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

CMS ESRD Measures Manual for the 2017 Performance Period

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1. Introduction

The *CMS ESRD Measures Manual* (*Manual*) represents an effort to respond to strong stakeholder interest in the detailed specifications that underwrite reporting and clinical performance measures in the Centers for Medicare & Medicaid Services (CMS) End Stage Renal Disease (ESRD) quality programs during the calendar year 2017. 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.

2. Measurement Information

2.1 Vascular Access Type Clinical Measure: Fistula (ESRD QIP and DFC)

2.1.1 Measure Name

Maximizing Placement of Arterial Venous Fistula (AVF) – NQF#0257

2.1.2 Measure Description

Percentage of patient-months for patients on maintenance hemodialysis (HD) during the last HD treatment of the month using an autogenous arterial venous (AV) fistula with two needles.

2.1.3 Measure Rationale

The studies referenced below demonstrate that AV fistulas have the best 5-year patency rates and require the fewest interventions compared with other access types. A study using data from the United States Renal Data System (USRDS) showed that patients receiving dialysis through catheters or AV grafts have greater mortality risk than patients dialyzed with fistula. Furthermore, infection-related deaths were significantly higher for catheters as compared to fistulas, in both diabetic and non-diabetic ESRD patients. Finally, the advantages of AV fistula over other accesses are clearly delineated in the National Kidney Foundation (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines, summarized as follows: (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, the epidemiologic studies referenced below consistently demonstrate the reduced morbidity and mortality associated with greater use of AV fistulas for vascular access in maintenance hemodialysis.

2.1.4 Measure Type

Process

2.1.5 Improvement Noted as Higher or Lower Rate

Higher numbers are better.

2.1.6 Risk Adjustment

None

2.1.7 Numerator Statement

Maintenance HD patient-months in which an autogenous AV fistula with two needles was in use at the last HD treatment of month.

2.1.8 Facility Exclusions

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

2.1.9 Denominator Statement

Maintenance hemodialysis patient-months in which maintenance hemodialysis was the last treatment of month at the facility.

2.1.10 Denominator Exclusions

- Patients younger than 18 years old
- Patients not on Hemodialysis
- Patients not on ESRD treatment as defined by a completed 2728 medical evidence form, a REMIS/CROWNWeb record, or a sufficient amount of dialysis reported on dialysis facility claims to indicate chronic dialysis (See Section 3.1.3)

  ESRD QIP only:

  – Patients with fewer than four eligible patient-months at the facility during the measurement period
  – Claims with both a fistula and graft reported
  – Claims with fistula, graft, and catheter reported
  – Claims with missing access type

  DFC only:

  – Patients on ESRD for fewer than 90 days (<90 days)

2.1.11 Mapping Patients to Facilities

A patient is assigned to a facility if there is at least one claim meeting the inclusion criteria submitted by the facility during the reporting period. A patient can be mapped to more than one facility during a single patient-month.

2.1.12 Calculating Numerators

Using claims assigned to the denominator, eligible patient-months are assigned to the numerator if HCPCS Modifier Code V7, associated with the hemodialysis revenue center codes on the claim line items (with or without V5, but without V6), is reported on the last claim of the month for the facility.

2.1.13 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.

CROWNWeb Data Elements

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

Claims Based Data Elements

Note: Non Type of Bill (TOB) 72x claims are not considered in the measure calculation.

- Claim CMS Process Date
- Claim Control Number
- Claim From Date
- Claim Through Date
- Claim Daily Process Date
- Claim Link Number
- HCPCS First Modifier Code
- HCPCS Second Modifier Code
- HCPCS Third Modifier Code
- HCPCS Fourth Modifier Code
- HCPCS Fifth Modifier Code
- Claim CCN
- Patient Medicare Claim Number
- Claim Line Institutional Revenue Center Date
- Claim Line Institutional Revenue Center Codes
- Calculated start of ESRD date (see section 3.1.3)

2.1.14 Flowchart

Figure 1 provides a flowchart that represents the processes used to calculate the Fistula Vascular Access Type measure rate.

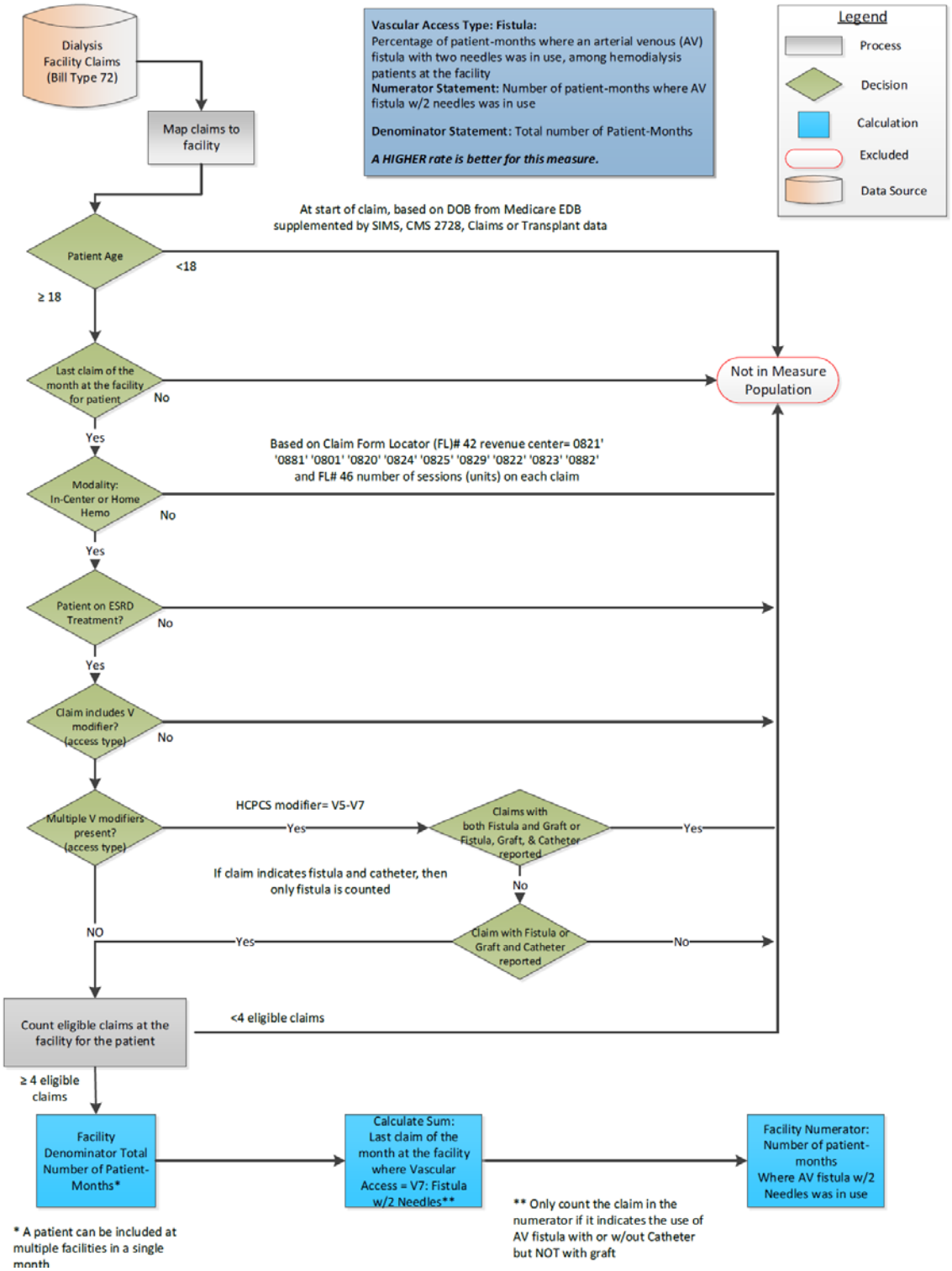

Figure 1. Vascular Access Type: Fistula Measure Rate Flowchart for ESRD QIP

2.1.15 Selected References

- U.S. Renal Data System, USRDS 2009 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, 2009.
- National Kidney Foundation: Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines for Vascular Access.

2.2 Vascular Access Type Clinical Measure: Catheter **≥ 90 Days** (ESRD QIP and DFC)

2.2.1 Measure Name

Minimizing Use of Catheters as Chronic Dialysis Access – NQF#0256

2.2.2 Measure Description

Percentage of patient-months for patients on maintenance hemodialysis (HD) during the last HD treatment of the month with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session.

2.2.3 Measure Rationale

The study referenced below demonstrates that long-term use of venous catheters for HD access is associated with greater morbidity and higher mortality. Whereas catheters have the advantage of immediate use without need for maturation time, as enumerated in the Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines, the long-term use of catheters is associated with substantially higher rates of infection-related complications and increased risk for central venous thrombosis, stenosis, and occlusion. The study referenced below has also shown that patients receiving dialysis using catheters have greater mortality risk than patients dialyzed with fistulas, whether or not diabetes mellitus was present. Higher case-mix adjusted mortality rates have been seen for HD patients dialyzing in facilities having greater catheter use.

2.2.4 Measure Type

Process

2.2.5 Improvement Noted as Higher or Lower Rate

Lower numbers are better

2.2.6 Risk Adjustment

None

2.2.7 Numerator Statement

Maintenance HD patient-months in which a chronic catheter was used as hemodialysis access for 90 days or longer prior to last hemodialysis session of the month at the facility.

2.2.8 Facility Exclusions

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

2.2.9 Denominator Statement

Medicare maintenance hemodialysis patient-months in which maintenance hemodialysis was the last treatment of month at the facility.

2.2.10 Denominator Exclusions

- Patients not on Hemodialysis
- Patients not on ESRD treatment as defined by a completed 2728 medical evidence form, a REMIS/CROWNWeb record, or a sufficient amount of dialysis reported on dialysis facility claims to indicate chronic dialysis (See Section 3.1.3)

ESRD QIP only:

- Patients younger than 18 years plus 90 days
- Patients with fewer than four consecutive patient-months at the facility (including the three-month eligibility look-back period)
- Claims with both a fistula and graft reported
- Claims with fistula, graft, and catheter reported
- Claims with missing access type

DFC only:

- Patients younger than 18 years old
- Patients on ESRD for fewer than 90 days (<90 days)

2.2.11 Mapping Patients to Facilities

A patient is assigned to a facility if there is at least one claim meeting the inclusion criteria submitted by the facility during the reporting period. A patient can be mapped to more than one facility during a single patient-month.

2.2.12 Calculating Numerators

Eligible patient-months are assigned to the numerator if V5 is the only modifier reported on claims from the facility in the previous 90 days.

2.2.13 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.

CROWNWeb Data Elements

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

Claims Based Data Elements

Note: Non Type of Bill (TOB) 72X claims are not considered in the measure calculation.

- Patient Medicare Claim Number
- Claim CMS Process Date
- Claim Control Number
- Claim From Date
- Claim Through Date
- Claim Daily Process Date
- Claim Link Number
- Claim Line Institutional Revenue Center Date
- HCPCS First Modifier Code
- HCPCS Second Modifier Code
- HCPCS Third Modifier Code
- HCPCS Fourth Modifier Code
- HCPCS Fifth Modifier Code
- Claim Line Institutional Revenue Center Codes
- Claim CCN
- Calculated start of ESRD date (see section 3.1.3)

2.2.14 Flowchart

Figure 2 provides a flowchart that represents the processes used to calculate the Catheter Vascular Access Type measure rate.

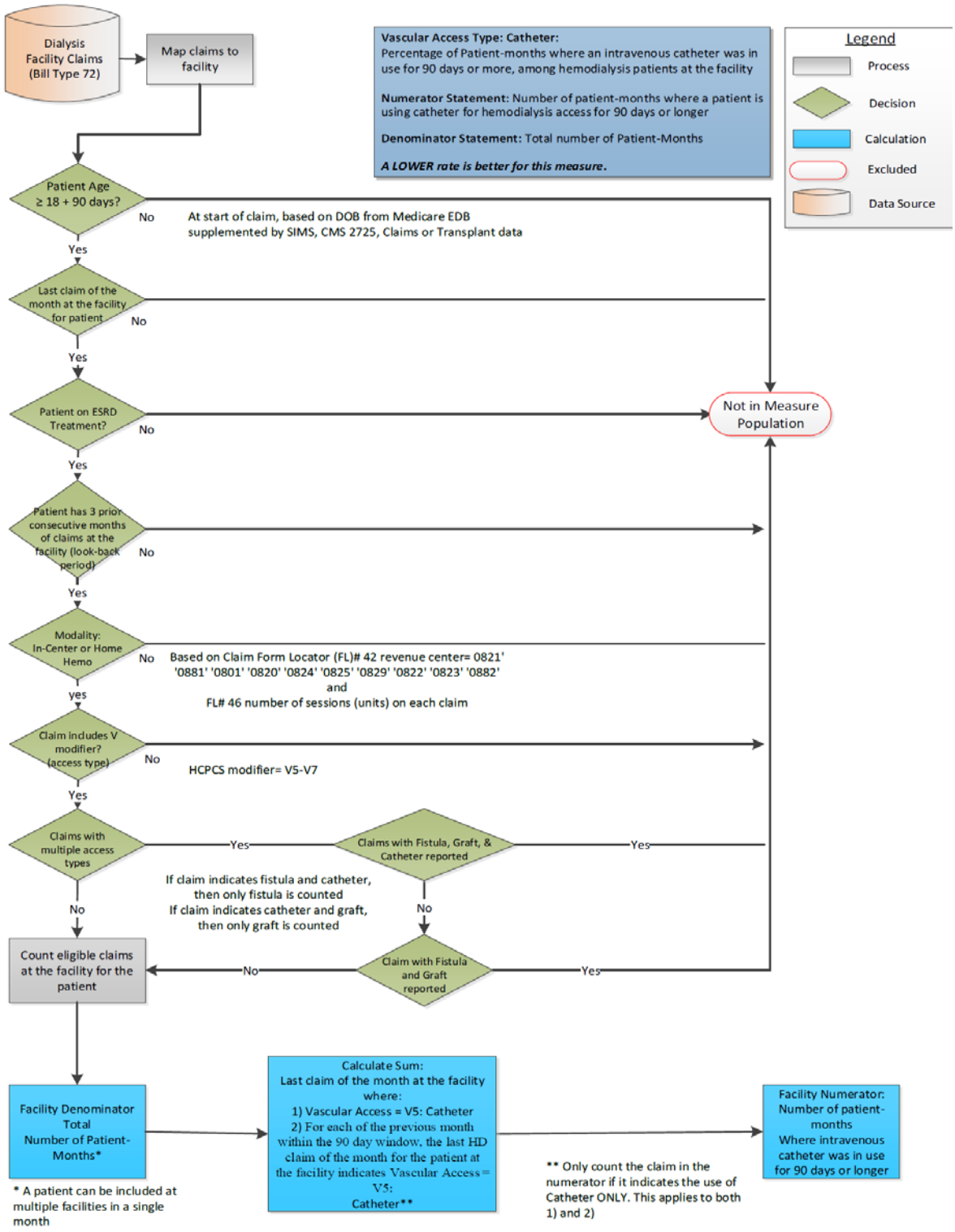

Figure 2. Vascular Access Type: Catheter Measure Rate Flowchart for ESRD QIP

2.2.15 Selected References

- National Kidney Foundation: KDOQI Clinical Practice Guidelines for Vascular Access.

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 (≥18 years old) patient-months in the sample for analysis who had ESRD treatment for 90 days or more and dialyzing thrice weekly whose delivered dose of hemodialysis (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 ≥ 1.2 during the study period.

2.3.3 Measure Rationale

The dose of dialysis is used to estimate the ability of hemodialysis to clear the blood of accumulated toxins. In the adult population, outcome studies, referenced below, have shown an association between dose of hemodialysis 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 outcome. 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 CROWNWeb 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

Higher rates are better

2.3.6 Risk Adjustment

None

2.3.7 Numerator Statement

Number of patient-months in denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V ≥ 1.2 and also in range (spKt/V ≤ 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) patients in the sample for analysis who have had ESRD for 90 days or more and dialyzing thrice weekly the entire month.

2.3.10 Denominator Exclusions

- Patients not assigned to the facility for the entire month
- Patients younger than 18 years old as of the first day of the month
- Patients not on hemodialysis the entire month
- Patients who have had ESRD treatment for less than 91 days as of the first of the month
- Patients not on thrice weekly dialysis (see Section 3.1.5)
  - If the patient is identified as not on thrice weekly dialysis anytime during the month, then the entire patient-month is excluded from the calculations. See section 3.1.5 below for more details regarding the determination of thrice weekly.

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 was identified primarily using data from CROWNWeb, the Medical Evidence Form (Form CMS-2728) and Medicare dialysis claims. Both patient assignment to the provider and modality (either hemodialysis or peritoneal dialysis) 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 there was a one-day gap or more in treatment at the facility during the reporting month, the patient-month was excluded. 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 CROWNWeb 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.

2.3.12 Calculating Numerators

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

- If a patient has multiple Kt/V values in CROWNWeb during a month, then the last reported value is selected.
- If an in-range value was not found in CROWNWeb 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 was selected (when available).
  - A claim was considered eligible if it was from a HD patient who had ESRD for at least 90 days and was at least 18 years old (as of the claim-from date), and the claim was neither a "frequent" dialysis claim nor an "infrequent" dialysis claim as described in Section 3.1.5.
  - The last eligible claim with an in-range (less than or equal to 5.0) and not expired (in-center HD with Kt/V reported from a previous claim, or home HD with Kt/V reported from more than four months prior) Kt/V value reported was selected when there were multiple claims reported in a month
  - If a multiple Kt/V values were reported on a single claim for a patient, then the following decision rules are used to select which value is considered when calculating the numerator:
    - Use the highest Kt/V value in the valid range ($\geq$1.2 and $\leq$ 5.0).
    - If no Kt/V values are reported within the valid range, then use any value not equal to 9.99 (This could be outside the valid range).
    - Use 9.99 if no other value is reported.

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.

CROWNWeb Data Elements

- CROWN Unique Patient Identifier (UPI)
- Facility CCN

- Patient Date of Birth (DOB)
- Patient Date of Death (DOD)
- Primary type of treatment ID (CROWNWeb 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

Claims Based Data Elements

Note: Non Type of Bill (TOB) 72x claims are not considered in the measure calculation.

- Patient Medicare Claim Number
- Claim Related Condition Code
- Claim CMS Process Date
- Claim Control Number
- Claim From Date
- Claim Through Date
- Claim 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
- Calculated start of ESRD date (see section 3.1.3)

2.3.15 Selected References

- Lowrie EG, et al. Effect of the hemodialysis prescription of patient morbidity: report from the National Cooperative Dialysis Study. N Engl J Med 305:1176–1181, 1981.
- Owen WF Jr, et al. The urea reduction ratio and serum albumin concentration as predictors of mortality in patients undergoing hemodialysis. N Engl J Med 329:1001–1006, 1993.

- 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, et al. 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, et al. 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, et al. 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 peritoneal dialysis patient-months with Kt/V greater than or equal to 1.7 Kt/V (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 peritoneal dialysis (CAPD) patients.

2.4.4 Measure Type

Intermediate Outcome

2.4.5 Improvement Noted as Higher or Lower Rate

A higher rate for the Kt/V Peritoneal Dialysis Adequacy measure is better.

2.4.6 Risk Adjustment

None

2.4.7 Numerator Statement

Patient-months in the denominator for patients whose delivered dose of peritoneal dialysis 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 90 days and receiving peritoneal dialysis the entire month.

2.4.10 Denominator Exclusions

- Patients not assigned to the facility for the entire month
- Patients younger than age 18 years old as of the first day of the month
- Patients not on peritoneal dialysis the entire month
- Patients on ESRD treatment for fewer than 91 days as of the first day of the month

2.4.11 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 was identified primarily using data from CROWNWeb, the Medical Evidence Form (Form CMS-2728) and Medicare dialysis claims. Both patient assignment to the provider and modality (either hemodialysis or peritoneal dialysis) 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 there was a one-day gap or more in treatment at the facility during the reporting month, the patient-month was excluded. 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 CROWNWeb 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.

2.4.12 Calculating Numerators

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

- If a patient has multiple Kt/V values in CROWNWeb during a month, then the last reported value is selected.
- If an in-range value was not found in CROWNWeb 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 was selected (when available).
    - A claim was considered eligible if it was from a PD patient who had ESRD for at least 90 days and was 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 (reported from more than four months prior) Kt/V value reported was selected when there were multiple claims reported in a month
- If a multiple Kt/V values were reported on a single claim for a patient, then the following decision rules are used to select which value is considered when calculating the numerator:
  - Use the highest Kt/V value in the valid range (≥ 1.7 and ≤ 8.5).
  - If no Kt/V values are reported within the valid range, then use any value not equal to 9.99 (This could be outside the valid range).
  - Use 9.99 if no other value is reported.

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.

CROWNWeb Data Elements

- CROWN Unique Patient Identifier (UPI)
- Facility CCN
- Patient Date of Birth (DOB)
- Patient Date of Death (DOD)
- Primary type of treatment ID (CROWNWeb dialysis type)
- Medicare Certified Services Offered
- Additional Services Offered (Non-Medicare)
- Kt/V

Claims Based Data Elements

Note: Non Type of Bill (TOB) 72x claims are not considered in the measure calculation.

- Claim Related Condition Code
- Claim CMS Process Date
- Claim Control Number
- Claim From Date
- Claim Through Date
- Claim Daily Process Date
- Claim Link Number
- Claim Occurrence Code
- Claim CCN
- Claim Value Code D5
- Claim Value Amount
- Claim Value Sequence Number
- Claim Line Institutional Revenue Center Codes
- Patient Medicare Claim Number
- Calculated start of ESRD date (see section 3.1.3)

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.” Journal of the American Society of Nephrology: JASN (2002) 13:1307-20. PMID: 11961019.
- Lo WK, Lui SL, Chan TM, et al. “Minimal and optimal peritoneal Kt/V targets: Results of an anuric peritoneal dialysis patient´s survival analysis.” Kidney international (2005) 67:2032-8. PMID: 15840054.

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 have had ESRD treatment for 90 days or more, and dialyzing three times weekly whose delivered dose of hemodialysis (calculated from the last measurements of the month using the Urea Kinetic Modeling **(**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 hemodialysis 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

Higher rates are better

2.5.6 Risk Adjustment

None

2.5.7 Numerator Statement

Number of patient-months in denominator whose delivered dose of hemodialysis (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 90 days or more and dialyzing thrice weekly the entire month.

2.5.10 Denominator Exclusions

- Patients not assigned to the facility for the entire month
- Patients 18 years and older as of the first day of the month
- Patients not on in-center hemodialysis the entire month
- Patients on ESRD treatment for fewer than 91 days as of the first day of the month
- Patient not on thrice weekly dialysis (see section 3.1.5)

If the patient is identified as not on thrice weekly dialysis anytime during the month, then the entire patient-month is excluded from the calculations. See section 3.1.5 below for more details regarding the determination of thrice weekly.

2.5.11 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 was identified primarily using data from CROWNWeb, the Medical Evidence Form (Form CMS-2728) and Medicare dialysis claims. Both patient assignment to the provider and modality (either hemodialysis or peritoneal dialysis) 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 there was a one-day gap or more in treatment at the facility during the reporting month, the patient-month was excluded. 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 CROWNWeb 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.

2.5.12 Calculating Numerators

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

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

- If an in-range value was not found in CROWNWeb 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 was selected (when available).
  - A claim was considered eligible if it was from a HD (in-center) patient who had ESRD for at least 90 days and was under 18 years old (as of the claim-from date), and the claim was neither a "frequent" dialysis claim nor an "infrequent" dialysis claim as described in Section 3.1.5.
  - The last eligible claim with an in-range (less than or equal to 5.0) and not expired (reported from a previous claim) Kt/V value reported was selected when there were multiple claims reported in a month
  - If a multiple Kt/V values were reported on a single claim for a patient, then the following decision rules are used to select which value is considered when calculating the numerator:
    - Use the highest Kt/V value in the valid range (≥1.2 and ≤ 5.0).
    - If no Kt/V values are reported within the valid range, then use any value not equal to 9.99 (This could be outside the valid range).
    - Use 9.99 if no other value is reported.

2.5.13 Assigning Patient-Months to Numerators and Denominators

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

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

2.5.14 Data Elements and Data Sources

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

CROWNWeb Data Elements

- CROWN Unique Patient Identifier (UPI)
- Facility CCN
- Patient Date of Birth (DOB)
- Patient Date of Death (DOD)
- Primary type of treatment ID (CROWNWeb dialysis type)
- Number of dialysis sessions per week
- Medicare Certified Services Offered
- Additional Services Offered (Non-Medicare)

- Kt/V
- Kt/V Method
- Modality to determine frequent dialysis

Claims Based Data Elements

Note: Non Type of Bill (TOB) 72x claims are not considered in the measure calculation.

- Claim Related Condition Code
- Claim CMS Process Date
- Claim Control Number
- Claim From Date
- Claim Through Date
- Claim 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
- Patient Medicare Claim Number
- Calculated start of ESRD date (see section 3.1.3)

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 17:10-15, 2002.
- Leonard MB, et al. 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 (PD) Above Minimum

2.6.2 Measure Description

Percent of pediatric peritoneal dialysis 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 peritoneal dialysis to clear the blood of accumulated toxins. In the adult population, clinical practice guidelines have established an association between dose of hemodialysis 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 peritoneal dialysis population but smaller scale observational studies support the association between delivered peritoneal dialysis 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 for the Kt/V Pediatric Peritoneal Dialysis Adequacy measure is better.

2.6.6 Risk Adjustment

None

2.6.7 Numerator Statement

Patient-months in the denominator for patients whose delivered dose of peritoneal dialysis was equal to or greater than 1.8 Kt/V (dialytic+ residual, measured in the last 6 months).

- Numerator must 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 90 days and receiving peritoneal dialysis the entire month.

2.6.10 Denominator Exclusions

- Patients not assigned to the facility for the entire month
- Patients age 18 years and older as of the first day of the month
- Patients not on peritoneal dialysis the entire month
- Patients on ESRD treatment for fewer than 91 days as of the first day of the month

2.6.11 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 was identified primarily using data from CROWNWeb, the Medical Evidence Form (Form CMS-2728) and Medicare dialysis claims. Both patient assignment to the provider and modality (either hemodialysis or peritoneal dialysis) 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 there was a one-day gap or more in treatment at the facility during the reporting month, the patient-month was excluded. 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 CROWNWeb 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.

