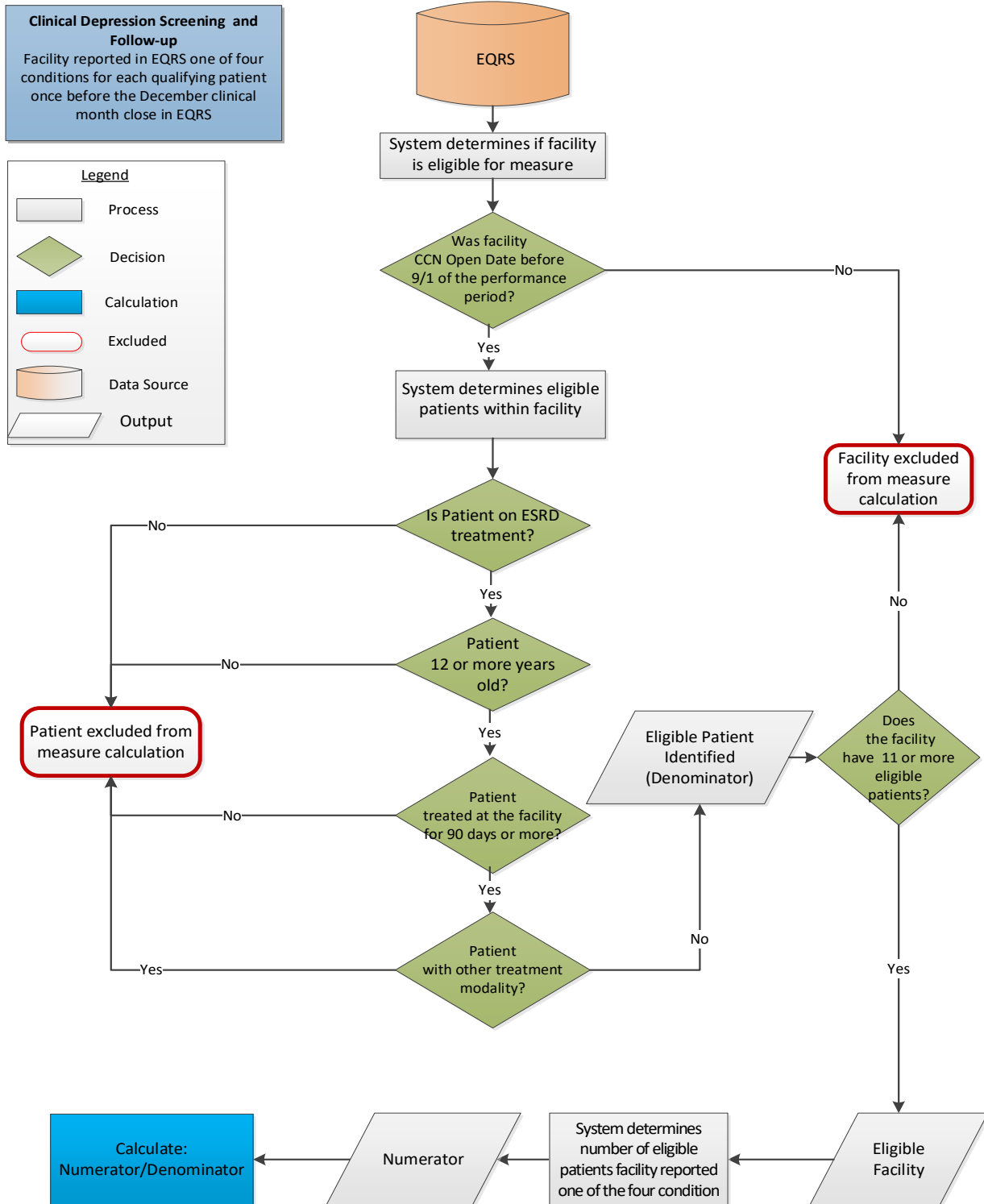
Figure 10: Screening for Clinical Depression and Follow-Up Clinical Measure Flowchart (ESRD QIP Only)

2.10 Standardized Readmissions Ratio (SRR) Clinical Measure (Dialysis Facility Measures Only)

2.10.1 Measure Name

Standardized Readmission Ratio for Dialysis Facilities

2.10.2 Measure Description

The Standardized Readmission Ratio (SRR) is defined to be the ratio of the number of index discharges from acute care hospitals that resulted in an unplanned readmission to an acute care hospital within 4-30 days of discharge for Medicare-covered dialysis patients treated at a particular dialysis facility, to the number of readmissions that would be expected given the discharging hospitals and the characteristics of the patients, as well as the national norm for dialysis facilities. Note that in this measure, "hospital" always refers to acute care hospital.

2.10.3 Measure Rationale

Unplanned readmission rates are an important indicator of patient morbidity and quality of life. On average, dialysis patients are admitted to the hospital nearly twice a year and hospitalizations account for approximately 38 percent of total Medicare expenditures for dialysis patients (U.S. Renal Data System, 2012). In 2010, more than 30% of dialysis patient discharges from an all-cause hospitalization were followed by an unplanned readmission within 30 days (U.S. Renal Data System, 2012). Measures of the frequency of unplanned readmissions, such as SRR, help efforts to control escalating medical costs, play an important role in providing cost-effective health care, and support coordination of care across inpatient and outpatient settings: discharge planning, transition, and follow-up care.

2.10.4 Measure Type

Outcome

2.10.5 Improvement Noted as Higher or Lower Rate

A lower ratio indicates better quality.

2.10.6 Numerator Statement

The observed number of index hospital discharges that are followed by an unplanned hospital readmission within 4–30 days of discharge.

2.10.7 Facility Exclusions

The standardized readmission ratio is only calculated for facilities with at least 11 index hospital discharges in a performance year.

2.10.8 Denominator Statement

The expected number of index discharges followed by an unplanned readmission within 4-30 days in each facility, which is derived from a model that accounts for patient characteristics, the dialysis facility to which the patient is discharged, and the discharging acute care or critical access hospitals involved.

Index Discharge Exclusions

Index hospital discharges exclude discharges that:

- Occur at a non-acute care hospital.
- End in death.
- Are against medical advice.
- Include a primary diagnosis for certain types of cancer, mental health or rehab prosthesis. Use the ICD diagnosis code information related to this edition of the *Manual*, which can be found on the [Measuring Quality page](#) on the ESRD QIP section of CMS.gov.
- Includes a revenue center code indicating rehabilitation.
- Occur after a patient's 12th admission in the calendar year.).
- Are from a PPS-exempt cancer hospital.
- Occur while the patient was not on dialysis and not under care of a dialysis facility at discharge.
- Are followed within three days by any hospitalization (at acute care, long-term care, rehabilitation, or psychiatric hospital or unit), death, transplant, loss to follow-up, withdrawal from dialysis, or recovery of renal function.
- Are associated with an inpatient stay of 365 days or longer.

2.10.9 Mapping Patients to Facilities

Index discharges are attributed to the dialysis provider to which the patient is discharged at the end of the hospital stay. In other words, the facility to which the patient is discharged is held responsible for any unplanned readmissions occurring within 4-30 days of the index discharge, regardless of whether the patient is still being treated at the facility associated with the index discharge at the time of readmission.

2.10.10 Defining Readmissions

Index discharges are restricted to Medicare-covered hospitalizations for inpatient care at short-term acute care hospitals and critical access hospitals. Discharges from SNFs, long-term care hospitals (LTCHs), rehabilitation hospitals and PPS-exempt cancer hospitals - as well as those from separate dedicated units for hospice, rehabilitation and psychiatric care - are excluded. Potential readmissions are:

- Medicare-covered hospitalizations for inpatient care at short-term acute care hospitals and critical access hospitals.
- Classified as either a planned or unplanned admission according to planned readmission algorithm (see below for further discussion).

Note that hospitalizations where the patient dies on the date of discharge are included for consideration as potential readmissions.

The numerator for a given facility is the total number of index hospital discharges that are followed by unplanned readmissions within 4-30 days of discharge and that are not preceded by a "planned" readmission or other competing event that also occurred within 4-30 days of discharge (competing events include admissions to rehabilitation or psychiatric hospitals, death, transplant, loss to follow-up, withdrawal from dialysis, and recovery of renal function). If the first event during days 4-30 after discharge is an unplanned hospitalization, then the index discharge is classified as having a readmission. If the first event during days 4-30 is a planned hospitalization or other competing event, then the index discharge is classified as not having a readmission. A readmission is considered "planned" under three scenarios:

   i) The patient undergoes a procedure that is always considered planned (e.g., kidney transplant) or has a primary diagnosis that always indicates the hospitalization is planned (e.g., maintenance chemotherapy).

   ii) The patient undergoes a procedure that MAY be considered planned if it is not accompanied by an acute diagnosis. For example, a hospitalization involving a heart valve procedure accompanied by a primary diagnosis of diabetes would be considered planned, whereas a hospitalization involving a heart valve procedure accompanied by a primary diagnosis of acute myocardial infarction (AMI) would be considered unplanned.

   iii) The readmission was to a rehabilitation, long-term, or psychiatric hospital.

This definition follows from the algorithm developed by Yale New Haven Health Services Corporation/Center for Outcomes Research & Evaluation (YNHHSC/CORE) for The Centers for Medicare and Medicaid Services 2018 All-Cause Hospital Wide Measure Updates and Specifications Report Hospital Level 30-Day Risk-Standardized Readmission Measure – Version 7.0.
https://qualitynet.cms.gov/files/5d0d375a764be766b010141f?filename=2018_Rdmsn_Updates%26Specs_Rpts.zip

2.10.11 Risk Adjustment

The risk adjustment approach used in the model for the SRR was adapted from CMS' Standardized Hospitalization Ratio (SHR) and CMS' Hospital-Wide Readmission (HWR) measure. The regression model used to compute a facility's "expected" number of readmissions for the SRR measure contains many factors thought to be associated with readmission event rates. Specifically, the model adjusts for age, sex, diabetes, duration of ESRD, BMI at start of dialysis, past-year comorbidities, length of the index discharge hospital stay, nursing home status in previous 365 days, Medicare Advantage status at time of index discharge, and the presence of a high-risk diagnosis (defined below) at index discharge. The model will also include an adjustment for diagnosis of COVID-19 determined from Medicare claims. In addition to

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adjusting for facility indicators as fixed effects, the model also adjusts for the effects of discharging hospitals as random effects, accounting for the variation in readmission outcome across different hospitals.

Below are details on the SRR's risk adjustors:

- **Sex**: Determine each patient's sex from multiple sources.
- **Age at Index Discharge**: Determined from the birth date provided in EQRS, Medicare Claims, and the Medical Evidence Form (CMS-2728). Three age spline variables centered at 60 were defined (0-13, 14-59, and 60+).
- **Years on ESRD**: Determined using the first service date from patient's Medical Evidence Form (CMS-2728), claims history (all claim types with evidence of dialysis), EQRS, and Dialysis Facility Measures the Scientific Registry of Transplant Recipients (SRTR) database.
- **Diabetes as cause of ESRD**: Primary cause of ESRD determined from patient's Medical Evidence Form (CMS-2728) and EQRS. When primary cause of ESRD is missing, we assume diabetes is not the cause of ESRD.
- **Interaction terms:** Two interaction terms between diabetes as cause of ESRD and Age (spline 14-59 and 60+).
- **BMI at incidence**: Calculated based on the height and weight provided on patient's Medical Evidence Form (CMS-2728) and group patients into the following categories: BMI < 18.5, 18.5 ≤ BMI < 25, 25 ≤ BMI < 30, or BMI ≥ 30. BMI is imputed to the BMI ≥ 30 category when either missing, or outside the range of 10 to 70 for adults or 5 to 70 for children.
- **Days hospitalized during index hospitalization**: Each hospitalization's length is determined by taking the difference between the date of admission and the date of discharge available on the inpatient claim. For patients who are transferred between one acute care hospital and another, the measure considers these multiple contiguous hospitalizations as a single acute episode of care, and the length is calculated by taking the difference between the date of admission for the first hospitalization and the date of discharge from the last hospitalization included. Time in the hospital is included as a categorical variable based on quartiles (1 variable for each quartile).
- **Nursing home status**: Uses multiple sources* including the CMS Nursing Home Minimum Data Set. 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) at time of index hospitalization discharge.
- **Medicare Advantage:** Using the Medicare EDB, determine whether the patient was enrolled as a Medicare Advantage (MA) patient at the time of the index hospitalization discharge.
- **Past-year comorbidities (risk variables):** Determined by identifying unique ICD-10 diagnosis codes for each patient reported on Medicare inpatient claims in the 365 days preceding (and inclusive of) the index discharge date. Diagnosis codes are grouped using 53 comorbidity groups defined by the 2019.1 version of the Agency for Healthcare Research and Quality (AHRQ) Clinical Classifications Software (CCS). See Section 2.11.15 for a list of AHRQ categories included.

- **COVID-19 diagnosis**: COVID-19 diagnosis is obtained from Medicare inpatient claims only. A claim record is confirmed as a COVID-19 diagnosis if the patient's inpatient claim reports any COVID-19 diagnosis codes (ICD-10-CM: U071, B9729, J1282) as primary or secondary diagnoses. Secondary diagnoses include 2nd through 25th ordered diagnoses. Index discharges with an inpatient COVID-19 diagnosis during the hospitalization are identified as COVID-19 index discharges. Since comorbidities in the SRR are based solely on inpatient claims, we do not include COVID-19 diagnoses or other diagnoses from claims associated only with laboratory testing or outpatient visits.
- **Discharged with high-risk condition**: A *high-risk* diagnosis is any diagnosis area (grouped by the AHRQ CCS) that was rare in the population but had a 30-day readmission rate of at least 40%. Note that high-risk diagnosis groups related to cancer or mental health are excluded from index discharges. The CCS areas identified as high-risk are:
  - CCS 5: HIV infection
  - CCS 6: Hepatitis
  - CCS 56: Cystic fibrosis
  - CCS 57: Immunity disorders
  - CCS 61: Sickle cell anemia
  - CCS 190: Fetal distress and abnormal forces of labor
  - CCS 151: Other liver diseases
  - CCS 182: Hemorrhage during pregnancy; abruptio placenta; placenta previa
  - CCS 186: Diabetes or abnormal glucose tolerance complicating pregnancy; childbirth; or the puerperium
  - CCS 210: Systemic lupus erythematosus and connective tissue disorders
  - CCS 243: Poisoning by nonmedicinal substances

* This may include information from: EQRS (including the Medical Evidence Form (CMS 2728) and Medicare Claims).

In summary, the SRR indicates whether a facility experienced higher or lower readmission rates than the national average after accounting for differences that could be attributed to the patient characteristics listed above, as well as the discharging hospital.

2.10.12 Calculation of SRR

To estimate the probability of 30-day unplanned readmission, we use a three-stage model, the first of which is a fixed-effects logistic regression model. In this step, facility-hospital combinations are included as fixed effects, adjusting for a set of patient-level characteristics. The results of this step are estimates of the regression coefficients of patient-level characteristics in the logistic regression model. These estimates avoid issues of bias that arise through estimation of regression coefficients in a model with random effects. In particular, these estimates are unbiased regardless of correlations between hospital effects or facility effects and patient-case mix. These estimated regression coefficients are then used as an offset variable in the second stage model.

The next stage is a double random-effects logistic regression model. In this stage of the model, both dialysis facilities and hospitals are represented as random effects, and the sum of regression adjustments multiplied by estimated parameters obtained in the first stage is included as the offset

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variable. From this model, we obtain the estimated standard deviation of the random effects of hospitals (Diggle et al. 2002).

The third stage of the model is a mixed-effects logistic regression model, in which dialysis facilities are modeled as fixed effects and hospitals are modeled as random effects, with the standard deviation specified as equal to its estimate from the second-stage model and the estimated parameters obtained in the first stage providing an offset. The expected number of readmissions for each facility is estimated as the sum of the probabilities of readmission of all index discharges in this facility and assuming the national norm (i.e., the median) for the facility effect. This model accounts for a given facility's case mix using the same set of patient-level characteristics as those in the first model.

The model and methods are described in some additional detail below:

- To estimate the probability of 30-day unplanned readmission following an index discharge, we use a three-stage approach. The main model, which produces the estimates used to calculate SRR, takes the form:

$$\log \frac{p_{ijk}}{1-p_{ijk}} = \gamma_i + \alpha_j + \beta^T Z_{ijk} , \tag{1}$$

where p_{ijk} represents the probability of an unplanned readmission for the kth discharge among patients who are discharged from j^{th} hospital to the ith facility, and Z_{ijk} represents the set of patient-level characteristics. Here, γ_i is the fixed effect for facility and α_j is the random effect for hospital j. It is assumed that the α_js arise as independent normal variables (i.e., $\alpha_j \sim N(0, \sigma^2)$).

- We then use the estimates from this model to calculate each facility's SRR:

$$SRR_i = \frac{O_i}{E_i} = \frac{O_i}{\sum_{j\in H(i)} \sum_{k=1}^{n_{ij}} \tilde{p}_{ijk}} , \tag{2}$$

where, for the ith facility, O_i is the number of observed unplanned readmissions, E_i is the expected number of unplanned readmissions for discharges, $H(i)$ is the collection of indices of hospitals from which patients are discharged, and $\tilde{p}_{ijk}$ is the predicted probability of unplanned readmission under the national norm for each discharge. Specifically, $\tilde{p}_{ijk}$ takes the form

$$\tilde{p}_{ijk} = \frac{\exp(\widehat{\gamma_M}+\widehat{\alpha_j}+\widehat{\beta}^T Z_{ijk})}{1+\exp(\widehat{\gamma_M}+\widehat{\alpha_j}+\widehat{\beta}^T Z_{ijk})} , \tag{3}$$

which estimates the probability that a discharge from hospital j of an individual in facility i with characteristics Z_{ijk} would result in an unplanned readmission if the facility effect corresponded to the median of national facility effects, denoted by $\widehat{\gamma_M}$. Here, $\widehat{\alpha_j}$

and $\hat{\beta}$ are estimates from model (1). The sum of these probabilities is the expected number of unplanned readmissions E_i at facility i; e.g., the number of readmissions that would have been expected in facility i had they progressed to the readmissions at the same rate as the national population of dialysis patients.

2.10.13 Calculation of SRR P-Values and Confidence Intervals for Dialysis Facility Measures

Measuring or assessing significance of a large SRR (i.e., an SRR greater than 1) is based on the p-value. To calculate the p-value, we use an exact method that assesses the probability that the facility would experience a number of readmissions as extreme as that observed if the null hypothesis were true; this calculation accounts for each facility's patient mix. For instance, to test the hypothesis that a facility's true SRR is 1.0, we calculate the positive one-tailed p-value or significance level (SL+) for each facility as the probability that the number of readmissions in that facility would be at least as large as that observed under the assumption that this facility has readmission rates corresponding to the median facility, and given the patient characteristics or covariates. The negative one-tailed p-value (SL-) is defined correspondingly (e.g., as small as). The two-tailed p-value is then defined as p = 2*min (SL+, SL-). We use a "mid-p" value to avoid two-tailed p-values greater than 1. Approaches for flagging are based on converting the p-values to z-statistics and using methods based on the empirical null hypothesis, which accounts for over dispersion in the data (Efron, 2004; Kalbfleisch and Wolfe, 2013). In effect, this method takes into account the natural variation observed between facilities and that cannot be accounted for by the model. To implement the empirical null methods, we stratify facilities into four groups based on the number of eligible patient-years at risk within each facility. We then plot the histograms of Z-scores for each strata along with normal curves fitted to the center of the histograms using a robust M-estimation method. We use these empirical null distributions to assess outlier facilities. This empirical null method makes appropriate adjustment in each of the strata and yields fairly consistent flagging rates across all strata.

To calculate the 95% interval estimate for SRR, we use an exact method that assesses the range of facility effects, such that the probability the facility would experience a number of readmissions more extreme than that observed under the assumed facility effect is non-significant (e.g., p > 0.05). To account for natural facility variation not explained by the model, evaluation of significance is based on the empirical null distribution, instead of the standard normal density.

2.10.14 Flagging Rules for Dialysis Facility Measures

As currently implemented for Dialysis Facility Measures, for reporting purposes we identify outlier facilities from amongst those with at least 11 index discharges during the time period. If the 95% interval lies entirely above the value of 1.00 (i.e., both endpoints exceed 1.00), the facility is said to have outcomes that are "worse than expected." However, if the 95% interval lies entirely below the value 1.00, the facility is said to be "better than expected." If the interval contains the value 1.00, the facility is said to have outcomes that are "as expected."

2.10.15 Data Elements and Data Sources

Data are derived from an extensive national ESRD patient database based on data from the CMS and EQRS system, Medicare dialysis and hospital payment records, the OPTN, and the Social Security Death Master File (CMS-2744), the CMS Medical Evidence Form (CMS-2728), and the Death Notification Form (CMS-2746) (Table 3). The database is comprehensive for Medicare-covered ESRD patients. Information on hospitalizations is obtained from Medicare Inpatient Claims Standard Analysis Files (SAFs) and past-year comorbidity is obtained from inpatient Medicare Claims SAFs. The data are comprehensive for Medicare patients, including non-traditional Medicare patients, through the use of Medicare Part A shadow records for Medicare Advantage patients.

AHRQ CCS categories are used in the risk adjustment model to identify past year comorbidities and high-risk conditions. See https://www.hcup-us.ahrq.gov/toolssoftware/ccsr/ccsr_archive.jsp#ccsr.

Variable	Primary Data Source
Facility CCN	Multiple data sources[1]
Date of birth	Multiple data sources[1]
Sex	Multiple data sources[1]
Date of first ESRD service	Multiple data sources[1]
Date of death	Multiple data sources[1]
Date of transplant(s)	Multiple data sources[1]
BMI at incidence	Medical Evidence Form (CMS-2728)
Nursing Home Status	CMS Nursing Home Minimum Data Set
Medicare Advantage Status	Medicare Enrollment Database
Diabetes - Primary cause of ESRD	Medical Evidence Form (CMS-2728) EQRS
High-risk diagnoses	Inpatient Medicare claims
Planned readmissions	Inpatient Medicare claims
Hospital admissions	Inpatient Medicare claims
Discharge status	Inpatient Medicare claims
COVID-19 Diagnosis	Inpatient Medicare claims

Table 3: Data Elements and Sources for Standardized Readmissions Ratio (SRR) Clinical Measure (Dialysis Facility Measures Only)

1.   This may include information from (EQRS, Medicare Enrollment Database (EDB), Medical Evidence Form (CMS 2728), Medicare Claims, and Organ Procurement and Transplantation Network Database (OPTN). Unique patients are identified by using a combination of SSN, first name, surname, sex, Medicare Beneficiary ID, patient Health Insurance Claim Number and

birth date. Dialysis Facility Measures patient-matching process is performed to ensure that minor typos and misspellings do not cause a patient record to fall out of their history. The matching process is able to successfully match 99.5% of patients. The remaining patients have incomplete or incorrect data that does not allow them to be matched.

CCS Category	Detailed Description
6	Hepatitis
10	Immunizations and screening for infectious disease
42	Secondary malignancies
50	Diabetes mellitus with complications
51	Other endocrine disorders
52	Nutritional deficiencies
55	Fluid and electrolyte disorders
59	Deficiency and other anemia
64	Other hematologic conditions
95	Other nervous system disorders
96	Heart valve disorders
97	Peri-; endo-; and myocarditis; cardiomyopathy (except that caused by tuberculosis or sexually transmitted disease)
100	Acute myocardial infarction
101	Coronary atherosclerosis and other heart disease
102	Nonspecific chest pain
106	Cardiac dysrhythmias
107	Cardiac arrest and ventricular fibrillation
108	Congestive heart failure; nonhypertensive
117	Other circulatory disease
118	Phlebitis; thrombophlebitis and thromboembolism
120	Hemorrhoids
121	Other diseases of veins and lymphatics
122	Pneumonia (except that caused by tuberculosis or sexually transmitted disease)
127	Chronic obstructive pulmonary disease and bronchiectasis

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CCS Category	Detailed Description
130	Pleurisy; pneumothorax; pulmonary collapse
131	Respiratory failure; insufficiency; arrest (adult)
133	Other lower respiratory disease
134	Other upper respiratory disease
135	Intestinal infection
138	Esophageal disorders
140	Gastritis and duodenitis
141	Other disorders of stomach and duodenum
151	Other liver diseases
152	Pancreatic disorders (not diabetes)
153	Gastrointestinal hemorrhage
154	Noninfectious gastroenteritis
155	Other gastrointestinal disorders
158	Chronic kidney disease
159	Urinary tract infections
197	Skin and subcutaneous tissue infections
198	Other inflammatory condition of skin
199	Chronic ulcer of skin
201	Infective arthritis and osteomyelitis (except that caused by tuberculosis or sexually transmitted disease)
237	Complication of device; implant or graft
244	Other injuries and conditions due to external causes
251	Abdominal pain
253	Allergic reactions
255	Administrative/social admission
259	Residual codes; unclassified
651	Anxiety disorders
659	Schizophrenia and other psychotic disorders

CCS Category	Detailed Description
660	Alcohol-related disorders
661	Substance-related disorders

Table 4: Past Year Comorbidities, Grouped by AHRQ CCS Categories for Standardized Readmissions Ratio (SRR) Clinical Measure (Dialysis Facility Measures Only)

The list of 53 past-year comorbidity variables was selected from 233 AHRQ CCS diagnosis categories with prevalence greater than 0.1% using a score-test based sample splitting forward selection approach. In particular, the data sample is randomly split into two halves. The first half is used for fitting a first-stage fixed effects logistic regression model to select a set of comorbidity variables via a forward selection scheme using single variable score tests with 0.01 p-value cutoff, and adjusting for patient-level characteristics such as age splines, sex, BMI, etc. The second half is then used to fit another first-stage model adjusting for patient-level risk factors as well as those selected variables using the first-half data sample. Single variable score tests are performed after model fitting to obtain p-values for selected variables. A common p-value of 1 is assigned to unselected variables using the first-half data sample. The steps above are repeated 50 times to generate 50 sets of p-values for all 233 variables. The 50 p-values of each variable are aggregated following Bühlmann and van de Geer and the 53 prevalent comorbidities with aggregated p-values less than 0.01 are selected.

2.10.16 Flowchart

Figure 11 provides a flowchart that represents the processes used to calculate the Standardized Readmissions Ratio (SRR) for Dialysis Facility Measures.

Standardized Readmission Ratio: The ratio of observed to expected hospital readmissions
Numerator Statement: Number of hospital readmissions observed
Denominator Statement: Number of hospital readmissions expected based on the national rate for patients with similar characteristics
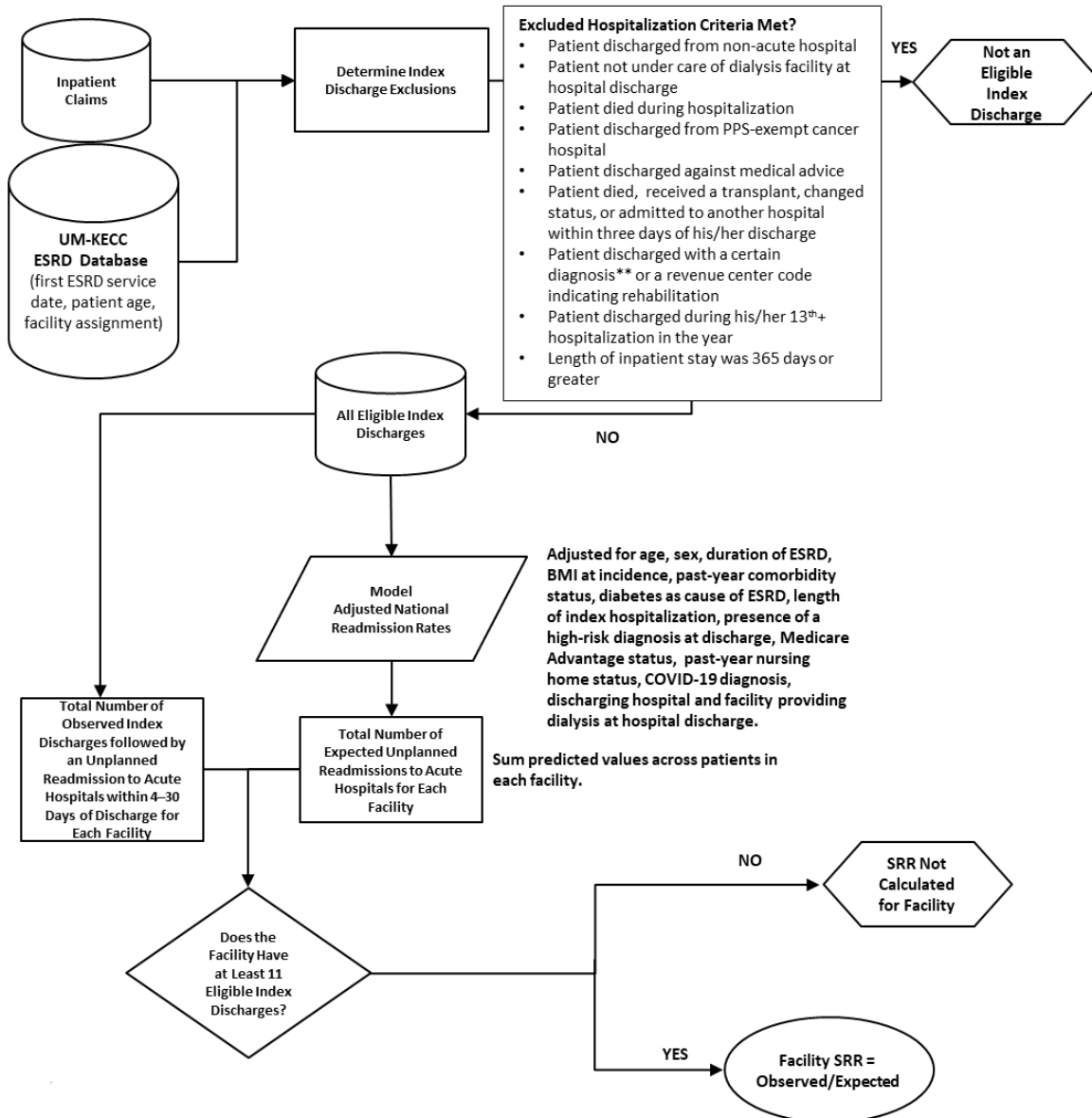
Certain cancers, mental health conditions or rehabilitation for prosthesis

Figure 11: Standardized Readmissions Ratio (SRR) Flowchart (Dialysis Facility Measures Only)

From Figure 8:

* A patient changed status if they recovered, discontinued dialysis, or were lost to follow-up.** Certain cancers, mental health conditions, or rehabilitation for prosthesis.

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2.11 Standardized Readmissions Ratio (SRR) Clinical Measure (ESRD QIP Only)

2.11.1 Measure Name

Standardized Readmission Ratio for Dialysis Facilities

2.11.2 Measure Description

The SRR is defined to be the ratio of the number of index discharges from acute care hospitals that resulted in an unplanned readmission to an acute care hospital within 4-30 days of discharge for Medicare-covered dialysis patients treated at a particular dialysis facility, to the number of readmissions that would be expected given the discharging hospitals and the characteristics of the patients, as well as the national norm for dialysis facilities. Note that in this measure, "hospital" always refers to acute care hospital. SRR can be expressed as a risk-standardized rate, which is the product of the facility SRR and the national average readmission rate.

2.11.3 Measure Rationale

Unplanned readmission rates are an important indicator of patient morbidity and quality of life. On average, dialysis patients are admitted to the hospital nearly twice a year and hospitalizations account for approximately 38 percent of total Medicare expenditures for dialysis patients (U.S. Renal Data System, 2012). In 2010, more than 30% of dialysis patient discharges from an all-cause hospitalization were followed by an unplanned readmission within 30 days (U.S. Renal Data System, 2012). Measures of the frequency of unplanned readmissions, such as SRR, help efforts to control escalating medical costs, play an important role in providing cost-effective health care, and support coordination of care across inpatient and outpatient settings: discharge planning, transition, and follow-up care.

2.11.4 Measure Type

Outcome

2.11.5 Improvement Noted as Higher or Lower Rate

A lower rate/ratio indicates better quality.

2.11.6 Numerator Statement

The observed number of index hospital discharges that are followed by an unplanned hospital readmission within 4–30 days of discharge.

2.11.7 Facility Exclusions

The SRR is only calculated for facilities with at least 11 index hospital discharges in a performance year. Calculations of index discharges will exclude the months covered by a granted ECE (see Section 3.4).

2.11.8   Denominator Statement

The expected number of index discharges followed by an unplanned readmission within 4-30 days in each facility, which is derived from a model that accounts for patient characteristics, the dialysis facility to which the patient is discharged, and the discharging acute care or critical access hospitals involved.

Index Discharge Exclusions

Index hospital discharges exclude discharges that:

- End in death.
- Result in a patient dying within 30 days with no readmission.
- Are against medical advice.
- Include a primary diagnosis for certain types of cancer, mental health or rehab prosthesis. Use the ICD diagnosis code information related to this edition of the *Manual*, which can be found on the Measuring Quality page on the ESRD QIP section of CMS.gov.
- Occur after a patient's 12th admission in the calendar year.
- Are from a PPS-exempt cancer hospital.
- Result in a transfer to another acute care or critical access hospital on the same day, or the day after the discharge date.
- Result in an unplanned readmission occurring within the first three days following discharge from the acute care hospital.
- Where the patient was not on dialysis at discharge.

2.11.9   Patient Exclusions

- Patient with a functioning transplant on the date of the index discharge. Patient is determined to have a functioning transplant on the discharge date when the discharge date occurs on or between the transplant start and end dates.

2.11.10   Mapping Patients to Facilities

Index discharges are attributed to the dialysis provider to which the patient is discharged at the end of the hospital stay. In other words, the facility to which the patient is discharged is held responsible for any unplanned readmissions occurring within 4-30 days of the index discharge, regardless of whether the patient is still being treated at the facility associated with the index discharge at the time of readmission. ESRD QIP assigns to the CCN the facility used as of date of discharge.

2.11.11   Defining Readmissions

Index discharges are restricted to Medicare-covered hospitalizations for inpatient care at short-term acute care hospitals and critical access hospitals. Discharges from SNFs, LTCHs, rehabilitation hospitals and PPS-exempt cancer hospitals - as well as those from separate dedicated units for hospice, rehabilitation and psychiatric care - are excluded. To be counted as

an index discharge, the patient must be receiving dialysis treatment for ESRD at the time of discharge.

See denominator exclusions section for further exclusion criteria applied to index discharges.

Potential readmissions are restricted to:

- Medicare-covered hospitalizations for inpatient care at short-term acute care hospitals and critical access hospitals. Discharges from SNFs, LTCHs, and rehabilitation hospitals are excluded.
- Each potential readmission can be classified as a planned or unplanned admission according to planned readmission algorithm (see Section 2.12.17 for sources for further detail).
- Note that unlike index discharges, a patient does not need to be alive and receiving dialysis treatment for ESRD at the time of discharge from the hospitalization to be considered as a potential readmission.
- Hospitalizations where the patient dies before the date of discharge are excluded from all SRR calculations. Hospitalizations where the patient dies on the date of discharge are included for consideration as potential readmissions.

From this pool of potential readmissions, we identify for each index discharge the first admission within 30 days of the discharge for the patient. This information is then used to classify the index discharge by whether or not it was followed by an unplanned readmission* within 4-30 days as follows:

- If the first admission is unplanned and occurs during days 4-30 after discharge, then the index discharge is classified as having a readmission. (If the first admission is unplanned and occurs during days 1-3 after discharge, the index discharge is excluded).
- If the first admission during days 1-30 is planned* then the index discharge is classified as not having a readmission.
- If there is no admission during days 1-30 and the patient did not die within 30 days of the index discharge, then the index discharge is also classified as not having a readmission. (If there is no admission and the patient died within 30 days of the index discharge then the index discharge is excluded).

* Planned readmissions are determined using the algorithm developed by Yale New Haven Health Services Corporation/Center for Outcomes Research & Evaluation (YNHHSC/CORE) for CMS. Measure Updates and Specifications Report: Hospital-Wide All-Cause Unplanned Readmission Measure.

https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Hospital-Wide-All-Cause-Readmission-Updates.zip

2.11.12 Calculation of National Average

The national average readmission rate is determined by calculating the total number of unplanned readmissions to an acute care hospital within 4-30 days of discharge divided by the

total number of discharges from an acute care hospital in the performance period. This national average rate is multiplied by each facility's SRR, resulting in a risk-standardized readmission rate.

2.11.13 Risk Adjustment

The risk adjustment approach used in the model for the SRR was adapted from CMS' Standardized Hospitalization Ratio (SHR) and CMS' Hospital-Wide Readmission (HWR) measure. The regression model used to compute a facility's "expected" number of readmissions for the SRR measure contains many factors thought to be associated with readmission event rates. Specifically, the model adjusts for age, sex, diabetes, duration of ESRD, BMI at start of dialysis, past-year comorbidities, length of the index discharge hospital stay, and the presence of a high-risk diagnosis (defined below) at index discharge. The model will also include an adjustment for diagnosis of COVID-19 determined from Medicare claims. In addition, the model adjusts for the effect of the discharging hospital (via random effects).

Below are details on the SRR's risk adjustors:

- **Sex**: Determined from EQRS.
- **Age at Index Discharge**: Determined from the birth date provided in EQRS, Medicare Claims, and the Medical Evidence Form (CMS-2728).
- **Years on ESRD**: Determined using the first service date from patient's Medical Evidence Form (CMS-2728), claims history (all claim types with evidence of dialysis), and EQRS.
- **Diabetes as cause of ESRD**: Primary cause of ESRD determined from patient's Medical Evidence Form (CMS-2728) and EQRS. When primary cause of ESRD is missing, we assume diabetes is not the cause of ESRD.
- **BMI at incidence**: Calculated based on the height and weight provided on patient's Medical Evidence Form (CMS-2728). BMI is imputed when either missing, or outside the range of 10 to 70 for adults or 5 to 70 for children. We match patients with missing BMI to patients with non-missing BMI based on the patients' age, race, sex, and diabetes, and then assign the average BMI of the patient subgroup to those patients with missing BMI. However, not all patient subgroups will have a BMI calculated after this process is completed. For these cases, we match the patients based on age and race, and then assign the average BMI in the corresponding age and race category to these remaining patients with missing BMI.
- **Days hospitalized during index hospitalization**: Each hospitalization's length is determined by taking the difference between the date of admission and the date of discharge available on the inpatient claim. For patients who are transferred between one acute care hospital and another, the measure considers these multiple contiguous hospitalizations as a single acute episode of care, and the length is calculated by taking the difference between the date of admission for the first hospitalization and the date of discharge from the last hospitalization included. Time in the hospital is included as a categorical variable based on quartiles (1 variable for each quartile).
- **Past-year comorbidities (risk variables):** Determined by identifying unique ICD-10 diagnosis codes for each patient reported on Medicare claims in the 365 days preceding

(and inclusive of) the index discharge date. Five claim types are examined: inpatient, outpatient, SNF, hospice, and home health claims. Diagnosis codes are grouped using CMS' Condition Categories (CCs; see https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/evaluation_risk_adj_model_2011.pdf). The HWR measure has determined that a subset of these diagnosis areas is appropriate to use in accounting for case mix; see Section 2.12.15 for a list of the CCs included in these areas.

- **COVID-19 diagnosis**: COVID-19 diagnosis is obtained from Medicare inpatient claims only. A claim record is confirmed as a COVID-19 diagnosis if the patient's inpatient claim reports any COVID-19 diagnosis codes (ICD-10-CM: U071, B9729, J1282) as primary or secondary diagnoses. Secondary diagnoses include 2nd through 25th ordered diagnoses. Index discharges with an inpatient COVID-19 diagnosis during the hospitalization are identified as COVID-19 index discharges. Since comorbidities in the SRR are based solely on inpatient claims, we do not include COVID-19 diagnoses or other diagnoses from claims associated only with laboratory testing or outpatient visits.

- **Discharged with high-risk condition**: A *high-risk* diagnosis is any diagnosis area (grouped by the AHRQ CCS) that was rare in the population but had a 30-day readmission rate of at least 40%. Note that high-risk diagnosis groups related to cancer or mental health are excluded from index discharges. The CCS areas identified as high-risk are:
  - CCS 5: HIV infection
  - CCS 6: Hepatitis
  - CCS 56: Cystic fibrosis
  - CCS 57: Immunity disorders
  - CCS 61: Sickle cell anemia
  - CCS 190: Fetal distress and abnormal forces of labor
  - CCS 151: Other liver diseases
  - CCS 182: Hemorrhage during pregnancy; abruptio placenta; placenta previa
  - CCS 186: Diabetes or abnormal glucose tolerance complicating pregnancy; childbirth; or the puerperium
  - CCS 210: Systemic lupus erythematosus and connective tissue disorders
  - CCS 243: Poisoning by nonmedicinal substances

In summary, the SRR indicates whether a facility experienced higher or lower readmission rates than the national average after accounting for differences that could be attributed to the patient characteristics listed above, as well as the discharging hospital.

2.11.14 Calculation of SRR

The expected number of readmissions in the denominator of the SRR is calculated based on a statistical model for the probability that a given hospital discharge will give rise to an unplanned readmission within the next 4–30 days. This model is technically termed a hierarchical logistic model and takes into account the patient characteristics or covariates discussed above. In addition, our model includes a random effect term for hospital of discharge, and so, makes an adjustment in patient outcomes for the potential effect of the care received at the hospital. This adjustment acknowledges the fact that there is a shared responsibility between the dialysis

facility and the discharging hospital for patient care. At the same time, the model retains an incentive for facilities and hospitals to coordinate care in order to improve outcomes with respect to readmissions. Facility effects are also estimated in the model, and the number of readmissions in each facility is compared to the number that would be expected at a facility under the national norm (i.e., with median facility effect) given the patient characteristics. There are a number of technical details associated with this computation that are not dealt with in this summary. The interested reader is referred to He et al. (2013).

In general, we aim to adjust for patient characteristics that affect the endpoint of interest. These include such factors as age, BMI and comorbidities as measured at the time origin or baseline. For SRR, the relevant time origin is the index discharge, and so we adjust for most of the patient's characteristics around the time of that discharge.

In assessing the effects of patient covariates or characteristics, we estimate the within facility differences in outcomes that can be attributed to that covariate. To do this, we estimate the regression coefficients for the covariate while adjusting for potential facility effects through inclusion of facilities in the model as fixed effects. It is important in estimating covariate effects to take this approach since otherwise, there is a potential confounding between the effects of facilities and patient characteristics. For example, suppose that older patients are associated with poorer outcomes and tended to attend facilities that provided better care and that, as a result, tended to have better outcomes. If the effect of the covariates were estimated without adjusting for facilities, either by ignoring possible facility effects or including facilities as random effects, the age effect would be incorrectly estimated. In effect, we would underestimate the negative effect of older age on the outcome.

From a technical perspective, fixed effects provide more precise estimation of the true effects for those facilities with extreme outcomes, as opposed to random effects, which result in shrinkage estimators (where the estimate for each facility is shifted toward the overall mean). The shrinkage becomes substantial for smaller facilities, making identification of poor performance in smaller facilities even more difficult. Issues associated with this choice are described in some detail in Kalbfleisch and Wolfe (2013) and He et al. (2013).

The equations used in the measure calculation are as follows:

The main model, which produces the estimates used to calculate SRR, takes the form:

(1)

$$\log \frac{p_{ijk}}{1 - p_{ijk}} = \gamma_i + \alpha_j + \beta^T Z_{ijk}$$

Where p_{ijk} represents the probability of an unplanned readmission for the kth discharge among patients from the ith facility who are discharged from j^{th} hospital, and z_{ijk} represents the set of patient-level characteristics. Here, γ_i is the fixed effect for facility and α_j is the random effect for hospital j. It is assumed that the α_js arise as independent normal variables (i.e., $\alpha_j \sim N(0, \sigma^2)$).

We use the estimates from this model to calculate the ith facility's SRR:

(2)

$$SRR_i = \frac{O_i}{E_i} = \frac{O_i}{\sum_{j \in H(i)} \sum_{k=1}^{n_{ij}} \tilde{p}_{ijk}}$$

where, for the ith facility, O_i is the number of observed unplanned readmissions, E_i is the expected number of unplanned readmissions, $H(i)$ is the collection of indices of hospitals from which patients are discharged to the ith facility, n_{ij} is the number of discharges from hospital j and facility i, and $\tilde{p}_{ijk}$ is the estimated probability of an unplanned readmission under the assumption that the corresponding discharge belongs to a facility with national norm.

More specifically,

(3)

$$\tilde{p}_{ijk} = \frac{\exp(\widehat{\gamma_M} + \widehat{\alpha_j} + \widehat{\beta}^T Z_{ijk})}{1 + \exp(\widehat{\gamma_M} + \widehat{\alpha_j} + \widehat{\beta}^T Z_{ijk})}$$

estimates the probability that a discharge from hospital j to facility i of a patient with characteristics z_{ijk} would result in an unplanned readmission; this probability is being estimated assuming that the facility's effect corresponds to the median of national facility effects, denoted by γM. Here, $\widehat{\alpha_j}$ and $\beta^\wedge$ are estimates from model (1). The sum of these probabilities is the expected number of unplanned readmissions E_i at facility i, adjusting for patient mix and under the national norm.

2.11.15 Data Elements and Data Sources

Data are derived from an extensive national ESRD patient database based on data from the CMS and EQRS system, Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (CMS-2728), and the Death Notification Form (CMS-2746) (Table 5). The database is comprehensive for Medicare-covered ESRD patients. Information on hospitalizations is obtained from Medicare Inpatient Claims SAFs and past-year comorbidity is obtained from multiple types (inpatient, outpatient institutional, physician/supplier, home health, hospice, SNF claims) of Medicare Claims SAFs.

The data are comprehensive for Medicare patients. Non-Medicare patients are included in all sources except for the Medicare claims, which do include non-traditional Medicare such as the Part A shadow records for MA patients. EQRS provides tracking by dialysis provider and treatment modality for non-Medicare patients. Information on hospitalizations is obtained from Part A Medicare Inpatient Claims, and information on past-year comorbidities is obtained from

multiple Part A claim types (inpatient, outpatient, home health, hospice, SNF claims) and Part B outpatient institutional Medicare Claims.

Two grouping systems are used in the risk adjustment model to identify comorbidities and high-risk conditions. For past year comorbidity adjustment, the measure groups diagnosis codes by diagnosis area using HHS' Hierarchical Condition Categories (CCs); (Table 6) see https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/HealthCareFinancingReview/downloads/04summerpg119.pdf. To identify high-risk conditions, the measure groups diagnosis codes using the AHRQ CCS; see https://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccs.jsp .

Variable	Primary Data Source
Facility CCN	Multiple data sources[1]
Date of birth	Multiple data sources[1]
Sex	Multiple data sources[1]
Date of first ESRD service	Multiple data sources[1]
Date of death	Multiple data sources[1]
Date of transplant(s)	Multiple data sources[1]
BMI at incidence	Medical Evidence Form (CMS-2728)
Diabetes - Primary cause of ESRD	Medical Evidence Form (CMS-2728) EQRS
High-risk diagnoses	Medicare Claims[2]
Planned readmissions	Medicare Claims[2]
Hospital admissions	Inpatient Medicare claims
Discharge status	Inpatient Medicare claims
COVID-19 Diagnosis	Inpatient Medicare claims

Table 5: Data Elements and Sources for Standardized Readmissions Ratio (SRR) Clinical Measure (ESRD QIP Only)

1. This may include information from (EQRS, Medicare Enrollment Database (EDB), Medical Evidence Form (CMS 2728), and Medicare Claims. Unique patients are identified by using a combination of SSN, first name, surname, sex, Medicare Beneficiary ID, patient Health Insurance Claim Number and birth date.

2. Medicare claims include Part A claims such as inpatient admissions and Part B claims such as outpatient claims (including dialysis claims) and physician services.

