Centers for Medicare & Medicaid Services
Center for Clinical Standards and Quality

CMS ESRD Measures Manual for the 2021 Performance Period

Final

Version 6.1

November 30, 2020

Table of Contents

List of Figures

List of Tables

1. Introduction

The *CMS ESRD Measures Manual* (*Manual*) Version 6.1 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 2021 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 Compare (DFC). 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.

Previous versions of the *Manual* will remain posted on the appropriate CMS webpage for review. Please note this version of the *Manual* replaces all references to CROWNWeb and REMIS with EQRS (End Stange Renal Disease Quality Reporting System). On November 9, 2020, CMS incorporated all functionality of the legacy CROWNWeb and REMIS systems into the EQRS system.

2. Measurement Information

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

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. (National Quality Foundation [NQF] #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.

This measure is intended to be jointly reported with the Hemodialysis Vascular Access-Standardized Fistula Rate. These two vascular access quality measures, when used together, consider arteriovenous (AV) fistula use as a positive outcome and prolonged use of a tunneled catheter as a negative outcome. With the growing recognition that some patients have exhausted options for an arteriovenous fistula (AVF) or have comorbidities that may limit the success of AVF creation, joint reporting of the measures accounts for all three vascular access options. The fistula measure adjusts for patient factors where fistula placement may be either more difficult or not appropriate and acknowledges that in certain circumstances an AV graft may be the best access option. This paired incentive structure that relies on both measures reflects consensus best practice and supports maintenance of the gains in vascular access success achieved via the Fistula First/Catheter Last project over the last decade.

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 HDs patients (in-center HD 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 ESRD Quality Reporting System (EQRS). Determination of patient modality is derived from a combination of Medicare-paid dialysis claims, the Medical Evidence Form (CMS-2728), and data from CROWNWeb (DFC 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 (eg. 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 ID" having any of the following values: (16,18,19,20,21,"·"), where Access_Type_ID "16" represents AV Fistula combined with a Catheter, "18" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21" represents other/unknown, and "·" represents 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 if 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-9/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 in-center HD 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 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 hemodialysis session of the of the reporting month.

For a given month, if any of the following "Access Type IDs" in EQRS are reported as 16,18,19,20,21, 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. Access Type ID "16" represents AV Fistula combined with a Catheter, "18" represents AV Graft combined with

a Catheter, "19" represents Catheter only, "20" represents Port access only, "21" represents other/unknown, and "." represents missing. 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 a facility reports multiple vascular access types for a patient during a reporting month, only the last vascular access type reported by that facility is used in the calculation.

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 DFC)

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 – DFC 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 if 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-9/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.

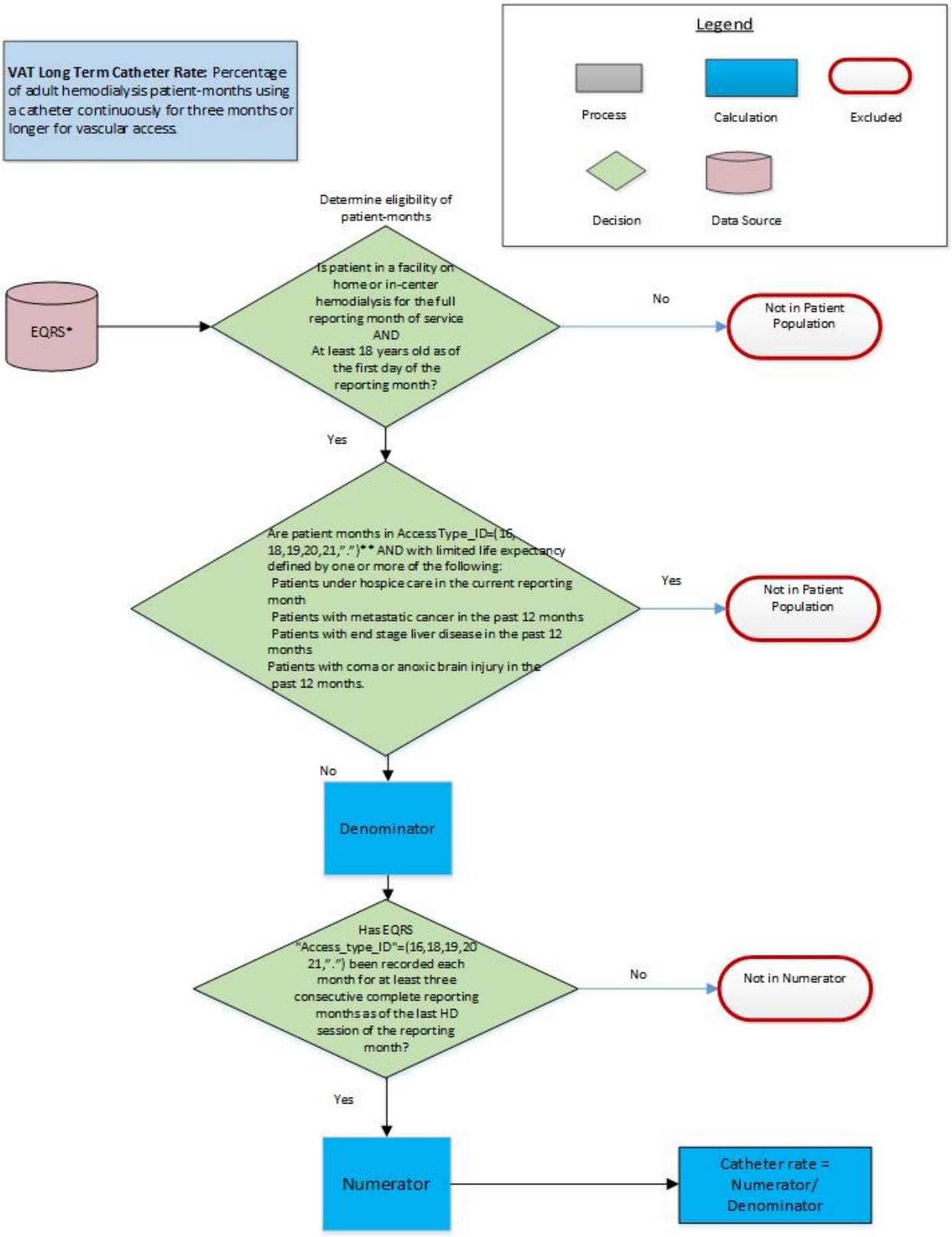

Figure 1: Vascular Access Type Clinical Measure: Hemodialysis Vascular Access: Long-term Catheter Rate Flowchart (ESRD QIP and DFC)

* 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) (DFC only), the Death Notification Form (CMS-2746), the Dialysis Facility Compare (DFC) and the Social Security Death Master File (DFC only).

** Access_Type_ID "16" represents AV Fistula combined with a Catheter, "18" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21" represents other/unknown, and "." represents missing.

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 (ESRD QIP and DFC)

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 AVF as the sole means of vascular access.

2.2.3 Measure Rationale

The National Kidney Foundation National Kidney Foundation (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.

This measure is intended to be jointly reported with Hemodialysis Vascular Access: Long-term Catheter Rate. These two vascular access quality measures, when used together, consider AVF use as a positive outcome and prolonged use of a tunneled catheter as a negative outcome. With the growing recognition that some patients have exhausted options for an AVF or have comorbidities that may limit the success of AVF creation, joint reporting of the measures accounts for all three vascular access options. The fistula measure adjusts for patient factors where fistula placement may be either more difficult or not appropriate and acknowledges that in certain circumstances an AV graft may be the best access option. This paired incentive structure that relies on both measures (SFR, long-term catheter rate) reflects consensus best practice, and supports maintenance of the gains in vascular access success achieved via the Fistula First/Catheter Last project over the last decade.

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 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:
  - 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 CCN becomes effective and the following three months (see Section 3.5).

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. 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 ID" having any of the following values: (16,18,19,20,21,"·"), where Access_Type_ID "16" represents AV Fistula combined with a Catheter, "18" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21" represents other/unknown, and "·" represents 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 if 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-9/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 in-center HD 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 Type IDs" of 14 or 22 has been recorded for a given month, where "14" represents AVF only (with 2 needles) and "22" represents AVF only with an approved single needle device. If a facility reports multiple vascular access types for a patient during a reporting month, only the last vascular access type reported by that facility is used in the calculation.

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 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.
    - BMI is divided into the following categories: <18.5, 18.5-24.9, and >24.9.
- Nursing home status in previous year
- Nephrologist's care prior to ESRD incidence 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 Medicare coverage for at least 6 months during the past 12 months

Let n_i be the number of patients treated at the i^{th} 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 j^{th} patient in the i^{th} facility (for $j = 1,\ldots,n_i$) in the m^{th} 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-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 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 (i=1,..., 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:

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

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]

Variable	Primary Data Source
Date of first ESRD	Medical Evidence Form (CMS-2728) EQRS Patient Events Medicare Claims[3] Organ Procurement and Transplantation Network Database (OPTN)
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 calendar year)	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)
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)

Variable	Primary Data Source
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 (ESRD QIP and DFC)

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 - DFC only). For DFC 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. DFC 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. See Section 3.2.2 for details on how unique patients are identified for ESRD QIP.

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 if 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-9 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-9/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.

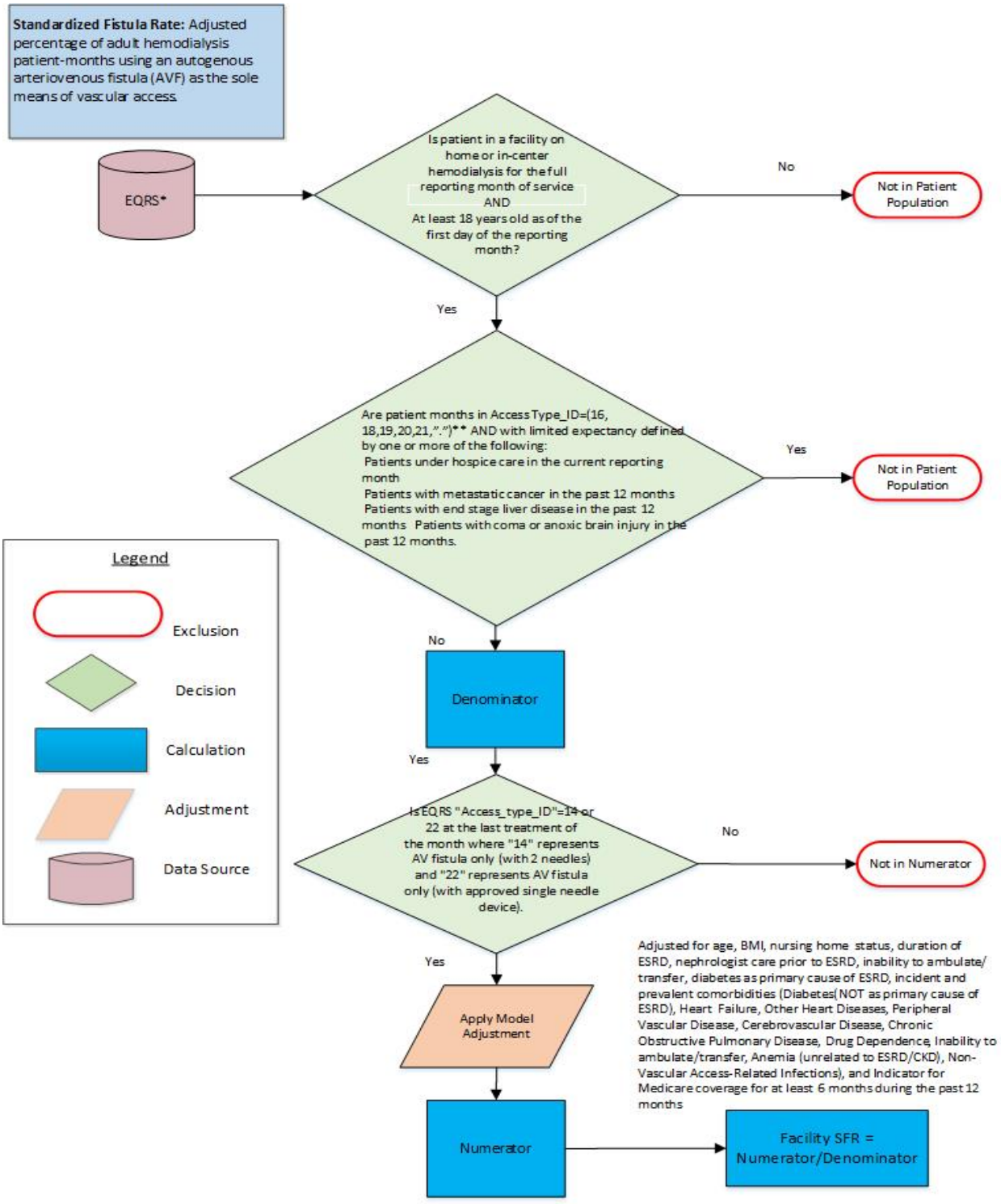

Figure 2: Hemodialysis Vascular Access: Standardized Fistula Rate (ESRD QIP and DFC)

* 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) (DFC only), the Death Notification Form (CMS-2746), the Dialysis Facility Compare (DFC) and the Social Security Death Master File (DFC only).

** Access_Type_ID "16" represents AV Fistula combined with a Catheter, "18" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21" represents other/unknown, and "." represents missing.

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.

2.3 Adult Hemodialysis Adequacy Measure (DFC Only)

2.3.1 Measure Name

Delivered Dose of Hemodialysis Above Minimum – NQF# 0249

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.

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

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

2.3.9 Denominator Statement

All patient-months for adult (≥ 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 facility for the entire month
- Patients younger than 18 years old as of the first day of the month (or as of the claim-from date if claims data are used)
- 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 of the month
- Patients-months where patients are not dialyzing greater than 2 and less than 4 times weekly (see Section 3.1.4)

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 are 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 spKt/V ≥ 1.2 and Kt/V ≤ 5.0.

- If a patient has multiple 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).
    - 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 in-center HD 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.org.

EQRS Data Elements:

- CROWN 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 to determine frequent dialysis
- 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 database (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

2.3.15 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 Adequacy Measure (DFC Only)

2.4.1 Measure Name

Delivered Dose of Peritoneal Dialysis (PD) Above Minimum – NQF #0318

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.

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 > 1.7 for adult patients and Kt/V urea > 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 with in 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 must also be in range (Kt/V $\leq$ 8.5).

2.4.8 Facility Exclusions

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

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 facility for the entire month
- Patients younger than age 18 years old as of the first day of the month (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 of the month

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 ≥ 1.7 and Kt/V ≤ 8.5.

- If a patient has multiple 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).
    - 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.org.

EQRS Data Elements:

- CROWN Unique Patient Identifier (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 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 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 Adequacy Measure (DFC Only)

2.5.1 Measure Name

Minimum spKt/V for Pediatric Hemodialysis Patients – NQF #1423

2.5.2 Measure Description

Percentage of all pediatric (≤ 18 years old) patient-months in the sample for analysis who were on ESRD treatment for 91 days or more and dialyzing greater than 2 and less than 4 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 ≥ 1.2 during the study period.

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 ≥ 1.2. Kt/V must also be in range (spKt/V ≤ 5.0).

2.5.8 Facility Exclusions

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

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 2 and less than 4 times weekly the entire month.

2.5.10 Denominator Exclusions

- Patient-months for patients not assigned to the facility for the entire month
- Patients 18 years and older as of the first day of the month (see Section 3.1.3)
- Patient-months for patients not on in-center HD 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 2 and less than 4 times weekly (see Section 3.1.4)

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 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).
    - 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 ($\leq$ 5.0) and meets the Kt/V value threshold ($\geq$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.org.

EQRS Data Elements:

- CROWN 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
- Kt/V method
- Modality to determine frequent dialysis
- 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 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 Adequacy Measure (DFC Only)

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 6 months). Kt/V must also be in range (Kt/V$\leq$ 8.5).

2.6.8 Facility Exclusions

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

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 facility for the entire month
- Patients aged 18 years and older as of the first day of the month (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

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 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).
    - 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 (≤ 8.5) and meets the Kt/V value threshold (≥ 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.org.

EQRS Data Elements:

- CROWN 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 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 Kt/V Dialysis Adequacy Comprehensive Clinical Measure (ESRD QIP Only)

2.7.1 Measure Name

Kt/V Dialysis Adequacy Comprehensive Clinical Measure

2.7.2 Measure Description

Percentage of all patient months for patients whose delivered dose of dialysis (either HD or PD) met the specified threshold during the reporting period.

2.7.3 Measure Rationale

See above for the clinical rationale associated with each of the four components of the comprehensive Kt/V clinical measure.

The primary rationale for the combined measure is to make more facilities eligible for public reporting of these metrics by meeting the ≥ 11 eligible patients requirement. For public reporting on DFC and the ESRDQIP, a facility has to treat at least 11 qualifying patients for each measure in order to receive a score on that measure. The 11-patient requirement is anchored in Health and Human Services (HHS) policy related to small cell sizes to protect identification of patients and release of protected health information. An additional reason is the need for sufficient data to achieve reliability of a measure calculation, and less than 11 patients is not a statistically reliable sample size. We recognize there is no published evidence describing use of the combined subpopulation and modality measures. However, each component measure has strong evidence support from literature and each also reflects consensus guideline recommendations. Combining these established consensus measures to counter an unintended consequence of the application of federal protected health information regulations should not require additional scientific justification beyond what already exists.

In the case of dialysis adequacy, CMS found that a significant number of facilities that have less than 11 PD patients or less than 11 pediatric patients would be included in the new combined measure but excluded from the individual measures, leading to the systematic exclusion of these facilities from assessment on these measures because of the reporting requirements.

2.7.4 Measure Type

Intermediate outcome

2.7.5 Improvement Noted as Higher or Lower Rate

A higher rate indicates better quality.

2.7.6 Risk Adjustment

None.

2.7.7 Numerator Statement

Number of patient months in the denominator for patients whose delivered dose of dialysis met the specified thresholds. The thresholds are as follows:

- HD (all ages): spKt/V ≥ 1.2 (calculated from the last measurement of the month using UKM or Daugirdas II)
- PD (pediatric < 18 years old, see Section 3.1.3): Kt/V ≥ 1.8 (dialytic + residual, measured within the past 6 months)
- PD (adult ≥ 18 years old): Kt/V ≥ 1.7 (dialytic + residual, measured within the past 4 months)

2.7.8 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).
- Calculations will exclude lab values reported by new facilities during the month in which the CCN becomes effective and the following three months.

2.7.9 Denominator Statement

- All adult HD patients who received dialysis greater than two and less than four times a week (adults, ≥ 18 years old), and all pediatric in-center HD patients who received dialysis greater than two and less than four times a week (pediatric, < 18 years old), and the claim or EQRS did not indicate frequent dialysis.
- All patients (both HD and PD) who are assigned to the facility for the entire month and have had ESRD for 90 days or more (see Section 3.1.5).
- Note, patient age is determined as of the first of the month when Kt/V is reported in EQRS, and as of the claim-from date when Kt/V is obtained from claims.

2.7.10 Denominator Exclusions

- For new facilities only, the month in which the CCN becomes effective and the following three months (see Section 3.5).
- Adult HD patients and pediatric in-center HD patients receiving dialysis less than or equal to 2 times weekly or greater than or equal to 4 times weekly (see Section 3.1.4).
- Pediatric home HD patients. When Kt/V is reported in EQRS, pediatric patients are defined as patients < 18 years old as of the first day of the reporting month. If Kt/V is obtained from claims, pediatric patients < 18 years old as of the claim-from date are excluded.
- Patient-months on ESRD treatment for fewer than 90 days at the beginning of the reporting month when using EQRS as the Kt/V data source. If claims are used as the data source, the 90 days on ESRD treatment is determined based on the claim-from date, representing the start of when care was provided.

- Patients who changed dialysis modality during the month. Note: For adult HD patients, a change from in-center to home HD (or vice versa) is not considered a modality change. Modality determination is described in Section 3.1.1.
- Patients who were not assigned to the facility for the entire month due to death or discharge for one of the following reasons: discontinued, involuntary discharge, transplant, or other reasons for leaving dialysis (see Section 3.1.5).
- Patients who were not assigned to the facility for the entire month due to transfer to a different facility.
- Criteria for selecting claims and their Kt/V values:
  - A HD claim is considered eligible if it is for an in-center HD (adult or pediatric) or adult home HD patient and meets all three of the following conditions:
    - The patient has had ESRD for at least 90 days as of the claim-from date;
    - The home HD patient 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.
  - A PD claim is considered eligible if it is from a PD patient who had ESRD for at least 90 days.
  - If there are multiple claims for a patient during a month, the last valid claim is the eligible claim with the latest claim-from date.
  - For a HD patient, if multiple Kt/V values are reported on the last eligible claim, then the following decision rules are used to select the Kt/V value:
    - First, select the highest numeric Kt/V value that is not 8.88 or 9.99
    - Second, select 8.88 if reported and no other valid value is reported
    - Third, select 9.99 if reported and no other value is reported.
  - For HD patients, the reported spKt/V should not include residual renal function.
  - For a PD patient, the last eligible claim with a Kt/V value that is not expired (i.e. the Kt/V occurrence date is less than or equal to four months prior to the end of the claim for an adult, six months prior to the end of the claim for pediatric) is selected when there are multiple claims reported in a month.
  - If multiple eligible claims are submitted for a patient in the same month and there is at least one Kt/V=9.99 and at least one Kt/V not equal to 9.99 then the claims with Kt/V 9.99 are considered ineligible.
  - Claims reported during ECE months will not be used in calculations.

2.7.11 Mapping Patients to Facilities

See Section 2.3.11.

2.7.12 Calculating Numerators

2.7.12.1 Adult HD Kt/V:

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. Out of range values (spKt/V>5.0) are excluded from the numerator (i.e. set to missing). Patient age is determined as of the first of the month when Kt/V is reported in EQRS, and as of the claim-from date when Kt/V is obtained from claims.

- If a patient has multiple Kt/V values in EQRS during a month, then the last reported value is selected.
- If a Kt/V value is not found in EQRS for the patient during the reporting month, the following logic applies to selecting a Kt/V value from claims, if possible.
    - For in-center HD patients, the system will select the appropriate non-missing Kt/V value reported on the last eligible Medicare claim from the assigned facility (when available) for the patient during the month.
    - For home HD patients, the system will select the appropriate non-missing Kt/V value reported on the last eligible Medicare claim from the assigned facility (when available) for the patient during the month where the Kt/V reading date is within the four months of the claim through date.

2.7.12.2 Kt/V lab values reported by facilities during ECE months will not be used in calculations. Adult PD Kt/V:

Number of patient-months 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. Out of range values (Kt/V>8.5) are excluded from the numerator (i.e. set to missing). Patient age is determined as of the first of the month when Kt/V is reported in EQRS, and as of the claim-from date when Kt/V is obtained from claims.

- If a patient has multiple Kt/V values in EQRS during the month under consideration or in the 3 months prior, then the last reported value is selected.
- If a value is not found in EQRS for the patient during the four-month study period, then the last reported non-missing value reported on the last eligible Medicare claim from the assigned facility (when available) for the patient during the four-month study period is selected (when available).
- Kt/V lab values reported by facilities during granted ECE months will not be used in calculations.
- Kt/V lab values reported by facilities in the month in which the CCN becomes effective and the following three months will not be used in calculations.
- The length of the study period is based on patient age determination.

2.7.12.3 Pediatric HD Kt/V:

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. Out of range values (spKt/V>5.0) are excluded from the numerator (i.e. set to missing). Patient age is determined as of the first of the month when Kt/V is reported in EQRS, and as of the claim-from date when Kt/V is obtained from claims.

- If a patient has multiple Kt/V values in EQRS during a month, then the last reported value is selected.
- If a Kt/V value is not found in EQRS for the patient during the reporting month, the following logic applies to selecting a Kt/V value from claims, if possible.
  - For in-center HD pediatric patients, the system will select the appropriate non-missing Kt/V value reported on the last eligible Medicare claim from the assigned facility (when available) for the patient during the month.
- Kt/V lab values reported by facilities during granted ECE months will not be used in calculations.

2.7.12.4 Pediatric PD Kt/V:

Number of patient-months in denominator whose delivered dose of PD (dialytic + residual, calculated from the last measurements of the six-month study period) was a Kt/V $\geq$ 1.8. Out of range values (Kt/V>8.5) are excluded from the numerator (i.e. set to missing). Patient age is determined as of the first of the month for EQRS, and as of the claim-from date for claims.

- If a patient has multiple Kt/V values in EQRS during the month under consideration or in the 5 months prior, then the last reported value is selected.
- If a value is not found in EQRS for the patient during the six-month study period, then the last reported non-missing value reported on the last eligible Medicare claim from the assigned facility (when available) for the patient during the six-month study period (reporting month and five prior months) is selected (when available).
- Kt/V lab values reported by facilities during ECE months will not be used in calculations.
- Kt/V lab values reported by facilities in the month in which the CCN becomes effective and the following three months will not be used in calculations.
- The length of the study period is based on patient age determination.

2.7.13 Assigning Patient-Months to Numerators and Denominators

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

- If selected Kt/V value is missing or 9.99 (i.e. when using claims) or expired, include patient-month in the denominator, but not in the numerator.
- If selected Kt/V value meets the Kt/V value threshold ($\geq$ 1.2 for HD, $\geq$ 1.7 for adult PD, or $\geq$ 1.8 for pediatric PD) and is not expired, then include patient month in denominator and numerator.

2.7.14 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.org.

EQRS Data Elements:

- Facility CCN
- Patient date of birth
- Patient date of death
- CROWN UPI
- Primary type of treatment ID (EQRS dialysis type)
- Number of prescribed 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 method
- Kt/V value
- Reporting/clinical month
- Modality (to determine look-back period and assess if modality changed during the month)

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

2.7.15 Flowchart

Figure 3 provides a flowchart that represents the processes used to calculate the Kt/V Dialysis Adequacy Comprehensive Clinical Measure Rate.