2.6.12 Calculating Numerators

Number of patients in denominator whose delivered dose of peritoneal dialysis (dialytic + residual, calculated from the last measurements of the four-month study period) was a Kt/V $\geq$1.8.

- If a patient has multiple Kt/V values in CROWNWeb during a month, then the last reported value is selected.
- If an in-range value was not found in CROWNWeb 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 was selected (when available).

- A claim was considered eligible if it was from a PD patient who had ESRD for at least 90 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 (reported from more than six months prior) Kt/V value reported was selected when there were multiple claims reported in a month
- If a multiple Kt/V values were reported on a single claim for a patient, then the following decision rules are used to select which value is considered when calculating the numerator:
  - Use the highest Kt/V value in the valid range (≥ 1.8 and ≤ 8.5).
  - If no Kt/V values are reported within the valid range, then use any value not equal to 9.99 (This could be outside the valid range).
  - Use 9.99 if no other value is reported.

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.

CROWNWeb Data Elements

- CROWN Unique Patient Identifier (UPI)
- Facility CCN
- Patient Date of Birth (DOB)
- Patient Date of Death (DOD)
- Primary type of treatment ID (CROWNWeb dialysis type)
- Medicare Certified Services Offered
- Additional Services Offered (Non-Medicare)
- Kt/V

Claims Based Data Elements

Note: Non Type of Bill (TOB) 72x claims are not considered in the measure calculation.

- Claim Related Condition Code
- Claim CMS Process Date
- Claim Control Number
- Claim From Date
- Claim Through Date
- Claim Daily Process Date
- Claim Link Number
- Claim Occurrence Code
- Claim CCN
- Claim Value Code D5
- Claim Value Amount
- Claim Value Sequence Number
- Claim Line Institutional Revenue Center Codes
- Patient Medicare Claim Number
- Calculated start of ESRD date (see section 3.1.3)

2.6.15 Selected References

- National Kidney Foundation. KDOQI 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).

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 hemodialysis or peritoneal dialysis) 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 measures is to make more facilities eligible for public reporting of these metrics by meeting the >11 eligible patients restriction. For public reporting on Dialysis Facility Compare (DFC) and the ESRD Quality Incentive Program (QIP), 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 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 for <11 patients. 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 <11 PD patients, or <11 pediatric patients would be included in the new combined measures but excluded from the individual measure, leading to the systematic exclusion of these facilities from assessment on these measures because of the reporting requirements.

To account for this, CMS proposed the three new measures that assess dialysis adequacy by modality that includes both adult and pediatric populations (#2703, #2704), and an overall measure of all adult and pediatric hemodialysis and peritoneal dialysis patients (#2705). CMS also seeks maintenance endorsement of the individual measures previously endorsed, based on the same level of evidence presented for those measures. It is CMS's intention to eventually retire the individual measures once the combined measures are endorsed and implemented.

2.7.4 Measure Type

Intermediate outcome

2.7.5 Improvement Noted as Higher or Lower Rate

Higher rates are better

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:

- Hemodialysis (all ages): spKt/V ≥ 1.2 (calculated from the last measurement of the month using UKM or Daugirdas II)
- Peritoneal dialysis (pediatric <18 years old): Kt/V ≥ 1.8 (dialytic + residual, measured within the past 6 months)
- Peritoneal dialysis (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 performance period are excluded from the measure.

2.7.9 Denominator Statement

- All adult hemodialysis patients who received dialysis greater than two and less than four times a week (adults, ≥ 18 years old), and all pediatric in-center hemodialysis patients who received dialysis greater than two and less than four times a week (pediatric, <18 years), and did not indicate frequent dialysis.
- All patients (both Hemodialysis and Peritoneal dialysis) who are assigned to the facility for the entire month, and have had ESRD for 90 days or more

2.7.10 Denominator Exclusions

- HD patients receiving dialysis less than or equal to 2 times weekly or greater than or equal to 4 times weekly (See Section 3.1.5)
- Pediatric home hemodialysis patients
- Patients on ESRD treatment for fewer than 90 days at the beginning of the reporting month
- 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.
- Patients who were not assigned to the facility for the entire month.

2.7.11 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 was identified primarily using data from CROWNWeb, the Medical Evidence Form (Form CMS-2728) and Medicare dialysis claims. Both patient assignment to the provider and modality (either hemodialysis or peritoneal dialysis) 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 there was a one-day gap or more in treatment at the facility during the reporting month, the patient-month was excluded. 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 paid Medicare dialysis claims nor CROWNWeb 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.

2.7.12 Calculating Numerators

2.7.12.1 Adult HD Kt/V:

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

- If a patient has multiple Kt/V values in CROWNWeb during a month, then the last reported value is selected.
- If a value was not found in CROWNWeb 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 was selected (when available).
  - A claim was considered eligible if it was from a HD patient who had ESRD for at least 90 days and was at least 18 years old (as of the claim-from date), and the claim was neither a "frequent" dialysis claim nor an "infrequent" dialysis claim, as described in Section 3.1.5.
  - The last eligible claim not expired (in-center HD with a Kt/V occurrence date from a previous month, or home HD with a Kt/V occurrence date that is more than four months prior to the end of the claim) Kt/V value reported was selected when there were multiple claims reported in a month. If multiple valid 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 invalid.

- If a multiple Kt/V values were reported on a single claim for a patient, then the following decision rules are used to select which value is considered when calculating the numerator:
  - Use the highest Kt/V value
  - Use 9.99 if reported and no other value is reported

2.7.12.2 Adult PD Kt/V:

Number of patients in denominator whose delivered dose of peritoneal dialysis (dialytic + residual, calculated from the last measurements of the four-month study period) was a Kt/V ≥1.7.

- If a patient has multiple Kt/V values in CROWNWeb during a month, then the last reported value is selected.
- If a value was not found in CROWNWeb for the patient during the four-month study period, then the last reported non-missing value reported on the last eligible Medicare claim for the patient during the four-month study period was selected (when available).
  - A claim was considered eligible if it was from a PD patient who had ESRD for at least 90 days and was at least 18 years old (as of the claim-from date).
  - The last eligible claim not expired (Kt/V occurrence date is more than four months prior to the end of the claim) Kt/V value reported was selected when there were multiple claims reported in a month. If multiple valid 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 invalid.
  - If a multiple Kt/V values were reported on a single claim for a patient, then the following decision rules are used to select which value is considered when calculating the numerator:
    - Use the highest Kt/V value
    - Use 9.99 if reported and no other value is reported

2.7.12.3 Pediatric HD Kt/V:

Number of patient-months in denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V ≥ 1.2.

- If a patient has multiple Kt/V values in CROWNWeb during a month, then the last reported value is selected.
- If a value was not found in CROWNWeb 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 was selected (when available).
  - A claim was considered eligible if it was from a HD (in-center) patient who had ESRD for at least 90 days and was under 18 years old (as of the claim-from date), and the claim was neither a “frequent” dialysis claim nor an “infrequent” dialysis claim as described in Section 3.1.5.

- The last eligible claim not expired (Kt/V occurrence date is from a previous month) Kt/V value reported was selected when there were multiple claims reported in a month. If multiple valid 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 invalid.
- If multiple Kt/V values were reported on a single claim for a patient, then the following decision rules are used to select which value is considered when calculating the numerator:
  - Use the highest Kt/V value
  - Use 9.99 if reported and no other value is reported

2.7.12.4 Pediatric PD Kt/V:

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

- If a patient has multiple Kt/V values in CROWNWeb during a month, then the last reported value is selected.
- If a value was not found in CROWNWeb for the patient during the six-month study period then the last reported non-missing value reported on the last eligible Medicare claim for the patient during the six-month study period was selected (when available).
  - A claim was considered eligible if it was from a PD patient who had ESRD for at least 90 days and was under 18 years old (as of the claim-from date).
  - The last eligible claim and not expired (Kt/V occurrence date is more than six months prior to the end of the claim) Kt/V value reported was selected when there were multiple claims reported in a month. If multiple Kt/V values were reported on a single claim for a patient, then the following decision rules are used to select which value is considered when calculating the numerator:
    - Use the highest Kt/V value
    - Use 9.99 if reported and no other value is reported
    - If multiple valid 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 invalid.

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), 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), 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.

CROWNWeb Data Elements

- Facility CCN
- Patient Date of Birth (DOB)
- Patient Date of Death (DOD)
- CROWN Unique Patient Identifier (UPI)
- Primary type of treatment ID (CROWNWeb 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 and assess if modality changed during the month

Claims Based Data Elements

Note: Non Type of Bill (TOB) 72x claims are not considered in the measure calculation.

- Patient Medicare Claim Number
- Claim Related Condition Code
- Claim CMS Process Date
- Claim Control Number
- Claim From Date
- Claim Through Date
- Claim 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
- Calculated start of ESRD date (see section 3.1.3)

2.7.15 Flowchart

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

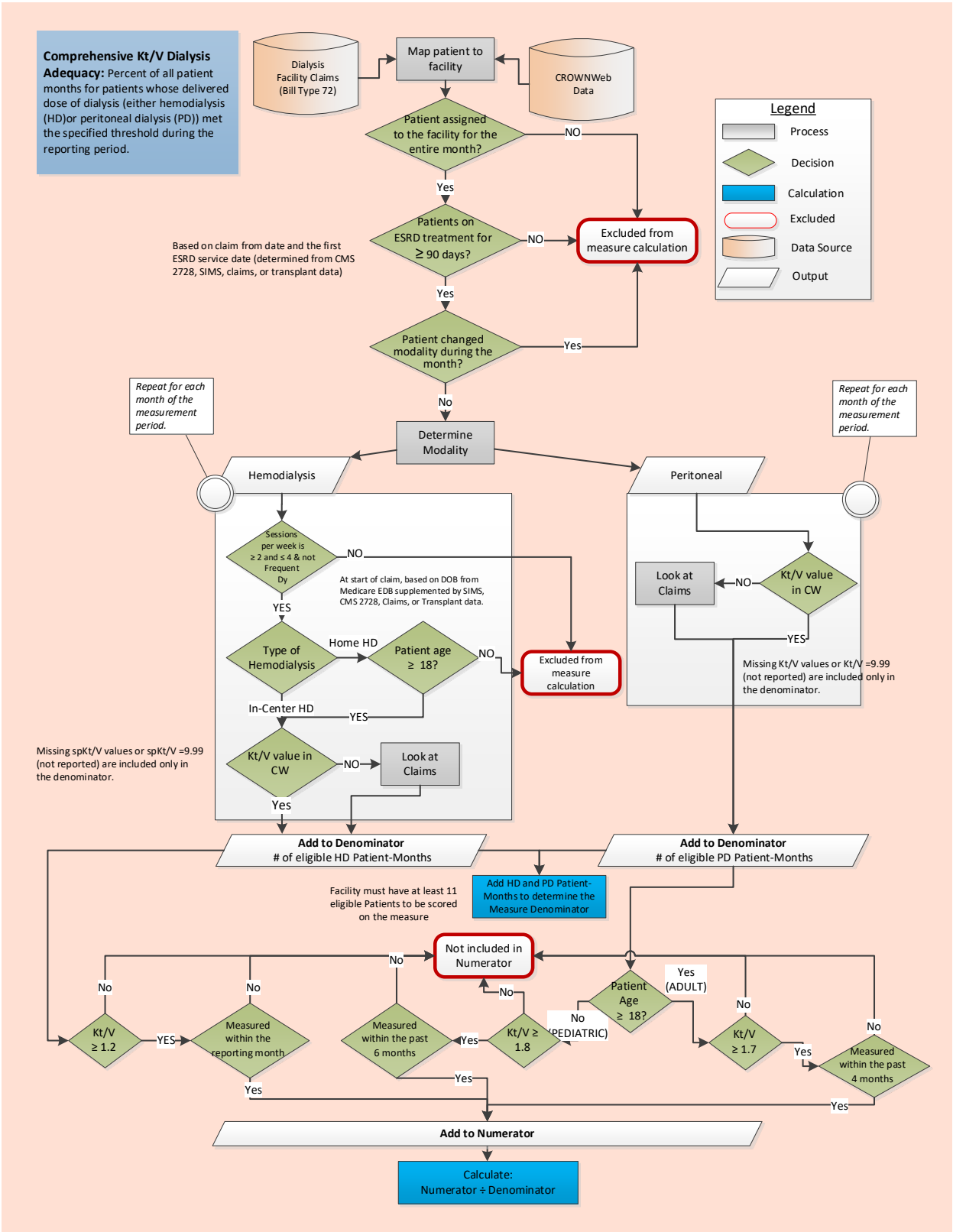

Figure 3. Kt/V Dialysis Adequacy Comprehensive Clinical Measure Rate Flowchart for ESRD QIP

2.7.16 Selected References

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- Leonard MB, et al. 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.

- National Kidney Foundation. KDOQI 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).

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2.8 Hypercalcemia Clinical Measure (ESRD QIP and DFC)

2.8.1 Measure Name

Proportion of Patients with Hypercalcemia – NQF# 1454

2.8.2 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.

2.8.3 Measure Rationale

The hypercalcemia measure was developed in 2010 based on the recommendations of a clinical technical evaluation 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 needs 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 (http://www.qualityforum.org/measures_reports_tools.aspx).

Given both the 2010 TEP and 2013 TEP recommendations, and the additional evidence cited in the current National Quality Foundation (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 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 Quality Incentive Program (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. This hypercalcemia measure is the only measure of which we are aware that meets these requirements and the NQF criteria.

2.8.4 Measure Type

Intermediate Outcome

2.8.5 Improvement Noted as Higher or Lower Rate

Lower rates are better

2.8.6 Risk Adjustment

None

2.8.7 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.

ESRD QIP only:

- 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 in the preceding three months.

2.8.8 Facility Exclusions

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

2.8.9 Denominator Statement

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

ESRD QIP only

- 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.

DFC only

- Patient-months with missing values in the reporting month and the two months prior are included in the denominator

2.8.10 Denominator Exclusions

- Patient younger than age 18 years old
- Patient 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:

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

- Patients not assigned to the facility for the entire reporting month.

ESRD QIP only:

- Patients for whom the facility reported fewer than 3 months of calcium values in CROWNWeb during the measurement period, plus the two months prior. (i.e. the November and December of the Performance Period or the November and December of the year prior to the 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.

2.8.11 Mapping Patients to Facilities

A patient is assigned to a facility based on admit and discharge data from CROWNWeb.

ESRD QIP:

- Patients can be attributed to multiple facilities within the same month.

DFC:

- Patients can be attributed to only one facility per month.

2.8.12 Calculating Numerators

A patient-month is included in the numerator if the average calcium level is greater than 10.2 mg/dL. 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.

ESRD QIP:

- A patient only needs a calcium value during the three-month window for the rolling average (with the value carried forward in months where no calcium value is reported) to be included in the measure.
- 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 in calculating the three-month rolling average for January and February in the Improvement Threshold rate.

- 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 peritoneal dialysis patients.
- "Uncorrected" indicates albumin is not considered in the calculation.
- 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).
- A one, two, or three month average can be calculated as long as there is a 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.

DFC:

- A patient need only have an uncorrected serum calcium or plasma calcium value for one of the 3 months to be included in the 3-month rolling average, (i.e., a one, two, or three month average) for the numerator. Any value reported during the two months prior to the reporting month will be included in the 3-month rolling average. For example, the percentage calculated for January of the performance period (the reporting month), would be based on the average of uncorrected serum calcium values submitted in January, December and/or November. If the values are missing for all three months, the patient would be included in the denominator but not the numerator.
- If there are multiple calcium measurements during the month, the last in-range value will be used for the calculation.

2.8.13 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.

CROWNWeb Data Elements:

- Facility CCN
- Initial Certification Date
- Patient Date of Birth (DOB)
- Patient Date of Death (DOD)
- CROWN Unique Patient Identifier (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

Claims Based Data Elements

Note: Non Type of Bill (TOB) 72x claims are not considered in the measure calculation.

- Claim Control Number
- Claim From Date
- Claim Through Date
- Patient Medicare Claim Number
- Claim CCN
- Calculated start of ESRD date (see section 3.1.3)

2.8.14 Flowchart

Figure 4 provides a flowchart that represents the processes used to calculate the Hypercalcemia Clinical Measure Rate for ESRD QIP.

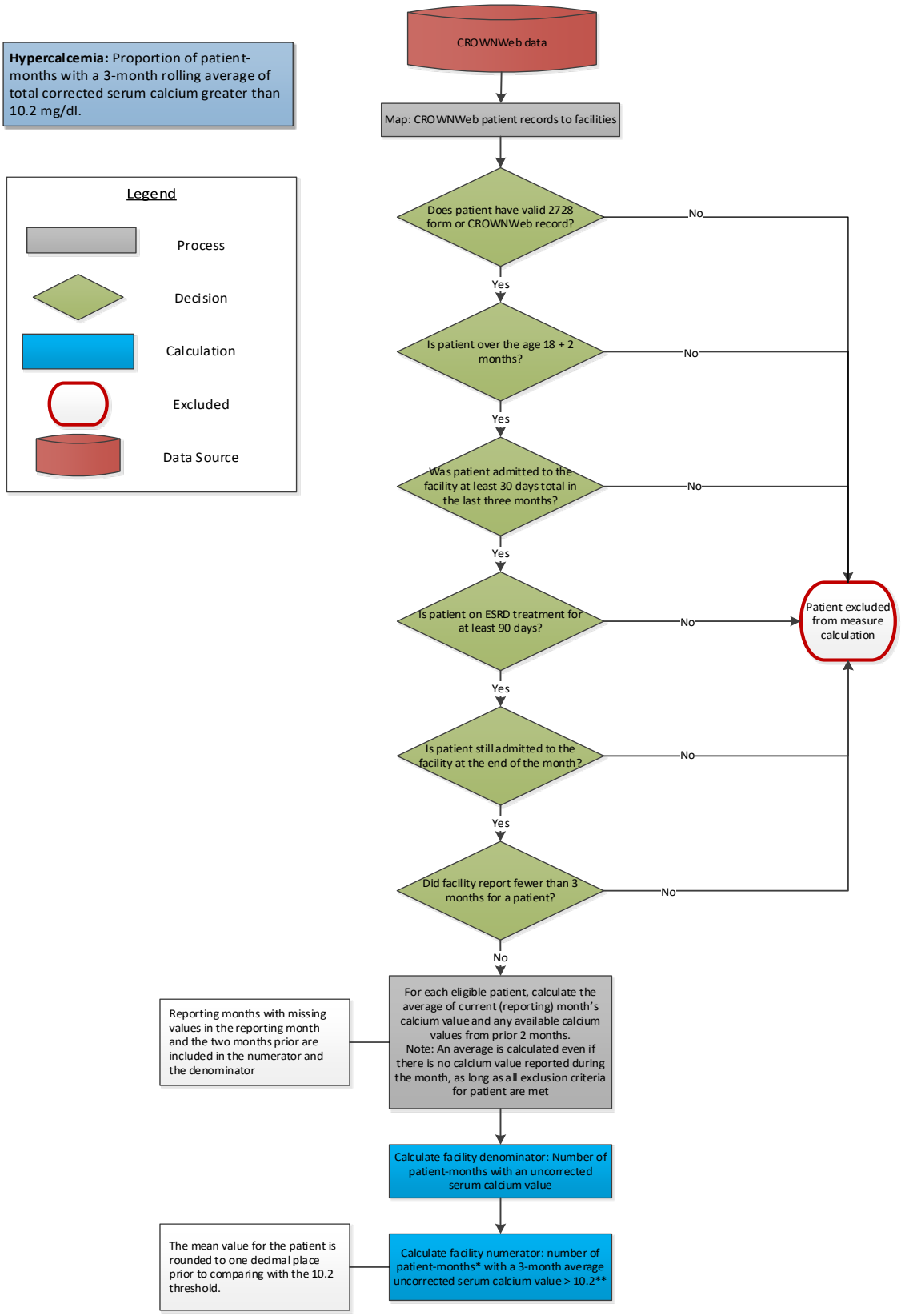

Figure 4. Hypercalcemia Clinical Measure Rate Flowchart for ESRD QIP

2.8.16 Selected References

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2.9 Anemia Management Reporting Measure (ESRD QIP Only)

2.9.1 Measure Name

Anemia Management Reporting Measure

2.9.2 Measure Description

Number of months for which facility reports erythropoiesis stimulating agent (ESA) dosage (as applicable) and hemoglobin/hematocrit for each Medicare patient at least once per month.

2.9.3 Measure Type

Reporting measure

2.9.4 Facility-Level Exclusions

- Facilities with fewer than 11 eligible patients during the performance period.
- Facilities with a CMS certification number (CCN) certification date on or after July 1, 2017.

2.9.5 Patient-Level Exclusions

- In-center hemodialysis patients treated at a facility fewer than 7 times during claim month.
- Home dialysis patients for whom a facility does not submit a claim during the claim month.
- Patients with other-peritoneal dialysis, missing or undetermined modality

2.9.6 Facility-Month-Level Exclusions

- No eligible patients in the reporting month
- Certification dates on or after the 1st day of the reporting month (the scenario can only occur during January, 2017 – June, 2017)

2.9.7 Determining Successful Reporting for a Patient

A facility is considered to have successfully reported for a patient-month if a hemoglobin or hematocrit value is reported one or more times on the patient's claim(s) during the month. A facility may obtain hemoglobin or hematocrit values from an external source.

During the first month a facility submits claims for a patient, 99.99 is considered a valid value and constitutes successful reporting. After the first month in which a facility submits claims for a patient, 99.99 is not considered a valid value and does not constitute successful reporting.

Note: A patient may be considered to be in his or her first month of treatment at a facility multiple times during the performance period.

The patient's first month of dialysis treatment at the facility will be determined as follows:

- If a patient has both claims and CROWNWeb treatments at a facility during the reporting month, then the patient must have an admission at the facility for that month in CROWNWeb and no claim reported in the prior month by the facility. For each reporting month, only claims with 1) a CROWNWeb admit in the current reporting month; and 2) no claim reported by the facility in the prior month is considered as "first month".
- If a patient with claims is not linked to a patient in CROWNWeb (i.e. is a 'claims-only' patient), then the first month is determined by evaluating claims reported for the patient in the prior month. Only claims reported by the facility in the current month and not the prior month are considered as "first month."

2.9.8 Calculating Monthly Reporting Percentages

A facility's monthly reporting percentage is calculated as follows:

$$\frac{\textit{Number of Eligible Patients for Whom a Facility Successfully Reports in This Reporting Month}}{\textit{Total Number of Eligible Patients in This Reporting Month}}$$

2.9.9 Determining Successful Reporting for a Month

A facility is considered to have successfully reported for a month if its reporting percentage is greater than or equal to the lower of the following thresholds:

1. 99%
2. The 50th percentile of facility reporting in Calendar Year (CY) 2016.

2.9.10 Determining Requisite Reporting-Months for a Facility

A facility's CCN certification date is used for purposes of determining requisite reporting months.

If the facility's certification date was prior to January 1, 2017, then the facility is required to report data for the entirety of the performance period (i.e. all 12 months in 2017).

If the facility's certification date was between January 1, 2017 and June 30, 2017, the facility is required to report on the first day after the month in which the facility is certified to participate in Medicare. For example, if the facility certification date is in March of 2017, then reporting requirements begin on April 1, and the facility is required to report nine months of data.

If the facility's certification date was after June 30, 2017, then the facility is exempt from all reporting measures and will not receive a Total Performance Score (because a facility must have at least one clinical measure score and one reporting measure score to receive a Total Performance Score).

2.9.11 Calculating a Facility's Score on the Anemia Management Reporting Measure

Once numbers have been calculated for months of successful reporting and requisite reporting months, a facility's score on the Anemia Management reporting measure is calculated according to the following equation:

$$\left(\frac{Number\ of\ months\ the\ facility\ successfully\ reports}{Number\ of\ months\ the\ facility\ is\ required\ to\ report}\ x\ 12\right) - 2$$

Facility scores are rounded to the nearest integer (with half rounded up), to yield a score of 0-10. If the above equation yields a negative number, then the facility receives a score of 0 on the measure.

2.9.12 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.

CROWNWeb Data Elements

- Network
- Certification Date
- CROWN Unique Patient Identifier (UPI)
- Patient Medicare Claim Number
- Facility CCN
- Admit Date

Claims Based Data Elements

Note: Non Type of Bill (TOB) 72x claims are not considered in the measure calculation.

- Claim Related Condition Code
- Claim Control Number
- Claim From Date
- Claim Through Date
- Claim Line Institutional Revenue Center Codes
- Claim Value Code
- Patient Medicare Claim Number
- Claim CCN
- Claim Value Amount

2.9.13 Flowchart

Figure 5 provides a flowchart that represents the processes used to calculate the Anemia Management Reporting Measure for ESRD QIP.