Description	CC	Detailed Description (if applicable)
Severe infection	**1, 3–5**	
	1	HIV/AIDS
	3	Central nervous system infection

Description	CC	Detailed Description (if applicable)
	4	Tuberculosis
	5	Opportunistic infections
Other infectious disease & pneumonias	**6, 111–113**	
	6	Other infectious disease
	111	Aspiration and specified bacterial pneumonias
	112	Pneumococcal pneumonia, emphysema, lung abscess
	113	Viral and unspecified pneumonia, pleurisy
Metastatic cancer/acute leukemia	**7**	
Severe cancer	**8–9**	
	8	Lung, upper digestive tract, and other severe cancers
	9	Other major cancers
Other major cancers	**10–12**	
	10	Breast, prostate, colorectal and other cancers and tumors
	11	Other respiratory and heart neoplasms
	12	Other digestive and urinary neoplasms
End-stage liver disease	**25–26**	
	25	End-stage liver disease
	26	Cirrhosis of liver
Other hematological disorders	**44**	
Drug and alcohol disorders	**51–52**	
	51	Drug/alcohol psychosis
	52	Drug/alcohol dependence
Psychiatric comorbidity	**54–56, 58, 60**	
	54	Schizophrenia
	55	Major depressive, bipolar, and paranoid disorders
	56	Reactive and unspecified psychosis
	58	Depression
	60	Other psychiatric disorders
Hemiplegia, paraplegia, paralysis	**67–69, 100–101**	

Description	CC	Detailed Description (if applicable)
	67	Quadriplegia, other extensive paralysis
	68	Paraplegia
	69	Spinal cord disorders/injuries
	100	Hemiplegia/hemiparesis
	101	Diplegia (upper), monoplegia, and other paralytic syndromes
Amputation	**177–178**	
	177	Amputation status, lower limb/amputation
	178	Amputation status, upper limb
Seizure disorders and convulsions	**74**	
Chronic obstructive pulmonary disease	**108**	
Fibrosis of lung or other chronic lung disorders	**109**	
Ulcers	**148–149**	
	148	Decubitus ulcer
	149	Decubitus ulcer or chronic skin ulcer
Septicemia/shock	**2**	
Cardio-respiratory failure or cardio-respiratory shock	**79**	
Pancreatic disease	**32**	
Rheumatoid arthritis and inflammatory connective tissue disease	**38**	
Respirator dependence/tracheostomy status	**77**	
Major organ transplant status	**174**	
Coagulation defects and other specified hematological disorders	**46**	
Hip fracture/dislocation	**158**	

Table 6: Past Year Comorbidities, Grouped by CMS' Condition Categories for Standardized Readmissions Ratio (SRR) Clinical Measure (ESRD QIP Only)

2.11.16 Flowchart

Figure 12 provides a flowchart that represents the processes used to calculate the SRR for ESRD QIP.

Standardized Readmission Ratio (SRR): The ratio of the number of index discharges from acute care hospitals that resulted in an unplanned readmission to an acute care hospital within 30 days of discharge for Medicare-covered dialysis patients treated at a particular dialysis facility to the number of readmissions that would be expected given the discharging hospitals and the characteristics of the patients as well as the national norm for dialysis facilities. Note that in this measure, "hospital" always refers to acute care hospital.
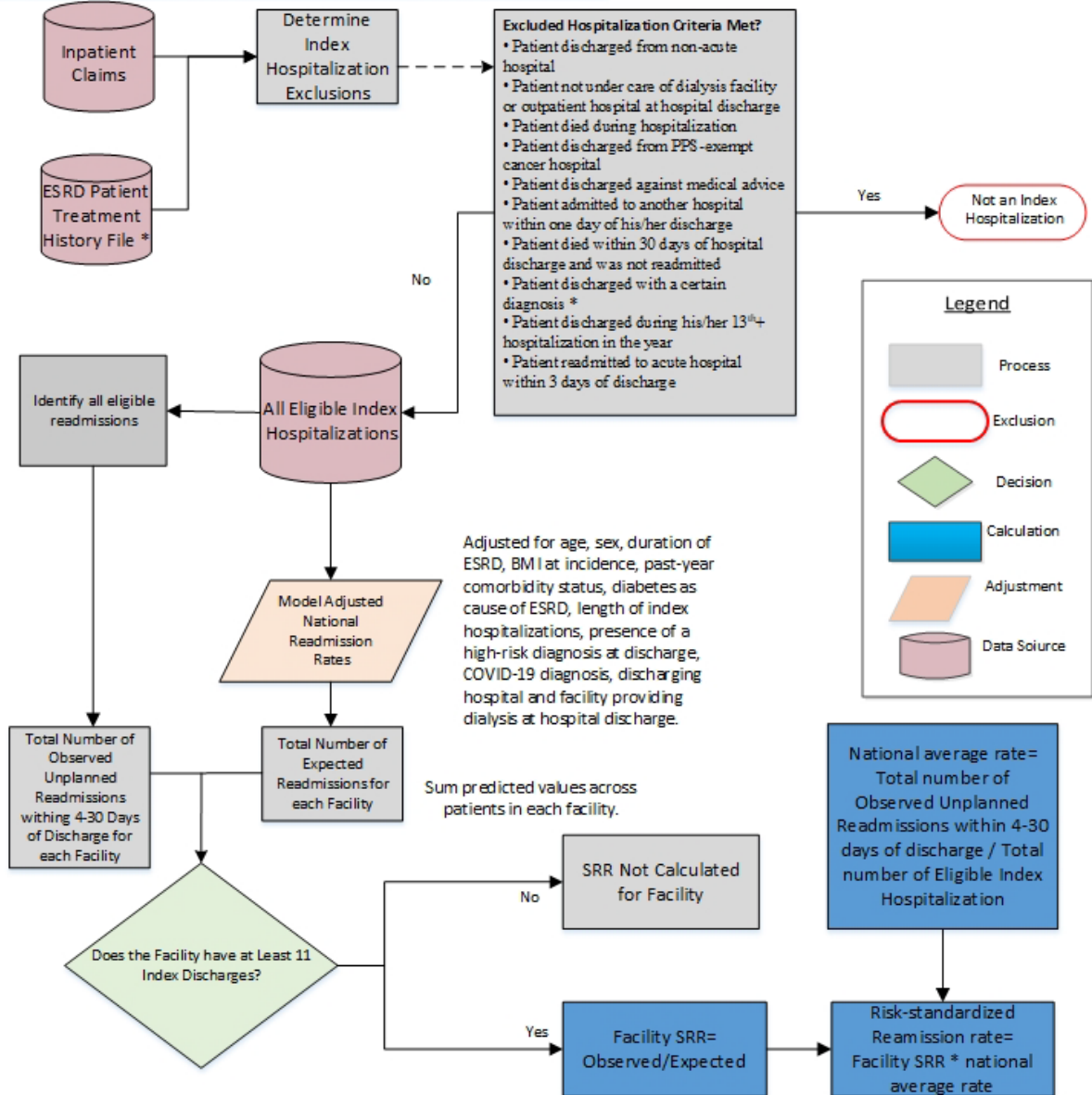
Figure 12: Standardized Readmissions Ratio (SRR) Flowchart (ESRD QIP Only)

From Figure 9:

* = Multiple data sources include EQRS - including the CMS Annual Facility Survey (Form CMS-2744), the CMS Medical Evidence Form (CMS-2728), and the Death Notification Form (Form CMS-2746), and Medicare dialysis and hospital payment records.

2.11.17 Selected References

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2.12 Standardized Transfusion Ratio (STrR) Clinical Measure (ESRD QIP and Dialysis Facility Measures)

2.12.1 Measure Name

Standardized Transfusion Ratio for Dialysis Facilities

2.12.2 Measure Description

The risk adjusted facility level transfusion ratio "STrR" is specified for all adult Medicare dialysis patients (CBE ID 2979). It is a ratio of the number of eligible red blood cell transfusion events observed in patients dialyzing at a facility, to the number of eligible transfusion events that would be expected under a national norm, after accounting for the patient characteristics within each facility. Eligible transfusions are those that do not have any claims pertaining to the comorbidities identified for exclusion in the one-year look-back period prior to each observation window. STrR can be expressed as a risk-standardized rate, which is the product of the facility STrR and the national average transfusion rate.

2.12.3 Measure Rationale

Several changes in the ESRD system are likely to impact anemia management. These include identification of safety concerns associated with aggressive ESA use, expansion of the ESRD PPS bundled payment, and the development of the ESRD QIP. There are concerns that these changes could result in underutilization of ESAs, with lower achieved hemoglobin values that may increase the frequency of red blood cell transfusion in the US chronic dialysis population.

Blood transfusion may be an indicator for underutilization of treatments to increase endogenous red blood cell production (e.g., ESA, iron). In addition, dialysis patients who are eligible for kidney transplant and are transfused risk the development of becoming sensitized to the donor pool thereby making transplant more difficult to accomplish. Blood transfusions carry a small risk of transmitting blood borne infections, development of a transfusion reaction, and using infusion centers or hospitals to transfuse patients is expensive, inconvenient, and could compromise future vascular access.

Monitoring the risk-adjusted transfusion rate at the dialysis facility level, relative to a national standard, allows for detection of treatment patterns in dialysis-related anemia management. This is of particular importance due to FDA guidance regarding minimizing the use of ESAs, and economic incentives to minimize ESA use introduced by Medicare's bundling of payment for ESAs. As providers use less ESAs in an effort to minimize the risks associated with aggressive anemia treatment it becomes more important to monitor for an overreliance on transfusions.

2.12.4 Measure Type

Outcome

2.12.5   Outcome Improvement Noted as Higher or Lower Rate

A lower rate/ratio indicates better quality.

2.12.6   Numerator Statement

Number of eligible observed red blood cell transfusion events: An event is defined as the transfer of one or more units of blood or blood products into a recipient's blood stream (code set is provided in the numerator details) among patients dialyzing at the facility during the inclusion episodes of the reporting period. Inclusion episodes are those that do not have any claims pertaining to the comorbidities identified for exclusion, in the one-year look-back period prior to each observation window.

2.12.7   Facility Exclusions

The standardized transfusion ratio is only calculated for facilities with at least 10 patient-years at risk.

ESRD QIP Only:

Calculations will exclude the months covered by a granted ECE (see Section 3.4).

2.12.8   Denominator Statement

Number of eligible red blood cell transfusion events (as defined in the numerator statement) that would be expected among patients at a facility during the reporting period, given the patient mix at the facility. Inclusion episodes are those that do not have any claims pertaining to the comorbidities identified for exclusion, in the one-year look-back period prior to each observation window.

2.12.9   Denominator Exclusions

For all patients, time at risk begins at the start of the facility treatment period and continues until the earliest occurrence of the following: three days prior to a transplant; date of death; end of facility treatment; or December 31 of the year. This convention is used with other Dialysis Facility Measures developed and previously endorsed by the CBE (like SHR CBE ID 1463 https://p4qm.org/measures/1463). Patient time at risk is excluded for:

- Patients less than 18 years old (see Section 3.1.3).
- Patients in the first 90 days of ESRD treatment.
- Patients on dialysis at the facility for fewer than 60 days.
- Time during which patient has a functioning kidney transplant (exclusion begins three days prior to the date of transplant).
- Patients who have not been treated by any facility for a year or longer.
- Time during which patient is enrolled in MA according to the Medicare Enrollment Database.

- Patients with a Medicare claim (Part A inpatient, home health, hospice, and SNF claims; Part B outpatient and physician supplier) for one of the following conditions in one-year look-back period:
  - Hemolytic and aplastic anemia
  - Solid organ cancer (breast, prostate, lung, digestive tract and others)
  - Lymphoma
  - Carcinoma in situ
  - Coagulation disorders
  - Multiple myeloma
  - Myelodysplastic syndrome and myelofibrosis
  - Leukemia
  - Head and neck cancer
  - Other cancers (connective tissue, skin, and others)
  - Metastatic cancer
  - Sickle cell anemia

The 2012 Anemia TEP felt that development of a risk-adjustment strategy encompassing these specific comorbidity categories for use in the facility-level transfusion metric was critically important. These prevalent comorbidities define a sub-population of patients who are at increased risk of blood transfusions, and in addition, are less likely to respond to recommended doses of exogenous ESAs. Furthermore, they are likely at increased risk for ESA-related complications. Lastly, the TEP members agreed that the aforementioned comorbidities were outside the sphere of influence of the dialysis facilities. The TEP considered additional comorbidities but recommended against their use in the risk-adjustment paradigm if the comorbidity could potentially be the result of care provided by the dialysis facility. The ICD information related to this edition of the *Manual* can be found on the Measuring Quality page on the ESRD QIP section of CMS.gov.

Since these comorbidities are associated with higher risk of transfusion and require different anemia management practices that this measure is not intended to address, every patient's risk window is modified to have at least one year free of claims that contain diagnoses on the exclusion list. We assessed the predictive power of comorbidities on future transfusions as a function of the time interval between development of the comorbidity and the occurrence of the transfusion, by performing multivariate logistic regression with transfusion count as the dependent variable. Results showed that one-year look-back period for each of the above-mentioned comorbidities was the most predictive of one or more red blood cell transfusions.

Figure 10 describes the inclusion and exclusion period of a hypothetical patient.
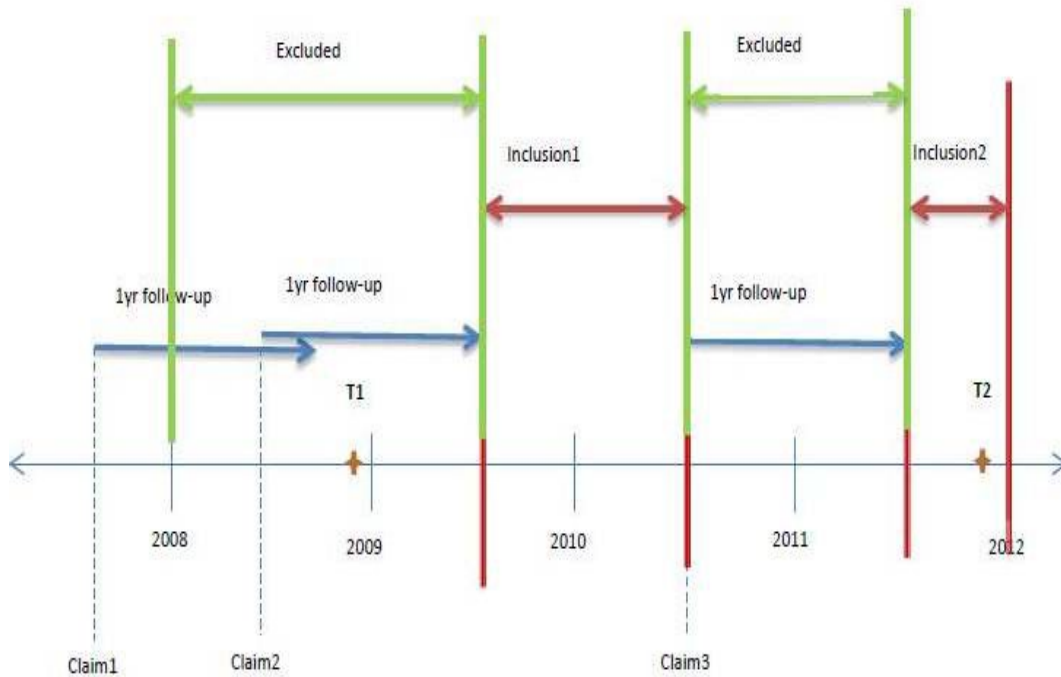
Figure 13: Algorithm for Exclusion of Periods of Time Within 1 Year of an Exclusion Comorbidity

In the figure, a hypothetical patient has patient-years at risk at a facility from 1/1/2008 to 12/31/2011. Review of Medicare claims identified presence of one or more exclusion comorbidities in 2007 (Claim1), 2008 (Claim2) and 2010 (Claim3). Each claim is followed by a one-year exclusion period. The revised inclusion periods are defined as risk windows with at least one year of claim-free period (Inclusion1 and Inclusion2 in figure). The patient has two transfusion events, marked as T1 and T2 in late 2008 and late 2011 respectively. However, since T1 falls in the exclusion period, it will not be counted towards the facility's transfusion count as presence of exclusion comorbidity claims within a year might have increased the risk of transfusion unrelated to dialysis facility anemia management practice. However, T2, which occurs in late 2011 and in Inclusion2 period, will be counted since there is at least a year gap between this transfusion event and the last claim observed.

2.12.10   Mapping Patients to Facilities

Starting with day 91 of ESRD, a patient is attributed to a facility according to the following rules. A patient is attributed to a facility once the patient has been treated there for 60 days. When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 60 days and then is attributed to the destination facility. In particular, a patient is attributed to their current facility on day 91 of ESRD if that facility had treated them for at least 60 days. If on day 91, the facility had treated a patient for fewer than 60 days, we wait until the patient reaches day 60 of treatment at that facility before attributing the patient to that facility. When a patient is 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 do not attribute that patient to any

facility. Patients are removed from facilities three days prior to transplant in order to exclude the transplant hospitalization. Patients who withdrew from dialysis or recovered renal function remain assigned to their treatment facility for 60 days after withdrawal or recovery.

If a period of one year passes with neither paid dialysis claims nor EQRS information to indicate that a patient was receiving dialysis treatment, we consider the patient lost to follow-up and do not include that patient in the analysis. If dialysis claims or other evidence of dialysis reappears, the patient is entered into analysis after 60 days of continuous therapy at a single facility.

2.12.11 Calculating Numerators

The method for counting transfusion events relies on a conservative counting algorithm and, because of the way transfusion information is reported in Medicare claims, uses different rules for counting transfusion events, depending on whether or not the event occurs in the inpatient setting, or an outpatient setting. The most common way that events are reported on claims is by reporting a revenue center, procedure, or value code (inpatient claims), or for outpatient claims, reporting HCPCS codes with at least one revenue center code.

One "transfusion event" is counted per inpatient claim if one or more transfusion-related procedure, revenue center, or value codes are present. A single transfusion event for an inpatient claim is counted regardless of the number of transfusion revenue center, procedure, and value codes reported so that the number of discrete events counted is the same whether the claim indicates one unit of blood or multiple units of blood. This results in a very conservative estimate of blood transfusions from inpatient claims.

Transfusion events are not common in outpatient settings, but similar rules apply. One or more transfusion-related HCPCS codes with at least one transfusion-related revenue center code, or one or more transfusion-related value codes listed on an outpatient claim are counted as a single transfusion event regardless of the number of units of blood recorded. In other words, three units of blood would be counted as a single transfusion event. If there is more than one event on a given day for a patient, this is counted as a single transfusion event.

Because we identify transfusions only if they appear in Medicare inpatient and outpatient claims, we only want to include patients during time periods in which all of the patients' transfusions are included in Medicare billing records. To achieve this goal, we require that patients either reach a certain level of Medicare-paid dialysis bills or have Medicare-paid inpatient claims during the period. Specifically, patient-months within a given dialysis patient-period are used for STrR calculation when they meet the criterion of being within two months after a month with either: (a) $1,200+ of Medicare-paid dialysis claims OR (b) at least one Medicare inpatient (hospital and SNF) claim. The intention of this criterion is to assure completeness of information on transfusions for all patients included in the analysis. The detailed procedures to determine unique transfusion events at the claim level are presented in a flow chart later in this section.

2.12.12 Days at Risk for Medicare Dialysis Patients

After patient treatment histories are defined as described in the Denominator Exclusions Section, periods of follow-up in time since ESRD onset are created for each patient. In order to adjust for duration of ESRD appropriately, we define six-time intervals with cut points at six months, one year, two years, three years, and five years. A new time period begins each time the patient is determined to be at a different facility, or at the start of a new COVID-19 diagnosis category (see 2.13.13 for description) each calendar year, or when crossing any of the above cut points.

The number of days at risk in each of these patient-ESRD-year-facility time periods is used to calculate the expected number of transfusions for the patient during that period. The STrR for a facility is the ratio of the total number of observed transfusions to the total number of expected transfusions during all time periods at the facility.

2.12.13 Risk Adjustment

The regression model used to compute a facility's "expected" number of transfusions for the STrR measure contains many factors that are associated with hospitalization frequency and transfusion event rates. Specifically, the model adjusts for patient age, diabetes as cause of ESRD, duration of ESRD, nursing home status, BMI at incidence, comorbidities at incidence, and COVID-19 diagnosis. This model allows the baseline transfusion rates to vary between strata (facilities) but assumes that the regression coefficients are the same across all strata; this approach is robust to possible differences between facilities in the patient mix being treated.

The patient characteristics included in the stage 1 model as covariates also include COVID-19 diagnosis determined from Medicare claims or EQRS data sources, as well as the following:

- Age: Determine each patient's age for the birth date provided in the EQRS database, Medicare Claims, and the Medical Evidence Form (CMS-2728). Patients are grouped into the following categories: 18-24 years old, 25-44 years old, 45-59 years old, 60-74 years old, or 75+ years old.
- Diabetes as cause of ESRD: Determine each patient's primary cause of ESRD from his/her CMS-2728, and EQRS.
- Duration of ESRD: Determine each patient's length of time since start of ESRD treatment using patient's CMS-2728, claims history (all claim types), the EQRS patient events file, and OPTN (Dialysis Facility Measures only). Duration is categorized as 91 days- < 6 months, 6 months- < 1 year, 1- < 2 years, 2- < 3 years, 3- < 5 years, or 5+ years as of the period start date.
- Nursing home status: Uses multiple sources* including the 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) as of the period start date.
- BMI at incidence: Calculate each patient's BMI based on the height and weight provided on his/her CMS 2728 and group patients into the following categories: BMI < 18.5, 18.5 ≤ BMI < 25, 25 ≤ BMI < 30, or BMI ≥ 30. Missing and out-of-range BMIs are categorized into the mode group (i.e., >=30).

- Comorbidities at incidence are determined using a selection of comorbidities reported on the 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 covariate in the model.
- COVID-19 diagnosis: Information on COVID-19 diagnosis is obtained from Medicare claims Part A and Part B. Since this measure uses outpatient claims for some transfusions, the measure is based on all Medicare fee for services patients. MA patients are excluded. 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. COVID-19 diagnoses also come from the CMS Form-2728. Patients with a COVID-19 event on February 20, 2020 or later (including during the ECE period of March-June 2020) are identified as COVID-19 patients. The COVID-19 clock starts at the claim from date of the first COVID-19 diagnosis and is assumed to continue after this date. We divided the period following the first COVID-19 diagnosis into three stages: the first month (days 1-30) after the first COVID-19 diagnosis is defined as "COVID1"; the second month (days 31-60) is defined as "COVID2"; more than two months (> 60 days) after the first diagnosis date is defined as "COVID3". In this way, STrR allows for separate parameters measuring the COVID-19 effect during the 1st month, the 2nd month, and more than two months. COVID1, COVID2, and COVID3 are all included as covariates in the model, while No COVID is the reference group.

* This may include information from: EQRS (including the Medical Evidence Form (CMS 2728) and Medicare Claims).

Categorical indicator variables are included as covariates in the stage 1 model to account for records with missing values for cause of ESRD and comorbidities at incidence (missing Medical Evidence Form (CMS-2728)). These variables have a value of 1 if the patient is missing the corresponding variable and a value of 0 otherwise. Another categorical indicator variable is included as a covariate in the stage 1 model to flag records where the patient has at least one of the incident comorbidities listed earlier. This variable has a value of 1 if the patient has at least one of the comorbidities and a value of 0 otherwise.

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

- Diabetes as cause of ESRD and Duration of ESRD.
- Diabetes as cause of ESRD and Age.

2.12.14 Calculating Expected Number of Transfusions

The denominator of the STrR stems from a proportional rates model (Lawless and Nadeau, 1995; Lin et al., 2000; Kalbfleisch and Prentice, 2002). This is the recurrent event analog of the well-

known proportional hazards or Cox model (Cox, 1972; Kalbfleisch and Prentice, 2002). To accommodate large-scale data, we adopt a model with piecewise constant baseline rates (e.g., Cook and Lawless, 2007) and the computational methodology developed in Liu, Schaubel and Kalbfleisch (2012).

The modeling process has two stages and is run separately for each calendar year. At **stage 1**, a stratified model is fitted to the national data with piecewise-constant baseline rates and stratification by facility. Specifically, the model is of the following form:

*Pr(*transfusion on day *t* given covariates *X) = $r_{0k}(t)$*exp($\boldsymbol{\beta'X_{ik}}$)*

where $\boldsymbol{X_{ik}}$ is the vector of covariates for the *(i,k)*th patient and $\boldsymbol{\beta}$ is the vector of regression coefficients. The baseline rate function $r_{0k}(t)$ is assumed specific to the kth facility, which is assumed to be a step function with break points at six months, one year, two years, three years, and five years since the onset of dialysis. This model allows the baseline transfusion rates to vary between strata (facilities) but assumes that the regression coefficients are the same across all strata; this approach is robust to possible differences between facilities in the patient mix being treated. The stratification on facilities is important in this phase to avoid bias due to possible confounding between covariates and facility effects.

The patient characteristics X_{ik} included in the stage 1 model are listed above (under risk adjustment).

At **stage 2**, the relative risk estimates from the first stage are used to create offsets and an unstratified model is fitted to obtain estimates of an overall baseline rate function. That is, we estimate a common baseline rate of transfusions, $r_0(t)$, across all facilities by considering the model:

*Pr(*transfusion on day *t* given covariates *X) = $r_0(t) R_{ik,}$*

where $R_{ik} = $ exp($\boldsymbol{\beta'X_{ik}}$) is the estimated relative risk for patient i in facility k estimated from the stage 1. In our computation, we assume the baseline to be a step function with six unknown parameters, $\alpha_1, ..., \alpha_6$, to estimate. These estimates are used to compute the expected number of transfusions given a patient's characteristics.

Specifically, let t_{iks} represent the number of days that patient i from facility k is under observation in the *s*th time interval with estimated rate α_s. The corresponding expected number of transfusions in the *s*th interval for this patient is calculated as:

$$\mathbf{E_{iks}=\alpha_s\ t_{iks}\ R_{ik}}.$$

It should be noted that $\mathbf{t_{iks}}$ and hence $\mathbf{E_{iks}}$ can be 0 if patient i from facility k is never at risk during the *s*th time interval. Summing the $\mathbf{E_{iks}}$ over all 6 intervals and all N_k patients in a given facility, k, gives:

$$E = \sum_{i=1}^{N} \sum_{s=1}^{6} E_{iks} = \sum_{i=1}^{N} \sum_{s=1}^{6} \alpha_s \, t_{iks} \, R_{ik},$$

which is the expected number of transfusions during follow-up at that facility.

Let **O** be the observed total number of transfusions at this facility. The STrR for transfusions is the ratio of the observed total transfusions to this expected value, or

$$\text{STrR} = O/E$$

2.12.15 Calculation of National Average

The national average transfusion rate is determined by calculating the total number of transfusions divided by the total number of patient-years at risk in the performance period. This national average rate is then multiplied by each facility's STrR, resulting in a risk-standardized transfusion rate.

2.12.16 Calculation of STrR P-values and Confidence Intervals

To overcome the possible over-dispersion of the data, we compute the p-value for our estimates using the empirical null distribution, an approach that possesses more robustness (Efron, 2004; Kalbfleisch and Wolfe, 2013). Our algorithm consists of the following concrete steps. First, we fit an over-dispersed Poisson model (e.g., SAS PROC GENMOD with link=log, dist=poisson and scale=dscale) for the number of transfusions as:

$$\log(E[n_{ik}]) = \log(E_{ik}) + \theta_k,$$

where n_{ik} is the observed number of events for patient i in facility k, E_{ik} is the expected number of events for patient i in facility k and θ_k is the facility-specific intercept. Here, i ranges over the number of patients n_{ik} who are treated in the kth facility. The natural log of the STrR for the kth facility is then given by the corresponding estimate of θ_k. The standard error of θ_k is obtained from the robust estimate of variance arising from the overdispersed Poisson model.

Second, we obtain a z-score for each facility by dividing the natural log of its STrR by the standard error from the general linear model described above. These z-scores are then grouped into quartiles based on the number of patient-years at risk for Medicare patients in each facility. Finally, using robust estimates of location and scale based on the normal curve fitted to the center of the z-scores for the STrR, we derive the mean and variance of a normal empirical null distribution for each quartile. This empirical null distribution is then used to calculate the p-value for a facility's STrR.

The uncertainty or confidence intervals are obtained by applying the following steps:

- From the general linear model, we obtain the natural log of the STrR (ln STrR) as well as its standard error, (SE). From the empirical null, we obtain a mean (μ) and a standard deviation (σ). The 95% uncertainty interval for the 'true' log standardized transfusion ratio for this facility is:

$$\ln STrR - \mu * SE \pm 1.96 * \sigma * SE.$$

Note that 1.96 is the critical point from the standard normal distribution for a 95% interval.

- Exponentiating the endpoints of this interval gives the uncertainty interval for the true STrR.

2.12.17 Data Elements and Data Sources

Table 7 shows the CMS data sources[1] are used as the data sources for establishing the denominator. Medicare claims is the data source for establishing the numerator. CMS Medical Evidence form 2728 is data sources for the risk adjustment factors. Medicare claims are used for the exclusion criteria.

Variable	Primary Data Source
Facility CCN	CMS data sources[1]
Date of birth	CMS data sources[1]
Date of first ESRD	Medical Evidence Form (CMS-2728) EQRS Patient Event OPTN Data (Dialysis Facility Measures only) Medicare Claims[2]
BMI at incidence	Medical Evidence Form (CMS-2728)
Nursing home status (in the previous calendar year)	CMS Minimum Data Set
Diabetes - Primary cause of ESRD	Medical Evidence Form (CMS-2728) (EQRS)
Incident comorbidities as the risk adjustment factors[3]	Medical Evidence Form (CMS-2728)
Transfusion events[4]	Medicare Claims[2]
Prevalent comorbidities used for exclusion[5]	Medicare Claims[2]
COVID-19 diagnosis	Medicare Claims and Medical Evidence Form (CMS-2728)

Table 7: Data Elements and Sources for the Standardized Transfusion Ratio (STrR) Clinical Measure

1. This may include information from: EQRS Medicare Claims, Medicare Enrollment Database (EDB), Medical Evidence Form (CMS 2728), and Organ Procurement and Transplantation Network Database (OPTN) (Dialysis Facility Measures only). For Dialysis Facility Measures, unique patients are identified by using a combination of SSN, first name, surname, sex, Medicare Beneficiary ID, Patient Health Insurance Claim Number and birth date. The Dialysis Facility Measures patient-matching process is performed to ensure that minor typos and misspellings do not cause a patient record to fall out of their history. The matching process is able to successfully match 99.5% of patients. The remaining patients have incomplete or incorrect data that does not allow them to be matched (see Section 3.2). See Section 1.1 for patient matching details used in ESRD QIP.

2. Medicare claims include Part A claims such as inpatient admissions and Part B claims such as outpatient claims (including dialysis claims) and physician services. Claims from providers, such as laboratories, that report diagnosis codes when testing for the presence of a condition are excluded.

3. Incident comorbidities as the risk adjustment factors: Comorbidities at incidence are determined using a selection of comorbidities reported on the Medical Evidence Form (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 covariate in the model.

4. Details in Determining Transfusion Events Flow Chart (Figure 12).

5. Prevalent comorbidities used for exclusion: Patient time at risk is excluded if there is a Medicare claim (Part A inpatient, home health, hospice, and skilled and nursing facility claims; Part B outpatient and physician supplier) for hemolytic and aplastic anemia, solid organ cancer (breast, prostate, lung, digestive tract and others), lymphoma, carcinoma in situ, coagulation disorders, multiple myeloma, myelodysplastic syndrome and myelofibrosis, leukemia, head and neck cancer, other cancers (connective tissue, skin, and others), metastatic cancer, or sickle cell anemia within one year of their patient at risk time.

2.12.18 Flowchart

Figure 14 provides a flowchart that represents the processes used to calculate the STrR measure.
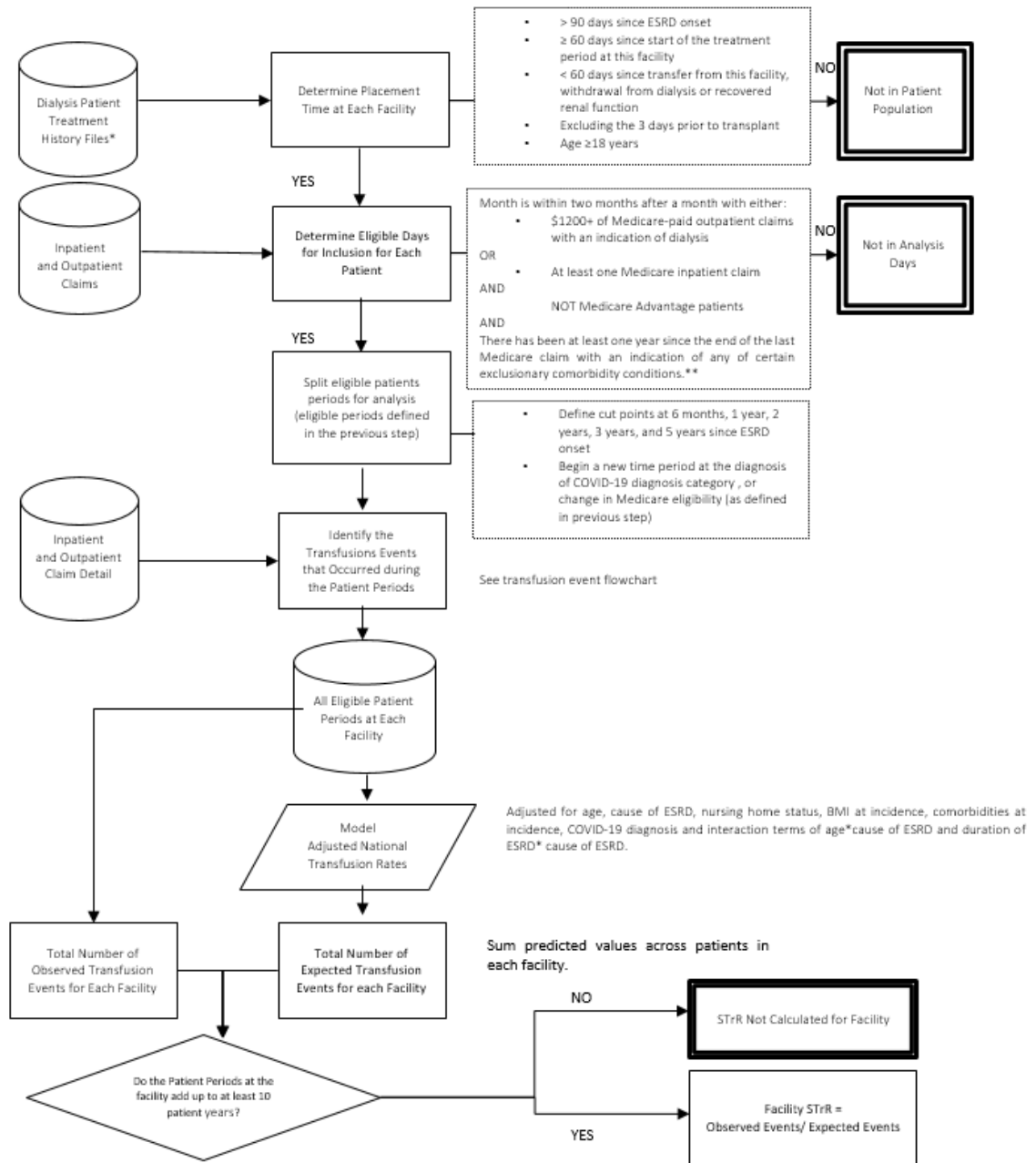
Figure 14: Standardized Transfusion Ratio Measure Flowchart (ESRD QIP and Dialysis Facility Measures)

*Multiple data sources include CMS EQRS, the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment claims, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN – Dialysis Facility Measures only), the Death Notification Form (Form CMS-2746), the Dialysis Facility Compare (Dialysis Facility Measures) and the Social Security Death Master File. Also see Section 3.1.6.

**Exclusionary comorbidity conditions: hemolytic and aplastic anemia, solid organ cancer (breast, prostate, lung, digestive tract and others), lymphoma, carcinoma in situ, coagulation disorders, multiple myeloma, myelodysplastic syndrome and myelofibrosis, leukemia, head and neck cancer, other cancers (connective tissue, skin, and others), metastatic cancer, sickle cell anemia.

2.12.19 Determining Transfusion Events Flow Chart

Figure 15 shows the method of determining transfusion events.
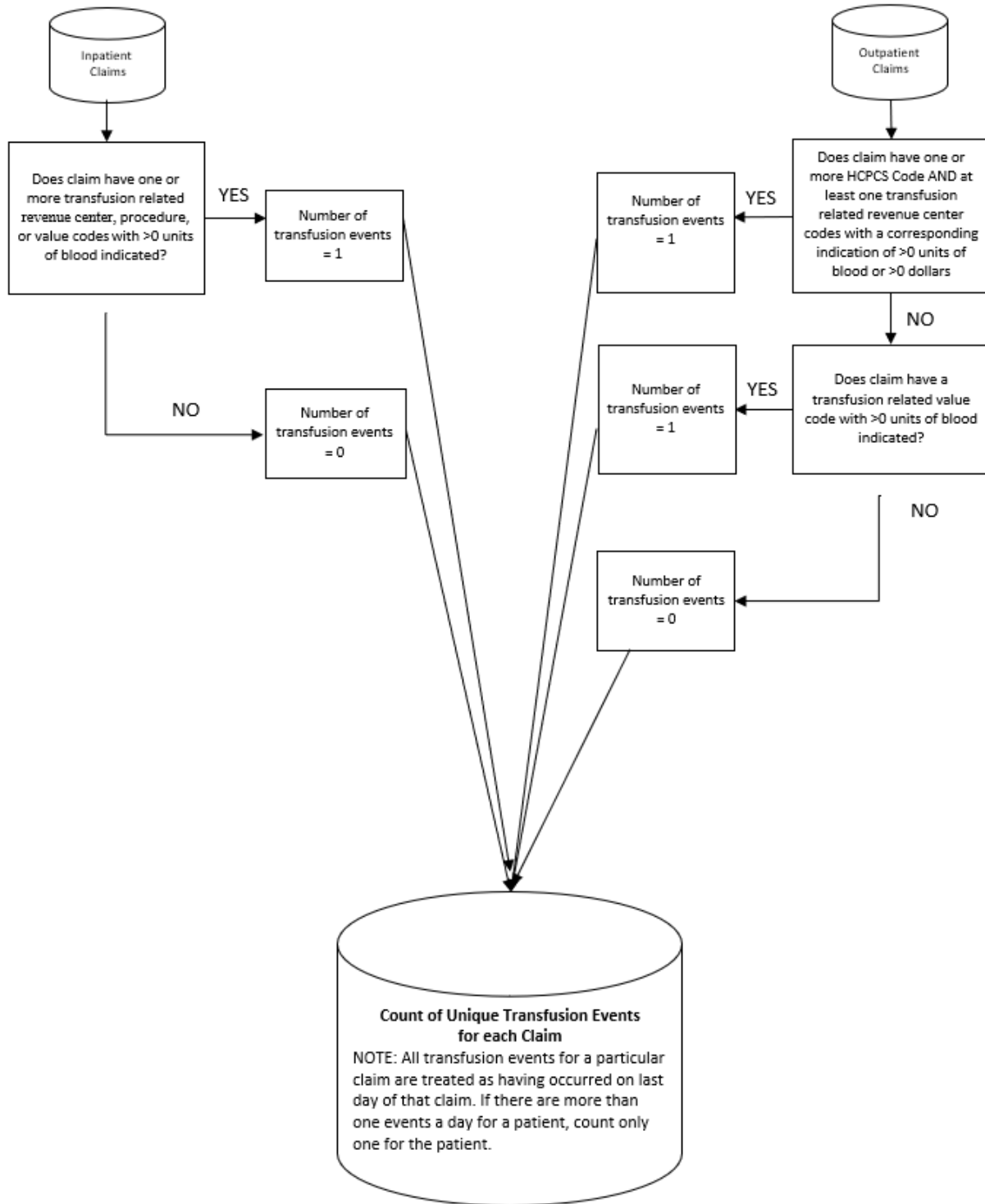
Figure 15: Method of Determining Transfusion Events Flowchart (ESRD QIP and Dialysis Facility Measures)

Table 8 below gives the description of Relevant Revenue Center Codes, Procedure Codes, Value Codes, and HCPCS Codes.

ICD Version	Code	Description	Field
	0380	Blood - General Classification	Revenue Center Codes
	0381	Blood - Packed Red Cells	Revenue Center Codes
	0382	Blood - Whole Blood	Revenue Center Codes
	0389	Blood - Other Blood	Revenue Center Codes
	0390	Blood Storage and Processing - General Classification	Revenue Center Codes
	0391	Blood Storage and Processing - Administration	Revenue Center Codes
	0392	Blood Storage and Processing - Blood Processing and Storage	Revenue Center Codes
	0399	Blood Storage and Processing - Other Storage & Processing	Revenue Center Codes
10	30230H1	Transfusion of Nonautologous Whole Blood into Peripheral Vein, Open Approach	Procedure Codes
10	30233H1	Transfusion of Nonautologous Whole Blood into Peripheral Vein, Percutaneous Approach	Procedure Codes
10	30233P1	Transfusion of Nonautologous Frozen Red Blood Cells into Peripheral Vein	Procedure Codes
10	30240H1	Transfusion of Nonautologous Whole Blood into Central Vein, Open Approach	Procedure Codes
10	30243H1	Transfusion of Nonautologous Whole Blood into Central Vein, Percutaneous Approach	Procedure Codes
10	30250H1	Transfusion of Nonautologous Whole Blood into Peripheral Artery, Open Approach	Procedure Codes
10	30253H1	Transfusion of Nonautologous Whole Blood into Peripheral Artery, Percutaneous Approach	Procedure Codes
10	30260H1	Transfusion of Nonautologous Whole Blood into Central Artery, Open Approach	Procedure Codes
10	30263H1	Transfusion of Nonautologous Whole Blood into Central Artery, Percutaneous Approach	Procedure Codes
10	30230N1	Transfusion of Nonautologous Red Blood Cells into Peripheral Vein, Open Approach	Procedure Codes
10	30230P1	Transfusion of Nonautologous Frozen Red Cells into Peripheral Vein, Open Approach	Procedure Codes

ICD Version	Code	Description	Field
10	30233N1	Transfusion of Nonautologous Red Blood Cells into Peripheral Vein, Percutaneous Approach	Procedure Codes
10	30240N1	Transfusion of Nonautologous Red Blood Cells into Central Vein, Open Approach	Procedure Codes
10	30240P1	Transfusion of Nonautologous Frozen Red Cells into Central Vein, Open Approach	Procedure Codes
10	30243N1	Transfusion of Nonautologous Red Blood Cells into Central Vein, Percutaneous Approach	Procedure Codes
10	30243P1	Transfusion of Nonautologous Frozen Red Cells into Central Vein, Percutaneous Approach	Procedure Codes
10	30250N1	Transfusion of Nonautologous Red Blood Cells into Peripheral Artery, Open Approach	Procedure Codes
10	30250P1	Transfusion of Nonautologous Frozen Red Cells into Peripheral Artery, Open Approach	Procedure Codes
10	30253N1	Transfusion of Nonautologous Red Blood Cells into Peripheral Artery, Percutaneous Approach	Procedure Codes
10	30253P1	Transfusion of Nonautologous Frozen Red Cells into Peripheral Artery, Percutaneous Approach	Procedure Codes
10	30260N1	Transfusion of Nonautologous Red Blood Cells into Central Artery, Open Approach	Procedure Codes
10	30260P1	Transfusion of Nonautologous Frozen Red Cells into Central Artery, Open Approach	Procedure Codes
10	30263N1	Transfusion of Nonautologous Red Blood Cells into Central Artery, Percutaneous Approach	Procedure Codes
10	30263P1	Transfusion of Nonautologous Frozen Red Cells into Central Artery, Percutaneous Approach	Procedure Codes
	37	Pints of blood furnished	Value Code
	P9010	Whole blood for transfusion	HCPCS Codes
	P9011	Blood split unit	HCPCS Codes
	P9016	RBC leukocytes reduced	HCPCS Codes
	P9021	Red blood cells unit	HCPCS Codes
	P9022	Washed red blood cells unit	HCPCS Codes
	P9038	RBC irradiated	HCPCS Codes
	P9039	RBC deglycerolized	HCPCS Codes
	P9040	RBC leukoreduced irradiated	HCPCS Codes
	P9051	Blood, l/r, cmv-neg	HCPCS Codes

ICD Version	Code	Description	Field
	P9054	Blood, l/r, froz/degly/wash	HCPCS Codes
	P9056	Blood, l/r, irradiated	HCPCS Codes
	P9057	Red blood cells, frozen/deglycerolized/washed, leukocytes reduced, irradiated, each unit	HCPCS Codes
	P9058	RBC, l/r, cmv-neg, irrad	HCPCS Codes
	36430	Current Procedural Terminology (CPT) code (transfusion, blood or blood components)	HCPCS Codes

Table 8: Description of Relevant Revenue Center Codes, Procedure Codes, Value Codes, and HCPCS Codes

2.12.20 Selected References

- Cox DR. Regression Models and Life Tables (with Discussion). J R Stat Soc Series B Stat Methodol. 1972; 34:187-220.
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- Ma JZ, Ebben J, Xia H, Collins AJ. Hematocrit level and associated mortality in hemodialysis patients. J Am Soc Nephrol. 1999; Mar;10(3):610-9.

2.13 Standardized Hospitalization Ratio (SHR) Measure (ESRD QIP and Dialysis Facility Measures)

2.13.1 Measure Name

Standardized Hospitalization Ratio for Dialysis Facilities

2.13.2 Measure Description

Risk-adjusted standardized hospitalization ratio of the number of observed hospitalizations to the number of expected hospitalizations for dialysis facility patients (CBE ID 1463). This measure is calculated as a ratio but can also be expressed as a rate. SHR can be expressed as a risk-standardized rate, which is the product of the facility SHR and the national average hospitalization rate.

2.13.3 Measure Rationale

Hospitalization rates are an important indicator of patient morbidity and quality of life. On average, dialysis patients are admitted to the hospital nearly twice a year and spend an average of 11.2 days in the hospital per year. Hospitalizations account for approximately 40 percent of total Medicare expenditures for ESRD patients. Measures of the frequency of hospitalization have the potential to help efforts to control escalating medical costs and to play an important role in identifying potential problems and helping facilities provide cost-effective health care.

2.13.4 Measure Type

Outcome

2.13.5 Improvement Noted as Higher or Lower Rate

A lower ratio indicates better quality.

2.13.6 Numerator Statement

Number of inpatient hospital admissions among eligible patients at the facility during the reporting period.

2.13.7 Facility Exclusions

The SHR is only calculated for facilities with at least five patient-years at risk (see Section 2.14.10.1 for details on patient-years at risk).

ESRD QIP Only:

Calculations will exclude the months covered by a granted ECE (see Section 3.4).

2.13.8   Denominator Statement

Number of hospital admissions that would be expected among eligible patients at the facility during the reporting period, given the patient mix at the facility.

2.13.9   Denominator Exclusions

Patient Time at Risk Exclusions:

- First 90 days of ESRD treatment.

- Time during which patients were treated at the facility for fewer than 60 days.

- Time during which patient has a functioning kidney transplant (exclusion begins three days prior to the date of transplant).

- Time at risk once a patient has not been treated by any facility for a year or longer.

- Months which do not fulfill at least one of these criteria:
  - Month is within or in the two months following a month in which the patient has $1,200 of Medicare-paid dialysis claims.
  - Month is within or in the two months following a month in which the patient has at least one Medicare inpatient (hospital or SNF) claim submitted during the month.
  - Patient is enrolled in MA during the month according to the Medicare Enrollment Database.

2.13.10   Mapping Patients to Facilities

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 (Dialysis Facility Measures only), the Death Notification Form (CMS-2746) and the Social Security Death Master File (Dialysis Facility Measures only). Also see Section 3.1.6. Additionally, for Dialysis Facility Measures, a new treatment history record is created for each patient each time he/she changes facility or treatment modality. Each record represents a time period associated with a specific modality and dialysis facility.

As patients can receive dialysis treatment at more than one facility in a given year, each patient day is assigned to a facility (or no facility, in some cases) based on a set of conventions described below.