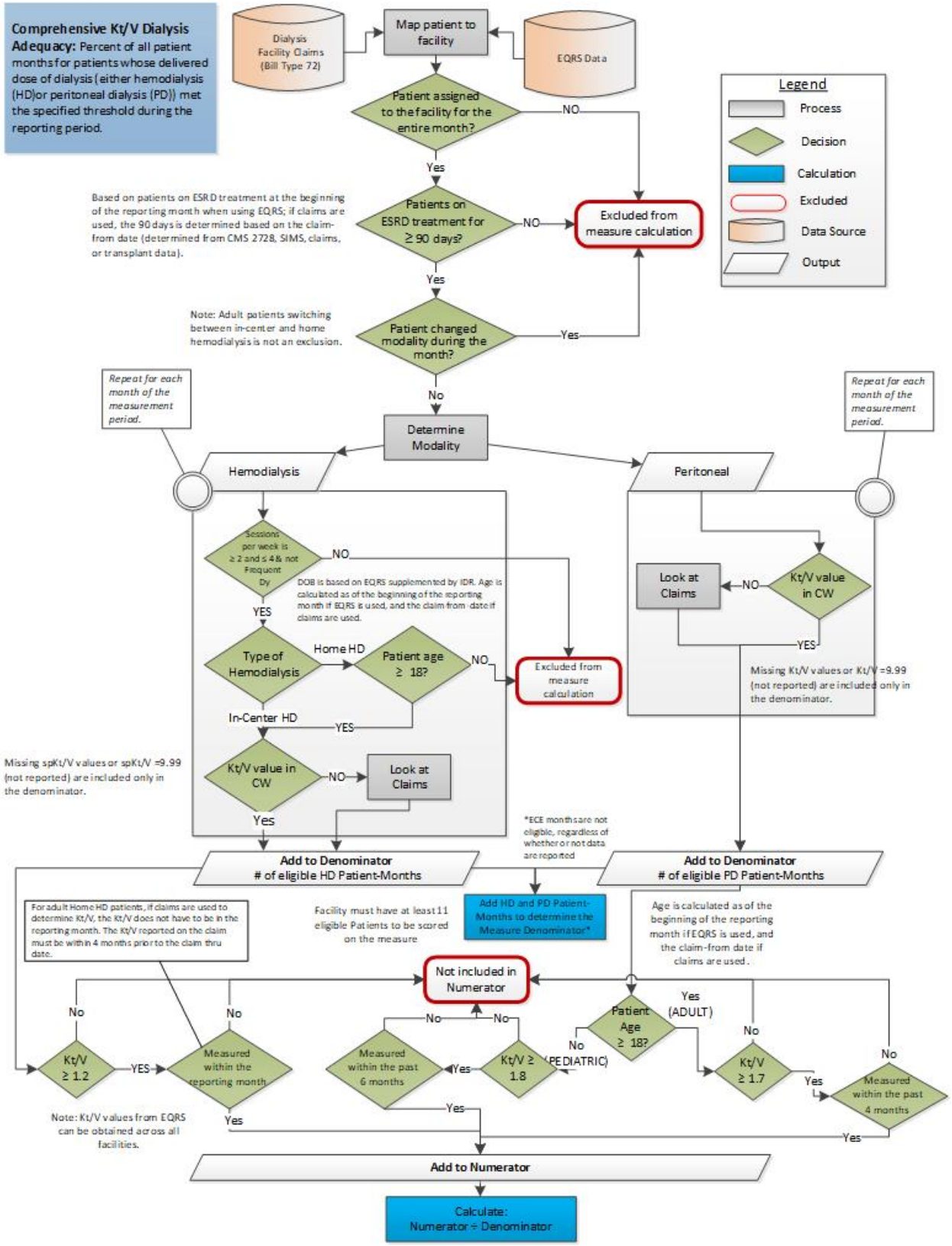

Figure 3: Kt/V Dialysis Adequacy Comprehensive Clinical Measure Rate Flowchart (ESRD QIP Only)

2.8 nPCR for Pediatric Hemodialysis Patients (DFC only)

2.8.1 Measure Name

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

2.8.2 Measure Description

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

2.8.3 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.

2.8.4 Measure Type

Process

2.8.5 Improvement Noted as Higher or Lower Rate

A higher number indicates better quality.

2.8.6 Risk Adjustment

None.

2.8.7 Numerator Statement

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

2.8.8 Facility Exclusions

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

2.8.9 Denominator Statement

Number of all patient months for pediatric (less than 18 years old) in-center HD patients (irrespective of frequency of dialysis).

2.8.10 Denominator Exclusions

Exclusions that are implicit in the denominator definition include:

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

- Home HD patients

2.8.11 Mapping Patients to Facilities

See Section 2.3.11

2.8.12 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, delivered minutes of BUN HD session, and intradialytic time) and the date of collection are all known.

2.8.13 Data Elements and Data Sources

EQRS Data Elements:

- CROWN 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
- Intradialytic time
- 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 fate
- Patient health insurance claim number
- Patient date of death
- Patient date of birth

2.8.14 Flowchart

Figure 4 provides a flowchart that represents the processes used to calculate the nPCR for Pediatric Hemodialysis Patients Rate.

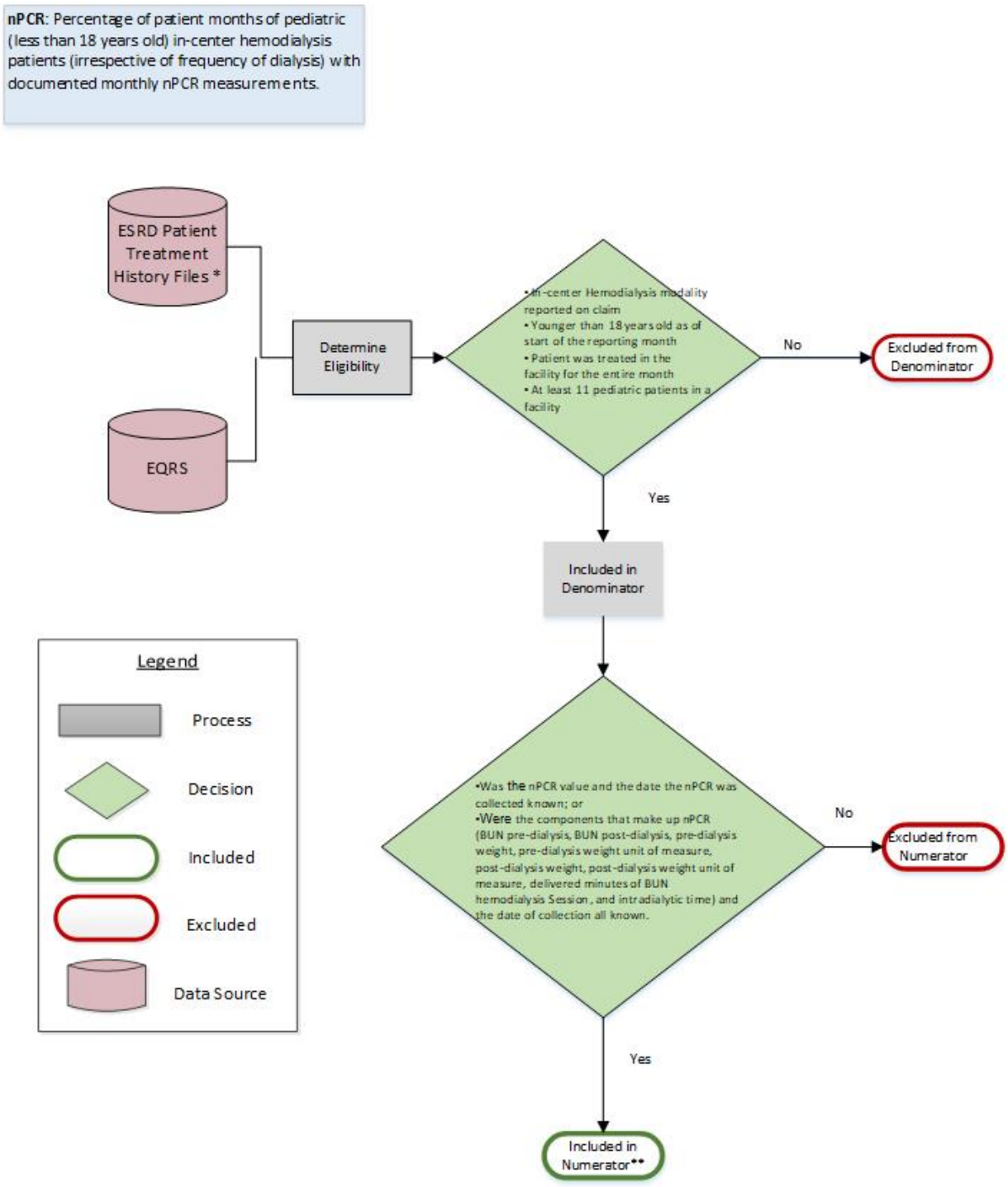

Figure 4: nPCR for Pediatric Hemodialysis Patients Flowchart (DFC only)

* 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 (DFC) and the Social Security Death Master File .

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

2.8.15 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.
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- 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.

2.9 Hypercalcemia Clinical Measure (ESRD QIP and DFC)

2.9.1 Measure Name

Proportion of Patients with Hypercalcemia – NQF #1454

2.9.2 Measure Description

Proportion of all adult patient-months (Medicare and non-Medicare patients) with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.

2.9.3 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 NQF 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 NQF 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.

2.9.4 Measure Type

Intermediate Outcome

2.9.5 Improvement Noted as Higher or Lower Rate

A lower rate indicates better quality.

2.9.6 Risk Adjustment

None.

2.9.7 Numerator Statement

Number of patient-months in the denominator with 3-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. 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.

2.9.8 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).

2.9.9 Denominator Statement

Number of patient-months at the facility during the measurement period. Includes all patients, both Medicare and non-Medicare patients. Patient-months with missing values in the reporting month and the two months prior are included in the denominator to minimize any incentive favoring non-measurement of serum calcium in the preceding three months.

2.9.10 Denominator Exclusions

- Patients on ESRD treatment for fewer than 90 days as of the first day of the reporting month.
- Patients who died prior to the last day of the reporting month.

DFC only:

- Patients not assigned to the facility for the entire reporting month.
- Patient younger than age 18 years old two months prior to the reporting month (see Section 3.1.3)

ESRD QIP only:

- Patients for whom the facility reported fewer than 3 months of calcium values in EQRS during the measurement period, plus the two months prior (i.e. November and December of the previous year will be used in calculating the three-month rolling average for January and February of the baseline and performance period).

- Patient was at the facility for fewer than 30 days (either consecutive or non-consecutive) during the reporting month and the two months prior (the 3-month calculation period).
- Patient was discharged from the facility prior to the last day of the reporting month.
- Patient was not on ESRD treatment during the month.
- Patient younger than age 18 years old as of the first day of the reporting month (see Section 3.1.3).
- For new facilities only, the month in which the CCN becomes effective and the following three months (see Section 3.5).
- Calculations will exclude the months covered by a granted ECE (see Section 3.4).

2.9.11 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.

DFC:

- 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 sessions are 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 him or her in the analysis.

2.9.12 Calculating Numerators

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 3-month rolling average if applicable.

- The last calcium value reported in the month is used for calculation.
- The calcium value reported by the facility is used. The facility may obtain this value from an external source.
- 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 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:

- November and December of the year before the performance period may be used in calculating the three-month rolling average for January and February of the performance period. November and December of the year before the improvement baseline period may be used (if reported) in calculating the three-month rolling average for January and February in the Improvement Threshold Rate.
- The monthly rolling average for each patient with an average calcium greater than 10.2 mg/dL is rounded to one decimal place (XX.X), with half rounded up, prior to comparing the average to the threshold rate (10.2 mg/dL).
- For new facilities only, calcium values reported during the first three months (based on initial certification date) will not be used (see Section 3.5).

2.9.13 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.org.

EQRS Data Elements:

- Facility CCN
- Initial certification date
- Patient date of birth
- Patient date of death
- CROWN UPI
- Admit date
- Discharge date
- Date of month/year associated with clinical record
- Uncorrected serum 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

2.9.14 Flowchart for ESRD QIP

Figure 5 provides a flowchart that represents the processes used to calculate the Hypercalcemia Clinical Measure Rate for ESRD QIP.

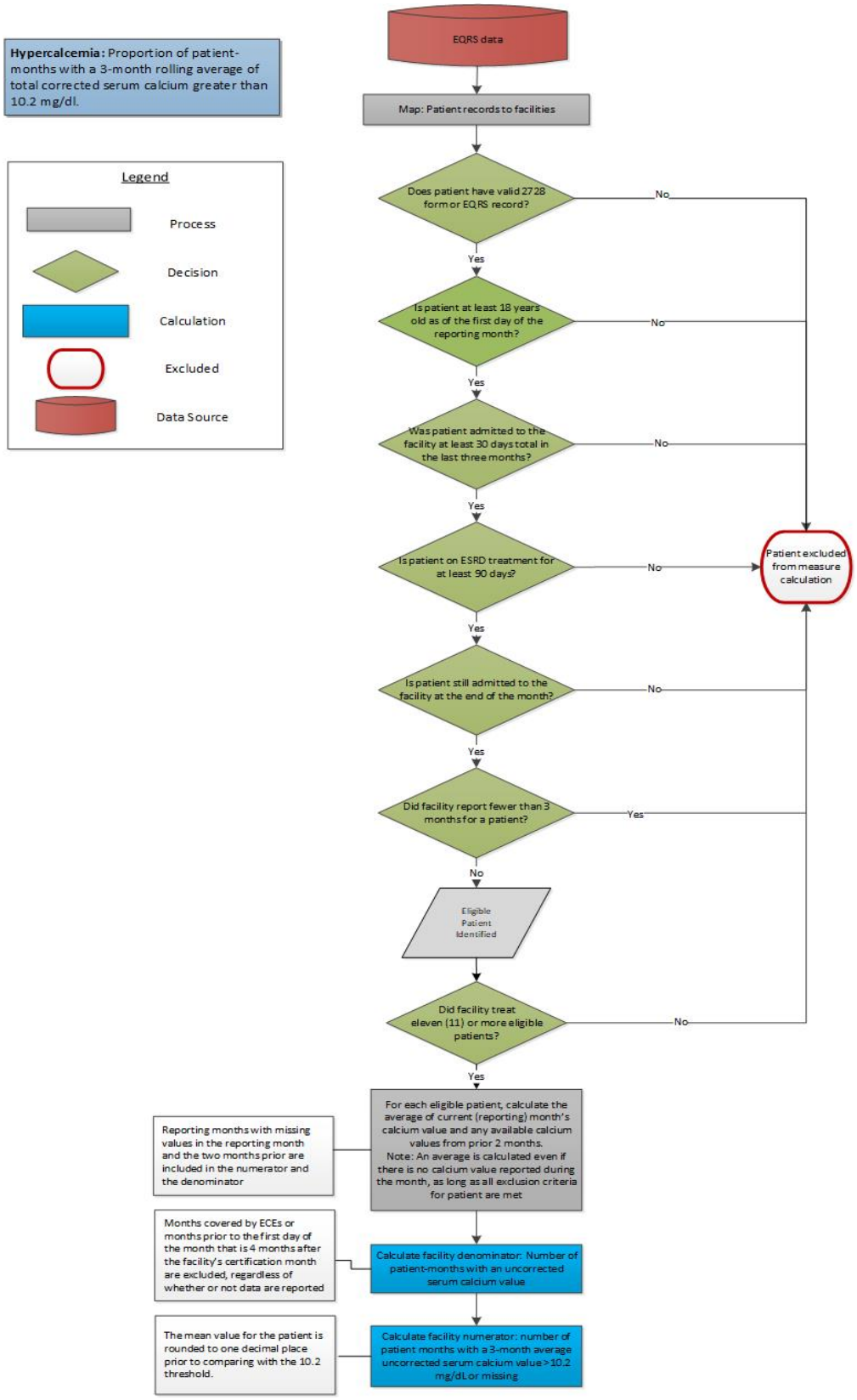

Figure 5: Hypercalcemia Clinical Measure Rate Flowchart (ESRD QIP Only)

2.9.15 Flowchart for DFC

Figure 6 provides a flowchart that represents the processes used to calculate the Hypercalcemia Clinical Measure Rate for DFC.

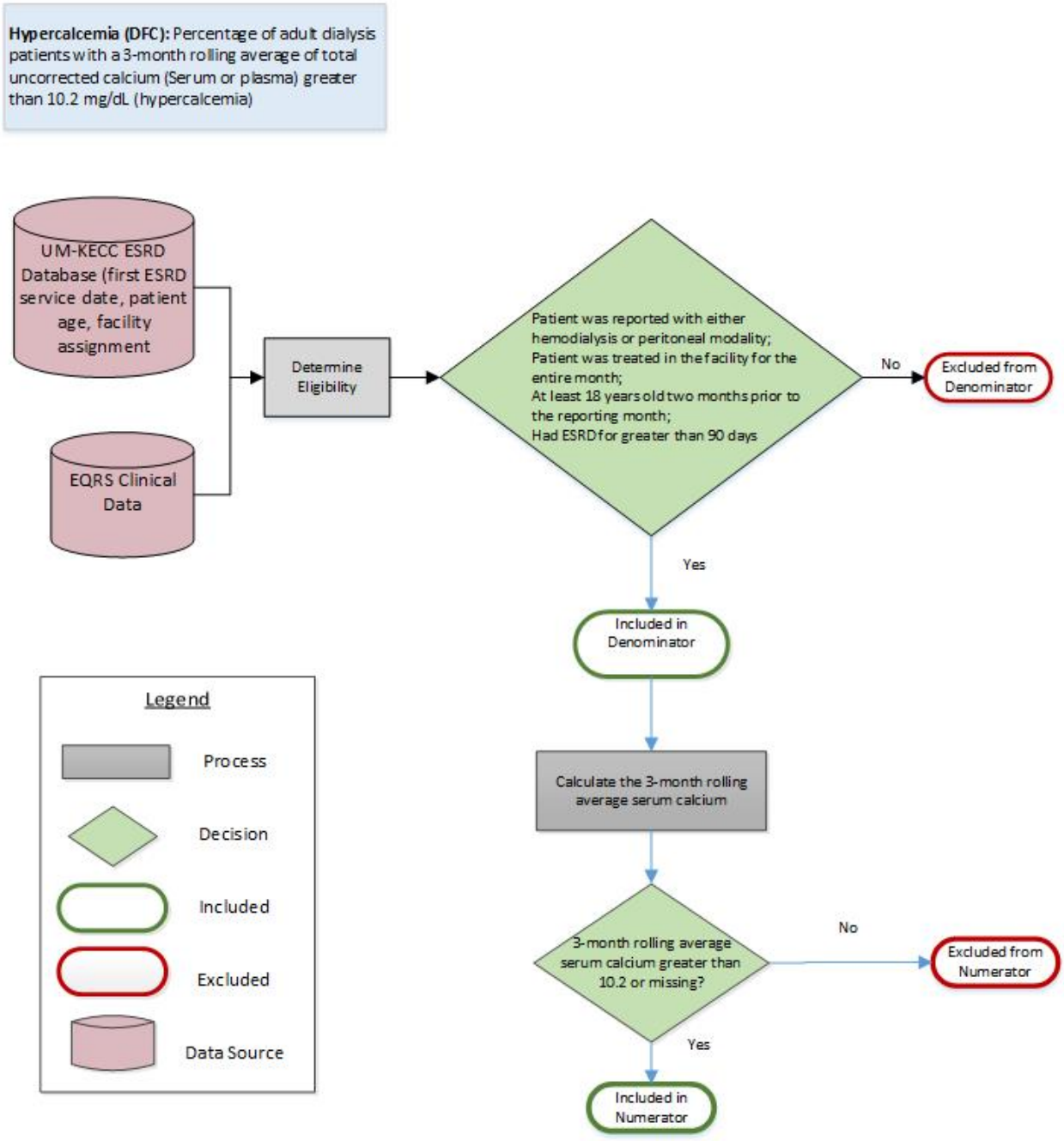

Figure 6: Hypercalcemia Clinical Measure Rate Flowchart (DFC Only)

2.9.16 Selected References

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- 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.
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- 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.

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

2.10.1 Measure Name

Screening for Clinical Depression and Follow-Up Reporting Measure – NQF #0418

2.10.2 Measure Description

Facility reports in EQRS one of the six conditions below 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 medical record:

- 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

2.10.3 Measure Type

Process

2.10.4 Facility Exclusions

- Facilities with fewer than 11 eligible patients during the performance period (see Section 2.10.5 below).
- Facilities with a CCN certification date on or after April 1 of the performance period.
- Calculations will exclude the months covered by a granted ECE.

2.10.5 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) between 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.

2.10.6 Determining Successful Reporting for a Patient

A facility is considered to have successfully reported for a patient if it reports one of the following six conditions in EQRS for the patient once before the close of the December clinical month. 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. (See Section 2.10.2 for definitions of bold terms)

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

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

2.10.7 Calculating a Facility's Score on the Depression Screening and Follow-Up Reporting Measure

An eligible facility's score on the Depression Screening and Follow-Up Reporting Measure is calculated according to the following equation:

$$\left[\frac{\text{Number of Eligible Patients for Whom a Facility Successfully Reports One of Six Conditions During the Performance Period}}{\text{Total number of Eligible Patients During the Performance Period}}\right] \times 10$$

The result of the division portion of the formula will be rounded to 8 decimals, then multiplied by 10. This will then be rounded to the nearest whole number (with half rounded up) to generate a measure score between 0-10. Negative scores will be rounded to zero.

2.10.8 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.org.

EQRS Data Elements:

- Facility CCN
- Initial certification date
- Patient date of birth
- CROWN UPI
- Admit date
- Discharge date
- Patient reporting measure type
- Patient reporting option info
- Patient reporting time period assessment

2.10.9 Flowchart

Figure 7 provides a flowchart that represents the processes used to calculate the Screening for Clinical Depression and Follow-Up Reporting Measure Rate.

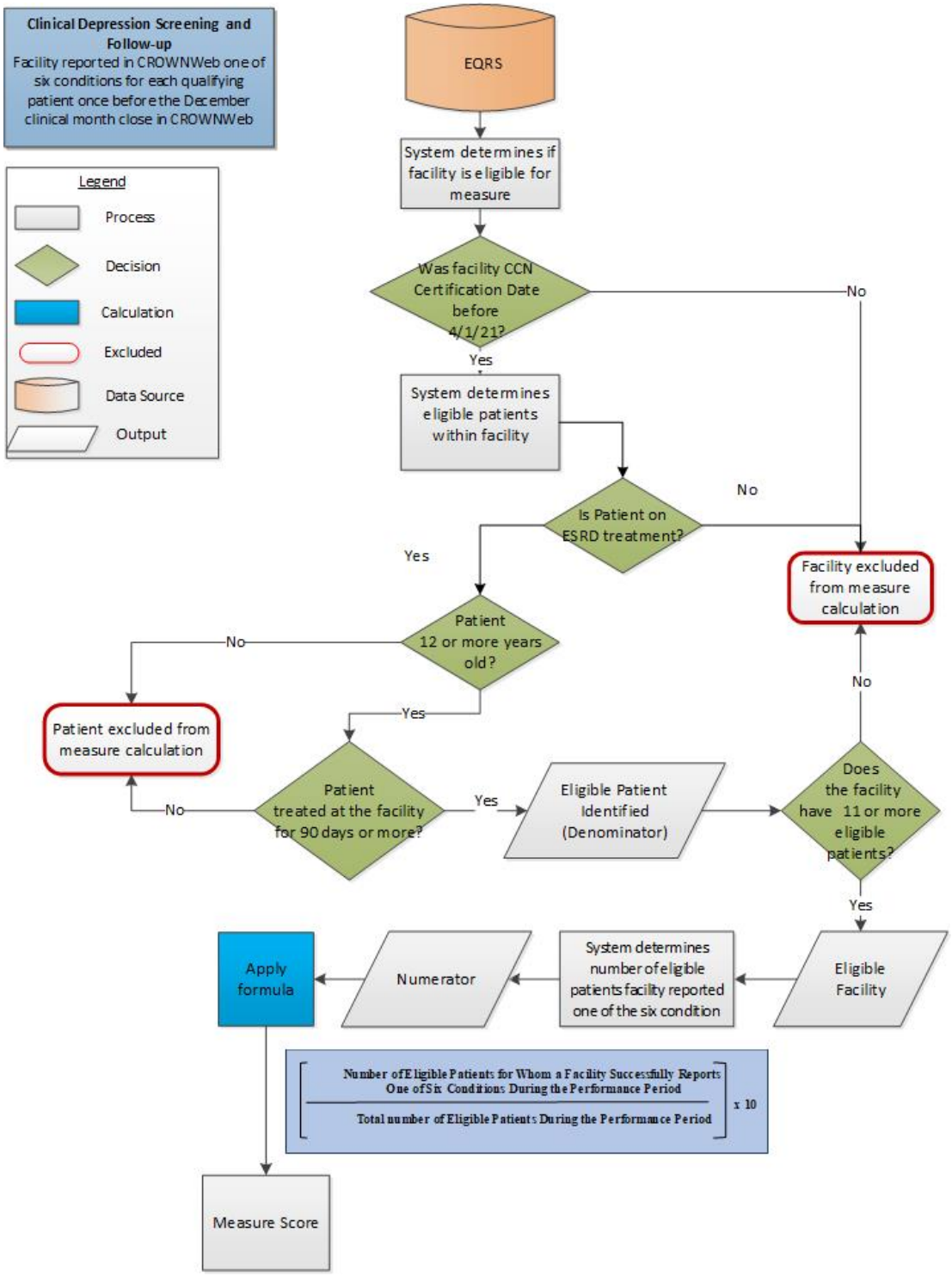

Figure 7: Screening for Clinical Depression and Follow-Up Reporting Measure Flowchart (ESRD QIP Only)

2.11 Standardized Readmissions Ratio (SRR) Clinical Measure (ESRD QIP and DFC)

2.11.1 Measure Name

Standardized Readmission Ratio for Dialysis Facilities (NQF #2496)

2.11.2 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.

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

ESRD QIP only:

- 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 skilled nursing facilities

(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. 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 2.11.17 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 the Centers for Medicare and Medicaid Services (CMS). 2013 Measure Updates and Specifications Report: Hospital-Wide All-Cause Unplanned Readmission Measure. https://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228890434757&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3DDryRun_HWR_TechReport_081012%2C0.pdf&blobcol=urldata&blobtable=MungoBlobs

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. 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. DFC also uses 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.
- **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-9-CM and 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 2.11.15 for a list of the CCs included in these areas.

- **Discharged with high-risk condition**: A *high-risk* diagnosis is any diagnosis area (grouped by the Agency for Healthcare Research and Quality (AHRQ) Clinical Classification Software (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.

2.11.12 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 k^{th} discharge among patients from the i^{th} 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 i^{th} 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 i^{th} 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 $\gamma\hat{}M$. Here, $\alpha\hat{}_j$ and β^ 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.

2.11.13 Calculation of SRR P-Values and Confidence Intervals (DFC only)

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 three groups based on the number of eligible patients 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.

2.11.14 Flagging Rules for Dialysis Facility Compare (DFC only)

As currently implemented for DFC, 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”.

2.11.15 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 OPTN (DFC only), and the Social Security Death Master File (DFC only) (CMS-2744), the CMS Medical Evidence Form (CMS-2728), and the Death Notification Form (CMS-2746) come from EQRS (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 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 Medicare Advantage 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 4) 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 Agency for Healthcare Research and Quality (AHRQ) Clinical Classification Software (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)

Variable	Primary Data Source
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

Table 3: Data Elements and Sources for Standardized Readmissions Ratio (SRR) Clinical Measure (ESRD QIP and DFC)

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) (DFC 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. DFC's 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.

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
	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

Description	CC	Detailed Description (if applicable)
	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

Description	CC	Detailed Description (if applicable)
Hemiplegia, paraplegia, paralysis	**67–69, 100–101**	
	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**	

Description	CC	Detailed Description (if applicable)
Respirator dependence/tracheostomy status	**77**	
Major organ transplant status	**174**	
Coagulation defects and other specified hematological disorders	**46**	
Hip fracture/dislocation	**158**	

Table 4. Past Year Comorbidities, Grouped by CMS' Condition Categories for Standardized Readmissions Ratio (SRR) Clinical Measure (ESRD QIP and DFC)

This grouping of CCs is based on the Hospital-wide Readmission Measure (HWR) measure; we removed or modified the following risk variable areas:

Removed

- Diabetes: Already adjusted for in model
- Protein calorie malnutrition: Present in many ESRD patients, potentially modifiable
- CHF: Present in many ESRD patients, potentially modifiable
- CAD/CVD: Present in many ESRD patients
- Arrhythmia: Present in many ESRD patients
- Dialysis status: Inappropriate to adjust for in dialysis population
- Fluid/electrolyte disorders: Inappropriate to adjust for in dialysis population; most patients have it and thus essentially an indicator of ESRD
- Iron deficiency: Inappropriate to adjust for in dialysis population; most patients have it and thus essentially an indicator of ESRD
- Acute renal failure: Inappropriate to adjust for in dialysis population

Modified

- Removed CC 102 (Speech, language, cognitive, perceptual) from HWR's original functional status adjustment: This comorbidity was found to have a much smaller effect than CCs 177 and 178, and was deemed clinically unrelated.
- Removed CCS 128 (Kidney transplant status) from HWR's original "Major organ transplant" adjustment: All patients in our population are currently on dialysis.