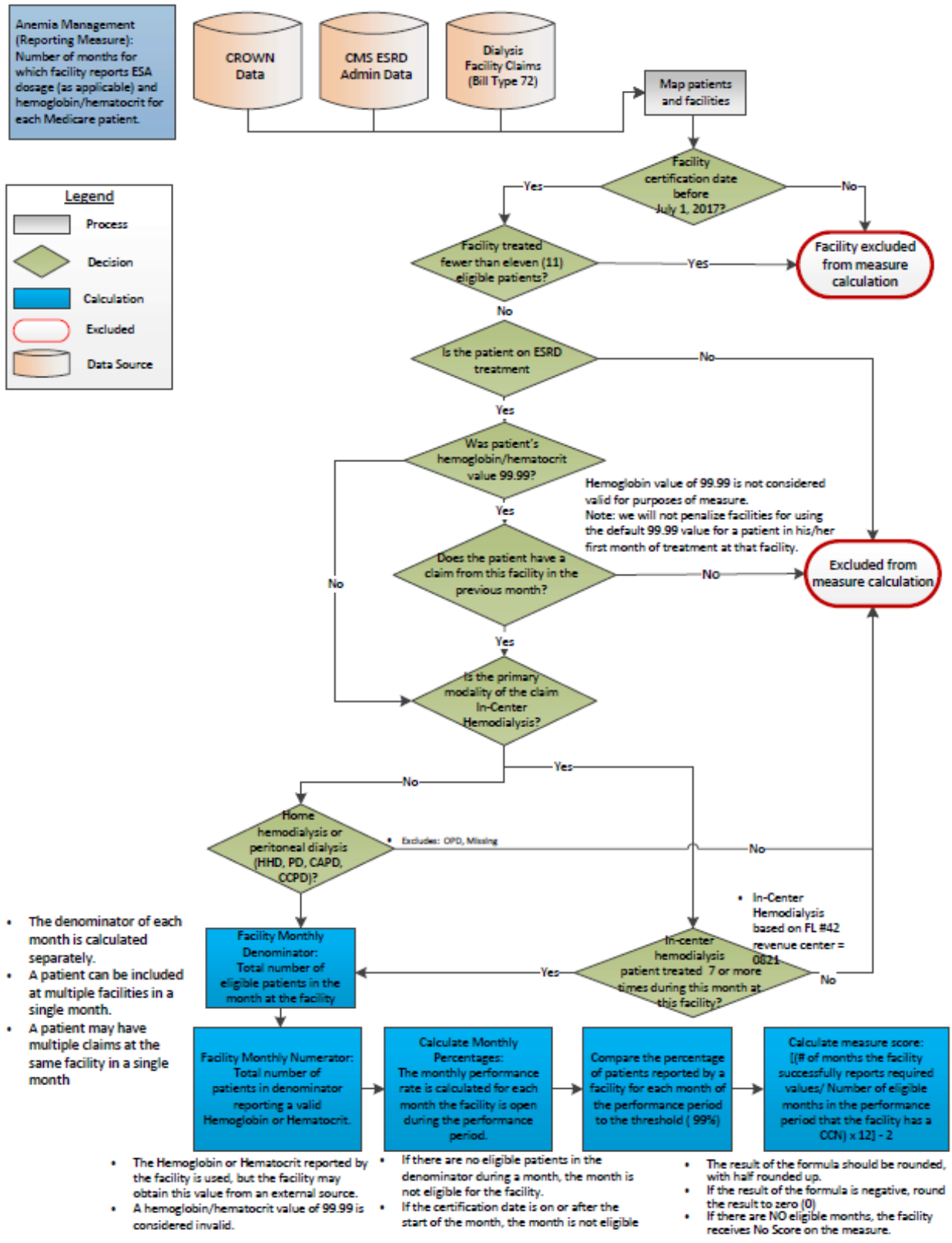

Figure 5. Anemia Management Reporting Measure Flowchart for ESRD QIP

2.10 Mineral Metabolism Reporting Measure (ESRD QIP Only)

2.10.1 Measure Name

Mineral Metabolism Reporting Measure

2.10.2 Measure Description

Number of months for which facility reports serum or plasma phosphorus values for each Medicare patient.

2.10.3 Measure Type

Reporting measure

2.10.4 Facility-Level Exclusions

- Facilities with fewer than 11 eligible patients during the performance period (see Section 2.10.5 below).
- Facilities with a CMS certification number (CCN) certification date on or after July 1, 2017.
- Facilities without eligible patients in the performance year.

2.10.5 Patient-Level Exclusions

- In-center hemodialysis patients treated at a facility fewer than 7 times during claim month
- Home dialysis patients for whom a facility does not submit a claim during the claim month
- Patients with other-pertioneal dialysis, missing or undetermined modalities

2.10.6 Facility-Month-Level Exclusions

- No eligible patients in the reporting month
- Certification dates on or after the 1st day of the reporting months (the scenario can only occur during January, 2017 – June, 2017)

2.10.7 Determining Successful Reporting for a Patient

A facility is considered to have successfully reported for a patient-month if it reports a serum or plasma phosphorus value in CROWNWeb for the patient one or more times during the month.

If a patient is attributed to more than one facility during a month, both facilities will receive credit for reporting if one or both of the facilities reports a serum or plasma phosphorus value in CROWNWeb for the patient during the month.

2.10.8 Calculating Monthly Reporting Percentages

A facility's monthly reporting percentage is calculated as follows:

$$\frac{\textit{Number of Eligible Patients for Whom a Facility Successfully Reports in This Reporting Month}}{\textit{Total Number of Eligible Patients in This Reporting Month}}$$

2.10.9 Determining Successful Reporting for a Month

A facility is considered to have successfully reported for a month if its reporting percentage is greater than or equal to the lower of the following thresholds:

- 97%
- The 50th percentile of facility reporting in Calendar Year (CY) 2016

2.10.10 Determining Requisite Reporting-Months for a Facility

A facility's CCN certification date is used for purposes of determining requisite reporting months.

If the facility's certification date was prior to January 1, 2017, then the facility is required to report data for the entirety of the performance period (i.e., all 12 months in 2017).

If the facility's certification date was between January 1, 2017, and June 30, 2017, the facility is required to report on the first day after the month in which the facility is certified to participate in Medicare. For example, if the facility certification date is in March of 2017, then reporting requirements begin on April 1, and the facility is required to report nine months' worth of data.

If the facility's certification date was after June 30, 2017, then the facility is exempt from all reporting measures and will not receive a Total Performance Score (because a facility must have at least one clinical measure score and one reporting measure score to receive a Total Performance Score).

2.10.11 Calculating a Facility's Score on the Mineral Metabolism Reporting Measure

Once numbers have been calculated for months of successful reporting and requisite reporting months, a facility's score on the Mineral Metabolism reporting measure is calculated according to the following equation:

$$\left(\frac{Number\ of\ months\ the\ facility\ successfully\ reports}{Number\ of\ months\ the\ facility\ is\ required\ to\ report}\ x\ 12\right) - 2$$

Facility scores are rounded to the nearest integer (with half rounded up), to yield a score of 0-10.

If the above equation yields a negative number, then the facility receives a score of 0 on the measure.

2.10.12 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.

CROWNWeb Data Elements

- Initial Certification Date
- CROWN Unique Patient Identifier (UPI)
- Patient Medicare Claim Number
- Facility CCN
- Admit Date
- Date of Month/Year associated with CROWNWeb Clinical Record
- Phosphorus

Claims Based Data Elements

Note: Non Type of Bill (TOB) 72x claims are not considered in the measure calculation.

- Claim Related Condition Code
- Claim Control Number
- Claim From Date
- Claim Through Date
- Claim CCN
- Patient Medicare Claim Number
- Claim Line Institutional Revenue Center Codes

2.10.13 Flowchart

Figure 6 provides a flowchart that represents the processes used to calculate the Mineral Metabolism Reporting Measure for ESRD QIP.

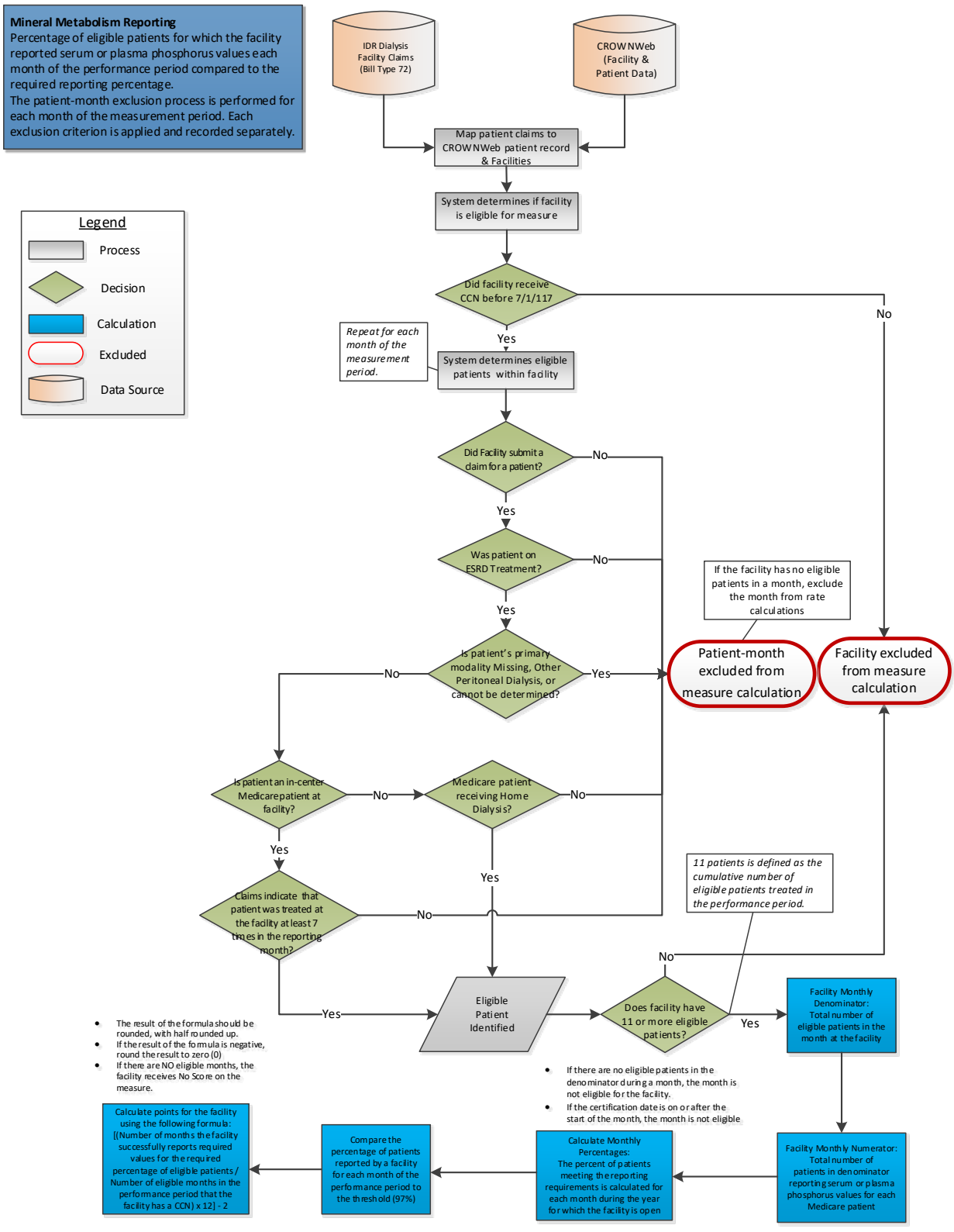

Figure 6. Mineral Metabolism Reporting Measure Flowchart for ESRD QIP

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

2.11.1 Measure Name

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

2.11.2 Measure Description

Facility reports in CROWNWeb one of the six conditions below for each qualifying patient once before February 1, 2018.

2.11.3 Measure Type

Reporting measure

2.11.4 Facility-Level Exclusions

- Facilities with fewer than 11 eligible patients during the performance period (see Section 2.11.5 below)
- Facilities with a CCN certification date on or after July 1, 2017.

2.11.5 Patient-Level Exclusions

- Patients who are younger than 12 years old as of October 31, 2017
- Patients who are treated at the facility for fewer than 90 days between January 1 and December 31, 2017

2.11.6 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 CROWNWeb for the patient once before February 1, 2018. 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.

- **Screening for clinical depression** (see 1 below) is documented as being **positive** (see 2 below) and a **follow-up plan** (see 3 below) is documented.
- Screening for clinical depression documented as **positive** (see 2 below), a follow-up plan is not documented, and the facility possesses documentation that the patient is **not eligible** (see 4 below).
- Screening for clinical depression documented as **positive** (see 2 below), 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** (see 5 below).
- Clinical depression screening not documented, and no reason is given.

Note: the follow terms highlighted above are defined as follows:

1. **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. Example tools include, but are not limited to: Adolescent Screening Tools (12-17 years) Patient Health Questionnaire for Adolescents (PHQ-A), Beck Depression Inventory-Primary Care Version (BDI-PC), Beck Depression Inventory-Primary Care Version (BDI-PC), PRIME MD-PHQ2, Mood Feeling Questionnaire (MFQ); Adult Screening Tools (18 years and older) Patient Health Questionnaire (PHQ-9), Beck Depression Inventory (BDI or BDI-II), Center for Epidemiologic Studies Depression Scale (CES-D), PRIME MD-PHQ2, Depression Scale (DEPS), Duke Anxiety-Depression Scale (DADS), Geriatric Depression Scale (GDS). **The name of the standardized assessment tool used must be documented in the medical record.**
2. **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.**
3. **Follow-Up Plan** – A documented outline of care for a positive depression screening.
4. **Not eligible** – 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 pain because such treatments are medically contraindicated**. Justification for a patient's ineligibility for follow-up treatment should be documented in the patients' medical record.**
5. **Not eligible** – 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

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

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

$$\frac{\textit{Number of Eligible Patients for Whom a Facility Successfully Reports one of six conditions during the performance period}}{\textit{Total number of Eligible Patients during the performance period}}$$

2.11.8 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.

CROWNWeb Data Elements:

- Facility CCN
- Initial Certification Date
- Patient Date of Birth (DOB)
- CROWN Unique Patient Identifier (UPI)
- Admit Date
- Discharge Date
- Patient reporting measure type
- Patient reporting option info
- Patient reporting time period assessment

Claims Based Data Elements

- Patient Medicare Claim Number

2.11.9 Flowchart

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

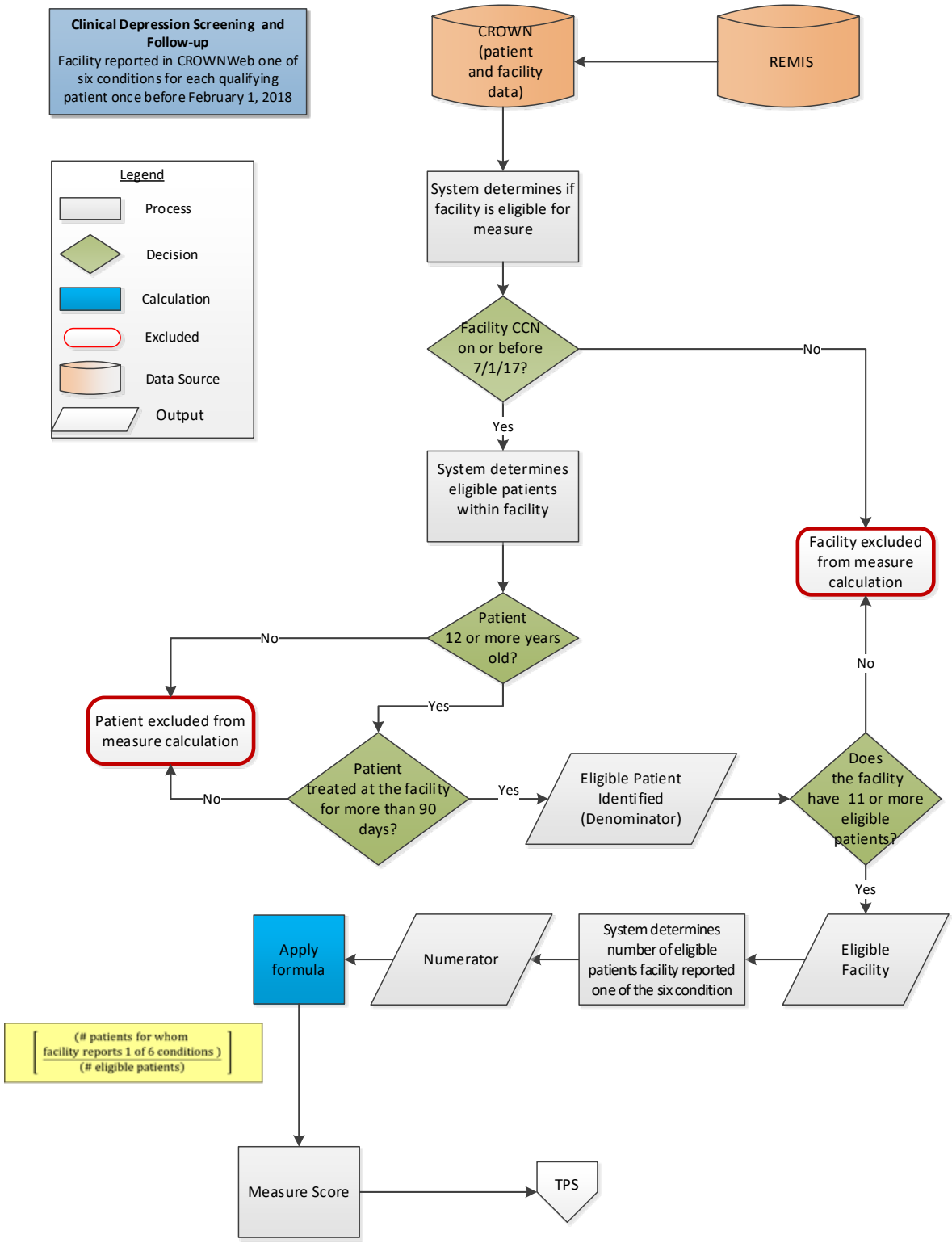

Figure 7. Screening for Clinical Depression and Follow-Up Reporting Measure Flowchart for ESRD QIP

2.12 Pain Assessment and Follow-Up Reporting Measure (ESRD QIP Only)

2.12.1 Measure Name

Pain Assessment and Follow-Up Reporting Measure – NQF #0420

2.12.2 Measure Description

Facility reports in CROWNWeb one of the six conditions below for each qualifying patient once starting from January 1, 2017, through July 31, 2017 (for the first assessment period), and once starting from July 1, 2017, through January 31, 2018 (for the second assessment period). Please note that CROWNWeb will allow facilities to report for multiple assessment periods during the months of July 2017 and January 2018.

2.12.3 Measure Type

Reporting measure

2.12.4 Facility-Level Exclusions

- Facilities with fewer than 11 eligible patients during the performance period (see Section 2.12.5 below).
- Facilities with a CCN certification date on or after July 1, 2017.

2.12.5 Patient-Level Exclusions

- Patients who are younger than 18 years old as of April 30, 2017 for August 1, 2017 reporting deadline, and as of October 31, 2017 for the February 1, 2018 reporting deadline.
- Patients who are treated at the facility for fewer than 90 days between January 1 and June 30, 2017 for the August 1, 2017 deadline, and between July 1 and December 31, 2017 for the February 1, 2018 deadline.

2.12.6 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 CROWNWeb for the patient once during the first six-month reporting period, and once during the second six-month reporting period. 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.

- **Pain assessment** (see 1 below) using a standardized tool is documented as **positive** (see 2 below) and a **follow-up plan** (see 3 below) is documented
- Pain assessment documented as **positive** (see 2 below), a follow-up plan is not documented and the facility possesses documentation that the patient is **not eligible** (see 4 below).

- Pain assessment documented as **positive** (see 2 below) using a standardized tool, a follow-up plan is not documented and no reason is given.
- Pain assessment using a standardized tool is documented as negative and no follow-up plan required.
- No documentation of pain assessment and the facility possesses documentation the patient is **not eligible** (see 5 below) for a pain assessment using a standardized tool
- No documentation of pain assessment and no reason is given.

Note: the follow terms highlighted above are defined as follows:

1. **Pain assessment** – Documentation of a clinical assessment for the presence or absence of pain using a standardized tool. 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. Example tools include, but are not limited to: Brief Pain Inventory (BPI); Faces Pain Scale (FPS); McGill Pain Questionnaire (MPQ); Multidimensional Pain Inventory (MPI); Neuropathic Pain Scale (NPS); Numeric Rating Scale (NRS); Oswestry Disability Index (ODI); Roland Morris Disability Questionnaire (RMDQ); Verbal Descriptor Scale (VDS); Verbal Numeric Rating Scale (VNRS); and Visual Analog Scale (VAS). **The name of the standardized assessment tool used must be documented in the medical record.**
2. **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 pain. **Justification for or against a positive screening should be documented in the medical record.**
3. **Follow-Up Plan** – A documented outline of care for a positive pain assessment.
4. **Not eligible** – 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 pain because such treatments are medically contraindicated**. Justification for a patient's ineligibility for follow-up treatment should be documented in the patients' medical record.**
5. **Not eligible** – A patient is not eligible for Pain Assessment if one or more of the following reasons is documented in the patient's medical record:
    - Severe mental and/or physical incapacity where the person is unable to express himself/herself in a manner understood by others. For example, cases where pain cannot be accurately assessed through use of nationally recognized standardized pain assessment tools.
    - 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.

2.12.7 Calculating a Facility's Score on the Pain Assessment and Follow-Up Reporting Measure

A facility's score on the Pain Assessment and Follow-Up Reporting Measure is calculated according to the following equation:

$$\frac{\left(\frac{\text{Number of Eligible Patients for Whom a Facility Successfully Reports one of six conditions during the first six months}}{\text{Total number of Eligible Patients during the the first six months}}\right)+\left(\frac{\text{Number of Eligible Patients for Whom a Facility Successfully Reports one of six conditions during the second six months}}{\text{Total number of Eligible Patients during the second six months}}\right)}{2}$$

Note: If a facility treats no eligible patients in one of the two six-month periods, then that facility's score will be based solely on the percentage of eligible patients treated in the other six-month period for whom the facility reports one of six conditions.

2.12.8 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.

CROWNWeb Data Elements:

- Facility CCN
- Initial Certification Date
- Patient Date of Birth (DOB)
- CROWN Unique Patient Identifier (UPI)
- Admit Date
- Discharge Date
- Patient reporting measure type
- Patient reporting option information
- Patient reporting time period assessment

Claims Based Data Elements:

- Patient Medicare Claim Number

2.12.9 Flowchart

Figure 8 provides a flowchart that represents the processes used to calculate the Pain Assessment and Follow-Up Reporting Measure for ESRD QIP.

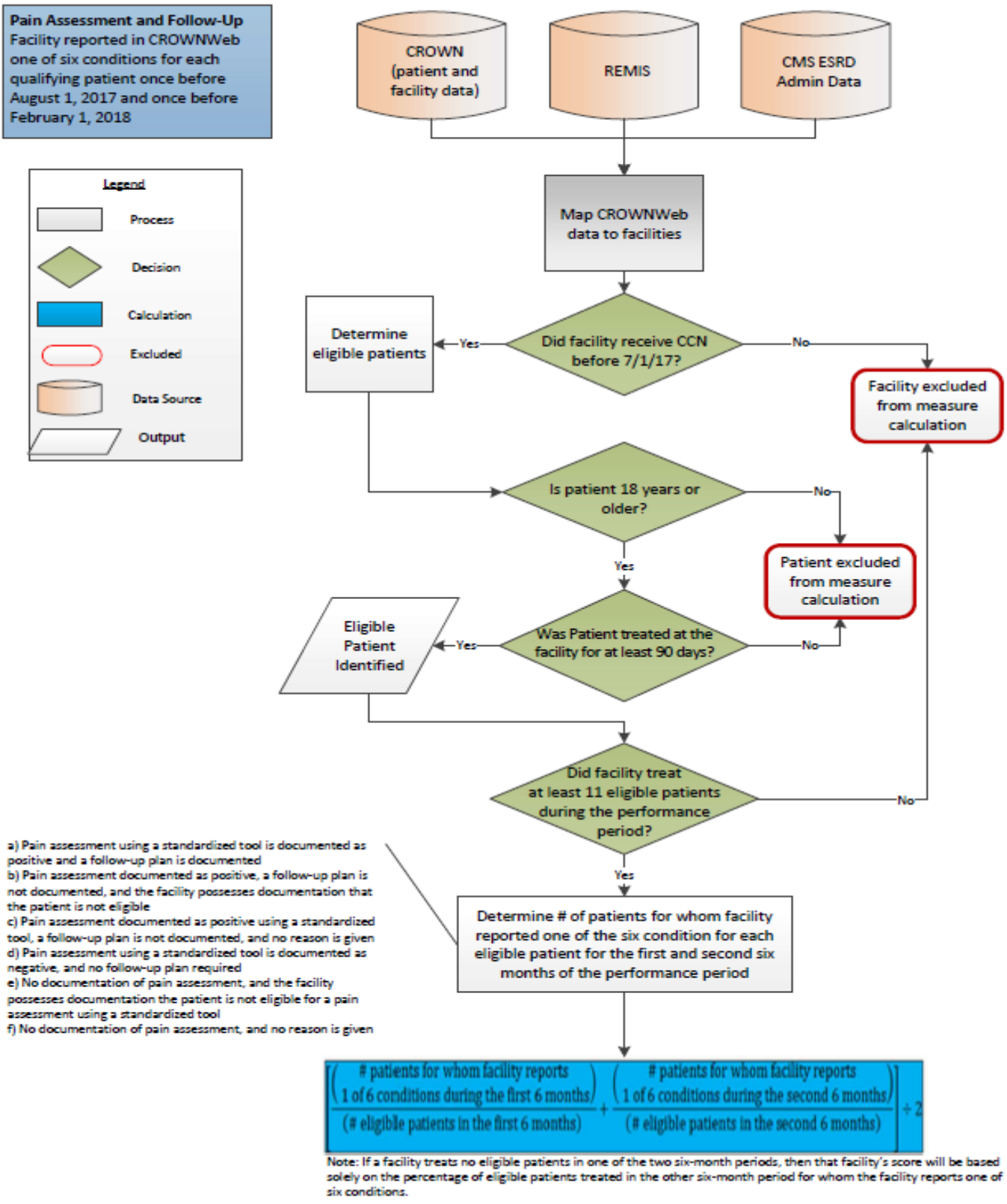

Figure 8. Pain Assessment and Follow-Up Reporting Measure Flowchart for ESRD QIP

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

2.13.1 Methods

The following subsection describes the methods that are used to construct the SRR measure.

2.13.1.1 Overview

The risk-adjusted Standardized Readmission Ratio (SRR) was developed to be a measure of 30-day unplanned hospital readmission for dialysis patients discharged from any acute care hospital in the U.S. (He et al., 2013). The event of interest is an unplanned readmission within 30 days following an initiating hospitalization, termed an index hospital discharge, identified through the Medicare administrative data. To properly adjust for patient characteristics that may make unplanned readmission more likely, we used Medicare administrative data to characterize each patient's comorbidity history, which we derived from inpatient, outpatient institutional, home health, hospice and skilled nursing facility claims.

The SRR reflects the number of readmission events for the patients at a facility, relative to the number of readmission events that would be expected based on overall national rates and the characteristics of the hospitalized patients at that facility. Specifically, the SRR is calculated as the ratio of two numbers; the numerator ("observed") is the actual number of readmission events over a specified time period, and the denominator ("expected") is the number of readmission events that would be expected if patients discharged while at that facility experienced readmission events at the national median rate for hospitalized patients with similar characteristics. Where it was considered appropriate, the SRR was developed to be consistent with the (NQF# 1789) Hospital-Wide Readmission Measure (HWR) for hospitals, and incorporates a number of similar elements, including planned readmissions exclusions (YNHHSC/CORE, 2014) and several denominator exclusion criteria.

