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

CMS ESRD Measures Manual

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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 clinical performance measures in the Centers for Medicare & Medicaid Services (CMS) End-Stage Renal Disease (ESRD) quality programs. 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 envisions multiple ways in which the *Manual* will enhance dialysis facilities' quality improvement efforts. First, 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.

Second, CMS has designed the *Manual* to serve as a resource for improving the reliability and validity of CMS ESRD measures. CMS recognizes that patients, physicians, dialysis facilities, and other external partners are an important source of new ideas about how to collect and interpret quality data used in CMS ESRD quality programs. CMS anticipates that these ideas will be more forthcoming once the *Manual* provides interested stakeholders with a comprehensive and consolidated source of information about the measures used in CMS ESRD quality programs. Accordingly, CMS has created a feedback system on the Office of the National Coordinator's JIRA platform that anyone can use to submit questions about CMS ESRD quality measures, as well as recommendations for non-substantive, technical changes. Members of the public can access this platform at the following JIRA website. Further information about how to submit feedback to the JIRA platform, and the types of feedback expected, can be found in the JIRA user guide located at the ESRD QIP section of CMS.gov.

This first version of the *Manual* is intended to serve as an "as-is" edition. First, this means that the specifications contained within the *Manual* are applicable to the calendar year 2016 performance period. At present, the *Manual* does not convey information about measures that are planned for future adoption, nor information about the way CMS ESRD measures were implemented in the past. Second, this "as-is" version of the *Manual* consolidates published and unpublished documentation of CMS ESRD measure specifications, instead of attempting to add additional details to documentation that already exists. CMS expects to incorporate additional details in future iterations of the *Manual*, particularly in response to questions from the public and non-substantive measure changes that are recommended by interested parties.

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* via the JIRA site feedback process.

2. Measurement Information

2.1 Vascular Access Type: Fistula

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 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.

2.1.8   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.

2.1.9   Facility Exclusions

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

2.1.10   Denominator Statement

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

2.1.11   Denominator Exclusions

Denominator exclusions include:

- Patients younger than 18
- Patients not on Hemodialysis
- Patients not on ESRD treatment

Program Specific Exclusions:

ESRD QIP:
- 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

2.1.12   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

- Patient Medicare Claim Number
- Facility CCN
- Patient date of birth (DOB)

- Primary Type of Treatment ID (CROWNWeb dialysis type)
- Medicare Certified Services Offered
- Additional Services Offered (Non-Medicare)

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)

2.1.13   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.

2.1.14   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.

2.1.15   Flowchart

Figure 1 provides a flowchart that represents the processes used to calculate the Fistula Vascular Access Type measure rate.
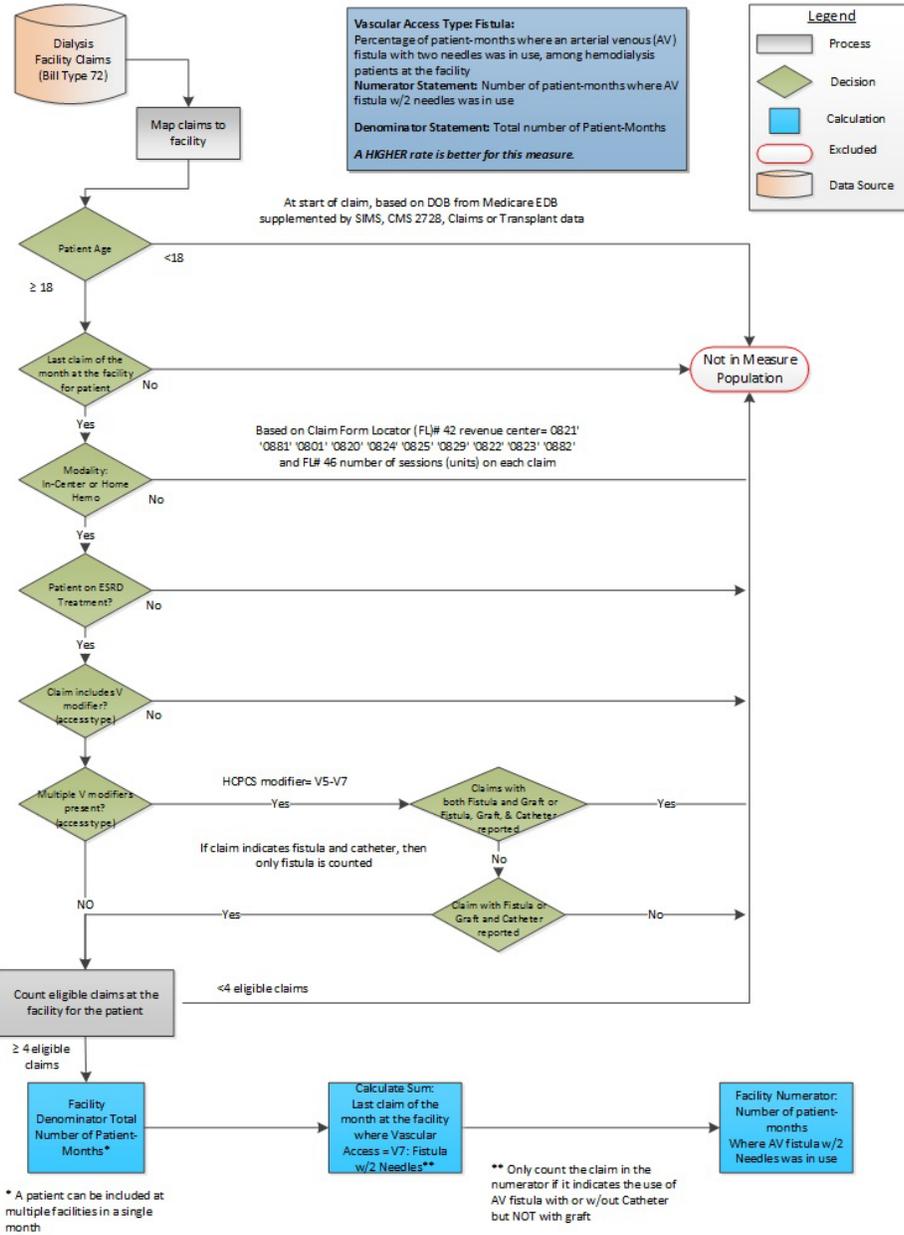
Figure 1. Vascular Access Type: Fistula Measure Rate Flowchart for ESRD QIP

2.2   Vascular Access Type: Catheter ≥ 90 Days

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   Selected References

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

2.2.8   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.

2.2.9   Facility Exclusions

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

2.2.10   Denominator Statement

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

2.2.11   Denominator Exclusions

Denominator exclusions include:

- Patients not on Hemodialysis
- Patients not on ESRD treatment

Program Specific Exclusions:

DFC Exclusions:

- − Patients younger than 18

ESRD QIP:
- − Patients younger than 18 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

2.2.12   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

- Patient Medicare Claim Number
- Facility CCN
- Patient date of birth (DOB)
- Primary Type of Treatment ID (CROWNWeb dialysis type)
- Medicare Certified Services Offered
- Additional Services Offered (Non-Medicare)

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)

2.2.13   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.

2.2.14   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.