2.11.16 Flowchart

Figure 8 provides a flowchart that represents the processes used to calculate the Standardized Readmissions Ratio (SRR).

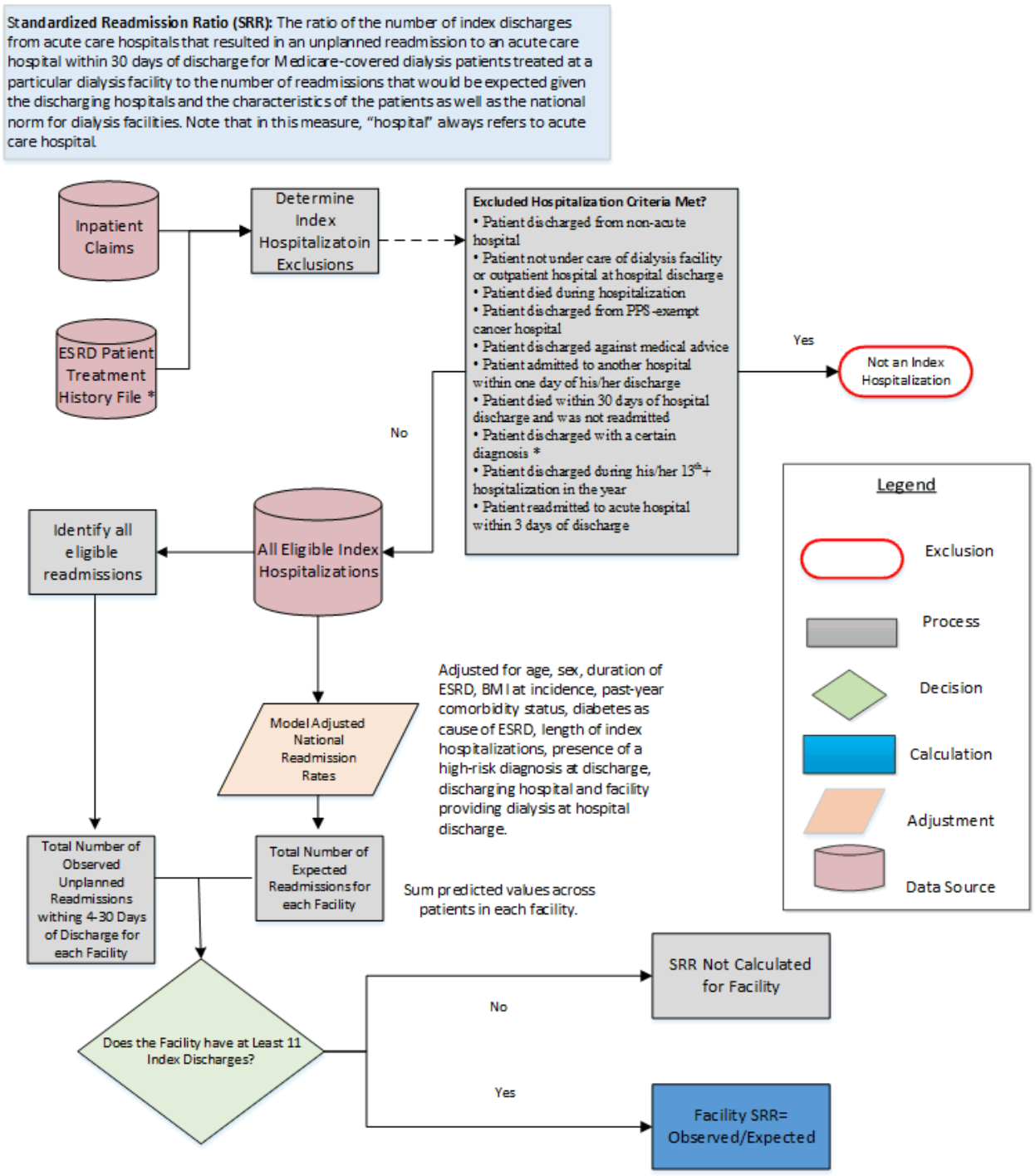

Figure 8: Standardized Readmissions Ratio (SRR) Flowchart (ESRD QIP and DFC)

From Figure 8:* = Multiple data sources include 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 (DFC), QIES, and the Social Security Death Master File (DFC).

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2.12 Standardized Transfusion Ratio (STrR) Clinical Measure (DFC only)

2.12.1 Measure Name

Standardized Transfusion Ratio for Dialysis Facilities (Based on NQF #2979)

2.12.2 Measure Description

The risk adjusted facility level transfusion ratio "STrR" is specified for all adult Medicare dialysis patients. 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.

This measure is calculated as a ratio but can also be expressed as a 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 erythropoiesis-stimulating agent (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 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 NQF (like SHR NQF #1463 http://www.qualityforum.org/QPS/1463). Patient time at risk is excluded for:

- Patients less than 18 years old (see Section 3.1.3)
- Patients on ESRD treatment for fewer than 90 days
- Patients on dialysis at the facility for fewer than 60 days
- Time during which patient has a functioning kidney transplant (exclusion begins 3 days prior to the date of transplant). Patients who have not been treated by any facility for a year or longer
- 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. 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.

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 9 describes the inclusion and exclusion period of a hypothetical patient.

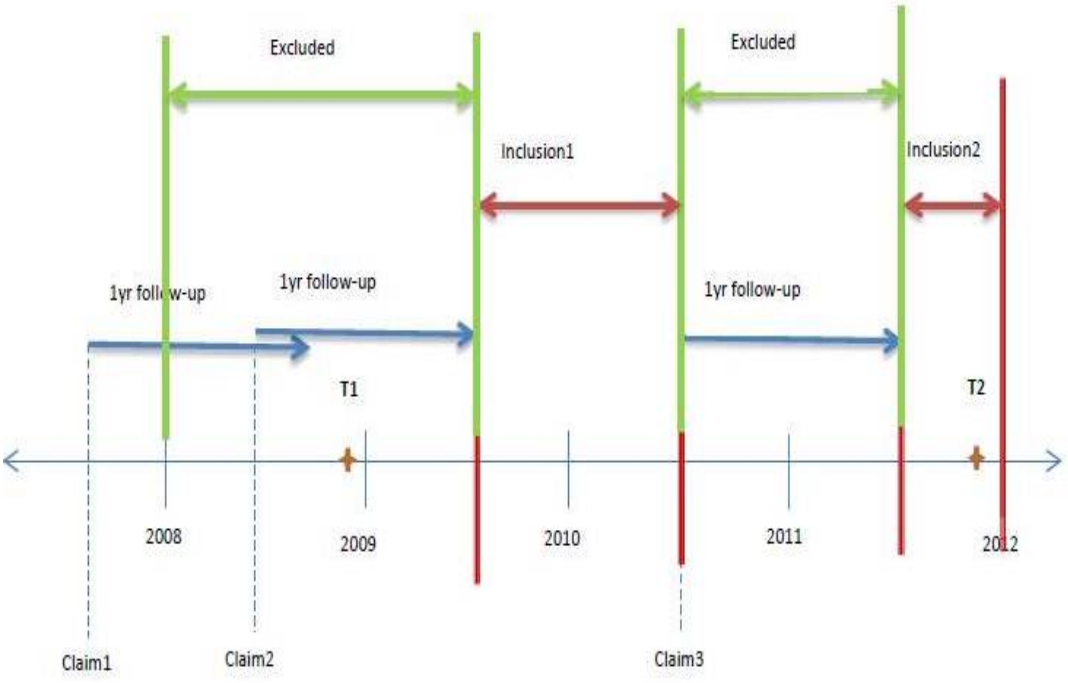

Figure 9: Algorithm for Exclusion of Periods of Time Within 1 Year of an Exclusion Comorbidity

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 1 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 90 after onset 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 90 of ESRD if that facility had treated him or her for at least 60 days. If on day 90, 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 Healthcare Common Procedure Coding System (HCPCS) codes with at least one revenue center codes.

One "transfusion event" is counted per inpatient claim if one or more transfusion-related procedure or value codes are present. A single transfusion event for an inpatient claim is counted regardless of the number of transfusion procedures 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 codes, 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.

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 patient's 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) $900+ 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 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 calendar year. 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 are:

- 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 (DFC only). Duration is categorized as 90 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: Using the Nursing Home MDS, determine if a patient was in a nursing home the previous year.
- BMI at incidence: Calculate each patient's BMI as the height and weight provided on his/her CMS 2728. BMI is included as a log-linear term.
- 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. 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.

- Calendar year

Categorical indicator variables are included as covariates in the stage 1 model to account for records with missing values for cause of ESRD, comorbidities at incidence (missing Medical Evidence Form (CMS-2728)), and BMI. 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. 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 $X) = r_{0k}(t)\exp(\boldsymbol{\beta}'\boldsymbol{X_{ik}})$

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 k^{th} facility, which is assumed to be a step function with break points at 6 months, 1 year, 2 years, 3 years, and 5 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 6 unknown parameters, $\alpha_1, \ldots, \alpha_6$, 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 sth time interval with estimated rate α_s. The corresponding expected number of transfusions in the sth interval for this patient is calculated as

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

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 sth time interval. Summing the $\mathbf{E_{iks}}$ over all 6 intervals and all N_k patients in a given facility, k, gives:

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

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

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

2.12.15 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

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

where $\mathbf{n_{ik}}$ is the observed number of event 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 $\mathbf{n_{ik}}$ 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 $\boldsymbol{\theta_k}$. The standard error of $\boldsymbol{\theta_k}$ 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

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

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.

2.12.16 Calculation of ESRD QIP STrR score

The STrR measure will be scored as a reporting measure for the ESRD QIP for PY 2023. Facilities that meet the minimum data and eligibility requirements (i.e. have at least 10 patient-years at risk in CY 2020), will receive a score of 10. All facilities that do not have at least 10 eligible patient-years at risk will receive a score of 'N/A'.

2.12.17 Data Elements and Data Sources

Table 5 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 (DFC 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

Variable	Primary Data Source
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]

Table 5: 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) (DFC only). For DFC, 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 DFC 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 3.2.2 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 (Figures 10-11)

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 10 provides a flowchart that represents the processes used to calculate the Standardized Transfusion Ratio (STrR) for DFC.

Standardized Transfusion Ratio: The risk adjusted facility level transfusion ratio "STrR" is specified for all adult Medicare dialysis patients. 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.

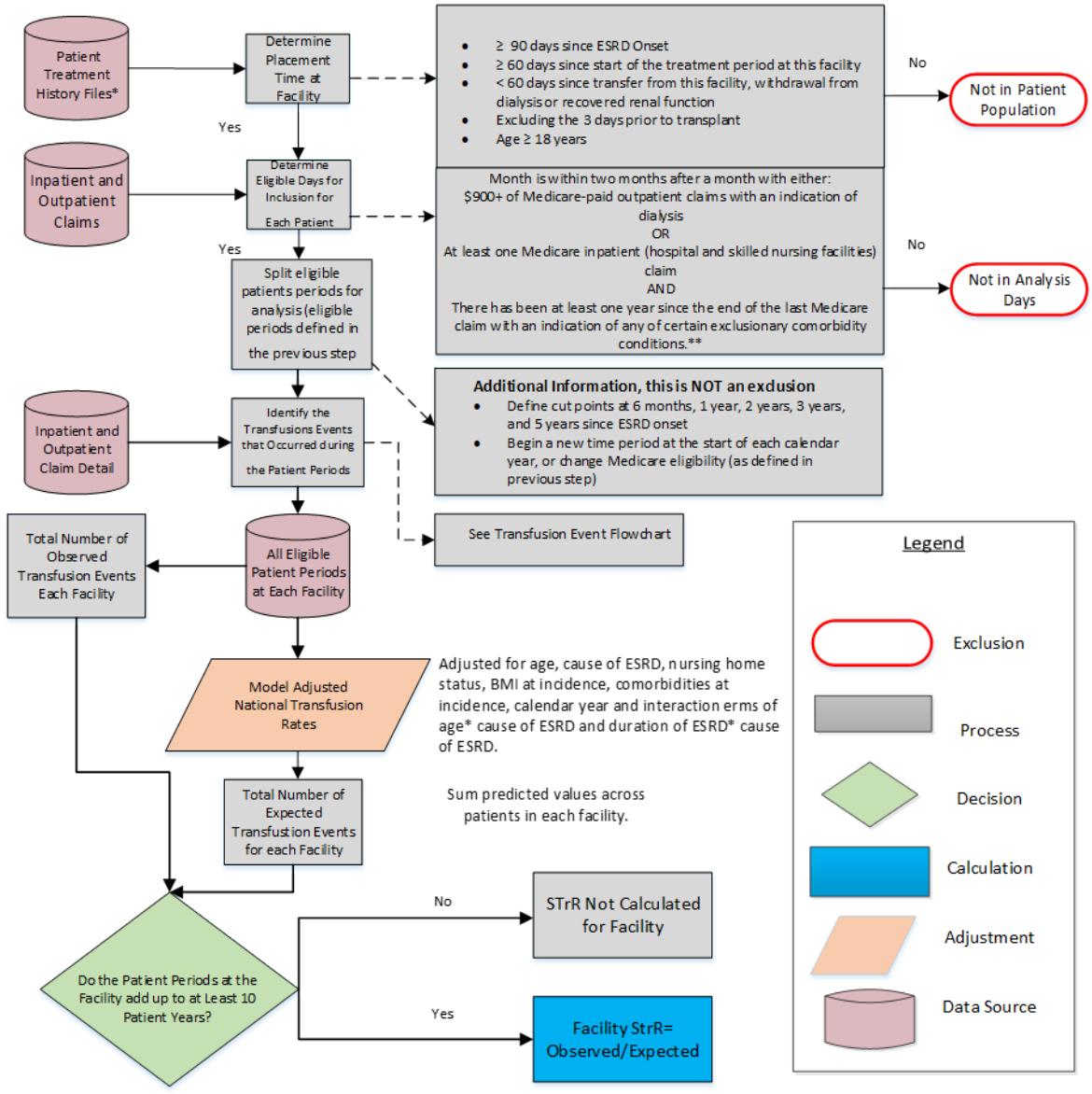

Figure 10: Standardized Transfusion Ratio Measure Flowchart (DFC only)

* 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 – DFC only), the Death Notification Form (Form CMS-2746), the Dialysis Facility Compare (DFC) 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 11 shows the method of determining transfusion events.

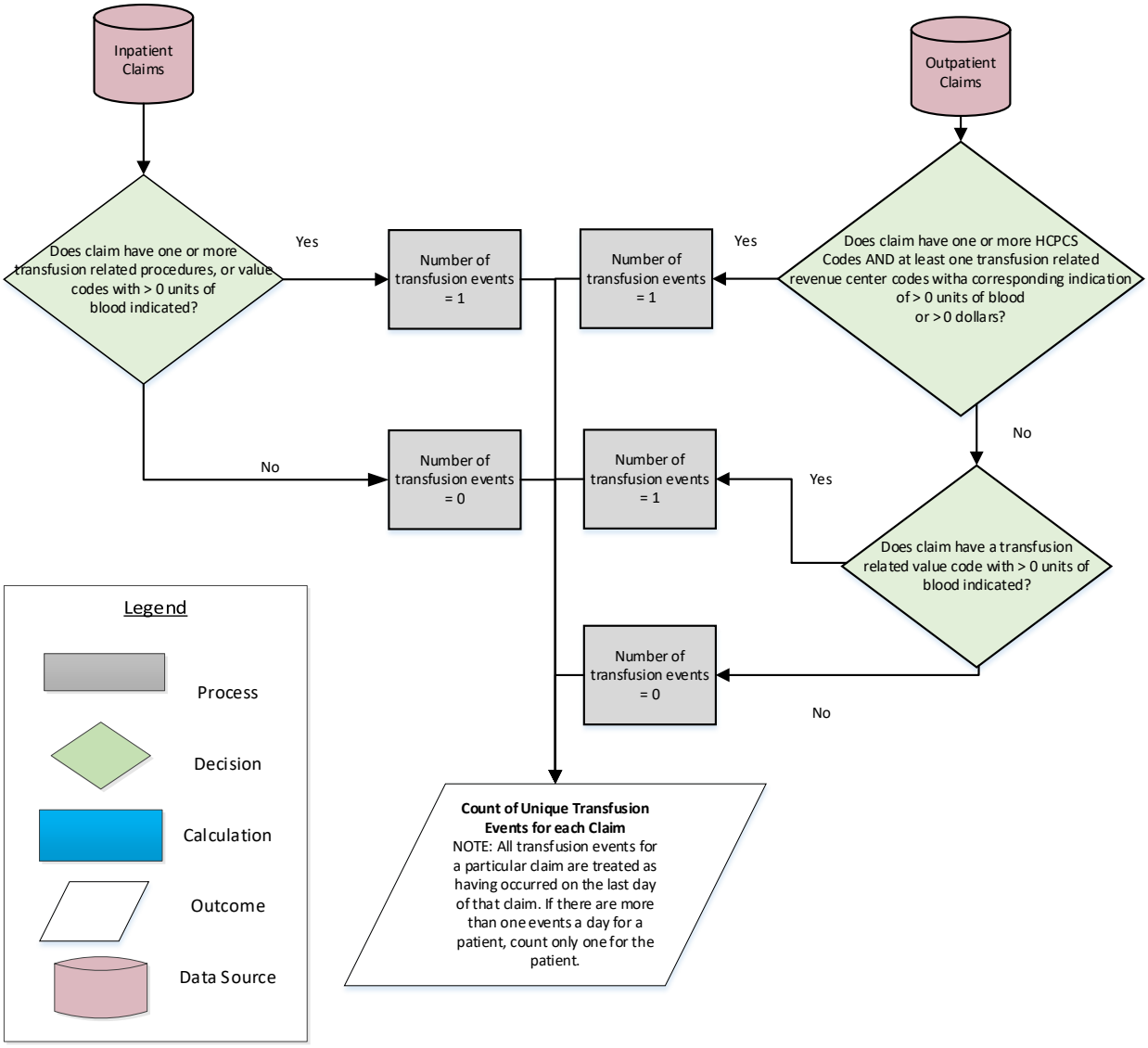

Figure 11: Method of Determining Transfusion Events Flowchart (DFC only)

Table 6 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
9	9903	Other Transfusion Of Whole Blood	Procedure Codes
9	9904	Transfusion Of Packed Cells	Procedure 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

ICD Version	Code	Description	Field
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
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

ICD Version	Code	Description	Field
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
	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

ICD Version	Code	Description	Field
	36430	Current Procedural Terminology (CPT) code	HCPCS Codes

Table 6: 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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2.13 Standardized Hospitalization Ratio (SHR) Measure (ESRD QIP and DFC)

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. This measure is calculated as a ratio but can also be expressed as a rate (NQF# 1463).

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 standardized hospitalization ratio is only calculated for facilities with at least 5 patient years at risk (see Section 2.13.10.1 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. Denominator Exclusions

Patient Time at Risk Exclusions:

- First 89 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 3 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 are not within or in the two months following a month in which the patient has $900 of Medicare-paid dialysis claims or at least one Medicare inpatient (hospital orSNF) claim.

2.13.9 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 (DFC only), the Death Notification Form (CMS-2746) and the Social Security Death Master File (DFC only). Also see Section 3.1.6. Additionally, for DFC, 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 90 days. Thus, hospitalizations, mortality and survival during the first 89 days of ESRD do not enter into the calculations. This minimum 90-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 89 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 90 after onset 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 his or her current facility on day 90 of ESRD if that facility had treated him or her for the past 60 days. If on day 90, 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.

2.13.9.1 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 6-time intervals with cut points at 6 months, 1 year, 2 years, 3 years and 5 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 each calendar year.

Because we identify hospitalizations only if they appear in Medicare inpatient claims, we only include patients during time periods in which all of the patient's hospitalizations are included in Medicare billing records. Therefore, we require that patients either reach a certain level of Medicare-paid dialysis bills or have Medicare inpatient claims during the period. Specifically, months within a given dialysis patient-period are used for SHR calculation when they meet the criterion of being during or within two months after a month with either: (a) $900+ of Medicare-paid dialysis claims OR (b) at least one Medicare (hospital and SNF) inpatient claim. The intention of this criterion 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).

2.13.10 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 rules discussed above. The numerator is the count of all such hospitalizations over the reporting period.

2.13.11 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, nursing home status, BMI at incidence, comorbidities at incidence, prevalent comorbidities, and calendar year. 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 for the birth date provided by multiple data sources* group patients into the following categories: 0-14 years old, 15-24 years old, 25-44 years old, 45-59 years old, 60-74 years old, or 75+ years old.
- 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 90 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: Using the Nursing Home MDS, determine if a patient was in a nursing home the previous year.
- BMI at incidence: Calculate each patient's BMI as the height and weight provided on his/her CMS 2728. BMI is included as a log-linear term.
- 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. 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). Each comorbidity is included as a separate covariate in the model.

- Prevalent comorbidities: 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*, which can be found on the Measuring Quality page on the ESRD QIP section of CMS.gov.
- 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, comorbidities at incidence (missing 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. 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 age, sex, and duration and cause of ESRD are also included. Interactions between the following pairs of variables are included:

- Diabetes as cause of ESRD and duration of ESRD (categorical, as defined above)
- Diabetes as cause of ESRD and Sex
- Diabetes as cause of ESRD and Age
- Age and Sex

2.13.12 Calculating Expected Hospital Admissions

The modeling process has two stages. 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 i^{th} patient in the k^{th} 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 k^{th} facility and is assumed to be a step function with break points at 6 months, 1 year, 2 years, 3 years, and 5 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 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 6 unknown parameters, $\alpha_1, \ldots, \alpha_6$, 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 s^{th} time interval with estimated rate α_s. The corresponding expected number of hospital admissions in the s^{th} 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 s^{th} time interval. Summing the E_{iks} over all 6 intervals and all N_k patients in facility k gives

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

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

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

2.13.13 Calculation of SHR P-Values and Confidence Intervals (DFC 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

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

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 SHR 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 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

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

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

2.13.14 Flagging Rules for Dialysis Facility Compare (DFC only)

As currently implemented for DFC, for reporting purposes we identify outlier facilities from amongst those with at least 5 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".

2.13.15 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]
BMI at incidence	Medical Evidence Form (CMS-2728)
Nursing home status (in the previous calendar year)	Nursing Home Minimum Data Set
Diabetes - Primary cause of ESRD	Medical Evidence Form (CMS-2728) EQRS
Incident comorbidities	Medical Evidence Form (CMS-2728)

Variable	Primary Data Source
Prevalent comorbidities	Medicare Claims[2]
Hospital admissions	Inpatient Medicare claims

Table 7: Data Elements and Sources for the Standardized Hospitalization Ratio (ESRD QIP and DFC)

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) (DFC 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. DFC 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. 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.

2.13.16 Flowchart

Figure 12 provides a flowchart that represents the processes used to calculate the Standardized Hospitalization Ratio (SHR).

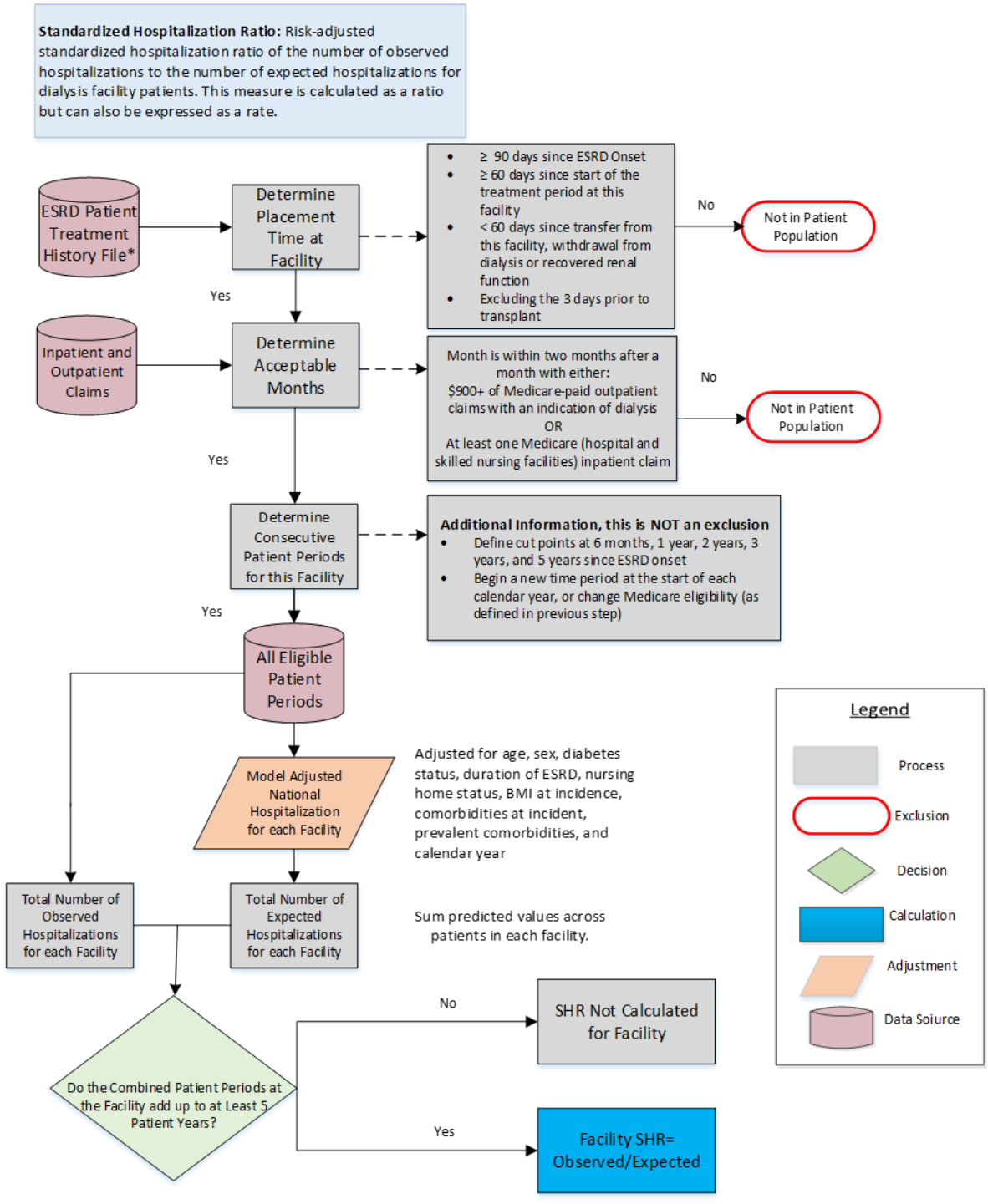

Figure 12: Standardized Hospitalization Ratio (SHR) Flowchart (ESRD QIP and DFC)

* 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 (DFC), the Nursing Home Minimum Data Set (MDS), Quality Improvement Evaluation System (QIES), and the Social Security Death Master File.