As the denominator of the SRR estimates the expected number of readmissions given the observed number of discharges, the SRR may suggest a very high rate of readmissions even though the facility in question has a relatively low overall hospitalization rate. To avoid this situation, it has been suggested that the SRR should take as a reference the set of all patients in the facility rather than the set of hospital discharges. The Standardized Hospitalization Ratio (SHR) is an overall measure of hospital usage by patients at a dialysis facility and evaluates the overall rate of hospitalizations taking account of the number and characteristics of patients in the facility. Consideration of the SHR and the SRR together may prove useful in this respect. They measure two distinct aspects of the hospital usage by patients at a dialysis facility. As indicated, the SHR measures the effectiveness of care for chronically ill patients who frequently have multiple comorbidities, whereas the SRR focuses on communication and care coordination as patients return from acute hospitalization. A facility with a low SHR and high SRR is one for which the overall frequency of hospitalization is relatively low, but there may still be advantage in reviewing the processes associated with hospital discharge and readmission.

2.13.1.2 Data Sources

Data are derived primarily from the CMS Consolidated Renal Operations in a Web-enabled Network (CROWN) system. The CROWN data include the Renal Management Information System (REMIS), CROWNWeb facility-reported clinical and administrative data (including CMS-2728 Medical Evidence Form, CMS-2746 Death Notification Form, and CMS-2744 Annual Facility Survey Form data), the historical Standard Information Management System (SIMS) database (formerly maintained by the 18 ESRD Networks until replaced by CROWNWeb in May 2012), the National Vascular Access Improvement Initiative's Fistula First project (in CROWNWeb since May 2012), Medicare dialysis and hospital payment records, transplant data (Organ Procurement and Transplant Network (OPTN) for DFC, and IDR, REMIS, and CROWNWeb admissions to transplant facilities for ESRD QIP), and the Nursing Home Minimum Dataset. DFC also uses the Quality Improvement Evaluation System (QIES) Workbench, which includes data from the Certification and Survey Provider Enhanced Report System (CASPER), the Dialysis Facility Compare (DFC) and the Social Security Death Master File.

The database is comprehensive for Medicare patients. Non-Medicare patients are included in all sources except for the Medicare payment records, which do include non-traditional Medicare such as the Part A shadow records for Medicare Advantage patients. CROWNWeb 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, home health, hospice, skilled nursing facility claims) and Part B outpatient institutional Medicare Claims.

2.13.1.3 Outcome Definition

The event is defined to be an unplanned readmission to an acute care hospital for any cause within 4-30 days of the discharge date for the index hospitalization.

2.13.1.4 Identifying Patients Treated at Each Facility

We identified each patient's dialysis provider over time using a combination of Medicare claims with evidence of dialysis treatment, the Medical Evidence Form (Form CMS - 2728) and admissions from CROWNWeb. The data sources are prioritized to identify a patient's dialysis treatment facility at the time of each index discharge. We removed patients from a facility upon receiving a transplant, withdrawing from dialysis or recovering renal function. A patient for whom the only evidence of dialysis treatment is the existence of Medicare outpatient claims with evidence of dialysis treatment is 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. If evidence of dialysis reappeared, the patient re-entered the analysis. We did not create periods of lost to follow-up after CROWNWeb events that noted continuing dialysis. For these patients, the record was extended until the appearance of any evidence of recovery, transplant, transfer or death. The net effect is to look back up to one year prior to each discharge for evidence of treating facility if that discharge date is not covered by a CROWNWeb admission, outpatient dialysis facility claim, form 2728 or functioning transplant. ESRD QIP replicates the DFC treating dialysis facility identification concepts.

2.13.1.5 Cohort Definition and Inclusion/Exclusion

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 prospective payment system (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.

In addition, index discharges exclude hospitalizations:

- for patients who died during the hospitalization (because there was no opportunity for readmission);
- for patients who were discharged against medical advice (AMA);
- that were followed within 30 days by the patient's death (and no readmission);
- that ended in a transfer to another acute care facility (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 readmission for transferred patients is attributed to the hospital that ultimately discharges the patient to a non-acute care setting);
- that took place at Prospective Payment System (PPS)-exempt cancer hospitals;
- that occurred after a patient's 12th hospital admission in the time period;
- for which the patient was admitted for medical treatment of cancer, primary psychiatric diagnoses or rehabilitation; or
- resulting in readmissions occurring within the first three days following discharge from the acute care hospital.

Index discharges are assigned 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 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.

2.13.2 Risk Adjustment

We adapted the risk adjustment approach used in the model for CMS' Standardized Hospitalization Ratio (SHR) and CMS' Hospital-Wide Readmission (HWR) measure in the calculation of the SRR. 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 end-stage renal disease (ESRD), body mass index (BMI) at start of dialysis, past-year comorbidities, length of the index hospital stay, and the presence of a high-risk diagnosis 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:** We determine each patient's sex from his/her CMS Form 2728. Patients with unknown sex are excluded from the calculation.
- **Age:** We determine each patient's age at index discharge from the birth date provided in the SIMS and REMIS databases. Patients who were older than 120 years at discharge are removed from the calculation.
- **Duration of ESRD:** We determine each patient's length of time on ESRD using the first service date. (See section 3.1.3) from his/her CMS 2728, claims history (all claim types), the SIMS database and the STrR database.
- **Diabetes as cause of ESRD:** We determine each patient's primary cause of ESRD from his/her CMS 2728.
- **BMI:** We calculate each patient's BMI at ESRD incidence based on the height and weight provided on his/her CMS 2728.
- **Days hospitalized during index admission:** Each admission's length is determined by taking the difference between the date of admission and the date of discharge available on the inpatient claim.
- **Past-year comorbidities (risk variables):** We identify all unique ICD-9 diagnosis codes from each patient's prior year of Medicare claims, using six available claim types: inpatient, outpatient, skilled nursing facility [SNF], hospice and home health claims. We group these diagnosis codes by diagnosis area using HHS' Hierarchical Condition Categories (CCs; see https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/HealthCareFinancingReview/downloads/04summerpg119.pdf). The HWR measure has determined that a subset of these diagnosis areas is appropriate to use in accounting for case mix;
- **Discharged with high-risk condition:** We define a high-risk diagnosis as any diagnosis area (grouped by the Agency for Healthcare Research and Quality (AHRQ) Clinical Classification Software (CCS)) that was extremely rare in our 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 not index discharges and so such diagnoses are not included. The CCS areas identified as high-risk are:
  - CCS 5: Human Immunodeficiency Virus (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.

2.13.3 Readmission Model and SRR Calculation

The following subsections discuss the readmission model and how the SRR measure is calculated.

2.13.3.1 Overview

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 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 with the number that would be expected at an "average" facility (actually the median facility) given the characteristics of its hospitalized patients. 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 that older patients tend to attend facilities that provide better care and, as a result, have better outcomes. If the effect of the covariates were estimated without adjusting for facilities, 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).

In what follows we give a brief overview of the approach taken in a more technical framework for any reader who would like to have a more specific summary of the approach. The section can, however, be omitted by the reader who is not interested in such detail.

2.13.3.2 Calculation of SRR

The equations used in the measure calculation are as follows:

2.13.3.2.1 *Properties of the Hierarchical Logistic Model*

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

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

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., $\alpha_j \sim N(0, \sigma^2)$)

2. We use the estimates from this model to calculate the *i*[th] facility's SRR:

$$SRR_i = \frac{O_i}{E_i} = \frac{O_i}{\sum_{j\in H(i)}\sum_k^{n_{ij}} = 1\widehat{p_{ijk}}}$$

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, and $\boldsymbol{p_{ijk}}$ is the estimated probability of an unplanned readmission under the national norm for each discharge. More specifically,

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

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 estimated assuming that the facility's effect corresponds to the median of national facility effects, denoted by γ_M. Here, $\widehat{\alpha_j}$ and $\hat{\beta}$ are estimates from model (1). The sum of these probabilities is the expected number of unplanned readmissions E_i at facility *i*, adjusting for patient mix and under the national norm.

2.13.3.2.2 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.

2.13.4 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 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."

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2.14 Standardized Transfusion Ratio (STrR) Clinical Measure (ESRD QIP and DFC)

2.14.1 Methods

The following subsection describes the methods that are used to construct the STrR measure.

2.14.1.1 Data Sources

Data are derived from the CMS Consolidated Renal Operations in a Web-enabled Network (CROWN) system. The CROWN data include the Renal Management Information System (REMIS), CROWNWeb facility-reported clinical and administrative data (including CMS-2728 Medical Evidence Form, CMS-2746 Death Notification Form, and CMS-2744 Annual Facility Survey Form data), the historical Standard Information Management System (SIMS) database (formerly maintained by the 18 ESRD Networks until replaced by CROWNWeb in May 2012), the National Vascular Access Improvement Initiative's Fistula First project (in CROWNWeb since May 2012), Medicare dialysis and hospital payment records, transplant data (Organ Procurement and Transplant Network (OPTN) for DFC, and IDR, REMIS, and CROWNWeb admissions to transplant facilities for ESRD QIP), and the Nursing Home Minimum Dataset. DFC also uses the Quality Improvement Evaluation System (QIES) Workbench, which includes data from the Certification and Survey Provider Enhanced Report System (CASPER), the Dialysis Facility Compare (DFC) and the Social Security Death Master File. The database is comprehensive for Medicare patients. Non-Medicare patients are included in all sources except for the Medicare payment records, which do include non-traditional Medicare such as the Part A shadow records for Medicare Advantage patients. CROWNWeb 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, home health, hospice, skilled nursing facility claims) and Part B outpatient institutional and physician/supplier Medicare Claims.

2.14.1.2 Outcome Definition

The outcome for this measure is the risk adjusted facility level transfusion event count among adult Medicare eligible dialysis patients.

2.14.1.3 Identification of Transfusion Events

Our method for counting transfusion events relies on a conservative counting algorithm and, because of the way transfusion information is reported in Medicare claims, we use 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 revenue center, procedure or value codes are present. We only count a single transfusion event for an inpatient claim regardless of the number of transfusion revenue center, procedureand value codes

reported so that the number of discrete events counted is the same whether the claim indicates 1 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 HCPCS codes with at least one revenue center 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, 3 units of blood would be counted as a single transfusion event. Cohort Definition

The following subsections discuss how a facility's cohort is defined for the STrR measure.

2.14.1.3.1 Assignment of Patients to Facilities

As patients can receive dialysis treatment at more than one facility in a given year, we assign each patient day to a facility (or no facility, in some cases) using a combination of Medicare-paid claims with evidence of dialysis treatment, the Medical Evidence Form (Form CMS - 2728) and admissions from CROWNWeb. The data sources are prioritized to identify a patient's dialysis treatment facility at the time of each patient day in the transfusion event period. Patients are excluded from a facility upon receiving a transplant, withdrawing from dialysis or when renal function is recovered. A patient for whom the only evidence of dialysis treatment is the existence of Medicare-paid outpatient claims with evidence of dialysis treatment is 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. If evidence of dialysis reappeared, the patient re-entered the analysis. We did not create periods of lost to follow-up after CROWNWeb events that noted continuing dialysis. For these patients, the record was extended until the appearance of any evidence of recovery, transplant, transfer or death. The net effect is to look back up to one year prior to each patient day for evidence of treating facility if that date is not covered by a CROWNWeb admission, outpatient dialysis facility claim, form 2728 or functioning transplant. ESRD QIP replicates the DFC treating dialysis facility identification concepts, with the exception of assigning to the CCN the facility was using on that date. The patient-days at risk are attributed to a provider based on a set of conventions below, which largely align with those for the Standardized Mortality Ratio (SMR) and Standardized Hospitalization Ratio (SHR). We detail patient inclusion criteria, facility assignment and how to count days at risk, all of which are required for the risk adjustment model.

2.14.1.3.2 General Inclusion Criteria for Dialysis Patients

Though a patient's follow-up in the database can be incomplete during the first 90 days of ESRD therapy, we only include a patient's follow-up into the tabulations after that patient has received chronic renal replacement therapy for at least 90 days. Thus, hospitalizations, mortality and survival during the first 90 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 90 days of ESRD.

In order to exclude patients who only received temporary dialysis therapy, we assigned patients to a facility only after they had been on dialysis there for at least 60 days. This 60-day period is used both for patients who started ESRD for the first time and for those who returned to dialysis

after a transplant. That is, transfusion events during the first 60 days of dialysis at a facility do not affect the STrR of that facility.

2.14.1.3.3 Identifying Facility Treatment Histories for Each Patient

For each patient, we identify the dialysis provider at each point in time. Starting with day 91 after onset of ESRD, we attribute patients to facilities according to the following rules. A patient is attributed to a facility once the patient has been treated there for 60 days. When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 60 days and then is attributed to the destination facility. In particular, a patient is attributed to their current facility on day 91 of ESRD if that facility had treated him or her for at least 60 days. If on day 91 the facility had treated a patient for fewer than 60 days, we wait until the patient reaches day 60 of treatment at that facility before attributing the patient to that facility. When a patient is not treated in a single facility for a span of 60 days (for instance, if there were two facility 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 dialysis claims nor CROWNWeb 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.

2.14.1.3.4 Days at Risk for Medicare Dialysis Patients

After patient treatment histories are defined as described above, periods of follow-up 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 at the start of each calendar year or when crossing any of the above cut points.

Transfusion rates are similar to hospitalization rates in that patients can be transfused more than once during a year and transfusion data are not always as complete as mortality data. As with the hospitalization statistics, this measure should ideally include only patients whose Medicare billing records include all transfusions for the period. To achieve this goal, we apply the same rules as for the hospitalization measure and require that patients reach a certain level of Medicare-paid dialysis bills to be included in transfusion statistics, or patients have a Medicare inpatient claim during the period. For the purpose of analysis, each patient's follow-up time is broken into periods defined by time since dialysis initiation. For each patient, months within a given period are included if that month in the period is considered 'eligible'; a month is deemed eligible if it is within two months of a month having at least $900 of Medicare–paid dialysis claims or at least one Medicare inpatient claim. In setting this criterion, our aim is to achieve completeness of information on transfusions for all patients included in the analysis.

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.

2.14.2 Risk Adjustment

The regression model used to compute a facility's "expected" number of transfusions for the STrR measure contains many factors associated with frequency of hospitalization and thought to be associated with transfusion event rates. Specifically, the model adjusts for patient age, diabetes, duration of ESRD, nursing home status, body mass index (BMI) at incidence, individual comorbidities at incidence, reported on the Medical Evidence Form (CMS-2728), 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:** We determine each patient's age for the birth date provided the SIMS and the Renal Management Information System (REMIS) databases and categorize as 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 (diabetes or other):** We determine each patient's primary cause of ESRD from his/her CMS 2728.
- **Nursing home status:** Using the Nursing Home Minimum Dataset, we determine if a patient was in a nursing home the previous year.
- **BMI at incidence:** We calculate each patient's BMI as the height and weight provided on his/her CMS 2728. BMI is included as a log-linear term.
- **Individual comorbidities at incidence:** Reported on the Medical Evidence Form (CMS-2728) namely alcohol dependence, atherosclerotic heart disease, cerebrovascular disease, chronic obstructive pulmonary disease, congestive heart failure, diabetes, drug dependence, inability to ambulate, inability to transfer, malignant neoplasm, cancer, other cardiac disease, peripheral vascular disease, tobacco use (current smoker).
- **Duration of ESRD:** We determine each patient's length of time on dialysis using the first service date (see section 3.1.3) and categorize as 91 days-6 months, 6 months-1 year, 1-2 years, 2-3 years, 3-5 years, or 5+ years as of the period start date.
- **Calendar year:** The year in which performance is assessed.
- **Categorical indicator variables:** Included as covariates in the stage 1 model to:
  - Flag records with missing values for cause of ESRD, and BMI. These variables have a value of 1 if the patient is missing the corresponding piece of information and a value of 0 otherwise.
  - Flag records with missing all comorbidities and having at least one comorbidity at incidence reported on the Medical Evidence Form.

Beside main effects, some two way interaction terms are also included in the model based on their clinical and statistical significance.

- Diabetes as cause of ESRD * Time on ESRD
- Age * Diabetes as cause of ESRD

2.14.3 Comorbidity Exclusions and Method of Testing Exclusions

In addition to the aforementioned general risk-adjustments, the STrR risk adjustment paradigm utilizes several patient exclusions described here. Transfusions associated with a transplant hospitalization are excluded as they mark a transition of care from the dialysis facility to a transplant team.

Patients are also excluded if they have 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 the year prior to their patient risk time.

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 1 year free of claims that contain diagnoses on the exclusion list.

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

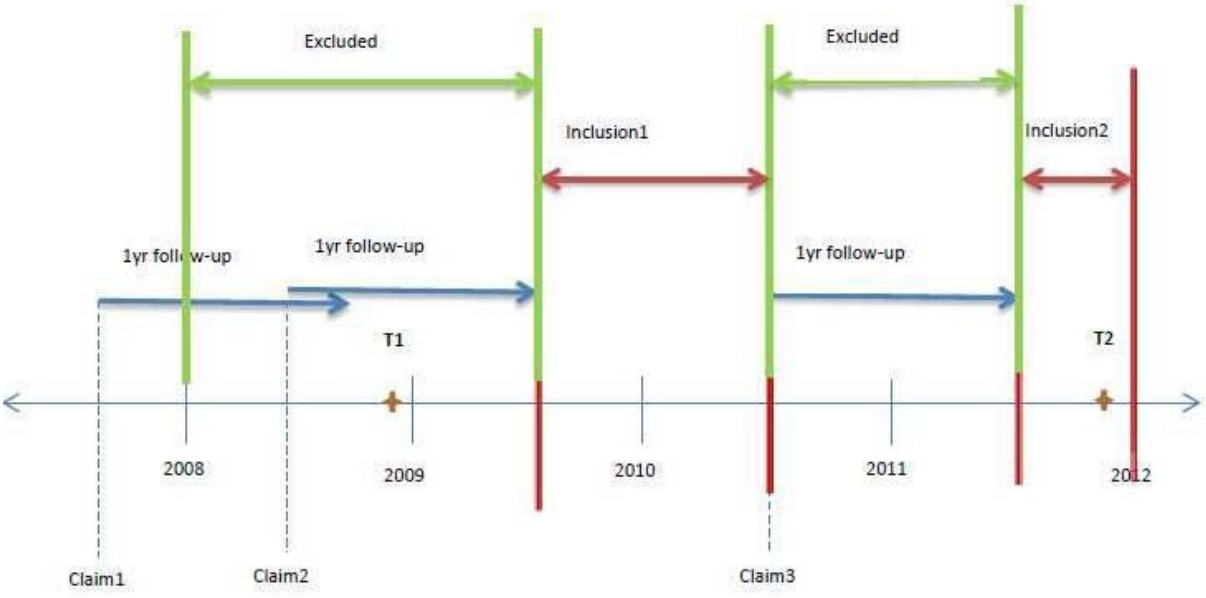

Figure 9. Algorithm for exclusion of periods of time within 1 year of an exclusion comorbidity

In Figure 9, 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 (see above and Additional Information section below) 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 9). 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.

2.14.4 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 I, a stratified model is fitted to the national data with piecewise-constant baseline rates and stratification by facility. Specifically, the model is of the following form:

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

where X_{ik} is the vector of covariates for the (i,k)th patient and β 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 I model are age (18-24 years old, 25-44 years old, 45-59 years old, 60-74 years old, or 75+ years old), cause of ESRD (diabetes or other), duration of ESRD (91 days-6 months, 6 months-1 year, 1-2 years, 2-3 years, 3-5 years, or 5+ years as of the period start date), nursing home status, BMI at incidence, individual comorbidities at incidence, reported on the Medical Evidence Form (CMS-2728), calendar year, and two-way interaction terms between age and duration and cause of ESRD. Nursing home status is identified as in or not in a nursing home in the previous calendar year. BMI is included as a log-linear term. Categorical indicator variables are included as covariates in the stage I model to flag records missing values for cause of ESRD, and BMI. These variables have a value of 1 if the patient is missing the corresponding piece of information and a value of 0 otherwise. Another two categorical indicator variables are included to flag records with having no comorbidities and having at least one comorbidity at incidence reported on the Medical Evidence

Form. These variables have a value of 1 if the patient is having no comorbidities or having at least one comorbidity and a value of 0 otherwise.

At stage II, the relative risk estimates from the first stage are used to create offsets and an unstratified model is fitted to obtain estimates of an overall baseline rate function. That is, we estimate a common baseline rate of transfusions, r0(t), across all facilities by considering the model

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

where $R_{ik} = \exp(\beta' X_{ik})$ is the estimated relative risk for patient i in facility k estimated from the stage I. 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 s^{th} time interval with estimated rate α_s. The corresponding expected number of transfusions in the s^{th} interval for this patient is calculated as:

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

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 a given facility, k, gives

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

which is the expected number of 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

$$STrR = O / E$$

2.14.5 Missing Data

Patients with missing data are not excluded from the model. For the purposes of calculation, missing values for BMI are replaced with mean values for patients of similar age and identical race, sex, and cause of ESRD. Missing values for cause of ESRD are replaced with the other/unknown category. No patients were missing age, sex, or date of first ESRD treatment. Indicator variables identifying patients with missing values for cause of ESRD, comorbidities at incident, and BMI are also included as covariates in the model.

2.14.6 Calculation of STrR P-Values and Confidence Intervals (DFC Only)

A p-value assesses the probability that the facility would experience a number of transfusions more extreme than that observed if the null hypothesis were true; accounting for each facility's patient mix. To do this, a z-score is first calculated using the estimate and standard error for each

facility using the method of generalized estimating equations (GEE; Liang & Zeger, 1986). Specifically, the transfusion rate (or, equivalently: the mean transfusion count, given the exposure) was assumed to follow a multiplicative model and a robust (sandwich) standard error was used. The use of robust standard errors has been advocated for modeling recurrent events (i.e., multiple events per subject) by several previous authors; e.g., Lawless & Nadeau (1995); Lin, Wei, Yang & Ying (2000); Cai & Schaubel (2004). For each facility, the Z-score was computed as the facility's log(STrR), divided by its standard error. Since log(STrR) is undefined for facilities with 0 transfusions, the Z-score in such cases was computed as (STrR-1), divided by a standard error estimate (sandwich estimator) for STrR.

To account for the over dispersion in the z-scores, as used in Standardized Hospitalization Ratio (NQF #1463 http://www.qualityforum.org/QPS/1463), we use robust estimates of location and scale based on the center of the z-scores (by fitting robust regression on z- scores) and derive normal curves that more closely describes the z-score distribution. This new distribution is referred to as the "empirical null hypothesis" (Efron, 2004) and provide references for assessing the extent to which a given facility's outcomes are extreme in comparison with other facilities. We then use the mean and standard deviation from the empirical null distribution of the STrR z-scores to calculate the p-value for classifying facility performance.

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

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

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

2.14.7 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 10 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. For other purposes (e.g. ESRD QIP) other scoring methods may be used.

2.14.8 Selected References

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2.15 Standardized Hospitalization Ratio (SHR) Measure (DFC Only)

2.15.1 Methods

The following subsection describes the methods that are used to construct the SHR measure.

2.15.1.1 Overview

The denominator of SHR, the expected number of hospital admissions, is calculated from a Cox model for recurrent events, adjusting for age, sex, diabetes, duration of ESRD, nursing home status, comorbidities at incidence, body mass index (BMI) at incidence, and calendar year. The SHR is not adjusted for race and ethnicity. Duration of ESRD is divided into six intervals with cut points at 6 months, 1 year, 2 years, 3 years and 5 years, and hospitalization rates are estimated separately within each interval. For each patient, the time at risk in each ESRD interval is multiplied by the (risk-adjusted) national admissions rate for that interval, and a sum over the intervals gives the expected number of admissions for each patient in a facility.

The SHR is an overall measure of hospital use and is comprised of many different causes or reasons for hospitalization. In 2007, a Technical Expert Panel (TEP) was convened; the TEP provided advice on various aspects of the hospitalization measure, including adjustment factors. The TEP considered the possibility of devising cause specific SHRs, but recommended the use of overall SHR measures due to various reasons including the lack of clear research to indicate what causes should be selected as indicative of poor ESRD care and issues associated with inter-rater reliability in assessing cause of hospitalization. The TEP reached a strong consensus that the overall measures should give a reliable and valid measure that would typically be related to quality of care.

The SHR is currently endorsed by the National Quality Forum (NQF), with initial endorsement given in 2011, and the SHR for most dialysis facilities in the United States are posted on the Centers for Medicare and Medicaid Services' (CMS) Dialysis Facility Compare (DFC) website.

2.15.1.2 Data Sources

A treatment history file is the data source for this measure. This 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. CROWNWeb 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 CROWNWeb (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.

In calculating the SHR, Medicare inpatient claims that are adjacent or overlap with another inpatient claim are collapsed into one record. Specifically, if the admission date of an inpatient record is within one day of a previous admission's discharge date, these adjacent inpatient records will be collapsed into one inpatient record that takes on the first hospitalization's

admission date and the following hospitalization's discharge date. Similarly, if an inpatient record overlaps with another inpatient record, the two records are collapsed into one record where the earliest admission date between the two records becomes the new admission date and the latest discharge date between the two records becomes the new discharge date.

2.15.1.3 Outcome Definition

The outcome for this measure is admission to a hospital among Medicare eligible dialysis patients.

2.15.1.4 Cohort Definition

As patients can receive dialysis treatment at more than one facility in a given year, we assign each patient day to a facility (or no facility, in some cases) based on a set of conventions below, which largely align with those for the Standardized Mortality Ratio (SMR) and the Standardized Transfusion Ratio (STrR). We detail patient inclusion criteria, facility assignment and how to count days at risk, all of which are required for the risk adjustment model.

2.15.1.5 General Inclusion Criteria for Dialysis Patients

Since a patient's follow-up in the database can be incomplete during the first 90 days of ESRD therapy, we only include a patient's follow-up into the tabulations after that patient has received chronic renal replacement therapy for at least 90 days. Thus, hospitalizations, mortality and survival during the first 90 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 90 days of ESRD treatment.

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 both for patients who started ESRD for the first time and for those who 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.

2.15.1.6 Identifying Facility Treatment Histories for Each Patient

For each patient, we identify the dialysis provider at each point in time. Starting with day 91 after onset of ESRD treatment, we attribute patients to facilities according to the following rules. A patient is attributed to a facility once the patient has been treated there for 60 days. When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 60 days and then is attributed to the destination facility. In particular, a patient is attributed to their current facility on day 91 of ESRD if that facility had treated him or her for at least 60 days. If on day 91, the facility had treated a patient for fewer than 60 days, we wait until the patient reaches day 60 of treatment at that facility before attributing the patient to that facility. When a patient is not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we do not attribute that patient to any facility. Patients are removed from facilities three days prior to transplant in order to exclude the transplant hospitalization. Patients who withdrew from dialysis or recovered renal function remain assigned to their treatment facility for 60 days after withdrawal or recovery.