2.2.15   Flowchart

Figure 2 provides a flowchart that represents the processes used to calculate the Catheter Vascular Access Type measure rate.
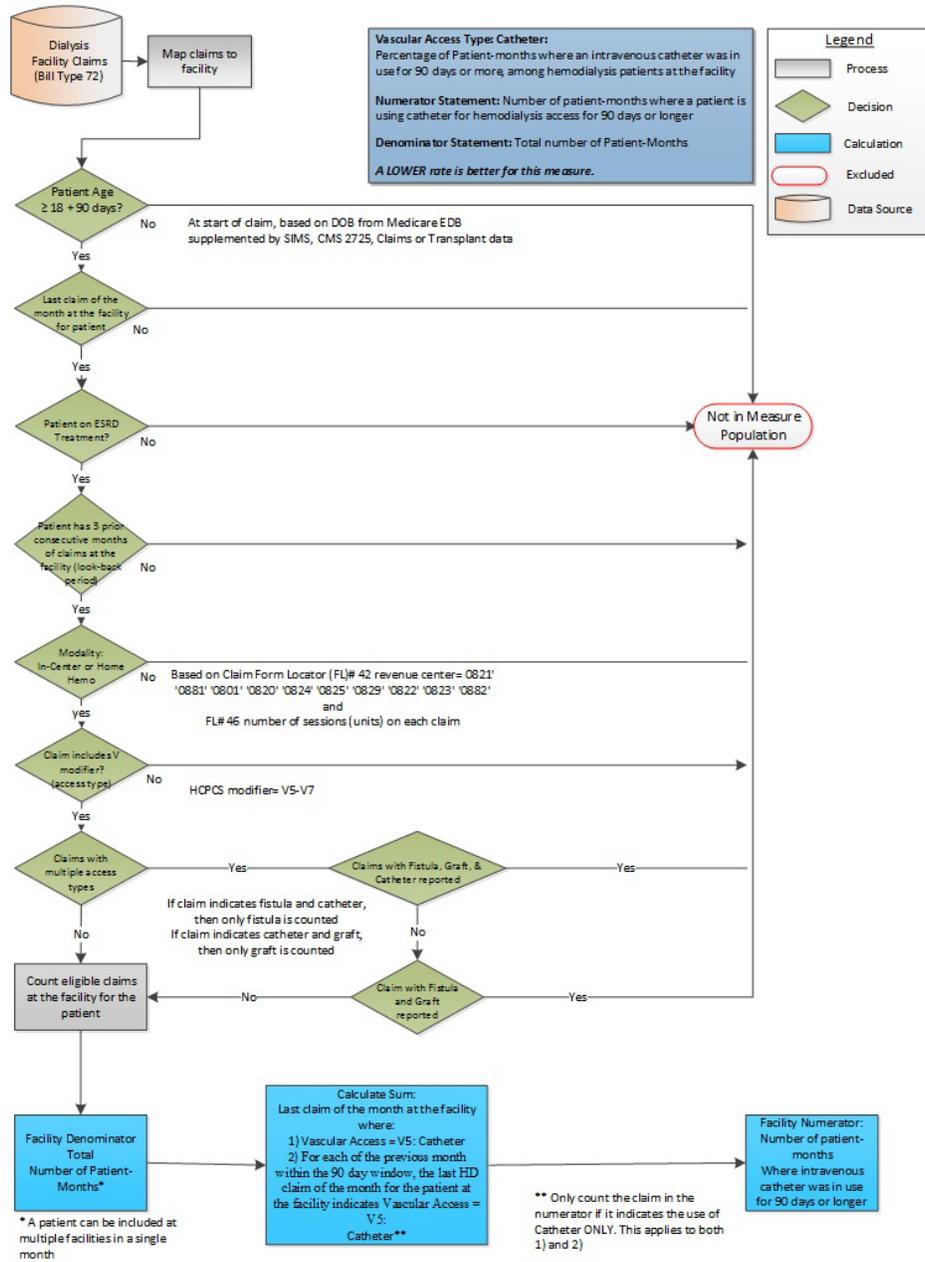
Figure 2. Vascular Access Type: Catheter Measure Rate Flowchart for ESRD QIP

2.3   Adult Hemodialysis Adequacy

2.3.1   Measure Name

Delivered Dose of Hemodialysis Above Minimum – NQF# 0249

2.3.2   Measure Description

Percentage of all adult ($\geq$ 18 years old) patient-months in the sample for analysis who had ESRD treatment for 90 days or more and dialyzing thrice weekly whose average 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 $\geq$ 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 indicate 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   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.

2.3.8   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 $\geq$ 1.2. Numerator must be in range ($0.5 \leq$ spKt/V ≤ 2.5).

2.3.9   Facility Exclusions

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

2.3.10 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.

2.3.11 Denominator Exclusions

Denominator exclusions include:

- Patients younger than 18 years

- Patients not on hemodialysis

- Patients who have had ESRD treatment for less than 90 days

- Patients on "frequent dialysis" (see Section 3.1.5)

- Patients dialyzing 2 times or fewer per week for claims covering more than 7 days

If the facility reports all non-expired Kt/V values within the valid range (that are not 9.99) on multiple claims for a patient during a month, then the last reported value is selected.

If a facility reports multiple Kt/V values 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.
- 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.

Program Specific Exclusions:

DFC:

- If any claim in the month indicates frequent or infrequent dialysis, then the entire patient-month is excluded from the calculations. See section 3.1.5 below for more details regarding the frequent dialysis exclusion.
- If the facility reported no values inside the value range, then use the value reported on the latest-reported claim.

ESRD QIP:

Patient-months are excluded from the denominator if:

- The only Kt/V value the facility reported for the patient on the claim under consideration was less than 0.5 (but not missing).
- The only Kt/V value the facility reported for the patient on the claim under consideration was greater than 2.5 (but not 9.99).
- The patient's primary treatment modality for the month is Home Hemodialysis or In-center Hemodialysis, but the primary treatment modality on the claim under consideration is Peritoneal Dialysis or Undetermined.
- The patient was treated at the facility less than seven times during the month.

- Note: If a Kt/V value of 8.88 is reported during the month, the claim will be excluded due to frequent dialysis exclusion – see Section 3.1.5 below.

If the facility reports Kt/V values on multiple valid claims for a patient in a month, then the following decision rules are used to select which value is considered when calculating the numerator:

- If all of the values reported are within the valid range, use the last reported value.
- If the facility reports a Kt/V value inside valid range without an occurrence code, and reports a 9.99 on a different claim, then use a Kt/V value of 9.99.
- If the facility reports Kt/V value inside the valid range with an occurrence code, and reports 9.99 on a different claim, then use the Kt/V value inside the valid range.

- If facility reports a Kt/V value of 8.88 and a Kt/V inside the valid range with an occurrence code, then use the last claim reported Kt/V value.

- If the facility reported no values inside the valid range, then use the latest-reported value outside the valid range that is not 9.99.

2.3.12   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

- Patient Medicare Claim Number

- 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)

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)

2.3.13   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 month. A patient can be mapped to more than one facility during a single patient-month.

2.3.14   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 ≥ 1.2.

Kt/V should also be in range (value between 0.5 and 2.5) and not expired. In-center HD Kt/V values are considered expired when they are associated with an occurrence date that is outside the first of the month and the Claim ThroughDate. Home HD Kt/V values are considered expired when they are associated with an occurrence code that is greater than four months from the claim thru date.

2.3.15   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 primary modality is In-center Hemodialysis and the selected Kt/V value has occurrence date outside the first of the month and the claim thru date, include the patient-month in the denominator, but not the numerator.

- If the primary modality is home hemodialysis and the selected Kt/V value has occurrence date greater than four months from the claim thru date, include the patient-month in the denominator, but not the numerator.

- If selected Kt/V value is missing or 9.99, include patient-month in the denominator but not the numerator.

- If selected Kt/V value is in the valid range (≥ 0.5 and ≤ 2.5) and meets the Kt/V value threshold (≥ 1.2), then include patient month in denominator and numerator.

Program Specific Calculation:

DFC:
- If the selected Kt/V value is outside of the valid Kt/V range (≥ 0.5 and ≤ 2.5) then include the patient-month in the denominator but not the numerator.

ESRD QIP:

- − If the selected Kt/V value is outside of valid Kt/V range (> 0.5 and < 2.5) and not missing or 9.99, then exclude the patient month from both the numerator and denominator.