2.13.17 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 (DFC Only)

2.14.1 Measure Name

Standardized Mortality Ratio for Dialysis Facilities

2.14.2 Measure Description

Standardized mortality ratio 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 3 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, and BMI at incidence. 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 90 days. This minimum 90-day period assures that most patients are eligible for Medicare insurance either as their primary or secondary insurer. It also excludes from analysis patients who died during the first 90 days of ESRD.

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

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 his or her 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 him or her 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. When patients are treated at the same facility for two or more separate time periods during a year, the days at risk at the facility is the sum of all time spent at the facility for the year so that a given patient can generate only one patient-record per year at a given facility. For example, consider a patient who spends two

periods of 100 days assigned to a facility, but is assigned to a different facility for the 165 days between these two 100-day periods. This patient will give rise to one patient-record of 200 days at risk at the first facility, and a separate patient-record of 165 days at risk at the second facility.

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. 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) $900+ of Medicare-paid dialysis claims OR (b) at least one Medicare inpatient claim.

Then 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 death 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 and BMI at incidence. 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 0-13 years old, 14-60 years old, or 61+ years old.
- Sex: Determine each patient's sex from EQRS.

- Race (White, Black, Asian/PI, Native American or other): We determine race from EQRS, Medical Evidence Form (CMS-2728), and the CMS Medicare Enrollment Database 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: We 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 (DFC 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 in previous year: Using the Nursing Home Minimum Dataset, determine if a patient was in a nursing home the previous year.
- BMI at incidence: Calculate each patient's BMI as the height and weight provided on patient's CMS-2728. BMI is included as a log-linear term. The logarithm of BMI is included as a piecewise continuous log-linear term with different coefficients based on whether the log of BMI is greater or less than 3.5.
    - BMI is imputed when either missing, or outside the range of 10 to 70 for adults or 5 to 70 for children. For patients with missing BMI, we match them to patients with non-missing BMI based on age, race, sex, and diabetes and assign the average BMI of the patient subgroup. However, not all patient subgroups will have a BMI calculated. For these cases, we match the patients based on age and race and assign the patients the average BMI in the corresponding age and race category.
- 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.
- Calendar year

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
- Duration of ESRD: less than or equal to 1 year and Sex
- Diabetes as cause of ESRD and Sex
- 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 U.S. Centers for Disease Control National Center for Health Statistics. The 2018 October Release of DFC used age-adjusted death rates for 2013-2015 from Table 16 of the publication Health, United States, 2016, 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 i^{th} 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. Note that each patient record corresponds to a single facility and to a single calendar year.

The Cox model is applied in two stages. Stage 1 yields estimates of the coefficients ($ß_j$) for the 56 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 j^{th} characteristic for the i^{th} patient-record. In stage 1, for patient-record i, we denote the measured characteristics or covariates in a vector form as

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

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, $\beta_1, \beta_2, \ldots, \beta_p$ and the corresponding predicted value for the i^{th} patient-record is given by

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

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

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

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:

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

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:

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

Note that, patient-records with 100 days of follow-up, who are otherwise the same, give rise to the same expected mortality even if the 100-day period started at different dates during the year. This approximation is made to simplify the calculations.

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

The p-value for a given facility is a measure of the strength of the evidence against the hypothesis that the mortality rate for this facility is identical to that seen nationally overall, having adjusted for the patient mix. Thus, the p-value is the probability that the facility's SMR would deviate from 1.00 by at least as much as the facility's observed SMR. In practice, the p-value is computed using a Poisson approximation under which the distribution of the number of deaths in the facility is Poisson with a mean value equal to E, the expected number of deaths as computed from the Cox model and described in the previous section. Accordingly, if the observed number, O, is greater than E, then

$$\text{p-value} = 2 * Pr(X \geq O)$$

where X has a Poisson distribution with mean E. Similarly, if O<E, the p-value is

$$\text{p-value} = 2 * \Pr(X \leq E).$$

If the p-value is small (<5%, say), then there is substantial evidence that the true SMR is not equal to 1. If in addition O>E, then the evidence suggests that the true SMR is larger than 1; if O<E, the evidence suggests that the true SMR is less than 1.

The 95% confidence interval (or range of uncertainty) for a given facility gives a range of plausible values for the true SMR, that is the true ratio of facility-to-national death rates. The upper and lower limits enclose the true ratio between them approximately 95% of the time. If the p-value is ≤5%, then the 95% confidence interval does not include the value 1.0 that corresponds to the null hypothesis that this facility has death rates identical to the national norm.

To compute the confidence intervals, the test described above is generalized to allow a test that the true SMR is equal to any specified value θ. Under this hypothesis, the expected number of events in the facility is θE and this is the mean of the approximate Poisson distribution for the number of failures X. Thus, we can compute a p-value as above for each specified value of θ to obtain:

$$P(\theta) = 2 * \min[\Pr(X \geq O) , \Pr(X \leq O)]$$

where X has a Poisson distribution with mean θE. The 95% confidence interval is the set of all values of θ that give a p-value that exceeds 5%. More specifically,

$$CI = \{ \theta \mid P(\theta) > 0.05\}.$$

2.14.15 Flagging Rules for Dialysis Facility Compare (DFC)

As currently implemented for DFC, for reporting purposes we identify outlier facilities from amongst those with at least 5 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.”

2.14.16 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]
Gender	CMS data sources[1]

Variable	Primary Data Source
Date of first ESRD	Medical Evidence Form (CMS-2728) EQRS Patient Event OPTN Data Medicare Claims
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)
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]

Table 8: Data Elements and Sources for the Standardized Mortality Ratio Measure (DFC 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) (DFC 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. DFC 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 13 provides a flowchart that represents the processes used to calculate the Standardized Mortality Ratio.

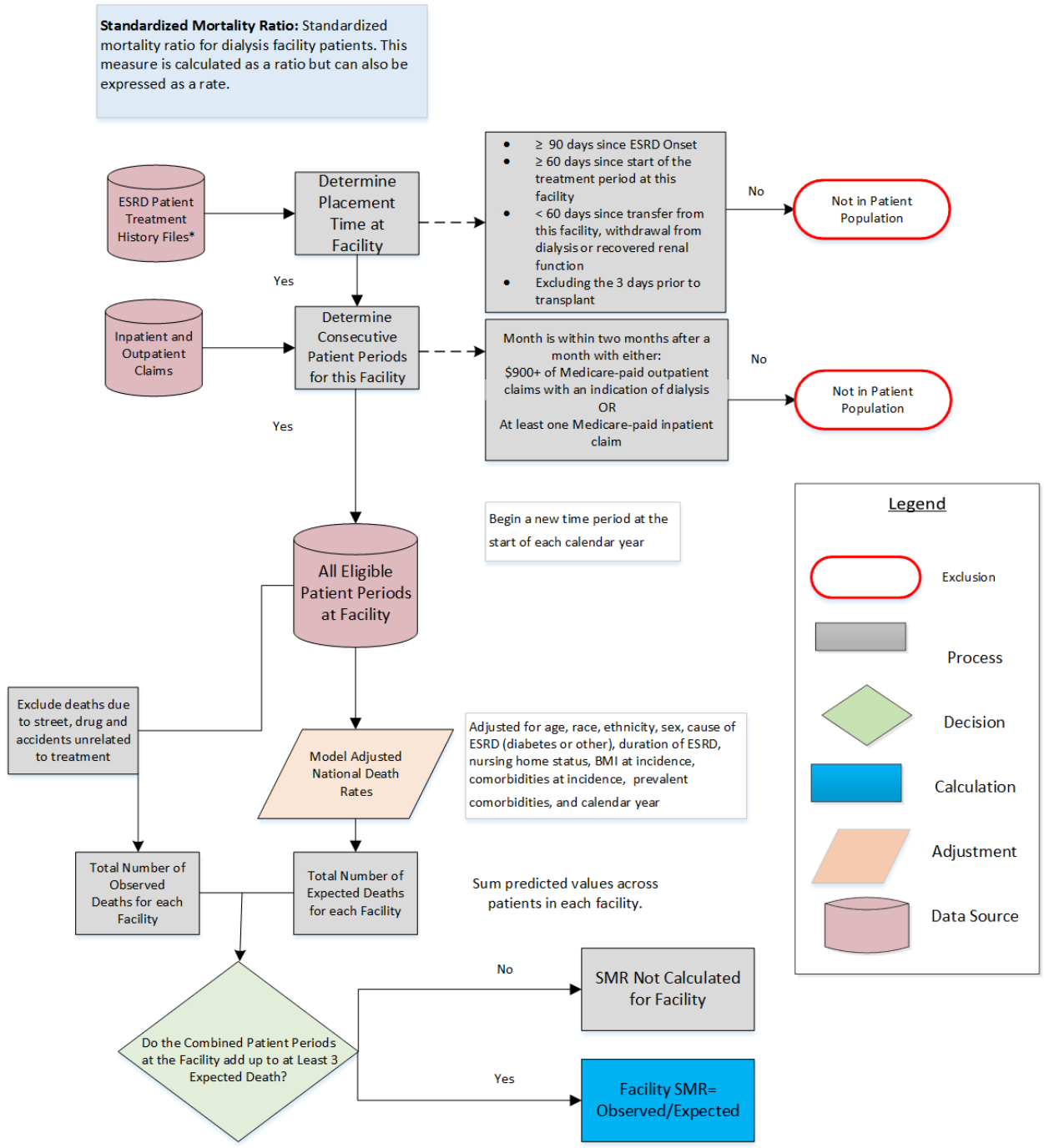

Figure 13: Standardized Mortality Ratio Flowchart (DFC Only)

* 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 (DFC), 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 (DFC Only)

2.15.1 Measure Name

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

2.15.2 Measure Description

The 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 Standardized Waitlist Ratio (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 Percentage of Prevalent Patients Waitlisted (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 2 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 Minimum Data Set (MDS) were the data sources used for determining SNF patients. Patients who were identified in Questions 17u and 22 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 or
- 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 j^{th} characteristic for the i^{th} patient-record. At the first stage, for patient-record i, we denote the measured characteristics or covariates as

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

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, $ß_1$, $ß_2$, …, $ß_p$ and the corresponding predicted value for the i^{th} patient-record is given by

$$\mathbf{X_i ß} = ß_1 x_{i1} + ß_2 x_{i2} + \ldots + ß_p x_{ip}. \quad (1)$$

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

$$\mathbf{A_i} = ß_0x_{i0} + \mathbf{X_i ß} = ß_0x_{i0} + ß_1x_{i1} + ß_2x_{i2} + \ldots + ß_px_{ip} \qquad (2)$$

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:

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

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

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

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

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

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

$$\mathbf{SWR = O/E.} \qquad (6)$$

2.15.14 Creating Interval Estimates

Similar to the Standardized Mortality Ratio (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 (DFC)

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 DFC for facilities with less than 11 patients or less than 2 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 Minimum Dataset 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, CVA, 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)

Variable	Primary Data Source
Needs assistance with daily activities	Medical Evidence Form (CMS-2728)
Nursing home status*1*2	Medical Evidence Form (Form CMS-2728) Question 17u and 22
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 9: Data Elements and Sources for the Standardized Waitlist Ratio (DFC 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 Minimum Dataset 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 14 provides a flowchart that represents the processes used to calculate Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR).

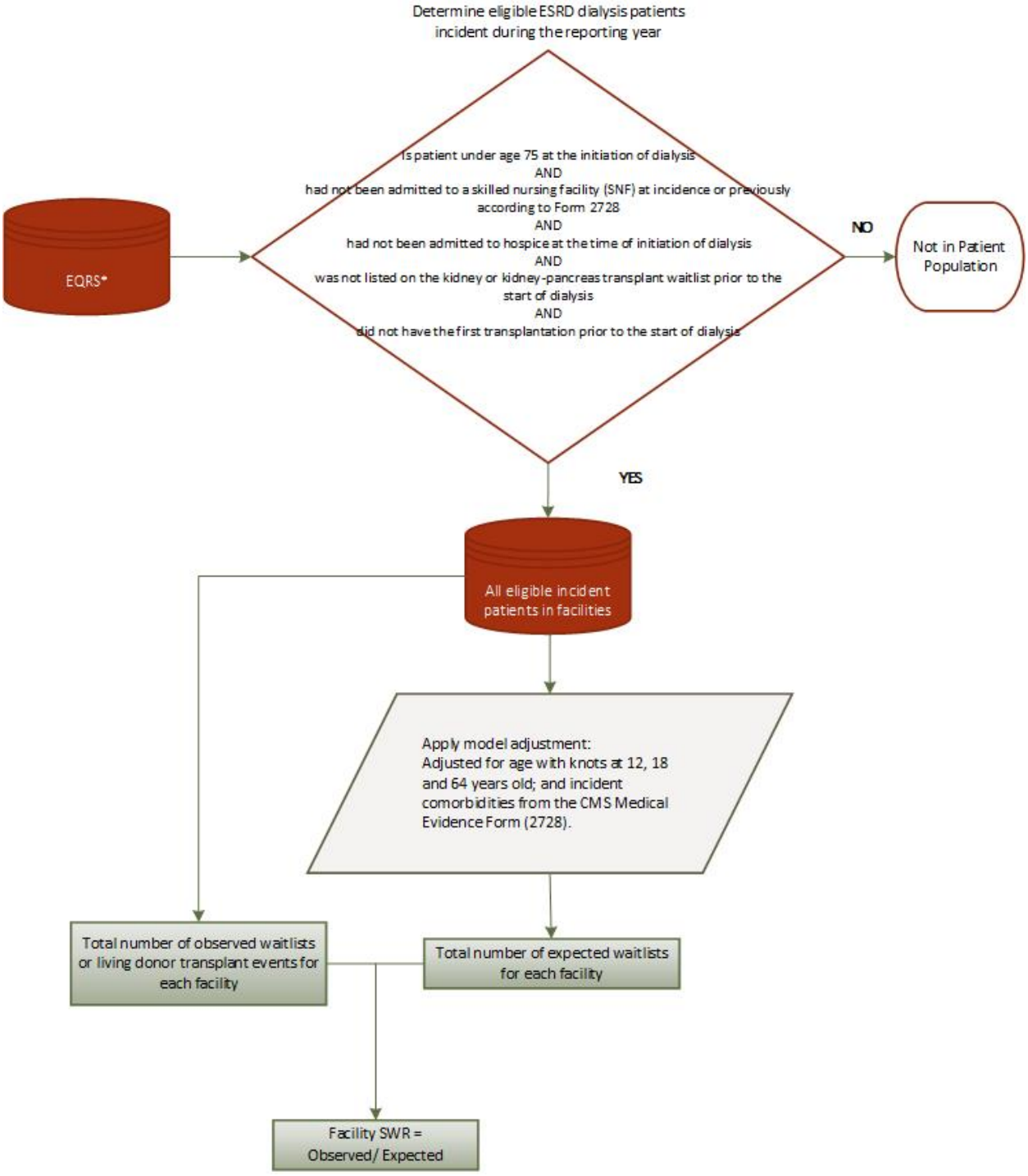

Figure 14: Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) Measure (DFC Only)

* 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 Minimum Dataset 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 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 DFC)

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. Results are averaged across patients prevalent on the last day of each month during the reporting year, adjusted for age.

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

Process

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.
- Patient who were admitted to an SNF or a hospice during the month of evaluation were excluded from that month; patients who were admitted to an SNF at incidence or previously according to Form CMS-2728 were also excluded.

The Nursing Home Minimum Dataset and the Questions 16u and 21 on 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 additional sources including the CMS Medical Evidence Form (CMS-2728), transplant data from the OPTN (DFC only), the Death Notification Form (CMS-2746) and the Social Security Death Master File (DFC only). Also see Section 3.1.6. Additionally, for DFC, 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. The model is adjusted for age,

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

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, $\beta A_{ij,}$ 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., $SE(PPPW_j)=d_j \ x \ SE(a_j)$, 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 (DFC 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 (DFC 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 DFC, respectively. The Nursing Home Minimum Dataset 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) Question 17u and 22
Nursing home status in the current month [3]	CMS Long Term Care Minimum Data Set (MDS)

Variable	Primary Data Source
Hospice status in the current month [3]	CMS Hospice file

Table 10: 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 Minimum Dataset 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 15 provides a flowchart that represents the processes used to calculate Percentage of Prevalent Patients Waitlisted Measure (PPPW).

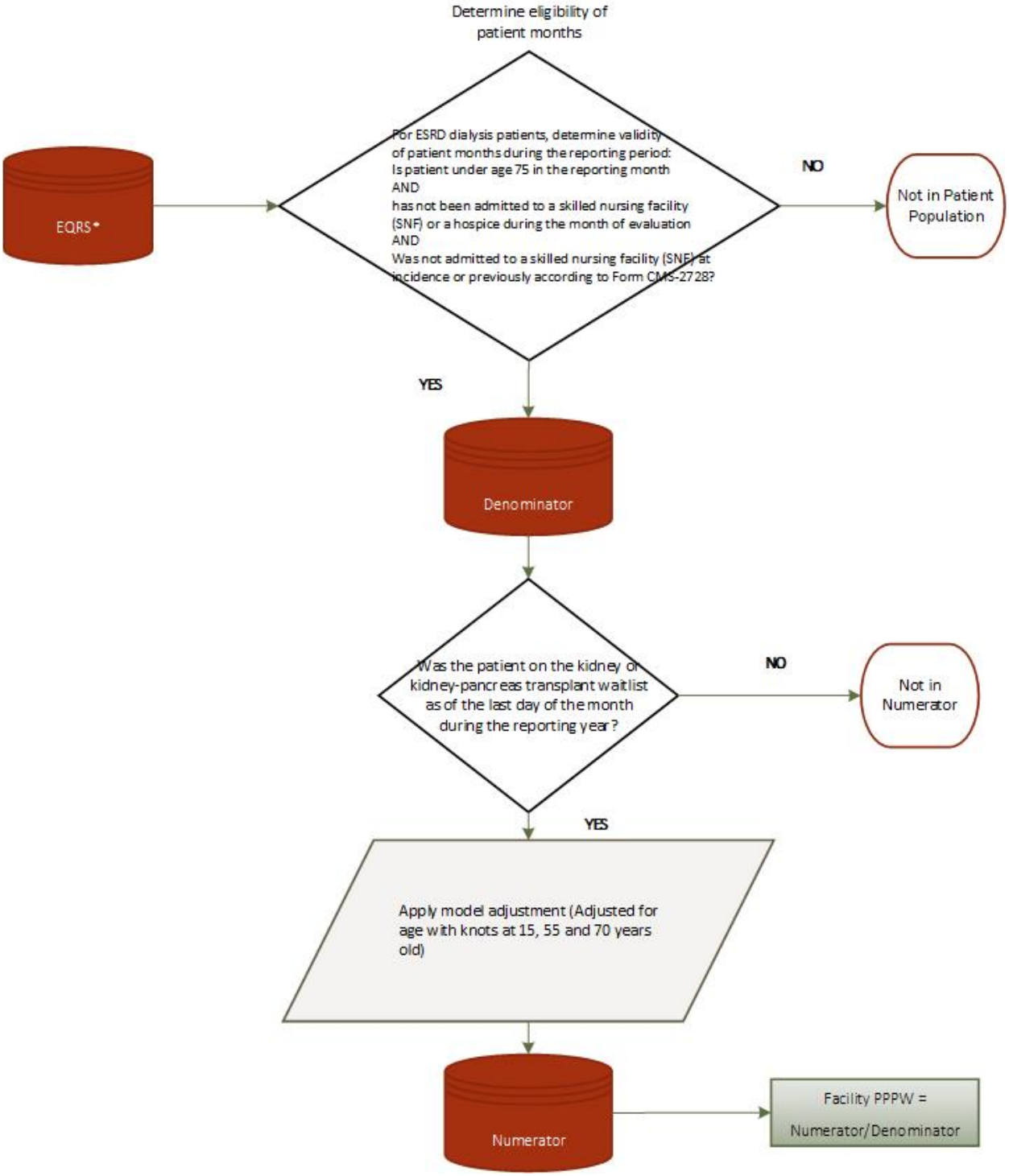

Figure 15: Flowchart for the Percentage of Prevalent Patients Waitlisted Measure

*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 (DFC only). For denominator exclusions, the Nursing Home Minimum Dataset and the Questions 17u and 22 on 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.
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- 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) - NQF #0258

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. (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 measures 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 in-center hemodialysis 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 in-center HD as of December 31 of the performance period. 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 in-center HD at sampled facility for the past 3 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 receiving HD from their current facility for less than 90 days
- Patients receiving hospice care
- Patients currently residing in an institution, such as a residential nursing home or other long-term care facility, or a jail or prison

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 CROWNWeb 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.org.

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

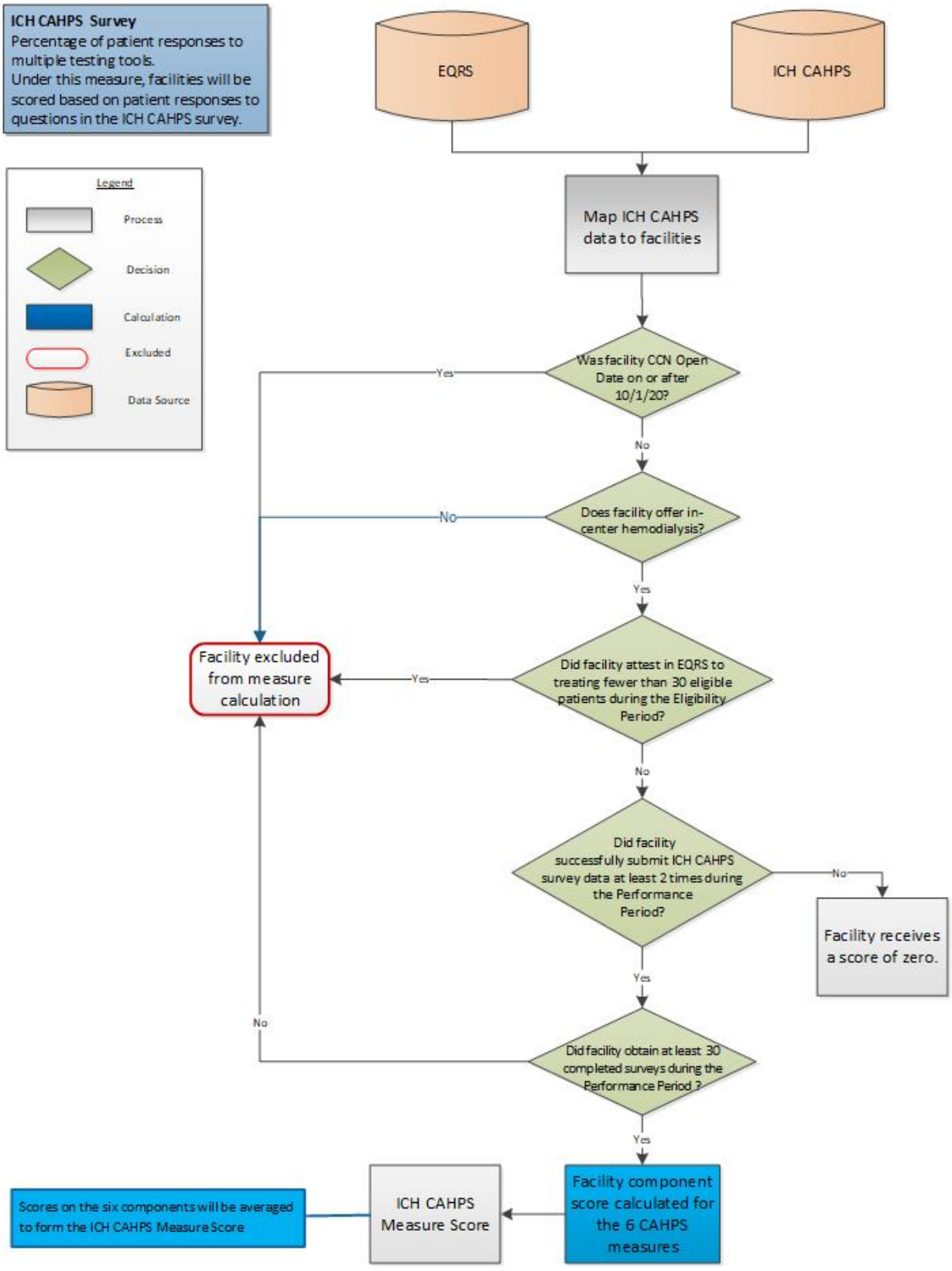

Figure 16: ICH CAHPS Survey Flowchart (ESRD QIP Only)

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 – NQF #1460

2.18.2 Measure Description

The SIR of BSI will be calculated among patients receiving HD at outpatient HD centers.

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 in-center HD 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 in-center HD patients during the performance period, where in-center HD patients are defined as patients whose primary treatment modality is in-center HD and (1) have a Medicare claim submitted by the facility during the performance year; or (2) have a treatment at an outpatient dialysis facililty 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 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 a 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 quarterly deadlines specified by the CDC's NHSN and ESRD QIP website: https://www.cdc.gov/nhsn/faqs/dialysis/faq-esrd-qip.html. 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.

CDC Data Elements:

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

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

- Certification Date
- CROWN Unique Patient Identifier (UPI)
- CROWN 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 17 provides a flowchart that represents the processes used to calculate the NHSN BSI in HD outpatient's measure in the ESRD QIP.

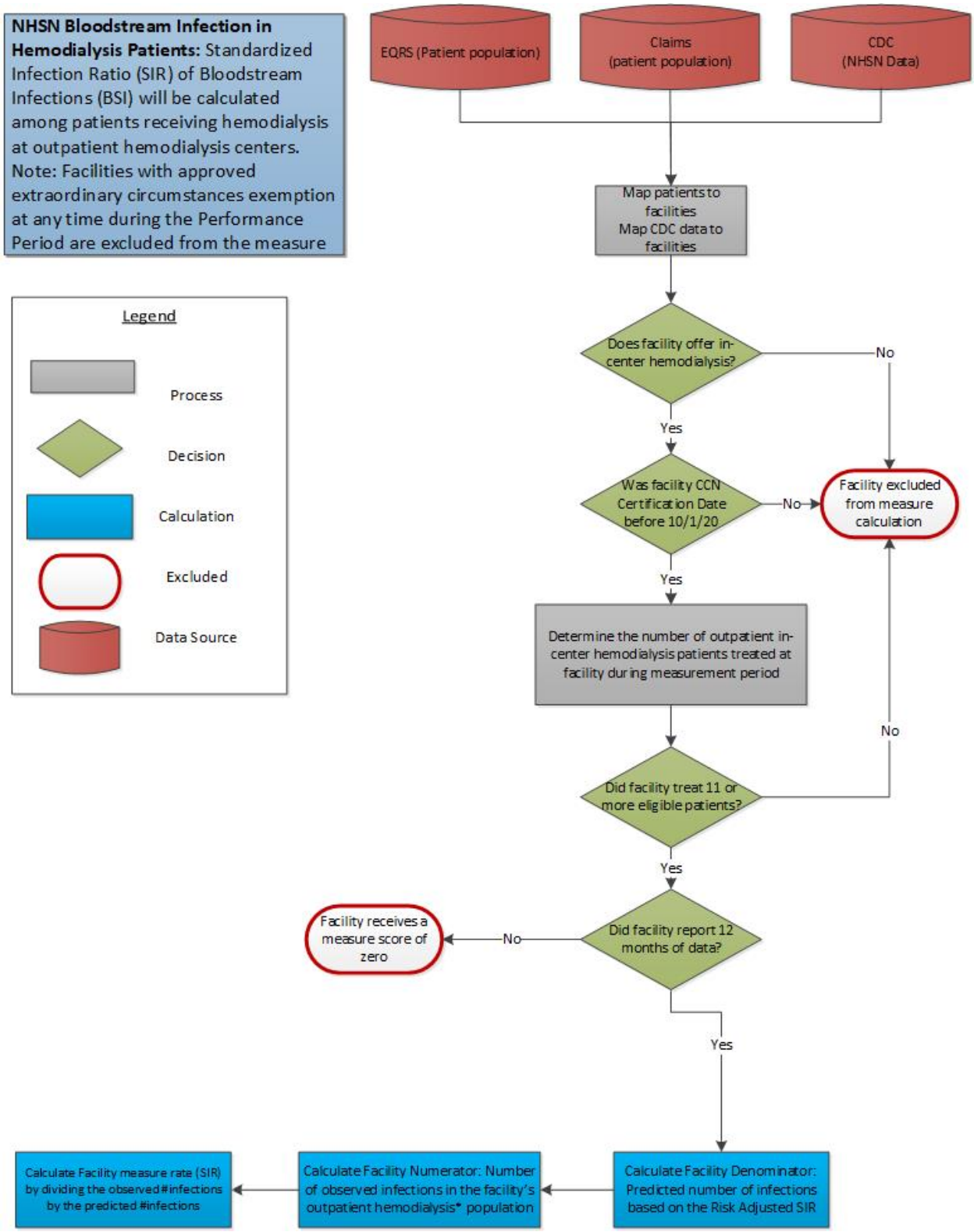

Figure 17: NHSN Bloodstream Infection in Hemodialysis Outpatients Flowchart (ESRD QIP Only)

2.19 NHSN Dialysis Event Reporting Measure (ESRD QIP Only)

2.19.1 Measure Name

The National Healthcare Safety Network (NHSN) Dialysis Event Reporting

2.19.2 Measure Description

Number of months for which facility reports NHSN Dialysis Event data to the CDC. There are three types of dialysis events reported by users: IV antimicrobial start; positive blood culture; and pus, redness, or increased swelling at the vascular access site.