A patient's follow-up is included after that patient has received chronic dialysis for at least 91 days. Thus, hospitalizations, mortality and survival during the first 90 days of ESRD do not enter into the calculations. This minimum 91-day period also assures that most patients are eligible for Medicare, either as their primary or secondary insurer. It also excludes from analysis patients who die or recover during the first 90 days of ESRD.

In order to exclude patients who only received temporary dialysis therapy, we assigned patients to a facility only after they had been on dialysis there for at least 60 days. This 60-day period is

used any time a patient begins therapy at a new facility whether the patient transferred from another facility, started ESRD for the first time, or returned to dialysis after a transplant. That is, hospitalizations during the first 60 days of dialysis at a facility do not affect the SHR of that facility.

For each patient, we identify the dialysis provider at each point in time. Starting with day 91 of ESRD, patients are attributed to facilities according to the following rules:

- A patient is attributed to a facility once the patient has been treated there for the past 60 days. When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 60 days and then is attributed to the destination facility.
- In particular, a patient is attributed to their current facility on day 91 of ESRD if that facility had treated them for the past 60 days. If on day 91, the facility had not treated a patient for the past 60 days, we wait until the patient reaches day 60 of continuous treatment at that facility before attributing the patient to that facility.
- When a patient is 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 do not attribute that patient to any facility.
- Patients are no longer attributed to facilities three days prior to transplant in order to exclude the transplant hospitalization.
- Patients who withdrew from dialysis or recovered renal function remain assigned to their treatment facility for 60 days after withdrawal or recovery.

If a period of one year passes with neither paid dialysis claims nor EQRS information to indicate that a patient was receiving dialysis treatment, the patient is designated lost to follow-up and is not included in the analysis. If dialysis claims or other evidence of dialysis reappears, the patient is re-entered into analysis after 60 days of continuous therapy at a single facility.

2.13.10.1 Days at Risk for Medicare Dialysis Patients

After patient treatment histories are defined as described above, periods of follow-up in time since ESRD onset are created for each patient. In order to adjust for duration of ESRD appropriately, we define six-time intervals with cut points at six months, one year, two years, three years and five years. A new time period begins each time the patient is determined to be at a different facility or crosses any of the above cut points, and at the start of a new COVID-19 diagnosis category (see 2.14.13 for description).

Because we can only identify hospitalizations if they appear in Medicare inpatient claims, we only include patients during time periods in which we are reasonably sure that all of the patient's hospitalizations would be included in Medicare billing records. Therefore, we require that patients reach a certain level of Medicare-paid dialysis bills, have Medicare inpatient claims, or are enrolled in MA during the period. Specifically, a patient-month within a given dialysis patient-period is included in the SHR calculation when at least one of the following is true:

(1) The patient had $1,200+ of Medicare-paid dialysis claims or at least one Medicare inpatient claim (hospital or SNF) during that month or one of the two prior months.

(2) The Medicare EDB indicates the patient was enrolled in MA during the month.

The intention of these criteria is to assure completeness of information on hospitalizations for all patients included in the analysis.

The number of days at risk in each of these patient-ESRD facility-year time periods is used to calculate the expected number of hospital admissions for the patient during that period. The SHR for a facility is the ratio of the total number of observed hospitalizations to the total number of expected hospitalizations during all time periods at the facility. Based on a risk adjustment model for the overall national hospitalization rates, we compute the expected number of hospitalizations that would occur for each month that each patient is attributed to a given facility. The sum of all such expectations for patients and months yields the overall number of hospital admissions that would be expected given the specific patient mix, and this forms the denominator of the measure.

The denominator of the SHR stems from a proportional rates model (Lawless and Nadeau, 1995; Lin et al., 2000; Kalbfleisch and Prentice, 2002). This is the recurrent event analog of the well-known proportional hazards or Cox model (Cox, 1972; Kalbfleisch and Prentice, 2002). To accommodate large-scale data, we adopt a model with piecewise constant baseline rates (e.g., Cook and Lawless, 2007) and the computational methodology developed in Liu, Schaubel and Kalbfleisch (2012).

2.13.11 Calculating Numerators

The numerator is calculated through use of Medicare claims. When a claim is submitted for an inpatient hospitalization, the patient is attributed to a dialysis facility following the rules discussed above. The numerator is the count of all such hospitalizations over the reporting period. Index COVID-19 Hospitalizations (ICovH) are not counted as hospitalization events.

2.13.12 Calculating National Average

The national average rate of hospitalization is determined by dividing the total number of hospitalizations by the total number of patient-years at risk. This national average rate is multiplied by each facility's SHR, resulting in a risk-standardized hospitalization rate.

2.13.13 Risk Adjustment

The regression model used to compute a facility's "expected" number of hospitalizations for the SHR measure contains many factors thought to be associated with hospitalization rates. Specifically, the model adjusts for patient age, sex, diabetes as cause of ESRD, duration of ESRD, MA coverage, nursing home status, BMI at incidence, comorbidities at incidence, prevalent comorbidities, and COVID-19 diagnosis. The stage 1 model allows the baseline hospitalization rates to vary between strata, which are defined by facilities, but assumes that the regression coefficients are the same across all strata; this approach is robust to possible differences between facilities in the patient mix being treated. In essence, it avoids a possible confounding between facility effects and patient covariates as can arise, for example, if patients with favorable values of the covariate tend to be treated at facilities with better treatment policies

and outcomes. Thus, for example, if patients with diabetes as a cause of ESRD tended to be treated at better facilities, one would underestimate the effect of diabetes unless the model is adjusted for facility. In this model, facility adjustment is done by stratification.

The patient characteristics included in the stage 1 model as covariates are:

- Age: Determine each patient's age as of the period start date for the birth date provided by multiple data sources.* Age, centered at 65 years, is included both as a linear (continuous) and a quadratic term.
- Sex: Determine each patient's sex from multiple sources.*
- Diabetes as cause of ESRD: Determine each patient's primary cause of ESRD from Medical Evidence Form (CMS-2728), and EQRS.
- Duration of ESRD: Determine each patient's length of time on dialysis using the first service date from multiple data sources* and categorize as 91 days- < 6 months, 6 months- < 1 year, 1- < 2 years, 2- < 3 years, 3- < 5 years, or 5+ years as of the period start date.
- Nursing home status: Uses multiple sources* including the 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) as of the period start date.
- BMI at incidence: Calculate each patient's BMI based on the height and weight provided on his/her CMS 2728 and group patients into the following categories: BMI < 18.5, 18.5 $\leq$ BMI < 25, 25 $\leq$ BMI < 30, or BMI $\geq$ 30. Missing and out-of-range BMIs are categorized into the mode group (i.e. >=30).
- Comorbidities at incidence are determined using a selection of comorbidities reported on the Medical Evidence Form (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 covariate in the model.
- MA coverage: Calculate the proportion of time during the treatment period that the patient is enrolled in MA from Medicare EDB.
- Prevalent comorbidities: Identify a patient's prevalent comorbidities based on inpatient 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 Measuring Quality page 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.
- 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. The COVID-19 clock starts at the discharge date of the first COVID-19 inpatient Medicare claim, which is the ICovH, and is then tracked for the following six months. The clock is not reset in the case of multiple COVID-19 hospitalizations. The period following the first ICovH is categorized into three mutually exclusive stages: the first month (days 1-30) after the ICovH discharge date is defined as "COVID1"; the second month (days 31-60) is defined as "COVID2"; the 3rd – 6th month (days 61-180) after the ICovH discharge is defined as "COVID3". Once it has been six months since the ICovH discharge, a patient is assigned to the "No COVID" group. COVID1, COVID2, and COVID3 are all included as covariates in the model, while No COVID is the reference group.

* This may include information from: EQRS, Medicare Claims, and the Medical Evidence Form (CMS 2728).

Categorical indicator variables are included as covariates in the stage 1 model to account for records with missing values for cause of ESRD, and comorbidities at incidence (missing CMS-2728). These variables have a value of 1 if the patient is missing the corresponding variable and a value of 0 otherwise. If a patient has less than six months of Medicare covered months in prior calendar year, prevalent comorbidities are set to a value of 0 and an indicator for missing prevalent comorbidities is included. This variable has a value of 1 if the patient is missing the corresponding comorbidities and a value of 0 otherwise. Another categorical indicator variable is included as a covariate in the stage 1 model to flag records where the patient has at least one of the incident comorbidities listed earlier. This variable has a value of 1 if the patient has at least one of the comorbidities and a value of 0 otherwise.

Beside main effects, two-way interaction terms between the following pairs of variables are included:

- Diabetes as cause of ESRD and Sex.
- Diabetes as cause of ESRD and Age.
- Age and Sex.

2.13.14 Calculating Expected Hospital Admissions

The modeling process has two stages and is run separately for each calendar year. At stage 1, a stratified model is fitted to the national data with piecewise-constant baseline rates and stratification by facility. Specifically, the model is of the following form:

$$Pr(\text{hospital admission on day } t \text{ given covariates } X) = r_{0k}(t)\exp(\beta'X_{ik})$$

where X_{ik} is the vector of covariates for the ith patient in the kth facility and β is the vector of regression coefficients. Time t is measured from the start of ESRD, given the inclusion criteria defined in section 2.14.9. The baseline rate function $r_{0k}(t)$ is specific to the kth facility and is assumed to be a step function with break points at six months, one year, two years, three years, and five years since the onset of dialysis. This model allows the baseline hospitalization rates to vary between strata (facilities) but assumes that the regression coefficients are the same across all

strata; this approach is robust to possible differences between facilities in the patient mix being treated. The stratification on facilities is important in this phase to avoid bias due to possible confounding between covariates and facility effects.

At stage 2, the relative risk estimates from the first stage are used to create offsets and an unstratified model is fitted to obtain estimates of an overall baseline rate function. That is, we estimate a common baseline rate of admissions, $r_0(t)$, across all facilities by considering the following model:

$$Pr(\text{hospital admission on day } t \text{ given covariates } X) = r_0(t)\, R_{ik,}$$

where $R_{ik} = \exp(\beta'X_{ik})$ is the estimated relative risk for patient i in facility k obtained from the stage 1. In our computation, we assume the baseline to be a step function with six unknown parameters, $\alpha_1,\ ...,\ \alpha_6$, to estimate. These estimates are used to compute the expected number of admissions given a patient's characteristics.

Specifically, let t_{iks} represent the number of days that patient i from facility k is under observation in the sth time interval with estimated rate α_s. The corresponding expected number of hospital admissions in the sth interval for this patient is calculated as:

$$E_{iks} = \alpha_s\, t_{iks}\, R_{ik}.$$

It should be noted that t_{iks} and hence E_{iks} can be 0 if patient i from facility k is never at risk during the sth time interval. Summing the E_{iks} over all 6 intervals and all N_k patients in facility k gives:

$$\text{Exp} = \sum_{i=1}^{N_k} \sum_{s=1}^{6} E_{iks} = \sum_{i=1}^{N_k} \sum_{s=1}^{6} \alpha_s t_{iks} R_{ik},$$

which is the expected number of hospital admissions during follow-up at that facility.

Let *Obs* be the observed total number of hospital admissions at this facility. The SHR for hospital admissions is the ratio of the observed total admissions to this expected value, or

$$\text{SHR} = \text{Obs}/\text{Exp}$$

2.13.15 Calculation of SHR P-Values and Confidence Intervals (Dialysis Facility Measures Only)

To adjust for over-dispersion of the data, we compute the p-value for our estimates using the empirical null distribution, a robust approach that takes account of the natural random variation among facilities that is not accounted for in the model (Efron, 2004; Kalbfleisch and Wolfe, 2013). Our algorithm consists of the following concrete steps. First, we fit an over-dispersed Poisson model (e.g., SAS PROC GENMOD with link=log, dist=poisson and scale=dscale) for the number of hospital admissions as:

$$\log(E[n_{ik}]) = \log(E_{ik}) + \theta_k,$$

where n_{ik} is the observed number of events for patient i in facility k, E_{ik} is the expected number of events for patient i in facility k and θ_k is the facility-specific intercept. Here, i ranges over the

number of patients N_k who are treated in the *kth* facility. The natural log of the SHR for the *kth* facility is then given by the corresponding estimate of θ_k. The standard error of θ_k is obtained from the robust estimate of variance arising from the over dispersed Poisson model.

Second, we obtain a z-score for each facility by dividing the natural log of its SHR by the standard error from the general linear model described above. These z-scores are then grouped into quartiles based on the number of patient-years at risk for Medicare patients in each facility. Finally, using robust estimates of location and scale based on the normal curve fitted to the center of the z-scores for the SHR, we derive the mean and variance of a normal empirical null distribution for each quartile. This empirical null distribution is then used to calculate the p-value for a facility's SHR.

The uncertainty or confidence intervals are obtained by applying the following steps:

- From the general linear model, we obtain the natural log of the SHR (ln SHR) as well as its standard error, (SE). From the empirical null, we obtain a mean (μ) and a standard deviation (σ). The 95% uncertainty interval for the 'true' log standardized hospitalization ratio for this facility is:

  ln SHR - μ * SE ± 1.96 * σ * SE.

- Exponentiating the endpoints of this interval gives the uncertainty interval for the true SHR.

2.13.16 Flagging Rules for Dialysis Facility Measures (Dialysis Facility Measures Only)

As currently implemented for Dialysis Facility Measures, for reporting purposes we identify outlier facilities from amongst those with at least five patient-years at risk during the time period. If the 95% interval lies entirely above the value of 1.00 (i.e., both endpoints exceed 1.00), the facility is said to have outcomes that are "worse than expected". On the other hand, if the 95% interval lies entirely below the value 1.00, the facility is said to be better than expected. If the interval contains the value 1.00, the facility is said to have outcomes that are "as expected".

2.13.17 Data Elements and Data Sources

Variable	Primary Data Source
Facility CCN	Multiple data sources[1]
Date of birth	Multiple data sources[1]
Sex	Multiple data sources[1]
Date of first ESRD	Multiple data sources[1]
Date of death	Multiple data sources[1]
Dates of transplant	Multiple data sources[1]
Medicare Advantage months	Medicare Enrollment Database (EDB)
BMI at incidence	Medical Evidence Form (CMS-2728)

Variable	Primary Data Source
Nursing home status (in the previous 365 days)	Nursing Home Minimum Data Set
Diabetes - Primary cause of ESRD	Medical Evidence Form (CMS-2728)
Incident comorbidities	Medical Evidence Form (CMS-2728)
COVID-19 diagnosis	Medicare Claims
Prevalent comorbidities	Inpatient Medicare Claims
Hospital admissions	Inpatient Medicare claims

Table 9: Data Elements and Sources for the Standardized Hospitalization Ratio (ESRD QIP and Dialysis Facility Measures)

1. This may include information from: EQRS, Medicare Enrollment Database (EDB), Medical Evidence Form (CMS 2728), Medicare Claims (inclusive of Medicare Advantage shadow claims), and Organ Procurement and Transplantation Network Database (OPTN) (Dialysis Facility Measures only). Also see Section 3.1.6. Unique patients are identified by using a combination of SSN, first name, surname, sex, Medicare Beneficiary ID, Patient Health Insurance Claim Number and birth date. Dialysis Facility Measures runs a matching process is performed to ensure that minor typos and misspellings do not cause a patient record to fall out of their history. The matching process is able to successfully match 99.5% of patients. The remaining patients have incomplete or incorrect data that does not allow them to be matched. Also see Section 3.2. See Section 3.2.2 for patient matching details used in ESRD QIP.

2.13.18 Flowchart

Figure 16 provides a flowchart that represents the processes used to calculate the Standardized Hospitalization Ratio (SHR).
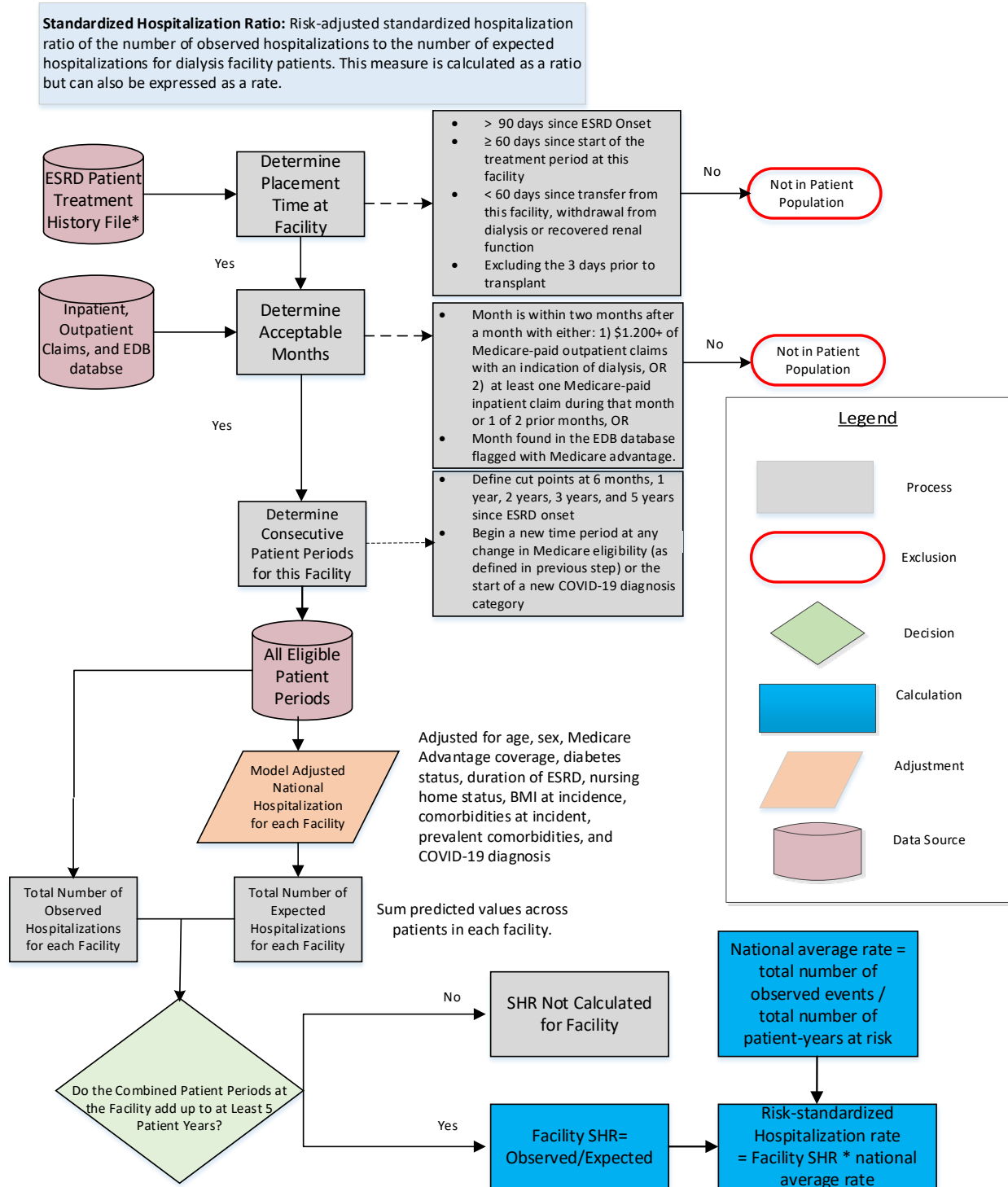
Figure 16: Standardized Hospitalization Ratio (SHR) Flowchart (ESRD QIP and Dialysis Facility Measures)

* Multiple data sources include CMS EQRS, the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN)/Scientific Registry of Transplant Recipients (SRTR), the Death Notification Form (Form CMS-2746), the Dialysis Facility Compare (Dialysis Facility Measures), the Nursing Home MDS, Quality Improvement Evaluation System (QIES), and the Social Security Death Master File.

2.13.19 Selected References

- United States Renal Data System. 2015 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, 2015.
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2.14 Standardized Mortality Ratio (SMR) Measure (Dialysis Facility Measures Only)

2.14.1 Measure Name

Standardized Mortality Ratio for Dialysis Facilities

2.14.2 Measure Description

SMR for dialysis facility patients. This measure is calculated as a ratio but can also be expressed as a rate.

2.14.3 Measure Rationale

US chronic dialysis patients are much more likely to die than age-matched individuals without ESRD. The excess mortality associated with ESRD patients on dialysis is influenced by dialysis facility practices and is one of several important health outcomes used by providers, health consumers, and insurers to evaluate the quality of care provided in dialysis facilities.

2.14.4 Measure Type

Outcome

2.14.5 Improvement Noted as Higher or Lower Rate

A lower ratio indicates better quality.

2.14.6 Numerator Statement

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

2.14.7 Facility Exclusions

The SMR is only calculated for a facility if there are at least three expected deaths for the time period.

2.14.8 Denominator Statement

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.

2.14.9 Denominator Exclusions

N/A

2.14.10 Mapping Patients to Facilities

2.14.10.1 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.

2.14.10.2 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 91 days. This minimum 91-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.

2.14.10.3 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.

2.14.10.4 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.

2.14.11 Calculating Numerators/Outcome Definition

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.

2.14.12 Risk Adjustment

The SMR 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 as cause of ESRD, duration of ESRD, nursing home status from previous year, patient comorbidities at incidence, prevalent 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 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.

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 Measuring Quality page 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.

2.14.13 Calculation of Expected Deaths at a Facility

Using the estimates of the regression coefficients from stage 1, we estimate the relative risk for each patient-record. The predicted value for the patient-record from stage 1 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.

Age-adjusted population death rates (per 100,000) by state and race are obtained from the Centers for Disease Control and Prevention National Center for Health Statistics. The 2023 October Release of Dialysis Facility Measures used age-adjusted death rates for 2014-2016 from Table 16 of the publication Health, United States, 2018, available at http://www.cdc.gov/nchs/data/hus/hus16.pdf.

Each patient typically gives rise to several patient-records. Specifically, a new patient record is defined for each calendar year and each time a patient changes facilities. The ith patient record is associated with a risk period t_i, which specifies the number of days that the patient is at risk during that record.

The Cox model is applied in two stages. Stage 1 yields estimates of the coefficients ($ß_j$) for the 147 covariates that are measured on individual patients (or patient-records). The coefficients

measure the within-facility effects for individual risk factors or comorbidities. Using these coefficients, a relative risk or predicted risk is calculated for each patient-record. Stage 2 adjusts for the differences in mortality rate at the state level. The model of this stage uses only one covariate, the log of the population death rate for that patient's race within the state where the patient is being treated. The predicted value for the patient-record from stage 1 is used as an offset in the stage 2 model and the stage 2 analysis is not stratified. The combined predicted values from stages 1 and 2, and the baseline survival curve from stage 2 of the Cox model are then used to calculate the expected number of deaths for a specific patient-record.

Let p denote the number of patient characteristics in the model and x_{ij} be the specific value of the jth characteristic for the ith patient-record. In stage 1, for patient-record i, we denote the measured characteristics or covariates in a vector form as:

$$X_i = (x_{i1}, x_{i2}, \dots , x_{ip})$$

and use this to define the regression portion of a Cox model in which facilities define the strata. Note that for a categorical characteristic, the x_{ij} value is 1 if the patient falls into the category and 0 otherwise. The output of this model is a set of regression coefficients, $\beta_1, \beta_2, \dots, \beta_p$ and the corresponding predicted value for the ith patient-record is given by:

$$X_i\beta = \beta_1 x_{i1} + \beta_2 x_{i2} + \dots + \beta_p x_{ip}. \quad (1)$$

In stage 2, the only covariate is x_{i0}, which specifies the logarithm of the state age-adjusted population death rate corresponding to the race of the patient giving rise to patient-record i. The stage 2 model is not stratified, so there is a single baseline survival function assumed. The stage 1 $X_i\beta$ from equation (1) is used as an offset in the analysis. The Stage 2 Cox model gives rise to an estimate of the regression coefficient β_0 and of the baseline survival function, $S_0(t)$. After stage 2, the linear prediction is:

$$A_i = \beta_0 x_{i0} + X_i\beta = \beta_0 x_{i0} + \beta_1 x_{i1} + \beta_2 x_{i2} + \dots + \beta_p x_{ip}$$

Suppose that t_i is the end of follow-up time for patient-record i, so that $S_0(t_i)$ is the baseline survival probability at time t_i. The survival probability for this patient-record i at time t_i is:

$$S_i(t_i) = [S_0(t_i)]^{\exp(A_i)} .$$

The expected number of deaths for this patient-record during follow-up time t_i arises from considerations in the Cox model and can be written as:

$$-\ln(S_i(t_i)) = -\exp(A_i) \ln [S_0(t_i)].$$

The expected number of deaths at a given facility can now be computed simply by summing these expected values over the totality of patient-records in that facility. Specifically, the expected value is the sum over the N patient-records at the facility giving:

$$Exp = \sum_{i=1}^{N} -\ln[S_i(t_i)] = -\sum_{i=1}^{N} \exp(A_i) \ln[S_0(t_i)].$$

Let *Obs* be the total number of deaths observed at the facility during the total four years follow-up period. As stated above, the SMR is the ratio of the total number of deaths observed to the expected number so that:

$$SMR = Obs/Exp.$$

2.14.14 Creating Interval Estimates

To adjust for over-dispersion of the data, we compute the p-value for our estimates using the empirical null distribution, a robust approach that takes account of the natural random variation among facilities that is not accounted for in the model (Efron, 2004; Kalbfleisch and Wolfe, 2013).

Our algorithm consists of the following concrete steps. First, we take the probability values between the facility observed and expected deaths based on the Poisson distribution. The normal inverse cumulative distribution function is then used to transform these probability values into a z-score based on the normal distribution.

These z-scores are then grouped into quartiles based on the number of patient-years at risk for Medicare patients in each facility. Finally, using robust estimates of location and scale based on the normal curve fitted to the center of the z-scores for the SMR, we derive the mean and variance of a normal empirical null distribution for each quartile. This empirical null distribution is then used to calculate the p-value for a facility's SMR.

The uncertainty or confidence intervals are obtained by numerically calculating the upper and lower values of deaths that would coincide to a p-value of 0.025 when tested against observed deaths using the empirical null. These upper and lower values are then divided by the expected deaths from the SMR model to achieve the boundary points for the confidence interval for SMR.

2.14.15 Flagging Rules for Dialysis Facility Compare (Dialysis Facility Measures)

As currently implemented for Dialysis Facility Measures, for reporting purposes we identify outlier facilities from amongst those with at least three expected deaths during the time period. If the 95% interval lies entirely above the value of 1.00 (i.e., both endpoints exceed 1.00), the facility is said to have outcomes that are "worse than expected". On the other hand, if the 95% interval lies entirely below the value 1.00, the facility is said to be better than expected. If the interval contains the value 1.00, the facility is said to have outcomes that are "as expected."

2.14.16 Data Elements and Data Sources

Variable	Primary Data Source
Facility CCN	CMS data sources[1]
Race	CMS data sources[1]
Ethnicity	CMS data sources[1]
Date of birth	CMS data sources[1]

Variable	Primary Data Source
Gender	CMS data sources[1]
Date of first ESRD	Medical Evidence Form (CMS-2728) EQRS Patient Event OPTN Data Medicare Claims
BMI at incidence	Medical Evidence Form (CMS-2728)
Medicare Advantage coverage	Medicare Enrollment Database (EDB)
Nursing home status (in the previous calendar year)	CMS Minimum Data Set
Diabetes - Primary cause of ESRD	Medical Evidence Form (CMS-2728)
Race-Specific age adjusted State Death Rate	Health, United States, 2016[2] Medicare Claims[3]
Diabetes –Not as primary cause of ESRD	Medical Evidence Form (CMS-2728)
Incident comorbidities	Medical Evidence Form (CMS-2728)
Prevalent comorbidities	Medicare Claims[3]
Not having at least 6-month Medicare eligible in past 12 months	Medicare Claims[3]
COVID-19 diagnosis	Inpatient Medicare Claims

Table 10: Data Elements and Sources for the Standardized Mortality Ratio Measure (Dialysis Facility Measures Only)

1. This may include information from: CMS EQRS, Medicare Enrollment Database (EDB), Medical Evidence Form (CMS 2728), Medicare Claims, and Organ Procurement and Transplantation Network Database (OPTN) (Dialysis Facility Measures only). Unique patients are identified by using a combination of SSN, first name, surname, sex, Medicare Beneficiary ID, Patient Health Insurance Claim Number and birth date. Dialysis Facility Measures runs a matching process to ensure that minor typos and misspellings do not cause a patient record to fall out of their history. The matching process is able to successfully match 99.5% of patients. The remaining patients have incomplete or incorrect data that does not allow them to be matched.

2. Table 16 of the publication Health, United States, 2016, available at http://www.cdc.gov/nchs/data/hus/hus16.pdf

3. Medicare claims include Part A claims such as inpatient admissions and Part B claims such as outpatient claims (including dialysis claims) and physician services. Claims from providers, such as laboratories, that report diagnosis codes when testing for the presence of a condition are excluded.

2.14.17 Flowchart

Figure 17 provides a flowchart that represents the processes used to calculate the Standardized Mortality Ratio.
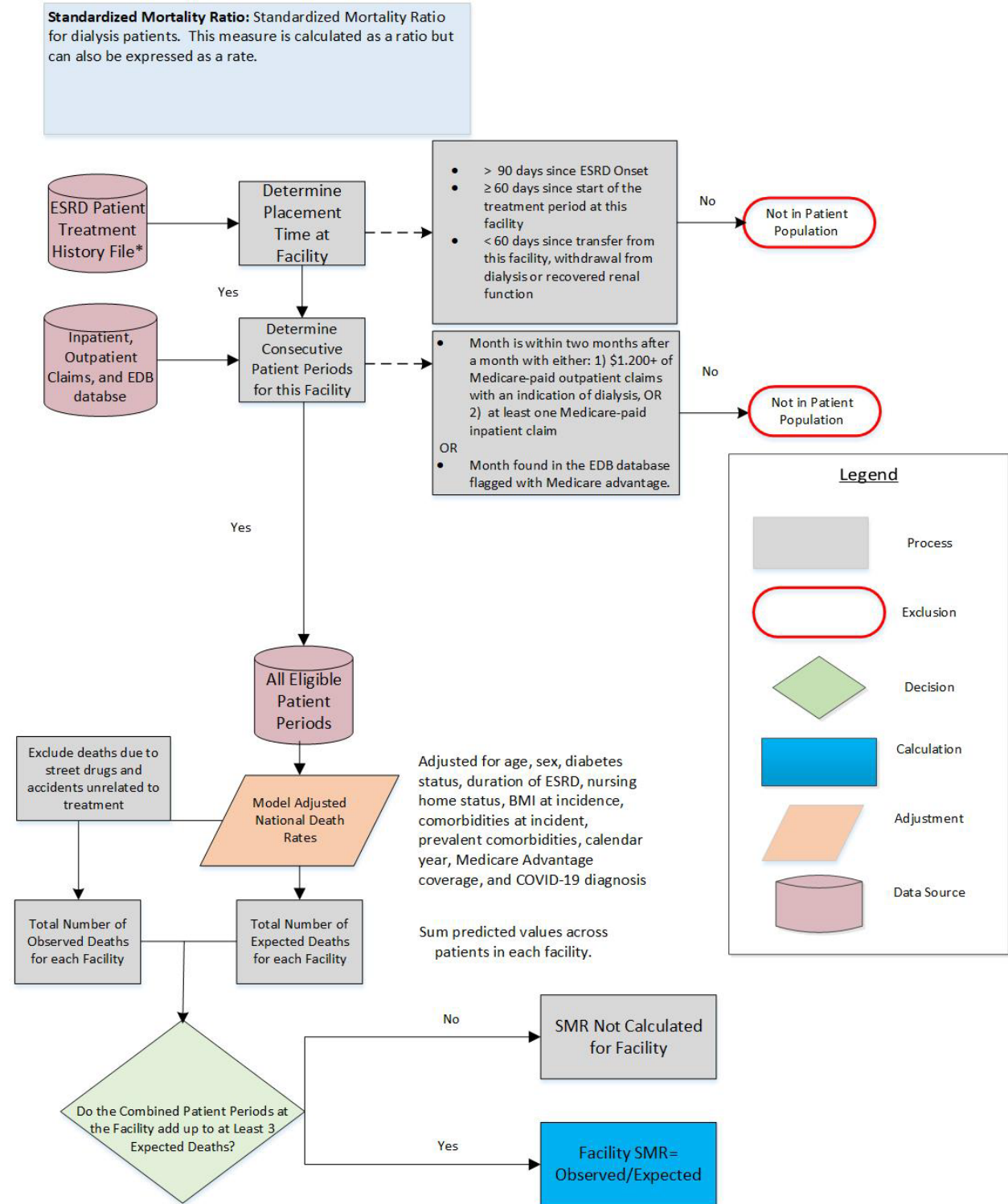
Figure 17: Standardized Mortality Ratio Flowchart (Dialysis Facility Measures Only)

* Multiple data sources include CMS EQRS, the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN)/Scientific Registry of Transplant Recipients (SRTR), the Death Notification Form (Form CMS-2746), the Dialysis Facility Compare (Dialysis Facility Measures), the Nursing Home Minimum Data Set (MDS), QIES, and the Social Security Death Master File.

2.14.18 Selected References

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2.15 Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) Measure (Dialysis Facility Measures Only)

2.15.1 Measure Name

Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR)

2.15.2 Measure Description

The Standardized Waitlist Ratio (SWR) measure tracks the number of incident patients at the dialysis facility under the age of 75 listed on the kidney or kidney-pancreas transplant waitlist or who received a living donor transplant within the first year of initiating dialysis. For each facility, we calculated the SWR to compare the observed waitlisting rate in the facility to the waitlisting rate that was expected. The SWR uses expected waitlisting calculated from a Cox model (SAS Institute Inc., 2004; Andersen, 1993; Collett, 1994), adjusting for age and patient comorbidities at incidence.

2.15.3 Measure Rationale

A measure focusing on the waitlisting process is appropriate for improving access to kidney transplantation for several reasons. First, waitlisting is a necessary step prior to potential receipt of a deceased donor kidney (receipt of a living donor kidney is also accounted for in the measure). Second, dialysis facilities exert substantial control over the process of waitlisting. This includes proper education of dialysis patients on the option for transplant, referral of appropriate patients to a transplant center for evaluation, assisting patients with completion of the transplant evaluation process, and optimizing the health and functional status of patients in order to increase their candidacy for transplant wait listing. These types of activities are included as part of the conditions for coverage for Medicare certification of ESRD dialysis facilities. Finally, wide regional variations in wait listing rates highlight substantial room for improvement for this process measure (Ashby 2007, Satayathum 2005, Patzer 2014).

This measure additionally focuses specifically on the population of patients incident to dialysis, examining for waitlist or living donor transplant events occurring within a year of dialysis initiation. This will evaluate and encourage rapid attention from dialysis facilities to wait listing of patients to ensure early access to transplantation, which has been demonstrated to be particularly beneficial (Meier-Kriesche 2002, Meier-Kriesche 2000). This measure contrasts with the other wait listing measure, the PPPW, which focuses on a prevalent population of dialysis patients and is primarily designed to additionally capture listing that occurs beyond the first year of dialysis initiation, as well as also maintenance of patients on the waitlist.

2.15.4 Measure Type

Process

2.15.5   Improvement Noted as Higher or Lower Rate

A higher number indicates better quality.

2.15.6   Numerator Statement

Number of patients at the dialysis facility listed on the kidney or kidney-pancreas transplant waitlist or who received living donor transplants within the first year following initiation of dialysis.

2.15.7   Facility Exclusions

The SWR is only reported for facilities with less than 11 patients or less than two expected events for the reporting period.

2.15.8   Denominator Statement

The denominator for the SWR is the expected number of waitlisting or living donor transplant events at the facility according to each patient's treatment history for patients within the first year following initiation of dialysis, adjusted for age and its functional forms, as well as incident comorbidities, among patients under 75 years of age who were not already waitlisted and did not have first transplantation prior to the initiation of ESRD dialysis.

2.15.9   Denominator Exclusions

Exclusions that are implicit in the denominator definition include:

- Patients who were 75 years of age or older at the initiation of dialysis.
- Preemptive patients: patients at the facility who had the first transplantation prior to the start of ESRD treatment; or were listed on the kidney or kidney-pancreas transplant waitlist prior to the start of dialysis.
- Patients who were admitted to a hospice at the time of initiation of dialysis.
- Patients who were admitted to an SNF at incidence or previously according to Form CMS-2728.

The CMS Medical Evidence Form and the CMS Long-Term Care MDS were the data sources used for determining SNF patients. Patients who were identified on the CMS Medical Evidence Form as institutionalized and SNF/Long-Term Care Facility, respectively, or who had evidence of admission to an SNF based on the MDS before their first service date and were not discharged prior to initiation of dialysis were identified as SNF patients. For hospice patients, a separate CMS file that contains final action claims submitted by hospice providers was used to determine the hospice status.

2.15.10 Mapping Patients to Facilities

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, age, and incident comorbidities adjustments, and transplant is obtained from EQRS (including the CMS Medical

Evidence Form (Form CMS-2728) and the Death Notification Form (Form CMS-2746)) and Medicare claims, as well as the OPTN and the Social Security Death Master File.

2.15.11 Calculating Numerators/Outcome Definition

The numerator for the SWR for a given facility is the observed number of patients on the waitlist (i.e., waitlisting or receipt of a living-donor transplant) within the first year following initiation of dialysis. To be included in the numerator for a particular facility, the patient must meet one of the two criteria:

- The patient is on the kidney or kidney-pancreas transplant waitlist.
- The patient has received a living donor transplant.

2.15.12 Risk Adjustment

The denominator represents a facility's expected number of events (waitlistings or living-donor transplants) and is calculated based on a two-stage Cox model (Cox, 1972; SAS Institute Inc., 2004; Kalbfleisch and Prentice, 2002; Collett, 1994). The SWR is adjusted for incident comorbidities and age, using a linear spline with knots at 12, 18, and 64. Knot placements were determined empirically based on a preliminary model that categorized age. In addition, incident comorbidities were selected for adjustment into the SWR model based on demonstration of a higher associated mortality (hazard ratio above 1.0) and statistical significance (p-value <0.01) in first year mortality model.

2.15.13 Calculation of SWR

The event was defined as waitlisting or living-donor transplantation. Time zero was defined as the first initiation of dialysis. Patients were followed until waitlisting, living donor transplantation, death, or one-year anniversary since first dialysis (i.e., the earliest thereof). A two-stage Cox model was fitted to calculate the expected number of events. At the first stage, a Cox model stratified on facility was fitted in order to obtain an estimate of the age and comorbidities effects (unconfounded by facility) to be used as an offset. At the second stage, a national average baseline hazard was estimated. The national average baseline (from the second stage), age, and comorbidities adjustments (from the first stage) were then used to compute the probability of an event for each patient, followed by the total expected number of events at each facility.

Let p denote the number of patient characteristics in the model and x_{ij} be the specific value of the jth characteristic for the ith patient-record. At the first stage, for patient-record I, we denote the measured characteristics or covariates as:

$$\mathbf{X_i} = (x_{i1}, x_{i2}, \dots, x_{ip}),$$

and use this to define the regression portion of a Cox model in which facilities define the strata. Note that for a categorical characteristic, the x_{ij} value is 1 if the patient falls into the category and 0 otherwise. The output of the first stage is a set of regression coefficients, $\beta_1, \beta_2, \dots, \beta_p$ and the corresponding predicted value for the ith patient-record is given by:

$$\mathbf{X_i\beta} = \beta_1 x_{i1} + \beta_2 x_{i2} + \ldots + \beta_p x_{ip}. \tag{1}$$

At the second stage, the relative risk estimates from the first stage were used as an offset, without stratification. After the second stage, the linear prediction is:

$$\mathbf{A_i} = \beta_0 x_{i0} + \mathbf{X_i\beta} = \beta_0 x_{i0} + \beta_1 x_{i1} + \beta_2 x_{i2} + \ldots + \beta_p x_{ip} \tag{2}$$

Suppose that t_i is the end of follow-up time for patient-record i, so that $S_0(t_i)$ is the baseline survival probability at time t_i. The survival probability for this patient-record i at time t_i is:

$$S_i(t_i) = [S_0(t_i)]^{\exp(A_i)}. \tag{3}$$

The expected number of waitlisting for this patient-record during follow-up time t_i arises from considerations in the Cox model and can be written as:

$$-\ln(S_i(t_i)) = -e^{A_i} \ln[S_0(t_i)]. \tag{4}$$

The expected number of waitlisting at a given facility can now be computed simply by summing these expected values over the totality of patient-records in that facility. Specifically, the expected value is the sum over the N patient-records at the facility giving:

$$E = \sum_{i=1}^{N} -\ln[S_i(t_i)] = -\sum_{i=1}^{N} e^{A_i} \ln[S_0(t_i)]. \tag{5}$$

Let O be the total number of waitlisting observed at the facility during the total four years follow-up period. As stated above, the SWR is the ratio of the total number of observed waitlisting to the expected number:

$$\mathbf{SWR = O/E.} \tag{6}$$

2.15.14 Creating Interval Estimates

Similar to the SMR, the 95% confidence interval gives a range of plausible values for the true ratio of facility-to-national waitlist event rates, in light of the calculated SWR. The upper and lower confidence limits enclose the true ratio approximately 95% of the time if this procedure were to be repeated on multiple samples. Statistically significant confidence intervals do not contain the ratio value 1.00, which denotes that the observed event rate was equal to the expected event rate.

The p-value measures the statistical significance (or evidence) of the hypothesis that the true transplant waitlist rate for a given facility is different from what would be predicted from the overall national rate. The p-value is the probability that the calculated SWR would deviate from 1.00 as much as it does, under the null hypothesis that this ratio is truly equal to 1.00. A smaller p-value tends to occur when the ratio differs greatly from 1.00 and/or when one uses more patient data to calculate the SWR value. A p-value less than 0.05 suggests that the ratio between the observed and expected waitlist event rates differs significantly from 1.00. The smaller the p-value, the lower the probability that a facility's waitlist event rate is equal to the national waitlist

event rate. A small p-value helps rule out the possibility that an SWR's deviance from 1.00 could have arisen by chance. However, a small p-value does not indicate the degree of importance of the difference between the facility waitlist event rate and the national rate.

2.15.15 Flagging Rules for Dialysis Facility Compare (Dialysis Facility Measures)

When a facility's SWR is greater than 1.00 and statistically significant (p-value < 0.05), it is classified as "Better than expected". When a facility's SWR is less than 1.00 and statistically significant (p-value < 0.05), it is classified as "Worse than expected". When a facility's SWR is not significantly different from 1.00, it is classified as "As expected". Please note that the classification of SWR is reported as "Not available" on Dialysis Facility Measures for facilities with less than 11 patients or less than two expected events for the relative reporting year.

2.15.16 Data Elements and Data Sources

EQRS (including CMS Medical Evidence Form [Form CMS-2728]) is the primary data source used for placing patients at dialysis facilities, age and incident comorbidities adjustments and exclusion of patients => 75-year-old (see information provided under "denominator details"). OPTN is the data source for waitlist or living donor transplant events. The Nursing Home MDS and the CMS Medical Evidence Form (Form CMS-2728) are used to identify SNF patients. A separate CMS file that contains final action claims submitted by hospice providers was used to determine the hospice status.

Variable	Primary Data Source
Facility CCN #	CMS data sources[1]
Reporting year	EQRS
Waitlist status	OPTN
Date of birth	CMS data sources[1]
Date of first ESRD	Medical Evidence Form (CMS-2728)
Heart disease	Medical Evidence Form (CMS-2728)
Inability to ambulate	Medical Evidence Form (CMS-2728)
Chronic obstructive pulmonary disease	Medical Evidence Form (CMS-2728)
Inability to transfer	Medical Evidence Form (CMS-2728)
Malignant neoplasm, cancer	Medical Evidence Form (CMS-2728)
Peripheral vascular disease	Medical Evidence Form (CMS-2728)
Cerebrovascular disease, cerebrovascular accident (CVA), Transient Ischemic Attack (TIA)	Medical Evidence Form (CMS-2728)
Alcohol dependence	Medical Evidence Form (CMS-2728)
Drug dependence	Medical Evidence Form (CMS-2728)
Amputation	Medical Evidence Form (CMS-2728)
Needs assistance with daily activities	Medical Evidence Form (CMS-2728)
Nursing home status[1,2]	Medical Evidence Form (Form CMS-2728)

Centers for Medicare & Medicaid Services

Variable	Primary Data Source
Nursing home status on the first service date[1,2]	CMS Long-Term Care Minimum Data Set (MDS)
Hospice status on the first service date[1,2]	CMS Hospice file

Table 11: Data Elements and Sources for the Standardized Waitlist Ratio (Dialysis Facility Measures Only)

1. EQRS (including CMS Medical Evidence Form (Form CMS-2728)) is the primary data source used for placing patients at dialysis facilities, age and incident comorbidities adjustments and exclusion of patients ≥75-year-old. Organ Procurement and Transplant Network (OPTN) is the data source for waitlist or living donor transplant events. The Nursing Home MDS and the CMS Medical Evidence Form (Form CMS-2728) are used to identify SNF patients. A separate CMS file that contains final action claims submitted by Hospice providers was used to determine the hospice status.

Unique patients are identified by using a combination of SSN, first name, surname, gender, Medicare Beneficiary ID, Medicare claim number and birth date. A matching process is performed to ensure that minor typos and misspellings do not cause a patient record to fall out of their history. The matching process is able to successfully match 99.5% of patients. The remaining patients have incomplete or incorrect data that does not allow them to be matched.

2. Exclusion factors

2.15.17 Flowchart

Figure 18 provides a flowchart that represents the processes used to calculate Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR).
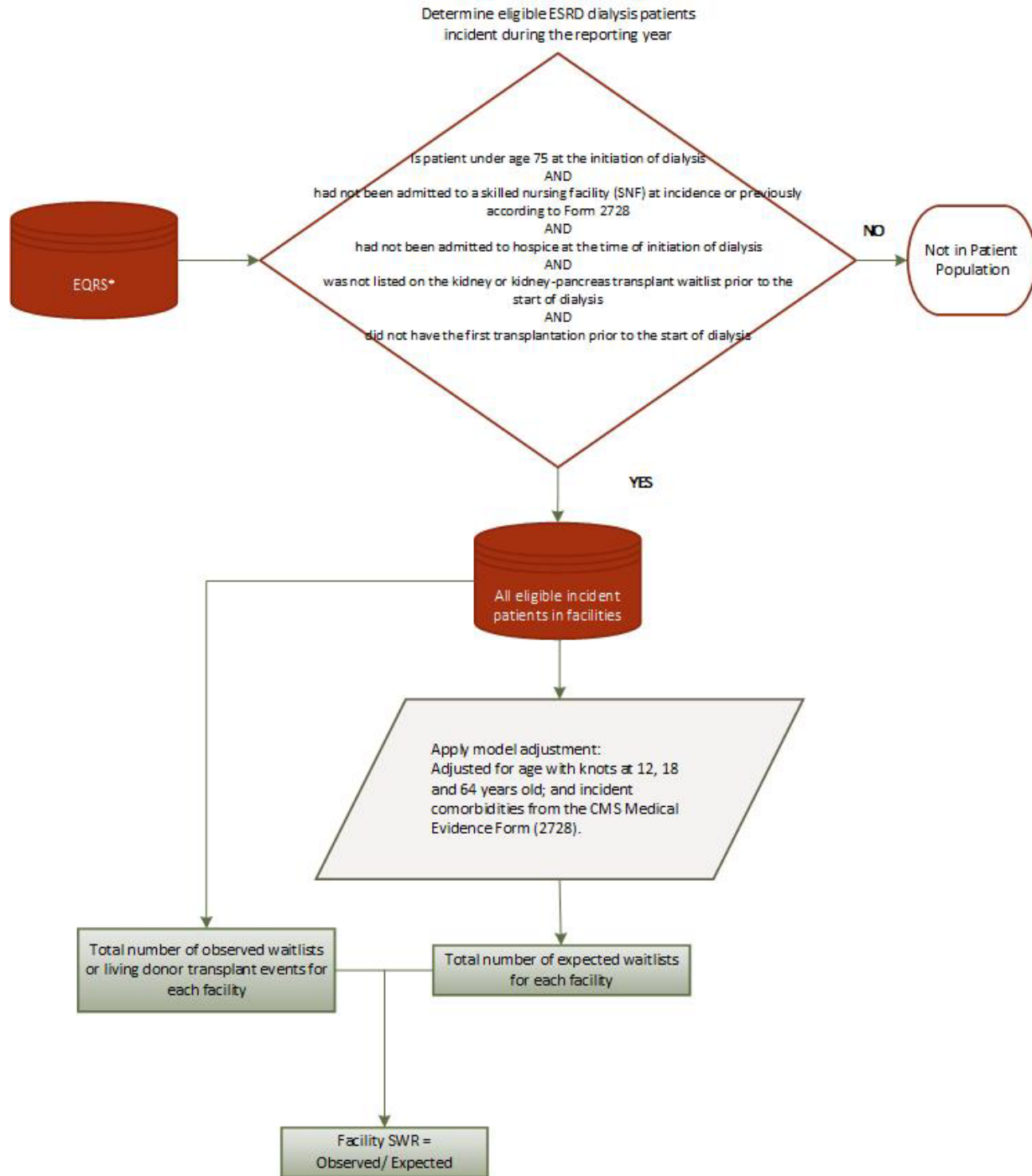
Figure 18: Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) Measure (Dialysis Facility Measures Only)

 * EQRS (including CMS Medical Evidence Form (Form CMS-2728)) is the primary data source used for placing patients at dialysis facilities, age and incident comorbidities adjustments and exclusion of patients ≥75-year-old. Organ Procurement and Transplant Network (OPTN) is the data source for waitlist or living donor transplant events. The Nursing Home MDS and the CMS Medical Evidence Form (Form CMS-2728) are used to identify SNF patients. A separate CMS file that contains final action claims submitted by hospice providers was used to determine the hospice status.