2.3.16 Flowchart

Figure 3 provides a flowchart that represents the processes used to calculate the Kt/V Dialysis Adequacy: Hemodialysis Measure Rate for ESRD QIP.
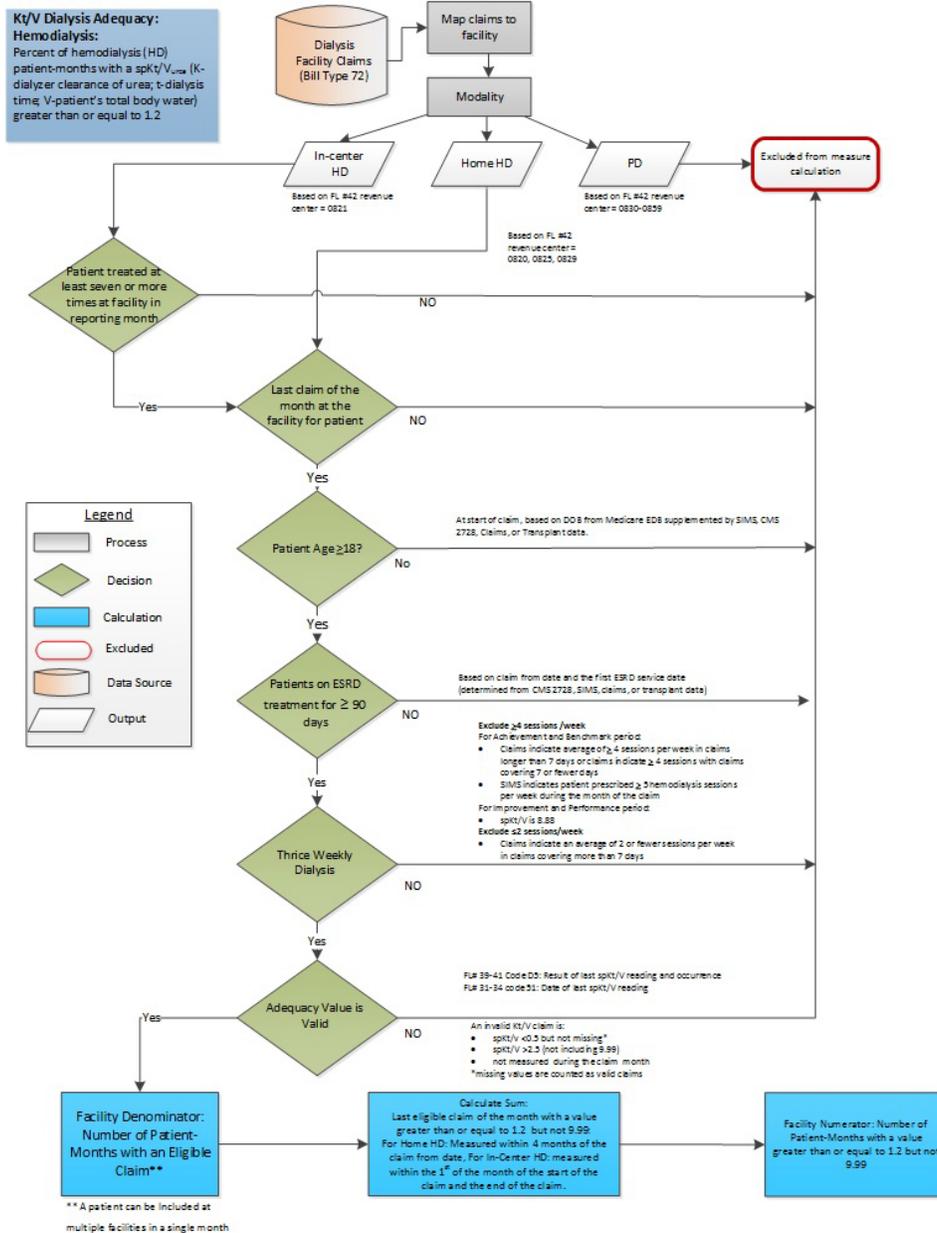
Figure 3. Kt/V Dialysis Adequacy: Hemodialysis Measure Rate Flowchart for ESRD QIP

2.4   Adult Peritoneal Dialysis Adequacy

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   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.

2.4.8   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). Numerator must be in range $(0.5 \leq \text{Kt/V} \leq 5.0)$.

2.4.9   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.

2.4.10   Denominator Statement

All adult $(\geq 18$ years old) patients in the sample for analysis who have had ESRD for 90 days and primary modality is PD.

2.4.11   Denominator Exclusions

Denominator exclusions include:

- Patients younger than age 18
- Patients not on peritoneal dialysis
- Patients on ESRD treatment for fewer than 90 days

If the facility reports all non-expired Kt/V values within the valid range (that are not 9.99) on multiple claims for a patient during a month, then the last reported value is selected.

If a facility reports multiple Kt/V values on a single claim for a patient, then the following decision rules are used to select which value is considered when calculating the denominator:

- Use the highest Kt/V value in the valid range.
- If no Kt/V values are report 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.

Program Specific Calculations:

DFC:

- If the facility reported no values inside the value range, then use the value reported on the latest-reported claim.

ESRD QIP:

Patient-months are excluded from the denominator if:

- The only Kt/V value the facility reported for the patient on the claim under consideration was less than 0.5 (but not missing).
- The only Kt/V value the facility reported for the patient on the claim under consideration was greater than 5.0 (but not 9.99).

– Patient's primary treatment modality for the month is Peritoneal Dialysis, but the patient's primary treatment modality on the claim under consideration is Home Hemodialysis, In Center Hemodialysis, or Undetermined.

If the facility reported Kt/V values on multiple valid claims for a patient during a month, then the following decision rules are used to select which value is considered when calculating the denominator:

- If the facility reports a Kt/V value inside valid range without an occurrence code, and reports a 9.99 on a different claim, then use a Kt/V value of 9.99.
- If the facility reports Kt/V value inside the valid range with an occurrence code, and reports 9.99 on a different claim, then use the Kt/V value inside the valid range.

2.4.12   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

- Patient Medicare Claim Number
- 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)

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)

2.4.13   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 month. A patient can be mapped to more than one facility during a single patient-month.

2.4.14   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 >1.7.

Kt/V should also be in range (value between 0.5 and 5.0) and not expired. PD Kt/V values are considered expired when they are associated with an occurrence code that is greater than 4 months from the claim thru date, or no occurrence code is reported.

2.4.15   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 has an occurrence code that is greater than 4 months from the Claim Through Date, or no occurrence code is reported, include the patient-month in the denominator, but not the numerator.
- If the selected Kt/V value is 9.99 or missing, include patient-month in the denominator but not the numerator.
- If selected Kt/V value is in valid range ($\geq$ 0.5 and $\leq$ 5.0) and meets the Kt/V value threshold ($\geq$ 1.7), then include the patient-month in denominator and the numerator.

Note: If the only Kt/V value the facility reports for the patient in a month is 9.99, the patient-month will be included in the denominator but not the numerator of the facility's measure rate.

Program Specific Calculation:

DFC:

- − If the selected Kt/V value is outside of valid Kt/V range ($\geq$ 0.5 and $\leq$ 5.0), then include the patient-month in the denominator but not the numerator.

ESRD QIP:

- If the selected Kt/V value is outside of valid Kt/V range (> 0.5 and < 5.0) and not 9.99 or missing, then exclude the patient month from both the numerator and denominator.