Dialysis Event data are due quarterly; please refer to the following CDC NHSN website link for further details: https://www.cdc.gov/nhsn/dialysis/event/index.html.

2.19.3 Measure Type

Process

2.19.4 Improvement Noted as Higher or Lower Rate

A higher number indicates better quality.

2.19.5 Facility Exclusions

- Facilities that do not offer in-center HD as of December 31 of the performance period
- Facilities with a CCN certification date on or after September 1 of the performance year
- Facilities that treat fewer than 11 in-center HD patients during the performance period, where in-center HD patients are defined as patients whose primary treatment modality is in-center HD 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

2.19.6 Additional Information

- Granted ECE months are not counted as eligible months.
- New facilities are required to report NHSN dialysis event on the first day of the month that is 4 months after the month in which the facility is certified to participate in Medicare.
- The NHSN Dialysis Event Reporting measure is scored as follows:
  - 10 points for reporting 100% of eligible months
  - 2 points for reporting less than 100% but no less than 50% of eligible months
  - 0 points for reporting less than 50% of eligible months.
  - Facilities are required to follow the NHSN Dialysis Event Protocol and submit data to NHSN by the quarterly deadlines specified by the CDC's NHSN and ESRD QIP website: https://www.cdc.gov/nhsn/faqs/dialysis/faq-esrd-qip.html. Once the quarterly reporting deadline has passed, a frozen data file is created for calculating

final 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.

Additional details on the specifications for the NHSN Dialysis Event Reporting measure can be found at the following website: http://www.cdc.gov/nhsn/Training/dialysis/index.html

2.19.7 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.org.

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

- Certification date
- CROWN UPI
- CROWN 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)

2.19.8 Flowchart

Figure 18 provides a flowchart that represents the processes used to calculate the NHSN Dialysis Event Reporting measure for the ESRD QIP.

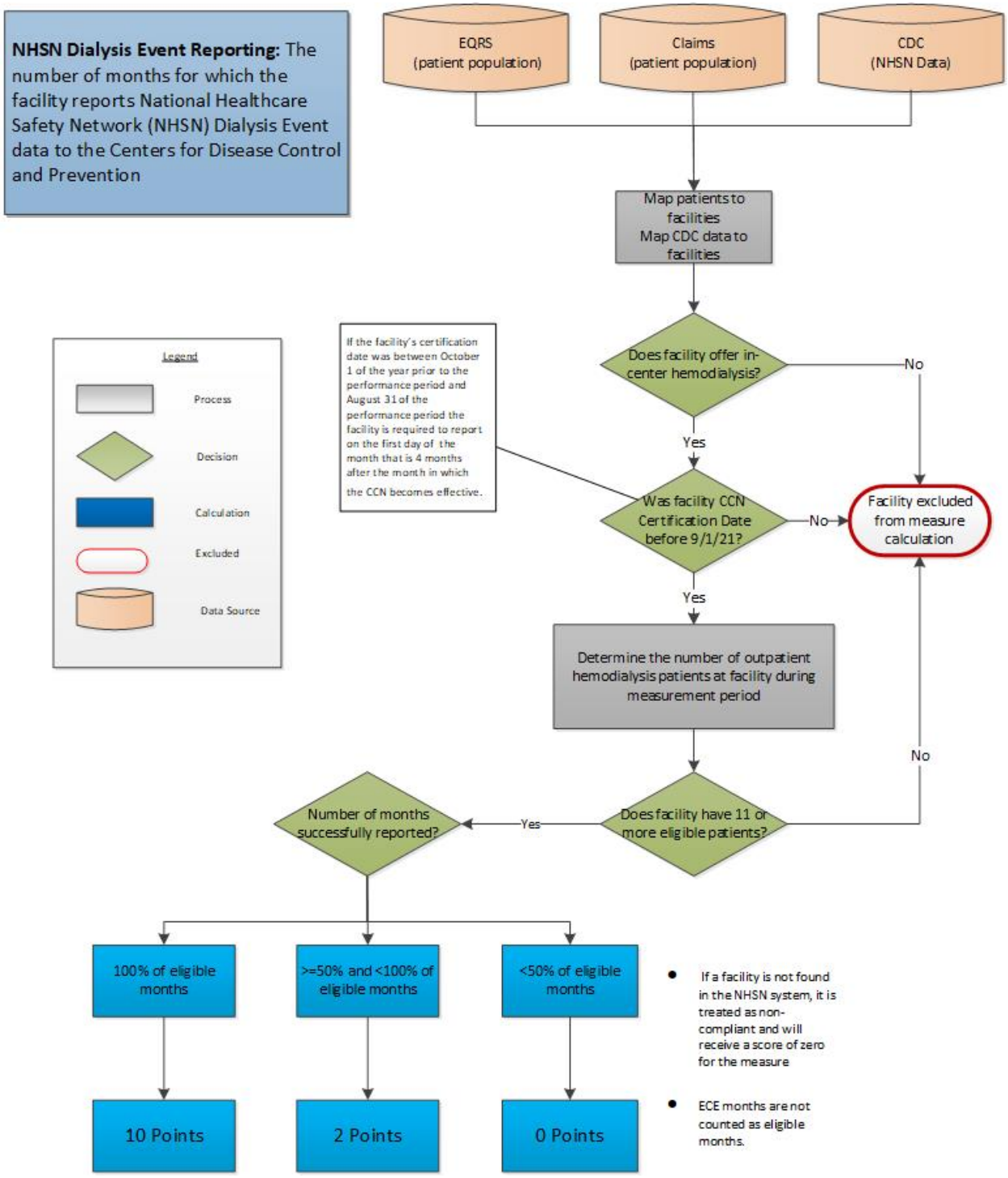

Figure 18: NHSN Dialysis Event Reporting Measure Flowchart (ESRD QIP Only)

2.20 Ultrafiltration Rate Reporting Measure (ESRD QIP Only)

2.20.1 Measure Name

Ultrafiltration Rate Reporting Measure

2.20.2 Measure Description

Number of months for which a facility reports all required data elements for ultrafiltration rate (UFR) in EQRS for all HD sessions during the week of the monthly Kt/V draw submitted for that clinical month for each eligible patient (both Medicare and non-Medicare dialysis patients), (based on NQF# 2701).

2.20.3 Measure Rationale

This measure is intended to guard against risks associated with high ultrafiltration (i.e., rapid fluid removal) rates for adult dialysis patient undergoing HD. Despite the majority of dialysis patients achieving targets for urea removal, the mortality rate among HD patients has remained unacceptably high. Published literature suggests that higher UFR is an independent predictor of mortality. Faster UFR (depending on the magnitude of interdialytic fluid loss and the duration of dialysis session) may lead to higher frequency of intradialytic hypotension (IDH), which currently occurs at high frequency and has been associated with higher mortality. Phenomena, such as repetitive 'myocardial stunning', recurrent central nervous system, bowel, and other organ-perfusion related damage could result if large volumes of fluid are removed rapidly during each dialysis session, with deleterious consequences for the patient both in the short and longer term.

2.20.4 Measure Type

Process

2.20.5 Numerator Statement

Number of months for which a facility reports all required data elements for UFR in EQRS for all HD sessions during the week of the monthly Kt/V draw submitted for that clinical month for each eligible patient.

See Section 2.20.10 for further detail on required data.

2.20.6 Facility Exclusions

- Facilities with a CCN open date on or after April 1, of the performance period (see Glossary at end of *Manual*)
- Facilities treating fewer than 11 eligible patients during the performance period
- Calculations will exclude the months covered by a granted ECE (see Section 3.4).

2.20.7 Denominator Statement

The number of eligible patient-months assigned to the facility in the performance period.

2.20.8 Patient Exclusions

- Patients less than 18 years of age (see Section 3.1.3) at the beginning of the reporting month
- Patients not assigned to the facility for the entire reporting month
- Patients not on in-center HD during the reporting month
- Patients on ESRD treatment (as defined by a completed 2728 form or an EQRS record) for less than 90 days at the beginning of the reporting month

2.20.9 Determining Successful Reporting for a Patient

A facility is considered to have successfully reported for a patient-month if the facility reported the following required data in EQRS for all HD sessions during the week of the monthly Kt/V draw submitted for that clinical month for each eligible patient:

(*Note: Not all UFR values need necessarily be from the same clinical month*)

- In-Center Hemodialysis (ICHD) Kt/V Date
- Post-Dialysis Weight
- Pre-Dialysis Weight
- Delivered Minutes of BUN HD
- Number of sessions of dialysis delivered by the dialysis unit to the patient in the reporting month

2.20.10 Calculating a Facility's Score on the Ultrafiltration Reporting Measure

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

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

2.20.11 Flowchart

Figure 19 provides a flowchart that represents the processes used to calculate the UFR Reporting Measure.

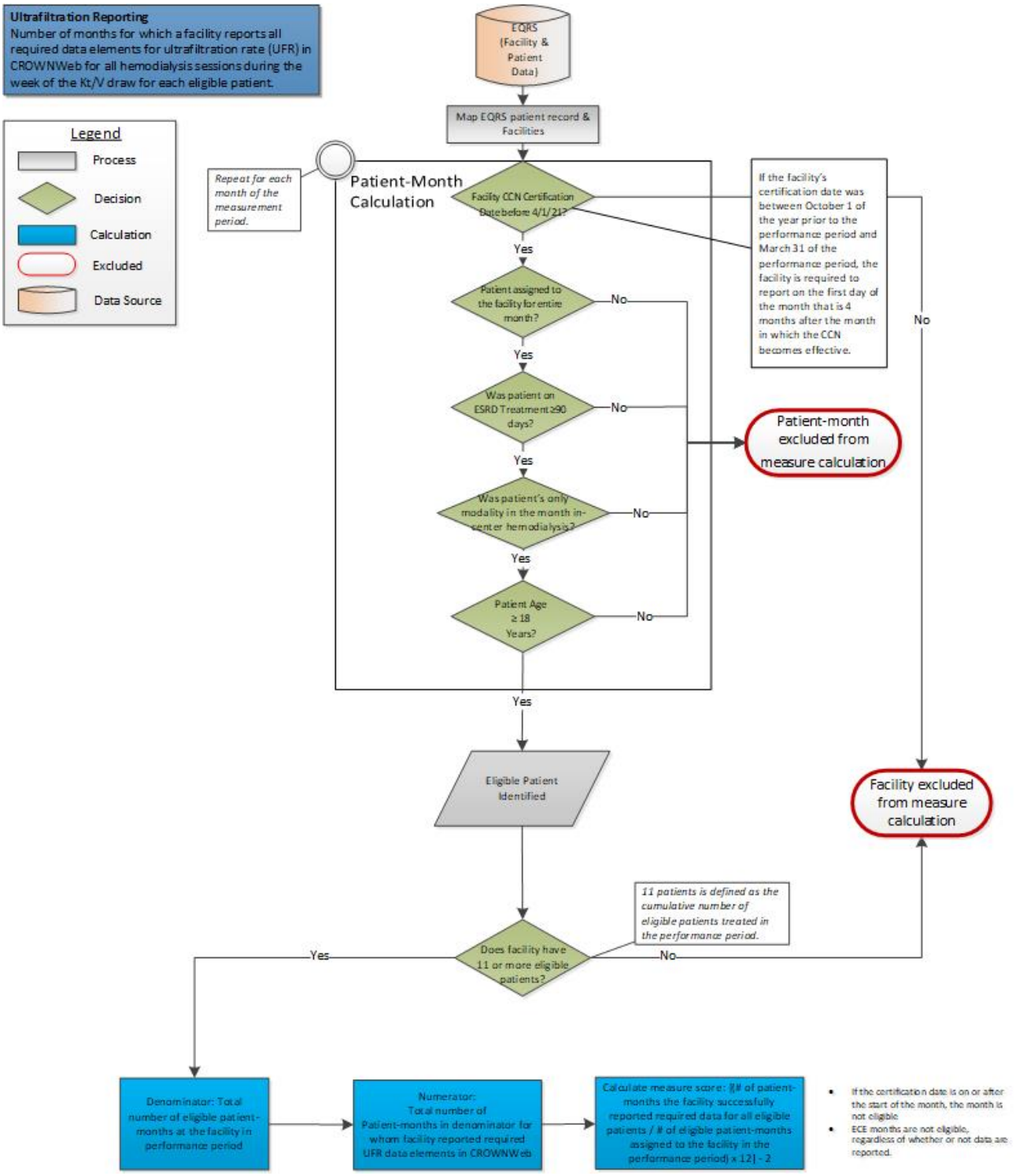

Figure 19: Ultrafiltration Rate Reporting Measure Flowchart (ESRD QIP Only)

2.20.12 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.org.

EQRS Data Elements:

- Initial certification date
- CROWN UPI
- Facility CCN
- Admit date
- Date of Month/Year associated with EQRS Clinical Record
- Patient date of birth
- Patient date of death
- Primary type of treatment ID (EQRS dialysis type)
- Number of prescribed dialysis sessions during the clinical month
- 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
- Kt/V reading date
- Pre-Dialysis weight (entered for Kt/V and UF session)
- Pre-Dialysis weight unit of measure (entered for Kt/V and UF session)
- Post-Dialysis weight (entered for Kt/V and UF session)
- Post-Dialysis weight unit of measure (entered for Kt/V and UF session)
- Delivered minutes (entered for Kt/V and UF session)
- Number of sessions of dialysis delivered by the dialysis unit to the patient in the reporting month

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

2.21.1 Measure Name

Medication Reconciliation Reporting Measure (MedRec)

2.21.2 Measure Description

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

2.21.3 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 United States, 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. 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).

2.21.4 Measure Type

Process

2.21.5 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
  - ARNP
  - PA
  - pharmacist
  - pharmacy technician personnel
- Name of eligible professional

2.21.6 Denominator Statement

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

2.21.7 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

2.21.8 Facility Exclusions

- Facilities with a CCN certification date on or after October 1 of the year prior to 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.

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

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

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

2.21.10 Flowchart

Figure 20 presents the flowchart that represents the processes used to calculate the MedRec Reporting Measure.

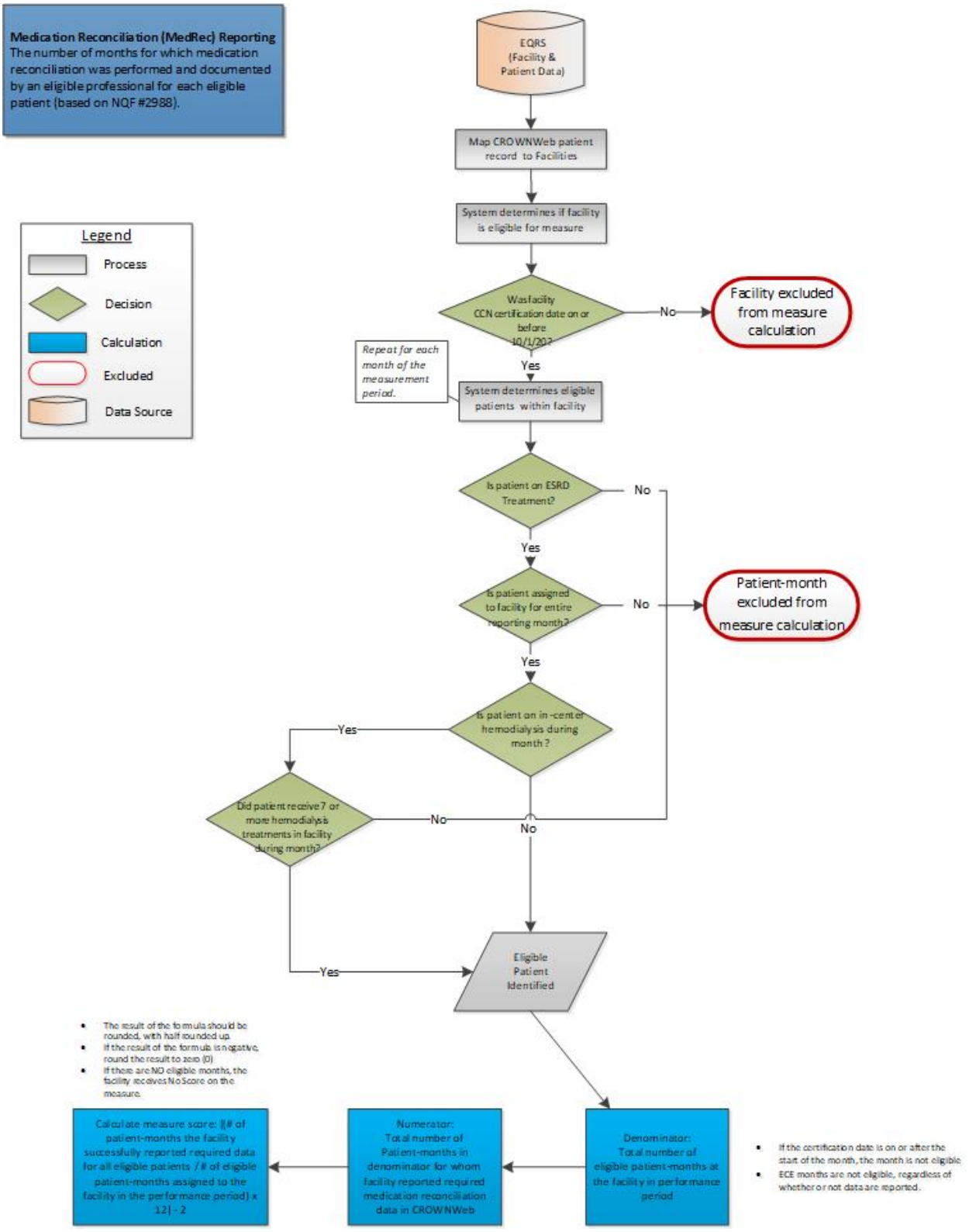

Figure 20: Medication Reconciliation Reporting Measure Flowchart (ESRD QIP Only)

2.21.11 Data Elements and Data Sources

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

EQRS Data Elements include:

- Initial certification date
- CROWN 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

2.21.12 References

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- Pai AB, Cardone KE, Manley HJ, St. Peter WL, Shaffer R, Somers M, Mehrotra R. Dialysis Advisory Group of American Society of Nephrology. Medication reconciliation and therapy management in dialysis-dependent patients: Need for a systematic approach. CJASN. 2013;8(11):1988-1999.

2.22 Standardized Transfusion Ratio (STrR) Reporting Measure (ESRD QIP only)

2.22.1 Measure Name

Standardized Transfusion Ratio Reporting for Dialysis Facilities (Based on NQF #2979)

2.22.2 Measure Description

Dialysis facility reporting of data on Medicare claims and in EQRS that are used to determine the number of eligible patient years at risk for calculating the risk adjusted facility level transfusion ratio (STrR) for adult Medicare dialysis patients (based on NQF #2979).

2.22.3 Measure Rationale

Several changes in the ESRD system are likely to impact anemia management. These include identification of safety concerns associated with aggressive erythropoiesis-stimulating agent (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.

2.22.4 Measure Type

Reporting

2.22.5 Numerator Statement

N/A

2.22.6 Denominator Statement

N/A

2.22.7 Facility Exclusions

Facilities with less than 10 patient-years at risk during the calendar year of assessment. Calculations will exclude the months covered by a granted ECE (see Section 3.4).

2.22.8 Patient 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 NQF (like SHR NQF #1463 http://www.qualityforum.org/QPS/1463). Patient time at risk is excluded for:

- Patients less than 18 years old (see Section 3.1.3)
- Patients on ESRD treatment for fewer than 90 days
- Patients on dialysis at the facility for fewer than 60 days
- Time during which patient has a functioning kidney transplant (exclusion begins 3 days prior to the date of transplant). Patients who have not been treated by any facility for a year or longer
- 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

2.22.9 Mapping Patients to Facilities

Starting with day 90 after onset 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 90 of ESRD if that facility had treated him or her for at least 60 days. If on day 90, 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.

2.22.10 Calculating a Facility's Score on the STrR Reporting Measure

Facilities with at least 10 patient-years at risk during the calendar year of assessment will receive a score of 10 for the STrR reporting measure. Facilities treating fewer than 10 patient-years at risk will receive No Score.

2.22.11 Flowchart

Figure 21 presents the flowchart that represents the processes used to calculate the STrR Reporting Measure.

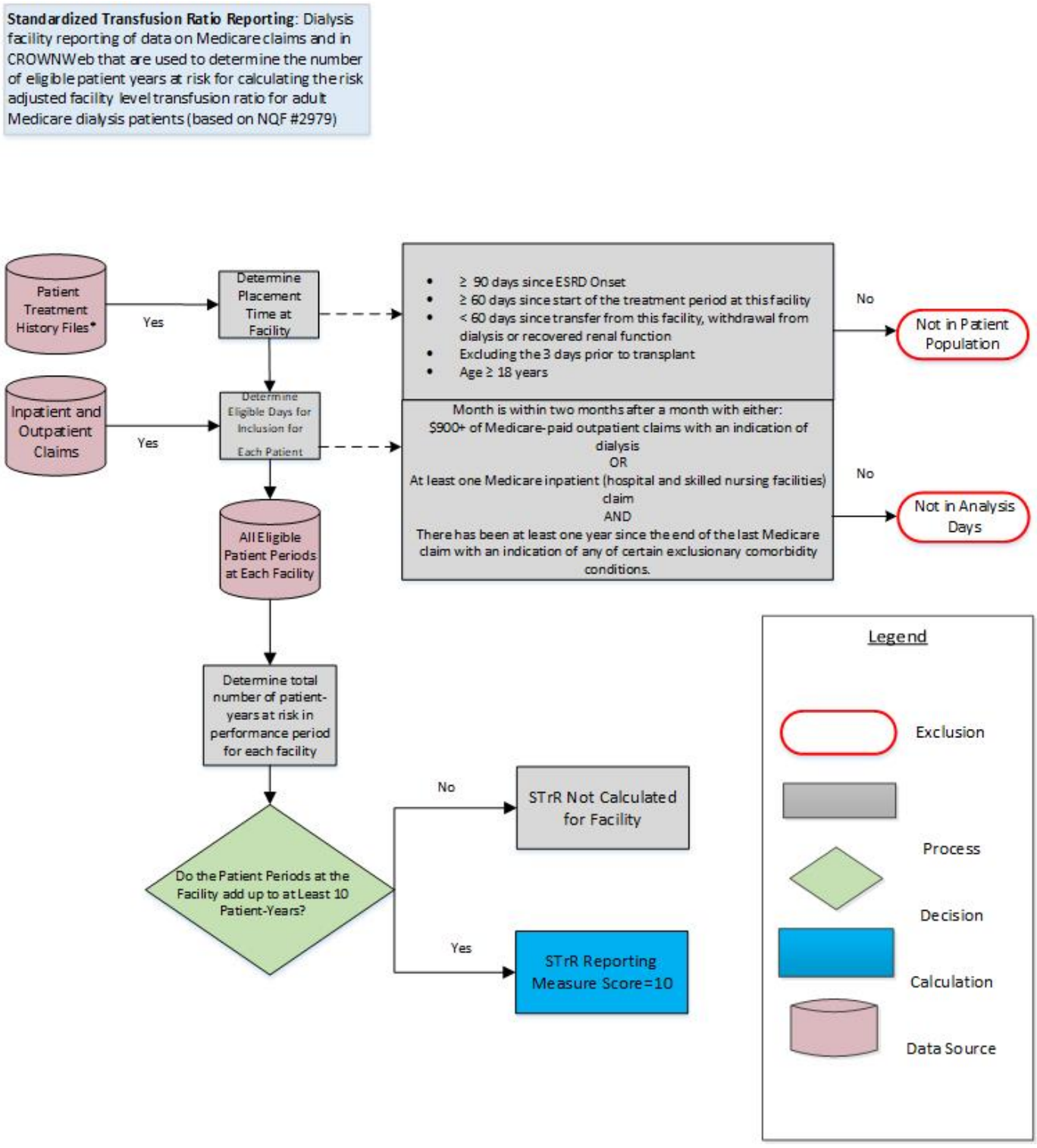


Figure 21: STrR Reporting Measure flowchartData Elements and Data Sources

Table 11 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 (DFC only) Medicare Claims[2]
Prevalent comorbidities used for exclusion[3]	Medicare Claims[2]

Table 11: Data Elements and Sources for the Standardized Transfusion Ratio (STrR) Reporting Measure

1. This may include information from: EQRS, Medicare Enrollment Database (EDB), Medical Evidence Form (CMS 2728), and Medicare Claims.

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. 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.

3. Cross-Measure Determinations

The following subsections describe calculations that are used in multiple measure calculations. Note, some ESRD QIP functionality will be replaced by reading key patient attributes from the EQRS Patient Repository, which is expected to serve as the source of ESRD QIP patient information in CY 2021.

3.1 Determining Patient-Level Exclusions

The subsections below explain how the DFC and ESRD QIP assign modalities to patients.

3.1.1 Modality Determination

DFC 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 LTC, and SFR, patient modality is determined solely on EQRS treatment records. Patient modality is derived from EQRS as follows:

- In-Center HD:
  - 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 in-center HD and home HD which 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 in-center HD, 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 12):
    - 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 12 (below).

  c. When there are revenue center codes with the same line item date, use Table 12 (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 12: 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:

- Composite revenue center codes (shown in the second column of Table 12):
  - 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).

- Non-composite revenue center codes are shown in the third column of Table 12 (above).

d. When there are revenue center codes with the same line item date, use Table 12 (above) 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

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 6
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 12), 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 12 (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 12 (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 6
- 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 Hemodialysis:

a. For patient months that have a single claim:

- 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:

- 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 12 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.