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2.15.18 Selected References

- Ashby VB, Kalbfleisch JD, Wolfe RA, Lin MJ, Port FK, Leichtman AB. Geographic variability in access to primary kidney transplantation in the United States, 1996-2005. Am J Transplant. 2007;7(5 Pt 2):1412-23.
- Satayathum S, Pisoni RL, McCullough KP, Merion RM, Wikström B, Levin N, Chen K, Wolfe RA, Goodkin DA, Piera L, Asano Y, Kurokawa K, Fukuhara S, Held PJ, Port FK. Kidney transplantation and wait-listing rates from the international Dialysis Outcomes and Practice Patterns Study (DOPPS). Kidney Int. 2005;68(1):330-337.
- Patzer RE, Plantinga L, Krisher J, Pastan SO. Dialysis facility and network factors associated with low kidney transplantation rates among United States dialysis facilities. Am J Transplant. 2014;14(7):1562-72.
- Meier-Kriesche HU, Kaplan B. Waiting time on dialysis as the strongest modifiable risk factor for renal transplant outcomes: A Paired Donor Kidney Analysis. Transplantation. 2002;74(10):1377-1381.
- Meier-Kriesche HU, Port FK, Ojo AO, Rudich SM, Hanson JA, Cibrik DM, Leichtman AB, Kaplan B. Effect of waiting time on renal transplant outcome. Kidney Int. 2000;58(3):1311-1317.

2.16 Percentage of Prevalent Patients Waitlisted (PPPW) Measure (ESRD QIP and Dialysis Facility Measures)

2.16.1 Measure Name

Percentage of Prevalent Patients Waitlisted (PPPW)

2.16.2 Measure Description

The PPPW measure tracks the percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waiting list (CBE ID 3695).

2.16.3 Measure Rationale

A measure focusing on the waitlisting process is appropriate for improving access to kidney transplantation for several reasons. First, waitlisting is a necessary step prior to potential receipt of a deceased donor kidney. Second, dialysis facilities exert substantial control over the process of waitlisting. This includes proper education of dialysis patients on the option for transplant, referral of appropriate patients to a transplant center for evaluation, assisting patients with completion of the transplant evaluation process, and optimizing the health and functional status of patients in order to increase their candidacy for transplant waitlisting. These types of activities are included as part of the conditions for coverage for Medicare certification of ESRD dialysis facilities. In addition, dialysis facilities can also help maintain patients on the waitlist through assistance with ongoing evaluation activities and by optimizing health and functional status. Finally, wide regional variations in waitlisting rates highlight substantial room for improvement for this process measure (Ashby 2007, Satayathum 2005, Patzer 2014).

This measure focuses specifically on the prevalent dialysis population, examining waitlisting status monthly for each patient. This allows evaluation and encouragement of ongoing waitlisting of patients beyond the first year of dialysis initiation who have not yet been listed. Patients may not be ready, either psychologically or due to their health status, to consider transplantation early after initiation of dialysis and many choose to undergo evaluation for transplantation only after years on dialysis. In addition, as this measure assesses monthly waitlisting status of patients, it also evaluates and encourages maintenance of patients on the waitlist. Maintenance of active status on the waitlist is important for increasing likelihood of transplantation (Grams 2013) and thus by extension, is waitlisting overall. This is an important area to which dialysis facilities can contribute through ensuring patients remain healthy and complete any ongoing testing activities required to remain on the waitlist. In contrast to this measure, another waitlisting measure, the Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR), focuses solely on new listing or living kidney donor transplantation within the first year after initiation of dialysis with the rationale of encouraging early access to transplantation or the waitlist.

2.16.4   Measure Type

Outcome

2.16.5   Improvement Noted as Higher or Lower Rate

A higher number indicates better quality.

2.16.6   Numerator Statement

To be included in the numerator for a particular month, the patient must be on the kidney or kidney-pancreas transplant waitlist as of the last day of the month during the reporting year.

2.16.7   Facility Exclusions

The PPPW calculation is restricted to facilities with 11 or more eligible patients during the reporting time period.

ESRD QIP Only:

Calculations will exclude the months covered by a granted ECE (see Section 3.4).

2.16.8   Denominator Statement

The denominator for the PPPW is the sum of all patient-months for patients who are under the age of 75 in the reporting month and who are assigned to the dialysis facility according to each patient's treatment history as of the last day of each month during the reporting year.

Calculations will exclude the months covered by a granted ECE (see Section 3.4).

2.16.9   Denominator Exclusions

Exclusions that are implicit in the denominator definition include:

- Patients who were at age 75 or older on the last day of each month.
- Patients who were admitted to a SNF or a hospice during the month of evaluation were excluded from that month; patients who were admitted to a SNF at incidence or previously according to Form CMS-2728 were also excluded.

The Nursing Home MDS and the CMS Medical Evidence Form are used to identify patients in SNFs. For hospice patients, a separate CMS file that contains final action claims submitted by hospice providers was used to determine the hospice status.

2.16.10   Mapping Patients to Facilities

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 several sources including the CMS Medical Evidence Form (CMS-2728), transplant data from the OPTN (Dialysis Facility Measures only), the Death Notification Form (CMS-2746) and the Social Security Death Master File (Dialysis Facility Measures only). Also

see Section 3.1.6. Additionally, for Dialysis Facility Measures, a new treatment history record is created for each patient each time he/she changes facility or treatment modality. Each record represents a time period associated with a specific modality and dialysis facility.

2.16.11 Calculating Numerators/Outcome definition

To be included in the numerator for a particular month, the patient must be on the kidney or kidney-pancreas transplant waitlist as of the last day of the month during the reporting period.

2.16.12 Risk Adjustment

Age adjustment was deemed necessary on clinical grounds. Although age alone is not a contraindication to transplantation, older patients are likely to have more comorbidities and be generally more frail thus making them potentially less suitable candidates for transplantation and therefore some may be appropriately excluded from waitlisting for transplantation. This may affect waitlisting rates for facilities with a substantially older age composition than the average.

A linear spline was used to model the effect of (continuous) age. The spline's knots at 15, 55, and 70 were determined empirically using standard techniques.

2.16.13 Calculation of PPPW

We assume a logistic regression model for the probability that a prevalent patient is waitlisted. Consider patient i at facility j during calendar month k; we set the response variate to $Y_{ijk} = 1$ if the patient is on the waitlist and Y_{ijk} 0 if not according to the following equation:

$$\text{logit}(p_{ijk}) = \alpha_j + \beta A_{ij},$$

The model is adjusted for age, coded as a linear spline with empirically determined knots at ages 15, 55, and 70. As such, the only factors in the logistic model are age and i and the facility indicators. The model is fitted using Generalized Estimating Equations (GEE; Liang and Zeger, 1986) in order to account for the correlation within-patient across months.

With over 7,000 facilities, it is difficult to estimate all parameters (i.e., including the facility indicators) simultaneously. Therefore, we break the fitting process into stages. At the first stage, we estimate the β vector by averaging 10 subgroups of approximately 700 facilities each. At the second stage, we then estimate the α_j (j=1, .., 7000) by fitting facility-specific intercept-only GEE models, with the linear predictor from the first stage, βA_{ij}, serving as an offset. Per well-established GEE results (e.g., Liang and Zeger, 1986), the estimator of α_j is consistent for its target value and follows a Normal distribution with standard error given by the robust 'sandwich' estimator computed via GEE. We can then compute $PPPW_j$ for each facility j as follows:

$$PPPW_j = \sum_i \sum_l \sum_k \, exp(a_j + \beta A_{il}) \, / \, \{1 + exp(a_j + \beta A_{il})\} / \, n,$$

where n = total number of patient-months included in the overall study sample. The standard error of $PPPW_j$ is estimated through the Delta method; i.e., $SE(PPPW_j) = d_j \times SE(a_j)$, where $d_j = \sum_i \sum_l \sum_k \, exp(a_j + \beta A_{il}) \, / \, \{1 + exp(a_j + \beta A_{il})\}^2 / \, n.$

We then carry out a two-sided Wald test (0.05 significance level) that $PPPW_j=PPPW$, where $PPPW$ equals the national average percentage waitlisted. Note that the Wald test is based on the logit of $PPPW_j$, which is much more likely to follow a Normal distribution than $PPPW_j$ itself, due to the symmetry and lack of range restrictions of the transformed version.

2.16.14 Creating Interval Estimates (Dialysis Facility Measures Only)

The 95% confidence interval gives a range of plausible values for the true waitlist percentage. The upper and lower limits of the confidence interval enclose the true percentage approximately 95% of the time if this procedure were to be repeated on multiple samples.

A two-sided Wald test (0.05 significance level) is used to measure the statistical significance of (or evidence against) the hypothesis that the PPPW for a facility is the same as (neither higher nor lower than) that from the national average percentage waitlisted. A p-value of less than 0.05 is usually taken as evidence that the facility PPPW differs from the national PPPW.

2.16.15 Flagging Rules for Dialysis Facility Compare (Dialysis Facility Measures Only)

Facilities were classified as "Better than expected", "As expected", or "Worse than expected" based on their Z score of the logit of PPPW. The z score value is much more likely to follow a normal distribution than PPPW itself, due to the symmetry and lack of range restrictions of the transformed version.

2.16.16 Data Elements and Data Sources

EQRS (including CMS Medical Evidence Form (Form CMS-2728)) is the primary data source used for placing patients at dialysis facilities, age and incident comorbidities adjustments and exclusion of patients => 75-year-old (see information provided under "denominator details"). United Network for Organ Sharing (UNOS) and OPTN are data sources for waitlist or living donor transplant events for ESRD QIP and Dialysis Facility Measures, respectively. The Nursing Home MDS and the CMS Medical Evidence Form (Form CMS-2728) are used to identify SNF patients. A separate CMS file that contains final action claims submitted by hospice providers was used to determine the hospice status.

Variable	Primary Data Source
Facility CCN	CMS data sources[1]
Reporting year and month	EQRS
Waitlist status	UNOS/OPTN[2]
Date of birth	CMS data sources[1]
Date of first ESRD	Medical Evidence Form (CMS-2728)
Nursing home status on the Medical Evidence Form[3]	Medical Evidence Form (CMS-2728)

Variable	Primary Data Source
Nursing home status in the current month[3]	CMS Long-Term Care Minimum Data Set (MDS)
Hospice status in the current month[3]	CMS Hospice file

Table 12: Data Elements and Sources for the Percentage of Prevalent Patients Waitlisted

[1]EQRS (including CMS Medical Evidence Form (Form CMS-2728)) is the primary data source used for placing patients at dialysis facilities, age, and incident comorbidities adjustments, and exclusion of patients ≥75-years-old.

[2.]United Network for Organ Sharing (UNOS)/OPTN are the data sources for waitlist or living donor transplant events.

[3]The Nursing Home MDS and the CMS Medical Evidence Form (Form CMS-2728) are used to identify SNF patients. A separate CMS file that contains final action claims submitted by hospice providers was used to determine the hospice status.

2.16.17 Flowchart

Figure 19 provides a flowchart that represents the processes used to calculate Percentage of Prevalent Patients Waitlisted Measure (PPPW).
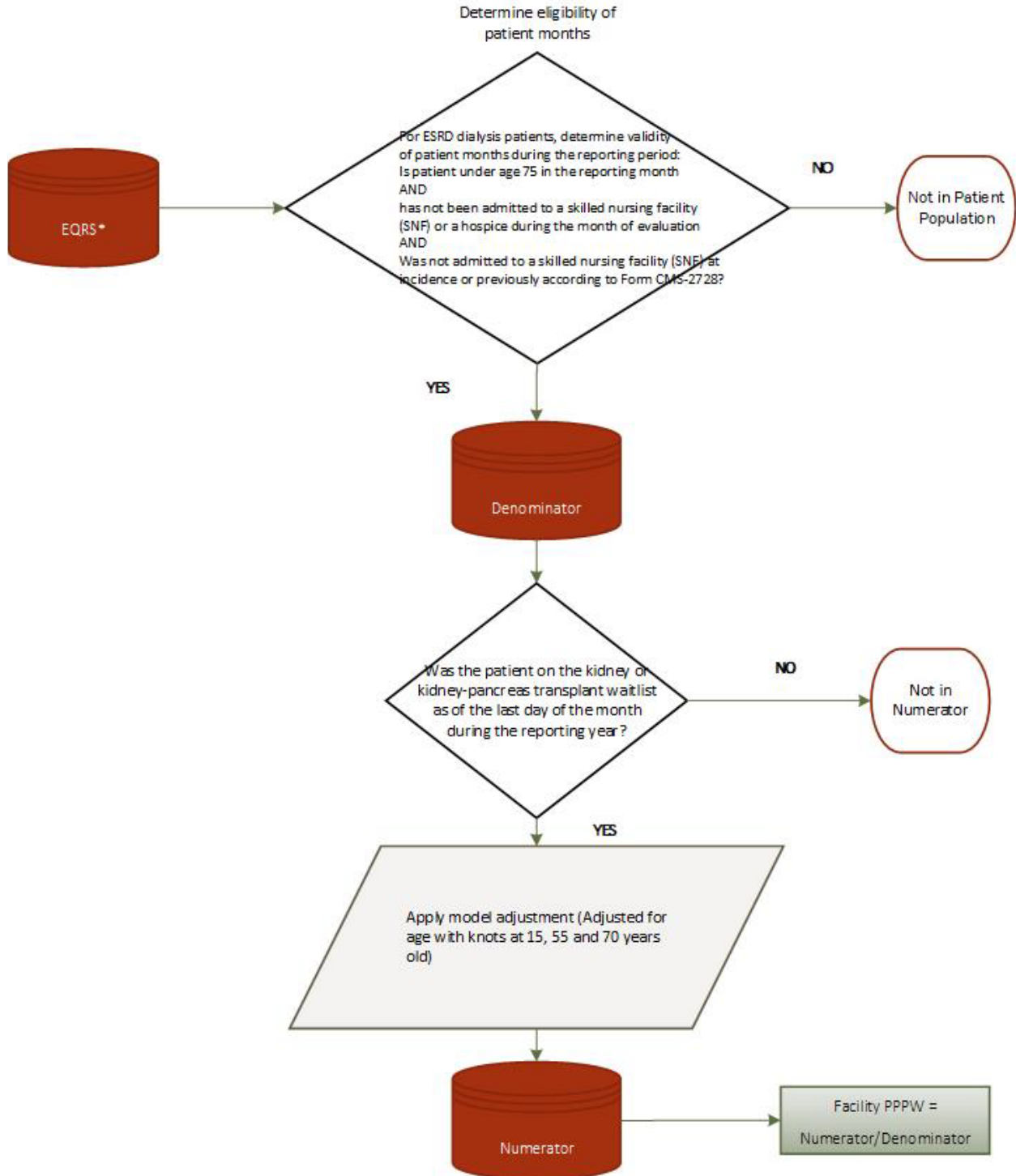
Figure 19: Flowchart for the Percentage of Prevalent Patients Waitlisted Measure

*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, waitlist status and transplant is obtained from EQRS (including the CMS Medical Evidence Form (Form CMS-2728) and the Death Notification Form (Form CMS-2746)) and Medicare claims, as well as the Organ Procurement and Transplant Network (OPTN) and the Social Security Death Master File (Dialysis Facility Measures only). For denominator exclusions, the Nursing Home MDS and the CMS Medical Evidence Form are used to identify patients in SNFs. Additionally, a separate CMS file that contains final action claims submitted by hospice providers was used to determine the hospice status.

2.16.18 Selected References

- Ashby VB, Kalbfleisch JD, Wolfe RA, et al. Geographic variability in access to primary kidney transplantation in the United States, 1996-2005. Am J Transplant.2007;7 (5 Part 2):1412-1423.
- Satayathum S, Pisoni RL, McCullough KP, Merion RM, Wikström B, Levin N, Chen K, Wolfe RA, Goodkin DA, Piera L, Asano Y, Kurokawa K, Fukuhara S, Held PJ, Port FK. Kidney transplantation and wait-listing rates from the international Dialysis Outcomes and Practice Patterns Study (DOPPS). Kidney Int. 2005;68(1):330-337.
- Patzer RE, Plantinga L, Krisher J, Pastan SO. Dialysis facility and network factors associated with low kidney transplantation rates among United States dialysis facilities. Am J Transplant. 2014;14(7):1562-72.
- Grams ME, Massie AB, Schold JD, Chen BP, Segev DL. Trends in the inactive kidney transplant waitlist and implications for candidate survival. Am J Transplant. 2013;13(4):1012-1018.
- Liang, KY, Zeger SL. Longitudinal Data Analysis Using Generalized Linear Models. Biometrika. 1986; 73:13–22.

2.17 ICH CAHPS Clinical Measure (ESRD QIP Only)

2.17.1 Measure Name

In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS)

2.17.2 Measure Description

Percentage of patient responses to multiple survey measures to assess their dialysis providers, the quality of dialysis care they receive, and information sharing about their disease (CBE ID 0258). (Survey is administered twice a year).

Three Composite Measure Scores: The proportion of respondents answering each response option by item, created from six or more questions from the survey that are reported as one measure score. Composites include: Nephrologists' Communication and Caring, Quality of Dialysis Center Care and Operations, and Providing Information to Patients.

Three Global Items: A scale of 0 to 10 to measure the respondent's assessment of the following: Rating of the Nephrologist, Rating of Dialysis Center Staff, and Rating of the Dialysis Facility.

2.17.3 Measure Type

Outcome – Patient Reported Outcome (PRO).

2.17.4 Improvement Noted as Higher or Lower Rate

A higher rate indicates better quality.

2.17.5 Numerator Statement

Each measure encompasses the responses for all questions included in the particular measure. Missing data for individual survey questions are not included in the calculations. Only data from a completed survey is used in the calculations. The measure score averages the proportion of those responding to each answer choice in all questions. Each global rating will be scored based on the number of respondents in the distribution of top responses, e.g., the percentage of patients rating the facility a "9" or "10" on a 0 to 10 scale (with 10 being the best).

2.17.6 Facility Exclusions

- Facilities that attest in EQRS that they treated fewer than 30 eligible ICHD adult patients during the eligibility period, which is defined as the year prior to the performance period.
- Facilities that treat 30 or more eligible in-center hemodialysis adult patients during the eligibility period but are unable to obtain at least 30 completed surveys during the performance period.
- Facilities with a CCN certification date on or after October 1 of the year prior to the performance year.

- Facilities not offering ICHD as of December 31 of the performance period.

    o Note: Adult and pediatric facilities that treat fewer than 30 eligible patients during the eligibility period must attest to this in EQRS in order to not receive a score on the measure; facilities that do not attest that they are ineligible will be considered eligible and will receive a score on the measure if they obtain at least 30 completed surveys, or if they are non-compliant (see Section 2.17.9).

2.17.7   Denominator Statement

Patients with ESRD receiving ICHD at sampled facility for the past three months or longer are included in the sample frame. The denominator for each question is the sample patients that responded to the particular question.

2.17.8   Denominator Exclusions

The following patients are excluded in the count of 30 eligible patients:

- Patients less than 18 years old (see Section 3.1.3) on the last day of the sampling window (see https://ichcahps.org for dates) for the semiannual survey.
- Patients not receiving ICHD.
- Patients receiving HD from their current facility for less than 90 days.
- Patients receiving hospice care.
- Patients currently residing in an institution, such as jail or prison.
- Patients who receive ICHD at a nursing home or SNF where they reside (as opposed to traveling to an ICHD facility).

2.17.9   Additional Information

- Facilities are required to register on the https://ichcahps.org website in order to authorize a CMS-approved vendor to administer the survey and submit data on their behalf.
- Facilities are required to administer the survey twice during the performance period, using a CMS-approved vendor.
- Facilities are required to ensure that vendors submit survey data to CMS by the date specified at https://ichcahps.org.
- Adult and pediatric facilities that treat fewer than 30 eligible patients during the eligibility period must attest to this in EQRS in order to not receive a score on the measure; facilities that do not attest that they are ineligible will be considered eligible and will receive a score on the measure.
- Facilities that do not administer two surveys during the performance period will receive a score of 0 on the measure.
- Facilities that administer two surveys during the performance period, but less than 30 completed surveys will be excluded from the measure.
- Additional specifications may be found at https://ichcahps.org.

2.17.10 Data Elements and Data Sources

The data elements used for this measure are listed below. A complete description of the EQRS data elements can be found at the [ESRD section of QualityNet.gov](#).

EQRS Data Elements:

- ICH CAHPS Attestation Indicator
- Initial Facility Certification Date
- Medicare Certified Services Offered as of 12/31 of the performance period
- Additional Services Offered (non-Medicare) as of 12/31 of the measurement period

ICH CAHPS Data Elements:

- Reporting Compliance Indicator
- Number of Completed Surveys
- Nephrologists' Communication and Caring Composite Measure Score
- Quality of Dialysis Center Care and Operations
- Composite Measure Score
- Providing Information to Patients Composite Measure Score
- Overall Rating of Nephrologists Global Rating
- Overall Rating of the Dialysis Center Staff Global Ratings
- Overall Rating of the Dialysis Facility Global Ratings

2.17.11 Flowchart

Figure 20 provides a flowchart that represents the processes used to calculate the ICH CAHPS Clinical Measure.

Centers for Medicare & Medicaid Services
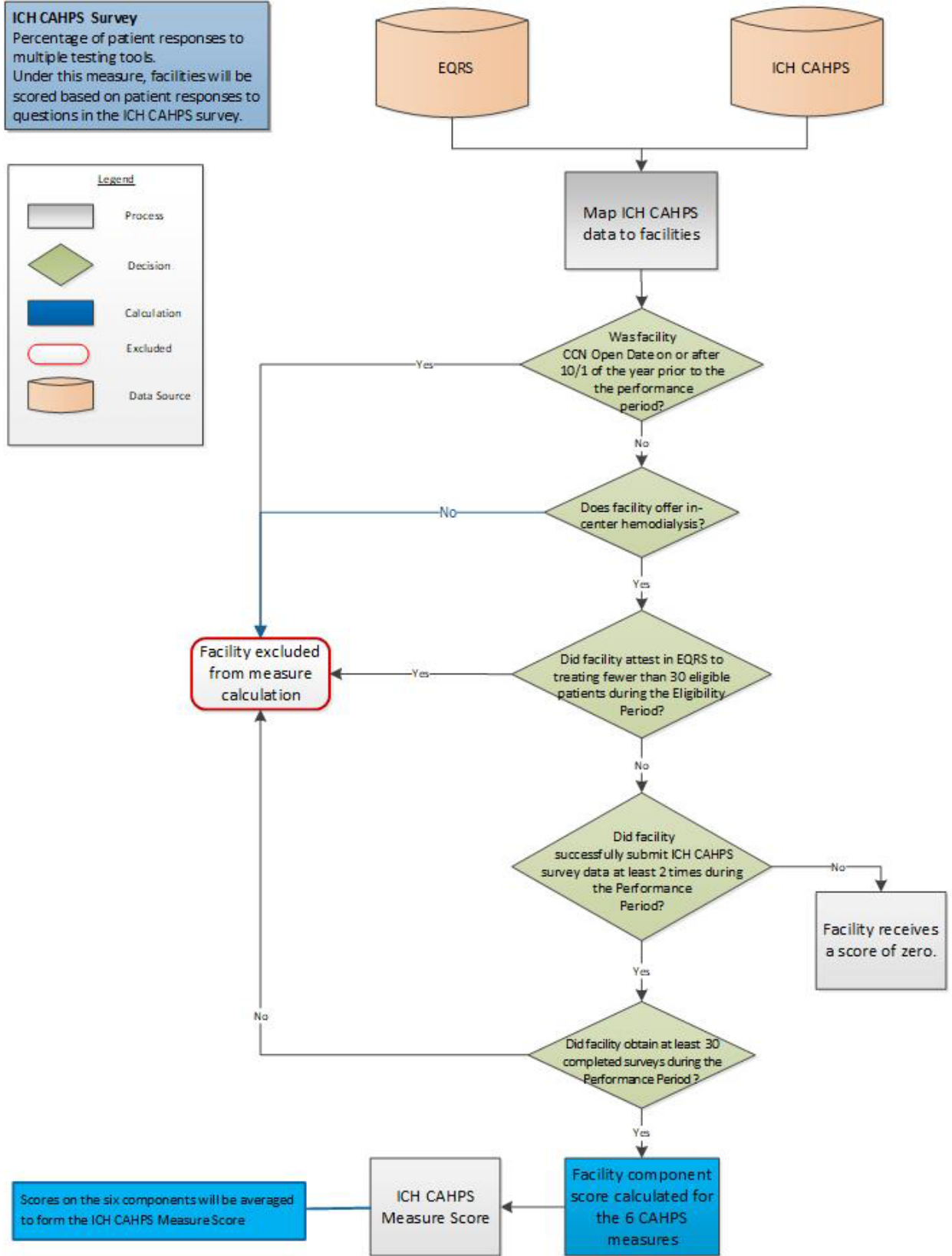
Figure 20: ICH CAHPS Survey Flowchart (ESRD QIP Only)

2.17.12 Selected References

- https://ichcahps.org/Home.aspx

2.18 NHSN Bloodstream Infection in Hemodialysis Patients Clinical Measure (ESRD QIP Only)

2.18.1 Measure Name

The National Healthcare Safety Network (NHSN) Standardized Infection Ratio (SIR) of Bloodstream Infections (BSI) in Hemodialysis Outpatients

2.18.2 Measure Description

The SIR of BSI will be calculated among patients receiving HD at outpatient HD centers (CBE ID 1460).

2.18.3 Measure Type

Outcome

2.18.4 Improvement Noted as Higher or Lower Rate

A lower ratio indicates better quality.

2.18.5 Numerator Statement

The number of new positive blood culture events based on blood cultures drawn as an outpatient or within one calendar day after a hospital admission. A positive blood culture is considered a new event and counted only if it occurred 21 days or more after a previous positive blood culture in the same patient.

2.18.6 Facility Exclusions

- Facilities that do not offer ICHD as of December 31 of the performance period.
- Facilities with a CCN certification date on or after October 1 of the year prior to the performance year.
- Facilities that treat fewer than 11 ICHD patients during the performance period, where ICHD patients are defined as patients whose primary treatment modality is ICHD and (1) have a Medicare claim submitted by the facility during the performance year; or (2) have a treatment at an outpatient dialysis facility or a long-term care facility.
- Facilities with an approved ECE.

2.18.7 Denominator Statement

Number of maintenance HD patients treated in the outpatient HD center on the first two working days of the month.

2.18.8 Patient Exclusions

- Patients receiving only inpatient HD.
- Patients receiving only home HD or PD.

- Patients not on ESRD treatment as defined by a completed 2728 form, an EQRS record, or a sufficient amount of dialysis reported on dialysis facility claims.

2.18.9 Additional Information

Facilities must submit 12 months of accurately reported dialysis event data in order to receive an SIR. Eligible facilities that do not submit 12 months of accurately reported data according to the requirements receive zero points for the measure.

Facilities are required to follow the NHSN Dialysis Event Protocol and submit data to NHSN by the following quarterly deadlines, which are also specified on the CDC's NHSN and ESRD QIP website (https://www.cdc.gov/nhsn/faqs/dialysis/faq-esrd-qip.html):

- Q1 (Jan.-March): June 30
- Q2 (April-June): September 30
- Q3 (Jul.-Sept.): December 31
- Q4 (Oct.-Dec.): March 31.

Please note when deadline falls on a Saturday, Sunday, or Federal holiday, the deadline is moved to next business day.

Once the quarterly reporting deadline has passed, a frozen data file is created for calculating final ESRD QIP scores. Although the NHSN Dialysis Event Protocol includes an expectation that users report any additional information retrospectively in order to ensure NHSN data are complete and accurate, only data reported prior to the ESRD QIP quarterly reporting deadline will be used to calculate ESRD QIP scores.

Facilities are required to meet enrollment and training requirements, as specified at http://www.cdc.gov/nhsn/dialysis/enroll.html and http://www.cdc.gov/nhsn/Training/dialysis/index.html.

Additional details on the specifications for the NHSN BSI measure can be found at the following website: http://www.cdc.gov/nhsn/pdfs/dialysis/understanding-the-de-bsi-sir.pdf

2.18.10 Data Elements and Data Sources

The data elements used for this measure are listed below. A complete description of the EQRS and Claims data elements can be found at the ESRD section of QualityNet.org.

Centers for Disease Control and Prevention (CDC) Data Elements:

- Quarterly reporting compliance indicator (from CDC)
- SIR for BSI (from as calculated by CDC)

EQRS Data Elements: (used to determine facility eligibility and eligible patient count)

- Certification Date
- UPI

- Provider ID

- Admit Date

- Discharge Date

- Primary Type of Treatment ID (EQRS dialysis type)

- Primary Dialysis Setting

- Medicare Certified Services Offered as of 12/31 of the performance period

- Additional Services Offered (non-Medicare) as of 12/31 of the measurement period

Claims Based Data Elements: *Note: Only Type of Bill (TOB) 72x claims are considered in the measure calculation.*

- Claim CCN

- Patient Health Insurance Claim Number

- Claim Related Condition Code

- Claim Control Number

- Claim-From Date

- Claim Through Date

- Claim NCH Daily Process Date

- Claim Link Number

- Claim Line Institutional Revenue Center Codes

- Claim Line Institutional Revenue Center Dates

- Calculated start of ESRD date (see Section 3.1.2).

2.18.11 Flowchart

Figure 21 provides a flowchart that represents the processes used to calculate the NHSN BSI in HD outpatient's measure in the ESRD QIP.

NHSN Bloodstream Infection in Hemodialysis Patients: Standardized Infection Ratio (SIR) of Bloodstream Infections (BSI) will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers. Note: Facilities with approved extraordinary circumstances exemption at any time during the Performance Period are excluded from the measure

Legend

- Process
- Decision
- Calculation
- Excluded
- Data Source

EQRS (Patient population)

Claims (patient population)

CDC (NHSN Data)

Map patients to facilities
Map CDC data to facilities

Does facility offer in-center hemodialysis? — No

Yes

Was facility CCN certification date before Oct. 1, year prior to the performance period? — No

Facility excluded from measure calculation

Yes

Determine the number of outpatient in-center hemodialysis patients treated at facility during measurement period

Did facility treat 11 or more eligible patients? — No

Yes

Facility receives a measure score of zero — No — Did facility report 12 months of data?

Yes

Calculate Facility Denominator: Predicted number of infections based on the Risk Adjusted SIR

Calculate Facility Numerator: Number of observed infections in the facility's outpatient hemodialysis population

Calculate Facility measure rate (SIR) by dividing the observed #infections by the predicted #infections

Figure 21: NHSN Bloodstream Infection in Hemodialysis Outpatients Flowchart (ESRD QIP Only)

2.19 Medication Reconciliation Reporting Measure (MedRec) (ESRD QIP Only)

2.19.1 Measure Name

Medication Reconciliation Reporting Measure (MedRec)

2.19.2 Measure Description

The percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional (based on CBE ID 2988).

2.19.3 Measure Rationale

Medication management is a critical safety issue for all patients, but especially so for patients with ESRD, who often require 10 or more medications and take an average of 17-25 doses per day, have numerous comorbid conditions, have multiple healthcare providers and prescribers, and undergo frequent medication regimen changes (Hakim 2014; Cardone 2010; Shoemaker 2011; esrdnetworks.org). Medication-related problems (MRPs) contribute significantly to the approximately $40 billion in public and private funds spent annually on ESRD care in the US, and it is believed that medication management practices focusing on medication documentation, review, and reconciliation could systematically identify and resolve MRPs, improve ESRD patient outcomes, and reduce total costs of care (Parker 2015). As most HD patients are seen at least thrice weekly and PD patients monthly, the dialysis facility has been suggested as a reasonable locale for medication therapy management (Pai 2013).

2.19.4 Measure Type

Process

2.19.5 Numerator Statement

Number of patient-months in the denominator for which the facility reported the following required data in EQRS:

- Date of the medication reconciliation.
- Type of eligible professional who completed the medication reconciliation:
  - physician
  - nurse
  - advanced registered nurse practitioner (ARNP)
  - physician assistant (PA)
  - pharmacist, or
  - pharmacy technician personnel
- Name of eligible professional

2.19.6   Denominator Statement

Total number of eligible patient-months for all patients assigned to a dialysis facility during the performance period.

2.19.7   Patient Exclusions

- In-center patients who receive < 7 HD treatments in the facility during the reporting month.
- Patients who are not assigned to the facility for the entire reporting month.
- Patients not on ESRD treatment as defined by a completed 2728 form, an EQRS record, or a sufficient amount of dialysis reported on dialysis facility claims.

2.19.8   Facility Exclusions

- Facilities with a CCN certification date on or after September 1 of the performance period.
- Calculations will exclude the months covered by a granted ECE (see Section 3.4).
- Facilities treating fewer than 11 eligible patients during the performance period.
- For new facilities only, the month in which the CCN becomes effective and the following three months.

2.19.9   Calculating a Facility's Score on the Medication Reconciliation Reporting Measure

An eligible facility's score is calculated according to the following equation:

$$\left[\frac{\text{\# patient-months facility reported required MedRec data elements in EQRS}}{\text{\# eligible patient-months assigned to the facility in the performance period}} x12 \right] - 2$$

2.19.10 Flowchart

Figure 22 presents the flowchart that represents the processes used to calculate the MedRec Reporting Measure.

Medication Reconciliation (MedRec) Reporting
The number of months for which medication reconciliation was performed and documented by an eligible professional for each eligible patient (based on NQF #2988).

EQRS (Facility & Patient Data)

Map EQRS patient record to Facilities

System determines if facility is eligible for measure

If the facility's certification date was between October 1 of the year prior to the performance period and August 31 of the performance period the facility is required to report on the first day of the month that is 4 months after the month in which the CCN becomes effective.

Was CCN Open Date before 9/1 of the performance period? — No → Facility excluded from measure calculation

Yes

Repeat for each month of the measurement period.

System determines eligible patients within facility

Is patient on ESRD Treatment? — No

Yes

Is patient assigned to facility for entire reporting month? — No → Patient-month excluded from measure calculation

Yes

Is patient on in-center hemodialysis during month? — Yes

No

Did patient receive 7 or more hemodialysis treatments in facility during month? — No

Yes

Eligible Patient Identified

Legend
- Process
- Decision
- Calculation
- Excluded
- Data Source

- The result of the formula should be rounded, with half rounded up.
- If the result of the formula is negative, round the result to zero (0)
- If there are NO eligible months, the facility receives No Score on the measure.

Calculate measure score: [(# of patient-months the facility successfully reported required data for all eligible patients / # of eligible patient-months assigned to the facility in the performance period) x 12] - 2

Numerator: Total number of Patient-months in denominator for whom facility reported required medication reconciliation data in CROWNWeb

Denominator: Total number of eligible patient-months at the facility in performance period

- ECE months are not eligible, regardless of whether or not data are reported.

Figure 22: Medication Reconciliation Reporting Measure Flowchart (ESRD QIP Only)

2.19.11 Data Elements and Data Sources

Facility medical records, EQRS, and other CMS administrative data will be used.

EQRS Data Elements include:

- Initial certification date

- UPI

- Facility CCN

- MedRec date

- MedRec clinician type

- MedRec clinician name

- Primary type of treatment ID (EQRS dialysis type)

- Number of sessions of dialysis delivered by the dialysis unit to the patient in the reporting month

2.19.12 Selected References

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2.20 NHSN COVID-19 Vaccination Coverage among Healthcare Personnel Reporting (ESRD QIP Only)

2.20.1 Measure Name

COVID-19 Vaccination Coverage among Healthcare Personnel (HCP)

2.20.2 Measure Description

Percentage of months for which the facility successfully reports NHSN COVID-19 vaccination data for eligible healthcare personnel in the CDC's NHSN system.

2.20.3 Measure Rationale

CDC currently collects data that are voluntarily reported on COVID-19 (Severe Acute Respiratory Syndrome Coronavirus-2) vaccination coverage among healthcare personnel through the NHSN. The NHSN Healthcare Personnel (HCP) COVID-19 Vaccination Cumulative Summary Module was developed to help guide the public health emergency response to the COVID-19 pandemic. As the pandemic phase of the COVID-19 epidemic wanes and public health vaccination priorities shift from emergency response to measurement for ensuring the safety of patients and healthcare workers, CDC intends to align NHSN COVID-19 vaccination coverage surveillance with the Consensus-Based Entity (CBE)-endorsed quality measure for annual influenza vaccination coverage among Healthcare Personnel (CBE ID 0431), which is collected through the NHSN Healthcare Personnel Influenza Vaccination Module.

2.20.4 Measure Type

Process

2.20.5 Numerator Statement

Cumulative number of HCP in the denominator population who are considered up to date with recommended COVID-19 vaccines.

2.20.6 Denominator Statement

Number of HCP eligible to work in the facility for at least one day during the reporting period, excluding persons with contraindications to COVID-19 vaccination that are described by the CDC.

2.20.7 Patient Exclusions

The denominator for this measure excludes HCP with documented contraindications to COVID-19 vaccine. As of April 2023, CDC considers contraindications to vaccination with COVID-19 vaccines to be:

1. History of severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine.

2. History of known (diagnosed) allergy to a component of the vaccine.

2.20.8   Facility Exclusions

1. Facilities with a CCN certification date on or after September 1 of the performance year.
2. Calculations will exclude the months covered by a granted ECE.
3. For new facilities only, the month in which the CCN becomes effective and the following three months.

2.20.9   Additional Information

1. Facilities should submit COVID-19 vaccination data via the Weekly COVID-19 Vaccination Module for at least one week per month to fulfill CMS reporting requirements. For facilities that report more than one week per month, the last week of the reporting month will be shared with CMS. NHSN guidance and definitions for reporting weekly HCP COVID-19 vaccination data can be found in the NHSN HCP COVID-19 Vaccination Protocol: https://www.cdc.gov/nhsn/hps/weekly-covid-vac/#protocol.

2. If the facility's certification date was between October 1 of the year prior to the performance year and August 31 of the performance year, the facility is required to report on the first day of the month that is four months after the month in which the facility is certified to participate in Medicare.

3. Facilities are required to report COVID-19 vaccination data for four required categories of HCP including:
   a.   Employees (required): This includes all persons receiving a direct paycheck from the reporting facility (i.e., on the facility's payroll), regardless of clinical responsibility or patient contact.
   b.   Licensed independent practitioners (LIPs) (required): This includes physicians (MD, DO), advanced practice nurses, and physician assistants who are affiliated with the reporting facility, but are not directly employed by it (i.e., they do not receive a paycheck from the facility), regardless of clinical responsibility or patient contact. Post-residency fellows are also included in this category if they are not on the facility's payroll.
   c.   Adult students/trainees and volunteers (required): This includes medical, nursing, or other health professional students, interns, medical residents, or volunteers aged 18 or older who are affiliated with the healthcare facility, but are not directly employed by it (i.e., they do not receive a paycheck from the facility), regardless of clinical responsibility or patient contact.
   d.   Other contract personnel (required): This includes all persons providing care, treatment, or services at the facility through a contract who do not fall into any of the

other denominator categories. This also includes vendors providing care, treatment, or services at the facility who may or may not be paid through a contract.

4. Facilities are not required to report for HCP who:
    a. Were determined to have a medical contraindication or condition specified by Food and Drug Administration (FDA) labeling or authorization, CDC or Advisory Committee on Immunization Practices (ACIP) recommendations.
    b. Can provide verbal statements for medical contraindications to (and declination of) the vaccine. Written documentation is not required.

5. The definition of "up to date vaccination status" may change over time. Facilities should refer to the definition of "up to date" as of the first day of the applicable reporting quarter. As of Quarter 4 2023, "up to date" with COVID-19 vaccines is defined as follows:
    a. Received an updated (bivalent) booster dose, or
    b. Completed their primary series less than two months ago.

2.20.10 Calculating a Facility's Score

Facilities will receive credit for successfully reporting numerator and denominator information prior to the reporting deadlines. The measure will be scored according to the following formula:

$$\left[\frac{\text{\# Months successfully reporting data}}{\text{\# Eligible months}} * 12\right] - 2$$

2.20.11 Flowchart

Figure 23 presents the flowchart that represents the processes used to calculate the COVID-19 Healthcare Personnel (HCP) Vaccination Reporting Measure.
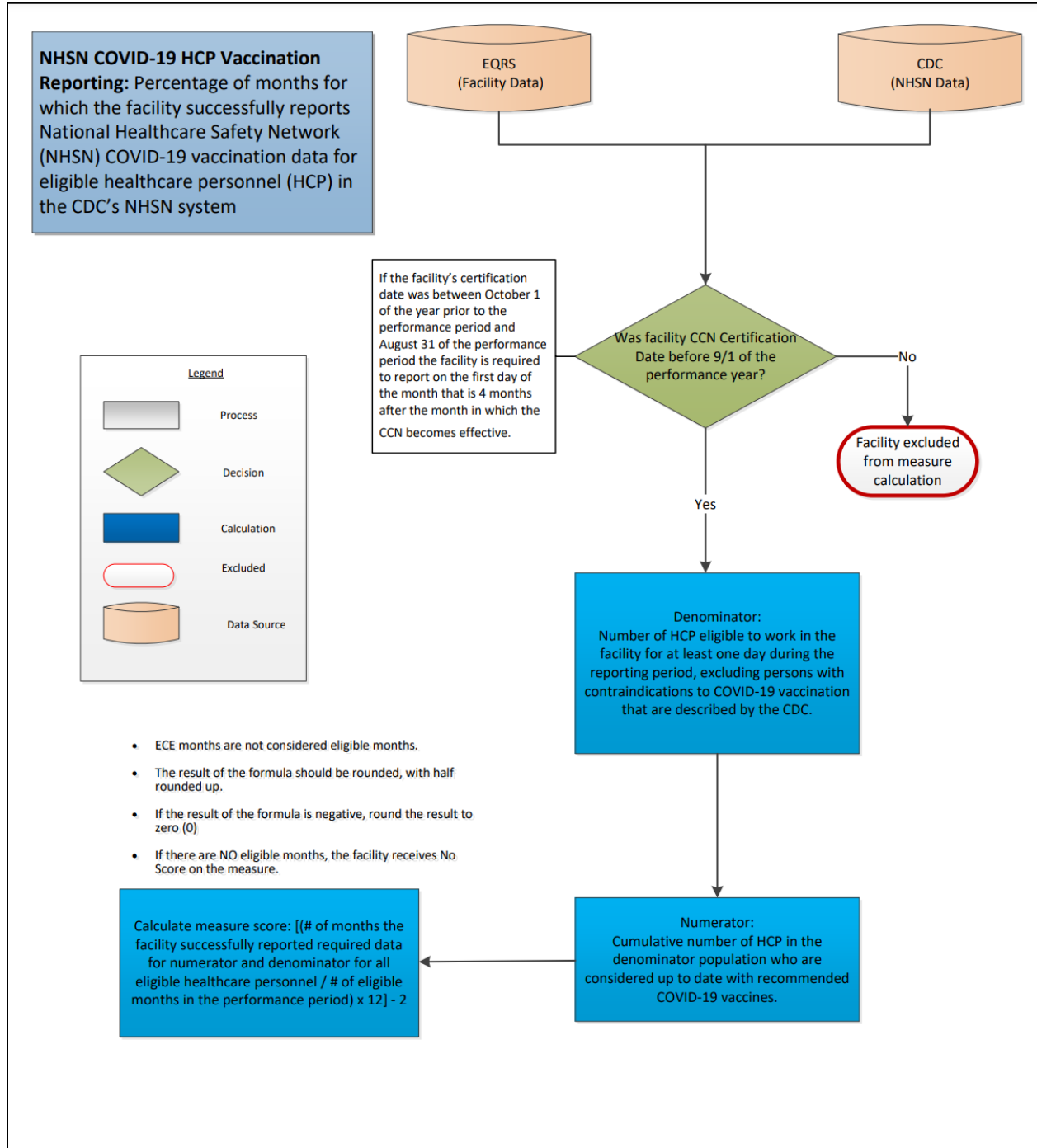
Figure 23: COVID-19 Healthcare Personnel Vaccination Reporting Measure Flowchart (ESRD QIP Only)

2.20.12 Data Elements and Data Sources

1. CDC's NHSN system
2. EQRS

2.21 NHSN COVID-19 Vaccination Coverage among Healthcare Personnel Reporting (Dialysis Facility Measures Only)

2.21.1 Measure Name

COVID-19 Vaccination Coverage among Healthcare Personnel (HCP)

2.21.2 Measure Description

Percentage of healthcare personnel vaccination adherence for which the facility successfully reports NHSN COVID-19 vaccination data for eligible healthcare personnel in the CDC's NHSN system.

2.21.3 Measure Rationale

CDC currently collects data that are voluntarily reported on COVID-19 (Severe Acute Respiratory Syndrome Coronavirus-2) vaccination coverage among healthcare personnel through the NHSN. The NHSN Healthcare Personnel (HCP) COVID-19 Vaccination Cumulative Summary Module was developed to help guide the public health emergency response to the COVID-19 pandemic.

2.21.4 Measure Type

Process

2.21.5 Numerator Statement

Cumulative number of HCP in the denominator population who are considered up to date with recommended COVID-19 vaccines.

2.21.6 Denominator Statement

Number of HCP eligible to work in the facility for at least one day during the reporting period, excluding persons with contraindications to COVID-19 vaccination that are described by the CDC.

2.21.7 Patient Exclusions

The denominator for this measure excludes HCP with documented contraindications to COVID-19 vaccine. As of April 2023, CDC considers contraindications to vaccination with COVID-19 vaccines to be:

1. History of severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine.
2. History of known (diagnosed) allergy to a component of the vaccine.

2.21.8   Additional Information

1. Facilities should submit COVID-19 vaccination data via the Weekly COVID-19 Vaccination Module for at least one week per month to fulfill CMS reporting requirements. For facilities that report more than one week per month, the last week of the reporting month will be shared with CMS. NHSN guidance and definitions for reporting weekly HCP COVID-19 vaccination data can be found in the NHSN HCP COVID-19 Vaccination Protocol: https://www.cdc.gov/nhsn/hps/weekly-covid-vac/#protocol.