2.4.16 Flowchart

Figure 4 provides a flowchart that represents the processes used to calculate the Kt/V Dialysis Adequacy: Peritoneal Dialysis Measure Rate for ESRD QIP.
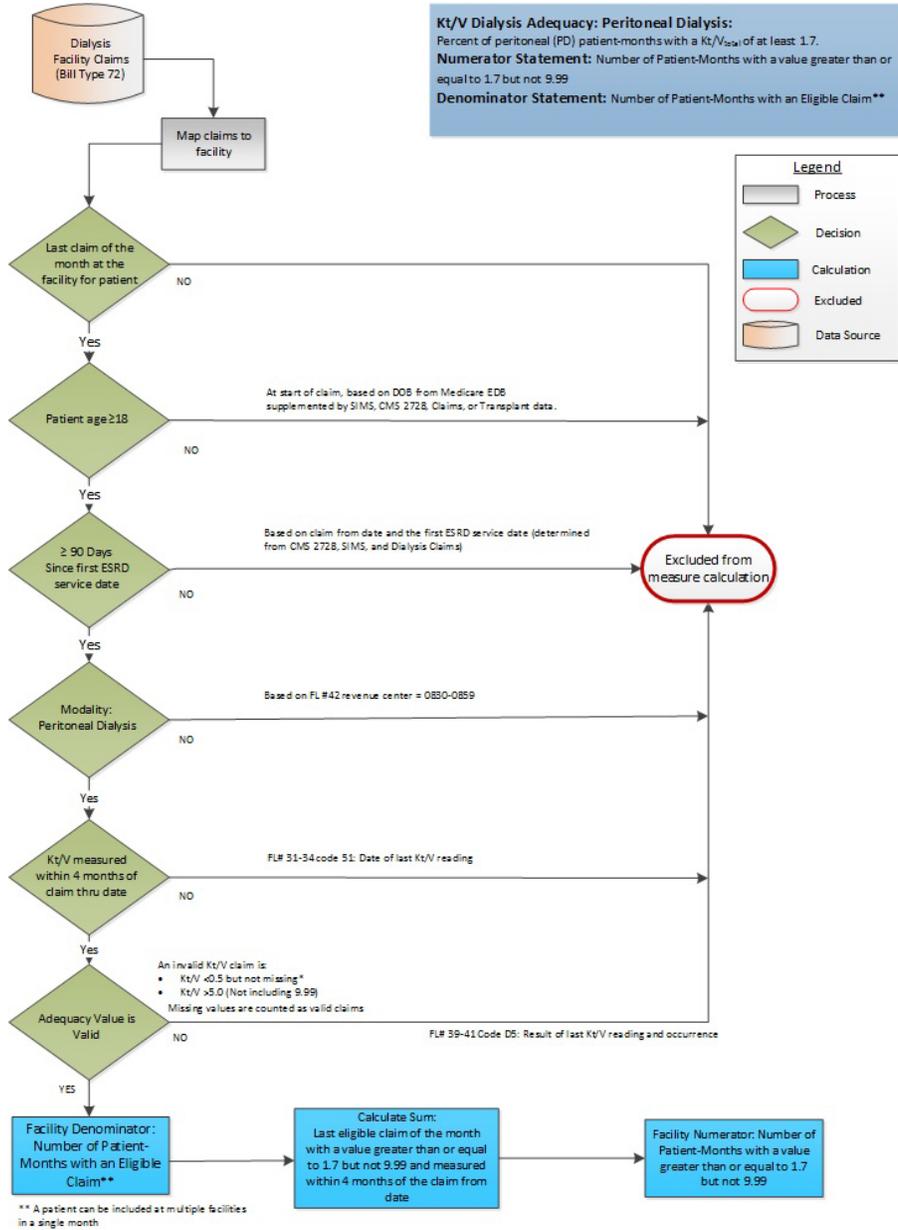
Figure 4. Kt/V Dialysis Adequacy: Peritoneal Dialysis Measure Rate Flowchart for ESRD QIP

2.5   Pediatric Hemodialysis Adequacy

2.5.1   Measure Name

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

2.5.2   Measure Description

Percentage of all pediatric ($\leq$ 18 years old) patient-months in the sample for analysis who have had ESRD treatment for 90 days or more, and dialyzing three or four times weekly whose average 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 $\geq$ 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 CPM 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   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.

2.5.8   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 $\geq$ 1.2. Numerator must be in range ($0.5\leq$ spKt/V $\leq$ 2.5).

2.5.9   Facility Exclusions

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

2.5.10   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 three or four times weekly.

2.5.11   Denominator Exclusions

Denominator exclusions include:

- Patients 18 years and older

- Patients not on in-center hemodialysis

- Patients on ESRD treatment for fewer than 90 days

- Patients dialyzing 2 times or fewer per week on average for claims covering more than 7 days. (Sessions per week is determined by dividing the total sessions by claims days and multiplying the result by seven.)

If the facility reports all non-expired Kt/V values within the valid range (that are not 9.99) on multiple claims for a patient in a month, then the last reported value is selected.

If a facility reports multiple Kt/V values 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.

- 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.

Program Specific Exclusions:

DFC:

– Note: If a Kt/V value of 8.88 is reported during the month, the patient-month will be excluded due to frequent dialysis exclusion – see Section 3.1.5 below.

ESRD QIP:

Patient-months are excluded from the denominator if:

– The only Kt/V value the facility reported for the patient on the claim under consideration was less than 0.5 (but not missing).

– The only Kt/V value the facility reported for the patient on the claim under consideration was greater than 2.5 (but not 9.99).

- The patient's primary treatment modality for the month is In-center Hemodialysis, but the primary treatment modality on the claim under consideration is Peritoneal Dialysis or Undetermined.

- The patient was treated at the facility less than seven times during the month.

- Note: If a Kt/V value of 8.88 is reported on a claim during the month, the claim will be excluded due to frequent dialysis exclusion – see Section 3.1.5 below.

If the facility reports Kt/V values on multiple valid claims for a patient in a month, then the following decision rules are used to select which value is considered when calculating the numerator:

- If the facility reports a Kt/V value inside valid range without an occurrence code, and reports a 9.99 on a different claim, then use a Kt/V value of 9.99.

- If the facility reports Kt/V value inside the valid range with an occurrence code, and reports 9.99 on a different claim, then use the Kt/V value inside the valid range.

- If facility reports a Kt/V value of 8.88 and a Kt/V inside the valid range with an occurrence code, then use the last claim reported Kt/V value.

- If the facility reported no values inside the valid range, then use the latest-reported value outside the valid range that is not 9.99.

2.5.12 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

- Patient Medicare Claim Number

- 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)

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)

2.5.13   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.

2.5.14   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.

Kt/V should also be in range (value between 0.5 and 2.5) and not expired. In-center HD Kt/V values are considered expired when they are associated with an occurrence date that is outside the first of the month and the Claim Through Date.

2.5.15   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 primary modality is In-center Hemodialysis and the selected Kt/V value has occurrence date outside the first of the month and the claim thru date, include the patient-month in the denominator, but not the numerator.
- If selected Kt/V value is 9.99 or missing, include patient-month in the denominator but not the numerator.
- If selected Kt/V value is in the valid range ($\geq$ 0.5 and $\leq$ 2.5) and meets the Kt/V value threshold ($\geq$ 1.2), then include patient month in denominator and numerator.

Program Specific Calculation:

DFC:
- − If the selected Kt/V value is outside of the valid Kt/V range (≥ 0.5 and ≤ 2.5) then include the patient-month in the denominator but not the numerator.

ESRD QIP:
- − If the selected Kt/V value is outside of valid Kt/V range (> 0.5 and < 5.0) and not 9.99 or missing, then exclude the patient month from both the numerator and denominator.