Program Specific Calculation:

DFC:

- 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) EQRS, (2) medical evidence, (3) claims, and (4) transplant.
- 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 > 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 first ESRD service date has been set to the 2728 date but there is an EQRS event of "new patient" more than 1 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 defined as the length of time from the initiation of ESRD date and the claim start date, as reported on the claim used for the patient-month.

- The date regular chronic dialysis began from the earliest completed Medical Evidence (CMS 2728) form. 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 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.

- Earliest transplant date. If the first ESRD service date was selected from a dialysis claim and there is a Medical Evidence 2728 form and a dialysis facility EQRSadmit 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 EQRSadmit, whichever was earlier.

If first ESRD service date has been set to the Medical Evidence 2728 form date but there is a dialysis facility EQRSadmit with admit reason of "new patient" more than one year later, and that date is earlier than any other dialysis facility EQRSadmit, transplant, or claim, then the first ESRD service date is changed to the dialysis facility EQRSadmit 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 2 and less than 4 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 2 and less than 4 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 in-center HD for pediatric HD measure). The patient must also be on ESRD treatment for at least 90 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 7 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 7 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 4 or more dialysis-related revenue center codes per week
- Short HD claim (7 days or fewer) with 4 or more total dialysis-related revenue center codes

An HD claim is defined as indicating infrequent dialysis if it covers more than 7 days and has an average rate of 2 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 13) 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	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 (DFC 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 (DFC 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 (DFC 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 (DFC 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 (DFC 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 (ESRD QIP and DFC)	2.9.11	Review dialysis facility calcium values during a three-month window
Clinical Depression Screening and Follow-Up Reporting Measure (ESRD QIP Only)	2.10.5	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 DFC)	2.11.10	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 DFC)	2.12.10	For each day of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims
Standardized Hospitalization Ratio (SHR) Measure	2.13.10	For each day of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims
Standardized Mortality Ratio (SMR) Measure (DFC Only)	2.14.10	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 (DFC Only)	2.15.10	For each day of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims
Percent of Prevalent Patients Waitlisted Measure	2.16.10	For each day of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims
Ultrafiltration Rate Reporting Measure (ESRD QIP Only)	2.20.7	For each month of treatment, dialysis provider is determined using admissions in EQRS, form CMS-2728 and claims

Measure	Measure Subsection	Method Summary
Medication Reconciliation Reporitng 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 13: 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 DFC using a prioritized hierarchy.

For DFC, 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 Compare

Determining a unique identifier:

Quality measures regularly combine information on the same patient from different data sources. Patients are matched across data sources using the identifying information available in each of those sources. There can be inconsistencies, so several logical tests are applied to determine if a patient matches across data sources. A unique, internal identifier is assigned to each patient as the result of this matching process.

DFC combines data for a given patient from multiple sources. The primary match includes two components and utilizes a number of patient-identifying variables.

Match method components:

1. Candidate search and selection (candidates consist of known ESRD patients)
2. Match quality evaluation

Patient variables used to match:

1. Medicare Beneficiary ID (MBI)
2. Medicare claim number
3. Social security number
4. Last name
5. First name
6. Birthdate
7. Sex

When linked on these variables, these "match candidates" are then compared, with the quality of the comparison evaluated. Tests include equality in:

- MBI and/or Claim Number
- SSN and first 9 characters of current Claim Number
- SSN
- First name and last name
- First 9 characters of MBI, Claim Number or SSN with first 9 characters of previous MBI or Claim Number
- Last name and first initial
- Last name and first initial compared with first name and first character of last name
- Birth date

Next, the comparison algorithm examines each item and considers a number of factors which might cause a good match to be discounted including partial matches, shifted or transposed characters or numbers, and differences between dates when some parts of it do match. The algorithm assigns letter values to the comparisons in descending order of match quality, based on our experience and observation of the kind of matches that are produced. Matches are categorized into the following groups:

- Exact match
- Very confident match
- Somewhat less confident match
- Questionable match
- Non-match
- No match candidates found

Matches that are "Questionable" or "Non-match" are rejected.

If no match candidates are found, the patient is considered "new" and is added to the database and assigned a new unique internal identifier.

Linking a patient to other data sources:

- Claims: Claims are linked with patients by extracting from the IDR based on finder files consisting of either the traditional Medicare Claim Number, or the new MBI.

- The Enrollment Database (EDB): Patients are linked to their EDB data thru their SSN
- EQRS patient data (Medical Evidence, Death Notification, patient events, clinical data): Linkages are done using the EQRS ID
- Transplants: Patients are matched to our database with the match methods described above
- Nursing Home Minimum Dataset: Patients are matched using a finder file consisting of claim number/MBI, SSN, surname, first name, birth date, gender, death date. The exact sequence of match algorithms are unclear, this process is managed by the QIES data team.

3.2.2 ESRD QIP

For ESRD QIP, the patient linkage across data sources will be performed by the EQRS Patient Repository. QIP will input the source data identifier for each data source where a patient has data from the EQRS Patient Repository. Then QIP will use those native patient identifiers to import data from each of these sources: EQRS, Medicare claims, transplants, and the Nursing Home Minimum Dataset.

3.3 Facility Mapping and Impacts of Change of Ownership

3.3.1 DFC 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 Compare (QDFC) 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 QDFCs use the CMS Certification Number (CCN) as a primary provider identifier for quality measurement purposes. A valid CCN must be exactly 6 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 2 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 2 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 CHOW, 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 not manually linked to the old provider number(s). Instead, the new CCN is treated as a new facility and a QDFC 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 (POS) files. The Dialysis Facility Compare (DFC) file, which is also extracted from EQRS, is also used to obtain newly certified facilities that will receive a QDFC 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 QDFC Preview Report.

The provider number reported on DFC is used as the main provider number for the QDFC 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 DFC file.

Summary: Process the DFC file received from CMS and append the current DFC data to the cumulative DFC 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 2 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 QDFC 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 QDFC 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 QDFC 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 QDFC 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 DFC file (created in Step 2) or facility services file (i.e., closed facilities that aren't in the DFC 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 DFC. We consider there to be evidence of change of ownership (CHOW) when multiple records match on facility characteristics (name, address, etc.) and also have 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 CHOW (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 CHOW, 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 CHOW, 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 CHOW, 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 DFC, 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 DFC 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 are received quarterly via CROWN RDS. 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 DFC 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 Compare (DFC) File

The DFC project covers all open facilities at a given time. The DFC 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 In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH-CAHPS) survey, or CDC's National Healthcare Safety Network (NHSN) using multiple CCNs, QIP tries to combine all data for the facility to avoid penalizing the facility for using multiple CCNs. QIP reports data under the

"primary" CCN for the dialysis facility but includes 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.
- ESRD QIP evaluates all facility records in EQRS and determines 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).
- ESRD QIP relies primarily on EQRS as the data source for facility information. Potential issues are identified by comparison with the DFC facility list and data availability in each QIP source through the ESRD QIP Validation process. 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:
    - Primary CCN and alternate CCN in prior years of QIP
    - Shared physical address in EQRS and POS
    - Comparison of dates CCN was certified and was closed/terminated from EQRS, POS, and QIES
    - 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
    - EQRS database facility information audit logs that indicate date, time, and user altering a facility's CCN
    - EQRS admits and discharges for each facility for each month covered by the QIP data window
    - 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 needs to be consolidated under a single CCN for ESRD QIP. In the ESRD QIP system, one of the "merged" facilities becomes the primary source and is used for the basis for 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 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 reports the dialysis facility CCN as primary when associated with an alternate CCN. ESRD QIP forces this order through a data quality update process if it is not what is observed in EQRS.
- EQRS has duplicate CCNs which cause no problems internally to EQRS but can cause duplication and distortion of ESRD QIP data. The ESRD QIP data quality update process is also used to ensure there are no duplicated CCNs.

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 change of CCN are treated as if the facility closed under the prior CCN then re-opened in ESRD QIP under the new CCN. This has the effect of severing the past performance under the prior CCN from current ESRD QIP 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 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 Comprehensive	• All months covered by a granted ECE excluded from the measure calculations. • Kt/V lab values reported by facilities during granted ECE months 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.
Standardized Fistula Rate	• All months covered by a granted ECE would be excluded from the measure calculations.
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. • Hospitalization 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 Bloodstrean Infection Ratio	• Facilities with granted ECE would be excluded from the measure calculations.
Hypercalcemia	• All months covered by a granted ECE would be excluded from the measure calculations. • Calcium values reported by facilities during granted ECE months would not be used in calculations; specifically, if Calcium values reported during granted ECE months are during the three-month study period, they would not be used in calculations.
Standardized Transfusion Ratio reporting	• Days covered by granted ECE would be excluded from the patient-years at risk calculations.
Ultrafiltration Rate 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.
NHSN Dialysis Event reporting	• All months covered by a granted ECE would be excluded from the measure calculations.
Clinical Depression reporting	• Calculations will exclude ECE months. However, facilities are required to report clinical depression data for all patients admitted to the facility during non-ECE months.

Table 14: Application of ECE by Measure

More information on the ECE program is available on the QualityNet website at:

https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228776130457

For DFC, 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 4 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 Acute Kidney Injury (AKI) (see section 1861(s)(2)(F) and 1834(r) of the Act). 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 DFC, 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 15 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
Standardized Readmission Ratio	11	41	Lower Ratio indicates better performance	Index Discharges
Standardized Hospital Ratio	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
VAT: Standardized Fistula Rate	11	25	Higher Rate indicates better performance	Eligible Patients
Dialysis Adequacy: Kt/V Comprehensive	11	25	Higher Rate indicates better performance	Eligible Patients
Hypercalcemia	11	25	Lower Rate indicates better performance	Eligible Patients
NHSN Bloodstream Infection in Hemodialysis Outpatients	11	25	Lower Rate indicates better performance	Eligible Patients
NHSN Dialysis Event (Reporting)	11	25	Higher Rate indicates better performance	Eligible Patients
PPPW	11	25	Higher Rate indicates better performance	Eligible Patients

Table 15: PY 2023 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 the ESRD QIP system will take to calculate a small facility adjustment for a facility's clinical measure rate:

1) The ESRD QIP system will perform exclusions for the measure to determine the number of measure units (MUs) at the facility during the performance period.
2) The ESRD QIP System will calculate the Benchmark (B), which is set to 90th percentile for each clinical measure using the applicable performance period data.
3) The ESRD QIP system will calculate the facility's unadjusted measure rate (UMR) for the measurement period.
4) The ESRD QIP system will 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 system will begin the small facility adjustment process:

a) The ESRD QIP system will 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) The ESRD QIP system will determine the preferred measure rate directionality for the given clinical measure:
    - For measures where the higher rates are better (for example, the Vascular Access Type (VAT): Fistula 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 Hypercalcemia, 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 the system will 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) 2023

Table 16 defines key achievement and improvement scoring terms.

Term	Definition
Achievement threshold	The 15th percentile of performance rates nationally during 2019
Benchmark	The 90th percentile of performance rates nationally during 2019
Improvement threshold	Your facility's performance rate during 2020
Performance period	All of calendar year 2021
Performance standard	The 50th percentile of performance rates nationally during 2019
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 16: Key Achievement and Improvement Scoring Terms

NOTES:

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 2019).

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 2020 – 90th percentile of performance rates nationally during 2019).

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 9 points for improvement.

If a facility does not have sufficient data to calculate a measure improvement rate during 2020but does has sufficient information to calculate an achievement rate during 2021, 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:

- 3 Composite measures
  - Nephrologists' Communication and Caring (6 questions)
  - Quality of Dialysis Center Care and Operations (12 questions)
  - Providing Information to Patients (9 questions)
- 3 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 two vascular access type clinical measures (VAT Fistula and VAT Catheter). The scores for this measure topic are discussed below in the example table template.

4.1.4.1 VAT Measure Topic

1) The first step is identifying the individual measure scores within the measure topic (see Section 4.1.2 for more information).

Example #1

#	Calculation Definition	Value
	VAT Measures Domain Scores	
a	VAT Standardized Fistula Rate Measure Score	5
b	VAT Long Term Catheter Rate Measure Score	4

2) Next, 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	Value
	Measure Weight Calculation	
c	Number of patients included in VAT Standardized Fistula Rate Measure Score calculation	100
d	Number of patients included in VAT Long Term Catheter Rate Measure Score calculation	100
e	Determine total number of patients for weighting denominator *Add c and d*	200

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: Only eligible measures are considered when determining the total number of patients across all measures within a topic.

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.

#	Calculation Definition	Value
	Measure Topic Score Calculation	
f	Weight the VAT Standardized Fistula Rate Measure Score *Calculate a x (c ÷ e)*	2.5
g	Weight the VAT Long Term Catheter Rate Measure Score *Calculate b x (d ÷ e)*	2.0
h	Combine Measure Scores *Add f + g and round*	5.0
i	Vascular Access Type Measure Topic Score (from h)	**5.0**

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 four 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 four measure domain scores, which are then used to determine the facility's TPS. The four 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 Measure Domain

Safety Measure Domain

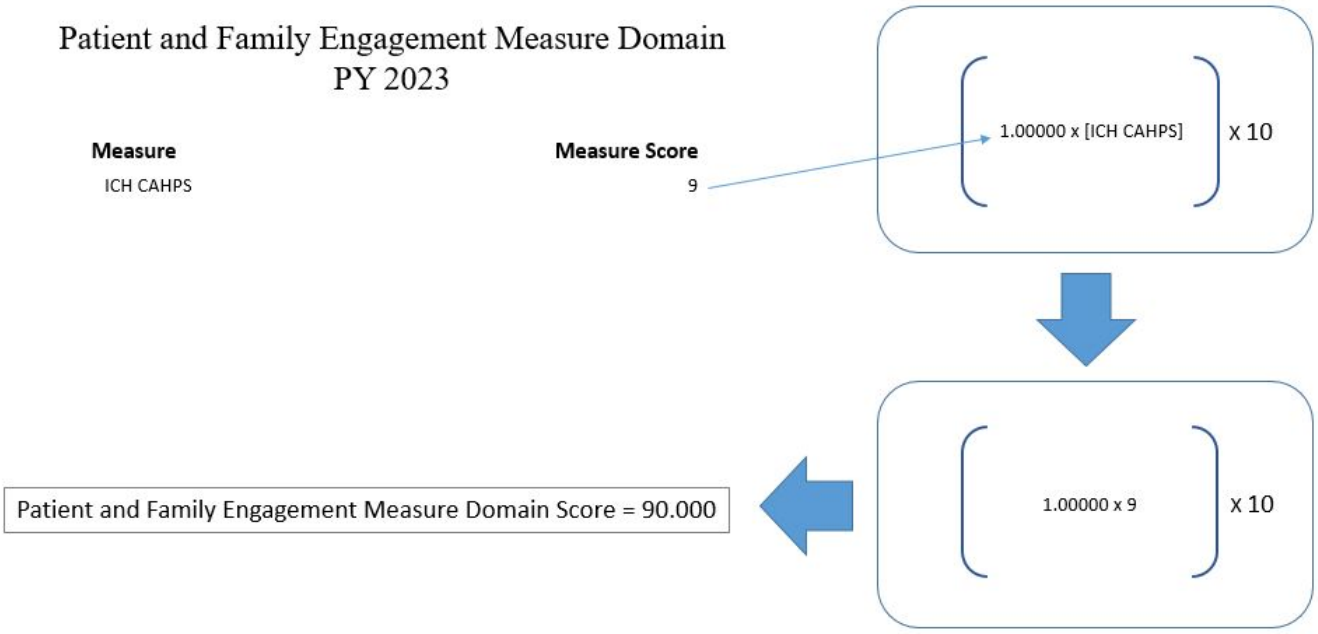
4.2.1 Calculating the Patient and Family Engagement Measure Domain

The Patient and Family Engagement Measure Domain is comprised of one measure, the ICH CAHPS Measure. As seen in Table 17 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 2023 Patient and Family Engagement Measure	Measure Weight in the Patient and Family Engagement Measure Domain Score
ICH CAHPS Measure	100.00%

Table 17: Patient and Family Engagement Measure Weight

Example 1: Eligible for all Measures in the Patient and Family Engagement Domain for PY 2023



4.2.2 Calculating the Care Coordination Measure Domain Score

The Care Coordination Measure Domain is comprised of three measures. As seen in Table 18 below, each individual clinical measure is assigned a specific weight as a percent of the domain score.

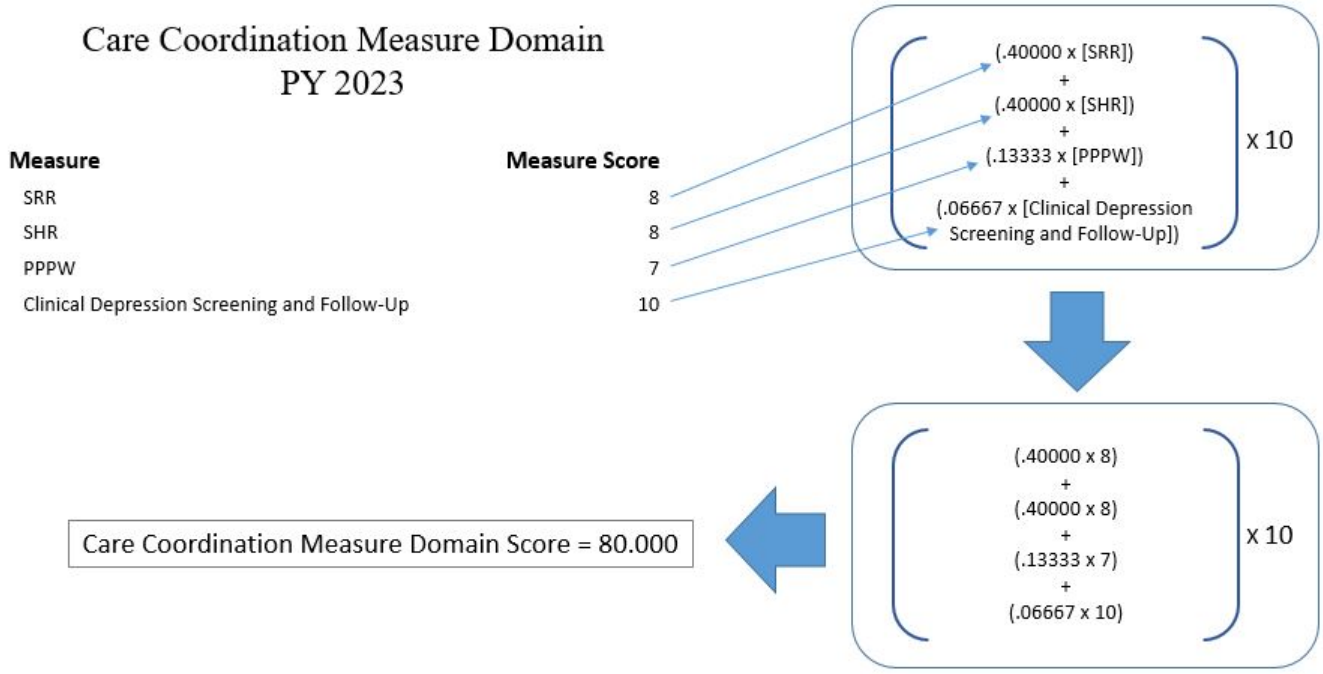
PY 2023 Care Coordination Measures	Measure Weight in the Care Coordination Measure Domain Score
SRR Measure	40.00%

PY 2023 Care Coordination Measures	Measure Weight in the Care Coordination Measure Domain Score
SHR Measure	40.00%
PPPW Measure	13.33%
Clinical Depression and Follow-up Reporting Measure	6.67%

Table 18: 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 2023



4.2.3 Calculating the Clinical Measure Domain Score

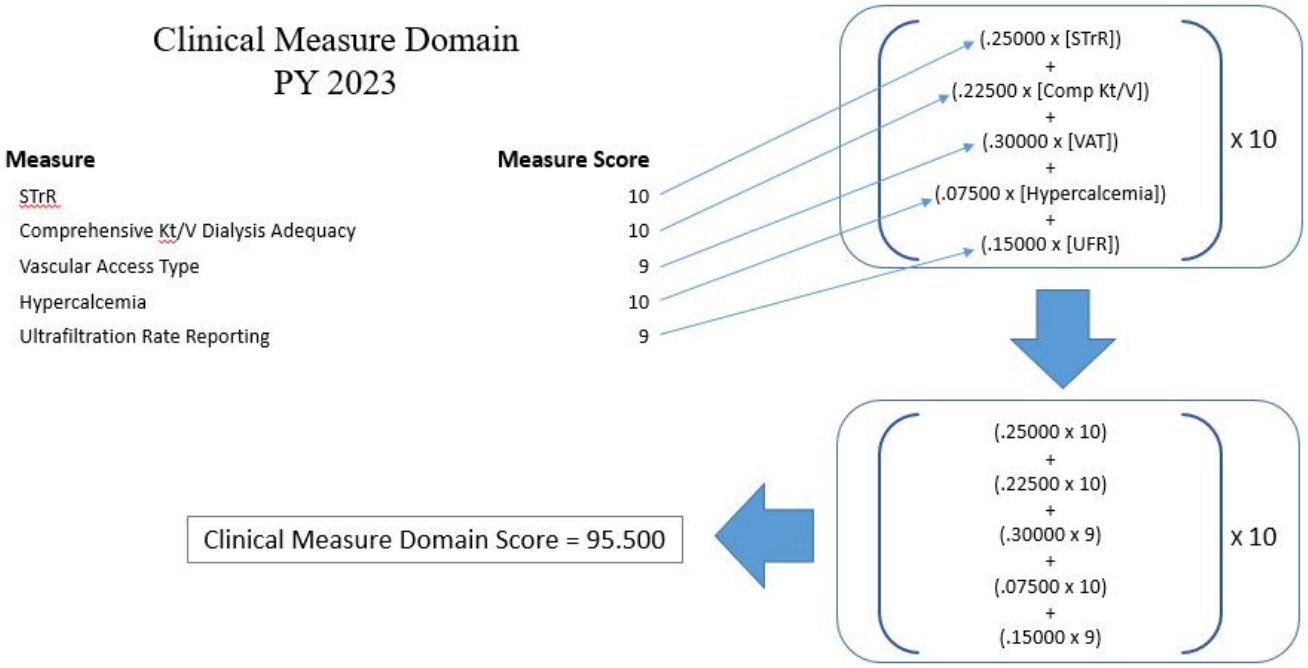
The Clinical Measure Domain is comprised of five measures. As seen in Table 19 below, each individual clinical measure is assigned a specific weight as a percent of the domain score.

PY 2023 Clinical Measures	Measure Weight in the Clinical Measure Domain Score
STrR Reporting Measure	25.00%
Kt/V Comprehensive Dialysis Adequacy Measure	22.50%
Vascular Access Type Measure Topic	30.00%
Hypercalcemia Measure	7.50%
Ultrafiltration Rate Reporting Measure	15.00%

Table 19: Clinical Measure/Measure Topic Weights

In order to calculate the Clinical 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 Measure Domain score. See the example below for a hypothetical scenario of the Clinical Measure Domain Score calculation.

Example 3: Eligible for all Measures in the Clinical Domain for PY 2023



4.2.4 Calculating the Safety Measure Domain Score

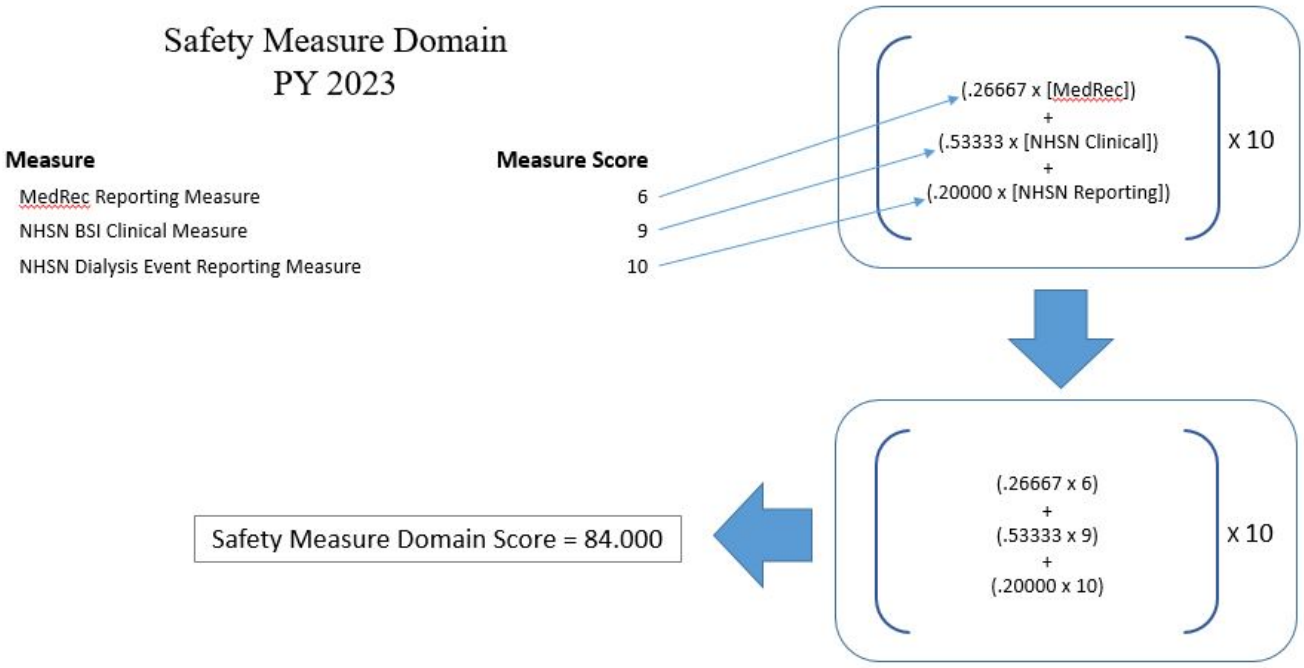
The Safety Measure Domain is comprised of two measures. As seen in Table 20 below, each individual measure is assigned a specific weight as a percent of the domain score.

PY 2023 Safety Measure	Measure Weight in the Safety Measure Domain Score
MedRec	26.67%
NHSN BSI Clinical Measure	53.33%
NHSN Dialysis Event Reporting Measure	20.00%

Table 20: Safety Measures Weights

In order to calculate the Safety 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 Safety Measure Domain score. See the example below for a hypothetical scenario of the Safety Measure Domain Score calculation.