2. Facilities are required to report COVID-19 vaccination data for four required categories of HCP including:
   a. Employees (required): This includes all persons receiving a direct paycheck from the reporting facility (i.e., on the facility's payroll), regardless of clinical responsibility or patient contact.
   b. Licensed independent practitioners (LIPs) (required): This includes physicians (MD, DO), advanced practice nurses, and physician assistants who are affiliated with the reporting facility, but are not directly employed by it (i.e., they do not receive a paycheck from the facility), regardless of clinical responsibility or patient contact. Post-residency fellows are also included in this category if they are not on the facility's payroll.
   c. Adult students/trainees and volunteers (required): This includes medical, nursing, or other health professional students, interns, medical residents, or volunteers aged 18 or older who are affiliated with the healthcare facility, but are not directly employed by it (i.e., they do not receive a paycheck from the facility), regardless of clinical responsibility or patient contact.
   d. Other contract personnel (required): This includes all persons providing care, treatment, or services at the facility through a contract who do not fall into any of the other denominator categories. This also includes vendors providing care, treatment, or services at the facility who may or may not be paid through a contract.

3. Facilities are not required to report for HCP who:
   a. Were determined to have a medical contraindication or condition specified by Food and Drug Administration (FDA) labeling or authorization, CDC or Advisory Committee on Immunization Practices (ACIP) recommendations.
   b. Can provide verbal statements for medical contraindications to (and declination of) the vaccine. Written documentation is not required.

4. The definition of "up to date vaccination status" may change over time. Facilities should refer to the definition of "up to date" as of the first day of the applicable

reporting quarter. As of Quarter 4 2023, "up to date" with COVID-19 vaccines is defined as follows:

    a. Received an updated (bivalent) booster dose, or

    b. Completed their primary series less than two months ago.

2.21.9   Data Elements and Data Sources

1. CDC's NHSN system
2. EQRS

2.22 Facility Commitment to Health Equity Reporting Measure (ESRD QIP Only)

2.22.1   Measure Name

Facility Commitment to Health Equity Reporting Measure

2.22.2   Measure Description

This structural measure assesses facility commitment to health equity using a suite of equity-focused organizational competencies aimed at achieving health equity for racial and ethnic minority groups, people with disabilities, members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community, individuals with limited English proficiency, rural populations, religious minorities, and people living near or below poverty level.

2.22.3   Measure Rationale

This measure supports the CMS Meaningful Measures 2.0 initiative's goal of leveraging quality measures to promote health equity and close gaps in care, and the CMS National Quality Strategy Goal of advancing health equity. There are no other health equity measures for this population. The Measure Applications Partnership (MAP) reviewed a version of this measure as part of the 2021-2022 pre-rulemaking cycle. The measure, Hospital Commitment to Health Equity (MUC2021-106), was submitted for the Hospital Inpatient Quality Reporting (IQR) Program. It received a recommendation of Conditional Support for Rulemaking, with the following conditions: (1) endorsement by a consensus-based entity (CBE); (2) committing to look at outcomes in the future; (3) providing more clarity on the measure and supplementing interpretations with results, and (4) verifying attestation provided by the accountable entities. The measure was finalized for use in the Hospital IQR Program in the fiscal year (FY) 2023 Inpatient Prospective Payment System (IPPS) and LTCH PPS rule.

Reducing healthcare disparities would represent a substantial benefit to the overall quality of care. However, the literature currently does not closely link this measure to clinical outcomes; likewise, a performance gap at the individual dialysis-facility level on these specific structural elements has not been established in the literature. The MAP conditionally supported MUC2021-106 for rulemaking, and the recommendation for that measure seems relevant for this measure. This measure assesses whether the facility has developed a plan to address health equity

issues, has collected and analyzed the data needed to act on that plan, and has evaluated their progress towards attaining their objectives.

2.22.4 Measure Type

Process

2.22.5 Numerator Statement

Number of domains of commitment to advancing health equity of which the facility completes attestations. Attestation of all elements within a domain is required in order to qualify for the measure numerator.

2.22.6 Denominator Statement

The denominator for each facility is ten, which represents two points for each of the following domains of commitment to advancing health equity:

1. Equity is a strategic priority
2. Data Collection
3. Data Analysis
4. Quality Improvement
5. Leadership Engagement

2.22.7 Patient Exclusions

1. Patients treated at the facility for fewer than 90 days in the performance period.
2. Patients not on ESRD treatment as defined by a completed 2728 form, an EQRS record, or a sufficient amount of dialysis reported on dialysis facility claims.

2.22.8 Facility Exclusions

- Facilities with a CCN certification date on or after September 1 of the performance year.
- Facilities treating fewer than 11 eligible patients during the performance period.
- Calculations will exclude the months covered by a granted ECE.

2.22.9   Additional Information

- Facilities will receive two points each for attesting to five different domains of commitment to advancing health equity for a total of ten points.
- There is no partial credit for any domain attestation. Attestation of all elements in each domain is required in order to qualify as a completed domain attestation for the measure numerator.

2.22.10 Calculating a Facility's Score

The measure will be scored out of 10, with two points given for each of the following domains of commitment to advancing health equity:

1. Equity is a strategic priority

2. Data Collection
3. Data Analysis
4. Quality Improvement
5. Leadership Engagement

2.22.11 Flowchart

Figure 24 presents the flowchart that represents the processes used to calculate the: Facility Commitment to Health Equity Reporting Measure.
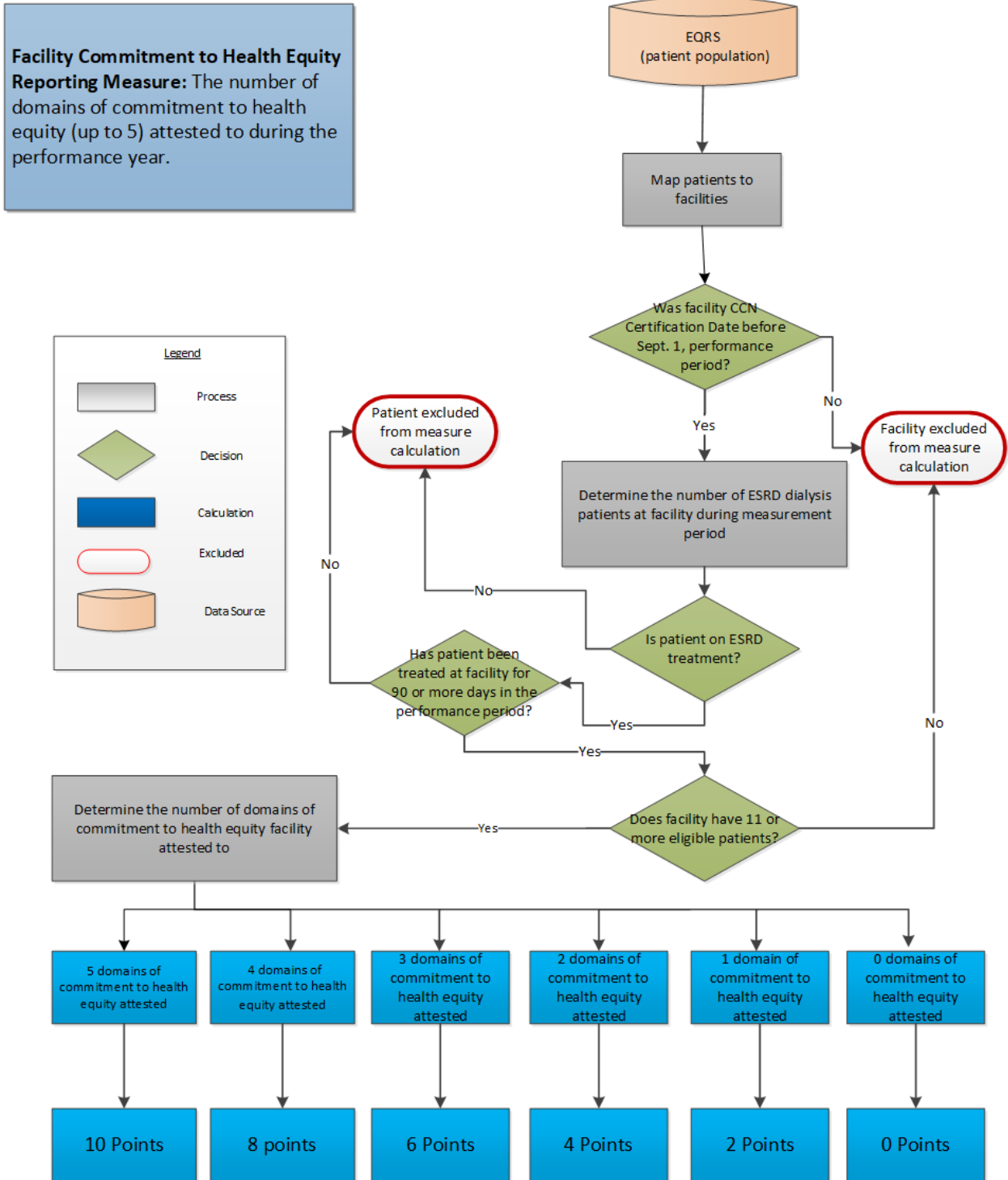
Figure 24: Facility Commitment to Health Equity Reporting Measure Flowchart (ESRD QIP Only)

2.22.12 Data Elements and Data Sources

EQRS, EDB, and other CMS administrative data will be used.

EQRS Data Elements include:

- Initial certification date

- Facility CCN

- Facility attestation to health equity domains

- Admit date

- Discharge date

- Primary type of treatment ID (EQRS dialysis type)

2.23 Screening for Social Drivers of Health Reporting Measure (ESRD QIP Only)

2.23.1 Measure Name

Screening for Social Drivers of Health Reporting Measure.

2.23.2 Measure Description

The Screening for Social Drivers of Health Reporting measure assesses the percentage of patients, aged 18 years and older, screened for health-related social needs (HRSNs) (specifically, food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) during established care in dialysis facilities.

2.23.3 Measure Rationale

This measure captures those who are screened for five social determinants of health domains (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) during their facility stay or during established care. There are no other measures in the ESRD QIP measure set that implement screening for social determinants of health.

The measure cites a study which found that only 24 percent of hospitals and 16 percent of physician practices reported screening for food insecurity, housing instability, utility needs, transportation needs, and interpersonal violence (Fraze et al, 2019), indicating a gap in care provided. Health outcomes are around 80 percent driven by socioeconomic factors, health behaviors, and the physical environment (Hood et al, 2016). Several studies provided by the measure developer identify a relationship between health outcomes and socioeconomic factors including, but not limited to, housing (Stafford and Wood, 2017), food (Altarum Healthcare Value Hub, 2020), and other needs screened for by the tool cited in this measure (Davidson et al, 2020). The developer noted that screening for these socioeconomic factors is consistent with guidelines implemented by the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and guidance by the U.S. Preventive Services Task Force (USPSTF).

2.23.4 Measure Type

Process

2.23.5 Numerator Statement

Number of eligible patients who were screened for all five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, or interpersonal safety.

2.23.6 Denominator Statement

Number of eligible adult patients that have received care at the dialysis facility for at least 90 days.

2.23.7   Patient Exclusions

- Patients who are younger than 18 years.
- Patients who are treated by dialysis facility for fewer than 90 days in the performance period.
- Patients not on ESRD treatment as defined by a completed 2728 form, an EQRS record, or a sufficient amount of dialysis reported on dialysis facility claims.
- Patients who opt out of screening.
- Patients who are unable to complete the screening during their admission and have no legal guardian or caregiver able to do so on the patient's behalf.

2.23.8   Facility Exclusions

- Facilities with a CCN certification date on or after September 1 of the performance year.
- Facilities treating fewer than 11 eligible patients during the performance period.
- Calculations will exclude the months covered by a granted ECE.

2.23.9   Additional Information

- Patient age is determined as of January 1 of the performance year.

2.23.10   Calculating a Facility's Score

The measure will be scored using the following equation:

$$\left[\frac{\text{Number of Eligible Patients for Whom a Facility Screened for all Five HRSNs During the Performance Period}}{\text{Total Number of Eligible Patients During the Performance Period}}\right] \times 10$$

2.23.11   Flowchart

Figure 25 presents the flowchart that represents the processes used to calculate the Screening for Social Drivers of Health Reporting Measure.

Screening for Social Drivers of Health: The percent of patients that were screened for five health related social needs.

If the facility's certification date was between October 1 of the year prior to the performance period and August 31 of the performance period the facility is required to report on the first day of the month that is 4 months after the month in which the CCN becomes effective.

Legend

Process	
Decision	
Calculation	
Excluded	
Data Source	

EQRS (patient population)

System determines if facility is eligible for measure

Was facility CCN Certification Date before Sept. 1, performance period?

Yes — No

System determines the number of eligible patients at facility during measurement period

Is patient 18 years or older?

No — Yes

Facility excluded from measure calculation

Is patient on ESRD treatment?

No — Yes

Patient is not eligible and is excluded from measure calculation

Has patient been treated at dialysis facility for 90 days or more?

No — Yes

Yes — Did patient opt out of screening? — Yes — Was patient able to complete screening? — Yes

No

No

Does facility have 11 or more eligible patients?

No — Yes

Calculate number of eligible patients the facility reports screening results for all five HRSNs during performance period (numerator)

Calculate reporting rate using equation: (numerator/denominator) x 10

Calculate numerator and denominator

Calculate number of eligible patients during performance period (denominator)

Round to nearest whole number to get Measure Score

Figure 25: Screening for Social Drivers of Health Reporting Measure Flowchart (ESRD QIP Only)

2.23.12 Data Elements and Data Sources

EQRS, EDB, and other CMS administrative data will be used.

EQRS Data Elements include:

- Initial certification date

- Facility CCN

- Patient screening for HRSNs: food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety

- Admit date

- Discharge date

- Primary type of treatment ID (EQRS dialysis type)

- Patient date of birth

2.23.13 Selected References

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2.24 Screen Positive Rate for Social Drivers of Health Reporting Measure (ESRD QIP Only)

2.24.1 Measure Name

Screen Positive Rate for Social Drivers of Health Reporting Measure.

2.24.2   Measure Description

The Screen Positive Rate for Social Drivers of Health is a structural measure that provides information on the percent of patients that were screened for all five HRSNs, and who screen positive for one or more of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, or interpersonal safety. For ESRD QIP, facilities will receive credit for reporting 'Yes' or 'No' (non-missing) responses.

2.24.3   Measure Rationale

The measure would be the first measure in the (ESRD QIP) measure set to implement screening for social determinants of health, which would support both a Meaningful Measures 2.0 priority to develop and implement measures that reflect social and economic determinants and a program priority to promote measures that expand the collection of social risk factor data for future measure development.

Research has found an association between social determinants of health and chronic conditions (Dean et al., 2020; Hill-Briggs et al., 2021), as well as an association between providers with patient populations facing social risks and their poor performance on healthcare metrics (Baker et al., 2021; Khullar et al., 2020). However, there is not a clear connection between screening for social determinants and improving patient outcomes and there needs to be additional research on the topic (Davidson et al., 2017). The MAP noted that this measure to document positive screen rates for social drivers of health is an important first step to addressing important social drivers of health outcomes and may be used to stratify other data, leading to the reallocation of financial resources in the future. However, the MAP also expressed concern that the positivity rate may be challenging for consumers to interpret when publicly reported.

2.24.4   Measure Type

Process

2.24.5   Numerator Statement

Number of eligible patients with 'Yes' or 'No' (non-missing) screening responses for each of the HRSNs.

2.24.6   Denominator Statement

Number of eligible adult patients who have received care at the dialysis facility and have screenings for each of the five HRSNs reported during the performance period.

2.24.7   Patient Exclusions

- Patients who are younger than 18 years.
- Patients who are treated by dialysis facility for fewer than 90 days in the performance period.

- Patients not on ESRD treatment as defined by a completed 2728 form, an EQRS record, or a sufficient amount of dialysis reported on dialysis facility claims.
- Patients who opt out of screening.
- Patients who are unable to complete the screening during their admission and have no legal guardian or caregiver able to do so on the patient's behalf.

2.24.8 Facility Exclusions

- Facilities with a CCN certification date on or after September 1 of the performance year.
- Facilities treating fewer than 11 eligible patients during the performance period.
- Calculations will exclude the months covered by a granted ECE.

2.24.9 Additional Information

- Patient age is determined as of January 1 of the performance year.
- Facilities must report the screening outcome for each of the five HRSNs in order to receive credit in the numerator. Credit will be received for 'Yes' or 'No' responses.

2.24.10 Calculating a Facility's Score

Facilities will be scored using the following equation:

$$\left[\frac{\begin{array}{c} \text{Number of Eligible Patients for Whom a Facility Reports} \\ \text{"Yes" or "No" (Non−missing) Screening Results for each of the Five} \\ \text{HRSNs During the Performance Period} \end{array}}{\begin{array}{c} \text{Total Number of Eligible Patients for Whom a Facility Reportswho were} \\ \text{Screened for each of the Five HRSNs During the Performance Period} \end{array}} \right] \text{x } 10$$

2.24.11 Flowchart

Figure 26 presents the flowchart that represents the processes used to calculate the Screen Positive Rate for Social Drivers of Health Reporting Measure.

Screen Positive for Social Drivers of Health: The percent of patients that were screened for five health related social needs who had non-missing screening values reported.

If the facility's certification date was between October 1 of the year prior to the performance period and August 31 of the performance period the facility is required to report on the first day of the month that is 4 months after the month in which the CCN becomes effective.

EQRS (patient population)

System determines if facility is eligible for measure

Was facility CCN Certification Date before Sept. 1, performance period?

Legend

	Process
	Decision
	Calculation
	Excluded
	Data Source

System determines the number of eligible patients at facility during measurement period

Is patient 18 years or older?

Facility excluded from measure calculation

Is patient on ESRD treatment?

Patient is not eligible and is excluded from measure calculation

Has patient been treated at dialysis facility for 90 days or more?

Did patient opt out of screening?

Was patient able to complete screening?

Does facility have 11 or more eligible patients?

Calculate number of eligible patients the facility reports non-missing screening results for all five HRSNs during performance period (numerator)

Calculate reporting rate using equation: (numerator/denominator) x 10

Calculate numerator and denominator

Round to nearest whole number to get Measure Score

Calculate number of eligible patients the facility reports screening for all five HRSNs during performance period (denominator)

Figure 26: Screen Positive Rate for Social Drivers of Health Reporting Measure Flowchart (ESRD QIP Only)

2.24.12 Data Elements and Data Sources

EQRS, EDB, and other CMS administrative data will be used.

EQRS Data Elements include:

- Initial certification date

- Facility CCN

- Patient screening for HRSNs: food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety

- Admit date

- Discharge date

- Primary type of treatment ID (EQRS dialysis type)

- Patient date of birth

2.24.13 Selected References

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2.25 Standardized Emergency Department Encounter Ratio (SEDR) for Dialysis Facilities (Dialysis Facility Measures Only)

2.25.1 Measure Name

Standardized Emergency Department Encounter Ratio (SEDR) for Dialysis Facilities.

2.25.2   Measure Description

The Standardized Emergency Department Encounter Ratio is defined to be the ratio of the observed number of emergency department (ED) encounters that occur for adult Medicare ESRD dialysis patients treated at a particular facility to the number of encounters that would be expected given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. Note that in this document an "emergency department encounter" always refers to an outpatient encounter that does not end in a hospital admission. This measure is calculated as a ratio but can also be expressed as a rate.

2.25.3   Measure Rationale

ED encounters are an important indicator of care coordination and quality of life. In the general population studies have shown higher risk of an ED encounter subsequent to a discharge from an inpatient hospitalization or an outpatient emergency department encounter (e.g., see Hastings et al., 2008).

Rates of ED visits among ESRD dialysis patients have increased between 2007 and 2016. As reported by the United States Renal Data System (USRDS), the unadjusted ED visit rate among HD patients increased from 2.6 to 3.0 per patient-year, and from 2.2 to 2.4 per patient-year for PD patients (USRDS ADR 2018), while the national percentage of ED visits among dialysis patients is 62% as of 2018 (FY 2020 Dialysis Facility Report). More than half (55.0%) of all patients with ESRD visit the ED during their first year of dialysis, and patients with ESRD have a mean of 2.7 ED visits per patient-year (Lovasik et al., 2016). This rate is six-fold higher than the national mean rates for US adults in the general population (Lovasik et al 2016). Furthermore, the Lovasik study notes that among Medicare beneficiaries with ESRD, 30% of hospital admissions that originate in the ED are for diagnoses that are often dialysis related such as complications of vascular access, congestive heart failure/fluid overload, septicemia, and hyperkalemia. A study by Zhang and colleagues (Zhang et al, 2019) reported that rates of ED visits among patients on thrice weekly ICHD vary by dialysis schedule (Mon/Weds/Fri; Tues/Thurs/Sat) and by day of week. For example, the ED visit rate (without hospital admission) was highest on the day following the longer interdialytic interval over the weekend (Mondays), suggesting an association with facility structure and treatment schedule.

Cohen and colleagues (Cohen et al 2020) reported that missed dialysis treatments are associated with an over two-fold higher risk of an ED visit, suggesting an opportunity for dialysis facilities to establish or strengthen facility practices that can help to reduce skipped treatments through increased communication, care coordination, and patient education. This in turn, has the potential to reduce avoidable ED visits.

Finally, the CMS Centers for Medicare and Medicaid Innovation's Comprehensive ESRD Care model emphasizes care coordination as a central feature of care delivery in order to reduce utilization and improve outcomes. During the second performance year, the original Wave 1 cohort of ESRD Seamless Care Organizations (ESCOs) experienced about a 3% reduction in ED

use relative to the period before the Comprehensive ESRD Care (CEC) model was launched (Marrufo et al., CEC Annual Report Performance Year 2, 2019).

Measures of the frequency of ED use may help dialysis facility level efforts to prevent emergent unscheduled care and control escalating medical costs.

2.25.4 Measure Type

Outcome

2.25.5 Improvement Noted as Higher or Lower Rate

A lower ratio indicates better quality.

2.25.6 Numerator Statement

The observed number of outpatient ED encounters during the reporting period among eligible adult Medicare patients at a facility.

2.25.7 Facility Exclusions

The SEDR is only calculated for facilities with greater than five patient-years at risk in the reporting year.

2.25.8 Denominator Statement

The expected number of ED encounters among eligible Medicare patients at the facility during the reporting period adjusted for the characteristics of the patients at the facility.

2.25.9 Denominator Exclusions

Exclusions that are implicit in the denominator definition include time at risk while a patient:

- Has MA coverage
- Has had ESRD for 90 days or less
- Treated at the facility for fewer than 60 days
- Is less than 18 years of age

2.25.10 Calculating Numerators

ED encounters are identified from Medicare outpatient claims using revenue center codes that indicate an ED visit (0450, 0451, 0452, 0453, 0454, 0455, 0456, 0457, 0458, 0459, 0981). Note that this means that we include both outpatient ED visits and those that result in an observation stay, but not those that result in a hospital admission. Outpatient ED claims that have overlapping or consecutive dates of service are combined and considered as a single ED encounter. To further ensure that these outpatient ED encounters are distinct from those associated with hospitalizations, we exclude ED encounters where there is an inpatient claim for

the patient that has dates of service including any of the same time period covered by the ED encounter.

The total number of ED encounters includes multiple encounters (i.e., second, third, etc.) for the same patient during the reporting period. The time period for the measure calculation is one calendar year.

2.25.11 Mapping Patients to Facilities

An eligible Medicare patient is defined as an adult (aged 18 or more) dialysis patient with at least 91 days of ESRD treatment. Because we only include a patient's follow-up in the tabulations for this measure after that patient has received chronic renal replacement therapy for at least 91 days, ED encounters during the first 90 days of ESRD are not counted. We assign patients to a particular facility only after they have been on chronic 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. ED encounters during the first 60 days of dialysis at a facility do not affect the facility's Standardized Emergency Department Encounter Ratio.

We require that patients reach a certain level of Medicare dialysis bills to be included in the ED encounter ratio. Specifically, months within a given dialysis patient-period are used for the Standardized ED Encounter Ratio calculation when they meet the criterion of being within two months after a month with either: (a) $1,200+ of Medicare dialysis claims OR (b) at least one Medicare inpatient claim. The intention of this criterion is to assure completeness of information on ED encounters for all patients included in the analysis. Months in which a patient is enrolled in MA are excluded from the analysis. This is because outpatient claims for MA patients are not available; therefore, we do not have information on the outcome of this measure, ED encounters.

2.25.12 Identifying Facility Treatment Histories for Each Patient

For each patient, we identify the dialysis provider at each point in time. Starting with day 91 after onset of ESRD, we attribute patients to facilities according to the following rules. A patient is attributed to a facility once the patient has been treated there for the past 60 days. When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 60 days and then is attributed to the destination facility. In particular, a patient is attributed to their current facility on day 91 of ESRD if that facility had treated them for the past 60 days. If on day 91, the facility had not treated a patient for the past 60 days, we wait until the patient reaches day 60 of continuous treatment at that facility before attributing the patient to that facility. When a patient is 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 do not attribute that patient to any facility. Patients who withdrew from dialysis or recovered renal function remain assigned to their treatment facility for 60 days after withdrawal or recovery.

If a period of one year passes with neither Medicare dialysis claims nor EQRS information to indicate that a patient was receiving dialysis treatment, we consider the patient lost to follow-up

and do not include that patient in the analysis. If dialysis claims or other evidence of dialysis reappears, the patient is entered into analysis after 60 days of continuous therapy at a single facility.

2.25.13 Days at Risk for Medicare Dialysis Patients

After patient treatment histories are defined as described above, periods of follow-up in time since ESRD onset are created for each patient. In order to adjust for duration of ESRD appropriately, we define six time intervals with cut points at six months, one year, two years, three years, and five years. A new time period begins each time the patient is determined to be at a different facility, or at the start of each calendar year or when crossing any of the above cut points.

The number of days at risk in each of the time intervals listed above is used to calculate the expected number of ED encounters for the patient during that period. The Standardized ED Encounter Ratio for a facility is the ratio of the total number of observed ED encounters to the total number of expected ED encounters during all time periods at the facility. Based on a risk adjustment model for the overall national ED encounter rate, we compute the expected number of ED encounters that would occur for each month that each patient is attributed to a given facility. The sum of all such expectations for patients and months yields the overall number of ED encounters that would be expected at the facility given the specific patient mix. This forms the denominator of the measure.

The denominator of the Standardized ED Encounter Ratio is derived from a proportional rates model (Lawless and Nadeau, 1995; Lin et al., 2000; Kalbfleisch and Prentice, 2002). This is the recurrent event analog of the well-known proportional hazards or Cox model (Cox, 1972; Kalbfleisch and Prentice, 2002). To accommodate large-scale data, we adopt a model with piecewise constant baseline rates (e.g. Cook and Lawless, 2007) and the computational methodology developed in Liu, Schaubel and Kalbfleisch (2012).

2.25.14 Risk Adjustment

- Patient age: Determine each patient's age as of the period start date for the birth date provided by multiple data sources.* Age is included both as a linear (continuous) and a quadratic term.
- Sex: Determine each patient's sex from multiple sources.*
- Diabetes as cause of ESRD: Determine each patient's primary cause of ESRD from Medical Evidence Form (CMS-2728), and EQRS.
- Duration of ESRD: Determine each patient's length of time on dialysis using the first service date from multiple data sources* and categorize as 91 days- < 6 months, 6 months- < 1 year, 1- < 2 years, 2- < 3 years, 3- < 5 years, or 5+ years as of the period start date.
- Nursing home status: Uses multiple sources* including the 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) as of the period start date.
- BMI at incidence: Calculate each patient's BMI based on the height and weight provided on his/her CMS 2728 and group patients into the following categories: BMI < 18.5, 18.5 ≤ BMI < 25, 25 ≤ BMI < 30, or BMI ≥ 30. BMI is imputed when either missing, or outside the range of 10 to 70 for adults. Missing and out-of-range BMIs are categorized into the mode group (i.e. >=30).
- Comorbidities at incidence are determined using a selection of comorbidities reported on Medical Evidence Form (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). No Medical Evidence Form (CMS-2728), and at least one of the comorbidities listed are also included.
- Each comorbidity is included as a separate covariate in the model.
- A set of prevalent comorbidities based on Medicare inpatient claims (individual comorbidities categorized into 66 groups). Prevalent comorbidities are determined using the previous calendar year of CMS claims. We grouped individual comorbidities into clinically related categories. Each comorbidity group is included as a separate covariate in the model. If a patient has less than six Medicare covered months in the prior calendar year, we consider prevalent comorbidities to be "missing" for that patient even if there are comorbidities identified in claims. It also includes an adjustment for less than six months of Medicare covered months in prior calendar year.
- Calendar year

* This may include information from: EQRS, Medicare Claims, and the Medical Evidence Form (CMS-2728).

Categorical indicator variables are included as covariates in the stage 1 model to account for records with missing values for cause of ESRD, and comorbidities at incidence (missing CMS-2728). These variables have a value of 1 if the patient is missing the corresponding variable and a value of 0 otherwise. If a patient has less than six months of Medicare covered months in prior calendar year, prevalent comorbidities are set to a value of 0 and an indicator for missing prevalent comorbidities is included. This variable has a value of 1 if the patient is missing the corresponding comorbidities and a value of 0 otherwise. Another categorical indicator variable is included as a covariate in the stage 1 model to flag records where the patient has at least one of the incident comorbidities listed earlier. This variable has a value of 1 if the patient has at least one of the comorbidities and a value of 0 otherwise.

Beside main effects, two-way interaction terms between the following pairs of variables are included:

- Diabetes as cause of ESRD and Sex.
- Diabetes as cause of ESRD and Age.
- Age and Sex.

2.25.15 Calculation of SEDR

The modeling process has two stages. At stage I, a stratified model is fitted to the national data with piecewise-constant baseline rates and stratification by facility. Specifically, the model is of the following form:

$$Pr(\text{ED encounter on day } t \text{ given covariates } X) = r_{0k}(t)\exp(\beta'X_{ik})$$

where X_{ik} is the vector of covariates for the ith patient in the kth facility and β is the vector of regression coefficients. Time t is measured from the start of ESRD. The baseline rate function $r_{0k}(t)$ is specific to the kth facility, and is assumed to be a step function with break points at six months, one year, two years, three years, and five years since the onset of dialysis. This model allows the baseline ED rates to vary between strata (facilities) but assumes that the regression coefficients are the same across all strata; this approach is robust to possible differences between facilities in the patient mix being treated. The stratification on facilities is important in this phase to avoid bias due to possible confounding between covariates and facility effects.

At stage II, the relative risk estimates from the first stage are used to create offsets and an unstratified model is fitted to obtain estimates of an overall baseline rate function. That is, we estimate a common baseline rate of encounters, $r_0(t)$, across all facilities by considering the model:

$$Pr(\text{ED encounter on day } t \text{ given covariates } X) = r_0(t)\, R_{ik,}$$

where $R_{ik} = \exp(\beta'X_{ik})$ is the estimated relative risk for patient i in facility k obtained from the stage I. We assume the baseline to be a step function with six unknown parameters: $\alpha_1, ..., \alpha_6$, to estimate. These estimates are used to compute the expected number of encounters given a patient's characteristics.

Specifically, let t_{iks} represent the number of days that patient i from facility k is under observation in the sth time interval with estimated rate α_s. The corresponding expected number of ED encounters in the sth interval for this patient is calculated as:

$$E_{iks} = \alpha_s\, t_{iks}\, R_{ik} .$$

It should be noted that t_{iks} and hence E_{iks} can be 0 if patient i from facility k is never at risk during the sth time interval. Summing the E_{iks} over all six intervals and all N_k patients in facility k gives:

$$Exp = \sum_{i=1}^{N_k}\sum_{s=1}^{6} E_{iks} = \sum_{i=1}^{N_k}\sum_{s=1}^{6} \alpha_s t_{iks} R_{ik} ,$$

which is the expected number of ED encounters during follow-up at that facility.

Let Obs be the observed total number of ED encounters at this facility. The SEDR for ED encounters is the ratio of the observed total encounters to this expected value, or

$$SEDR = Obs/Exp$$

2.25.16 Calculation of SEDR P-Values and Confidence Intervals for Dialysis Facility Measures

To adjust for over-dispersion of the data, we compute the p-value for our estimates using the empirical null distribution, a robust approach that takes account of the natural random variation among facilities that is not accounted for in the model (Efron, 2004; Kalbfleisch and Wolfe, 2013). Our algorithm consists of the following concrete steps. First, we fit an over-dispersed Poisson model (e.g., SAS PROC GENMOD with link=log, dist=poisson and scale=dscale) for the number of hospital admissions as follows:

$$\log(E[\mathbf{n_{ik}}]) = \log(\mathbf{E_{ik}}) + \boldsymbol{\theta_k},$$

where $\mathbf{n_{ik}}$ is the observed number of events for patient i in facility k, $\mathbf{E_{ik}}$ is the expected number of events for patient i in facility k and $\boldsymbol{\theta_k}$ is the facility-specific intercept. Here, i ranges over the number of patients $\mathbf{N_k}$ who are treated in the *kth* facility. The natural log of the SEDR for the *kth* facility is then given by the corresponding estimate of $\boldsymbol{\theta_k}$. The standard error of $\boldsymbol{\theta_k}$ is obtained from the robust estimate of variance arising from the over dispersed Poisson model.

Second, we obtain a z-score for each facility by dividing the natural log of its SEDR by the standard error from the general linear model described above. These z-scores are then grouped into quartiles based on the number of patient-years at risk for Medicare patients in each facility. Finally, using robust estimates of location and scale based on the normal curve fitted to the center of the z-scores for the SEDR, we derive the mean and variance of a normal empirical null distribution for each quartile. This empirical null distribution is then used to calculate the p-value for a facility's SEDR.

The uncertainty or confidence intervals are obtained by applying the following steps:

- From the general linear model, we obtain the natural log of the SEDR (ln SEDR) as well as its standard error, (SE). From the empirical null, we obtain a mean (μ) and a standard deviation (σ). The 95% uncertainty interval for the 'true' log SEDR for this facility is:
  $$\ln \text{SEDR} - \mu * \text{SE} \pm 1.96 * \sigma * \text{SE}.$$
- Exponentiating the endpoints of this interval gives the uncertainty interval for the true SEDR.

2.25.17 Flagging Rules for Dialysis Facility Measures

As currently implemented for Dialysis Facility Measures, for reporting purposes we identify outlier facilities from amongst those with at least five patient-years at risk during the time period. If the 95% interval lies entirely above the value of 1.00 (i.e., both endpoints exceed 1.00), the facility is said to have outcomes that are "worse than expected". On the other hand, if the 95% interval lies entirely below the value 1.00, the facility is said to be better than expected. If the interval contains the value 1.00, the facility is said to have outcomes that are "as expected."

2.25.18 Data Elements and Data Sources

Enrollment Database (EDB), and Medicare claims data. In addition, the database includes transplant data from the SRTR and data from the Nursing Home MDS, the QIES Business Intelligence Center (QBIC) (which includes Provider and Survey and Certification data from Automated Survey Processing Environment (ASPEN)), and the Dialysis Facility Care Compare (DFCC).

The database is comprehensive for Medicare patients not enrolled in MA. MA patients are included in all sources, but their Medicare payment records are limited to inpatient claims. Non-Medicare patients are included in all sources except for the Medicare payment records. Tracking by dialysis provider and treatment modality is available for all patients including those with only partial or no Medicare coverage.

Information on hospitalizations is obtained from Part A Medicare Inpatient Claims SAFs, and past-year comorbidity data are obtained from multiple Part A types (inpatient, home health, hospice, SNF claims) and Part B (outpatient) claims.

Data are derived from an extensive national ESRD patient database based on data from the CMS and EQRS system, Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (CMS-2728), and the Death Notification Form (CMS-2746). Information on hospitalizations is obtained from Medicare Inpatient Claims SAFs and past-year comorbidities are obtained from multiple types (inpatient, outpatient institutional, physician/supplier, home health, hospice, SNF claims) of Medicare Claims SAFs.

The database is comprehensive for Medicare patients not enrolled in MA. MA patients are included in all sources, but their Medicare payment records are limited to inpatient claims. Non-Medicare patients are included in all sources except for the Medicare payment records. Tracking by dialysis provider and treatment modality is available for all patients including those with only partial or no Medicare coverage.

2.25.19 Flowchart

Figure 27 presents the flowchart that represents the processes used to calculate the Standardized Emergency Department Encounter Ratio (SEDR) for Dialysis Facilities Measure.

Standardized Emergency Department Encounter Ratio (SEDR): The ratio of observed to expected emergency department visits (that do not result in an admission)

Numerator Statement: Number of emergency department visits (that do not result in an admission) observed

Denominator Statement: Number of emergency department visits (that do not result in an admission) expected based on the national rate for patients with similar characteristics

*Multiple data sources include EQRS, the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746), the Dialysis Facility Compare (DFC) and the Social Security Death Master File.

Standardized Emergency Department Encounter Ratio (SEDR): The ratio of observed to expected emergency department visits (that do not result in an admission)
Numerator Statement: Number of emergency department visits (that do not result in an admission) observed
Denominator Statement: Number of emergency department visits (that do not result in an admission) expected based on the national rate for patients with similar characteristics

*Multiple data sources include CMS Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746), the Dialysis Facility Compare (DFC) and the Social Security Death Master File.

Figure 27: Standardized Emergency Department Encounter Ratio (SEDR) for Dialysis Facilities Reporting Measure Flowchart (Dialysis Facility Measures only)

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2.26 Standardized Ratio of Emergency Department Encounters Occurring Within 30 Days of Hospital Discharge (ED30) for Dialysis Facilities (Dialysis Facility Measures Only)

2.26.1 Measure Name

Standardized Ratio of ED Encounters Occurring Within 30 Days of Hospital Discharge (ED30) for Dialysis Facilities

2.26.2 Measure Description

The Standardized Ratio of Emergency Department Encounters Occurring Within 30 Days of Hospital Discharge for Dialysis Facilities (ED30) is defined to be the ratio of observed over expected events. The numerator is the observed number of index discharges from acute care hospitals that are followed by an outpatient ED encounter within 4-30 days after discharge for eligible adult Medicare dialysis patients treated at a particular dialysis facility. The denominator is the expected number of index discharges followed by an ED encounter within 4-30 days given the discharging hospital's characteristics, characteristics of the dialysis facility's patients, and the national norm for dialysis facilities. Note that in this document, acute care hospital includes critical access hospitals and "emergency department encounter" always refers to an outpatient encounter that does not end in a hospital admission. This measure is calculated as a ratio but can also be expressed as a rate.

2.26.3 Measure Rationale

ED encounters within 30 days of an index discharge are an important indicator of care coordination, care transitions, and quality of life. In the general population, studies have shown higher risk of an ED encounter subsequent to a discharge from an inpatient hospitalization or an outpatient ED encounter (e.g., see Hastings et al., 2008). This has been demonstrated in the ESRD population as well with 27% of patients being treated in an ED within 30 days of hospital discharge, most frequently for congestive heart failure (Harel et al., 2015).

Rates of ED visits among ESRD dialysis patients have increased between 2007 and 2016. As reported by the USRDS, the unadjusted ED visit among HD patients increased from 2.6 to 3.0 per patient-year, and from 2.2 to 2.4 per patient-year for PD patients (USRDS ADR 2018), while the national percentage of ED visits among dialysis patients is 62% as of 2018 (FY2020 Dialysis Facility Report). More than half (55.0%) of all patients with ESRD visit the ED during their first year of dialysis, and patients with ESRD have a mean of 2.7 ED visits per patient-year (Lovasik et al., 2016). This rate is six-fold higher than the national mean rates for US adults in the general population (Lovasik et al 2016). Furthermore, the Lovasik study notes that among Medicare beneficiaries with ESRD, 30% of hospital admissions that originate in the ED are for diagnoses that are often dialysis related such as complications of vascular access, congestive heart failure/fluid overload, septicemia, and hyperkalemia. A study by Zhang and colleagues (Zhang et al, 2019) reported that rates of ED visits among patients on thrice weekly ICHD vary by dialysis

schedule (Mon/Weds/Fri; Tues/Thurs/Sat) and by day of week. For example, the ED visit rate (without hospital admission) was highest on the day following the longer interdialytic interval over the weekend (Mondays), suggesting an association with facility structure and treatment schedule.

Cohen and colleagues (Cohen et al 2020) reported that missed dialysis treatments are associated with an over two-fold higher risk of an ED visit, suggesting an opportunity for dialysis facilities to establish or strengthen facility practices that can help to reduce skipped treatments through increased communication, care coordination, and patient education. This in turn has the potential to reduce avoidable ED visits.

Finally, the CMS Centers for Medicare and Medicaid Innovation's Comprehensive ESRD Care model emphasizes care coordination as a central feature of care delivery in order to reduce utilization and improve outcomes. During the second performance year, the original Wave 1 cohort of ESCOs experienced about a 3% reduction in ED use relative to the period before the CEC model was launched (Marrufo et al., CEC Annual Report Performance Year 2, 2019).

Measures of the frequency of ED encounters subsequent to a hospital discharge may help dialysis facility efforts to prevent emergent unscheduled care and to help control escalating medical costs, for example through greater care coordination and post-discharge transitional care. Specifically, dialysis facility activities such as evaluation of the patients target weight or medication reconciliation, and review may help reduce the risk of ED encounters after hospital discharge. This measure will complement existing measures targeting care coordination (such as the Standardized Readmission Ratio CBE ID 2496) by identifying impactful events that can be influenced by dialysis facility care.

2.26.4   Measure Type

Outcome

2.26.5   Improvement Noted as Higher or Lower Rate

A lower ratio indicates better quality.

2.26.6   Numerator Statement

The observed number of index hospital discharges during a year that are followed by an ED encounter within 4–30 days of the discharge among eligible adult Medicare patients at a facility.

2.26.7   Facility Exclusions

ED30 is only calculated for facilities with at least 11 eligible index discharges in the reporting year.

2.26.8   Denominator Statement

The expected number of index hospital discharges for eligible adult Medicare ESRD dialysis patients during the two-year period that are followed by an ED encounter within 4-30 days of the discharge among eligible patients at a facility. The expected value is the result of a risk-adjusted predictive model adjusted for the characteristics of the patients, the dialysis facility, and the discharging hospitals.

2.26.9   Mapping Patients to Facilities

Index discharges are attributed to the facility of record on the day of discharge for the patient. That is, if the patient transfers dialysis facilities at the time of hospital discharge, it is the new facility that is assigned the index discharge.

2.26.10 Calculating Numerators

Index Discharges
We use Medicare inpatient hospital claims to identify acute hospital discharges. Among these acute hospital discharges, all live discharges of eligible patients in a calendar year are considered eligible for this measure. Those that do not meet one of the index discharge exclusion criteria described in the next section are considered index discharges.

ED Encounters
ED encounters are identified from Medicare outpatient claims using revenue center codes that indicate an ED visit (0450, 0451, 0452, 0453, 0454, 0455, 0456, 0457, 0458, 0459, 0981). Note that this means that we include both outpatient ED visits and those that result in an observation stay, but not those that result in a hospital admission. Outpatient ED claims that have overlapping or consecutive dates of service are combined and considered as a single ED encounter. To further ensure that these outpatient ED encounters are distinct from those associated with hospitalizations, we exclude ED encounters where there is an inpatient claim that has dates of service included in any of the same time period covered by the ED encounter.

An ED encounter "follows" the index discharge only if there is no intervening inpatient hospitalization. In other words, if after hospital discharge there is another inpatient hospitalization and then an ED encounter within the time frame the original index discharge is not counted as having been followed by an ED encounter. If eligible, the second hospitalization could become a new index discharge. The measure does not count the number of ED encounters after each index discharge, but instead determines whether or not there is at least one such encounter. If there are multiple ED encounters during days 4-30 after an index discharge, only the first ED encounter during that time is relevant to determining whether or not the index discharge is counted as having been followed by an ED encounter. ED encounters that occur before the fourth day after index discharge are not considered.

The 4-30 day time frame was selected to harmonize with the SRR (CBE ID 2496) that also uses the same time period after an index hospitalization. This time interval was selected in response to

providers and stakeholders concerns that there may be up to 72 hours before a patient is seen at the facility after hospital discharge.

The time period for the measure calculation is two calendar years, meaning that index discharges must occur during the two-calendar year period. The subsequent ED encounters may occur during the calendar years or the first 30 days of the following calendar year.

2.26.11 Defining Index Discharges

Index Discharge exclusions that are implicit in the denominator definition include discharges for which the patient:

- Has MA coverage at the time of the index discharge.
- Has had ESRD for 90 days or less at time of discharge.
- Is less than 18 years of age at the time of discharge.

We also exclude discharges and ED encounters for which the patient was:

- Actively enrolled in hospice at any time of during the calendar month of the discharge date or ED encounter admit date.

Outpatient Medicare claims are the source of ED encounter data, and since outpatient claims are not available for all MA patients, we cannot identify ED encounters for MA patients. Therefore, we exclude index discharges for patients with MA at the time of discharge.

The hospice exclusion is needed because hospice patients are considered to be under the purview of hospice care givers and may have other reasons for ED use such as pain management.

2.26.12 Risk Adjustment

The model accounts for a set of patient-level characteristics:

- Sex: Determine each patient's sex from multiple sources.
- Age at Index Discharge: Determined from the birth date provided in EQRS, Medicare Claims, and the Medical Evidence Form (CMS-2728). Five age groups were defined (18-24, 25-44, 45-59, 60-74, and 75+).
- Years on dialysis: Determined using the first service date from patient's Medical Evidence Form (CMS-2728), claims history (all claim types with evidence of dialysis), EQRS, and Dialysis Facility Measures the SRTR database.
- Diabetes as cause of ESRD: Primary cause of ESRD determined from patient's Medical Evidence Form (CMS-2728) and EQRS. When primary cause of ESRD is missing, we assume diabetes is not the cause of ESRD.
- 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) at time of index hospitalization discharge.
- BMI at incidence: Calculated based on the height and weight provided on patient's Medical Evidence Form (CMS-2728) and group patients into the following categories: BMI < 18.5, 18.5 ≤ BMI < 25, 25 ≤ BMI < 30, or BMI ≥ 30. BMI is imputed to the BMI ≥ 30 category when either missing, or outside the range of 10 to 70 for adults. Length (days) of index hospitalization: Each hospitalization's length is determined by

taking the difference between the date of admission and the date of discharge available on the inpatient claim. For patients who are transferred between one acute care hospital and another, the measure considers these multiple contiguous hospitalizations as a single acute episode of care, and the length is calculated by taking the difference between the date of admission for the first hospitalization and the date of discharge from the last hospitalization included. Time in the hospital is included as a categorical variable based on quartiles (1 variable for each quartile).

- Past-year comorbidities (risk variables): Determined by identifying unique ICD-10 diagnosis codes for each patient reported on Medicare claims in the 365 days preceding (and inclusive of) the index discharge date. Diagnosis codes are grouped using 66 comorbidity groups defined by the 2019.1 version of the AHRQ CCS. See table 1 for a list of AHRQ categories included.