2.5.16 Flowchart

Figure 5 provides a flowchart that represents the processes used to calculate the Kt/V Dialysis Adequacy: Pediatric Hemodialysis Measure Rate for ESRD QIP.
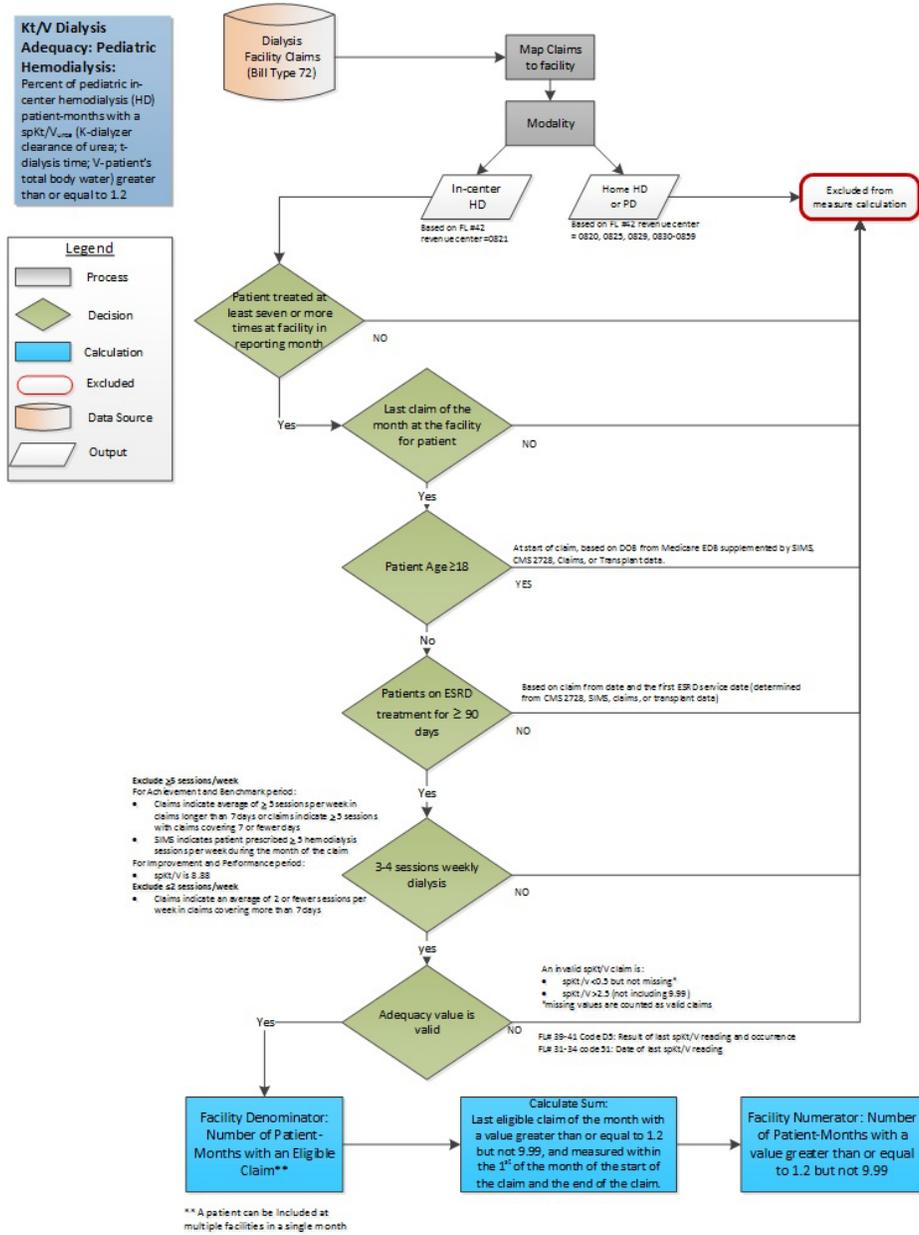
Figure 5. Kt/V Dialysis Adequacy: Pediatric Hemodialysis Measure Rate Flowchart for ESRD QIP

2.6   Pediatric Peritoneal Dialysis Adequacy

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, outcome studies referenced below have shown 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   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).

2.6.8   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).

Program Specific Calculation:

ESRD QIP:

- − Numerator must be in range (0.5< Kt/V< 5.0).

2.6.9   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.

2.6.10   Denominator Statement

All pediatric (< 18 years old) patient-months in the sample for analysis who have had ESRD for 90 days.

2.6.11   Denominator Exclusions

Denominator exclusions include:

- Patients age 18 and older
- Patients not on peritoneal dialysis
- Patients on ESRD treatment for fewer than 90 days

Program Specific Exclusions:

ESRD QIP:
- − The only Kt/V value the facility reported for the patient on the claim under consideration was less than 0.5 (but not missing).
- − The only Kt/V value the facility reported for the patient on the claim under consideration was greater than 5.0 (but not 9.99).
- − Patient's primary treatment modality for the month is Peritoneal Dialysis, but the patient's primary treatment modality on the claim under consideration is Home Hemodialysis, In Center Hemodialysis, or Undetermined.

2.6.12   Data Elements and Data Sources

These data elements have yet to be determined.

2.6.13   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 month. A patient can be mapped to more than one facility during a single patient-month.

2.6.14   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 >1.8.

Kt/V should also be in range (value between 0.5 and 5.0) and not expired. PD Kt/V values are considered expired when they are associated with an occurrence code that is greater than 6 months from the claim thru date, or no occurrence code is reported.

If the facility reports multiple Kt/V values on multiple claims for a patient during a month, then the following decision rules are used to select which value is considered when calculating the numerator:

- If all of the values reported are within the valid range, use the last reported value.

- If the facility reports a Kt/V value inside valid range without an occurrence code, and reports a 9.99 on a different claim, then use a Kt/V value of 9.99.

- If the facility reports Kt/V value inside the valid range with an occurrence code, and reports 9.99 on a different claim, then use the Kt/V value inside the valid range.

- When multiple Kt/V values are submitted on a single claims and the facility reported no values inside the valid range, then use the latest-reported value outside the valid range that is not 9.99.

If a facility reports multiple Kt/V values 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.

- If no Kt/V values are report 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.

2.6.15   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 has an occurrence code that is greater than 6 months from the claim through date, or no occurrence code is reported, include the patient-month in the denominator, but not the numerator.

- If the selected Kt/V value is 9.99 or missing, include patient-month in the denominator but not the numerator.

- If selected Kt/V value is in valid range (≥ 0.5 and ≤ 5.0) and meets the Kt/V value threshold (≥ 1.8), then include the patient-month in denominator and the numerator.

Program Specific Exclusions:

DFC:

– If the selected Kt/V value is outside of valid Kt/V range (≥ 0.5 and ≤ 5.0), then include the patient-month in the denominator but not the numerator.

ESRD QIP:

– If the selected Kt/V value is outside of valid Kt/V range (> 0.5 and <5.0) and not 9.99 or missing, then exclude the patient-month from both the numerator and denominator.

2.6.16   Flowchart

Figure 6 provides a flowchart that represents the processes used to calculate the Pediatric Peritoneal Dialysis Measure Rate for ESRD QIP.

Pediatric Peritoneal Dialysis
Percentage of pediatric peritoneal dialysis patient-months with Kt/V greater than or equal to 1.8 (dialytic+residual) during the performance period

Legend

	Process
◇	Decision
	Calculation
⬭	Excluded
	Data Source
▱	Output

Data Sources: CROWN (patient and facility data), REMIS, IDR, CMS ESRD Admin Data

Patients with less than one claim during the measurement period will be excluded from facility's measure score calculation.

Map patient claims to facilities. Map claims to patients

Repeat for each month of the measurement period.

Determine Number of eligible patient-months at the facility for each month of the measurement period

Patient 18 years or older? — Yes → Patient-month excluded

No ↓

Patient's primary modality Hemodialysis? — Yes → Patient-month excluded

No ↓

If no Kt/V value is reported for a given patient in a claim month, then the most recent Kt/V value in the prior 6 months is applied to the calculation for that month.

Patients with missing Kt/V values or Kt/V=9.99 (not reported) are included in the denominator.

Patient on dialysis for fewer than 90 days? — Yes → Patient-month excluded

No ↓

Patient has a Kt/V value less than 0.5 or greater than 5.0? — Yes → Patient-month excluded

No ↓

Patient on ESRD Treatment? — No → Patient-month excluded

Number of eligible Patient-months

Does facility have at least 11 eligible patients for the measurement period? — No → Facility excluded from measure calculation

Yes ↓

Calculate Facility Denominator: Number of eligible Patient-months → Calculate Facility Numerator: Number of Patient-months with a Kt/V value greater than or equal to 1.8 → Calculate facility measure rate for the measurement period

Figure 6. Pediatric Peritoneal Dialysis Measure Rate Flowchart for ESRD QIP

2.7   Hypercalcemia

2.7.1   Measure Name

Proportion of Patients with Hypercalcemia – NQF# 1454

2.7.2   Measure Description

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

2.7.3   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.