If a period of one year passes with neither dialysis claims nor SIMS 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.

2.15.1.7 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 at the start of each calendar year or when crossing any of the above cut points.

Since hospitalization data tend not to be as complete as mortality data, we include only patients whose Medicare billing records should include all hospitalizations. To achieve this goal, we require that patients reach a certain level of Medicare-paid dialysis bills to be included in the hospitalization statistics, or that patients 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 within two months after a month with either: (a) $900+ of Medicare-paid dialysis claims OR (b) at least one Medicare 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-year-facility 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.

2.15.2 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, individual comorbidities at incidence, 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, this is done by stratification.

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

- **Age:** We determine each patient's age for the birth date provided in the SIMS and the Renal Management Information System (REMIS) databases and 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:** We determine each patient's sex from his/her Medical Evidence Form (CMS-2728).
- **Diabetes as cause of ESRD:** We determine each patient's primary cause of ESRD from his/her CMS-2728.
- **Duration of ESRD:** We determine each patient's length of time on dialysis using the first service date from his/her CMS-2728, claims history (all claim types for dialysis related services), the SIMS database and the SRTR database and categorize as 91 days-6 months, 6 months-1 year, 1-2 years, 2-3 years, 3-5 years, or 5+ years as of the period start date.
- **Nursing home status:** Using the Nursing Home Minimum Dataset, we determine if a patient was in a nursing home the previous year.
- **BMI at incidence:** We calculate each patient's BMI as the height and weight provided on his/her CMS 2728. BMI is included as a log-linear term.
- **Individual comorbidities at incidence:** Reported on the Medical Evidence Form (CMS-2728) namely alcohol dependence, atherosclerotic heart disease, cerebrovascular disease, chronic obstructive pulmonary disease, congestive heart failure, diabetes, drug dependence, inability to ambulate, inability to transfer, malignant neoplasm, cancer, other cardiac disease, peripheral vascular disease, tobacco use (current smoker).
- **Calendar year:** The year in which performance is assessed.
- **Categorical indicator variables:** Included as covariates in the stage 1 model to flag records with missing values for cause of ESRD, and BMI. These variables have a value of 1 if the patient is missing the corresponding piece of information and a value of 0 otherwise.
- **Categorical indicator variables:** Included as covariates in the stage 1 model to flag records with missing all comorbidities and having at least one comorbidity at incidence reported on the Medical Evidence Form.

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

- Diabetes as cause of ESRD*Duration of ESRD
- Diabetes as cause of ESRD*Sex
- Diabetes as cause of ESRD*Age
- Age*Sex

2.15.3 Model for Calculating Expected Hospitalization

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).

The modeling process has two stages. At **stage I**, a stratified model is fitted to the national data with piecewise-constant baseline rates and stratification by facility. Specifically, the model is of the following form

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

where $\mathbf{X_{ik}}$ is the vector of covariates for the i^{th} patient in the k^{th} facility and $\boldsymbol{\beta}$ 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.

The patient characteristics $\boldsymbol{X_{ik}}$ included in the stage I model are age (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 (male or female), cause of ESRD (diabetes or other), duration of ESRD (91 days-6 months, 6 months-1 year, 1-2 years, 2-3 years, 3-5 years, or 5+ years as of the period start date), nursing home status, BMI at incidence, individual comorbidities at incidence, reported on the Medical Evidence Form (CMS-2728), calendar year, and two-way interaction terms between age, sex and duration and cause of ESRD. Nursing home status is identified as in or not in a nursing home in the previous calendar year. BMI is included as a log-linear term. Categorical indicator variables are included as covariates in the stage I model to flag records missing values for cause of ESRD, and BMI. These variables have a value of 1 if the patient is missing the corresponding piece of information and a value of 0 otherwise. Another two categorical indicator variables are included to flag records with having no comorbidities and having at least one comorbidity at incidence reported on the Medical Evidence Form. These variables have a value of 1 if the patient is having no comorbidities or having at least one comorbidity and a value of 0 otherwise.

At **stage II**, the relative risk estimates from the first stage are used to create offsets and an unstratified model is fitted to obtain estimates of an overall baseline rate function. That is, we estimate a common baseline rate of 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 $R_{ik} = \exp(\boldsymbol{\beta' X_{ik}})$ is the estimated relative risk for patient i in facility k obtained from the stage I. 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 $\boldsymbol{t_{iks}}$ 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

$$E = \sum_{i=1}^{N_k}\sum_{s=1}^{6} \mathrm{E}_{iks} = \sum_{i=1}^{N_k}\sum_{s=1}^{6} \alpha_s t_{iks} R_{ik}$$

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

Let O 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

$$\mathbf{SHR = O/E} \ .$$

Please note that the Standardized Hospitalization Ratio is only calculated for facilities with at least 5 patient years at risk for the time period.

2.15.4 Missing Data

Patients with missing data are not excluded from the model. For the purposes of calculation, missing values for BMI are replaced with mean values for patients of similar age and identical race, sex, and cause of ESRD. Missing values for cause of ESRD are replaced with the other/unknown category. No patients were missing age, sex, or date of first ESRD treatment. Indicator variables identifying patients with missing values for cause of ESRD, comorbidities at incident, and BMI are also included as covariates in the model.

2.15.5 Calculation of SHR P-Values and Confidence Intervals

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

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

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.

2.15.6 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. Selected References

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2.16 Standardized Mortality Ratio (SMR) Measure (DFC Only)

2.16.1 Methods

The following subsection describes the methods that are used to construct the SMR measure.

2.16.1.1 Overview

The SMR is designed to reflect the number of deaths for the patients at a facility, relative to the number of deaths that would be expected based on overall national rates and the characteristics of the patients at that facility. Specifically, the SMR is calculated as the ratio of two numbers; the numerator ("observed") is the actual number of deaths, excluding deaths due to street drugs (defined in Form CMS-2746, code 93) and accidents unrelated to treatment, over a specified time period. The denominator ("expected") is the number of deaths that would be expected if patients at that facility died at the national rate for patients with similar characteristics, over the same time period.

Qualitatively, the degree to which the facility's SMR varies from 1.00 is the degree to which it exceeds (>1.00) or is under (<1.00) the national death rates for patients with the same characteristics as those in the facility. For example, an SMR=1.10 would indicate that the facility's death rates typically exceed national death rates by 10% (e.g., 22 deaths observed where 20 were expected, according to the facility's patient mix). Similarly, an SMR=0.95 would indicate that the facility's death rates are typically 5% below the national death rates (e.g., 19 observed versus 20 expected deaths). An SMR=1.00 would indicate that the facility's death rates equal the national death rates, on average.

2.16.1.2 Data Sources

Data are derived from an extensive national ESRD patient database, which is largely derived from the CMS Consolidated Renal Operations in a Web-enabled Network (CROWN), which includes Renal Management Information System (REMIS), and the Standard Information Management System (SIMS) database (formally maintained by the 18 ESRD Networks and now maintained in CROWNWeb), Medicare claims, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746), the Nursing Home Minimum Dataset, the Dialysis Facility Compare (DFC) and the Social Security Death Master File.

2.16.1.3 Outcome Definition

The outcome for this measure is death. We define this as death due to any cause except street drugs or accidents unrelated to treatment. 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.

2.16.1.4 Cohort Definition and Inclusion/Exclusion

A patient's follow-up in the database can be incomplete during the first 90 days of ESRD therapy. For the purposes of this report, we entered a patient's follow-up into the tabulations only after that patient had received chronic renal replacement therapy for at least 90 days. Mortality

and survival during the first 90 days do not enter into the calculations. 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, since such patients may have incomplete data.

In order to exclude patients who received only temporary dialysis therapy, a patient's death is attributed to a facility only if the patient has been on dialysis there for at least 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 treatment at a facility do not affect the SMR of that facility.

2.16.1.5 Identifying Facility Treatment Histories for Each Patient

For each patient, we identified the dialysis provider at each point in time using data from a combination of Medicare dialysis claims, the Medical Evidence Form (Form CMS-2728), and dialysis claims. Starting with day 91 after onset of ESRD, we attribute patients to facilities according to the following rules. A patient is attributed to a facility once the patient has been treated there for 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 from day 61. In particular, a patient is attributed to their current facility on day 91 of ESRD if that facility had treated him or her for at least 60 days. If on day 91, the facility had treated a patient for fewer than 60 days, we wait until the patient reaches day 60 of treatment at that facility before attributing the patient to the 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's outcomes (death, in this case) to any facility. Patients were removed from a facility's analysis upon receiving a transplant. Patients who withdrew from dialysis or recovered renal function remained assigned to their treatment facility for 60 days after withdrawal or recovery.

If a period of one year passed with neither dialysis claims nor CROWNWeb information to indicate that a patient was receiving dialysis treatment, we considered the patient lost to follow-up and did not include that patient's subsequent time-at-risk in the analysis. When dialysis claims or other evidence of dialysis reappeared, the patient was entered into analysis after 60 days of continuous therapy at a single facility.

In addition, a patient is excluded from the Cox model if the patient's sex or age is unknown.

2.16.1.6 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 and 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 who patient

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.

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 as described in the "Risk Adjustment" section below. The SMR for a facility is the ratio of the total number of observed to the total number of expected deaths during all patient-records at the facility.

2.16.2 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, duration of ESRD, nursing home status from previous year, patient comorbidities at incidence, 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:** We determine each patient's age for the birth date provided in CROWNWeb and the Renal Management Information System (REMIS) databases. 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:** We determine each patient's sex from his/her Medical Evidence Form (CMS-2728).
- **Race** (white, black, Asian/Pacific Islander, Native American or other): We determine race from the Renal Beneficiary and Utilization System (REBUS), the Program Management and Medical Information System (PMMIS), the EDB (Enrollment Data Base), and SIMS.
- **Ethnicity (Hispanic, non-Hispanic or unknown):** We determine ethnicity from his/her CMS-2728.
- **Diabetes as cause of ESRD:** We determine each patient's primary cause of ESRD from his/her CMS-2728.
- **Duration of ESRD:** We determine each patient's length of time on dialysis using the first service date from his/her CMS-2728, claims history (all claim types), the SIMS database and the SRTR database and categorize 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, we determine if a patient was in a nursing home the previous year.
- **BMI at incidence:** We calculate each patient's BMI as the height and weight provided on his/her 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.

- **Comorbidities at incidence:** We determine each patient's comorbidities at incidence from his/her CMS-2728. Each comorbid condition has a categorical indicator variable, having a value of 1 if the patient has that comorbidity and a value of 0 otherwise. Comorbidities included as covariates are alcohol dependence, atherosclerotic heart disease, cerebrovascular disease, chronic obstructive pulmonary disease, congestive heart failure, diabetes, drug dependence, inability to ambulate, inability to transfer, malignant neoplasm, cancer, other cardiac disease, peripheral vascular disease, and tobacco use (current smoker). Another categorical indicator variable is included as a covariate in the stage 1 model to flag records where patients have at least one comorbid condition. This variable has a value of 1 if the patient has at least one comorbid condition and a value of 0 otherwise.
- **Calendar year:** The three years in which performance is assessed.
- **Missing indicator variables**: Categorical indicator variables are included as covariates in the stage I model to account for records with missing values for cause of ESRD, comorbidity at incidence, and BMI. These variables have a value of 1 if the patient is missing the corresponding variable and a value of 0 otherwise.
  - BMI is imputed when either missing, or BMI < 10 or BMI ≥ 70 for adults or BMI < 5 or BMI ≥ 70 for children. To impute BMI, we used the average values of the group of patients with similar characteristics (age, race, sex, diabetes) when data for all four of these characteristics were available. If either race or diabetes was also missing, the imputation was based on age and sex only. If either age or sex is missing, the patient is excluded from computations.

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

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.

2.16.3 Expected Mortality Model and SMR Calculation

The follow subsections describe the SMR's expected mortality model and the measure calculations.

2.16.3.1 Overview

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, duration of ESRD, nursing home status, patient comorbidities at incidence, calendar year and body mass index (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. The Cox model is applied in two stages. Stage 1 yields estimates of the coefficients (ßj) 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.

The patient characteristics included in the stage 1 model as covariates are age, race, ethnicity, sex, cause of ESRD (diabetes or other), duration of ESRD (<1 year, 1-2 years, 2-3 years, 3+ years as of the period start date), nursing home status, comorbidity at incidence, calendar year, BMI at incidence, and interaction terms between race, sex and duration and cause of ESRD. Age as of the period start date 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, and whether the patient is black or not. Ethnicity is included with different coefficients for white and non-white patients. Each comorbidity is included as an indicator. The logarithm of BMI is included as a piecewise continuous log-linear term with different coefficients based on whether the ln BMI is greater or less than 3.5. Categorical indicator variables flagging missing values for cause of ESRD, comorbidity, and BMI are included as covariates in the stage 1 model. These variables have a value of 1 if the patient is missing the corresponding piece of information and a value of 0 otherwise. A categorical indicator variable also flags records with at least one comorbidity. The stage 2 model includes the age-adjusted population death rates for patients of that race in that state as a covariate. In the stage 2 model, there is no stratification and there is a single baseline survival curve, which is estimated along with the estimates of the stage 2 regression parameters. The estimate of the baseline survival curve also arises from the fitting of the Cox model and is analogous the Kaplan-Meier (1958) estimate, except that it is adjusted for variation among patients.

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 2016 DFR used age-adjusted death rates for 2012-14 from Table 16 of the publication *Health, United States, 2015,* available at https://www.cdc.gov/nchs/data/hus/2015/016.pdf

2.16.3.2 Missing Data

Patients with missing data are not excluded from the model. Missing values for cause of ESRD are replaced with the other/unknown category. For the purposes of calculation, either missing, or outside the range of 10 to 70 for adults or 5 to 70 for children BMI is replaced with the average values of the group of patients with similar characteristics (age, race, sex, diabetes as cause of ESRD) when data for all four of these characteristics were available. If either race or diabetes as cause of ESRD was also missing, the imputation was based on age and sex only. Less than 5% patients have imputaed BMI. Patients with missing race are included in the "other" race group strata and classified as non-White in the model. Patients with missing ethnicity are classified as "unknown" ethnicity. No patients were missing age, sex, or date of first ESRD treatment. Indicator variables identifying patients with missing values for cause of ESRD, incident comorbidity, and BMI are also included as covariates in the model.

2.16.3.3 Calculation of Expected Deaths at a Facility

As described above, 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 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) and included in the model. Using these coefficients, a relative risk or predicted risk is calculated for each patient-record. Stage 2 of the model 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

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

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 this model is a set of regression coefficients, $ß_1, ß_2, \ldots, ß_p$ and the corresponding predicted value for the i^{th} patient record is given by

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

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 $\mathbf{X_i ß}$ 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 $ß_0$ and of the baseline survival function, $S_0(t)$. After stage 2, the linear prediction is

$$\mathbf{A_i} = ß_0 x_{i0} + \mathbf{X_i ß} = ß_0 x_{i0} + ß_1 x_{i1} + ß_2 x_{i2} + \ldots + ß_p x_{ip}$$

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

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

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

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

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

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

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 O be the total number of deaths observed at the facility during the total four year 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 = O/E.

Please note that the standardized mortality ratio is only calculated if there are at least 3 expected deaths for the time period.

2.16.3.4 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,

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

2.16.3.5 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.”

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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

Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple testing tools.

2.17.3 Improvement Noted as Higher or Lower Rate

Higher rate is better.

2.17.4 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).

2.17.5 Facility Exclusions

- Facilities treating 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 January 1, 2017
- Facilities not offering in-center hemodialysis

Note: 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.

2.17.6 Denominator Statement

Patients with ESRD receiving in-center hemodialysis 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.

2.17.7 Denominator Exclusions

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

- Patients less than 18 years old on the last day of the sampling window ((see https://ichcahps.org for dates) for the semiannual survey
- Patients receiving hemodialysis 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

2.17.8 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.
- Facilities that do not administer two surveys during the performance period will receive a score of 0 on the measure.
- Additional specifications may be found at https://ichcahps.org.

2.17.9 Data Elements and Data Sources

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

CROWNWeb Data Elements:

- ICH CAHPS Attestation Indicator
- Initial Certification Date
- Medicare Certified Services Offered
- Additional Services Offered (Non-Medicare)

ICH CAHPS Data Elements

- Reporting Compliance Indicator
- 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

2.17.10 Flowchart

Figure 10 provides a flowchart that represents the processes used to calculate the ICH CAHPS Clinical Measure in the ESRD QIP.

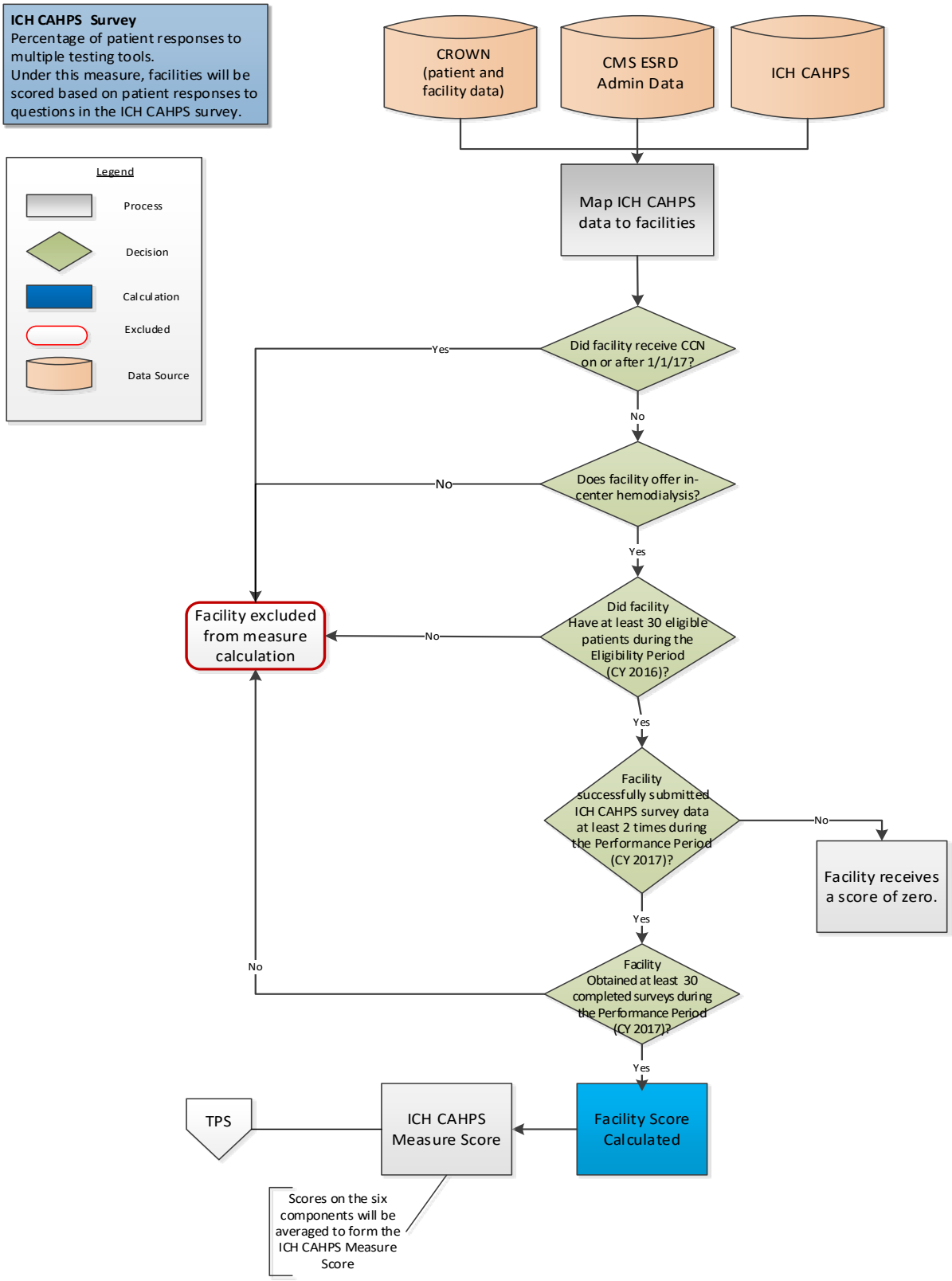


Figure 10. ICH CAHPS Survey Flowchart for ESRD QIP

2.17.11 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) – NQF #1460

2.18.2 Measure Description

Measure assesses facilities' ability to prevent healthcare acquired infections.

2.18.3 Improvement Noted as Higher or Lower Rate

Lower ratio is better.

2.18.4 Numerator Statement

The number of new positive blood culture events based on blood cultures drawn as an outpatient or within 1 calendar day after a hospital admission.

2.18.5 Facility Exclusions

- Facilities that do not offer in-center hemodialysis
- Facilities with a CCN certification date on or after January 1, 2017
- Facilities that treat fewer than 11 in-center hemodialysis patients during the performance period
- Facilities with approved Extraordinary Circumstances Exception

2.18.6 Denominator Statement

Number of maintenance in-center hemodialysis patients treated in an outpatient hemodialysis facility on the first 2 working days of the month.

2.18.7 Denominator Exclusions

None.

2.18.8 Additional Information

The minimum number of reports to NHSN is 12 months. Facilities that do not submit 12 months of accurately reported data receive zero points for the measure.

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

2.18.9 Data Elements and Data Sources

The data elements used for this measure are listed below. A complete description of the CROWNWeb 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 CDC)

CROWNWeb Data Elements

- Certification Date
- CROWN Unique Patient Identifier (UPI)
- CROWN Provider ID
- Admit Date
- Discharge Date
- Primary Type of Treatment ID (CROWNWeb dialysis type)
- Primary Dialysis Setting
- Medicare Certified Services Offered
- Additional Services Offered (Non-Medicare)

Claims Based Data Elements

- Patient Medicare Claim Number
- Claim CCN

2.18.10 Flowchart

Figure 11 provides a flowchart that represents the processes used to calculate the NHSN Bloodstream Infection in hemodialysis outpatient's measure in the ESRD QIP.

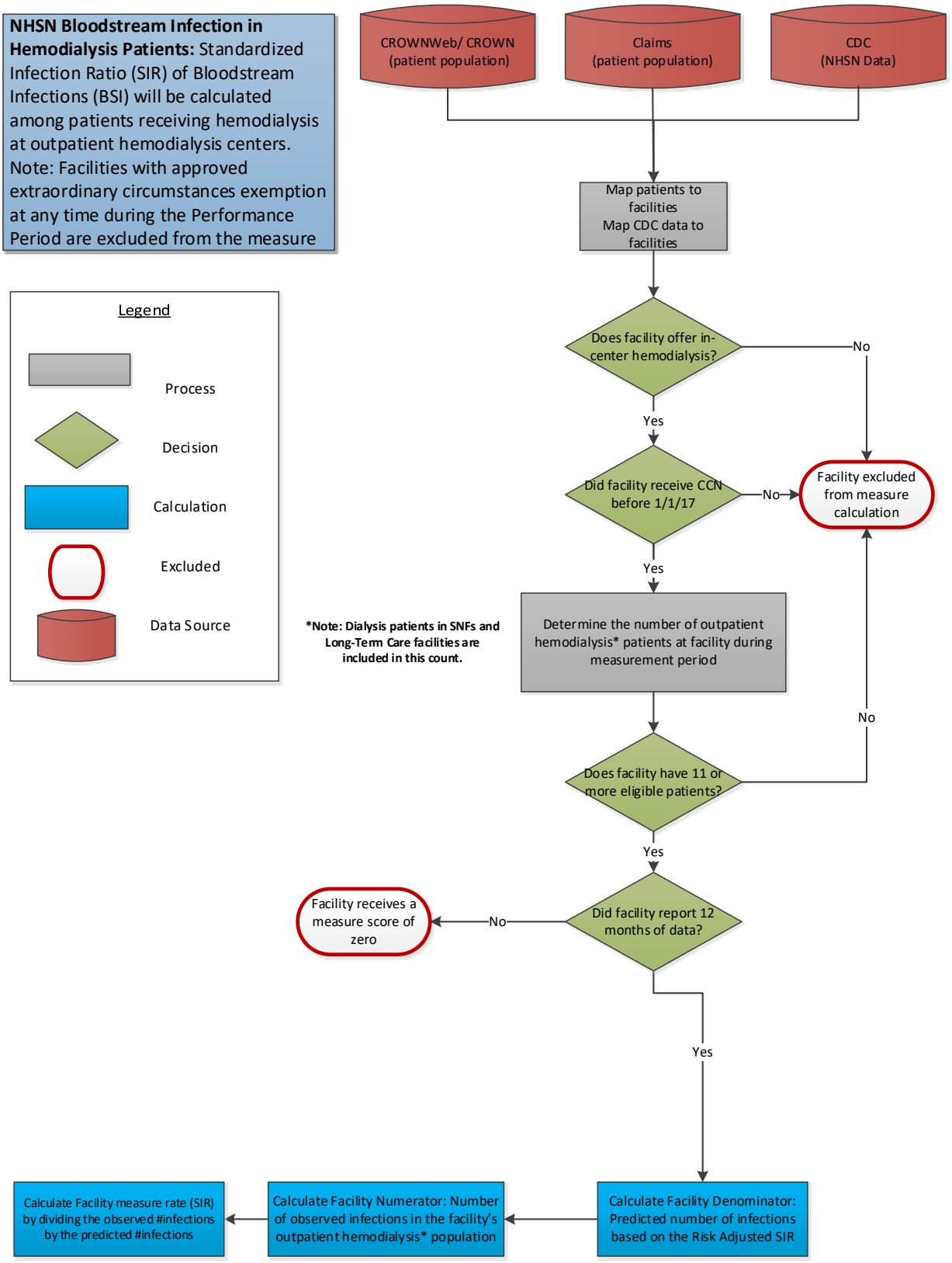


Figure 11. NHSN Bloodstream Infection in Hemodialysis Outpatients Flowchart for ESRD QIP

2.19 NHSN Health Care Personnel Influenza Vaccination Reporting Measure (ESRD QIP Only)

2.19.1 Measure Name

The National Healthcare Safety Network Health Care Personnel (NHSN HCP) Influenza Vaccination – NQF #0431

2.19.2 Measure Description

Measure assesses whether facilities report influenza vaccinations for their staff. Facility submits Healthcare Personnel Influenza Vaccination Summary Report to CDC's NHSN system, according to the specifications of the Healthcare Personnel Safety Component Protocol, by May 15, 2017.

2.19.3 Improvement Noted as Higher or Lower Rate

Higher rate is better.