CCS Category	Detailed Description
5	HIV infection
6	Hepatitis
7	Viral infection
8	Other infections; including parasitic
9	Sexually transmitted infections (not HIV or hepatitis)
22	Melanomas of skin
23	Other non-epithelial cancer of skin
46	Benign neoplasm of uterus
47	Other and unspecified benign neoplasm
49	Diabetes mellitus without complication
50	Diabetes mellitus with complications
76	Meningitis (except that caused by tuberculosis or sexually transmitted disease)
77	Encephalitis (except that caused by tuberculosis or sexually transmitted disease)
78	Other CNS infection and poliomyelitis
92	Otitis media and related conditions
93	Conditions associated with dizziness or vertigo
94	Other ear and sense organ disorders
95	Other nervous system disorders
98	Essential hypertension
99	Hypertension with complications and secondary hypertension
100	Acute myocardial infarction
101	Coronary atherosclerosis and other heart disease
102	Nonspecific chest pain
103	Pulmonary heart disease
104	Other and ill-defined heart disease
105	Conduction disorders
106	Cardiac dysrhythmias

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CCS Category	Detailed Description
117	Other circulatory disease
118	Phlebitis; thrombophlebitis and thromboembolism
124	Acute and chronic tonsillitis
125	Acute bronchitis
126	Other upper respiratory infections
127	Chronic obstructive pulmonary disease and bronchiectasis
128	Asthma
133	Other lower respiratory disease
134	Other upper respiratory disease
136	Disorders of teeth and jaw
137	Diseases of mouth; excluding dental
138	Esophageal disorders
139	Gastroduodenal ulcer (except hemorrhage)
140	Gastritis and duodenitis
141	Other disorders of stomach and duodenum
142	Appendicitis and other appendiceal conditions
147	Anal and rectal conditions
148	Peritonitis and intestinal abscess
152	Pancreatic disorders (not diabetes)
153	Gastrointestinal hemorrhage
154	Noninfectious gastroenteritis
155	Other gastrointestinal disorders
159	Urinary tract infections
161	Other diseases of kidney and ureters
164	Hyperplasia of prostate
165	Inflammatory conditions of male genital organs
166	Other male genital disorders
197	Skin and subcutaneous tissue infections
198	Other inflammatory condition of skin
199	Chronic ulcer of skin
200	Other skin disorders
201	Infective arthritis and osteomyelitis (except that caused by tuberculosis or sexually transmitted disease)
232	Sprains and strains
237	Complication of device; implant or graft
239	Superficial injury; contusion
241	Poisoning by psychotropic agents
242	Poisoning by other medications and drugs
243	Poisoning by nonmedicinal substances

CCS Category	Detailed Description
244	Other injuries and conditions due to external causes
245	Syncope
248	Gangrene
249	Shock
250	Nausea and vomiting
251	Abdominal pain
252	Malaise and fatigue
253	Allergic reactions
651	Anxiety disorders
652	Attention-deficit conduct and disruptive behavior disorders
654	Developmental disorders
657	Mood disorders
658	Personality disorders
659	Schizophrenia and other psychotic disorders
660	Alcohol-related disorders
661	Substance-related disorders
662	Suicide and intentional self-inflicted injury
663	Screening and history of mental health and substance abuse codes
670	Miscellaneous mental health disorders
83	Epilepsy; convulsions
84	Headache; including migraine
160	Calculus of urinary tract
204	Other non-traumatic joint disorders
205	Spondylosis; intervertebral disc disorders; other back problems
206	Osteoporosis
211	Other connective tissue disease
212	Other bone disease and musculoskeletal deformities

Table 13: Past Year Comorbidities, Grouped by AHRQ CCS Categories ED30 Measures

2.26.13 Calculation of ED30

To estimate the probability of 30-day ED encounter, we use a three-stage model, the first of which is a fixed-effects logistic regression model. In this first stage, facility-hospital combinations are included as fixed effects, adjusting for a set of patient-level characteristics. The results of this step are estimates of the regression coefficients of patient-level characteristics in the logistic regression model. These regression coefficients are then used as an offset variable in the second stage model. The results from this model are unbiased regardless of correlation between hospital effects and patient-case mix.

The second stage of the model is a double random-effects logistic regression model. In this stage of the model, both dialysis facilities and hospitals are represented as random effects, and the sum of regression adjustments multiplied by estimated parameters obtained from the first stage are included as the offset variable. From this model, we obtain the estimated standard deviation of the random effects of hospitals (Diggle, et. al., 2002).

The third stage of the model is a mixed-effects logistic regression model, in which dialysis facilities are modeled as fixed effects and hospitals are modeled as random effects, with the standard deviation specified as equal to its estimates from the second stage and the estimated parameters obtained in the first stage are included as the offset variable. The expected number of ED encounters for each facility is estimated as the summation of the probabilities of ED encounters of all patients in this facility and assuming the national norm (i.e., the median) for facility effect. This model accounts for a given facility's case mix using the same set of patient-level characteristics as those in the first stage model. The equations used in the measure calculation are as follows:

- To estimate the probability of 30-day ED encounter, we use a three-stage approach. The main model, which produces the estimates used to calculate ED30, takes the form:

$$\log \frac{p_{ijk}}{1 - p_{ijk}} = \gamma_i + \alpha_j + \beta^T Z_{ijk} , \qquad (1)$$

where p_{ijk} represents the probability of an ED encounter for the kth discharge among patients from the ith facility who are discharged from j^{th} hospital, and Z_{ijk} represents the set of patient-level characteristics. Here, γ_i is the fixed effect for facility and α_j is the random effect for hospital j. It is assumed that the α_js arise as independent normal variables (i.e., $\alpha_j \sim N(0, \sigma^2)$).

- We then use the estimates from this model to calculate each facility's ED30:

$$ED30_i = \frac{O_i}{E_i} = \frac{O_i}{\sum_{j \in H(i)} \sum_{k=1}^{n_{ij}} \tilde{p}_{ijk}} , \qquad (2)$$

where, for the ith facility, O_i is the number of observed ED encounter, E_i is the expected number of ED encounter for discharges, $H(i)$ is the collection of indices of hospitals from which patients are discharged, and $\tilde{p}_{ijk}$ is the predicted probability of ED encounter under the national norm for each discharge. Specifically, $\tilde{p}_{ijk}$ takes the form

$$\tilde{p}_{ijk} = \frac{\exp(\widehat{\gamma_M} + \widehat{\alpha_j} + \widehat{\beta}^T Z_{ijk})}{1 + \exp(\widehat{\gamma_M} + \widehat{\alpha_j} + \widehat{\beta}^T Z_{ijk})} , \qquad (3)$$

which estimates the probability that a discharge from hospital j of an individual in facility i with characteristics Z_{ijk} would result in an ED encounter if the facility effect corresponded to the median of national facility effects, denoted by $\widehat{\gamma_M}$. Here, $\widehat{\alpha_j}$ and $\widehat{\beta}$ are estimates from model (1). The sum of these probabilities is the expected number of

ED encounter E_i at facility i; e.g., the number of ED encounter that would have been expected in facility i had they progressed to the ED encounter at the same rate as the national population of dialysis patients. If a facility has less than 11 discharges, they are excluded from the measure for the purposes of modeling.

2.26.14 Calculation of ED30 P-Values and Confidence Intervals for Dialysis Facility Measures

Measuring or assessing significance of a large ED30 ratio (i.e., a ratio greater than 1) is based on the p-value. To calculate the p-value, we use an exact method that assesses the probability that the facility would experience a number of ED encounters as extreme as that observed if the null hypothesis were true; this calculation accounts for each facility's patient mix. For instance, to test the hypothesis that a facility's true ED30 ratio is 1.0, we calculate the positive one-tailed p-value or significance level (SL+) for each facility as the probability that the number of readmissions in that facility would be at least as large as that observed under the assumption that this facility has ED encounter rates corresponding to the median facility, and given the patient characteristics or covariates. The negative one-tailed p-value (SL-) is defined correspondingly (e.g., as small as). The two-tailed p-value is then defined as p = 2*min (SL+, SL-). We use a "mid-p" value to avoid two-tailed p-values greater than 1. Approaches for flagging are based on converting the p-values to z-statistics and using methods based on the empirical null hypothesis, which accounts for over dispersion in the data (Efron, 2004; Kalbfleisch and Wolfe, 2013). In effect, this method takes into account the natural variation observed between facilities and that cannot be accounted for by the model. To implement the empirical null methods, we stratify facilities into four groups based on the number of eligible patient-years at risk within each facility. We then plot the histograms of z-scores for each strata along with normal curves fitted to the center of the histograms using a robust M-estimation method. We use these empirical null distributions to assess outlier facilities. This empirical null method makes appropriate adjustment in each of the strata and yields fairly consistent flagging rates across all strata.

To calculate the 95% interval estimate for ED30, we use an exact method that assesses the range of facility effects, such that the probability the facility would experience a number of ED encounters more extreme than that observed under the assumed facility effect is non-significant (e.g., p > 0.05). To account for natural facility variation not explained by the model, evaluation of significance is based on the empirical null distribution, instead of the standard normal density.

2.26.15 Flagging Rules for Dialysis Facility Measures

As currently implemented for Dialysis Facility Measures, for reporting purposes we identify outlier facilities from amongst those with at least 11 index discharges during the time period. If the 95% interval lies entirely above the value of 1.00 (i.e., both endpoints exceed 1.00), the facility is said to have outcomes that are "worse than expected." However, if the 95% interval lies entirely below the value 1.00, the facility is said to be "better than expected". If the interval contains the value 1.00, the facility is said to have outcomes that are "as expected".

2.26.16 Data Elements and Data Sources

Data are derived from an extensive national ESRD patient database, which is primarily based on EQRS facility-reported clinical and administrative data (including CMS-2728 Medical Evidence Form, CMS-2746 Death Notification Form, and CMS-2744 Annual Facility Survey Form and patient tracking data), EQRS, the Medicare EDB, and Medicare claims data. In addition, the database includes transplant data from the SRTR, and data from the Nursing Home MDS, the Quality Improvement Evaluation System (QIES) Business Intelligence Center (QBIC) (which includes Provider and Survey and Certification data from Automated Survey Processing Environment [ASPEN]), and the Dialysis Facility Compare (DFC).

The database is comprehensive for Medicare patients not enrolled in MA. MA patients are included in all sources, but their Medicare payment records are limited to inpatient claims. Non-Medicare patients are included in all sources except for the Medicare payment records. Tracking by dialysis provider and treatment modality is available for all patients including those with only partial or no Medicare coverage.

Information on hospitalizations is obtained from Part A Medicare Inpatient Claims SAFs, and past-year comorbidity data are obtained from multiple Part A types (inpatient, home health, hospice, skilled nursing facility claims) and Part B (outpatient) claims.

2.26.17 Flowchart

Figure 28 presents the flowcharts that represent the processes used to calculate the Standardized Ratio of ED Encounters Occurring Within 30 Days of Hospital Discharge (ED30) for Dialysis Facilities Measure.

Standardized Ratio of Emergency Department Encounters Occurring Within 30 Days of Hospital Discharge (ED30): The ratio of observed to expected ED encounters occurring within 30 days of discharge
Numerator Statement: Number of emergency department encounters observed
Denominator Statement: Number of emergency department encounters expected based on the national rate for patients with similar characteristics

*Multiple data sources include EQRS, the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746), the Dialysis Facility Compare (DFC) and the Social Security Death Master File.

Emergency Department Merging with Index Discharge Criteria
Standardized Ratio of Emergency Department Encounters Occurring Within 30 Days of Hospital Discharge (ED30)***: The ratio of observed to expected ED encounters occurring within 30 days of discharge
Numerator Statement: Number of emergency department encounters observed
Denominator Statement: Number of emergency department encounters expected based on the national rate for patients with similar characteristics
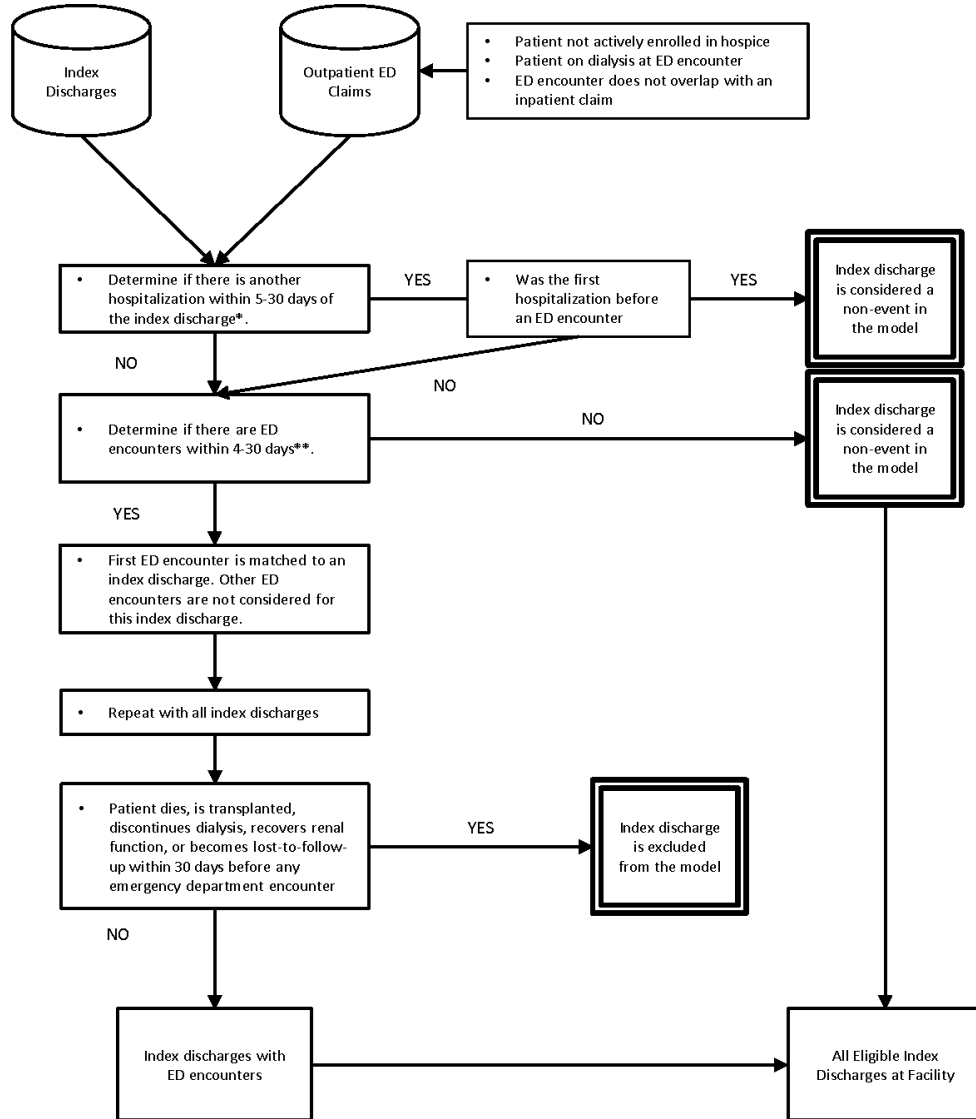
* We have already excluded index discharges with hospitalizations 1-4 days after discharge.
** ED encounters that occur before the 4th day after index discharge are not considered.
*** An index discharge is considered day 0.

Figure 28: Standardized Ratio of Emergency Department Encounters Occurring Within 30 Days of Hospital Discharge (ED30) for Dialysis Facilities Reporting Measure Flowchart (Dialysis Facility Measures only)

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2.27 Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR) (Dialysis Facility Measures Only)

2.27.1 Measure Name

Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR)

2.27.2   Measure Description

The standardized modality switch ratio (SMoSR) is defined to be the ratio of the number of observed modality switches (from in-center to home dialysis—peritoneal or home hemodialysis [HHD]) that occur for adult incident ESRD dialysis patients treated at a particular facility, to the number of modality switches (from in-center to home dialysis—peritoneal or home hemodialysis) that would be expected given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. The measure includes only the first durable switch that is defined as lasting 30 continuous days or longer.

The SMoSR estimates the relative switch rate (from in-center to home dialysis) for a facility, as compared to the national switch rate. Qualitatively, the degree to which the facility's SMoSR varies from 1.00 is the degree to which it exceeds (> 1.00) or is below (< 1.00) the national modality switch rates for patients with the same characteristics as those in the facility. Ratios greater than 1.00 indicate better than expected performance while ratios <1.00 indicate worse than expected performance.

2.27.3   Measure Rationale

Home dialysis rates remain low in the United States compared with many other countries (as of 2019, 10.8% PD, 1.8% HHD). This measure will allow one to compare the effectiveness of facility modality education and/or effective utilization of home dialysis modalities. This will be a facility outcome metric for comparison across the US including longitudinal monitoring. It is patient centered in that it is intended to facilitate on-going education that may result in patients choosing a home modality, particularly if there was no pre-dialysis modality education provided. The quality of care will be improved by better alignment between patients' goals and values and their dialysis modality. The focus is on incident patients since most modality changes occur during the first year and likely reflect robust education, effective presentation, and facilitation by the dialysis unit.

2.27.4   Measure Type

Outcome

2.27.5   Improvement Notes as Higher or Lower Rate

A higher rate/ratio indicates better quality.

2.27.6   Numerator Statement

Observed number of switches from in-center hemodialysis to a home dialysis modality (PD or HHD) among eligible patients at the facility during the time period.

2.27.7   Facility Exclusions

The SMoSR is only calculated for facilities with at least 11 index hospital discharges in a performance year. Calculations of index discharges will exclude the months covered by a granted ECE (see Section 3.4).

2.27.8   Denominator Statement

Expected number of switches from in-center hemodialysis to a home dialysis modality (PD or HHD) among eligible patients at the facility during the time period, given the national average of modality switches, and patient case-mix at the facility.

2.27.9   Patient Exclusions

Patients who are attributed to clinics with fewer than 1 expected modality switch are not excluded from the measure. All patients who meet the denominator inclusion criteria are included and used to model a given facilities expected switch rate to home dialysis. If that switch rate is <1, then the facility is excluded from reporting outcomes.

Determination of eligible patients is based on a non-missing Medical Evidence Form (Form CMS-2728). The intent of excluding patients with no Form 2728 is to exclude patients with Acute Kidney Injury (AKI) that are receiving temporary outpatient dialysis. The nursing home status information is determined from the Nursing Home Minimum Dataset (MDS). Time at risk for patients in a nursing home on home hemodialysis is excluded from the measure.

The patient's age is determined by subtracting the patient's date of birth from the first day of the reporting month. Patients that are <18 years old as of the first day of the reporting month are excluded.

Hospice status is determined from a separate CMS file that contains final action claims submitted by Hospice providers. Once a beneficiary elects a Hospice, all Hospice related claims will be found in this file, regardless of whether the beneficiary is in Medicare fee-for-service or in a Medicare managed care plan. Patients' time at risk is censored from the date of the first hospice care claim.

2.27.10 Mapping Patients to Facilities

We detail patient inclusion criteria, facility assignment and how to count days at risk, all of which are required for the risk adjustment model. As patients can receive dialysis treatment at more than one facility in a given year, we assign each patient's day to a facility (or no facility, in some cases) based on a set of conventions below.

General Inclusion Criteria for Chronic Dialysis Patients:

This measure includes all eligible incident ESRD dialysis patients and is not restricted to Medicare beneficiaries. To be included in the denominator, the patient must be ESRD as defined by a submitted Medical Evidence Form. Patients must be at least 18 years old as of the first day

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 30 days.

Identifying Facility Treatment Histories for Each Patient and Patient Attribution:

For each patient, we identify the dialysis provider each month using a combination of data from EQRS, Medicare-paid dialysis claims (primarily outpatient), and the Medical Evidence Form. These sources are used to identify patients that are on chronic in-center or home dialysis (PD or HHD) for the entire reporting period. Starting with the first day of ESRD, we attribute patients to facilities according to the following rules. If the initial modality is home dialysis, we exclude the home modality period from the denominator and consider the first day (following) in-center dialysis as the first day at risk. A patient is attributed to a facility once the patient has been treated there for the past 30 days. When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 30 days and then is attributed to the destination facility from day 31. In particular, a patient is attributed to their current facility on 31st day of ESRD if that facility had treated him or her for the past 30 days. For example, if a patient who is on ICHD changes from facility A to B and then switches to home dialysis within 30 days of arriving at facility B, facility A would receive credit for the switch. In this scenario, given the short timeframe between changing facilities and switching modalities, it is likely that facility A is responsible for the modality education. After 30 days, the switch would be attributed to the receiving facility (i.e., facility B). When a patient is not treated in a single facility for a span of 30 days (for instance, if there were two facility transfers within 30 days of each other), we do not attribute that patient to any facility.

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

2.27.11 Calculating Numerators

Information on modality type and modality switches is obtained from several sources which include EQRS, Medicare dialysis claims, and the Medical Evidence Form.

The numerator includes only the first durable switch to a home dialysis modality lasting >= 30 continuous days. An eligible modality switch is considered as an ICHD patient that switches to home dialysis (PD or HHD) within 365 days of ESRD onset, and the home modality is maintained for >= 30 days. Only the first durable modality switch is included if patients have multiple switches. Modality switches during the first 30 days of dialysis at a facility are not counted for that facility.

2.27.12 Risk Adjustment

The patient characteristics included in the stage 1 model as covariates are:

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- Age: Age is included as a piecewise continuous variable with different coefficients based on whether the patient is 18-25 years old, 26-35 years old, 36-45 years old, 46-55 years old, 56-65 years old, 66-75 years old, 76-85 years old, or 85+ years old.

- Diabetes as cause of ESRD: Determine each patient's primary cause of ESRD from his/her CMS-2728, and EQRS.

- BMI at ESRD incidence: Calculate each patient's BMI based on the height and weight provided on his/her CMS 2728 and group patients into the following categories: BMI < 18.5, $18.5 \leq$ BMI < 25, $25 \leq$ BMI < 30, or BMI $\geq$ 30. BMI is imputed when either missing, or outside the range of 10 to 70 for adults or 5 to 70 for children. Missing and out-of-range BMIs are categorized into the mode group (i.e., >=30).

- Comorbidities at ESRD incidence, determined using a selection of comorbidities reported on the CMS-2728:

  o Atherosclerotic heart disease

  o Other cardiac disease

  o Diabetes other than as primary cause of ESRD (all types including diabetic retinopathy)

  o Congestive heart failure

  o Inability to ambulate

  o Chronic obstructive pulmonary disease

  o Inability to transfer

  o Malignant neoplasm, cancer

  o Peripheral vascular disease

  o Cerebrovascular disease, CVA, TIA

  o Tobacco use (current smoker)

  o Alcohol dependence

  o Drug dependence

  o At least one of the comorbidities listed

- Calendar year

2.27.13 Calculation of SMoSR

The SMoSR is calculated by dividing the observed total modality switches in by the expected total modality switches. The observed number of switches is the total number of modality switches among the incident dialysis patients assigned to this facility. The modality switch only includes the first durable switch to a home dialysis modality lasting >= 30 continuous days. An eligible modality switch is considered as an in-center hemodialysis patient that switches to home dialysis within 365 days of ESRD onset, and the home modality is maintained for >= 30 days. Only the first durable modality switch is included if patients have multiple switches.

The expected number of switches is calculated using a two-stage Cox model, with the first stage being a patient model stratified by facility to avoid bias caused by different covariate distributions across facilities. In this model, covariates are taken to act multiplicatively on the modality switch rate and the adjustment model is fitted with facility defining strata in order to provide valid estimates even if the distribution of adjustment variables differs across facilities.

The denominator of SMoSR for a facility is the expected number of switches from the patient-records meeting the inclusion criteria, based on the number of days attributed to that facility. Specifically, the expectation is calculated using a two-stage model. At Stage 1, we fit a Cox model stratified by facility and adjusted for patient age, diabetes as cause of ESRD, patient comorbidities at ESRD incidence, calendar year, and BMI at incidence. This stratified model allows each facility to have a distinct baseline survival function while retaining the same regression coefficients of all the adjusters across all the facilities. Stratification by facility avoids estimating facility effects directly and also reduces computational burden. A linear predictor using the estimates of regression coefficients will be computed for each patient and will be used as the offset term in the Stage 2 modeling. At Stage 2, we fit an unstratified Cox model, which includes the offset term from Stage 1 model. The baseline hazard or survival function of this model has national norm interpretations. With the fitted model at Stage 2, we compute the expected probability of modality switch for each patient based on the aforementioned adjusters and the number of days assigned to a facility. The denominator of SMoSR for a facility is then the summation of expected probabilities of modality switch from all the patients assigned to that facility.

2.27.14 Creating Interval Estimates

The 95% confidence interval (or range of uncertainty) gives a range of plausible values for the true ratio of facility-to-national modality switches, in light of the observed SMoSR. The upper and lower confidence limits enclose the true ratio approximately 95% of the time if this procedure were to be repeated on multiple samples. Statistically significant confidence intervals do not contain the ratio value 1.00.

The p-value measures the statistical significance of (or evidence against) the hypothesis that the true modality switch ratio for your facility is the same as (neither higher nor lower than) what would be predicted from the overall national ratio of modality switches. The p-value is the probability that the observed SMoSR would deviate from 1.00 as much as it does under the null

hypothesis that this ratio is truly equal to 1.00. A small p-value (often taken as <0.05) indicates that the observed ratio would be highly unlikely under the null hypothesis, and the observed SMoSR suggests that the ratio between the observed and expected modality switches differs significantly from 1.00. The smaller the p-value, the lower the probability that a facility's ratio of modality switches is equal to the national ratio. Note that the p-value is less than 0.05 whenever the confidence interval does not include the value 1.00. Because the p-value depends on the facility size, a small p-value in a large facility does not necessarily indicate that the difference between this facility's ratio and the national ratio is of clinical importance. The SMoSR's actual value can be used to assess the clinical importance of the difference between your facility's and the national ratios of modality switches. A SMoSR of 1.25, for example, indicates that your facility's ratio is 25% higher than the national average, which may well be judged to be clinically important. On the other hand, SMoSR values in the range of 0.95 to 1.05 would generally not be considered to be of clinical interest. With very large facilities, however, even relatively small differences in the SMoSR can lead to significant results, so both aspects (the actual value of the SMoSR and the p-value) are important.

2.27.15 Flagging Rules (Dialysis Facility Measures)

When a facility's SMoSR is greater than 1.00 and statistically significant (p-value < 0.05), it is classified as "Better than expected". When a facility's SMoSR is less than 1.00 and statistically significant (p-value < 0.05), it is classified as "Worse than expected". When a facility's SMoSR is not significantly different from 1.00, it is classified as "As expected". Please note that the classification of SMoSR is reported as "Not available" on Dialysis Facility Measures for facilities with less than 11 patients or less than two expected events for the relative reporting year.

2.27.16 Data Elements and Data Sources

EQRS, Medicare Claims, CMS Minimum Data Set, CMS Hospice file, and the CMS Medical Evidence Form (CMS 2728) are used as the data sources for establishing the denominator. EQRS, Medicare dialysis claims, and the Medical Evidence Form are the data sources used for establishing the numerator. Medicare claims are used for the comorbidity conditions exclusion criteria.

Variable	Primary Data Source
Facility CCN #	CMS data sources[*1]
Reporting year and month	EQRS
Modality Type	EQRS
Date of Birth	CMS data sources[*1]
Date of First ESRD	Medical Evidence Form (CMS-2728)
Age at incidence	CMS data sources[*1]
BMI at incidence	Medical Evidence Form (CMS-2728)
Nursing home status	CMS Minimum Data Set

Variable	Primary Data Source
Atherosclerotic heart disease	Medical Evidence Form (CMS-2728)
Malignant neoplasm, cancer	Medical Evidence Form (CMS-2728)
Other cardiac disease	Medical Evidence Form (CMS-2728)
Peripheral vascular disease	Medical Evidence Form (CMS-2728)
Chronic obstructive pulmonary disease	Medical Evidence Form (CMS-2728)
Tobacco use (current smoker)	Medical Evidence Form (CMS-2728)
At least one incident comorbidity	Medical Evidence Form (CMS-2728)
Congestive heart failure	Medical Evidence Form (CMS-2728)
Diabetes as the primary cause of ESRD	Medical Evidence Form (CMS-2728)
Diabetes at incidence	Medical Evidence Form (CMS-2728)
Cerebrovascular disease, CVA, TIA	Medical Evidence Form (CMS-2728)
Inability to transfer	Medical Evidence Form (CMS-2728)
Alcohol dependence	Medical Evidence Form (CMS-2728)
Inability to ambulate	Medical Evidence Form (CMS-2728)
Drug dependence	Medical Evidence Form (CMS-2728)
Hospice status	CMS Hospice file[*2]

*1. Multiple data sources include CMS Consolidated Renal Operations in a Web-enabled Network (EQRS), the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746), the Dialysis Facility Measures and the Social Security Death Master File.

Unique patients are identified by using a combination of SSN, first name, surname, sex, Medicare claim number and birth date. A matching process is performed to ensure that minor typos and misspellings do not cause a patient record to fall out of their history. The matching process is able to successfully match 99.5% of patients. The remaining patients have incomplete or incorrect data that does not allow them to be matched.

*2. Hospice information comes from the CMS Hospice file that contains final action claims submitted by Hospice providers. Once a beneficiary elects Hospice, all Hospice related claims will be found in this file, regardless of if the beneficiary is in Medicare fee-for-service or in a Medicare managed care plan.

Table 14: Data sources used to calculate the SMoSR measure (Dialysis Facility Measures only)

2.27.17 Flowchart

Figure 29 presents the flowcharts that represent the processes used to calculate the SMoSR measure.

Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR)
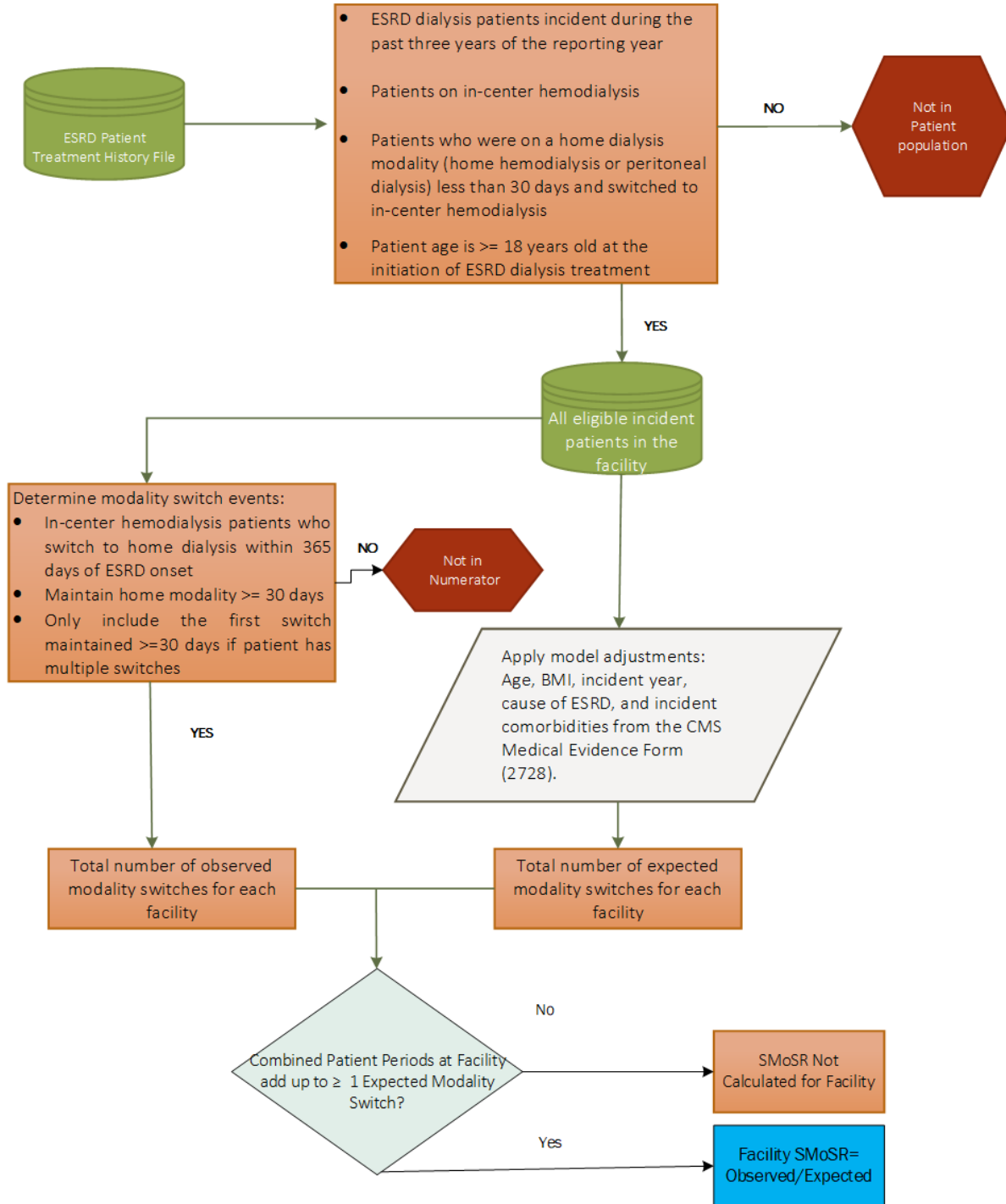
Figure 29: Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR) Flowchart (Dialysis Facility Measures only)

3. Cross-Measure Determinations

The following subsections describe calculations that are used in multiple measure calculations.

3.1 Determining Patient-Level Exclusions

The subsections below explain how Dialysis Facility Measures and ESRD QIP assign modalities to patients.

3.1.1 Modality Determination

Dialysis Facility Measures Only:

- A patient is defined as an HD patient if their modality reported in Medicare claims is any of the following: 'Hemodialysis', 'Center self hemo', 'Home hemo' or 'Hemo Training'.

- A patient is defined as a peritoneal patient if their modality reported in claims is any of the following: 'CAPD', 'CAPD Training', 'CCPD', 'CCPD Training', 'Other PD' where CAPD is continuous ambulatory PD and CCPD is continuous cycling PD.

ESRD QIP Only:

For EQRS-based measures including hypercalcemia, UFR, MedRec, vascular access long-term care (LTC), and SFR, patient modality is determined solely on EQRS treatment records. Patient modality is derived from EQRS as follows:

- ICHD:
  - Dialysis Type = HD
  - Dialysis Setting = Dialysis Center
- Home HD:
  - Dialysis Type = HD
  - Dialysis Setting = SNF/LTC or Home
- PD:
  - Dialysis Type = CAPD or CCPD
- Other:
  - Dialysis Type = Other

For the Kt/V Comprehensive measure only, modality is determined using either EQRS treatment records or claims, with preference given to EQRS. The system tracks if a patient changed modality during the month, with the exception that switching between ICHD and home HD is not considered a modality change for adults aged over 18 years. When treatment records submitted by different facilities cover the same dates, preference is given to the treatment records submitted by the assigned facility. Additionally, patients' prescribed number of treatment sessions is obtained from the treatment record used to assign modality.

When patient modality is not available in EQRS, patient modality for Kt/V Comprehensive is derived from claims by considering revenue center codes for ICHD, with condition codes used to identify home HD, and PD. Claims with revenue center codes indicating a mix of modalities are flagged as Multiple Modality.

For measures in which Medicare claims are used to determine modality, patient modality is derived for a given month as follows:

- In cases where a dialysis patient receives treatment with more than one dialysis treatment modality in a month, for some measures the system must determine the patient's primary treatment modality for that month. The system will use the logic described in this section to determine patient's primary treatment modality for single or a multiple-claim patient-month for each facility submitting claims for the patient in the month. For measures requiring modality determination at the level of detail corresponding to the individual claim, the portions of this process related to a single claim are followed.

  Step 1. For each claim, determine the presence of dialysis-related revenue center codes.

  a. Determine if any of the following dialysis-related **composite** revenue center codes (also known as primary codes) are on the claim:

  - Composite revenue center codes (shown in the second column of Table 15):
    - Hemodialysis - 0821, 0881
    - Other Peritoneal Dialysis - 0831
    - Peritoneal - CAPD (0841) or CCPD (0851)

  b. If only the following dialysis-related **non-composite** revenue center codes are present, skip to Step 5 (Section 3.1.1).

  - Non-composite revenue center codes are shown in the third column of Table 15 (below).

  c. When there are revenue center codes with the same line item date, use Table 15 (below) to determine modality type for each revenue center code.

  - If the modality types are the same, only count once when determining modality and number of sessions.
  - If the modality types are different, do not count either when determining modality and number of sessions.
  - If there are both composite and non-composite revenue center codes, only the composite codes will be counted when determining modality and number of sessions.

  d. If no dialysis-related revenue center codes are present, set the Primary Modality to **Undetermined**.

Modality Type	Revenue Center Codes Composite	Revenue Center Codes Non-Composite
In-Center Hemodialysis	0821, 0881	0801, 0820, 0824, 0825, 0829
HHD – Home Hemodialysis		0822, 0823, 0882
Peritoneal Dialysis	0841, 0851	0803, 0804, 0840, 0842, 0843, 0844, 0845, 0849, 0850, 0852, 0853, 0854, 0855, 0859
OPD – Other Peritoneal Dialysis	0831	0802, 0830, 0832, 0833, 0834, 0835, 0839
Undetermined		0800, 0809, 0880, 0889

Table 15: Modality Types for Revenue Center Codes

Step 2. For months where the facility has submitted multiple claims for the patient.

a. Determine the presence of dialysis-related revenue center codes across all claims and combine into one list.

b. Determine if any of the following dialysis-related **composite** revenue center codes (also known as primary codes) are on any of the claims:

- o Composite revenue center codes (shown in the second column of Table 14):
    - Hemodialysis - 0821, 0881
    - Other Peritoneal Dialysis - 0831
    - Peritoneal - CAPD (0841) or CCPD (0851)

c. If only dialysis-related **non-composite** revenue center codes are present, skip to Step 5 (Section 3.1.1).

- o Non-composite revenue center codes are shown in the third column of Table 14 (above).

d. When there are revenue center codes with the same line item date, use Table 14 (above) to determine modality type for each revenue center code.

- o If the modality types are the same, only count once when determining modality and number of sessions.
- o If the modality types are different, do not count either when determining modality and number of sessions.
- o If there are both composite and non-composite revenue center codes, only the composite codes will be counted when determining modality and number of sessions.

e. If no dialysis-related revenue center codes are present, set the Primary Modality to **Undetermined.**

Step 3. For claims with any of the five dialysis-related composite revenue center codes present, calculate the number of hemo-equivalent dialysis sessions using only composite revenue center codes and ignoring any non-composite revenue center codes that may be present.

a. Count sessions per modality type using revenue center codes as follows:
    - HD sessions = count incidences of revenue center codes 0821 and 0881
    - Other PD sessions = count incidences of revenue center code 0831
    - CAPD sessions = count incidences of revenue center code 0841
    - CCPD sessions = count incidences of revenue center code 0851
b. Sum HD sessions
c. Sum Other PD, CAPD, and CCPD sessions and convert to PD hemo-equivalent sessions. PD (hemo-equivalent) sessions = (OPD+CAPD+CCPD)*3/7

Step 4. Compare HD and PD (hemo-equivalent) dialysis sessions, determine the primary modality.

a. If there are more HD sessions set primary modality to **In-center Hemodialysis** and continue to step six.
b. If there are more PD sessions:
    - Sum Other PD sessions.
    - Sum CAPD and CCPD sessions.
    - If there are more Other Peritoneal sessions, set primary modality to **OPD.**
    - If there are more CAPD and CCPD sessions, set primary modality to **Peritoneal Dialysis.**
c. If there is a tie between the highest counts of two or more of different modality types, set primary modality to **Undetermined.**

Step 5. If the only dialysis-related codes on the claim are non-composite revenue center codes (shown in the third column of Table 14), set the primary modality according to which modality type code set occurs most frequently.

a. Count the non-composite codes of each type and set the Primary Modality according to which code occurs most frequently as shown in Table 14 (above).
b. For months where the facility has submitted multiple claims for the patient, and there are only non-composite revenue center codes, and there are non-composite revenue center codes with the same date, use Table 14 (above) to determine modality type:
    - If the modality types are the same, only count once when determining modality and number of sessions.
    - If the modality types are different, do not count either when determining modality and number of sessions.
c. Determine primary modality:
    - Sum HD code counts (one code=one session).
    - Sum PD and Other PD code counts (sessions) and convert to PD hemo-equivalent sessions. PD (hemo-equivalent) sessions = (PD+OPD)*3/7.
    - Compare HD and PD (hemo-equivalent) dialysis sessions, determine the primary modality.
    - If there are more HD sessions, set primary modality to **In-center Hemodialysis** and continue to step six.
    - If there are more PD sessions, set primary modality to **Peritoneal Dialysis.**
    - If there is a tie of the highest counts of two or more modality types, set primary modality to **Undetermined.**

Step 6. Determine if the patient was receiving Home HD:

a. For patient months that have a single claim:

o If the patient's primary modality is set to **In-Center Hemodialysis**, change to **Home Hemodialysis** if the Claim Related Condition Code is 74 or 75 (which correspond to 'Home - Billing is for a patient who received dialysis services at home' and 'Home 100% reimbursement - [not to be used for services after 4/15/90]. The billing is for home dialysis patient using a dialysis machine that was purchased under the 100% program').

b. For months where the facility has submitted multiple claims for the patient:

o If the patient's primary modality is set to **In-Center Hemodialysis**, and any one of the multiple claims have Claim Related Condition Code of 74 or 75:

- Set the claim with the highest number hemodialysis revenue center codes (shown in Table 14 with Modality Type In-center Hemodialysis) as the **Primary Single Claim**.
Note: Count all dialysis-related codes for this purpose, including those occurring on the same date and both composite and non-composite codes if both are present.
- If the **Primary Single Claim** has a claim-related condition code of 74 or 75 then switch the primary modality to **Home Hemodialysis**.
- If the **Primary Single Claim** does not have a claim-related condition code of 74 or 75 then the modality remains **In-center Hemodialysis**.
- If no Primary Single Claim can be determined (because there is a tie between two or more claims containing the highest number of hemodialysis revenue center codes), then:
  - If all claims with the highest number of hemodialysis revenue center codes also have a Claim Related Condition Code of 74 or 75, then switch the primary modality to **Home Hemodialysis**.
  - If any of the claims with the highest number of hemodialysis revenue center codes does not have a Claim Related Condition Code of 74 or 75, then the modality remains **In-center Hemodialysis.**

Step 7. If the primary modality is **In-center Hemodialysis** or **Home Hemodialysis,** save the count of revenue center codes (determined in Steps 2 or 5 of Section 3.1.1) as the number of sessions in the patient month.

3.1.2 Time on ESRD Treatment

If the patient is not undergoing ESRD treatment during the month, then the patient-month is excluded from the measure calculations.

Dialysis Facility Measures:

The first ESRD service date for each patient is obtained from the following data sources: CMS 2728 Medical Evidence form, the transplant standard analysis file (constructed from multiple sources), the EQRS events file, and CMS Institutional Claims. Patients often have data concerning their ESRD service from more than one of these sources. The earliest reported source is taken as the official first service date (FSD). If multiple data sources occur on the FSD, they are sorted as follows: (1) medical evidence, (2) EQRS, (3) claims, and (4) transplant. The order in which multiple data sources on the FSD are arranged is as follows: (1) medical evidence, (2) EQRS, (3) claims, and (4) transplant. The subsequent procedures for determining the patient's initial ESRD service date are as follows.

- If the first ESRD service date was selected from a dialysis claim and there is a 2728 AND an EQRS event that occur within 30 days of each other that are more than 90 days AFTER the dialysis claim date with NO transplants in between, then the first ESRD service date is moved to the next closest date, either the 2728 or the EQRS event, whichever was earlier.
- If the first ESRD service date has been set to the 2728 date but there is an EQRS event of "new patient" more than one year later, and that date is earlier than any other EQRS event, transplant, or claim, then the first ESRD service date is changed to the EQRS event date.
- If the ESRD first service date is not before the claim "from" date, then the claim is excluded from the measure calculations.

ESRD QIP:

A patient's initiation of ESRD date is the earliest among the four dates listed below. If multiple data sources have the earliest ESRD date, the source is identified by the following priority: (1) Medical Evidence 2728 form, (2) EQRS, (3) claims, and (4) transplant. Time on ESRD treatment is calculated as the duration between the initiation of ESRD date and the claim start date, as indicated on the claim used for the patient-month. The subsequent information outlines the procedures for determining a patient's initial ESRD service date:

- The date regular chronic dialysis began from the earliest completed Medical Evidence Form (CMS 2728). If this date is missing, the earliest date of these four other dates on the form is used to represent this date: physician's signature date, date of return to regular dialysis after transplant failure, date dialysis training began, and transplant date. If unable to assign a date from the earliest Medical Evidence form, the date regular chronic dialysis began as entered in EQRS by the treating facility is substituted.
- Earliest admit date reported in EQRS for any dialysis facility, excluding admissions with discharge reason of Acute.
- Earliest evidence of chronic dialysis from Medicare claims. This calculation uses any claim with evidence of dialysis (includes a dialysis-related composite revenue center code) or an outpatient dialysis facility claim (type of bill 72). The date used is the claim's start date from the earliest claim (inpatient or outpatient) where the average number of dialysis-related revenue center codes per day across all claims for the patient for the next 60 days is > 0.2.

- If the first ESRD service date was selected from a dialysis claim and there is a Medical Evidence Form (CMS-2728) and a dialysis facility EQRS admit date that occur within 30 days of each other that are over 90 days after the dialysis claim date, with no transplants in between, then the first ESRD service date is moved to the next closest date, either the Medical Evidence 2728 form or the dialysis facility EQRS admit, whichever was earlier.
- If first ESRD service date has been set to the date in the Medical Evidence Form (CMS-2728) but there is a dialysis facility EQRS admit with admit reason of "new patient" more than one year later, and that date is earlier than any other dialysis facility EQRS admit, transplant, or claim, then the first ESRD service date is changed to the dialysis facility EQRS admit date.

3.1.3   Patient Age

For claims, patient age is calculated as the length of time between the patient's date of birth and the claim "from" date (the start date for when care was provided. For EQRS, patient age is calculated as the days between date of birth and the first day of the reporting month. Age calculations accommodate leap years. Note, for ESRD QIP the source for patient date of birth will be the EQRS Patient Repository.

3.1.4   Determination of Weekly Dialysis and "Frequent Dialysis"

For the Kt/V measures, a patient is defined as not dialyzing greater than two and less than four times weekly if the prescribed number of sessions reported in EQRS for the patient by the facility assigned responsibility for the patient (see measure sections on mapping patients to facilities) is not greater than two and less than four times weekly and/or the patient is not identified in EQRS as undergoing "frequent" dialysis anytime during the reporting month. If information regarding the frequency of dialysis is not available for the reporting month in EQRS by the patient's facility (assigned by the facility mapping process), then session information in EQRS submitted by other dialysis facilities where the patient received treatment during the month is considered.

If the session information is not reported in EQRS for the patient at all for the reporting month, then eligible HD Medicare claims are considered. A claim is considered eligible if it indicated the patient was an adult (≥18 years old) HD patient (or pediatric ICHD for pediatric HD measure). The patient must also be on ESRD treatment for at least 91 days as of the start date of the claim. If an eligible claim submitted during the reporting month (from any facility) reports 8.88, then the patient month is excluded. If not, then sessions per week is calculated for the subset of eligible claims submitted during the reporting month by the patient's facility (assigned by the mapping process). If the calculation for any of these claims (from the patient's facility) indicates frequent or infrequent dialysis, the patient month is excluded (more details provided below.

If the prescribed dialysis information is not available for the patient during the reporting month in either data source (EQRS or Medicare claims), the patient-month is excluded from the Kt/V denominator.

Calculating "frequent" and" infrequent" dialysis in Medicare dialysis claims

This calculation is limited to outpatient dialysis facility claims submitted by the patient's facility as assigned during the mapping process. The number of days the claim covers is calculated by:

days = (ClaimThroughDate - (ClaimFromDate - 1))

For claims covering more than seven days, the number of dialysis sessions per week is calculated as an average rate: 7*(# of HD revenue center codes/# of days). For claims covering seven or fewer days, no dialysis sessions per week rate is calculated.

Frequent dialysis is defined as follows if any eligible claim for the patient starting during the month meets any of the following criteria:

- HD claim with Kt/V value of 8.88.
- HD claim with average rate of four or more dialysis-related revenue center codes per week.
- Short HD claim (seven days or fewer) with four or more total dialysis-related revenue center codes.

An HD claim is defined as indicating infrequent dialysis if it covers more than seven days and has an average rate of two or fewer dialysis-related revenue center codes per week.

Note: No rounding is used when determining dialysis frequency.

3.1.5   Length of Treatment at a Facility

This section (Table 16) summarizes the approaches to length of treatment. The following table indicates where treatment time by a facility is discussed, by measure.