Given both the 2010 TEP and 2013 TEP recommendations, and the additional evidence cited in the current National Quality Foundation (NQF) submission, we maintain its importance as a clinical intermediate outcome and patient safety measure. We acknowledge the lack of interventional trials supporting a specific threshold. However, 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 QIP as a safety measure against over-use of oral-only medications following changes to the ESRD Prospective Payment System (PPS) Bundle payment. We believe Congress 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.

2.7.4   Measure Type

Intermediate Outcome

2.7.5   Improvement Noted as Higher or Lower Rate

Lower rates are better

2.7.6   Risk Adjustment

None

2.7.7   Selected References

- National Kidney Foundation: K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. American Journal of Kidney Disease 2003 42:S1-S202 (suppl 3).

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

- Block GA, Klassen PS, Lazarus JM, et al. Mineral metabolism, mortality, and morbidity in maintenance hemodialysis. Journal of the American Society of Nephrology: JASN 2004 15:2208-18.

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- Tentori F, Blayney MJ, Albert JM, et al. Mortality risk for dialysis patients with different levels of serum calcium, phosphorus, and PTH: the Dialysis Outcomes and Practice Patterns Study (DOPPS). American journal of kidney diseases: the official journal of the National Kidney Foundation 2008 52:519-30.

- Chertow G.M., Raggi P., Chasan-Taber S., Bommer J., Holzer H., Burke S.K. Determinants of progressive vascular calcification in hemodialysis patients. Nephrology Dialysis Transplantation 2004 19 (6), pp. 1489-1496.

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

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

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

2.7.8   Numerator Statement

Number of patient-months in the denominator with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL.

2.7.9   Facility Exclusions

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

2.7.10   Denominator Statement

Number of patient-months at the facility during the measurement period. Includes all patients, not just those on Medicare.

2.7.11   Denominator Exclusions

Denominator exclusions include:

- Patient younger than age 18

- 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.

Program Specific Calculation:

DFC:
- Patients must have an in-range uncorrected serum calcium value (0.1<value≤20) during the reporting month. Otherwise they are excluded from the denominator.

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

ESRD QIP:
- The system shall exclude the following patients when calculating a facility's measure rates for the Hypercalcemia measure:
  - Patients for whom the facility reported fewer than 3 months of serum 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.

2.7.12 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

- Patient Medicare Claim Number
- 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)

2.7.13 Mapping Patients to Facilities

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

Program Specific Calculation:

DFC:
– Patients can be attributed to only one facility per month.

ESRD QIP:

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

2.7.14   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.

Program Specific Numerator Calculations:

DFC:
– A patient need only have an uncorrected serum calcium value for the reporting month to have an average calcium value calculated. However, any value reported during the two months prior to the reporting month will be included in the 3-month rolling average, i.e., a one, two, or three month average can be calculated as long as there is a value reported during the reporting month. For example, the percentage calculated for January (the reporting month), would be based on the average of uncorrected serum calcium values submitted in January, December, and/or November. If the value were missing for January (the reporting month) the patient-month would be excluded from the calculation (excluded from the denominator). If the value(s) for December and/or November are missing, then the measure will still be calculated using the January value and any non-missing values from December or November.
– If there are multiple calcium measurements during the month, the last in-range value will be used for the calculation.

ESRD QIP:
– A patient need only have an uncorrected serum calcium value during the three-month rolling average (with the value carried forward in months where no calcium value is reported) to be included in the measure.
– A one, two, or three month average can be calculated as long as there is a value reported during the three-month rolling average.
– 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 value reported in the month is used for calculation.
- No interpolation between uncorrected serum calcium values for peritoneal dialysis patients.
- The uncorrected serum calcium value reported by the facility is used. The facility may obtain this value from an external source.
- "Uncorrected" indicates albumin is not considered in the calculation.
- 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).

2.7.15   Flowchart

Figure 7 provides a flowchart that represents the processes used to calculate the Hypercalcemia Clinical Measure Rate for ESRD QIP.

Hypercalcemia: Proportion of patient-months with a 3-month rolling average of total corrected serum calcium greater than 10.2 mg/dl.

Legend

Process	
Decision	
Calculation	
Excluded	
Data Source	

CROWNWeb data

Map CROWNWeb patient records to facilities

Does patient have valid 2728 form or CROWNWeb record? — No

Is patient over the age 18 + 2 months? — No

Was patient admitted to the facility at least 30 days total in the last three months? — No

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

Is patient still admitted to the facility at the end of the month? — No

Patient-Month excluded from measure calculation

Is there at least one uncorrected Serum Calcium value at the facility during the last three months? — No

Did facility report fewer than 3 months for a patient during the performance period and the 2 months prior? — Yes — Patient excluded from measure calculation

No

For each eligible patient, calculate the average of current (reporting) month's calcium value and any available calcium values from prior 2 months.
Note: An average is calculated even if there is no calcium value reported during the month, as long as all exclusion criteria for patient are met

Calculate facility denominator: Number of patient-months with an uncorrected serum calcium value

The mean value for the patient is rounded to one decimal place prior to comparing with the 10.2 threshold.

Calculate facility numerator: number of patient-months* with a 3-month average uncorrected serum calcium value > 10.2**

Figure 7. Hypercalcemia Clinical Measure Rate Flowchart for ESRD QIP

2.8   Anemia Management Reporting (ESRD QIP only)

2.8.1   Measure Name

Anemia Management Reporting Measure

2.8.2   Measure Description

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

2.8.3   Measure Type

Reporting measure

2.8.4   Facility-Level Exclusions

- Facilities with fewer than 11 eligible patients during the performance period.
- Facilities with a CMS certification number (CCN) open date on or after July 1, 2016 or with a missing certification date.

2.8.5   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-PD, missing or undetermined modality

2.8.6   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 Jan, 2016 – June, 2016)

2.8.7   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 is not admitted 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."

2.8.8   Calculating Monthly Reporting Percentages

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

$$\frac{Number\ of\ Eligible\ Patient\ for\ Whom\ a\ Facility\ Successfully\ Reports\ in\ this\ reporting\ month}{Total\ number\ of\ Eligible\ Patients\ in\ this\ reporting\ month}$$

2.8.9   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) 2015.

Note: The 50th percentile of facility reporting in CY 2015 has yet to be calculated, so it is not yet possible to determine the threshold that defines successful reporting for a month.

2.8.10   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, 2016, then the facility is required to report data for the entirety of the performance period (i.e., all 12 months in 2016).

If the facility's Certification Date was between January 1, 2016, and June 30, 2016, 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 receives its CCN in March of 2016, 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, 2016, 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).

2.8.11   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:

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

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.

2.8.12   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
- Facility E-Mail
- Initial Certification Date
- CROWN Unique Patient Identifier (UPI)
- Patient Medicare Claim Number
- Facility CCN
- Date Regular Chronic Dialysis Began
- Admit Date
- Primary Type of Treatment ID (CROWNWeb dialysis type)
- Medicare Certified Services Offered
- Additional Services Offered (Non-Medicare