2.19.4 Facility Exclusions

Facilities with a CCN certification date on or after January 1, 2017

2.19.5 Additional Information

- A "qualifying healthcare personnel" is defined as an employee, licensed independent practitioner, or adult student/trainee/volunteer who works in a facility for at least one day between October 1, 2016 and March 31, 2017 (designated as the "flu season").
- NHSN Summary Reports submitted by May 15, 2017 document actions taken during the flu season that spans October 1, 2016 to March 31, 2017, and would count toward facilities' PY 2019 NHSN Healthcare Personnel Influenza Vaccination reporting measure scores.
- Additional information about the Protocol and Summary Report can be found at: http://www.cdc.gov/nhsn/PDFs/HPS-manual/vaccination/HPS-flu-vaccine-protocol.pdf.
- Additional details on the specifications for the NHSN HCP Influenza Vaccination measure can be found at the following website: http://www.cdc.gov/nhsn/dialysis/hcp-vaccination/index.html

2.19.6 Data Elements and Data Sources

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

CROWNWeb Data Elements:

- Facility CCN
- Initial Certification Date

NHSN Data Elements:

- NHSN performance year
- NHSN yearly compliance indicator

2.19.7 Flowchart

Figure 12 provides a flowchart that represents the processes used to calculate the NHSN HCP Influenza measure in the ESRD QIP.

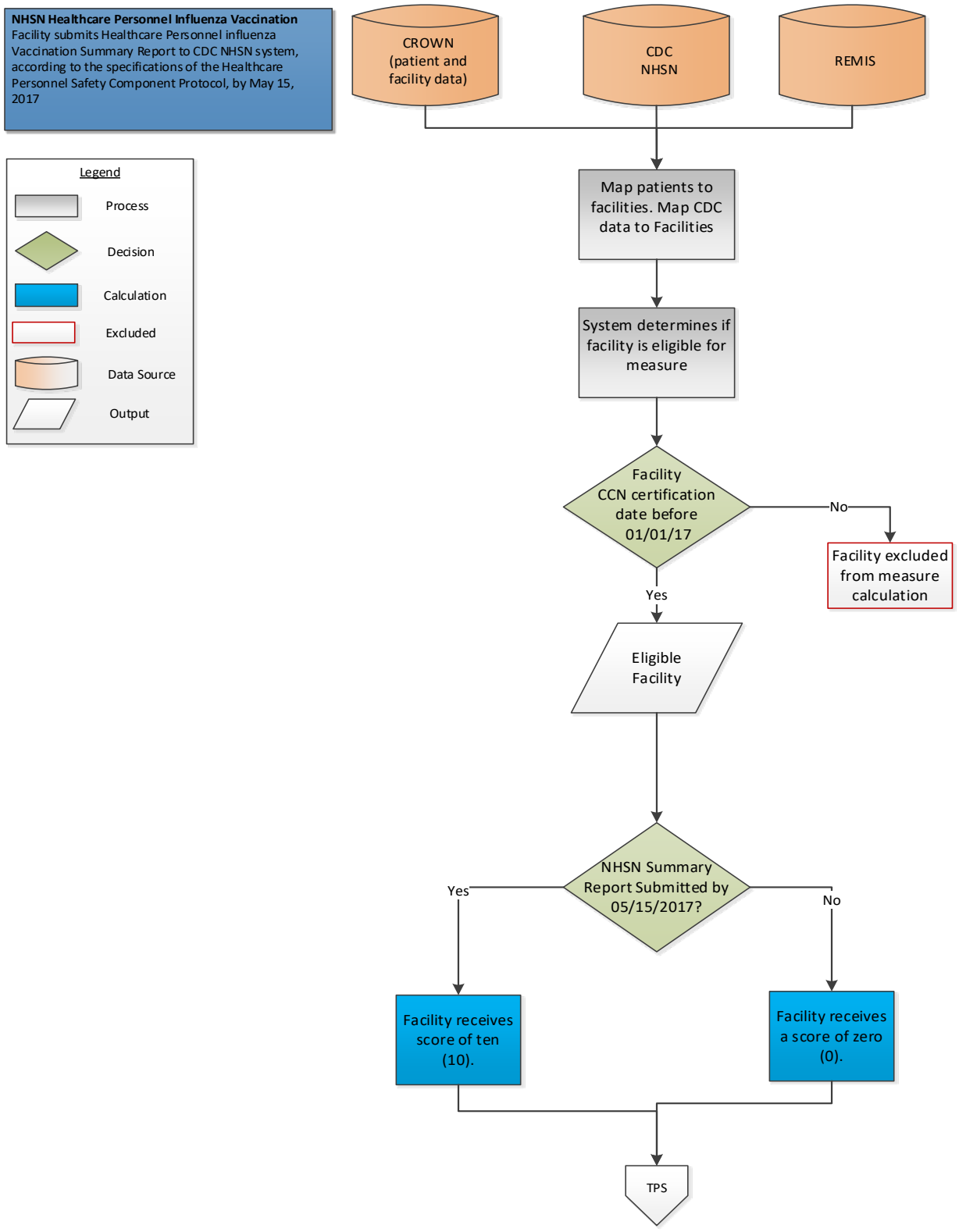


Figure 12. NHSN HCP Influenza Measure Flowchart for ESRD QIP

2.20 NHSN Dialysis Event Reporting Measure (ESRD QIP Only)

2.20.1 Measure Name

The National Healthcare Safety Network (NHSN) Dialysis Event Reporting

2.20.2 Measure Description

Number of months for which facility reports National Healthcare Safety Network (NHSN) Dialysis Event data to the Centers for Disease Control and Prevention (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.

2.20.3 Improvement Noted as Higher or Lower Rate

A higher rate is better.

2.20.4 Facility Exclusions

- Facilities which do not treat in-center hemodialysis patients.
- Facilities with a CMS certification date on or after January 1, 2017.
- Facilities treating fewer than 11 in-center hemodialysis patients
- Facilities with approved Extraordinary Circumstances Exception

2.20.5 Additional Information

Scoring Distribution for the NHSN Dialysis Event Reporting Measure:

- 10 points for reporting 12 months
- 2 points for reporting 6-11 months
- 0 points for reporting 0-5 months

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

2.20.6 Data Elements and Data Sources

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

CROWNWeb Data Elements:

- Facility CCN
- Initial Certification Date

NHSN Data Elements:

- NHSN performance year
- NHSN yearly compliance indicator

2.20.7 Flowchart

Figure 13 provides a flowchart that represents the processes used to calculate the NHSN Dialysis Event Reporting measure in the ESRD QIP.

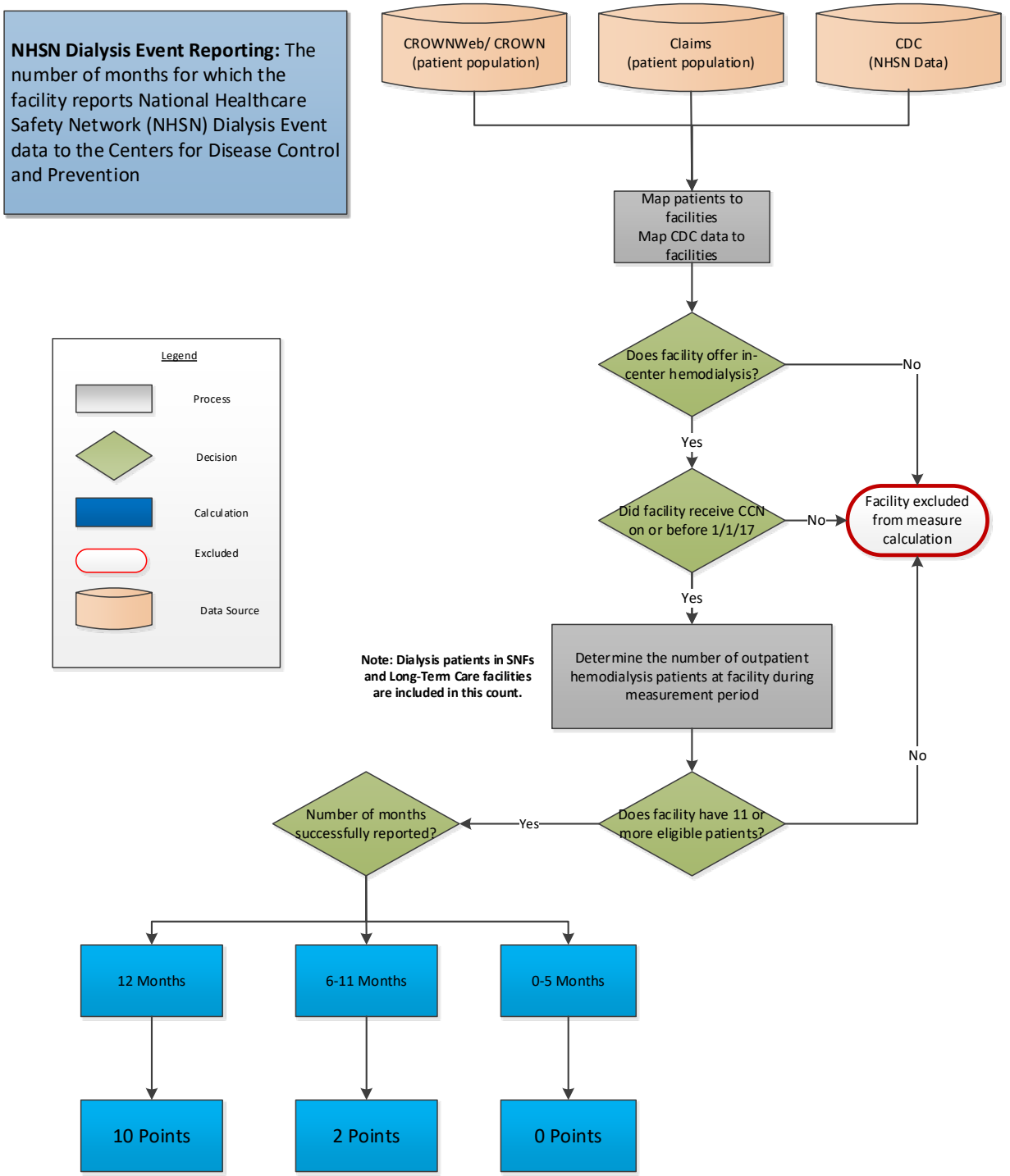


Figure 13. NHSN Dialysis Event Reporting Measure Flowchart for the ESRD QIP

3. Cross-Measure Determinations

The following subsections describe calculations that are used in multiple measure calculations.

3.1 Determining Patient-Level Exclusions

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

3.1.1 Modality Determination

DFC Only:

- A patient is defined as a hemodialysis 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 and excluded from this measure if their modality reported in claims is any of the following: 'CAPD', 'CAPD Training', 'CCPD', 'CCPD Training', 'Other PD' where CAPD is continuous ambulatory peritoneal dialysis and CCPD is continuous cycling peritoneal dialysis.

ESRD QIP Only:

- In cases where a dialysis patient receives treatment using 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 by facility. Note, for the comprehensive Kt/V measure, the system needs to track if a patient changed modality during the month to implement an exclusion.

    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 1):
                - 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.
            - Non-composite revenue center codes are shown in the third column of Table 1.

c. When there are revenue center codes with the same line item date, use Table 1 (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.

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 1: Modality Types for Revenue Center Codes

d. If no dialysis-related revenue center codes are present, set the Primary Modality to **Undetermined**.

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 1):
        - 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.

- Non-composite revenue center codes are shown in the third column of Table 1

d. When there are revenue center codes with the same line item date, use Table 1 (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**.

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. HD sessions = count incidences of revenue center codes ‘0821’ and ‘0881’

   b. Other PD sessions = count incidences of revenue center code ‘0831’

   c. CAPD sessions = count incidences of revenue center code ‘0841’

   d. CCPD sessions = count incidences of revenue center code ‘0851’

   - Sum HD sessions.
   - Sum Other PD, CAPD, and CCPD sessions and convert to PD hemo-equivalent sessions. PD (hemo-equivalent) sessions = (OPD+CAPD+CCPD)*3/7

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**

5. If the only dialysis-related codes on the claim are non-composite revenue center codes (shown in the third column of Table 1), set the primary modality according to which modality type code set occurs most frequently:

   a. Sum the non-composite codes of each type and set the Primary Modality according to which code occurs most frequently as shown in Table 1 (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 1 (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**.

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' claims).

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 1 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.**

7. If the primary modality is **In-center Hemodialysis** or **Home Hemodialysis,** store the count of revenue center codes (determined in Steps 2 or 5) as the number of sessions in the claim month.

3.1.2 Access Type Determination

The follow modifiers are used to determine access type:

- Modifier V5: Vascular Catheter
- Modifier V6: Arteriovenous Graft
- Modifier V7: Arteriovenous Fistula

The last claim of the month is used for the purposes of calculating the Vascular Access Type measures. If V6 and V7 are both reported on the last claim of the month, then the patient-month

is excluded from the calculations. If V5, V6 and V7 are all reported last claim of the month, then the patient-month is excluded from the calculations. If neither V5, V6 nor V7 is reported on the last claim of the month, then the patient-month is excluded from the calculations. If V5, V6 or V7 is not associated with a hemodialysis revenue center code on the last claim of the month, then the patient-month is excluded.

3.1.3 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 University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) transplant standard analysis file (constructed from multiple sources), the CROWNWeb 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) CROWNWeb, (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 a CROWNWeb 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 CROWNWeb event, whichever was earlier.
- If first ESRD service date has been set to the 2728 date but there is a CROWNWeb event of "new patient" more than 1 year later, and that date is earlier than any other CROWNWeb event, transplant, or claim, then the first ESRD service date is changed to the CROWNWeb 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 form, (2) CROWNWeb, (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.

If the first ESRD service date was selected from a dialysis claim and there is a 2728 AND a CROWNWeb 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 CROWNWeb event, whichever was earlier.

If first ESRD service date has been set to the 2728 date but there is a CROWNWeb event of "new patient" more than 1 year later, and that date is earlier than any other CROWNWeb event, transplant, or claim, then the first ESRD service date is changed to the CROWNWeb event date.

- 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: physician's signature date, date of return to regular dialysis after transplant failure, date dialysis training began, and transplant date. If patient does not have a date from the Medical Evidence form, the date regular chronic dialysis began in the CROWNWeb patient table is used.
- Earliest CROWNWeb admit date from any facility, excluding records with discharge reason of Acute.
- Earliest evidence of chronic dialysis from Medicare claims. Use the claim's start date from the earliest claim where the average number of sessions per day across all claims for the patient for the next 60 days is > 0.2.
- Earliest transplant date. Note, transplant dates are drawn from IDR and Medical Evidence (CMS 2728) form.

3.1.4 Patient Age

Patient age is defined 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), as reported on the claim used for the patient-month.

3.1.5 Determination of Thrice Weekly Dialysis and "Frequent Dialysis"

A patient was defined as not being on thrice weekly dialysis if the prescribed number of sessions reported in CROWNWeb by the patient's "assigned" facility was not equal to 3 and/or the patient was identified in CROWNWeb as undergoing "frequent" dialysis anytime during the reporting month. If information regarding the frequency of dialysis was not available for the reporting month in CROWNWeb by the patient's "assigned" facility, session information submitted by other dialysis facilities where the patient received treatment was considered.

If the session information was not reported in CROWNWeb for the reporting month, eligible hemodialysis Medicare claims submitted by the patient's "assigned" facility during the reporting month were considered. A claim was considered eligible if it was for an adult (≥18 years old) HD patient (or pediatric in-center HD for pediatric HD measure) with ESRD for at least 90 days as of the start of the claim. Any patient-month in which the patient received "frequent" or "infrequent" dialysis according to claims was excluded entirely (more details provided below).

If the prescribed dialysis information was not available for the patient during the reporting month in either data source (CROWNWeb or Medicare claims), the most recent information available in CROWNWeb were used to make the determination.

Calculating "frequent" and" infrequent" dialysis in Medicare dialysis claims

The number of days the claim covers was calculated by: days = (clm_thru-(claim-from-1)). For claims covering more than 7 days, the number of dialysis sessions per week is calculated as a rate: 7*(# of HD sessions/# 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 claim starting during the month met any of the following criteria:

- Claim with Kt/V value of 8.88
- Claim with rate of 4 or more sessions per week
- Short claim (7 days or fewer) with 4 or more total sessions

A claim is defined as indicating infrequent dialysis if it covers more than 7 days and had a rate of 2 or fewer sessions per week.

Note: *No rounding is used when determining dialysis frequency.*

3.2 Facility Mapping and Impacts of Change of Ownership

3.2.1 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.

3.2.2 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 of the digits must be a number except for the 6th digit, which can be 'F' indicating 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

Source: CMS Documentation (page 7 http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R146CP.pdf)

3.2.3 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.

Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb): 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 CROWNWeb and will have the same PROVNUM that is used in CROWNWeb.

- **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 CROWNWeb facility directory file and CASPER provider of services files (See Section 4.2.5).

Issue 2: Change of Ownership (CHOW)

A facility may change provider numbers due to an ownership change or other reasons. With a change of ownership, the facility either retains the former provider number or is issued a new provider number.

Solution (CHOW rule): If a facility changes ownership and obtains a new Medicare provider number, the new provider number is treated as a new facility and is 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 3.2.4.

3.2.4 Overview of the Facility List Creation Process

Two primary data sources are used to create the facility list; the CROWNWeb facility directory file and CASPER provider of services (POS) files. The Dialysis Facility Compare (DFC) file, which is also extracted from CROWNWeb, is also used to obtain newly certified facilities that will receive a Quarterly Dialysis Facility Compare (QDFC) Preview report. These files are described in more detail in section 3.2.5.

All facilities active as of the most recent data available will receive a Quaterly Dialysis Facility Compare (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 Dialysis Facility Compare file.

Summary: Process the DFC file received from CMS by converting it into SAS file and appending 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 of the digits must be a number except for the 6th digit, which can be 'F'. Note: We do not create reports for the latter (i.e., Veterans Affairs(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 I. 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 CROWNWeb 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 CROWNWeb facility ID. This has occurred when 1) a facility is shared by adult and pediatric units, or 2) by a hemodialysis and peritoneal units, or 3) a transplant facility and a dialysis facility, or 4) a permanent and temporary facility. The duplicates 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 CROWNWeb. 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 CROWNWeb 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 CROWNWeb).

a. For hospital-based facilities with missing hospital CCN, search for the ESRD CCN in the CASPER POS file.
b. 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 CROWNWeb 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.
c. Create a unique provider variable used for QDFC reporting and update the usage variables, variable labels, and formats.
d. Create the lookup file used to link all alternate/related provider numbers to the QDFC provider number.
e. 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 (DO), 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 CROWNWeb facility directory file. All related provider numbers from these files (created in step 5 above) are aggregated to a single record.

3.2.5 Additional Rules for linking provider numbers

In step 5b 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 Dialyis Orginazation inserted in name).

Issue 1: Two records match on facility characteristics or on facility id in CROWNWeb.

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 CROWNWeb 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 CROWNWeb, 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 CROWNWeb.

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 CROWNWeb.

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 CROWNWeb 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 CROWNWeb.

Solution: Link to the hospital satellite facility with the least ESRD provider number usage.

3.2.6 Descriptions of the Data Files Used to Create the Facility List

3.2.6.1 Facility Directory File

The facility directory file is extracted from CROWNWeb. 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

3.2.6.2 Facility Service File

This file is received quarterly along with the facility directory file; also extracted from CROWNWeb. 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.

3.2.6.3 Provider of Service File (POS)

The POS file is downloaded from the Quality Improvement Evaluation System (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 CROWNWeb 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 CROWNWeb before they show up in CASPER. These files are downloaded monthly.

The CASPER POS files include information for both active and terminated facilities.

3.2.6.4 Dialysis Facility Compare (DFC) File

The DFC project covers all open facilities at a given time. The DFC facility list is extracted quarterly from CROWNWeb . This file only included the CMS certification number prior to June 2015, so fields such as facility names, addresses were used to determine the linkage of provider number. However, beginning in June 2015, the CROWNWeb facility ID was added to the file and used to determine the linkages in addition to facility characteristic variables.

3.2.7 ESRD QIP Facility List and Changes of Ownership

- CROWN assigns a facility ID to each physical building and sub-unit providing dialysis. When data is extracted from CROWN, 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.
- For hospital-based facilities, the primary CCN is set to the dialysis facility and the alternate CCN is set to the hospital.
- Historical facility ownership changes are documented and used to assign patients to facility CCNs for measures requiring attribution of patient care to facilities
- ESRD QIP evaluates all facility records in CROWN 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 a ESRD QIP report).
- ESRD QIP relies primarily on CROWN as data source as it is the facility information system of record. Potential issues are identified by comparison with the DFC facility list through the ESRD QIP Validation process. Research of those issues is supported through Provider of Services, contact with Networks, and other supporting information, such as newspaper articles and press releases regarding changes to facilities.

3.2.8 CROWN Facility Record Consolidation

CROWN assigns different facility IDs to units that share a CCN. This happens most frequently when there are adult and pediatric units, or hemodialysis and peritoneal dialysis units. For these cases, data for these multiple CROWN 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 attributes such as name and address.

3.2.9 CROWN Data Clean-up

- CROWN data entry errors, or other inaccuracies, need to be corrected for ESRD QIP until the facility or network updates the information in CROWN. 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 CROWN.
- CROWN has duplicate CCNs which cause no problems internally to CROWN 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.

3.2.10 ESRD QIP Eligibility

All outpatient dialysis facilities open at the end of the performance year are eligible for ESRD QIP scores and reports. CROWN and claims include other facilities, such as hospitals or transplant centers, which are used to provide data supporting the measures but are not eligible for scoring. The eligibility criteria are:

- Facility CCN at end of performance year is not missing or null
- Facility is not closed as of the end of the performance year
- Facility certification date is on or before the end of the performance year
- Facility CCN has six digits with no alpha characters
- Facility provider type in CROWN is "Medicare"
- Facility program type in CROWN is "Dialysis"

3.2.11 CCN History

Facility ownership changes that result in a change of CCN are treated as if the facility closed then re-opened in ESRD QIP, 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 transfusions for STrR) are assigned to the facility responsible for their care at the time of the hospitalization or transfusion. If that care was provided under the prior management, the new management will not held responsible for that care.

4. Methodologies for Deriving ESRD QIP Scores

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 (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 2 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 Transfusion Ratio	10	21	Lower Ratio indicates better performance	Patient-years at Risk
VAT: Catheter	11	25	Lower Rate indicates better performance	Eligible Patients
VAT: Fistula	11	25	Higher Rate indicates better performance	Eligible Patients
Dialysis Adequacy: Comprehensive Kt/V	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

Table 2: PY 2019 Clinical Measures and the defined Lower Threshold, Upper Threshold, Preferred Measure 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 CY 2014 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 for the given measure (C).
   b) The ESRD QIP system will determine the preferred measure rate directionality for the given clinical measure:
      i) For measures where the higher rates are better (for example, the Vascular Access Type (VAT): Fistula clinical measure and the Dialysis Adequacy clinical measures), a small facility's adjusted performance rates (t) will be calculated as follows:
         (1) 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)

$$\text{If } p<B, \text{ then } t = [w * p] + [(1-w) * B]$$

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, Standardized Readmission Ratio (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: Add the results from Step 2 and Step 3 to get the small facility's adjusted measure rate (t)

$$\text{If } p>B \text{ then } t = [w * p] + [(1-w) * B]$$

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) 2019

Table 3 defines key achievement and improvement scoring terms.

Term	Definition
Achievement threshold	The 15th percentile of performance rates nationally during 2015
Benchmark	The 90th percentile of performance rates nationally during 2015
Improvement threshold	Your facility's performance rate during 2016
Performance period	All of calendar year 2017*
Performance standard	The 50th percentile of performance rates nationally during 2015
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 3. Key Achievement and Improvement Scoring Terms

NOTES:

* For the NHSN HCP Influenza measure, the performance period is October 1, 2016 through March 31, 2017.

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

(15^{th} Percentile – 90^{th} percentile of performance rates nationally during 2015).

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 2016 – 90^{th} percentile of performance rates nationally during 2014).

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 2014, but does has sufficient information to calculate an achievement rate during 2015, 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 Exception to PY 2019 Scoring for ICH CAHPS Clinical Measure

- The In-Center Hemodialysis - Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) survey is scored on the basis of 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.

  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, certain groups of measures are then combined to form a single measure topic score. This process is applied to the two vascular access type clinical measures. The scores for these measure topics are calculated using the following steps.

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

Example #1

#	Calculation Definition	Value
	Clinical Measure Scores	
a	VAT Fistula Measure Score	
b	VAT Catheter Measure Score	

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.

	Measure Weight Calculation	
c	Number of patients included in VAT Fistula Measure Score calculation	
d	Number of patients included in VAT Catheter Measure Score calculation	
e	Determine total number of patients for weighting denominator *Add c and d*	

3) Determine the weighted score for each measure within the topic. This is done by dividing the number of patients included in each individual measure by the total number of patients across all measures within the measure topic, and multiplying by the respective measure score.

   Note: When determining the total number of patients across all measures within a topic only eligible measures are considered.

Measure Topic Score Calculation		
f	Weight the VAT Fistula Measure Score *Calculate a x (c ÷ e)*	
g	Weight the VAT Catheter Measure Score *Calculate b x (d ÷ e)*	
21h	Combine Measure Scores *Add f + g and round*	
21i	**Vascular Access Type Measure Topic Score (from 21h)**	

Finally, to determine the measure topic score, sum the weighted measure scores of each eligible measure and round to the nearest whole number with halves rounded up.

> *Note: The number of patients is used when calculating measure topic scores regardless of whether the measure uses patients or patient months in its denominator. Furthermore, the number of patients represented in the denominator during the performance period is used regardless of whether the assigned measure score was taken from the achievement or improvement methodology.*

4.2 Calculating a Facility's Total Performance Score from the Facility's Measure Scores

To qualify for a Total Performance Score (TPS), the facility must have earned a score on at least one measure in the Clinical Measure Domain and one measure in the Reporting Measure Domain. Eligiblity in the Safety Measure Domain does not impact TPS eligibility. A facility that does not meet the requisite number of scored measures will receive a TPS of "No Score".

4.2.1 Calculating the Clinical Measure Domain Score

The Clinical Measure Domain is comprised of subdomains that group clinical measures in to two categories. As seen in Table 4 below, each individual clinical measure or measure topic is assigned a specific weight within its respective subdomain.