Measure	Measure Subsection	Method Summary
Vascular Access Type Clinical Measure: Long-term Catheter Rate	2.1.11	For each month of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims
Vascular Access Type Clinical Measure: Standardized Fistula Rate (Dialysis Facility Measures Only)	2.2.12	For each month of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims
Adult Hemodialysis Adequacy Measure (Dialysis Facility Measures Only)	2.3.11	For each month of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims
Adult Peritoneal Dialysis Adequacy Measure (Dialysis Facility Measures Only)	2.4.11	For each month of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims
Pediatric Hemodialysis Adequacy Measure (Dialysis Facility Measures Only)	2.5.11	For each month of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims
Pediatric Peritoneal Dialysis Adequacy Measure (Dialysis Facility Measures Only)	2.6.11	For each month of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims

Measure	Measure Subsection	Method Summary
Kt/V Dialysis Adequacy Comprehensive Clinical Measure (ESRD QIP Only)	2.7.11	For each month of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims
nPCR for Pediatric Hemodialysis Patients (Dialysis Facility Measures Only)	2.8.11	For each month of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims
Hypercalcemia Clinical Measure (Dialysis Facility Measures Only)	2.8.11	For each month of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims
Hypercalcemia Reporting Measure (ESRD QIP Only)	2.8.11	For each month of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims
Clinical Depression Screening and Follow-Up Clinical Measure (ESRD QIP Only)	2.9.5	Comparison of admit and discharge dates in EQRS. For patients with a death date, when calculating length of treatment at the facility, the system will use the death date as the end of treatment when the discharge date in EQRS is later than date of death or is blank
Standardized Readmissions Ratio (SRR) Clinical Measure (ESRD QIP and Dialysis Facility Measures)	2.11.9	For each day of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims
Standardized Transfusion Ratio (STrR) Clinical Measure (ESRD QIP and Dialysis Facility Measures)	2.13.10	For each day of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims
Standardized Hospitalization Ratio (SHR) Measure	2.14.10	For each day of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims
Standardized Mortality Ratio (SMR) Measure (Dialysis Facility Measures Only)	2.15.10	For each day of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims
Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients Measure (Dialysis Facility Measures Only)	2.16.10	For each day of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims
Percent of Prevalent Patients Waitlisted Measure	2.17.10	For each day of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims
Medication Reconciliation Reporting Measure (ESRD QIP Only)	2.21.7	For each month of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims

Table 16: Summary of Treatment Time Methods

3.1.6   Deriving Patient Date of Death

Because multiple sources report death information for the same patient, one patient may have several reported dates. Patient date of death is derived from multiple sources for Dialysis Facility Measures using a prioritized hierarchy.

For Dialysis Facility Measures, the death date is based on the hierarchy order below, with lower numbers having a higher priority:

1. CMS 2746 Death Notification form
2. CMS Medicare Enrollment Database
3. Patient Events reported in EQRS
4. SRTR Transplant data
5. CMS 2728 Medical Evidence form (only available on 2728 forms prior to 2005)
6. EQRS and SRTR Patient Lists
7. CMS Institutional Claims
8. Social Security Death Master File

ESRD QIP source for patient derived date of death will be the EQRS Patient Repository. ESRD QIP uses derived date of death to exclude all data for patients dated after derived date of death from the calculations, and to appropriately adjust patient attribution periods and terminate dialysis facility admissions and treatments in EQRS.

3.2   Linking Patient Data

3.2.1   Dialysis Facility Measures and ESRD QIP

Quality measures regularly combine information for the same patient from multiple data sources, most often between EQRS patient and Medicare claims data. These two different systems use independent key values such as claim beneficiary ID for claims and patient ID for EQRS to uniquely identify a patient but share common identifiers of MBI, HICN and SSN. Determining the relationship between claim beneficiary ID and patient ID is accomplished through a series of comparisons using MBIs, HICNs and SSNs, where a match or no match is assigned to each result. Non matches are submitted to the next comparison until all match attempts have been exhausted. When a match is identified, the EQRS patient ID is appended to the claim record.

The following is a description of the process as implemented:

- Create a dataset that includes all EQRS patients of interest, commonly known as a finder file. This dataset contains information such as a patient ID, date of birth (DOB), MBI, HICN and SSN. This finder dataset serves as one of two lookup tables.
- Create a dataset of historical MBI and HICN assignments for each EQRS patient. Order by patient ID and descending effective date so the most recent update is matched first. This history dataset servers as two of two lookup tables.
- Match each claim record against the finder lookup table then the history lookup table if not match is found. The order of lookups is outlined below.
  1. Attempt to match claim MBI and DOB with a finder file MBI and DOB, if a match is found append patient ID to the claim record and update the audit dataset noting where the match was found. End the process for the current EQRS patient and move to the next one.
     a. If a MBI and DOB match is not found, attempt a match using the historical dataset.

    b. If a match is found append patient ID to the claim record and update the audit dataset noting where the match was found.

    2. End the process for the current EQRS patient and move to the next one.

    3. Repeat this process for HICN and DOB until a match is found.

    4. Repeat this process without historical data for SSN and DOB until a match is found. Note: historical data for SSN does not exist.

- If at completion of the process a match has not been found, the claim appended patient ID is assigned the claim beneficiary ID as a negative value indicating a corresponding EQRS patient does not exist for that IDR claim.

The claim to EQRS patient matching process results in two output datasets, including claim records with an EQRS patient ID appended to the record, and a dataset with all matching results used to determine why a match did or did not occur. The following is a description of the process as implemented:

- Create a dataset that includes all EQRS patients of interest, commonly known as a finder file. This dataset contains information such as a patient ID, DOB, MBI, HICN and SSN. This finder dataset serves as one of two lookup tables.

- Create a dataset of historical MBI and HICN assignments for each EQRS patient. Order by patient ID and descending effective date. This history dataset serves as two of two lookup tables.

- Match each claim record against the finder lookup table then the history lookup table if not match is found. The order of lookups is as follows:
  1. Attempt to match claim MBI and DOB with a finder file MBI and DOB, if a match is found append patient ID to the claim record and update the audit dataset noting where the match was found. End the process for the current EQRS patient and move to the next one.
  2. If an MBI and DOB match is not found attempt a match using the historical dataset, if a match is found append patient ID to the claim record and update the audit dataset noting where the match was found. End the process for the current EQRS patient and move to the next one.
  3. Repeat this process for HICN and DOB until a match is found.
  4. Repeat this process without historical data for SSN and DOB until a match is found. Note historical data for SSN does not exist.

If at completion of the process a match has not been found, the claim appended patient ID is assigned the claim beneficiary ID as a negative value indicating a corresponding EQRS patient does not exist for any of the MBI, HICN or SSN values reported on that claim.

3.3 Facility Mapping and Impacts of Change of Ownership

3.3.1 Dialysis Facility Measures Specific

The next section provides an overview of the facility mapping that is used for creating a master facility list for the Quarterly Dialysis Facility Measures Compare Preview Reports. Facility mapping refers to the process by which provider numbers, in this case CMS Certification Numbers, are grouped together to define a single facility for quality measurement purposes.

3.3.2   Overview of Provider Numbers

The Dialysis Facility Measures use the CMS CCN as a primary provider identifier for quality measurement purposes. A valid CCN must be exactly six characters long. All but the first digit and last digit must be a number. The 6th digit can be an 'F', which indicates special purpose facilities. The middle two digits of the provider number indicate the type of the facility. Invalid provider numbers are deleted.

A **hospital-based facility** or **satellite facility** has two provider numbers associated with it. Besides its own provider number, it also has a hospital number that has '00' – '08' (Short Stay Hospitals), '13' (Critical Access Hospitals), '20' – '22' (Long-Term Hospital) or '33' (Children's Hospitals) as the middle two digits.

A dialysis service provider falls into one of the three main categories:

    (1) Freestanding (D25)

        25 – 28   Non-Hospital Renal Disease Treatment Centers

        29   Independent Special Purpose Renal Dialysis Facilities

    (2) Hospital based (D23)

        23 – 24   Hospital-Based Chronic Renal Care Facilities

    (3) Hospital satellites (D35)

        35- 36   Renal Disease Treatment Center (Hospital Satellites)

        37   Hospital-Based Special Purpose Renal Dialysis Facilities

3.3.3   Overview of Main Considerations Associated with Creating a Facility List

Issue 1: Various Data Sources Use Different Provider Numbers for the Same Facility

Provider numbers are used in various data files such as the medical evidence form, patient events file, the annual facility survey, facility cost reports, facility directory file, CMS survey and certification files, and Medicare claims. A major problem observed in these data sources is that hospital-based facilities (and hospital-satellite facilities) often utilize different provider numbers (ESRD or hospital) for different purposes. For example, a patient's Medical Evidence form may be filed under the hospital provider number, '210056', while Medicare dialysis claims were submitted under the ESRD provider number '212306'. The list below briefly describes many of the data sources that store one or more provider number fields.

The End Stage Renal Disease Quality Reporting System (EQRS): There are two fields, PROVNUM and ALTPROVNUM. For hospital-based dialysis facilities, either the ESRD provider number or the hospital provider number may be found in PROVNUM. Also, the ALTPROVNUM may be missing for hospital-based provider types. The following data are collected through EQRS and will have the same PROVNUM that is used in EQRS.

- **Annual Facility Survey (AFS) (CMS-2744)**
- **Medical Evidence Form (CMS-2728)**
- **Death Notification Form (CMS-2746)**
- **Facility Directory File**
- **Certification and Survey Provider Enhanced Report (CASPER) System:** ESRD provider numbers are stored in OSC_PROV_NUM. Any related or old provider numbers (ESRD or hospital) are stored in OSC_RELATED_PROV_NUM.

Medicare Claims: For hospital-based dialysis facilities, either the ESRD provider number or the hospital provider number may be used. CMS has instructed dialysis facilities to submit claims under their ESRD provider number (rather than hospital provider number).

Solution: Find all provider numbers that are associated with a given dialysis facility and create a lookup file that links all provider numbers (i.e., Medicare CCN numbers) that may be reported in the various data sources described above by a facility. This look up file is largely based on the EQRS facility directory file and CASPER provider of services files (See Section 3.3.6).

Issue 2: Change of Ownership (CHOW)

A facility may change provider numbers due to an ownership change or other reasons. With a change of ownership, the facility either retains the former provider number or is issued a new provider number.

Solution (CHOW rule): If a facility changes ownership and obtains a new Medicare provider number, the new provider number is treated as a new facility and is <u>not</u> manually linked to the old provider number(s). Instead, the new CCN is treated as a new facility and a Quarterly Dialysis Facility Measures Compare Preview Report is created for the new provider number only. If the provider number is retained (a new CCN is not issued), all information reported under this provider number, under the prior ownership, are also retained.

In some cases, errors are identified by facilities during the comment period, at which time they would request that the old provider number(s) be linked to the new provider number(s).

For more issues and rules associated with creating the facility list, please refer to Section 3.3.4.

3.3.4   Overview of the Facility List Creation Process

Two primary data sources are used to create the facility list: the EQRS facility directory file and CASPER provider of services files. The Dialysis Facility Measures Compare file, which is also extracted from EQRS, is also used to obtain newly certified facilities that will receive a Quarterly Dialysis Facility Measures Compare Preview report. These files are described in more detail in Section 3.3.6.

All facilities active as of the most recent data available will receive a Quarterly Dialysis Facility Measures Compare Preview Report.

The provider number reported on Dialysis Facility Measures is used as the main provider number for the Quarterly Dialysis Facility Measures Compare reports. For hospital-based or satellite facilities, this is either the ESRD or hospital provider number.

Step 1: Create provider number usage file.

Summary: This file summarizes the number of instances a provider number is reported in various CMS data files, such as the number of Medicare dialysis claims, medical evidence forms, the number of patients reported on the annual facility survey, and number of patient events (i.e., new ESRD patient, transfer in, transfer out, deaths), each year. The provider number usage file is used to help with the data cleaning process. In particular, this file is useful in determining which facility is utilizing the hospital CCN when a hospital number is associated with multiple ESRD facilities, or when a facility closed and/or changes ownership.

Step 2: Process the Dialysis Facility Measures file.

Summary: Process the Dialysis Facility Measures file received from CMS and append the current Dialysis Facility Measures data to the cumulative Dialysis Facility Measures file.

Step 3: Process the facility directory and services files.

Summary: Clean the provider number fields (PROVNUM & ALTPROVNUM) stored in the facility directory file as needed.

1. Eliminate invalid values for both PROVNUM and ALTPROVNUM.
    a. A valid value must be exactly 6 characters long.
    b. All but the 1st and 6th digits must be a number; the 6th digit can be 'F', which represents Veterans Affairs (VA) facilities. Note: We do not create reports for VA facilities.
2. Identify ESRD and HOSPITAL provider numbers for hospital-based facilities.
3. Select records for active facilities.

    The Facility Directory File is not restricted to dialysis facilities. It includes all types of outside organizations that are under the Networks. To select dialysis facilities that are active, the following variables may be used: *Facilityid, provtype, factype, dateclosed,certdate(facility_code)*. We create variables *current_record* and *current_idprov* to select the records for active facilities. Records with provider type (*provtype)* reported as "MEDICARE", "OTHER", "PENDING CERT" or missing; facility type (*factype)=*"Dialysis" and missing a closed date (*dateclosed)* are selected. In addition, the middle two digits of the CCN must be one of the values shown in Section 3.3.2. Variable facility_code indicates the type of facility certification and is retained for possible use in the future. Facilities missing provtype or certification date (but not both) are contacted by the ESRD helpdesk for this information in order to be included in the facility list.

    There are cases of multiple records in EQRS for a single facility and we employ different ways of handling different scenarios. One such scenario is when a facility's Medicare

provider number changed for any reason. A provider number could be changed at any point in time hence, a facility may have used more than one provider number resulting in two reports. A particular example of this is a change of ownership and issuance of a new provider number; the old and new provider numbers will be treated as separated entities and a report will be generated for the active facility only using its corresponding reported data. However, when there is a change of ownership, but the same provider number is retained, only one report will be created using all the data reported under that provider number.

Another scenario is when a provider number is associated with different EQRS facility ID. This has occurred when 1) a facility is shared by adult and pediatric units, or 2) by HD and PD units, or 3) a transplant facility and a dialysis facility, or 4) a permanent and temporary facility. The duplicate records with the same ESRD provider numbers are deleted and only one report is created.

In this step, data are output that identifies the active facilities. Transplant facilities and other facilities do not receive a Quarterly Dialysis Facility Measures Compare report and are output to other data files for data checking purposes only.

Step 4: Process and merge CASPER POS files (active and terminated) into one file to serve as a lookup file for the ESRD and hospital provider numbers of hospital-based dialysis facilities with missing ESRD or hospital provider numbers in the Facility Directory File.

Summary: Create a file that contains all active provider numbers. Note, there may be provider numbers listed in CASPER but not EQRS. Some variables are cleaned and corrected during the data creation processes.

Step 5: Create facility list and provider number lookup file.

Summary: Make a clean working copy of the EQRS facility directory file restricted to facilities receiving a Quarterly Dialysis Facility Measures Compare report. Then, for the hospital-based providers that are missing their hospital number or ESRD number, search for the missing CCN in the CASPER POS. These missing numbers may be reported in CASPER only (and not in EQRS).

1. For hospital-based facilities with missing hospital CCN, search for the ESRD CCN in the CASPER POS file.
2. For hospital-based facilities with missing ESRD CCN, search for the hospital CCN in the CASPER POS file. Also, from the CASPER POS file, obtain dialysis numbers that are not kept in the EQRS facility directory file (i.e., CASPER only provider numbers). Since more than one ESRD number could be associated with the same hospital, we also review the facility information (address, facility name, etc.) in order to determine which CCN is affiliated with the hospital. If there is an exact match on all the facility characteristics, the ESRD and hospital provider numbers are automatically linked, otherwise, we output the records for manual review. Records are grouped by Facility ID, address, name, and hospital number.

3. Create a unique provider variable used for Quarterly Dialysis Facility Measures Compare reporting and update the usage variables, variable labels, and formats.
4. Create the lookup file used to link all alternate/related provider numbers to the Dialysis Facility Measures provider number.
5. Manually link provider numbers previously requested by facilities that were approved by CMS.

Step 6: Create the Facility Information file.

Summary: This file includes the facility provider number(s), provider name, address, network, region, Dialysis Organization, certification date, open date, and services provided from the Dialysis Facility Measures file (created in Step 2) or facility services file (i.e., closed facilities that are not in the Dialysis Facility Measures file) received quarterly along with the EQRS facility directory file. All related provider numbers from these files (created in Step 5 above) are aggregated to a single record.

3.3.5 Additional Rules for Linking Provider Numbers

In Step 5 described above, a file is output for review from which the following scenarios are observed. In any of the cases described below, no two numbers will be linked together if both are reported on Dialysis Facility Measures. We consider there to be evidence of change of ownership when multiple records match on facility characteristics (name, address, etc.) and <u>also have</u> one of the following reported for one of the records: (1) a closed date, (2) new certification date, or (3) a name change indicating strong evidence of change of ownership (i.e., different dialysis organization inserted in name).

Issue 1: Two records match on facility characteristics or on facility ID in EQRS

Solution(s): If there is evidence of change of ownership, two reports are created. Otherwise, the two numbers are combined into a single report.

Issue 2: A record in EQRS matches on facility characteristics to a record reported in CASPER and all claims were submitted under the CASPER CCN

Solution(s): If there is evidence of change of ownership, two reports are created. Otherwise, the two numbers are combined into a single report.

Issue 3: Extra provider numbers

As described above in Step 3, if a second provider number of the same type (or any additional number for a freestanding facility) was reported as an alternate provider number in EQRS, it was stored as an 'extra' provider number.

Case 1: The alternate/extra provider number is not associated with any other facilities or reported on a separate record in EQRS.

Solution: Keep the alternate and main provider numbers linked in the report.

Case 2: The alternate/extra provider number is reported on a separate record in EQRS.

Solution: If there is evidence of change of ownership, do not link the alternate and main provider number. Otherwise, keep the alternate and main provider numbers linked in the report.

Case 3: The alternate provider number reported in EQRS for a freestanding provider is a hospital number. (i.e., PROVNUM = Freestanding & ALTPROVNUM= Hospital Number).

Solution(s):

a. If the hospital number was reported on Dialysis Facility Measures, a report is created for both the freestanding facility and hospital.

b. If a hospital-based or hospital-satellite ESRD CCN is found associated with the hospital CCN, then the alternate number is not linked to the freestanding provider number.

c. If no other ESRD numbers are found associated with the hospital CCN then the alternate provider number remains linked to the main number. If there were a separate record for the hospital CCN only and it is not reported on Dialysis Facility Measures then we would ignore the record (i.e., no separate report for hospital number).

Issue 4: Multiple ESRD provider numbers may be associated with the same hospital provider number

Solution: Search all data sources for all associated ESRD provider numbers and generate a report that includes the ESRD number usage, open and closed dates, certification dates, facility names, notes, etc. Generally, a hospital-based facility will be linked to the hospital number by definition (Case 1). However, if there are multiple hospital satellite facilities associated with the same hospital, the usage file is helpful. For example, if one hospital satellite facility has no usage under their ESRD number and the other hospital satellite facility does, we would link the hospital number to the first facility (Case 2).

Case 1: Both hospital-based and hospital satellite and/or freestanding facilities are associated with the same hospital number.

Solution: Link to the hospital-based facility by definition.

Case 2: Multiple hospital-based provider numbers are associated with the same hospital number.

Solution: Link to the facility with the least ESRD provider number usage.

Case 3: Multiple hospital-satellite facilities ('35') (and no hospital-based facilities) are associated with the same hospital number in EQRS.

Solution: Link to the hospital satellite facility with the least ESRD provider number usage.

3.3.6   Descriptions of the Data Files Used to Create the Facility List

3.3.6.1   Facility Directory File

The facility directory file is extracted from EQRS. The facility directory files include information such as the facility name, address, and telephone number, etc. Dialysis providers can be categorized into the following groups based on different criteria included in this file. Here are the most common:

- Active (open) or Closed Facilities
- Dialysis Facility or Transplant-only Facility
- Medicare Certified or Non-Medicare Certified Facility
- VA or Non-VA Facility
- Adult Facility or Pediatric Facility
- Permanent Facility or Temporary Facility

3.3.6.2   Facility Service File

This file is received quarterly along with the facility directory file; also extracted from EQRS. The original facility service file only has two columns which are used, ***facilityid*** and ***service***. The variable *facilityid* is the link between the facility directory file and the facility service file. The service information will be merged to the facility directory file for Dialysis Facility Measures during data processing.

3.3.6.3   Provider of Service File (POS)

The POS file is downloaded from the QIES Workbench, which includes data from the Certification and Survey Provider Enhanced Report System (CASPER) is used by the State Surveyors for recording results of surveys for certification or subsequent inspection of dialysis facilities. CASPER POS file is more "official" than EQRS facility directory file in the sense that it is tied to the certification process, but new facilities or changes to existing facilities may show up in EQRS before they show up in CASPER. These files are downloaded monthly.

The CASPER POS files include information for both active and terminated facilities.

3.3.6.4   Dialysis Facility Measures File

The Dialysis Facility Measures project covers all open facilities at a given time. The Dialysis Facility Measures facility list is extracted quarterly from EQRS. This file only included the CMS certification number prior to June 2015, so fields such as facility names and addresses were used to determine the linkage of provider number. However, beginning in June 2015, the EQRS facility ID was added to the file and used to determine the linkages in addition to facility characteristic variables.

3.3.7 ESRD QIP Facility List and Changes of Ownership

When a facility submits data to EQRS, claims, the ICH-CAHPS survey, or CDC's NHSN using multiple CCNs, all data are combined for the facility to avoid penalizing the facility for using multiple CCNs. For scoring and feedback purposes, results are reported under the "primary" CCN for the dialysis facility and include data for an "alternate" CCN that may have been used in other data sources. Changes of ownership have the further consideration of ensuring patient data associated with a prior facility owner do not impact the facility's QIP score under the current owner.

- EQRS assigns a facility ID to each physical building and sub-unit providing dialysis. When data are extracted, the system automatically supplies the current CCN for each facility ID. This needs to be converted to CCN in effect as of the date the care was provided for ESRD QIP measures relying on data prior to an ownership change.

- Historical facility ownership changes are documented and used to assign patients to an appropriate facility CCN for measures requiring attribution of patient care to facilities.

- All facility records in EQRS are evaluated to determine which are eligible to receive ESRD QIP reports and which may be used in the statistical modeling to support the standardized ratio measures (but not receive an ESRD QIP report).

- EQRS is the primary data source for facility information; however, potential issues are identified by comparison with the Dialysis Facility Measures facility list and data availability in other CMS data sources. Research of those issues is supported through Provider of Services (POS), QIES, annual facility survey (CMS form 2744) and Medical Evidence (CMS form 2728), contact with Networks, prior facility list versions, and other supporting information, such as newspaper articles, and press releases regarding changes to facilities. Evidence that is considered when deciding if different CCNs represent a single facility or different facilities includes:
  o Primary CCN and alternate CCN in prior years of QIP.
  o Shared physical address in EQRS and POS.
  o Comparison of dates CCN was certified and was closed/terminated from EQRS, POS, and QIES.
  o CCN assignment convention using middle two digits (positions 3 and 4 of the 6 character CCN) (described in Section 3.3.2 above) to identify the dialysis facility as "primary" CCN.
  o EQRS database facility information audit logs that indicate date, time, and user altering a facility's CCN.
  o EQRS admits and discharges for each facility for each month covered by the QIP data window.
  o Medicare claims for each CCN for each month covered by the QIP data window.

3.3.8   ESRD QIP EQRS Facility Record Consolidation

EQRS assigns different facility IDs to units that share a CCN. This happens most frequently when there are adult and pediatric units, or HD and PD units. For these cases, data for these multiple facility IDs are consolidated under a single CCN for ESRD QIP calculations. Then one of the "merged" facilities becomes the primary source and is used for the basis for ESRD QIP reports as well as attributes such as name and address.

3.3.9   ESRD QIP EQRS Data Clean-up

- EQRS data entry errors, or other inaccuracies, need to be corrected for ESRD QIP scoring and feedback reports until the facility or network updates the information in EQRS. An example might be errors in dates. The date a facility was certified or the date it was closed could have digits transposed, wrong month, etc.

- ESRD QIP scoring and feedback reports use the dialysis facility CCN as primary when associated with an alternate CCN. If this is not what is observed in EQRS, this order is forced through a data quality update process for ESRD QIP reports.

- EQRS has duplicate CCNs which do not cause problems internally to EQRS but can cause duplication and distortion of ESRD QIP measure calculations. Therefore, for scoring and feedback purposes, duplicated CCNs are removed from the ESRD QIP facility list.

3.3.10   ESRD QIP Eligibility

All outpatient dialysis facilities open on the last day in the performance year are eligible for ESRD QIP scores and reports. EQRS, claims and CDC's NHSN include other facilities, such as hospitals or transplant centers, which are used to provide data supporting the measures but are not eligible for scoring or reports. The eligibility criteria are:

- Facility CCN is not missing or null.
- Facility is not closed on the last day of the performance year.
- Facility certification date is on or before the last day of the performance year.
- Facility CCN has six digits with no alpha characters in the 2nd through 5th digit.
- Facility provider type in EQRS is "Medicare".
- Facility program type in EQRS is "Dialysis".

3.3.11   CCN History for ESRD QIP

Facility ownership changes that result in a facility receiving a new CCN are treated as if the facility closed under the prior CCN then re-opened under the new CCN. This has the effect of severing the past performance under the prior CCN from current data submitted with the new CCN. CMS intends that when a CCN changes, care provided under the prior management does not influence the new management's ESRD QIP scores, preventing the prior management impacting the new management's payment reduction (if any). For the standardized ratio measures, patient events (hospitalizations for SRR and SHR) are assigned to the facility

responsible for their care at the time of the hospitalization. If that care was provided under the prior management, the new management will not be held responsible for that care.

3.4 Extraordinary Circumstances Exception

CMS offers a process for dialysis facilities to request, and for CMS to grant, exemptions when extraordinary circumstances occur beyond the control of the facility that prevent timely submission of data supporting ESRD QIP. In this way, CMS ensures that facility performance during the extraordinary circumstance does not factor into ESRD QIP scores.

In the event of such circumstances, dialysis facilities must submit an Extraordinary Circumstances Exception (ECE) Request Form. The facility may request consideration for an exemption from the ESRD QIP for that payment year. The form must be signed by the dialysis facility's chief executive officer or designee and submitted via email to the ESRD QIP Mailbox at ESRDQIP@cms.hhs.gov. This form must be submitted within 90 days as of the date of the event of the ECE for the ESRD QIP.

For QIP, dialysis facilities granted an ECE will be exempt from all reporting requirements of the ESRD QIP clinical and reporting measures for the months covered by the ECE. Details regarding how the ECE applies to each measure are listed below:

Measure	How ECE applies to the measure calculations
Kt/V Dialysis Topic	• All months covered by a granted ECE excluded from the measure calculations. • Kt/V lab values reported by facilities during granted ECE months are not used in calculations; specifically, if PD Kt/V values reported during the ECE months are during the four-month study period for adult or six-month study period for pediatric, they would not be used in calculations. • Claims reported during ECE months would not be used in calculations.
ICH CAHPS	• Facilities with granted ECE would be excluded from the measure calculations. One or both sampling periods may be excluded, depending on circumstances of ECE.
Long-term Catheter Rate	• All months covered by a granted ECE would be excluded from the measure calculations. • Vascular access type data reported by facilities during granted ECE months would not be used in calculations. Additionally, vascular access type data reported during ECE months will not be used to determine the patient's time with catheter in use.
Standardized Readmission Ratio	• Index discharges occurring during granted ECE months would be excluded from the measure calculations. • Readmissions occurring during granted ECE months would be used in calculations if associated with an index discharge occurring in a non-ECE month.
Standardized Hospitalization Ratio	• Days covered by granted ECE months would be excluded from the patient-years at risk calculations. • Hospitalizations that occurred during granted ECE months would be excluded from the measure calculations.
Percentage of Prevalent Patients Waitlisted	• All months covered by a granted ECE would be excluded from the measure calculations.

Measure	How ECE applies to the measure calculations
NHSN Bloodstream Infection Ratio	• Facilities with granted ECE would be excluded from the measure calculations.
Standardized Transfusion Ratio	• Days covered by granted ECE would be excluded from the patient-years at risk calculations. • Transfusions that occurred during granted ECE months would be excluded from the measure calculations.
Hypercalcemia reporting	• All months covered by a granted ECE would be excluded from the measure calculations.
Medication Reconciliation reporting	• All months covered by a granted ECE would be excluded from the measure calculations.
Clinical Depression	• Calculations will exclude the months covered by a granted ECE.
COVID-19 HCP Vaccination reporting	• Calculations will exclude the months covered by a granted ECE.
Facility Commitment to Health Equity reporting	• Calculations will exclude the months covered by a granted ECE.
Screening for Social Drivers of Health reporting	• Calculations will exclude the months covered by a granted ECE.
Screen Positive Rate for Social Drivers of Health reporting	• Calculations will exclude the months covered by a granted ECE.

Table 17: Application of ECE by Measure

More information on the ECE program is available on the QualityNet website at:

https://qualitynet.cms.gov/esrd/esrdqip/participation#tab5

For Dialysis Facility Measures, there is no ECE. Facilities can request suppression during the preview period, and those requests are evaluated on a case-by-case basis.

3.5   Start Dates for Reporting Measures Data by New Facilities

New facilities are required to collect and report EQRS or NHSN data for purposes of the ESRD QIP beginning with services furnished on the first day of the month that is four months after the month in which the CCN becomes effective. For example, if a facility is certified in January of the performance period, the facility is not required to report data until May 1 of the performance period.

4.   Methodologies for Deriving ESRD QIP Scores

The services for which quality is measured under the ESRD QIP are renal dialysis services defined in section 1881(b)(14)(B) of the Social Security Act (SSA). Prior to January 1, 2017, these services could only be covered and reimbursed under Medicare if they were furnished to individuals with ESRD, but with the passage of the Trade Preferences Extension Act of 2015, these services are now also covered and reimbursed if they are furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the SSA to individuals with AKI (see section 1861(s)(2)(F) and 1834(r) of the SSA). In response to stakeholder concerns regarding the impact that AKI patients may have on ESRD QIP measure scores, and because CMS would like to learn more about this population and ensure AKI patients are included only as clinically appropriate, CMS has decided to exclude data from AKI patients from all of its measure score calculations for the ESRD QIP and Dialysis Facility Measures, pending future consideration of their inclusion on a measure-by-measure basis.

4.1   Calculating an ESRD QIP Score from a Facility's Performance Rate on a Clinical Measure

A measure rate of "No Rate" is assigned for measures from which a facility has been excluded from rate calculations, as defined by each measure's specifications. Scoring methodologies for reporting measures in ESRD QIP are described in the sections of the *Manual* that cover those measures. Facilities receiving a performance rate on a clinical measure in the ESRD QIP will receive a small facility adjustment to the Performance Period rate (if applicable), and then the achievement and improvement scoring methodology is employed.

4.1.1   Small Facility Adjustment

Facilities with a low patient census or nominal amounts of certain clinical events may be eligible to receive a favorable adjustment to their achievement score. This adjustment, known as the Small Facility Adjuster, is applied to account for one patient or event skewing a facility's measure score. A small facility adjustment may be applied to all clinical measures except ICH CAHPS.

The value of a facility's small facility adjustment for a measure depends on that facility's number of measure units for the measure, as well as that facility's unadjusted measure rate. The adjustment will be added to measure rates for which a higher rate indicates better performance and subtracted from those for which a lower rate indicates better performance. That is, the adjustment will always be applied to improve the facility's performance rate.

- The small facility adjustment will be applied to each clinical measure rate, for each eligible facility, for the performance period. This adjusted rate will then be used to calculate both the facility's achievement and improvement scores for the measure. Please note that there is no adjustment made to the ICH CAHPS clinical measure.

- A facility having between the lower and upper threshold (inclusive) of eligible patients (or other appropriate unit) —and thus being eligible for the small facility adjustment— will be determined independently for each measure. See Table 18 below.
- The system will store and report both the unadjusted and adjusted measure rates, for each facility for each measure to which the adjustment was applied.

Measure	Lower Threshold (L)	Upper Threshold (C)	Preferred Measure Rate Directionality	Measure Unit
Risk-Standardized Readmission Rate	11	41	Lower Rate indicates better performance	Index Discharges
Risk-Standardized Hospitalization Rate	5	14	Lower Rate indicates better performance	Patient-years at Risk
VAT: Long-Term Catheter Rate	11	25	Lower Rate indicates better performance	Eligible Patients
Adult Hemodialysis Adequacy	11	25	Higher Rate indicates better performance	Eligible Patients
Adult Peritoneal dialysis Adequacy	11	25	Higher Rate indicates better performance	Eligible Patients
Pediatric Hemodialysis Adequacy	11	25	Higher Rate indicates better performance	Eligible Patients
Pediatric Peritoneal dialysis Adequacy	11	25	Higher Rate indicates better performance	Eligible Patients
Risk-Standardized Transfusion Rate	10	21	Lower Rate indicates better performance	Patient-years at risk
NHSN Bloodstream Infection in Hemodialysis Outpatients	11	25	Lower Rate indicates better performance	Eligible Patients
PPPW	11	25	Higher Rate indicates better performance	Eligible Patients
Clinical Depression	11	25	Higher Rate indicates better performance	Eligible Patients

Table 18: PY 2027 Clinical Measures and the Defined Lower Threshold, Upper Threshold, Preferred Measures Rate Directionality, and the Measure Unit for Each Measure

The following describes the steps for calculating a small facility adjustment for a facility's clinical measure rate:

1) Apply measure exclusions to determine the number of measure units (MUs) at the facility during the performance period.
2) Calculate the Benchmark (B), which is set to 90th percentile for each clinical measure using the applicable performance period data.
3) Calculate the facility's unadjusted measure rate (UMR) for the measurement period.
4) Determine the number of unique, eligible MUs at the facility during the performance period (n). If the facility's number of MUs is greater than or equal to the lower threshold (L) AND less than or equal to the upper threshold (C), the small facility adjustment process begins:

a) Calculate the weighted coefficient for a given clinical measure (w) by dividing the number of MUs during the performance period (n) by the defined upper threshold plus one for the given measure (C+1).

b) Determine the preferred measure rate directionality for the given clinical measure:

- For measures where the higher rates are better (for example, the PPPW clinical measure and the Comprehensive Dialysis Adequacy clinical measures), a small facility's adjusted performance rates (t) will be calculated as follows:

    - If the unadjusted measure rate for the facility (p) is less than the Benchmark (B), then the system will use the following calculation to determine the small facility's adjusted measure rate (t):

    - Step 1: Subtract the weighted coefficient (w) from one (1).
    - Step 2: Multiply the result from Step 1 by the Benchmark (B).
    - Step 3: Multiply the weighted coefficient (w) by the performance rate (p).
    - Step 4: Add the results from Step 2 and Step 3 to get the small facility's adjusted measure rate (t) using the following equation:

$$\text{If } p<B, \text{ then } t = [w * p] + [(1-w) * B]$$

If the unadjusted measure rate for the facility (p) is greater than or equal to the Benchmark (B), the facility will not receive an adjustment.

For measures where lower rates are better (for example, VAT: Catheter, NHSN BSI and SRR), a small facility's adjusted measure rates (t) will be calculated as follows:

- If the unadjusted measure rate for the facility (p) is greater than the Benchmark (B), then use the following calculation to determine the small facility's adjusted performance rate (t):
    - Step 1: Subtract the weighted coefficient (w) from one (1).
    - Step 2: Multiply the result from Step 1 by the Benchmark (B).
    - Step 3: Multiply the weighted coefficient (w) by the performance rate (p).
    - Step 4: Subtract the results from Step 2 and Step 3 to get the small facility's adjusted measure rate (t) using the following equation:

$$\text{If } p>B \text{ then } t = [w * p] + [(1-w) * B]$$

If the unadjusted measure rate for the facility (p) is less than or equal to the Benchmark (B), the facility will not receive an adjustment.

4.1.2   Achievement and Improvement Scoring

Key Achievement and Improvement Definitions for Clinical Measure Scoring for Payment Year (PY) 2027

Table 18 defines key achievement and improvement scoring terms.

Term	Definition
Achievement threshold	The 15th percentile of performance rates nationally during 2023
Benchmark	The 90th percentile of performance rates nationally during 2023
Improvement threshold	Your facility's performance rate during 2024
Performance period	All of CY 2025
Performance standard	The 50th percentile of performance rates nationally during 2023
Facility performance rate	The percentage of a facility's patients either meeting or falling short of a measure's requirements during the performance period

Table 19: Key Achievement and Improvement Scoring Terms

A higher measure rate does not necessarily indicate a better score. See the respective measure chapters for details on preferred directionality of each measure.

A facility's score for each clinical measure is calculated using the achievement and improvement scoring methodology. The score is based on the facility's performance rate during the performance period compared to two ranges.

The **achievement range** is the scale running from the achievement threshold to the benchmark (15th Percentile – 90th percentile of performance rates nationally during 2023).

Each facility can earn 0–10 points for achievement.

The **improvement range** is the scale running from the improvement threshold to the benchmark (Facility performance rate during 2024 – 90th percentile of performance rates nationally during 2023).

Each facility can earn 0–9 points for improvement.

A facility's scores for achievement and improvement are based on where a facility's performance rate falls on the achievement and improvement ranges, respectively.

The score for each measure is based on the higher of the achievement or improvement score for that measure.

4.1.2.1   Calculating an Achievement Score

If a facility's performance meets or exceeds the achievement benchmark, the facility receives 10 points for achievement and no achievement score is calculated.

Note: for measures with a lower desired directionality, "meet or exceeds" indicates a rate that is less than or equal to the achievement benchmark.

If facility's performance rate is below the achievement threshold, a facility receives 0 points for achievement and no achievement score is calculated.

Note: for measures with a lower desired directionality, facility will receive a zero if their performance rate is greater than the achievement threshold.

If a facility's performance rate falls within the achievement range (i.e., between the achievement threshold and the benchmark), then the facility score is calculated using the following equation:

$$9 \times \left[\frac{\text{Facility's Performance Period Rate} - \text{Achievement Threshold}}{\text{Benchmark} - \text{Achievement Threshold}} \right] + 0.5$$

The score is then rounded to the nearest integer, with halves rounded up, resulting in an achievement score of 1 to 10.

Note: Measure rates, achievement thresholds, and benchmarks, are all rounded to the same degree of precision when calculating achievement scores.

4.1.2.2   Calculating an Improvement Score

If the facility's performance rate is below the facility improvement threshold, the facility receives 0 points for improvement and no improvement score is calculated.

Note: for measures with a lower desired directionality, facility will receive a zero if their performance rate is greater than the achievement threshold.

If a facility's performance rate or improvement threshold meets or exceeds the benchmark, no improvement score is calculated.

Note: for measures with a lower desired directionality, meet or exceeds indicates a rate that is less than or equal to the benchmark.

If a facility's performance rate falls between the improvement threshold and the benchmark, the following equation is used to calculate the facility's improvement score:

$$10 \times \left[\frac{\text{Facility's Performance Period Rate} - \text{Improvement Threshold}}{\text{Benchmark} - \text{Improvement Threshold}} \right] - 0.5$$

The score is then rounded to the nearest integer, with halves rounded up.

Note: Unlike the achievement score, the facility can only earn a maximum of nine points for improvement.

If a facility does not have sufficient data to calculate a measure improvement rate during 2024 but does have sufficient information to calculate an achievement rate during 2025, then the facility score for that measure is based solely on achievement.

Note: Measure rates, achievement thresholds, and benchmarks are all rounded to the same degree of precision when calculating improvement scores.

4.1.3   Scoring for ICH CAHPS Clinical Measure

The ICH CAHPS survey is scored based on three composite measures and three global ratings:

- Three Composite measures.
    - Nephrologists' Communication and Caring (6 questions).
    - Quality of Dialysis Center Care and Operations (12 questions).
    - Providing Information to Patients (9 questions).
- Three Global ratings (Scale of 0-10).
    - Overall rating of nephrologists.
    - Overall rating of the dialysis center staff.
    - Overall rating of the dialysis facility.
- Each composite measure/global rating is scored via achievement and improvement methods, with facilities receiving the better result for each.
- Scores on the six components will be averaged to form the ICH CAHPS measure score.

If the facility does not meet the survey administration and reporting requirements, the facility will receive a zero on the ICH CAHPS clinical measure, regardless of how many surveys were returned.

Note: The ICH CAHPS survey is administered twice within a single performance period. All calculations will be conducted using a single data set that is compiled from the aggregation of the two surveys submissions.

4.1.4   Scoring Measure Topics

After scores are calculated for each individual measure, one group of measures is then combined to form a single measure topic score. This process is applied to the four individual Kt/V clinical

measures (Adult Hemodialysis (HD), Adult Peritoneal Dialysis (PD), Pediatric HD, and Pediatric PD). The scores for this measure topic are discussed below in the example table template.

4.1.4.1   Kt/V Dialysis Adequacy Measure Topic

The scores for the Kt/V Dialysis Adequacy measure topic are calculated using the following steps.

1) Identify the individual measure scores within each measure topic (see section 4.1.2 for more information).

#	Calculation Definition
Clinical Measure Scores	
a	Kt/V Adult Hemodialysis Measure Score
b	Kt/V Adult Peritoneal Dialysis Measure Score
c	Kt/V Pediatric Hemodialysis Measure Score
d	Kt/V Pediatric Peritoneal Dialysis Measure Score

2) Determine the total number of patients for weighting the denominator. This number is calculated by taking the sum of all eligible patients included in each measure within the measure topic.

#	Calculation Definition
Measure Weight Calculation	
e	Number of patients included in Kt/V Adult Hemodialysis Measure Score calculation
f	Number of patients included in Kt/V Adult Peritoneal Dialysis Measure Score calculation
g	Number of patients included in Kt/V Pediatric Hemodialysis Measure Score calculation
h	Number of patients included in Kt/V Pediatric Peritoneal Dialysis Measure Score
i	Determine total number of patients for weighting denominator *Add e + f + g + h*

3) Determine the weighted score for each measure within the topic. This is done by dividing the number of patients included in each individual measure by the total number of patients across all measures within the measure topic, and multiplying by the respective measure score.

Note: When determining the total number of patients across all measures within a topic only eligible measures are considered.

#	Calculation Definition
Measure Weight Calculation	
j	Weight the Kt/V Adult Hemodialysis Measure Score *Calculate a x (e ÷ i)*
k	Weight the Kt/V Adult Peritoneal Dialysis Measure Score *Calculate b x (f ÷ i)*
l	Weight the Kt/V Pediatric Hemodialysis Measure Score *Calculate c x (g ÷ i)*
m	Weight the Kt/V Pediatric Peritoneal Dialysis Measure Score

	Calculate c x (g ÷ i)
n	Combine Measure Scores
	Add j + k + l + m and round
o	**Kt/V Dialysis Adequacy Measure Topic Score (from n)**

4) Finally, to determine the measure topic score, sum the weighted measure scores of each eligible measure and round to the nearest whole number with halves rounded up.
Note: The number of patients is used when calculating measure topic scores regardless of whether the measure uses patients or patient months in its denominator. Furthermore, the number of patients represented in the denominator during the performance period is used regardless of whether the assigned measure score was taken from the achievement or improvement methodology.

4.2 Calculating a Facility's Total Performance Score from the Facility's Measure Scores

To qualify for a Total Performance Score (TPS), the facility must have earned a score on at least one measure in two of the five domains. A facility that does not meet the requisite number of scored domains will receive a TPS of "No Score".

A facility's individual measure scores are used to determine the facility's five measure domain scores, which are then used to determine the facility's TPS. The five measure domains are listed below, and the methodology for calculating domain scores and TPS are described in more detail in subsequent sections:

- **Patient and Family Engagement Measure Domain**
- **Care Coordination Measure Domain**
- **Clinical Care Measure Domain**
- **Safety Measure Domain**
- **Reporting Measure Domain**

4.2.1 Calculating the Patient and Family Engagement Measure Domain

The Patient and Family Engagement Measure Domain is comprised of one measure, the ICH CAHPS Measure. As seen in Table 20 below, the individual measure is assigned a specific weight as a percent of the domain score. This weighted score then makes up the Patient and Family Engagement Measure Domain score.

PY 2027 Patient and Family Engagement Measure	**PY 2027 Measure Weight in the Patient and Family Engagement Measure Domain**
ICH CAHPS Measure	100.00%

Table 20: Patient and Family Engagement Measure Weight

Example 1: Eligible for all Measures in the Patient and Family Engagement Domain for PY 2027

Patient and Family Engagement Measure Domain
PY 2027

Measure	Measure Score
ICH CAHPS	9

$$(1.0000 \times [\text{ICH CAHPS}]) \quad \times \, 10$$

$$(1.0000 \times 9) \quad \times \, 10$$

Patient and Family Engagement Measure Domain Score = 90.000
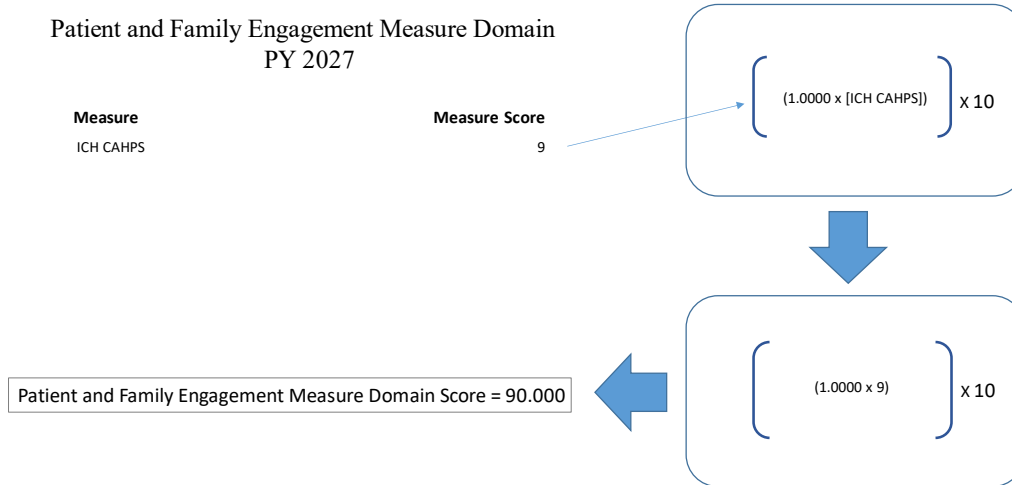
## 4.2.2   Calculating the Care Coordination Measure Domain Score

The Care Coordination Measure Domain is comprised of four measures. As seen in Table 20 below, each individual clinical measure is assigned a specific weight as a percent of the domain score.

PY 2027 Care Coordination Measures	PY 2027 Measure Weight in the Care Coordination Measure Domain
SRR Measure	25.00%
SHR Measure	25.00%
PPPW Measure	25.00%
Clinical Depression Measure	25.00%

Table 21: Care Coordination Measure Weights

In order to calculate the Care Coordination Measure Domain Score, each individual measure score is converted to a weighted measure score. These scores are then summed up and multiplied by 10 to equal the Care Coordination Measure Domain score. See the example below for a hypothetical scenario of the Care Coordination Measure Domain Score calculation.

Example 2: Eligible for all Measures in the Care Coordination Domain for PY 2027

Care Coordination Measure Domain
PY 2027

Measure	Measure Score
SRR	8
SHR	8
PPPW	7
Clinical Depression	10

$$\left[\begin{array}{c} (.2500 \times [SRR]) \\ + \\ (.2500 \times [SHR]) \\ + \\ (.2500 \times [PPPW]) \\ + \\ (.2500 \times [CD]) \end{array} \right] \times 10$$

$$\left[\begin{array}{c} (.2500 \times 8) \\ + \\ (.2500 \times 8) \\ + \\ (.2500 \times 7) \\ + \\ (.2500 \times 10) \end{array} \right] \times 10$$

Care Coordination Measure Domain Score = 82.500
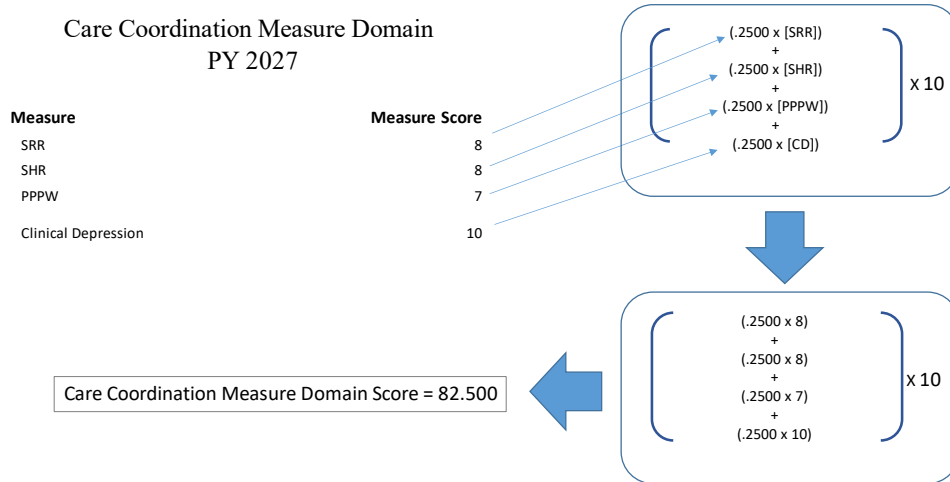
## 4.2.3   Calculating the Clinical Care Measure Domain Score

The Clinical Care Measure Domain is comprised of three measures. As seen in Table 22 below, each individual clinical measure is assigned a specific weight as a percent of the domain score.