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

2.8.13 Flowchart

Figure 8 provides a flowchart that represents the processes used to calculate the Anemia Management Reporting Measure for ESRD QIP.
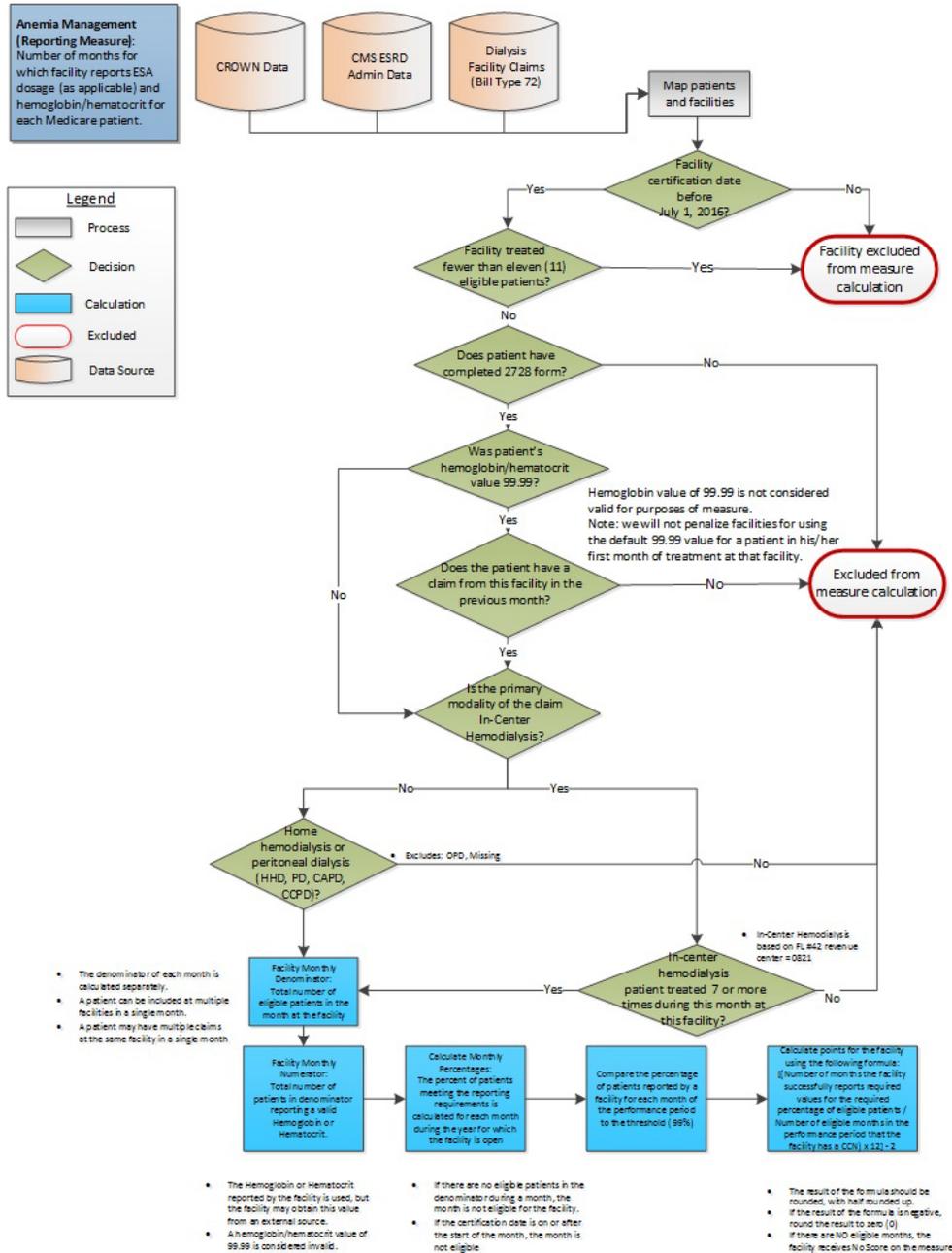
Figure 8. Anemia Management Reporting Measure Flowchart for ESRD QIP

2.9 Mineral Metabolism Reporting (ESRD QIP only)

2.9.1 Measure Name

Mineral Metabolism Reporting Measure

2.9.2 Measure Description

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

2.9.3 Measure Type

Reporting measure

2.9.4 Facility-Level Exclusions

- Facilities with fewer than 11 eligible patients during the performance period (see Section 2.9.5 below).

- Facilities with a CMS certification number (CCN) open date on or after July 1, 2016 or with a missing certification date.

- Facilities without eligible patients in the whole performance year

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-PD, missing or undetermined modalities

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 months (the scenario can only occur during Jan, 2016 – June, 2016)

2.9.7 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.

2.9.8 Calculating Monthly Reporting Percentages

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

$$\frac{Number\ of\ Eligible\ Patient\ for\ Whom\ a\ Facility\ Successfully\ Reports\ in\ this\ reporting\ month}{Total\ number\ of\ Eligible\ Patients\ in\ this\ reporting\ month}$$

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:

- 97%
- The 50th percentile of facility reporting in Calendar Year (CY) 2015

Note: The 50th percentile of facility reporting in CY 2015 has yet to be calculated, so it is not yet possible to determine the threshold that define successful reporting for a month.

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, 2016, then the facility is required to report data for the entirety of the performance period (i.e., all 12 months in 2016).

If the facility's Certification Date was between January 1, 2016, and June 30, 2016, 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 receives its CCN in March of 2016, 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, 2016, 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 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.

2.9.12   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 here.

CROWNWeb Data Elements

- Initial Certification Date
- CROWN Unique Patient Identifier (UPI)
- Patient Medicare Claim Number
- Facility CCN
- Date Regular Chronic Dialysis Began
- Admit Date
- Date of Month/Year Associated with Clinical Record
- Phosphorus
- Primary Type of Treatment ID (CROWNWeb dialysis type)
- Medicare Certified Services Offered
- Additional Services Offered (Non-Medicare)

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

2.9.13   Flowchart

Figure 9 provides a flowchart that represents the processes used to calculate the Mineral Metabolism Reporting Measure for ESRD QIP.
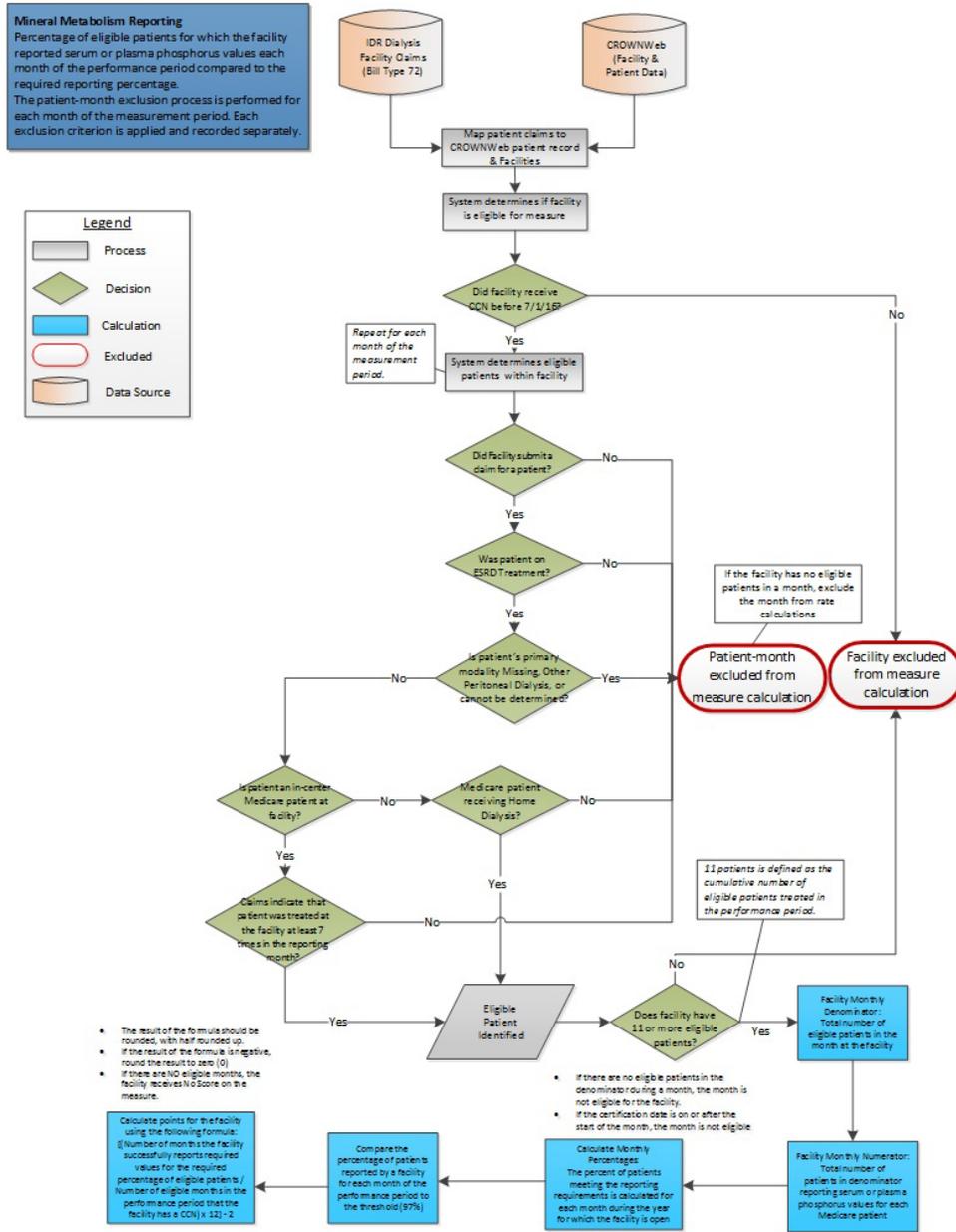
Figure 9. Mineral Metabolism Reporting Measure Flowchart for ESRD QIP