Example 4: – Calculating the Safety Measure Domain in PY 2023



4.2.5 Calculation of TPS Using Domain Weights and Scores

The TPS is comprised of the four measure domains below and their associated weights:

Patient and Family Engagement Measure Domain: 15%

Care Coordination Measure Domain: 30%

Clinical Measure Domain: 40%

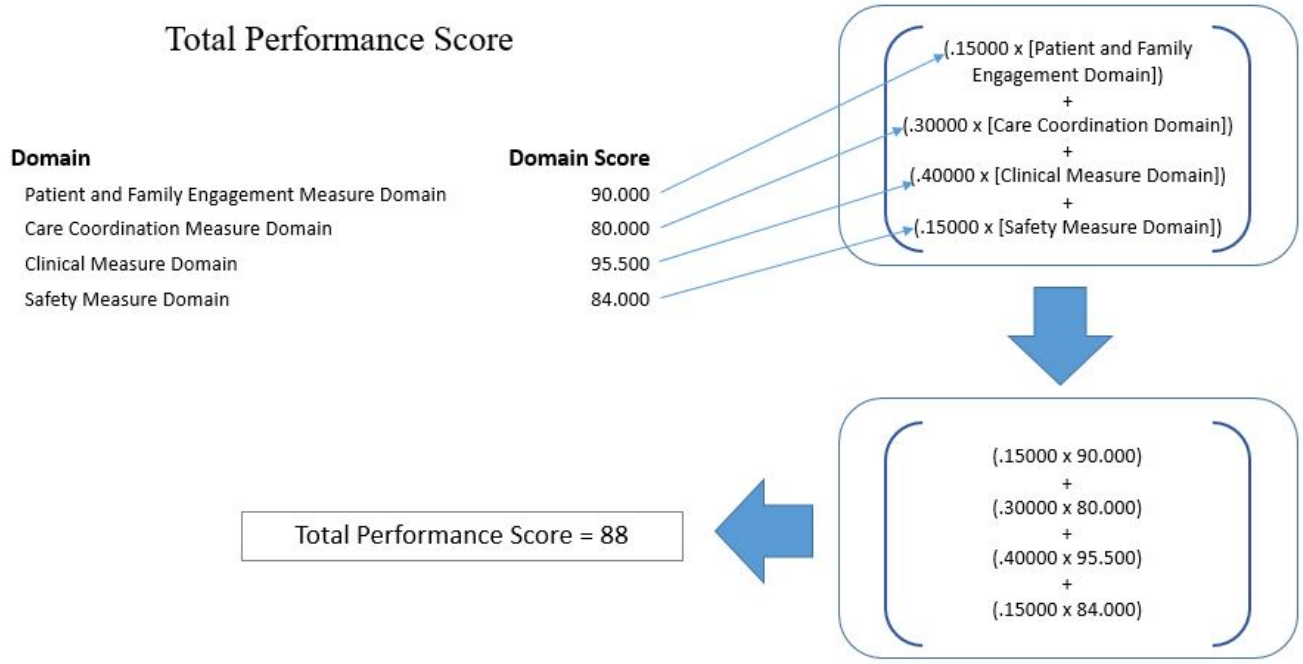
Safety Measure Domain: 15%

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 Domain score by 0.40 and the Safety Domain score by 0.15 and adding the results, as follows:

$$TPS = (0.15 * Patient\ and\ Family\ Engagement\ Domain\ Score) + (0.30 * (Care\ Coordination\ Domain\ Score) + (0.40 * Clinical\ Domain\ Score) + (0.15 * Safety\ Domain\ Score)$$¶

The TPS is rounded to the nearest integer, with halves rounded up, resulting in a range from 0–100 points.

Example 5: Total Performance Score Calculation for PY 2023



4.2.6 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 four 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.

4.2.6.1 Redistributing Measure Weights When a Facility Is Not Scored on a Measure

If a facility does not meet the eligibility requirements for a measure (or measure topic), 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 four domains, the domain weights will not change. Section 4.2.7.1. explains how to redistribute the weight of a domain that is missing all of its measures.

Table 21 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 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	40.00%	12.00%	40.00%	12.00%
SHR measure	40.00%	12.00%	40.00%	12.00%
PPPW measure	13.33%	4.00%	13.33%	4.00%
Clinical Depression and Follow-Up reporting measure	6.67%	2.00%	6.67%	2.00%
		30% of TPS		**30% of TPS**
CLINICAL CARE MEASURE DOMAIN				
Kt/V Dialysis Adequacy Comprehensive measure	22.50%	9.00%	N/A	N/A
Vascular Access Type measure topic	30.00%	12.00%	35.63%	14.25%

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 measure	7.50%	3.00%	13.13%	5.25%
STrR reporting measure	25.00%	10.00%	30.63%	12.25%
Ultrafiltration Rate reporting measure	15.00%	6.00%	20.63%	8.25%
		40% of TPS		**40% of TPS**
SAFETY MEASURE DOMAIN				
MedRec measure	26.67%	4.00%	26.67%	4.00%
NHSN BSI measure	53.33%	8.00%	53.33%	8.00%
NHSN Dialysis Event reporting measure	20.00%	3.00%	20.00%	3.00%
		15% of TPS		**15% of TPS**

Table 21: Measure Weights as a Percent of TPS and as a Percent of Domain Score When Kt/V Measure is Missing

4.2.6.2 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 4.2.6.1, the Clinical Care Measure Domain is missing the Kt/V Comprehensive measure (22.5%), leaving four measures remaining in the domain. As seen in Table 22 below, the missing measure (Kt/V Comprehensive) is assigned no weight and the corresponding 22.5% is evenly redistributed across each individual measure remaining in the domain.

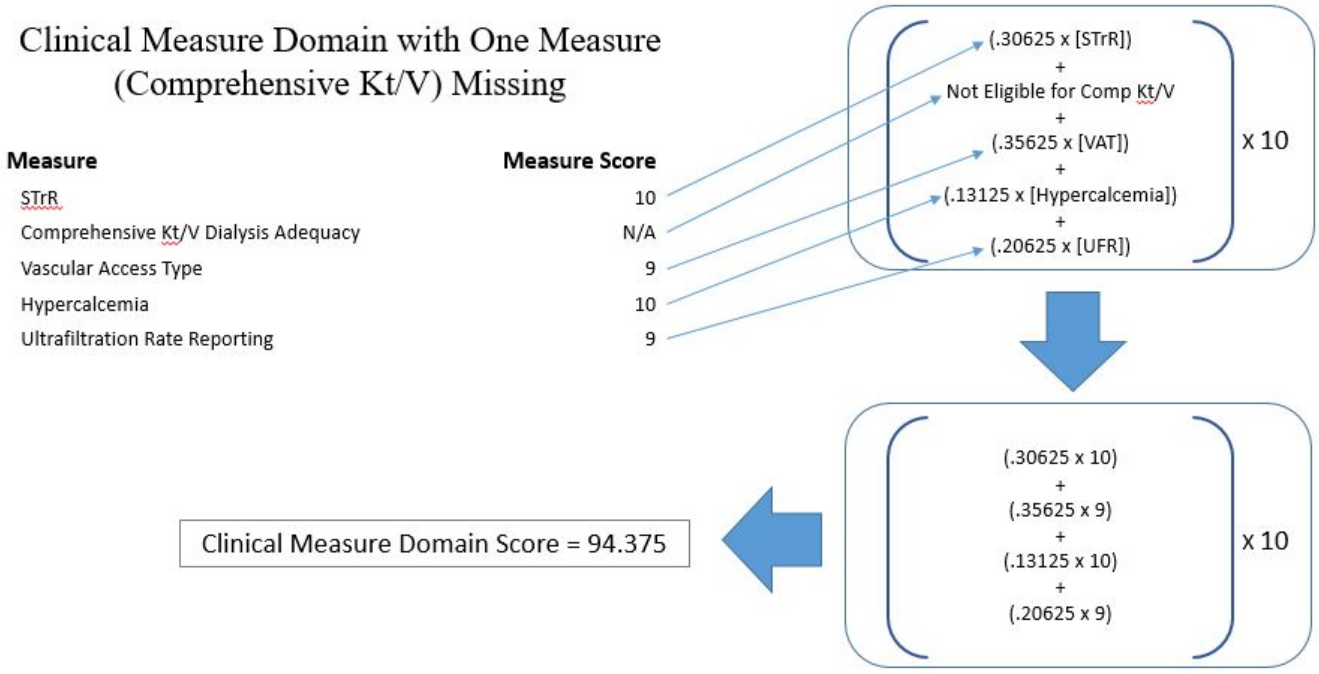
PY 2023 Clinical Care Measures	Measure Weight as a Percent of the Clinical Care Domain	Measure Weight as a Percent of the Clinical Care Domain Absent Comp Kt/V
Kt/V Dialysis Adequacy Comprehensive measure	22.50%	N/A
STrR reporting measure	25.00%	30.63%

PY 2023 Clinical Care Measures	Measure Weight as a Percent of the Clinical Care Domain	Measure Weight as a Percent of the Clinical Care Domain Absent Comp Kt/V
Vascular Access Type measure topic	30.00%	35.63%
Hypercalcemia measure	7.50%	13.13%
Ultrafiltration rate reporting measure	15.00%	20.63%

Table 22: Clinical Measure/Measure Topic Weights When Missing One Measure Score

These scores are then summed up and multiplied by 10 to equal the Clinical Measure Domain score. See the example below for a hypothetical scenario of this domain's calculation when missing a score for Kt/V.

Example 6: Eligible for the Clinical Domain and all but One Measure in the Clinical Domain for PY 2023



4.2.6.3 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 and NSHN Dialysis Event reporting measure scores and MedRec measure scores were missing, the TPS would be comprised of three domains (Patient & Family Engagement, Care Coordination, and Clinical Care).

As previously noted, domain weights are affected only when an entire domain is missing. For the example used in Section 4.2.6.1, where Comprehensive Kt/V is missing, the TPS would be comprised of the four 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%

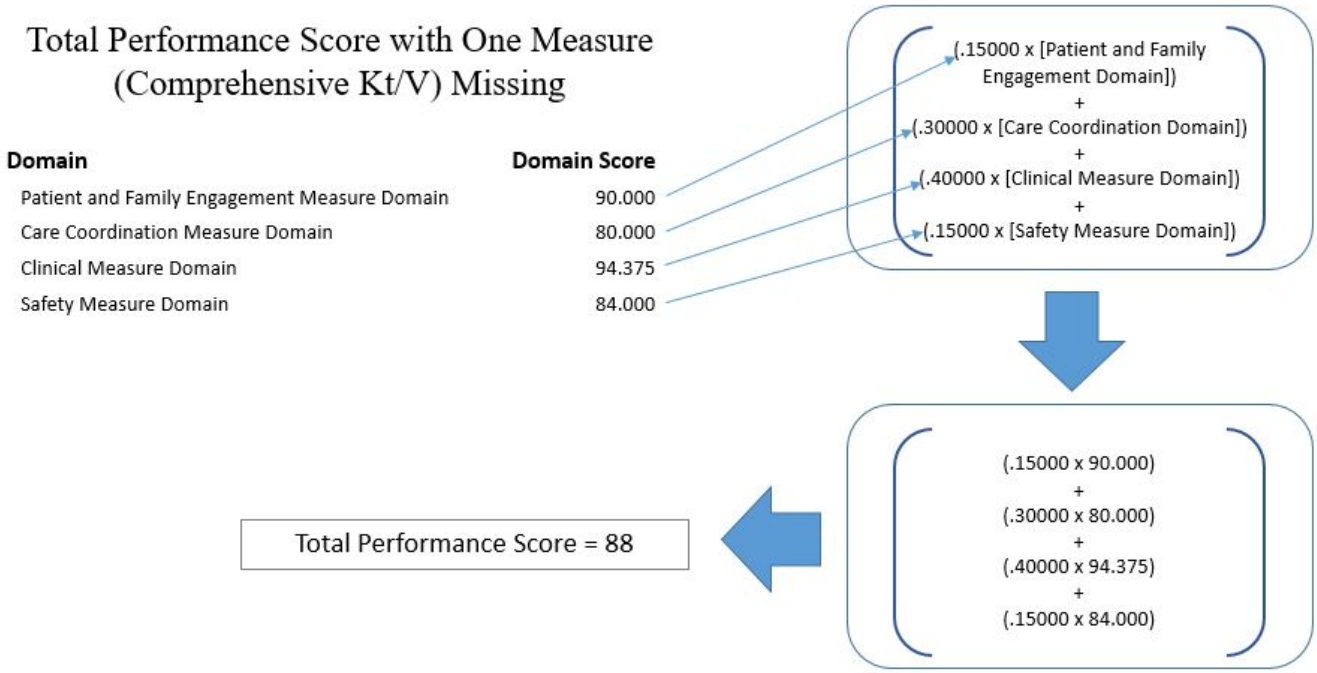
Clinical Measure Domain: 40%

Safety Measure Domain: 15%

In the example where Comprehensive Kt/V is missing, the facility's TPS would be calculated by multiplying the Patient and Family Engagement Domain score by .15, the Care Coordination Domain score by .30, the Clinical Domain score by .40 and the Safety Domain score by .15, and adding the results as follows:

$$TPS = (.15 * \textit{Patient and Family Engagement Domain Score}) + (.30 * \textit{Care Coordination Domain Score}) + (.40 * \textit{Clinical Domain Score}) + (.15 * \textit{Safety Domain Score})$$

Example 7: Total Performance Score Calculation for all but One Measure in the Clinical Domain for PY 2023



4.2.7 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 four 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.

4.2.7.1 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 (or measure topic), the facility is not scored on the measure. If a facility is not scored on any measures (or measure topics) in a domain, then that domain's weight is redistributed evenly across the remaining domains and then evenly across the measures within those domains.

Table 23 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 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 NHSN Safety Domain	Measure Weight as a Percent of TPS Absent Safety Measure Domain
PATIENT & FAMILY ENGAGEMENT MEASURE DOMAIN				
ICH CAHPS measure	100.00%	15.00%	100.00%	20.00%
		15.00% of TPS		**20.00% of TPS**
CARE COORDINATION MEASURE DOMAIN				
SRR measure	40.00%	12.00%	37.86%	13.25%
SHR measure	40.00%	12.00%	37.86%	13.25%
PPPW measure	13.33%	4.00%	15.00%	5.25%
Clinical Depression and Follow-Up reporting measure	6.67%	2.00%	9.29%	3.25%
		30% of TPS		**35% of TPS**
CLINICAL CARE MEASURE DOMAIN				
Kt/V Dialysis Adequacy Comprehensive measure	22.50%	9.00%	22.22%	10.00%
Vascular Access Type measure topic	30.00%	12.00%	28.89%	13.00%

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 NHSN Safety Domain	Measure Weight as a Percent of TPS Absent Safety Measure Domain
Hypercalcemia measure	7.50%	3.00%	8.89%	4.00%
STrR reporting measure	25.00%	10.00%	24.44%	11.00%
Ultrafiltration Rate reporting measure	15.00%	6.00%	15.56%	7.00%
		40% of TPS		**45% of TPS**
SAFETY MEASURE DOMAIN				
MedRec measure	26.7%	4.00%	N/A	N/A
NHSN BSI measure	53.3%	8.00%	N/A	N/A
NHSN Dialysis Event reporting measure	20.0%	3.00%	N/A	N/A
		15% of TPS		**0% of TPS**

Table 23: Measure Weights as a Percent of TPS and as a Percent of Domain Score When Safety Domain is Missing

4.2.7.2 Calculating TPS with One Domain Missing

For the example used in Section 4.2.7.1 where NSHN BSI measure and NSHN Dialysis Event reporting measure scores and MedRec measure scores are missing, the TPS would be comprised of the three domains listed below and their associated TPS weights would be as follows:

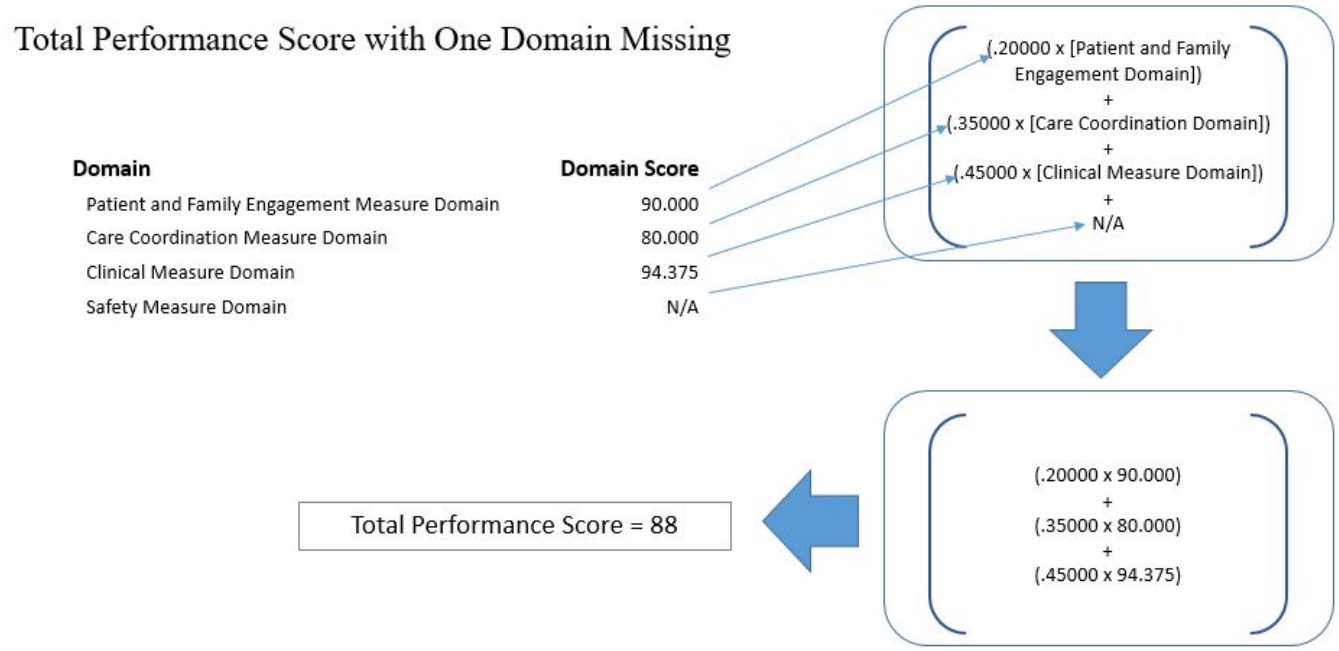
Patient and Family Engagement Measure Domain: 20%

Care Coordination Measure Domain: 35%

Clinical Measure Domain: 45%

Safety Measure Domain: 0%

Example 8: Total Performance Score Calculation for One Domain Missing for PY 2023



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 24 below for the payment reductions associated with the TPS received.

Total Performance Score	Payment Reduction
100-57 (Score meets or exceeds minimum TPS)	No reduction
56–47 (1 to 10 points below minimum TPS)	0.5%
46–37 (11 to 20 points below minimum TPS)	1.0%
36–27 (21 to 30 points below minimum TPS)	1.5%

Total Performance Score	Payment Reduction
27–0 (27 or more points below minimum TPS)	2.0%
No Score calculated	No reduction

Table 24: TPS and Payment Reduction for PY 2023

5. Calculating Star Ratings for DFC

5.1 Background and Introduction

The Centers for Medicare & Medicaid Services (CMS) developed the DFC 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 DFC Star Rating System was implemented in January 2015 on the Medicare DFC website. The technical report for the original Star Rating methodology is available at:

https://dialysisdata.org/sites/default/files/content/Methodology/StarRatings.pdf

An update to DFC Star Rating System methodology occurred in October 2016, based on feedback from a Technical Expert Panel (TEP) convened in April 2015. The updated technical report for the DFC Star Rating System, implemented since the October 2016 release, is available at:

https://dialysisdata.org/sites/default/files/content/Methodology/UpdatedDFCStarRatingMethodology.pdf

A DFC Star Rating TEP was convened in February 2017. The TEP recommendations on the candidate and updated measures are described in further detail in the 2017 DFC Star Rating Summary Report, is available at:

https://dialysisdata.org/sites/default/files/content/ESRD_Measures/ESRD_DFC_Star_Ratings_TEP_Summary_Report_2017.pdf

An update to DFC Star Rating System methodology occurred in October 2018. The updated technical report for the DFC Star Rating System is available at:

https://dialysisdata.org/sites/default/files/content/Methodology/Updated_DFC_Star_Rating_Methodology_for_October_2018_Release.pdf

5.2 Summary of Methodology Updates for the October 2018 DFC Release

The following are changes of the methodology used to calculate dialysis facility Star Ratings, beginning with the October 2018 DFC release:

1. For the October 2018 Star Rating release the measures used in this update to the DFC Star Rating System methodology include DFC measures implemented in the original 2015 release of the Star Rating System, updated or replaced versions of several of the

original DFC measures, and measures new to the Star Rating. See the next section (5.3) which lists all the measures.

2. In order to maintain the longitudinal continuity of Star Rating performance trends, the October 2018 DFC release will use the April 2018 DFC Star Rating distribution to establish a new set of cutoffs for the Star Rating categories. The October 2018 release will use the new measure specifications applied to the April 2018 release data to establish a new set of final score cutoffs. The cutoffs will reproduce the facility Star Rating distribution previously achieved for the April 2018 release using the prior measures and methodology. These cutoffs will be applied to the Star Ratings calculated for the October 2018 release. Thus, the April 2018 release serves as an evaluation period for the old measure methodology and as a baseline period for the new methodology.
3. The ICH CAHPS measure will be calculated and reported as separate Star Ratings. An overall Survey of Patients' Experience Star Rating will be calculated as a summary of these six measures.

5.3 DFC Quality Measures Used in Calculating the Star Ratings

Eleven of the DFC Quality Measures currently reported on the Medicare DFC website will be used to calculate the Quality of Patient Care Star Rating beginning in October 2018 (calendar year 2017 data). The measures used in this update of the DFC Star Rating System methodology include DFC measures implemented in the original 2015 Star Rating System, updated versions of several of the DFC measures, replaced versions of two DFC measures, and measures new to the Star Rating.

5.3.1 Measures Added, Replaced, or Updated for the 2018 DFC Star Rating System Release

5.3.1.1 New Measures

- Standardized Readmission Ratio for Dialysis Facilities (SRR, NQF #2496)
- Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V (Pediatric PD Kt/V, NQF #2706)

5.3.1.2 Replaced Measures

- Hemodialysis Vascular Access: Standardized Fistula Rate (SFR, NQF #2977), Replacing NQF #0257
- Hemodialysis Vascular Access: Long-Term Catheter Rate (Catheter, NQF #2978), Replacing NQF #0256

5.3.1.3 Updated Measures

- Standardized Mortality Ratio for Dialysis Facilities (SMR, NQF #0369), Updating existing NQF #0369
- Standardized Hospitalization Ratio for Dialysis Facilities (SHR, NQF #1463), Updating existing NQF #1463
- Standardized Transfusion Ratio for Dialysis Facilities (STrR, NQF #2979), Updating existing NQF #2979
- Proportion of Patients with Hypercalcemia (Hypercalcemia, NQF #1454), Updating existing NQF #1454
- Full documentation for all NQF endorsed measures can be viewed at: http://www.qualityforum.org/QPS/ by entering the measure's NQF number into the *Measure Search* toolbar.

5.4 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, NQF #2979)*
- Standardized Mortality Ratio for Dialysis Facilities (SMR, NQF #0369)*
- Standardized Hospitalization Ratio for Dialysis Facilities (SHR, NQF #1463)*
- Standardized Readmission Ratio for Dialysis Facilities (SRR, NQF# 2496)*
- Total Kt/V Measure§:
  - Delivered Dose of Hemodialysis Above Minimum (Adult HD Kt/V, NQF #0249)&, II
  - Minimum spKt/V for Pediatric Hemodialysis Patients (Pediatric HD Kt/V, NQF #1423)&, II
  - Delivered Dose of Peritoneal Dialysis Above Minimum (Adult PD Kt/V, NQF #0318)&, II
  - Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V

- (Pediatric PD Kt/V, NQF# 2706)[&]

- Hemodialysis Vascular Access: Standardized Fistula Rate (SFR, NQF #2977)[§]
- Hemodialysis Vascular Access: Long-Term Catheter Rate (Catheter, NQF #2978)[†]
- Proportion of Patients with Hypercalcemia (Hypercalcemia, NQF #1454)[†]

[*] Lower 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.

[ll] No changes to measure specifications

5.5 ICH CAHPS Star Rating Calculation

The calculation used in the ICH CAHPS® In-Center Hemodialysis Survey rating can be found at NQF #0258.

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.

5.6 Development of Measure Domains

The correlation structure of the measures (Table 25) reveals that some measures are more closely correlated than others. Based on this observation, the measures are grouped into domains in an empirical, data-driven manner using factor analysis. Measures are more correlated within each domain, while measures are less correlated across different domains. Equal weighting of these domains, rather than the individual measures, avoids overweighting particular measures that may represent a similar aspect of quality as other measures in the Star Rating.

Variable	SMR	SHR	SRR	STrR	Fistula	Catheter	Hypercal.	Total Kt/V
SMR	1.00	0.25	0.10	0.13	0.04	0.04	0.07	0.13
SHR	.	1.00	0.43	0.23	0.11	0.14	0.10	0.20
SRR	.	.	1.00	0.13	0.07	0.07	0.05	0.12
STrR	.	.	.	1.00	0.06	0.09	0.02	0.10

Variable	SMR	SHR	SRR	STrR	Fistula	Catheter	Hypercal.	Total Kt/V
Fistula	.	.	.	.	1.00	0.41	0.14	0.18
Catheter	.	.	.	.	.	1.00	0.19	0.20
Hypercalcemia	.	.	.	.	.	.	1.00	0.40
Total Kt/V	.	.	.	.	.	.	.	1.0

Table 25: Spearman Correlation Matrix, Calendar Year 2016 Data*

* *Correlations were statistically significant at p < 0.001 except between SMR and Catheter (p = 0.003) and Hypercalcemia and STrR (p = 0.1334)*

Analyses of data from the April 2018 DFC Star Rating release, and the expanded measure set, informed the creation of three measure domains to be used beginning with the October 2018 Star Rating release. Four standardized outcome measures form the first domain, which is named "Standardized Outcomes (SHR, SMR, STrR, and SRR)". The Standardized Fistula Rate and Long-Term Catheter Rate measures form the second domain, "Other Outcomes 1 (SFR, Catheter)". The Total Kt/V and Hypercalcemia measures form the third domain, "Other Outcomes 2 (Total Kt/V, Hypercalcemia)".

5.7 Measure Scoring in Baseline Period and an Evaluation Period

DFC clinical quality measures have different distributions and scales, therefore the values of individual measures to measure scores are first transformed in order to make them comparable in terms of scale and direction (scoring methodology is described further below).

5.7.1 *Baseline Period* Measure Scoring Methodology

The October 2016 DFC Star Rating release used January 2014 to December 2014 data as the baseline period. This allowed facilities to maintain or improve their Star Rating if they maintained or improved performance on the quality measures compared to their baseline period score. As new measures are added to the DFC Star Rating System, one cannot directly compare cutoff scores to the Star Rating cutoffs established for the October 2016 DFC update using January to December 2014 results. Additionally, several measures are updated for the October 2018 release (see Summary of Methodology Updates for the October 2018 DFC Release) for information on how this is addressed.

The measure values in the current DFC Star Rating are either standardized ratios or percentages. In developing scores for the baseline period, different scoring methods are applied, based on the measures' scales. The most up-to-date data, as of May 2018, were used for each of the measures: January 2016 to December 2016 data for the standardized measures and July 2016 to June 2017 data for the percent-based measures. These are the data reported in the April 2018 release.

5.7.1.1 Standardized Ratio Measures: STrR, SMR, SHR, SRR

The standardized ratio measures are scored differently than the percentage measures as the quality associated with a unit change in a ratio measure is not equally spaced. For example, the quality difference between an SMR of 0.5 versus 1.0 is not the same as the quality difference between an SMR 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, a ranking approach described below, better accounts for these spacing differences than z-scores, which assume equal spacing. In addition, since the probit function maps percentile ranks of the standardized ratio measures to a distribution with mean 0 and variance 1, this type of scoring can be easily combined with z-scores for the percentage measures, which also have mean 0 and variance 1. Therefore, probit scoring is used for the ratio measures to define scores in the baseline period. To calculate probit scores, we input a "percentile rank/100" into the probit function, ϕ^{-1}, the inverse cumulative distribution function for the standard normal distribution. This produces the normal quantile associated with the input percentile rank. Minimum and maximum values of probit scores are determined by precision of the percentile input into the probit function. The DFC Star Rating uses percentiles ranging from 0.5 to 99.5 in increments of 0.5, resulting in 199 distinct percentiles. The associated minimum probit score is ϕ^{-1} (0.5/100) = -2.58, and the maximum probit score is ϕ^{-1} (99.5/100) = 2.58.