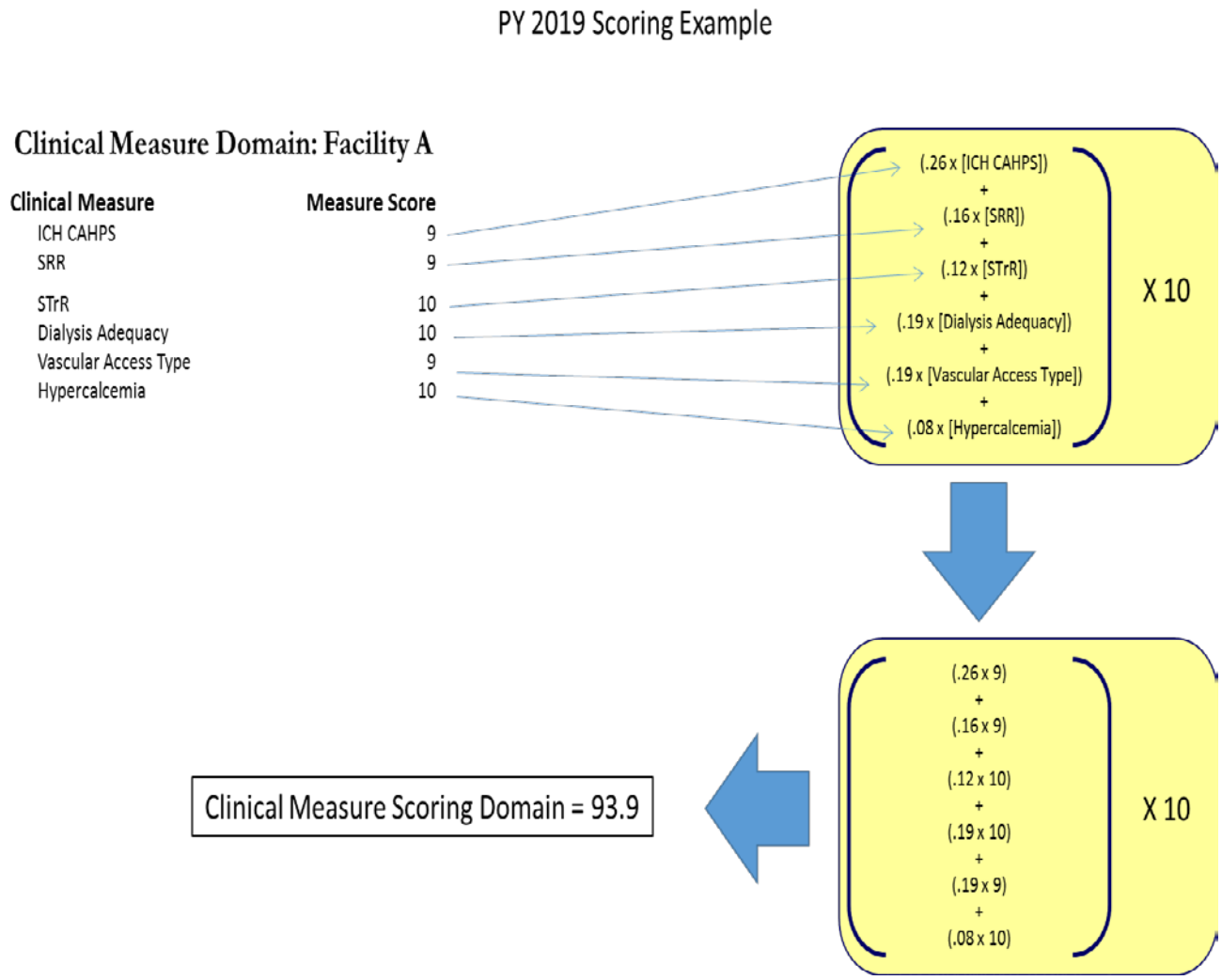
PY 2019 Measures/Measure Topic by Subdomain	Measure Weight in the Clinical Measure Domain Score
Patient and Family Engagement/ Care Coordination Subdomain	42%
ICH CAHPS measure	26%
SRR measure	16%
Clinical Care Subdomain	58%
STrR measure	12%
Dialysis Adequacy measure topic	19%
Vascular Access Type measure topic	19%
Hypercalcemia measure	8%

Table 4. Clinical Measure/ Measure Topic Weights

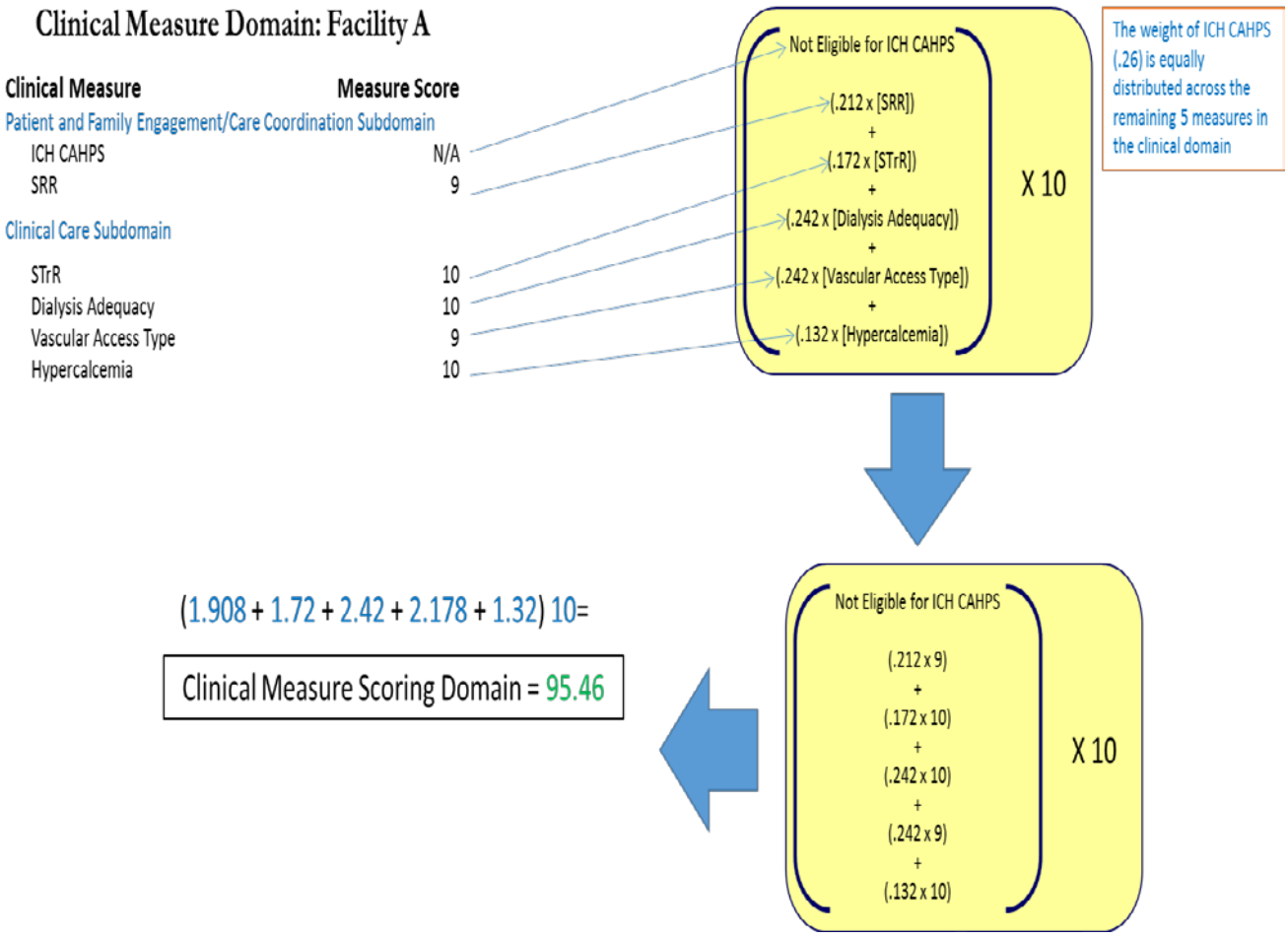
In order to calculate the Clinical Measure Domain Score, each individual measure, or measure topic score is converted to a weighted measure score. These scores are then summed to make up the Clinical Measure Domain score. The clinical subdomain scores can also be determined by summing the weighted scores within each of the respective subdomains. See the example below for a hypothetical scenario of the Clinical Measure Domain Score calculation.

Note: Although the description includes a step for calculating the subdomain scores, it is important to note that this calculation is not necessary. Clinical domain scores should be calculated solely based on the individual measure weights as shown in the examples below.

Example I: Eligible for all measures in PY 2019



Example II: Eligible for all but one measure in the Clinical Domain for PY 2019



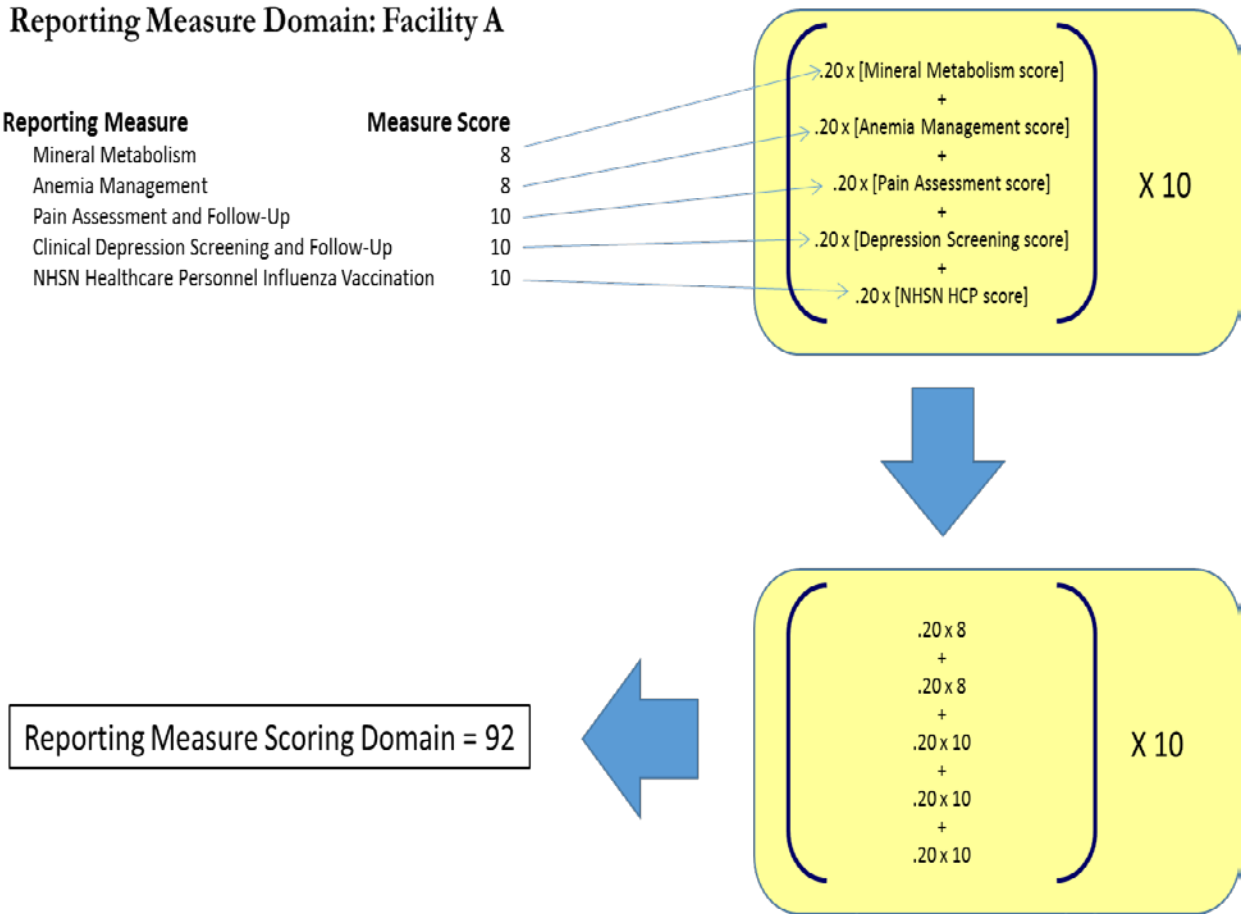
4.2.2 Calculating the Reporting Measure Domain Score

In order to calculate the Reporting Measure Domain Score, each individual measure is converted to a weighted measure score. As seen in Table 5 below, each individual measure is assigned a specific weight. These weighted scores are then summed to make up the Reporting Measure Domain score.

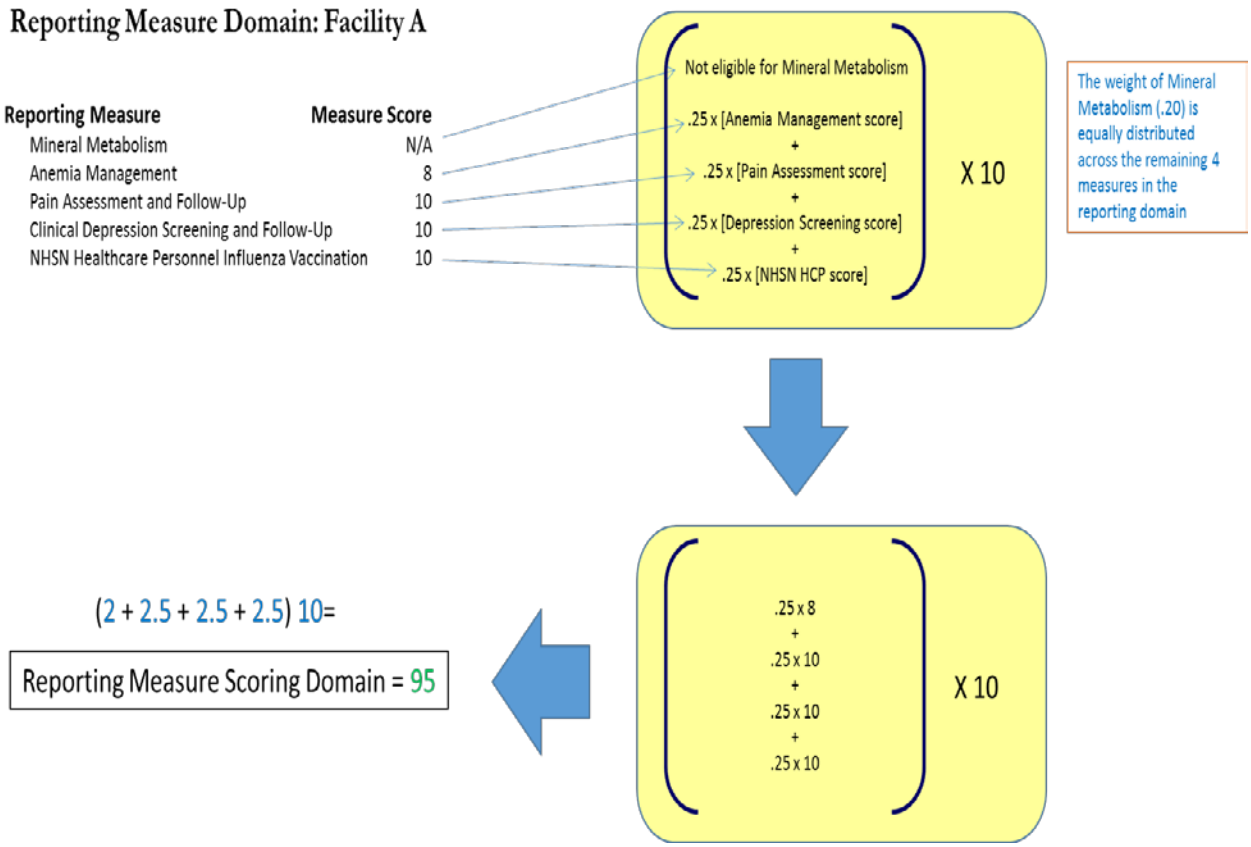
PY 2019 Reporting Measure	**Measure Weight in the Reporting Measure Domain Score**
Mineral Metabolism	20%
Anemia Management	20%
Pain Assessment and Follow-Up	20%
Clinical Depression Screening and Follow-Up	20%
NHSN Healthcare Personnel Influenza Vaccination	20%

Table 5. Reporting Measure Weights

Example I - Eligible for all Reporting Measures in PY 2019



Example II - Eligible for all but one Reporting Measures in PY 2019



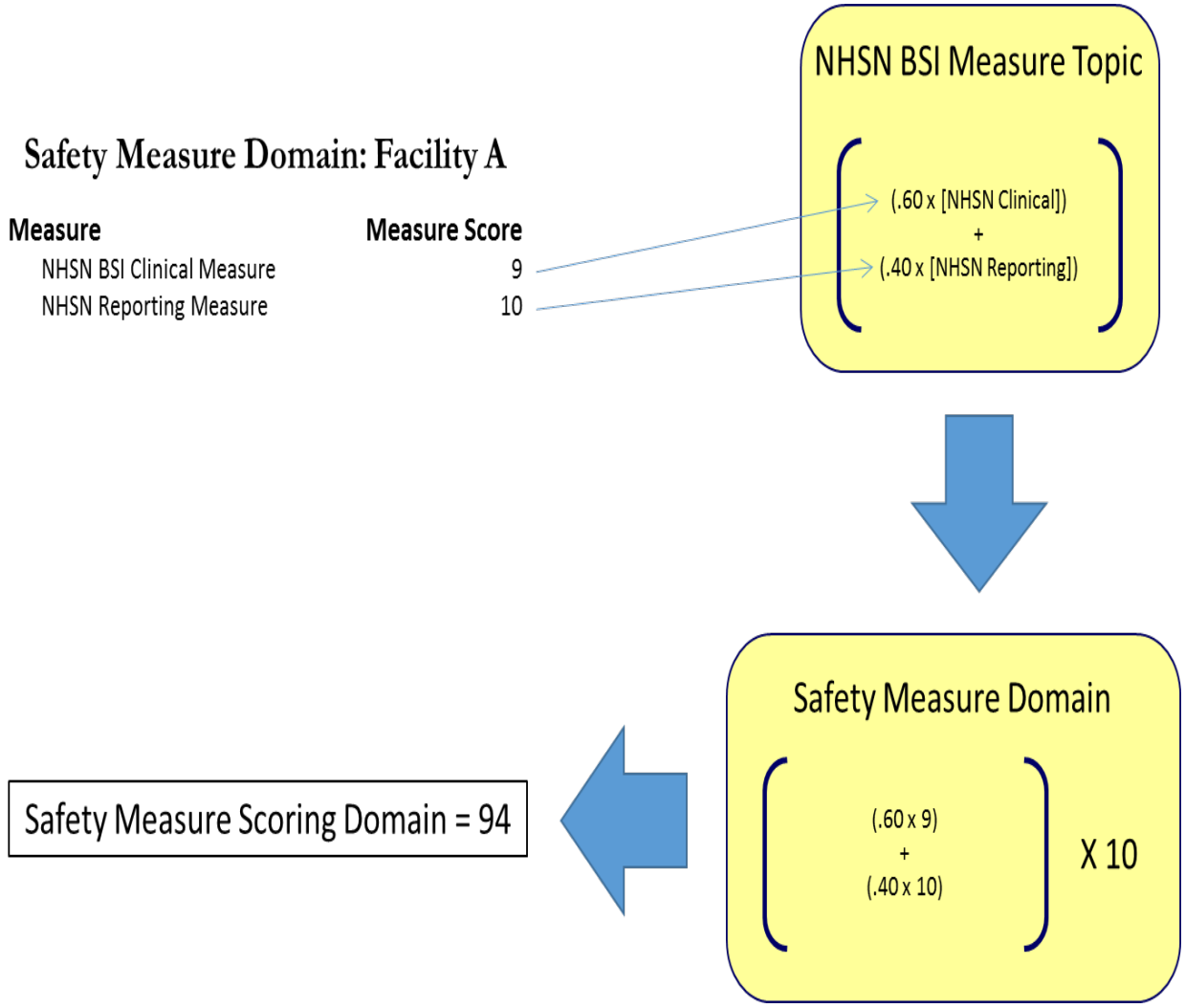
4.2.3 Calculating the Safety Measure Domain Score

In order to calculate the Safety Measure Domain Score, each individual measure is converted to a weighted measure score. As seen in Table 6 below, each individual measure is assigned a specific weight. These weighted scores are then summed to make up the Safety Measure Domain score. These scores are then summed to make up the Clinical Measure Domain score.

PY 2019 Safety Measure	Measure Weight in the Safety Measure Domain Score
NHSN BSI Clinical Measure	60%
NHSN Dialysis Event Reporting Measure	40%

Table 6. Safety Measure Weights

Example I – Calculating the safety measure domain in PY 2019



4.2.4 Redistributing 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 within the clinical domain, the facility is not scored on the measure and the corresponding measure weight will be reallocated equally across all remaining measures in the clinical domain.

Likewise, if a facility does not meet the eligibility requirements for a measure in the reporting domain, the facility is not scored on the measure and the corresponding measure weight will be reallocated equally across all remaining measures in the reporting domain.

The safety domain is handled slightly differently in that if a facility is not eligible to be scored in the safety domain, then the domain weight will be redistributed equally across all remaining measures (clinical and reporting).

Please note that it is not possible to be eligible for only one measure in the safety domain as they both have the same facility exclusion criteria.

Calculation of Relative Weights Applied to Measure Scores

- The Total Performance Score is comprised of the three measure domains below:
  - **Clinical measure Domain** 75%
  - **Reporting measure Domain:** 10%
  - **Safety measure Domain:** 15%

The Total Performance Score (TPS) for the facility is then calculated by multiplying the Clinical Domain score by 0.75 the Reporting Domain score by 0.10 and the Safety Domain score by 0.15 adding the results, as follows:

$$TPS = (0.75 * Clinical\ Domain\ Score) + (0.1 * Reporting\ Domain\ Score) + (0.15 * Safety\ Domain\ Score)$$

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

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 Total Performance Score (TPS) compares to the minimum Total Performance Score specified for the payment year. See Table 7 below for the payment reductions associated with the TPS received.

Total Performance Score	Payment Reduction
100-60 (Score meets or exceeds minimum TPS)	No reduction
59–50 (1 to 10 points below minimum TPS)	0.5%
49–40 (11 to 20 points below minimum TPS)	1.0%
39–30) 21 to 30 points below minimum Total Performance Score	1.5%
29–0 31 or more points below minimum Total Performance Score	2.0%
No Score calculated	No reduction

Table 7. TPS and Payment Reduction for PY 2019

5. Calculating Star Ratings for DFC

5.1 Introduction

The Centers for Medicare & Medicaid Services (CMS), developed the Dialysis Facility Compare (DFC) Star Rating System to rate the overall quality of care provided by dialysis facilities. Each facility receives a rating of between 1 and 5 stars. Facilities with 5 stars are considered to deliver much above average quality of care and those with 1 star are considered to deliver care that is rated much below average quality compared to other dialysis facilities in the United States. This section describes the updated methodology developed for the DFC Star Rating system, and highlights changes to the methodology originally implemented in January 2015 on the Medicare DFC website. The changes primarily focus on measure scoring relative to a baseline year in order to show facility improvement. The update reflects input received from a Technical Expert Panel (TEP) and other stakeholder input on the scoring of measures and calculation of the final Star Ratings.

5.2 DFC Quality Measures Used in Calculating the Star Ratings

The Dialysis Facility Compare (DFC) Quality Measures (QMs) used in the updated Star Ratings are the same measures that were included in the original Star Rating reported on DFC in January 2015, but are updated to include more current results. Specifically, nine of the thirteen QMs reported on the CMS DFC website are used to calculate the Star Rating for facilities based on the October 2016 release date (Calendar Year 2015 data).

5.2.1 Quality Measures Used in Star Rating Calculation

1. Standardized Transfusion Ratio (STrR) (lower is better, updated yearly)
2. Standardized Mortality Ratio (SMR) (lower is better, updated yearly)
3. Standardized Hospitalization Ratio (SHR) (lower is better, updated yearly)
4. Percentage of adult hemodialysis patients (HD adult) who had enough wastes removed from their blood during dialysis: Kt/V greater than or equal to 1.2 (higher is better, updated quarterly)
5. Percentage of pediatric hemodialysis patients (HD pediatric) who had enough wastes removed from their blood during dialysis: Kt/V greater than or equal to 1.2 (higher is better, updated quarterly)
6. Percentage of adult peritoneal dialysis patients (PD adult) who had enough wastes removed from their blood during dialysis: Kt/V greater than or equal to 1.7 (higher is better, updated quarterly)
7. Percentage of adult patients who received treatment through an arteriovenous fistula (AV fistula) (higher is better, updated quarterly)
8. Percentage of adult patients who had a catheter (tube) left in a vein 90 days or longer, for their regular hemodialysis treatment (catheter >90 days) (lower is better, updated quarterly)

9. Percentage of adult dialysis patients who had an average calcium over the past three months greater than 10.2 mg/d (hypercalcemia) (lower is better, updated quarterly)

To improve the ability to compare facilities with HD adult, HD pediatric, and PD adult patients, the three Kt/V measurements are combined into a single measure. The percentage of patients achieving Kt/V greater than the specified thresholds for each of the three respective patient populations (adult PD patients, adult HD patients, and pediatric HD patients) was weighted based on the number of patient-months of data available. The resulting measure (all 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 measures, seven final quality measures are used to calculate the Star Rating.

5.3 Overview of Star Rating Methodology

5.3.1 Developing Quality Measure Domains

The seven final quality measures are further grouped into different quality measure domains, which are derived in the same way as in the original Star Rating methodology.

Domains are empirically derived by using factor analysis, which assesses correlations among quality measures used in the Star Rating. Factor analysis detects underlying latent factors that are the source of correlations between variables. The method informed the creation of three domains of quality measures for previous iterations of the DFC Star Rating. Three outcome measures for transfusions, mortality, and hospitalization (STrR, SMR, and SHR) form the first domain, which is named "Standardized Outcomes (SHR, SMR, STrR)". The AV fistula and catheter measures formed the second domain, which is named "Other Outcomes 1 (fistula, catheter >90 days)." The all Kt/V and hypercalcemia QMs form the third domain which is named "Other Outcomes 2 (Kt/V, hypercalcemia)." These domains are equally weighted in determining the final score for the Star Rating.