PY 2027 Clinical Care Measures	PY 2027 Measure Weight in the Clinical Care Measure Domain
STrR Measure	34.29%
Kt/V Dialysis Adequacy Measure Topic	31.43%
Long-Term Catheter Measure	34.29%

Table 22: Clinical Care Measure/Measure Topic Weights

In order to calculate the Clinical Care Measure Domain Score, each individual measure score is converted to a weighted measure score. These scores are then summed up and multiplied by 10 to equal the Clinical Care Measure Domain score. See the example below for a hypothetical scenario of the Clinical Care Measure Domain Score calculation.

Example 3: Eligible for all Measures in the Clinical Care Domain for PY 2027

Clinical Care Measure Domain
PY 2027

Measure	Measure Score
STrR	10
Kt/V Dialysis Adequacy Topic	10
Long Term Catheter rate	9

$$\left[\frac{(.3429 \times [STrR])}{+ (.3143 \times [Kt/V \text{ Topic}]) +} (.3429 \times [LTC]) \right] \times 10$$

$$\left[(.3429 \times 10) + (.3143 \times 10) + (.3429 \times 9) \right] \times 10$$

Clinical Care Measure Domain Score = 96.581
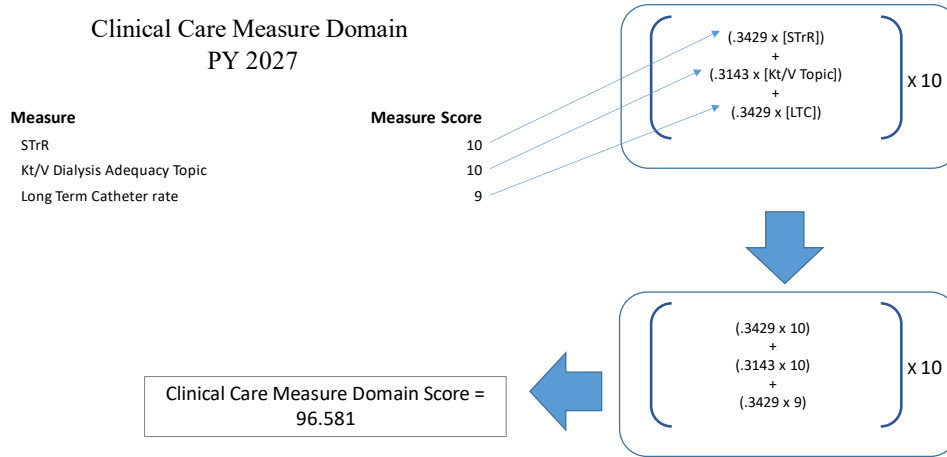
4.2.4   Calculating the Safety Measure Domain Score

The Safety Measure Domain is comprised of one measure, the NHSN BSI Measure. As seen in Table 23 below, the individual measure is assigned a specific weight as a percent of the domain score. This weighted score then makes up the Safety Measure Domain score.

PY 2027 Safety Measure	PY 2027 Measure Weight in the Safety Measure Domain
NHSN BSI Clinical Measure	100.00%

Table 23: Safety Measures Weights

Example 4: – Calculating the Safety Measure Domain in PY 2027

Safety Measure Domain
PY 2027

Measure	Measure Score
NHSN BSI Clinical Measure	9

$(1.0000x\ [NHSN\ BSI])$ x 10

(1.0000×9) x 10

Safety Measure Domain Score = 90.000
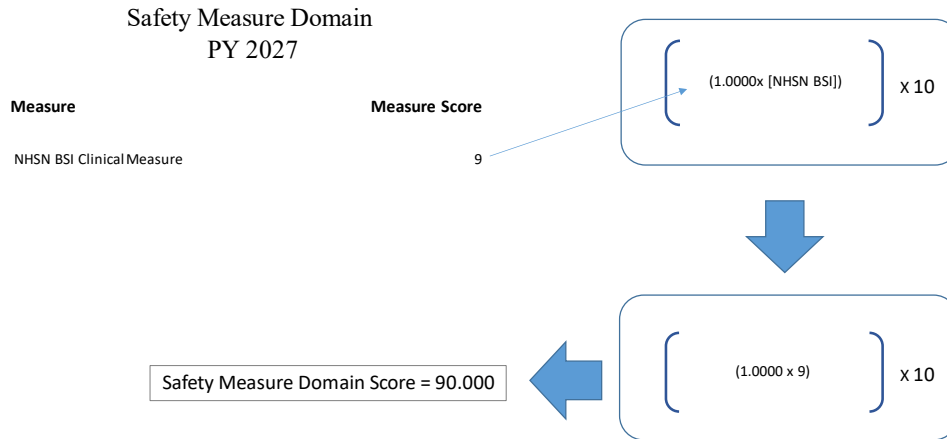
4.2.5   Calculating the Reporting Measure Domain Score

The Reporting Measure Domain is comprised of six measures for PY 2027. As seen in Table 24 below, each individual reporting measure is assigned a specific weight as a percent of the domain score.

PY 2027 Reporting Measures	PY 2027 Measure Weight in the Reporting Measure Domain
Hypercalcemia Reporting Measure	16.67%
MedRec Reporting Measure	16.67%
Facility Commitment to Health Equity Reporting Measure	16.67%
HCP COVID-19 Vaccination Reporting Measure	16.67%
Screening for Social Drivers of Health Reporting Measure	16.67%
Screen Positive Rate for Social Drivers of Health Reporting Measure	16.67%

Table 24: Reporting Measures Weights for PY 2027

In order to calculate the Reporting Measure Domain Score, each individual measure score is converted to a weighted measure score. These scores are then summed up and multiplied by 10

to equal the Reporting Measure Domain score. See the example below for a hypothetical scenario of the Reporting Measure Domain Score calculation.

Example 5: Eligible for all Measures in the Reporting Measure Domain for PY 2027

Reporting Measure Domain
PY 2027

Measure	Measure Score
Hypercalcemia	10
MedRec	10
Screening for Social Drivers of Health	9
Screen Positive Rate for Social Drivers of Health	8
Facility Commitment to Health Equity	10
HCP COVID-19 Vaccination	9

(.1667 x [Hypercalcemia])
+
(.1667 x [MedRec])
+
(.1667 x [Screening])
+
(.1667 x [Screen Positive])
+
(.1667 x [Commitment to Health Equity])
+
(.1667 x [COVID-19 Vaccination])
x 10

(.1667 x 10)
+
(.1667 x 10)
+
(.1667 x 9)
+
(.1667 x 8)
+
(.1667 x 10)
+
(.1667 x 9)
x 10

Reporting Measure Domain Score = 93.352

4.2.6   Calculation of TPS Using Domain Weights and Scores

The TPS is comprised of the five measure domains below and their associated weights:

Patient and Family Engagement Measure Domain: 15%

Care Coordination Measure Domain: 30%

**Clinical Care Measure Domain: 35%**

Safety Measure Domain: 10%

Reporting Measure Domain: 10%

The TPS for the facility is calculated by multiplying the Patient and Family Engagement Domain score by 0.15, the Care Coordination Domain score by 0.30, the Clinical Care Domain score by 0.35, the Safety Domain score by 0.10 and the Reporting Domain Score by 0.10 and adding the results, as follows:

$$TPS = (0.15 * Patient\ and\ Family\ Engagement\ Domain\ Score)$$
$$+ (0.30 * Care\ Coordination\ Domain\ Score)$$
$$+ (0.35 * Clinical\ Care\ Domain\ Score) + (0.10 * Safety\ Domain\ Score)$$
$$+ (0.10 * Reporting\ Domain\ Score)$$

The TPS is rounded to the nearest integer, with halves rounded up, resulting in a range from 0–100 points.

Example 6: Total Performance Score Calculation for PY 2027

Total Performance Score PY 2027

Domain	Domain Score
Patient and Family EngagementMeasure Domain	90.000
Care CoordinationMeasure Domain	82.500
Clinical Care Measure Domain	96.581
Safety Measure Domain	90.000
Reporting Measure Domain	93.352

(.1500 x [Patient and Family Engagement Domain])
+
(.3000 x [Care Coordination Domain])
+
(.3500 x [Clinical Care Measure Domain])
+
(.1000 x [Safety Measure Domain])
+
(.1000 x [Reporting Measure Domain])

(.1500 x 90.000)
+
(.3000 x 82.500)
+
(.3500 x 96.581)
+
(.1000 x 90.000)
+
(.1000 x 93.352)

Total Performance Score = 90

4.2.7   Calculation of TPS From a Facility's Measure Scores When Missing At Least One Measure Score

Facilities are eligible to receive a TPS score if they receive a score for at least one measure in two out of the five domains. The redistribution of the missing measure's weight (both as a percent of TPS and as a percent of its assigned domain), along with an illustrative example, is described in more detail below.

4.2.7.1   Redistributing Measure Weights When a Facility Is Not Scored on a Measure

If a facility does not meet the eligibility requirements for a measure, the facility is not scored on the measure and the corresponding weight will be redistributed across the measures for which the facility receives a score. This redistribution will occur evenly across the measures remaining in the missing measure's domain. As long as a facility receives at least one measure score in all

five domains, the domain weights will not change. Section 4.2.8.1. explains how to redistribute the weight of a domain that is missing all of its measures.

Table 25 provides an example of this redistribution, showing the measure weights as a percent of TPS and as a percent of the domain score when the Kt/V Topic measure is missing.

Measure/Measure Topics by Domain	Measure Weight as a Percent of Domain	Measure Weight as a Percent of TPS	Measure Weight as a Percent of Domain Absent Kt/V	Measure Weight as a Percent of TPS Absent Kt/V
PATIENT & FAMILY ENGAGEMENT MEASURE DOMAIN				
ICH CAHPS measure	100.00%	15.00%	100.00%	15.00%
		15.00% of TPS		**15.00% of TPS**
CARE COORDINATION MEASURE DOMAIN				
SRR measure	30.00%	9.00%	30.00%	9.00%
SHR measure	30.00%	9.00%	30.00%	9.00%
PPPW measure	20.00%	6.00%	20.00%	6.00%
Clinical Depression measure	20.00%	6.00%	20.00%	6.00%
		30% of TPS		**30% of TPS**
CLINICAL CARE MEASURE DOMAIN				
Kt/V Dialysis Adequacy Topic measure	31.43%	11.00%	N/A	N/A
Long-Term Catheter measure	34.29%	12.00%	50.00%	17.50%
STrR measure	34.29%	12.00%	50.00%	17.50%
		35% of TPS		**35% of TPS**
SAFETY MEASURE DOMAIN				
NHSN BSI measure	100.00%	10.00%	100.00%	10.00%
		10% of TPS		**10% of TPS**
REPORTING MEASURE DOMAIN				

Measure/Measure Topics by Domain	Measure Weight as a Percent of Domain	Measure Weight as a Percent of TPS	Measure Weight as a Percent of Domain Absent Kt/V	Measure Weight as a Percent of TPS Absent Kt/V
Hypercalcemia reporting measure	16.67%	1.67%	16.67%	1.67%
MedRec measure	16.67%	1.67%	16.67%	1.67%
Facility Commitment to Health Equity reporting measure	16.67%	1.67%	16.67%	1.67%
HCP COVID-19 Vaccination reporting measure	16.67%	1.67%	16.67%	1.67%
Screening for Social Drivers of Health reporting measure	16.67%	1.67%	16.67%	1.67%
Screen Positive Rate for Social Drivers of Health reporting measure	16.67%	1.67%	16.67%	1.67%
		10% of TPS		**10% of TPS**

Table 25: Measure Weights as a Percent of TPS and as a Percent of Domain Score When Kt/V Topic Measure is Missing

4.2.7.2 Calculating the Score for a Domain Missing At Least One Measure Score

In order to calculate the score for a domain with unscored measures, each remaining eligible measures' individual weight, as a percent of that domain, is increased by the same amount and converted to a weighted measure score. These scores are then summed up and multiplied by 10 to equal the domain's score.

Using the example described in Section 4.2.7.1, the Clinical Care Measure Domain is missing the Kt/V Dialysis Adequacy Topic measure (31.43%), leaving two measures remaining in the domain. As seen in Table 26 below, the missing measure (Kt/V Topic) is assigned no weight and the corresponding 31.43% is evenly redistributed across each individual measure remaining in the domain.

PY 2026 Clinical Care Measures	Measure Weight as a Percent of the Clinical Care Domain	Measure Weight as a Percent of the Clinical Care Domain Absent Kt/V Topic
Kt/V Dialysis Adequacy measure Topic	31.43%	N/A
STrR measure	34.29%	50.00%
Long-Term Catheter measure	34.29%	50.00%

Table 26: Clinical Care Measure/Measure Topic Weights When Missing One Measure Score

These scores are then summed up and multiplied by 10 to equal the Clinical Care Measure Domain score. See the example below for a hypothetical scenario of this domain's calculation when missing a score for Kt/V Topic.

Example 7: Eligible for the Clinical Care Domain and all but One Measure in the Clinical Care Domain for PY 2027
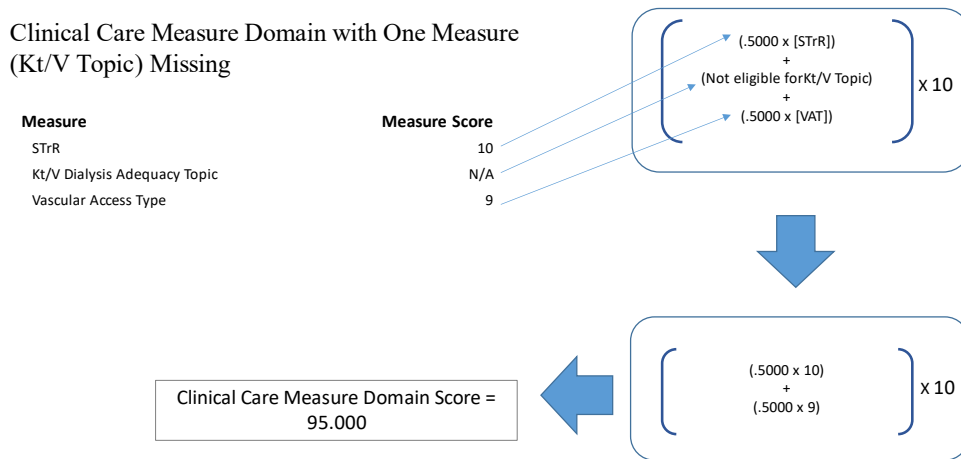
4.2.7.3   Calculating the TPS When Missing At Least One Measure Score

When missing at least one measure, the TPS is comprised of all measure domains having at least one measure score. For example, if the NSHN BSI measure was missing, the TPS would be comprised of four domains (Patient & Family Engagement, Care Coordination, Clinical Care, and Reporting).

As previously noted, domain weights are affected only when an entire domain is missing. For the example used in Section 4.2.7.1, where Kt/V Topic is missing, the TPS would be comprised of the five measure domains listed below and their associated TPS weights would be as follows:

    Patient and Family Engagement Measure Domain: 15%

    Care Coordination Measure Domain: 30%

    Clinical Care Measure Domain: 35%

    Safety Measure Domain: 10%

Reporting Measure Domain: 10%

In the example where Kt/V Topic is missing, the facility's TPS would be calculated by multiplying the Patient and Family Engagement Domain score by 0.15, the Care Coordination Domain score by 0.30, the Clinical Care Domain score by 0.35, the Safety Domain score by 0.10 and the Reporting Domain Score by 0.10 and adding the results, as follows:

$$TPS = (0.15 * Patient\ and\ Family\ Engagement\ Domain\ Score)$$
$$+ (0.30 * Care\ Coordination\ Domain\ Score)$$
$$+ (0.35 * Clinical\ Care\ Domain\ Score) + (0.10 * Safety\ Domain\ Score)$$
$$+ (0.10 * Reporting\ Domain\ Score)$$

Example 8: Total Performance Score Calculation for all but One Measure in the Clinical Care Domain for PY 2027

Total Performance Score with One Measure (Kt/V Topic) Missing

Domain	Domain Score
Patient and Family EngagementMeasure Domain	90.000
Care CoordinationMeasure Domain	78.000
Clinical Care Measure Domain	95.000
Safety Measure Domain	90.000
Reporting Measure Domain	93.352

(.1500 x [Patient and Family Engagement Domain])
+
(.3000 x [Care Coordination Domain])
+
(.3500 x [Clinical Care Measure Domain])
+
(.1000 x [Safety Measure Domain])
+
(.1000 x [Reporting Measure Domain])

(.1500 x 90.000)
+
(.3000 x 78.000)
+
(.3500 x 95.000)
+
(.1000 x 90.000)
+
(.1000 x 93.352)

Total Performance Score = 88

4.2.8   Calculation of TPS From a Facility's Measure Scores When Missing One Domain

Facilities are eligible to receive a TPS score if they are missing measure scores from two of five domains. The redistribution of the missing measure weights (both as a percent of TPS and as a percent of its assigned domain), along with an illustrative example, is described in more detail below.

4.2.8.1 Redistributing Domain Weights When a Facility Is Not Scored on Any Measures in a Domain

As previously noted, if a facility does not meet the eligibility requirements for a measure, the facility is not scored on the measure. If a facility is not scored on any measures in a domain, then that domain's weight is redistributed evenly across the remaining domains and then evenly across the measures within those domains.

Below is an example of this redistribution, showing the measure weights as a percent of TPS and as a percent of the domain score when the Safety Domain is missing.

Measure/Measure Topics by Domain	Measure Weight as a Percent of Domain	Measure Weight as a Percent of TPS	Measure Weight as a Percent of Domain Absent Safety Domain	Measure Weight as a Percent of TPS Absent Safety Domain
PATIENT & FAMILY ENGAGEMENT MEASURE DOMAIN				
ICH CAHPS measure	100.00%	15.00%	100.00%	17.50%
		15.00% of TPS		**17.50% of TPS**
CARE COORDINATION MEASURE DOMAIN				
SRR measure	30.00%	9.00%	29.62%	9.625%
SHR measure	30.00%	9.00%	29.62%	9.625%
PPPW measure	20.00%	6.00%	20.38%	6.625%
Clinical Depression measure	20.00%	6.00%	20.38%	6.625%
		30% of TPS		**32.50% of TPS**
CLINICAL CARE MEASURE DOMAIN				
Kt/V Dialysis Adequacy Topic measure	31.43%	11.00%	31.56%	11.83%
Long-Term Catheter measure	34.29%	12.00%	34.22%	12.83%
STrR measure	34.29%	12.00%	34.22%	12.83%
		35% of TPS		**37.50% of TPS**
SAFETY MEASURE DOMAIN				

Measure/Measure Topics by Domain	Measure Weight as a Percent of Domain	Measure Weight as a Percent of TPS	Measure Weight as a Percent of Domain Absent Safety Domain	Measure Weight as a Percent of TPS Absent Safety Domain
NHSN BSI measure	100.00%	10.00%	N/A	N/A
		10% of TPS		**0% of TPS**
REPORTING MEASURE DOMAIN				
Hypercalcemia reporting measure	16.67%	1.67%	16.67%	2.08%
MedRec measure	16.67%	1.67%	16.67%	2.08%
Facility Commitment to Health Equity measure	16.67%	1.67%	16.67%	2.08%
HCP COVID-19 Vaccination reporting measure	16.67%	1.67%	16.67%	2.08%
Screening for Social Drivers of Health reporting measure	16.67%	1.67%	16.67%	2.08%
Screen Positive Rate for Social Drivers of Health reporting measure	16.67%	1.67%	16.67%	2.08%
		10% of TPS		**12.50% of TPS**

Table 27: Measure Weights as a Percent of TPS and as a Percent of Domain Score When Safety Domain is Missing

4.2.8.2   Calculating TPS with One Domain Missing

For the example used in Section 4.2.8.1 where the NSHN BSI measure is missing, the TPS would be comprised of the remaining four domains listed below and their associated TPS weights would be as follows:

Patient and Family Engagement Measure Domain: 17.5%

Care Coordination Measure Domain: 32.5%

Clinical Care Measure Domain: 37.5%

Safety Measure Domain: 0%

Reporting Measure Domain: 12.5%

Example 9: Total Performance Score Calculation for One Domain Missing for PY 2027

Total Performance Score with One Domain Missing

Domain	Domain Score
Patient and Family EngagementMeasure Domain	90.000
Care CoordinationMeasure Domain	78.000
Clinical Care Measure Domain	95.000
Safety Measure Domain	N/A
Reporting Measure Domain	93.352

(.1750 x [Patient and Family Engagement Domain])
+
(.3250 x [Care Coordination Domain])
+
(.3750 x [Clinical Care Measure Domain])
+
N/A
+
(.1250 x [Reporting Measure Domain])

(.1750 x 90.000)
+
(.3250 x 78.000)
+
(.3750 x 95.000)
+
(.1250 x 93.352)

Total Performance Score = 88

4.3　Calculating a Facility's Payment Reduction for the Facility's TPS

The system shall calculate payment reduction percentages for a facility based on how a facility's TPS compares to the minimum TPS specified for the payment year. See Table 28 below for the payment reductions associated with the TPS received for Payment Year 2027.

Total Performance Score	Payment Reduction
100-51 (Score meets or exceeds minimum TPS)	No reduction
50–41 (1 to 10 points below minimum TPS)	0.5%
40–31 (11 to 20 points below minimum TPS)	1.0%
30–21 (21 to 30 points below minimum TPS)	1.5%
20–0 (31 or more points below minimum TPS)	2.0%
No score calculated	No reduction

Table 28: TPS and Payment Reduction for PY 2027

Calculating Star Ratings for Dialysis Facility Measures

4.4   Background and Introduction

CMS developed the Dialysis Facility Measures Star Rating System to rate the overall quality of care provided by dialysis facilities. The goal of the Star Rating System is to provide patients, their families, and caregivers information that they can use to easily compare dialysis facilities, as well as be aware of areas of care delivery where the quality of care differs. Each facility is rated between one and five stars. Facilities with five stars are considered to deliver much above average quality of care and those with one star are considered to deliver care that is rated much below average quality.

The original *Star Rating*s were implemented in January 2015. The technical report for the original *Star Rating* methodology is available at: https://dialysisdata.org/sites/default/files/content/Methodology/StarRatings.pdf.

A technical expert panel was convened in April 2015. The primary recommendations from this panel were (1) to establish baseline criteria for scoring dialysis facilities, to monitor changes in facility performance over time, and (2) to update the method in which certain quality measures are standardized for inclusion in the *Star Rating*s. Based on these recommendations, an update to the *Star Rating* methodology was implemented in October 2016. An updated technical report highlighting these changes to the *Star Rating* methodology is available at: https://dialysisdata.org/sites/default/files/content/Methodology/UpdatedDFCStarRatingMethodology.pdf.

A second technical expert panel convened in February 2017. The panel made recommendations on the inclusion of candidate and updated quality measures in the calculation of the *Star Rating*s. Based on these recommendations, an update to *Star Rating* methodology was implemented in October 2018. An updated technical report highlighting these changes to the *Star Rating* methodology is available at: https://dialysisdata.org/sites/default/files/content/Methodology/Updated_DFC_Star_Rating_Methodology_for_October_2018_Release.pdf.

A third technical expert panel convened in June 2019. The panel made recommendations on *resetting* the *Star Rating*s to increase the utility of the rating for patients and consumers and on weighting the relative importance that certain clinical quality measures have in determining a facility's *Star Rating*. Deliberations from this panel are described in a comprehensive summary report, available at: https://dialysisdata.org/sites/default/files/content/ESRD_Measures/2019_ESRD_DFC_Star_Rating_TEP_Summary_Report.pdf.

Due to the impact of the novel coronavirus (COVID-19) pandemic on data reporting and ESRD dialysis outcomes, methodological updates resulting from the June 2019 TEP deliberations were postponed. A fourth technical expert panel convened in March 2022. The panel made recommendations on the inclusion of two measures of transplant waitlisting and the establishment of a new *baseline period* against which to score facility performance in light of the COVID-19 pandemic. Deliberations from this panel are described in a comprehensive summary report, available at: https://dialysisdata.org/content/esrd-measures

4.5 Summary of Methodology Updates for October 2023

1. The *Star Ratings* will include two measures of transplant waitlisting: (1) the Standardized Waitlisting Ratio and (2) the Percentage of Prevalent Patients Waitlisted. Based on the results from factor analysis, these two measures will comprise a new, fourth domain of care (see Development of Measure Domains).

2. The 2019 TEP recommended reduction of the *weight* for the third domain, comprised of dialysis adequacy and hypercalcemia measures, to 50% the weight of the other three domains. Thus, the *domain scores* for Domains 1, 2, and 4 will each constitute 2/7 of a facility's *final score*, while the *domain score* for Domain 3 will constitute 1/7 of a facility's *final score.*

   Facilities that provide only PD services do not have *measure value*s for Domain 2, which is comprised of two measures of vascular access. These facilities are rated based on a weighted average of the other three *domain score*s, such that the *domain scores* for Domains 1 and 4 will constitute 2/5 of a facility's *final score*, while the *domain score* for Domain 3 will constitute 1/5 of a facility's *final score*.

3. Beginning with the October 2023 release, the *Star Rating* baseline distribution will be *reset*, such that 10% of facilities will receive 1-Star, 20% of facilities will receive 2-Stars, 40% of facilities will receive 3-Stars, 20% of facilities will receive 4-Stars, and 10% of facilities will receive 5-Stars. As a result, data collected for the October 2023 release will constitute a new *baseline period*. Future *evaluation periods* will use the criteria set by the October 2023 release, reflecting changes in facility performance over time since the October 2023 release.

4. As part of an ECE in light of the COVID-19 pandemic, CMS has offered regulatory relief on quality measure reporting, waiving data submission requirements for the national ESRD patient registry and quality measure reporting system. On March 27, 2020, CMS released guidance describing the scope and duration of the ECE granted under each program. Under this guidance, providers were relieved of their obligation to report clinical data for the first two quarters of 2020. Additionally for claims-based measures, claims data from March 1-

June 20, would be excluded from measure calculations. Additional details can be found at: https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.

5. The standardized mortality, hospitalization, readmission, and transfusion ratio measures will be appropriately risk-adjusted to mitigate the impact of COVID-19 on dialysis facility performance. Additional methodological details can be found at: https://dialysisdata.org/content/dfccmethodology.

4.6   Dialysis Facility Measures Quality Measures Used in Calculating the Star Ratings

Thirteen of the Dialysis Facility Measures quality measures currently reported on the Medicare website are used to calculate the Dialysis Facility Measures Star Ratings. The measures used in this update of the Dialysis Facility Measures Star Rating System methodology include Dialysis Facility Measures quality measures implemented in the original 2015 Star Rating System, updated versions of several of the Dialysis Facility Measures quality measures, replaced versions of two Dialysis Facility Measures quality measures, and measures new to the Star Rating.

4.7   Final Set of Quality Measures Used in the Clinical Star Rating Calculation

The final set of quality measures used in the Clinical Star Rating calculation include:

- Standardized Transfusion Ratio for Dialysis Facilities (STrR, CBE ID 2979)[*]

- Standardized Mortality Ratio for Dialysis Facilities (SMR, CBE ID 0369)[*]

- Standardized Hospitalization Ratio for Dialysis Facilities (SHR, CBE ID 1463)[*]

- Standardized Readmission Ratio for Dialysis Facilities (SRR, CBE ID 2496)[*]

- Standardized Waitlisting Ratio (SWR)[^]

- Percentage of Prevalent Patients Waitlisted (PPPW) [§]

- Total Kt/V Measure[§]:

  o Delivered Dose of Hemodialysis Above Minimum (Adult HD Kt/V, CBE ID 0249)[&, II]

  o Minimum spKt/V for Pediatric Hemodialysis Patients (Pediatric HD Kt/V, CBE ID 1423)[&, II]

  o Delivered Dose of Peritoneal Dialysis Above Minimum (Adult PD Kt/V, CBE ID 0318)[&, II]

- o Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V

- o (Pediatric PD Kt/V, CBE ID 2706)[&]

- Hemodialysis Vascular Access: Standardized Fistula Rate (SFR, CBE ID 2977)[§]

- Hemodialysis Vascular Access: Long-Term Catheter Rate (Catheter, CBE ID 2978)[†]

- Proportion of Patients with Hypercalcemia (Hypercalcemia, CBE ID 1454)[†]

[*]   Lower is better, updated yearly

[^]   Higher is better, updated yearly

[§]   Higher is better, individual measure updated quarterly

[†]   Lower is better, updated quarterly

[&]   The four Kt/V measurements are combined into a single, Total Kt/V measure. The average percentage of patients achieving Kt/V greater than the specified thresholds for each of the four respective patient populations (Adult HD, Adult PD, Pediatric HD, and Pediatric PD), was weighted based on the number of patient-months of data available for each patient population. The resulting measure (Total Kt/V) represents the percentage of total dialysis patients eligible for the measure who had enough wastes removed from their blood (Kt/V greater than or equal to the specified threshold). After combining these four Kt/V measures, eight final Quality Measures are used to calculate the Clinical Star Rating.

[‖]   No changes to measure specifications

4.8   ICH CAHPS Star Rating Calculation

The calculation used in the ICH CAHPS In-Center Hemodialysis Survey rating can be found at https://ichcahps.org.

The ICH CAHPS Star Rating will be calculated and reported as separate Star Ratings. Current measure specifications are available at: https://ichcahps.org/SurveyandProtocols.aspx.

The ICH CAHPS Star Rating Technical Notes are available at: https://ichcahps.org.

4.9   Measure Scoring for the *Star Rating*s

The clinical quality measures found on Care Compare have different distributions and scales. Therefore, the *measure values* for these individual measures must first be transformed in order to make them comparable in scale and direction. These transformations differ with respect to which period of data is being analyzed and what type of measure is being considered. As the current *Star Rating*s account for changes in dialysis facility performance over time, a *baseline period* is first established to set the criteria for scoring facilities. Facilities are scored using data collected during this *baseline period* to determine *cutoff values* for assigning *star rating*s in subsequent periods of data collection and evaluation (*evaluation period*).

4.9.1   Measure Scoring in a *Baseline Period*

Scoring facilities in an *evaluation period* against fixed thresholds established in a *baseline period* allows any facility that maintains or improves its performance on its quality measures to maintain or improve its *Star Rating*. Facilities are rated based on how their most recent performance compares to performance benchmarks in the *baseline period*. The *measure value*s in the current *Star Rating* are either standardized ratios or percentages. In developing scores for the *baseline period*, different scoring methods are applied, and these methods are described below.

4.9.1.1   *Percentage Measure*s

*Percentage measure*s are scored using *truncated z-scores*. *Truncated z-scores* represent the number of standard deviations away from the mean, truncated at lower and upper bounds. During the *truncation* process, these measures are iteratively re-scored to ensure that the resulting distribution has mean 0 and variance 1. Highly skewed measures have the potential to have large z-scores for facilities with extreme *measure values*. These scores may exert too much influence on the *Star Rating*s. Limiting the range of scores via *truncation* ensures a facility's rating is not determined primarily by outlier performance on a single measure. A detailed description of this approach is provided in Appendix A of the [Star Rating Technical Notes](#).

4.9.1.2   *Standardized Ratio Measure*s

Standardized ratio measures are scored using percentile ranks and *probit transformations*. These measures are scored differently from *percentage measures*, as a unit change in a ratio measure is not equally spaced. For example, the quality difference between standardized mortality ratio *measure values* of 0.5 versus 1.0 is not the same as the quality difference between *measure values* of 1.0 versus 1.5. The former represents a two-fold difference, while the latter represents a difference in mortality that is only 1.5 times higher.

Probit scoring better accounts for these spacing differences than *truncated z-scores*, which assume equal spacing. Since the *probit transformation* maps percentile ranks for the *standardized ratio measure*s to a distribution with mean 0 and variance 1, this type of scoring can also be easily combined with the *truncated z-scores* for the *percentage measure*s. A detailed description of this approach is provided in Appendix A of the [Star Rating Technical Notes](#).

4.9.2   Measure Scoring in an *Evaluation Period*

In order to compare current facility quality in an *evaluation period* to performance standards set in the *baseline period*, measures in the *evaluation period* are first mapped to values they would have received in the *baseline period* before scoring. The mapping and scoring processes are discussed separately for the percentage and *standardized ratio measure*s.

4.9.2.1   *Percentage Measures*

*Percentage measure*s in the *evaluation period* are mapped to the same score that the *measure value* would have been mapped to if it had been observed in the *baseline period*. *Measure scores* in the *evaluation period* are therefore calculated by subtracting the mean and dividing by the standard deviation of the measure in the *baseline period*. These *z-scores* are then truncated at the same values as truncated in the *baseline period* and re-standardized using the mean and the standard deviation of the *truncated z-scores* in the *baseline period*. A detailed example is given in Appendix A of the Star Rating Technical Notes.

4.9.2.2   *Standardized Ratio Measures*

The *standardized ratio measure*s represent observed/expected events in the *evaluation period*. We map the *standardized ratio measure*s in the *evaluation period* to the *baseline period* by multiplying them with an *adjustment factor*. The *adjustment factor*, which accounts for differences in population event rates between the *baseline period* and *evaluation period* data, is applied so that an adjusted *evaluation period* ratio value reflects the same value it would have had in the *baseline period*. The *adjustment factor* multiplied by the standardized ratio is the same for all facilities in the *evaluation period,* for that particular measure. For example, hospitalization rates were higher in 2019 than in 2018, so the expected number of events for the average facility is higher in 2019. The Standardized Hospitalization Ratio (SHR) in 2019 is then multiplied by an *adjustment factor* greater than one to calculate an adjusted SHR, so these facilities are effectively being measured by 2018, i.e., *baseline period* criteria. A detailed example is given in Appendix A of the Star Rating Technical Notes.

4.10   Combining Measure Scores into Final Scores

4.10.1   Development of Measure Domains

As some clinical quality measures are clinically more closely related than others, measures are grouped into *domains* in a data-driven manner using factor analysis.[1] Factor analysis is used to define domains where more highly correlated measures are grouped within a domain and less correlated measures are assigned to different domains. The standardized mortality, hospitalization, readmission, and transfusion ratios form one domain, the hemodialysis vascular access standardized fistula and long-term catheter rates form a second domain, and the total Kt/V and hypercalcemia measures form a third domain. Beginning with the October 2023 release, the Percentage of Prevalent Patients Waitlisted (PPPW) and Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) will form a new, fourth domain. Weighting *domain scores*, rather than *measure scores*, to calculate a facility's *final score* avoids overweighting particular measures that may represent a similar aspect of quality as other measures. Measure domains are re-established whenever *resetting* or *rebaselining* is performed.

4.10.2   Calculating Domain Scores and Final Scores

Calculated *measure scores* are combined to determine a facility's *final score* as follows. A facility's *measure scores* are first averaged within each of the four domains to calculate *domain scores*. Facilities are then given a *final score* by taking a weighted average of the four *domain scores*. Beginning with the October 2023 release, Domains 1, 2, 3, and 4 will constitute 2/7, 2/7, 1/7, and 2/7 of a facility's *final score*, respectively. Facilities are eligible to receive a *final score* if they have at least one *measure value* in each domain. Note that facilities providing only peritoneal dialysis do not have *measure values* for the Hemodialysis Vascular Access measure domain. These facilities are rated based on a weighted average of the other *domain scores*, where Domains 1, 3, and 4 constitute 2/5, 1/5, and 2/5 of their *final scores*, respectively.

4.10.3   Missing Values

With the exception of facilities that only provide peritoneal dialysis, facilities are eligible to receive a rating if they have at least one non-missing *measure value* in each *domain*. Missing measures for eligible facilities are imputed by the mean score for that measure in the *evaluation period*.[2] This imputation method ensures one measure does not exert too much influence on the *domain score*, and in turn, does not overly influence the *final score* used to determine the *Star Rating*. For example, consider a facility which had the maximum *measure score* of 2.58 for one measure and missing values all other measures in that domain. It would not be appropriate to assume that domain should be given the maximum score of 2.58 based on the one observed

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[1] Searle, S. R., Casella, G., & McCulloch, C. E. (2009). Variance components (Vol. 391). John Wiley & Sons.

[2] Little, R. J., & Rubin, D. B. (2019). Statistical analysis with missing data (Vol. 793). John Wiley & Sons.

measure in that domain. By imputing average scores for the other measures, we instead give the domain a submaximal above average score. The example facility is still above average for this domain, but the *domain score* will not be based solely on the one observed *measure score*, thus limiting the influence of that measure.

4.11 Translating Facility *Final Score*s into *Star Rating*s

4.11.1 Defining Final Score Cutoffs in a Baseline Period

Final scores in the *baseline period* are calculated, and this score distribution is used to define the *Star Rating* categories in all subsequent *evaluation period*s. Specifically, the distribution of stars in the *baseline period* is pre-specified, such that the lowest scoring 10% of facilities receive 1 star, the next 20% receive 2 stars, the next 40% receive 3 stars, the next 20% receive 4 stars, and the highest 10% receive 5 stars. *Star Rating cutoff values* are calculated as the average of the highest score in the lower category and the lowest score in the higher category between two adjacent star categories. The same *baseline period* and *cutoff value*s are used in subsequent *Star Rating* releases until new *baseline period* and *cutoff value*s are established.

4.11.2 Assigning Star Ratings in an Evaluation Period

The *final score cutoff values* that are defined in the *baseline period* are used to assign ratings to facilities in each subsequent *evaluation period*. The table below shows the average *measure values* for facilities within each star category in a given *evaluation period*. Better *measure values* and *final scores* correspond to higher star categories. Further, if the population of facilities improves in their measure performance from the year in which the cutoffs are established, more facilities could receive higher ratings compared to the *baseline period*, as they are being compared to performance measured in an earlier historical time period. Note, this table uses data from the October 2020 *Star Rating* release as an *evaluation period*, with data from the October 2019 *Star Rating* release as the *baseline period* to illustrate this example; all of the periods are prior to the COVID-19 pandemic that started in spring 2020.

Measure	★ N = 549 (7.8%)	★★ N = 1,153 (16.4%)	★★★ N = 2,923 (41.6%)	★★★★ N = 1,615 (23.0%)	★★★★★ N = 785 (11.2%)
SMR	1.19	1.10	1.01	0.92	0.84
SHR	1.25	1.10	1.00	0.89	0.79
SRR	1.20	1.10	1.00	0.91	0.83
STrR	1.65	1.23	0.97	0.77	0.59
Fistula	48.60	56.44	62.40	68.25	73.48
Catheter	24.49	16.47	12.49	9.49	7.25
Hypercalcemia	5.25	2.32	1.59	1.26	1.00

Measure	★ N = 549 (7.8%)	★★ N = 1,153 (16.4%)	★★★ N = 2,923 (41.6%)	★★★★ N = 1,615 (23.0%)	★★★★★ N = 785 (11.2%)
Total Kt/V	91.52	95.45	96.74	97.59	97.85
SWR	0.59	0.68	0.87	1.18	1.85
PPPW	10.73	13.24	16.50	20.28	27.58
Final Score	-0.81	-0.37	0.02	0.39	0.76

* October 2020 Star Rating release data used for the evaluation period, October 2019 release data used for the baseline period

Table 29: Mean *Measure Value*s and *Final Scores* within each *Star Rating* Category*

4.12 Rebaselining and Resetting the Star Ratings

4.12.1 Rebaselining

Data releases may incorporate new quality measures on different aspects of care, update current measure definitions, or retire certain measures that no longer provide actionable information in the calculation the *Star Rating*s. As the *Star Rating* measure set changes, one cannot directly compare current facility scores to the cutoffs established previously using the *baseline period* results. In order to maintain the longitudinal continuity of *Star Rating*s, the *Star Rating* release under a modified measure set will use the previous release's *Star Rating* distribution to *rebaseline* the *Star Rating*s. The current release will use the new measure specifications applied retrospectively to the prior release data to establish a new set of *final score* cutoffs. The cutoffs will reproduce the facility *Star Rating* distribution from the prior release using the prior measures and methodology. These cutoffs will be applied to all subsequent *Star Rating* releases. Thus, the prior release serves as an *evaluation period* for the former measure set and as the *baseline period* for the new measure set. For example, the October 2018 *Star Rating* release featured new, replaced, and updated measures. Therefore, it was not appropriate to directly compare this *evaluation period's* data to the original *baseline period* criteria. Instead, the new measure set was applied to the April 2018 release, and then the April 2018 *Star Rating* distribution was used to establish a new set of cutoffs for the October 2018 release.

4.12.2 Resetting

As the *Star Rating*s account for changes in dialysis facility quality of care over time, continued improvement may lead to progressive shifts in facility performance relative to the historical standards set in the *baseline period*. If progressive national improvement in facility performance occurs, the *Star Rating* distribution may become compressed due to overall high achievement relative to historic standards that may not reflect current care and outcomes. The *Star Rating*s then may not differentiate facility-level performance in a way that provides current, actionable information to patients and other consumers. In order to maintain the discriminatory power of the *Star Rating*s, the distribution will periodically be *reset* to update scoring cutoffs and reflect current performance. The purpose of the reset is to capture the full range of facility performance and to increase the effectiveness of the reporting program. For a release in which the *Star Rating*

distribution will be *reset*, facility *final scores* for this release will be calculated using the scoring methodology for a *baseline period*. As a result, the *reset* defines new baseline scoring cutoffs for facilities to be rated in the future *evaluation periods* and sets the proportion of facilities in each star category such that 10%, 20%, 40%, 20%, and 10% of facilities would receive 1, 2, 3, 4, and 5 stars, respectively, for the *reset Star Rating* release. The October 2023 *Star Rating*s will be reset as follows. First, the January 2023 release data will be used to establish a new *baseline period*; namely, to compute *final score*s used to rate facilities so that 10%, 20%, 40%, 20%, and 10% of facilities will receive 1, 2, 3, 4, and 5 stars, respectively. From this *Star Rating* distribution, new *Star Rating cutoff values* will be determined. Future releases, starting with October 2023, will allow the *Star Rating* distribution to shift from the distribution established in the *baseline period*, reflecting longitudinal changes in facility performance based on the new established cutoffs.

Acronyms

Acronym	Definition
ADEMEX	Adequacy of Peritoneal Dialysis in Mexico
AHRQ	Agency for Healthcare Research and Quality
AKI	Acute Kidney Injury
API	Asian/Pacific Islander
ARNP	Advanced Registered Nurse Practitioner
AV	Arteriovenous
AVF	Arteriovenous Fistula
BMI	Body Mass Index
BSI	Bloodstream Infections
BUN	Blood Urea Nitrogen
CAD	Coronary Artery Disease
CAPD	Continuous Ambulatory Peritoneal Dialysis
CASPER	Certification and Survey Provider Enhanced Report System
CBE	Consensus-based Entity
CC	HHS Hierarchical Condition Categories
CCN	CMS Certification Number
CCS	Clinical Classification Software
CEC	Comprehensive ESRD Care
CHF	Congestive Heart Failure
CHOW	Change of Ownership

Acronym	Definition
CKD	Chronic Kidney Disease
CMS	Centers for Medicaid and Medicare Services
CORE	Center for Outcomes Research & Evaluation
CPT	Current Procedural Terminology
CVA	Cerebrovascular Accident
CVD	Cardiovascular Disease
CY	Calendar Year
DFC	Dialysis Facility Compare
DFCC	Dialysis Facility Care Compare
DFR	Dialysis Facility Reports
ECE	Extraordinary Circumstances Exception
ED	Emergency Department
ED30	Standardized Ratio of Emergency Department Encounters Occurring Within 30 Days of Hospital Discharge
EDB	Enrollment Database
EQRS	ESRD Quality Reporting System
ESA	Erythropoiesis Stimulating Agents
ESCO	ESRD Seamless Care Organizations
ESRD	End Stage Renal Disease
FDA	Food and Drug Administration
FSD	First Service Date
FY	Fiscal Year
GEE	Generalized Estimating Equations
HCP	Healthcare Personnel
HCPCS	Healthcare Common Procedure Coding System
HD	Hemodialysis
HHD	Home Hemodialysis
HHS	Health and Human Services
HRSN	Health-Related Social Needs
HWR	Hospital-wide Readmission Measure
ICD	International Classification of Diseases

Centers for Medicare & Medicaid Services

Acronym	Definition
ICH CAHPS	In-Center Hemodialysis - Consumer Assessment of Healthcare Providers and Systems
ICHD	In-Center Hemodialysis
ICovH	Index of COVID-19 Hospitalizations
IDH	Intradialytic Hypotension
IDR	Integrated Data Repository
IPFQR	Inpatient Psychiatric Facility Quality Reporting
IPPS	Inpatient Prospective Payment System
IQR	Inpatient Quality Reporting
KDOQI	Kidney Disease Outcomes Quality Initiative
Kt/V	K (dialyzer clearance of urea)*t (dialysis time)/V (patient's total body water)
LIP	Licensed Independent Practitioners
LTC	Long-Term Care
LTCH	Long-Term Care Hospital
MA	Medicare Advantage
MAP	Measure Applications Partnership
MBI	Medicare Beneficiary ID
MedPAC	Medicare Payment Advisory Commission
MedRec	Medication Reconciliation Reporting Measure
MDS	Minimum Data Set
MIPS	Merit-based Incentive Payment System
MRPs	Medication-Related Problems
MU	Measure Unit
NCH	National Claims History database
NHSN	National Healthcare Safety Network
NHSN BSI	National Healthcare Safety Network Bloodstream Infection
NKF	National Kidney Foundation
nPCR	Normalized Protein Catabolic Rate
NQF	National Quality Foundation
OPTN	Organ Procurement and Transplant Network

Acronym	Definition
PA	Physician Assistant
PCHQR	Prospective Payment System-Exempt Cancer Hospital Quality Reporting
PD	Peritoneal Dialysis
PMMIS	Program Management and Medical Information System
POS	Provider of Service
PPPW	Percentage of Prevalent Patients Waitlisted
PPS	Prospective Payment System
PRO	Patient Reported Outcome
PY	Payment Year
QBIC	QIES Business Intelligence Center
QIES	Quality Improvement Evaluation System
QIP	Quality Incentive Program
REMIS	Renal Management Information System
SAF	Standard Analysis File
SEDR	Standardized Emergency Department Encounter Ratio
SFR	Standardized Fistula Rate
SHR	Standardized Hospitalization Ratio
SIR	Standardized Infection Ratio
SL	Significance Level
SMR	Standardized Mortality Ratio
SNF	Skilled Nursing Facility
SMoSR	Standardized Modality Switch Ratio
spKt/V	"Single pool" Kt/V as it assumes that excess water and urea are removed from only one body compartment and does not reflect rebound of water and waste products contributed by other body compartments.
SRR	Standardized Readmission Ratio
SSA	Social Security Act
STrR	Standardized Transfusion Ratio
SWR	Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients
TEP	Technical Expert Panel
TIA	Transient Ischemic Attack

Acronym	Definition
TOB	Type of Bill
TPS	Total Performance Score
UFR	Ultrafiltration Rate
UKM	Urea Kinetic Modeling
UNOS	United Network for Organ Sharing
UPI	Unique Patient Identifier
USRDS	United States Renal Data System
USPSTF	United States Preventive Services Task Force
VAT	Vascular Access Type
YNHHSC	Yale New Haven Health Services Corporation