The probit scores for ratio-based measures and the truncated z-scores for percentage-based measures have the same range of values when scoring. Therefore, the maximum and minimum probit scores (± 2.58) are chosen as the cutoffs to truncate the z-scores.

Probit scoring algorithm in the *baseline period*:

- Percentile ranks are calculated for the *baseline period* measure values, to then be fed into the probit function.
- The percentile ranks are realigned so that the highest value (99.5) represents care much above average and the lowest value (0.5) represents care much below average. This is to ensure the same directionality before combining measures.
- The percentiles are then mapped to the probit scores: probit score = ϕ^{-1}(percentile rank / 100) which has a range of -2.58 to 2.58. After the probit transformation, the standardized measure scores have mean 0 and variance 1.

Figure 22 shows the distribution of measure values for SMR on the left (where lower values are better) and the distribution of probit measure scores for SMR on the right (where higher scores are better).

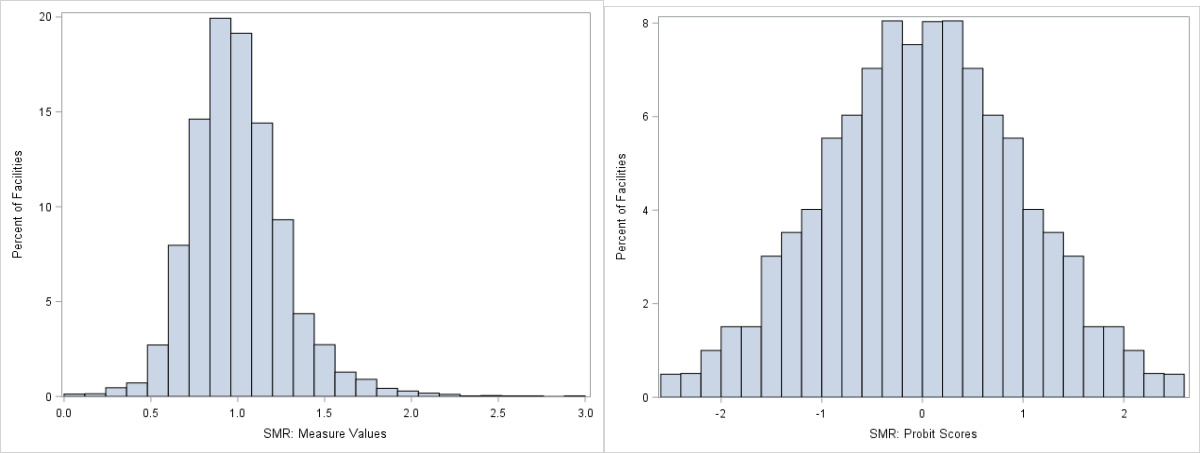


Figure 22: Example of Scoring SMR, January 2016 to December 2016 *Baseline Period*

5.7.1.2 Percentage Measures: SFR, Catheter, Hypercalcemia, Total Kt/V

The percentage measures vary in distribution and are scored using truncated z-scores. Truncated z-scores represent the number of standard deviations away from the mean, truncated at a maximum/minimum allowed value. During the truncation process, these measures are iteratively re-scored to ensure a final mean of 0 and variance of 1. Highly skewed measures have the potential to result in large z-scores for facilities in the tail of the measure. These large scores may exert too much influence on the Star Rating. Limiting the range of the scores through truncation ensures a facility's Star Rating is not determined primarily by outlier performance on a single measure. The scoring algorithm is as follows:

- Percentage measures in the *baseline period* are realigned so that the highest value (100) represents care much above average and the lowest value (0) represents the worst possible care quality. This is to ensure scored measures have the same directionality before they are combined.
- Z-scores are calculated. All z-scored measures now have mean of 0 and variance of 1 at this step.
- Z-scores are truncated at upper and lower bounds for each measure.
- These truncated scores are then re-standardized to ensure the final truncated z-scores still have mean of 0 and variance of 1. The upper and lower truncation bounds are different for each measure, and all measure scores have a maximum range of -2.58 to 2.58.

A detailed example of this calculation is shown in Section 5.12.2. Figure 23 shows the distribution of measure values for Kt/V (left) and the distribution of measure z-scores for Kt/V (right).

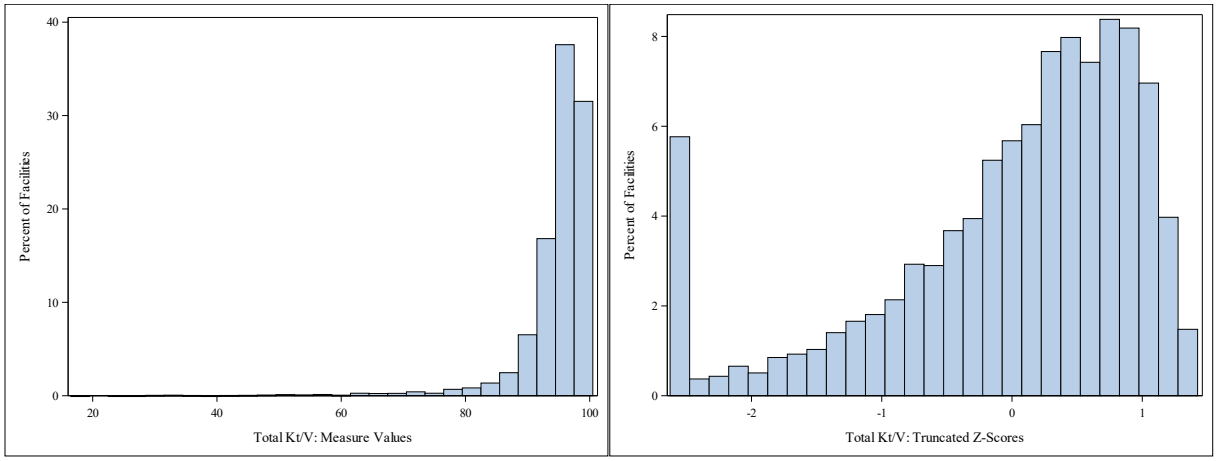


Figure 23: Example of Scoring Kt/V, July 2016 to June 2017 *Baseline Period*

5.7.2 Evaluation Period Measure Scoring Methodology

For the October 2018 DFC release, the Star Rating System has new, replaced, and updated measures in the measure set. Therefore, it would not be appropriate to directly compare this evaluation period's data to the original baseline period (January 2014 to December 2014) criteria established for the October 2016 release of the Star Ratings. Instead, the April 2018 Star Rating distribution will be used to establish a new set of cutoffs for the October 2018 release of the DFC Star Rating. This will maintain the longitudinal continuity of the current Star Rating distribution, while using the appropriate score cutoffs established for the new measure set.

5.7.2.1 Standardized Ratio Measures: STrR, SMR, SHR, SRR

The standardized ratio measures represent ratios (observed events/expected events) in the evaluation period. Before applying scores to standardized ratio measures in the evaluation period, we multiply these ratios by 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 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. It is the average national observed event rate in the evaluation period divided by the average national observed event rate in the baseline period. For the October 2018 Star Rating release, the evaluation period will use data from January 2017 to December 2017.

Below is an example using the April 2018 DFC release data as the evaluation period, adjusted to the October 2016 DFC release data event rates, which is the baseline period. As an illustration, the example below shows the adjustment that would be made for data collected in 2016 (i.e., evaluation period):$\text{SHR Adjustment Factor} = \frac{\text{Evaluation Period (Jan. - Dec. 2016) Hospitalizations per Patient-Year}}{\text{Baseline Period (Jan. - Dec. 2015) Hospitalizations per Patient-Year}} = \frac{1.81}{1.78} = 1.02$

Since hospitalization rates were higher in 2016 than in 2015, the expected number of events for the average facility is higher in 2016. By multiplying SHR in 2016 by a factor of 1.02 to calculate an adjusted SHR, these facilities are effectively being measured by 2015 criteria, i.e.,

baseline period criteria. This is interpreted as how the facility performed in the evaluation period relative to the typical facility in a pre-established baseline period.

Evaluation period facility ratios are first multiplied by the adjustment factor (as described earlier) in order to calculate individual facility adjusted ratios. Each adjusted ratio is mapped to the same percentile rank that the ratio would have been mapped to if it had been observed in the baseline period. The cutoffs used for the percentile ranks are determined by the best measure value within each percentile rank in the baseline period.

5.7.2.2 Percentage Measures: SFR, Catheter, Hypercalcemia, Total Kt/V

Each measure value is mapped to the same score that the measure value would have been mapped to if it had been observed in the baseline period (July 2016 to June 2017). Z-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 shown in Table 32: Defining Scores for Kt/V in the *Baseline Period* (January 2015 to December 2015) and Table 33: Defining Scores for Kt/V in the *Evaluation Period* (July 2016 to June 2017) in Section 5.12.2.

5.7.2.3 Combining Measure Scores into Final Facility Scores

In the DFC Star Rating, the measure scores are combined to calculate a final facility score for each facility. Each facility is first given domain scores between -2.58 and 2.58 by averaging the measure scores within each of the three domains. Facilities are then given a final score between -2.58 and 2.58 by averaging the domain scores. Facilities are given final scores as long as they have at least one measure value in each domain. Note that facilities that serve PD patients only (designated as PD-only facilities) do not have values for the "Other Outcomes 1 (SFR, Catheter)" domain. For the Star Rating, these facilities will be rated based on the average scores for the other domains.

5.8 Missing Values

As noted above, with the exception of PD-only facilities, all facilities will receive a rating if they have at least one measure value in each domain. Missing values (for facilities eligible for ratings) are assigned the mean of the scores given to that measure in the evaluation period. This method of imputation ensures one measure does not exert too much influence on the domain score, and in turn, the final score used to determine the Star Rating. For example, if one facility had the maximum measure score of 2.58 for STrR and had missing values for SMR, SRR, and SHR, it would not be appropriate to assume the Standardized Ratio Measure Domain should be given the maximum score of 2.58 based on the one measure for that domain (i.e., STrR in this case). By imputing the average score for the SMR, SHR, and SRR measure, we instead give the domain a submaximal above average score. In this example, this facility is still above average for this domain, but the domain score will not be based solely on the one observed score for STrR, and therefore limits the STrR score from being too influential on the final facility score.

5.9 Translating Facility Final Scores to Star Ratings

The ranges of the final score, i.e. the cutoff values, which determine facilities' five Star Rating categories are established by data from the baseline period (see Section 4).

5.9.1 Defining Final Score Cutoffs in the *Baseline Period*

Final scores for the *cutoff year* were calculated and used to define Star Rating categories in the *current year* Star Rating. The same *cutoff year* and cutoff values continue to be used in future Star Ratings until a new *cutoff year* (or *baseline year*) is established.

5.9.2 Maintaining Longitudinal Continuity in the Star Rating for the October 2018 Release

This release of the Star Rating system will incorporate the new, replaced, and updated measures described earlier in this report, and will be based on new Star Rating category cutoff values. The new cutoff values will preserve the Star Rating distribution from the previous Star Rating release. These cutoffs are established using the most recent full year of data: January 2016 to December 2016 for the standardized ratio measures and July 2016 to June 2017 for the percentage-based measures. The final facility score distribution will use the Star Rating proportions reported in the April 2018 release to establish new cutoffs. These cutoffs will then be applied to the facility final scores for the October 2018 release.

5.9.3 Assigning Star Ratings in the *Evaluation Period*

The final score cutoffs that are defined using the April 2018 data Star Rating distribution are used to assign Star Ratings to facilities for the *evaluation*. If the population of facilities improves in their measure performance from the year in which the cutoffs are established, more facilities could be in the higher Star Rating categories compared to the *baseline period*, as they are being compared to prior measure performance in the earlier year.

Table 26 below reports an example distribution of average *measure values* for facilities within each Star Rating category. As is shown, better measure values and final scores correspond with higher Star Rating categories. Note: This table uses the currently available April 2018 DFC data in order to illustrate this example.

Measure	★	★★	★★★	★★★★	★★★★★
Facility N (%)	228 (4%)	554 (9%)	2262 (43%)	1870 (30%)	1390 (22%)
SMR	1.34	1.13	1.06	0.98	0.88
SHR	1.33	1.21	1.09	0.96	0.80

Measure	★	★★	★★★	★★★★	★★★★★
SRR	1.17	1.15	1.05	0.96	0.82
STrR	1.68	1.25	1.00	0.78	0.54
Fistula	45.83	53.55	59.68	65.77	72.08
Catheter	28.45	19.52	13.89	10.33	7.51
Hypercalcemia	13.64	4.25	2.51	1.77	1.11
Total Kt/V	82.46	92.23	94.84	96.38	97.59
Final Score	-1.07	-0.39	0.08	0.46	0.85

Table 26: Mean Measure Values and Mean Final Facility Scores Within Each Star Rating Category*

* April 2018 DFC release data for the evaluation period, October 2016 DFC release data for the baseline period

5.10 An Illustration of the Star Rating Calculation

This section illustrates the updated Star Rating methodology that will be implemented beginning with the October 2018 DFC Star Rating release. The calculation is illustrated using two sample facilities: (1) A *Standard* facility, denoted as *Facility A,* which provides a combination of in-center HD, home HD, and/or PD, and (2) A *PD-Only* facility, denoted as *Facility B*, which provides only PD services. This illustrates how PD-only versus all other facilities are treated in the Star Rating calculation. Note these examples use currently available data, where January 2015 to December 2015 is the *baseline period*, and the data available from the April 2018 release is the *evaluation period* to illustrate this example.

Step 1: Apply Suppressions to *Cutoff Year* & *Current Year* Data

Facilities that are too new or too small to provide reliable clinical measure values are suppressed and set to missing. For this example, both *Facility A* and *Facility B* are facilities that were not suppressed.

Step 2: Define Scores in a *Cutoff Year*

- Standardized Ratio Measures: Apply probit scoring to each measure
  - Generate 199 percentile ranks for each measure (0.5 to 99.5)
  - Generate probit scores where the score = ϕ^{-1}(percentile rank / 100)
- Percentage Measures: Apply iterative truncated z-score algorithm to each realigned measure
  - Let the measure of interest be m and first standardize m to get z

- Iteratively truncate z at δ^+, δ^- to get t and standardize t to get w

The baseline period measure values and standardized measure scores are reported in Table 27 below.

Here, measure value refers to the value as reported for DFC. Standardized measure scores (Std. Score) refers to the transformed measure values for each individual metric, after applying Step 2, which are used to calculate a facility's final score and subsequent Star Rating:

Measure	**Facility A** (A Standard Facility)		**Facility B** (A PD-Only Facility)	
	Measure Value	**Std. Score**	**Measure Value**	**Std. Score**
SMR	0.92	0.27	0.91	0.29
SHR	0.71	1.08	0.65	1.34
SRR	0.63	1.25	1.23	-0.82
STrR	1.40	-0.79	Missing*	0.00
Fistula	59.19	-0.48	N/A	N/A
Catheter	3.55	1.62	N/A	N/A
Hypercalcemia	3.92	0.33	1.86	0.84
Total Kt/V	91.82	-0.08	95.65	0.70

Table 27: Cutoff Year Measure Values and Standardized Measure Scores

** A facility missing a value for STrR was chosen to demonstrate missing imputation (Step 2, Part 3)*

5.10.1 Step 3: Score Values in *Current Year* Based on *Cutoff Year* Standards

- Standardized Ratio Measures
  - Apply adjustment factor to *evaluation period* measure values.
  - Assign probit scores in the *evaluation period* using bounds defined in the *baseline period*
- Percentage Measures

- Standardize *evaluation period* measure values by subtracting the *baseline period mean* and dividing by the baseline period standard deviation
- Truncate standardized measure scores at truncation bounds from *baseline period*
- Re-standardize truncated scores by subtracting the *baseline period mean* and dividing by the baseline period standard deviation
- Impute eligible facility's missing values with the national average for that measure

In our example, the *evaluation* measure values and standardized measure scores are reported in Table 28.

Measure	Facility A		Facility B	
	Measure Value	Std. Score	Measure Value	Std. Score
SMR	1.11	-0.50	1.28	-1.10
SHR	0.91	0.23	0.83	0.60
SRR	0.88	0.43	0.33	1.96
STrR	1.38	-0.77	Missing*	0.22
Fistula	57.55	-0.63	N/A	N/A
Catheter	4.18	1.53	N/A	N/A
Hypercalcemia	2.30	0.73	4.84	0.10
Total Kt/V	94.97	0.56	97.85	1.14

Table 28: Current Year Measure Values and Standardized Measure Scores

** A facility missing a value for STrR was chosen to demonstrate missing imputation (Step 3, Part 3)*

5.10.2 Step 4: Define Final Score Cutoffs in *Cutoff Year*

- Determine which facilities will be rated in the *baseline period* based on the suppression criteria outlined in Step 1
- Score the facility in the *baseline period*
  - Average standardized measure scores within each domain to obtain domain scores
  - Average domain scores to obtain a final score

- Define Star Ratings in *baseline period* based on the defined Star Rating proportions reported for the *baseline period* data
- Define the Star Rating cutoffs as the average of the greatest lower bound and the least upper bound between two adjacent Star Rating categories

For our example facilities, the *baseline period* domain scores and final scores are reported in Table 29 below; the Star Rating cutoffs are reported in Table 30. Note that Cutoff 1 is defined to be the average score between the highest scoring facility in the 1-Star category and the lowest scoring facility in the 2-Star category. Cutoffs for categories 2-4 are defined similarly.

Measure	Facility A	Facility B
Domain 1	0.45	0.20
Domain 2	0.57	N/A
Domain 3	0.13	0.77
Final Score	0.45	0.20

Table 29: Baseline Period Domain Scores and Final Scores

Cutoff	Cutoff between 1-Star & 2-Stars	Cutoff between 2-Stars & 3-Stars	Cutoff between 3-Stars & 4-Stars	Cutoff between 4-Stars & 5-Stars
Value	-0.67	-0.22	0.30	0.641

Table 30: Cutoff Values for Star Rating Categories

5.11 Step 5: Apply Final Score Cutoffs in *Current Year*

- Determine which facilities will be rated in the *evaluation period* based on the suppression criteria
- Score the facility in the *evaluation period*
  - Average standardized measure scores within each domain to obtain domain scores
  - Average domain scores to obtain a final score
- Translate final scores to Star Ratings using the Star Rating cutoffs defined in the *baseline period*

The example *evaluation period* domain scores and final scores are reported in Table 31 below. Using the cutoffs reported in Table 30, both the Standard facility and the PD-Only facility would be assigned 4-Stars.

Measure	Facility A	Facility B
Domain 1	-0.15	0.42
Domain 2	0.45	N/A
Domain 3	0.65	0.62
Final Score	0.31	0.52
Star Rating	4-Star	4-Star

Table 31: Current Year Domain Scores and Final Scores

5.12 Additional Details

5.12.1 Detailed Example of Scoring Measures in the Standardized Outcomes Domain

In order to map the standardized ratio measure values in the *evaluation period* to the percentile ranks defined in the *baseline period*, percentile rank cutoffs must be established. The cutoffs are determined by the best measure value within each percentile rank in the *baseline period*. For any measure ratio value in the *evaluation period* that falls between the percentile rank cutoffs in the *baseline period*, the measure ratio value in the *evaluation period* will be "rounded up" to the higher of the two percentile rank values. A higher percentile rank indicates better performance. For example, suppose we are considering a measure for which a higher ratio indicates poorer performance on the measure. If the lowest value receiving a ratio measure percentile rank of 47.5 in the *baseline period* is 1.092 and the highest value receiving the next higher percentile rank value of 48.0 is 1.089, then the ratio measure in a future year (after applying the adjustment factor) of 1.090 would be given a percentile rank of 48.0. These "percentile ranks" are input into the probit function to determine the measure scores for the *evaluation period*.

5.12.2 Detailed Example of Scoring Percentage Measures

Here we show how truncated z-scores are defined in the *baseline period* and applied in the *evaluation period*. Table 32 shows how scoring is defined in the *baseline period*. In the first row, we display Kt/V and its summary statistics for January 2015 to December 2015. In the second row, the z-score is obtained by subtracting each Kt/V value by its mean (91.69) and dividing by its standard deviation (6.91). In the third row, initial truncated z-scores are calculated by truncating the z-score at a lower bound (-1.80) and upper bound (here no truncation is needed for the upper bound of Kt/V since it is already below 2.58). Finally, in the fourth row, the initial

Kt/V truncated z-score is re-standardized by subtracting each value by its mean (0.07) and dividing by its standard deviation (0.72). Note that the truncation bounds in row 2 are chosen by an iterative algorithm that ensures the re-standardized measure lies within -2.58 and 2.58. The summary statistics in this table are then used to calculate the scores in the *evaluation period* (July 2016 to June 2017).

Variable	Mean	SD	Minimum	Maximum
Kt/V Measure Value	91.69	6.91	12.44	100.00
Kt/V Z-Score	0.00	1.00	-11.47	1.20
Initial Kt/V Truncated Z-Score	0.07	0.72	-1.80	1.20
Final Kt/V Truncated Z-Score (Re-Standardized)	0.00	1.00	-2.58	1.57

Table 32: Defining Scores for Kt/V in the *Baseline Period* (January 2015 to December 2015)

Table 33 shows how scoring is defined in the *evaluation period*. The first row reports Kt/V and its summary statistics for July 2016 to June 2017. In the second row, the z-score is obtained by subtracting each Kt/V value by the *baseline period* mean (91.69) and dividing by the *baseline period* standard deviation (6.91) in Table 32. In the third row, initial truncated z-scores are formed by truncating the z-score at the lower bound (-1.80) and upper bound (no bound needed for Kt/V) used in the *baseline period*. Finally, in the fourth row, the initial Kt/V truncated z-score is re-standardized by subtracting each value by the mean (0.07) and dividing by the standard deviation (0.72) of the initial truncated z-scores in the *baseline period*. Using the summary statistics from the *baseline period*, the Kt/V values are scored by criteria defined in the *baseline period*. Note that the mean of the re-standardized score in Table 33 is greater than 0, indicating improvement in the population average of Kt/V from the *baseline period*.

Variable	Mean	SD	Minimum	Maximum
Kt/V Measure Value	94.64	6.44	18.31	100
Kt/V Z-Score	0.43	0.93	-10.62	1.20
Initial Kt/V Truncated Z-Score	0.48	0.63	-1.80	1.20
Final Kt/V Truncated Z-Score (Re-Standardized)	0.58	0.89	-2.58	1.57

Table 33: Defining Scores for Kt/V in the *Evaluation Period* (July 2016 to June 2017)

Acronyms

Acronym	Definition
ADEMEX	Adequacy of Peritoneal Dialysis in Mexico
AFS	Annual Facility Survey
AHRQ	Agency for Healthcare Research and Quality
AKI	Acute Kidney Injury
ARNP	Advanced Registered Nurse Practitioner
AV	Arteriovenous
AVF	Arteriovenous Fistula
BMI	Body Mass Index
BSI	Blood Stream Infections
BUN	Blood Urea Nitrogen
CAD	Coronary Artery Disease
CAPD	Continuous Ambulatory Peritoneal Dialysis
CASPER	Certification and Survey Provider Enhanced Report System
CC	HHS Hierarchical Condition Categories
CCN	CMS Certification Number
CCPD	Continuous Cycling Peritoneal Dialysis
CCS	AHRQ Clinical Classification Software
CHF	Congestive Heart Failure
CHOW	Change of Ownership
CKD	Chronic Kidney Disease
CMS	Centers for Medicaid and Medicare Services
CROWNWeb	Consolidated Renal Operations in a Web-enabled Network
CVD	Cardiovascular Disease
CY	Calendar Year
DFC	Dialysis Facility Compare
DFR	Dialysis Facility Reports
ECE	Extraordinary Circumstances Exception
EDB	Enrollment Database

Acronym	Definition
EQRS	ESRD Quality Reporting System
ESA	Erythropoiesis Stimulating Agents
ESRD	End Stage Renal Disease
FDA	Food and Drug Administration
FSD	First Service Date
GEE	Generalized Estimating Equations
HCP	Healthcare Personnel
HCPCS	Healthcare Common Procedure Coding System
HD	Hemodialysis
HHS	Health and Human Services
HIV	Human Immunodeficiency Virus
HWR	Hospital-wide Readmission Measure
ICH CAHPS	In Center Hemodialysis - Consumer Assessment of Healthcare Providers and Systems
ICD	International Statistical Classification of Diseases
IDH	Intradialytic Hypotension
IDR	Integrated Data Repository
KDOQI	Kidney Disease Outcomes Quality Initiative
Kt/V	K (dialyzer clearance of urea)*t (dialysis time)/V (patient's total body water)
LDO	Large Dialysis Organization
LTC	Long Term Care
LTCH	Long Term Care Hospital
MBI	Medicare Beneficiary ID
MedPAC	Medicare Payment Advisory Commission
MedRec	Medication Reconciliation
MDS	Minimum Data Set
MRPs	Medication-Related Problems
NCH	National Claims History database
NHSN	National Healthcare Safety Network
NHSN BSI	National Health Safety Network Blood Stream Infection

Acronym	Definition
NKF	National Kidney Foundation
nPCR	Normalized Protein Catabolic Rate
NQF	National Quality Foundation
OPTN	Organ Procurement and Transplant Network
PA	Physician Assistant
PD	Peritoneal Dialysis
PMMIS	Program Management and Medical Information System
POS	Provider of Service
PPPW	Percentage of Prevalent Patients Waitlisted
PPS	Prospective Payment System
PY	Payment Year
QDFC	Quarterly Dialysis Facility Compare
QIES	Quality Improvement Evaluation System
QIP	Quality Incentive Program
QM	Quality Measure
RBC	Red Blood Cell
RDS	Renal Data Systems
REBUS	Renal Beneficiary and Utilization System
SAF	Standard Analysis File
SFR	Standardized Fistula Rate
SHR	Standardized Hospitalization Ratio
SIR	Standardized Infection Ratio
SMR	Standardized Mortality Ratio
SNF	Skilled Nursing Facility
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

Acronym	Definition
SWR	Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients
TEP	Technical Expert Panel
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
URR	Urea Reduction Ratio
USRDS	United States Renal Data System
VA	Veterans Affairs
VAT	Vascular Access Type

Glossary

CMS Certification Number (CCN) Open Date

When CMS refers to CCN open date, they are referring to the date the facility can receive reimbursement from Medicare, which in the EQRS facility database is the CCN Certification Date, and thus, the date that is referenced in the *Manual* and used in the measures calculations.

Some stakeholders have expressed confusion about the use of the term ‘‘CMS Certification Number (CCN) Open Date’’ under the ESRD QIP (for example, see the CY 2105 ESRD PPS final rule, published in the *Federal Register* at 79 FR 66186). CMS interprets this term to mean the ‘‘Medicare effective date’’ under its Medicare provider agreement regulations at 42 CFR 489.13, which governs when the facility can begin to receive Medicare reimbursement for ESRD services under the ESRD prospective payment system (PPS). Thus, a facility is eligible, with respect to a particular payment year, to receive scores on individual measures and participate in general in the ESRD QIP based on the facility’s CCN Open Date (such as the Medicare effective date).