In the updated methodology, factor analysis is *only* conducted for the baseline year. The updated common factor analysis with 2014 data (the baseline year used to set scores for the quality measures in the updated DFC Star Rating) confirmed the appropriateness of retaining the current domains. Results of the updated analysis are summarized in Figure 14 and Table 8. In Figure 14, each eigenvalue reflects the proportion of data variance explained by the corresponding factor. The drop-off after the third eigenvalue shown in the figure implies that the data can be adequately represented by three factors. [1]

In Table 8, we show the quality measure loadings on three derived factors. Factor loadings represent the association between each measure and the derived factors, and confirmed the results derived previously. Table 9 further shows that within each domain of measures, the measures are more correlated with each other than with measures in other domains. Both of these

[1]SAS Annotated Output: Factor Analysis. UCLA: Statistical Consulting Group. From www.ats.ucla.edu/stat/sas/output/factor.htm (accessed March 3, 2016).

results support the decision to group measures as in previous iterations. We continue to call the domains Standardized Outcomes, Other Outcomes 1, and Other Outcomes 2.

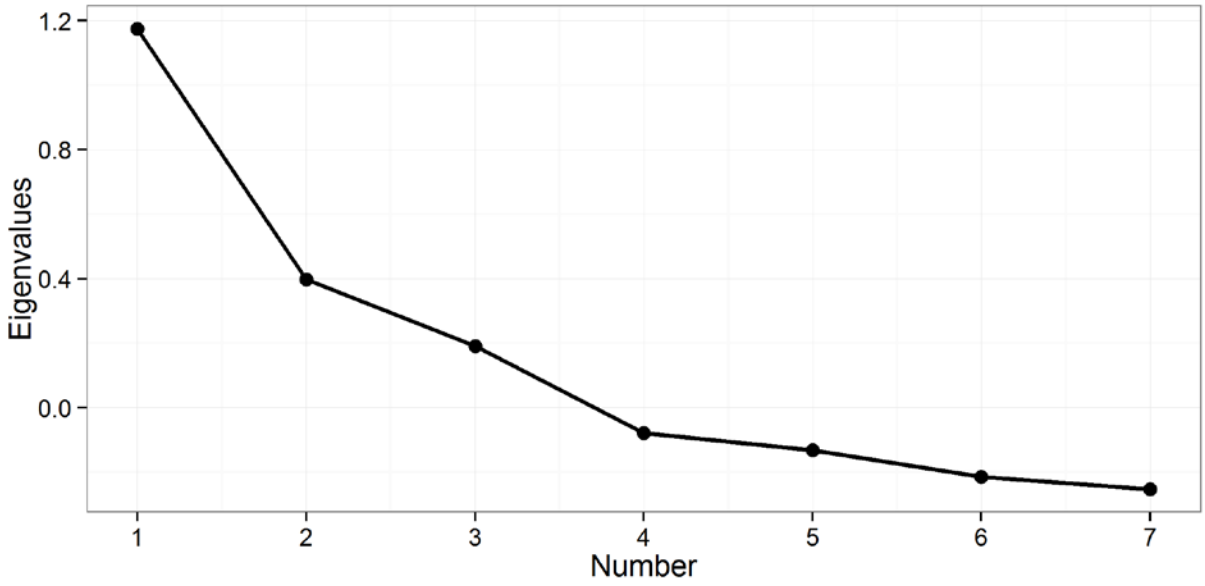


Figure 14. Factor Analysis: Screen Plot of Eigenvalues

	Factor 1	Factor 2	Factor 3
SMR	**37***	17	12
SHR	**55***	13	4
STrR	**53***	8	1
Kt/V	11	-9	**36***
Hypercalcemia	1	7	**35***
Fistula	14	**55***	12
Catheter > 90 days	17	**55***	16

Table 8. Factor Analysis: Loadings on Rotated Factors

Measures	STrR	SHR	SMR	All Kt/V	Hypercalcemia	Fistula	Catheter > 90 days
STrR	1.000	***0.423***	***0.227***	0.083	0.008	0.134	0.131
SHR		1.000	***0.239***	0.139	0.016	0.152	0.189
SMR			1.000	0.145	0.018	0.149	0.100
All Kt/V				1.000	***0.277***	0.094	0.102
Hypercalcemia					1.000	0.091	0.102
Fistula						1.000	***0.410***
Catheter > 90 days							1.000

Table 9. Spearman Correlation of Measures (Measures realigned so higher values are better)

5.3.2 Measure Scoring

As the DFC QMs have different distributions and scales, we transform the values of individual measures to measure scores in order to make them comparable across different measures and different facilities. The term "measure value" refers to the original value that a facility obtains on a quality measure (e.g., 65% with fistula). The term "measure score" refers to the score associated with a specific measure value that is used in generating the DFC Star Rating. The scoring methodology is described further below.

5.3.2.1 Baseline Year

In the updated methodology, the measure scores associated with a measure value are defined according to the criteria established in the *baseline year*. That is, every possible value for a quality measure is assigned a measure score based on analyzing the *baseline year* data. The initial *baseline year* will be data from 2014, which was released publically on Dialysis Facility Compare in October of 2015. This allows facilities to maintain or improve their Star Rating if they maintain or improve performance on the quality measures compared to the baseline year score. A new baseline will be established when the Star Rating distribution becomes ineffective at communicating differences in outcomes between facilities due to shifting to the extreme and/or when individual measures are added or removed.

In order to implement the baseline year score, it is important to recognize that SMR, SHR, and STrR measures represent ratios (observed events/expected events) based on expected events relative to the *current year*. Before applying scores to standardized ratio measures in the *current year*, we multiply these ratios by an adjustment factor. The adjustment factor, which accounts for differences in population event rates between the baseline year and the *current year*, is applied so that an adjusted current year ratio value reflects the same value it would have taken on in the baseline year. The adjustment factor multiplied to the standardized ratio is the same for all facilities in the *current year*; it is the average national observed event rate in the *current year* divided by the average national observed event rate in the baseline year. *Current year* refers to the calendar year of data that is being presented as new on DFC.

To illustrate, we provide an example using the 2013 data as a baseline with 2014 serving as the *current year*. The STrR example shows the adjustment that would be made for data collected in 2014 (i.e., *current year*) if the baseline year being implemented was 2013:

- 2013 transfusions per patient year: 0.433
- 2014 transfusions per patient year: 0.408
- Adjustment factor: 0.408 / 0.433 = 0.941

Since the transfusion event rate was lower in 2014 than in 2013, the expected number of events for the average facility is lower in 2014. By multiplying STrR in 2014 by a factor of 0.941 to create an adjusted STrR to use in the Star Rating, these facilities are effectively being measured by 2013 criteria.

Implementation of the baseline year fundamentally changes the interpretation of the measure scores and the resulting final facility scores and Star Ratings. In the original system, the values and ratings reflected the comparison of the specific facility to its peers in the same year. The revised system's values and ratings have the interpretation of how the facility performed in the *current year* relative to the typical facility in the baseline year. For example, if the *current year* is 2016 and the baseline year is 2014, a facility's values and ratings will reflect how well its *current year* performance would have rated in comparison the performance of peer facilities two years earlier.

5.3.2.2 Baseline Year Measure Scoring Methodology

This section outlines how the baseline year data is used to define measure scores. The measure values in the current DFC Star Rating are either ratios or percentages. Different scoring methods are applied to these two different types of measures when developing scores in the baseline year.

5.3.2.2.1 *Percentage Measures*

The four percentage measures (Kt/V, hypercalcemia, catheter >90 days, and fistula) vary in their distribution. These measures are scored with truncated z-scores in the updated methodology. 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.

The scoring algorithm follows:

- Percentage measures in the baseline year are realigned so that the highest value (100) represents care much above average and the lowest value (0) represents care that is much below average. This is to ensure scored measures have the same directionality before they are combined.
- Calculate the z-scores of realigned measures. All scored measures now have mean of 0 and variance of 1 at this step. Variance stabilization ensures that measures are given equal influence if equally weighted in the rating.

- Perform truncation of the z-scores at an upper and lower bound on the z-score distribution for each measure.
- These truncated scores are then subtracted by their mean and divided by their standard deviation 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 are chosen so that all final measure scores have a maximum range of -2.58 to 2.58. A detailed example is shown in the Additional Details section 5.8.

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 that Star Ratings are not determined by outlier performance on a single measure. Figure 15 shows the distribution of measure values for Kt/V on the left and the distribution of measure scores for Kt/V on the right.

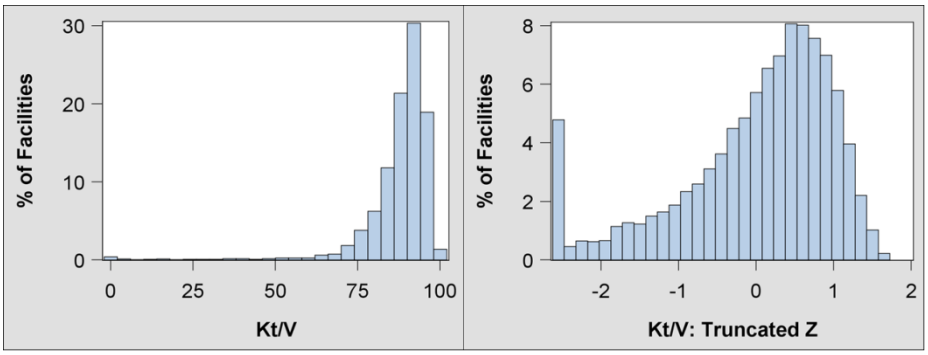


Figure 15. Example of Scoring Kt/V

5.3.2.2.2 *Standardized Ratio Measures*

The three standardized ratio measures are scored differently than the four percentage measures since the quality associated with a unit change in a ratio measure is not likely to be equally spaced. For example, the quality difference between ratios of 0.1 and 1 is not the same as the quality difference between ratios of 1 and 1.9. Probit scoring, a ranking approach described below, better reflects spacing differences than z-scores, which assume equal spacing. In addition, since the probit function maps percentiles of the standardized ratio measures to a distribution with mean 0 and variance 1, this type of scoring can be easily combined with the percentage measures (Kt/V, hypercalcemia, catheter >90 days, fistula), which are scored with truncated z-scores that also have mean 0 and variance 1. For this reason, the probit scoring technique is used for the ratio measures to define scores in the baseline year.

To create probit scores, we input a "percentile/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. 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 $\phi^{-1}(0.5/100) = -2.58$ and the maximum probit score is $\phi^{-1}(99.5/100) = 2.58$.

The probit scores for ratio based measures and the truncated z-scores for percentage based measures need to 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.

The probit scoring algorithm at the baseline year follows:

1. Calculate the percentiles of the baseline year measure values, which are to be fed into the probit function.
2. Realign the percentiles 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.
3. Map the percentiles to the probit scores: probit score = ϕ^{-1} (percentile ÷ 100). All scored measures now have mean 0 and variance 1 at this step.

Figure 16 shows the distribution of measure values for SMR on the left (where lower values are better) and the distribution of measure scores for SMR on the right (where higher scores are better).

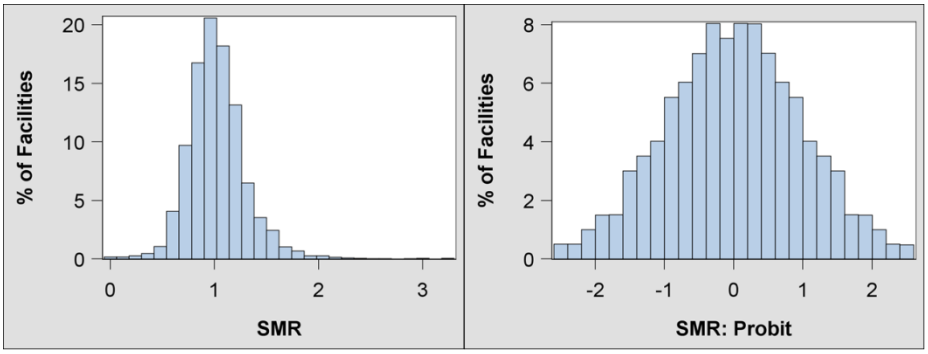


Figure 16. Example of Scoring SMR

5.3.3 Calculating Measure Scores for the Current Year

5.3.3.1 Percentage Measures

The key idea behind scoring measures relative to the baseline year data is to map each measure value to the same score that the measure value would have been mapped to if it had been observed in the baseline year. Z-scores in the *current year* are therefore calculated by subtracting the mean and dividing by the standard deviation of the measure in the baseline year. These z-scores are then truncated at the same values as truncated in the baseline year and re-standardized using the mean and the standard deviation of the truncated z-scores in the baseline year. A detailed example is shown in Tables 13 and 14 in the Additional Details section 5.8.

5.3.3.2 Ratio Measures

Current year facility ratios are first multiplied by the adjustment factor described earlier (on page 153) to create individual facility adjusted ratios. Each adjusted ratio is mapped to the same percentile that the ratio would have been mapped to if it had been observed in the baseline year. The cutoffs used for the percentiles are determined by the best measure value within each percentile in the baseline year. More detail is provided in the Additional Details section 5.8.

5.4 Combining DFC Measure Scores into Final Facility Scores

In the DFC Star Rating, the measure scores are combined to create 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 in each domain. However, a few facilities serve PD patients only and therefore do not have values for the two measures in the Other Outcomes 1 domain (fistula, catheter >90 days). These facilities are not excluded from the Star Rating, but, instead, will be rated based on the average scores for the other domains.

As noted above, with the exception of PD-only facilities, all facilities will receive a rating if they have at least one measure in each domain. Missing values for facilities that qualify for ratings are assigned the mean of the scores given to that measure in the *current year*. This method of imputation ensures that 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 and SHR, it would not be appropriate to assume that the Standardized Ratio Measure Domain should be given the maximum score of 2.58 based on the one measure for that domain (e.g., STrR). By imputing the average score for the SMR and SHR measure, we instead give the domain a submaximal above average score. In this example, this facility is still recognized as above average for this domain, but the domain score will not be based solely on the one observed score for STrR. This limits the measure score of STrR from being too influential on the final facility score.

5.5 Translating Final Scores to Star Ratings

To translate the final facility scores into 5 Star Rating categories, 4 cut-offs for the final facility scores are determined by data from the baseline year (2014). Determining these cutoffs in the baseline year further ensures that facilities are rated by the same criteria in subsequent years until a future re-baselining.

5.5.1 Defining Final Score Cutoffs in the Baseline Year

Final scores for the 2014 baseline year facilities were calculated for the purpose of determining final score cutoffs for the Star Ratings. Final score cutoffs for the baseline year (CY 2014) are set so that 10%, 20%, 40%, 20%, 10% facilities are 1-, 2-, 3-, 4-, 5-star facilities, respectively. These cutoffs are retained and further used to define Star Rating categories in the October 2016 Star Ratings, and in future Star Ratings (until a new baseline year is established).

5.5.2 Assigning Star Ratings in the Current Year

The final score cutoffs that are defined using the baseline year data are then used to assign Star Ratings to facilities for the *current year*. If the population of facilities improves in their measure performance from the baseline year, more facilities are likely to be in the higher Star Rating categories compared to the baseline year as they are being compared to the lower average performance that prevailed in the earlier baseline year rather than relative to the performance of their peers in the *current year*. In contrast to the original methodology, in this updated methodology the distribution of Star Ratings is *not fixed* for determining *current year* Star Ratings. When facilities move up in Star Ratings other facilities will not necessarily move down into lower Star Ratings, unless their performance declined compared to the baseline year.

5.6 Updated Scoring Methodology: Results

Due to the current data availability, we provide an example of implementing the updated methodology with 2014 as the *current year* and 2013 as the *baseline year* for determining measure scores and Star Rating cutoffs. In Figure 17, we show the distribution of final facility scores in 2014 using scoring criteria developed with 2013 as the baseline year. The vertical lines in the figure represent the Star Rating boundaries developed in the baseline year (2013). Since average measure values were better in 2014 than 2013, the final score distribution has shifted right, resulting in more facilities in the higher Star Rating categories.

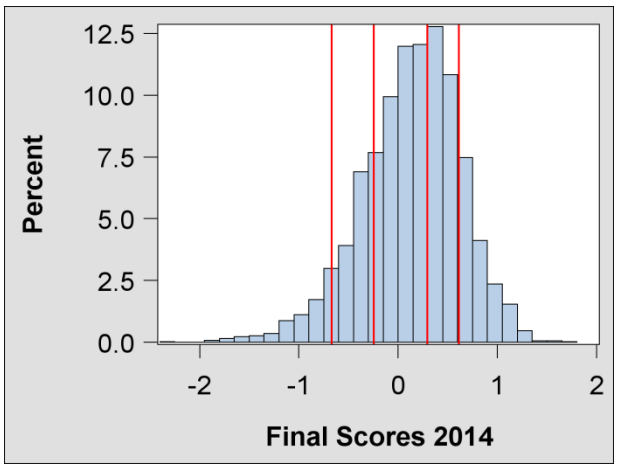


Figure 17. Distribution of Final Facility Scores in 2014
(scored and rated by 2013 baseline year criteria)

***** Red Lines represent Star Rating boundaries defined in the baseline year (2013 in this example)

In Table 10, we show the mean final score and measure value within each Star Rating category for this example. The average measure values observed in a given Star Rating category in 2014 are consistently better than the average measure values observed in a lower Star Rating category. Additionally, we provide the number and percentage of facilities in each category. In this example, there were approximately 5% more facilities in each of the 4 and 5 star categories than in 2014 compared to the baseline year (i.e., in the 2013 baseline year 20% of facilities were

assigned 4-stars; 10% assigned 5-stars). Similarly, there are fewer facilities assigned 1-star in 2014 compared to the baseline year (6% vs 10%).

Measure	★	★★	★★★	★★★★	★★★★★
Facility N (%)	373 (6%)	909 (15%)	2234 (38%)	1479 (25%)	877 (15%)
Final Score	-0.97	-0.41	0.05	0.45	0.83
SMR	1.38	1.12	1.04	0.95	0.84
SHR	1.31	1.15	1.03	0.92	0.75
STrR	1.50	1.28	1.05	0.85	0.64
Kt/V	80.05	87.23	90.16	92.77	94.05
Hypercalcemia	4.59	3.59	2.30	1.37	0.99
Fistula	49.31	57.42	63.14	68.32	75.35
Catheter	21.08	14.88	10.29	7.42	5.28

Table 10. Updated Methodology: Mean Measure Values and Final Facility Scores within each Star Rating Category (2014 results with 2013 as baseline year)

	Updated ★	Updated ★★	Updated ★★★	Updated ★★★★	Updated ★★★★★	Total
Original ★	316	240	24	0	0	580 (10%)
Original ★★	48	530	575	14	0	1167 (20%)
Original ★★★	2	126	1448	706	50	2332 (40%)
Original ★★★★	0	4	158	666	339	1167 (20%)
Original ★★★★★	0	0	0	87	485	582 (10%)
Total N (%)	366 (6%)	900 (15%)	2215 (38%)	1473 (25%)	874 (15%)	5828 (100%)

Table 11. Comparing Original and Updated DFC Star Rating Methodologies: 2014 Current Year Results with 2013 as Baseline Year for Updated Methodology

Note: Cell Counts = number of facilities

Note: Table 11 only includes facilities eligible to be scored under both the original method and updated method.

5.7 Summary of Changes Implemented for the DFC Star Ratings

This report describes the methodology that will be used to calculate dialysis facility Star Ratings in the upcoming October 2017 DFC release. It describes the updated methods used, and highlights changes from the methodology originally implemented in the January 2015 release. Major changes include:

1. Baseline Year
    - Star Ratings will be based on measure thresholds and Star Rating cutoffs developed using the 2014 DFC measure scoring results.
    - Defining the measure scores and Star Rating cutoffs in the baseline year allows the dialysis community to observe changes in performance over time, as the distribution of the Star Ratings is not constrained after the baseline year. This is illustrated in Table 11 showing the change in the distribution of the Star Ratings using the updated methodology. Facility improvement in Star Ratings in the current year will therefore not necessarily result in other facilities moving down in the Star Ratings.
    - A new baseline should be established when the Star Rating distribution becomes ineffective at communicating differences in outcomes between facilities due to shifting to the extreme and/or when individual measures are added or removed.

2. Measure Scoring
    - Apply truncated z-scores for all the percentage measures included in the Star Ratings. At present, these include: hypercalcemia, Kt/V, AV fistula, and catheter > 90 days. Using truncated z-scores is appropriate for all the percentage measures, and will handle subsequent measure shifts and skewness that could develop over time.
    - Retain the probit scoring technique for the standardized (ratio) measures. The probit scoring will be on the same scale and have the same mean (0) and variance (1) as the measures scored with truncated z- scores, facilitating the combination of all measures when calculating a final facility score.
3. Star Rating Cutoffs in the Baseline Year
    - Star Rating cutoffs in the baseline year are set based on the final facility score. These cutoffs will be retained and further used to assign Star Ratings to facilities in the *current year*.

5.8 Additional Details

5.8.1 A detailed example of scoring standardized measures

In order to map measures in the *current year* to the percentiles defined in the baseline year, percentile cutoffs must be established. Here, the cutoffs are determined by the best measure value within each percentile in the baseline year. For any measure value in the *current year* that falls in the gap between percentile cutoffs in the baseline year, the measure value in the *current year* will be "rounded up" to the higher of the two percentile values. For example, suppose we are considering a measure for which a higher ratio is worse. If the lowest value receiving a ratio measure percentile of 47.5 in the baseline year is 1.092 and the highest value receiving the next higher percentile value of 48.0 is 1.089, then the ratio measure in a future year (after the adjustment factor is applied) of 1.090 would be given a percentile of 48.0. These "percentiles" are then fed into the probit function to determine the measure scores for the current year.

5.8.2 A detailed example of scoring percentage measures

Here we show how truncated z-scores are defined in the baseline year and applied in the *current year*. Table 12 shows how scoring is defined in the baseline year. In the first row, we display Kt/V and its summary statistics in 2013. In the second row, the z-score is obtained by subtracting each Kt/V value by its mean (87.32) and dividing by its standard deviation (11.73). In the third row, initial truncated z-scores are formed by truncating the z-score at a lower bound (-1.39) and upper bound (no truncation needed for the upper bound of Kt/V). Finally, in the fourth row, the initial Kt/V truncated z-score is re-standardized by subtracting each value by its mean (0.10) and dividing by its standard deviation (0.58). Note that the truncation bounds in row 2 are chosen by an iterative algorithm that ensures that the re-standardized measure lies within -2.58 and 2.58. The summary statistics in this table are then used to formulate the scores in the *current year* (2014).

Variable	Mean	Std Dev	Minimum	Maximum
Kt/V	87.32	11.73	0	100
Kt/V Z-score	0	1	-7.44	1.08
Initial Kt/V Truncated Z-score	0.10	0.58	-1.39	1.08
Final Kt/V Truncated Z-score (re-standardized)	0	1	-2.58	1.71

Table 12. Defining Scores for Kt/V in the baseline year (2013)

Table 13 shows how scoring is defined in the *current year*. In the first row, we display Kt/V and its summary statistics in 2014. In the second row, the z-score is obtained by subtracting each Kt/V value by the baseline year mean (87.32) and dividing by the baseline year standard deviation (11.73) in Table 12. In the third row, initial truncated z-scores are formed by truncating the z-score at the lower bound (-1.39) and upper bound (no bound needed for Kt/V) used in the baseline year. Finally, in the fourth row, the initial Kt/V truncated z-score is re-standardized by subtracting each value by the mean (0.10) and dividing by the standard deviation (0.58) of the initial truncated z-scores in the baseline year. By using the summary statistics from the baseline year (Table 12), we score Kt/V values by criteria defined in the baseline year. Note that the mean of the re-standardized score in Table 13 is higher than 0, indicating the population average improvement of Kt/V from the baseline year.

Variable	Mean	Std Dev	Minimum	Maximum
Kt/V	89.95	8.98	0.00	100.00
Kt/V "Z-score"	0.22	0.77	-7.44	1.08
Initial Kt/V Truncated Z-score	0.27	0.50	-1.39	1.08
Final Kt/V Truncated Z-score (re-standardized)	0.30	0.87	-2.58	1.71

Table 13. Defining Scores for Kt/V in the *Current Year* (2014)

5.9 Selected References

1. SAS Annotated Output: Factor Analysis. UCLA: Statistical Consulting Group. From www.ats.ucla.edu/stat/sas/output/factor.htm (accessed March 3, 2015).

Acronyms

Acronym	Definition
AFS	Annual Facility Survey
AHRQ	Agency for Healthcare Research and Quality
AV	Arterial Venous
AVF	Arterial Venous Fistula
BMI	Body Mass Index
BSI	Blood Stream Infections
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
CHOW	Change of Ownership
CKD	Chronic Kidney Disease
CMS	Centers for Medicaid and Medicare Services
CROWNWeb	Consolidated Renal Operations in a Web-enabled Network
CY	Calendar Year
DFC	Dialysis Facility Compare
DFR	Dialysis Facility Reports
EDB	Enrollment Database
ESA	Erythropoiesis Stimulating Agents
ESRD	End Stage Renal Disease
FDA	Food and Drug Administration
FSD	First Service Date
HCP	Healthcare Personnel
HCPCS	Healthcare Common Procedure Coding System
HD	Hemodialysis
HHS	Health and Human Services

Acronym	Definition
HIV	Human Immunodeficiency Virus
HWR	Hospital-wide Readmission Measure
ICH CAHPS	In Center Hemodialysis - Consumer Assessment of Healthcare Providers and Systems
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
LTCH	Long Term Care Hospitals
MedPAC	Medicare Payment Advisory Commission
NHSN	National Healthcare Safety Network
NHSN BSI	National Health Safety Network Blood Stream Infection
NQF	National Quality Foundation
OPTN	Organ Procurement and Transplant Network
PD	Peritoneal Dialysis
PMMIS	Program Management and Medical Information System
POS	Provider of Service
PPS	Prospective Payment System
PY	Payment Year
QDFC	Quarterly Dialysis Facility Compare
QIES	Quality Improvement Evaluation System
QIP	Quality Incentive Program
QM	Quality Measure
RDS	Renal Data Systems
REBUS	Renal Beneficiary and Utilization System
REMIS	Renal Management Information System
SAF	Standard Analysis File
SHR	Standardized Hospitalization Ratio
SIMS	Standard Information Management System
SMR	Standardized Mortality Ratio
SNF	Skilled Nursing Facility

Acronym	Definition
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
STrR	Standardized Transfusion Ratio
TEP	Technical Evaluation Panel
TPS	Total Performance Score
UKM	Urea Kinetic Modeling
URR	Urea Reduction Ratio
USRDS	United States Renal Data System
VA	Veterans Affairs
VAT	Vascular Access Type