2.10 Screening for Clinical Depression and Follow-Up Reporting (ESRD QIP only)

2.10.1 Measure Name

Screening for Clinical Depression and Follow-Up Reporting Measure

2.10.2 Measure Description

Facility reports in CROWNWeb one of the six conditions below for each qualifying patient once before February 1, 2017.

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 CCN certification date on or after July 1, 2016.

2.10.5 Patient-Level Exclusions

- Patients who are younger than 12 years as of October 31, 2016
- Patients who are treated at the facility for fewer than 90 days between January 1 and December 31, 2016

2.10.6 Determining Successful Reporting for a Patient

A facility is considered to have successfully reported for a patient if it reports one of the following six conditions in CROWNWeb for the patient once before February 1, 2017. 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**[2] 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: <u>Adolescent Screening Tools (12-17 years)</u> 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); <u>Adult Screening Tools (18 years and older)</u> 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 patients' <u>medical record</u>:
   - Patient refuses to participate
   - Patient is in an urgent or emergent situation where time is of the essence and to delay treatment would jeopardize the patient's health status
   - Situations where the patient's motivation to improve may impact the accuracy of results of nationally recognized standardized depression assessment tools. For example: certain court appointed cases
   - Patient was referred with a diagnosis of depression
   - Patient has been participating in on-going treatment with screening of clinical depression in a preceding reporting period
   - Severe mental and/or physical incapacity where the person is unable to express himself/herself in a manner understood by others. For example: cases such as delirium or severe cognitive impairment, where depression cannot be accurately assessed through use of nationally recognized standardized depression assessment tools

2.10.7　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:

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

2.10.8　Data Elements and Data Sources

These data elements have yet to be determined.

2.10.9　Flowchart

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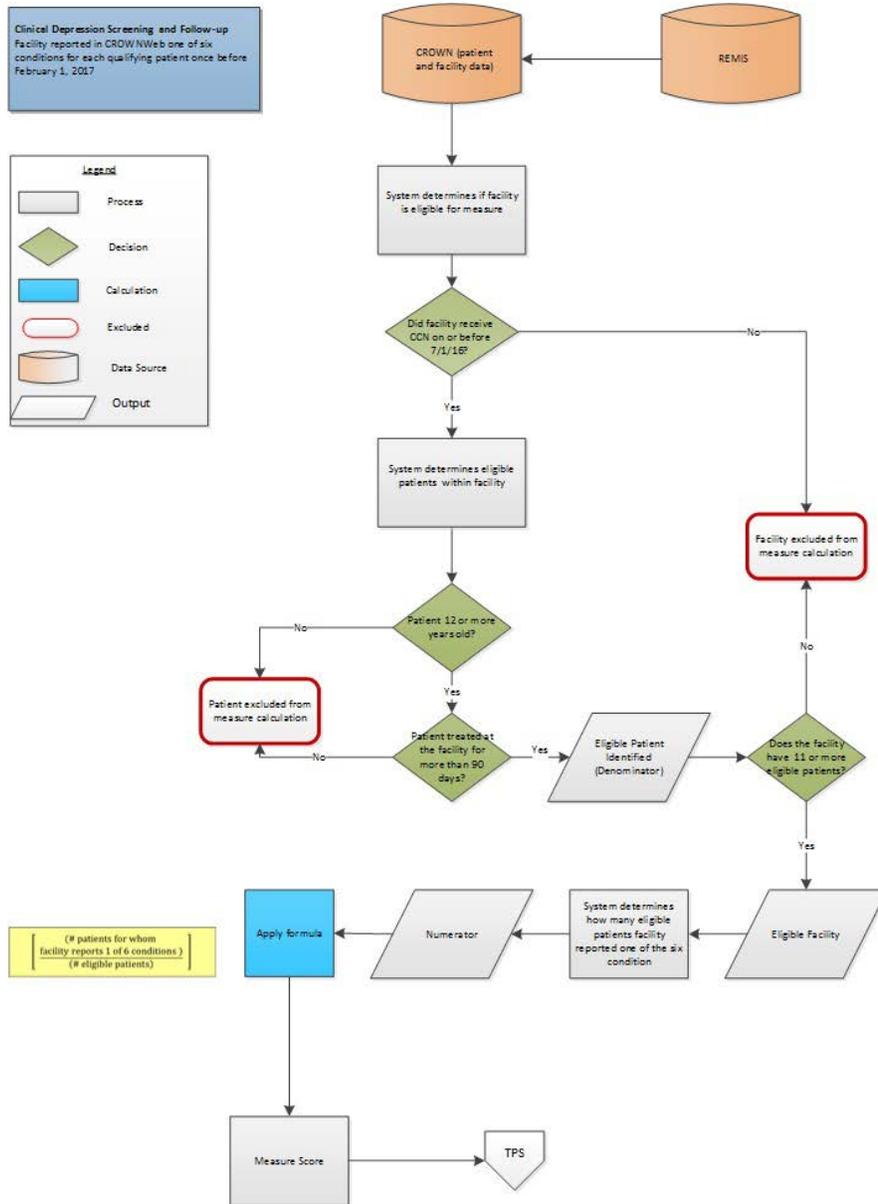
Figure 10. Screening for Clinical Depression and Follow-Up Reporting Measure Flowchart for ESRD QIP

2.11 Pain Assessment and Follow-Up Reporting (ESRD QIP only)

2.11.1 Measure Name

Pain Assessment and Follow-Up Reporting Measure

2.11.2 Measure Description

Facility reports in CROWNWeb one of the six conditions below for each qualifying patient once before August 1, 2016 and once before February 1, 2017.

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, 2016.

2.11.5 Patient-Level Exclusions

- Patients who are younger than 18 years as of April 30, 2016 for August 1, 2016 reporting deadline, and as of October 31, 2016 for the February 1, 2017 reporting deadline.
- Patients who are treated at the facility for fewer than 90 days between January 1 and June 30, 2016 for the August 1, 2016 deadline, and between July 1 and December 31, 2016 for the February 1, 2017 deadline.

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 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[2]** 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 patients' 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.

2.11.7 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:

$$\dfrac{\left(\left(\dfrac{\begin{array}{c}\textit{Number of Eligible Patients for Whom a Facility Successfully Reports one of six}\\ \textit{conditions during the first six months}\end{array}}{\textit{Total number of Eligible Patients during the the first six months}}\right) + \left(\dfrac{\begin{array}{c}\textit{Number of Eligible Patients for Whom a Facility Successfully Reports one of six}\\ \textit{conditions during the second six months}\end{array}}{\textit{Total number of Eligible Patients during the second six months}}\right)\right)}{2}$$

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.

2.11.8   Data Elements and Data Sources

These data elements have yet to be determined.

2.11.9   Flowchart

Figure 11 provides a flowchart that represents the processes used to calculate the Pain Assessment and Follow-Up Reporting Measure for ESRD QIP.
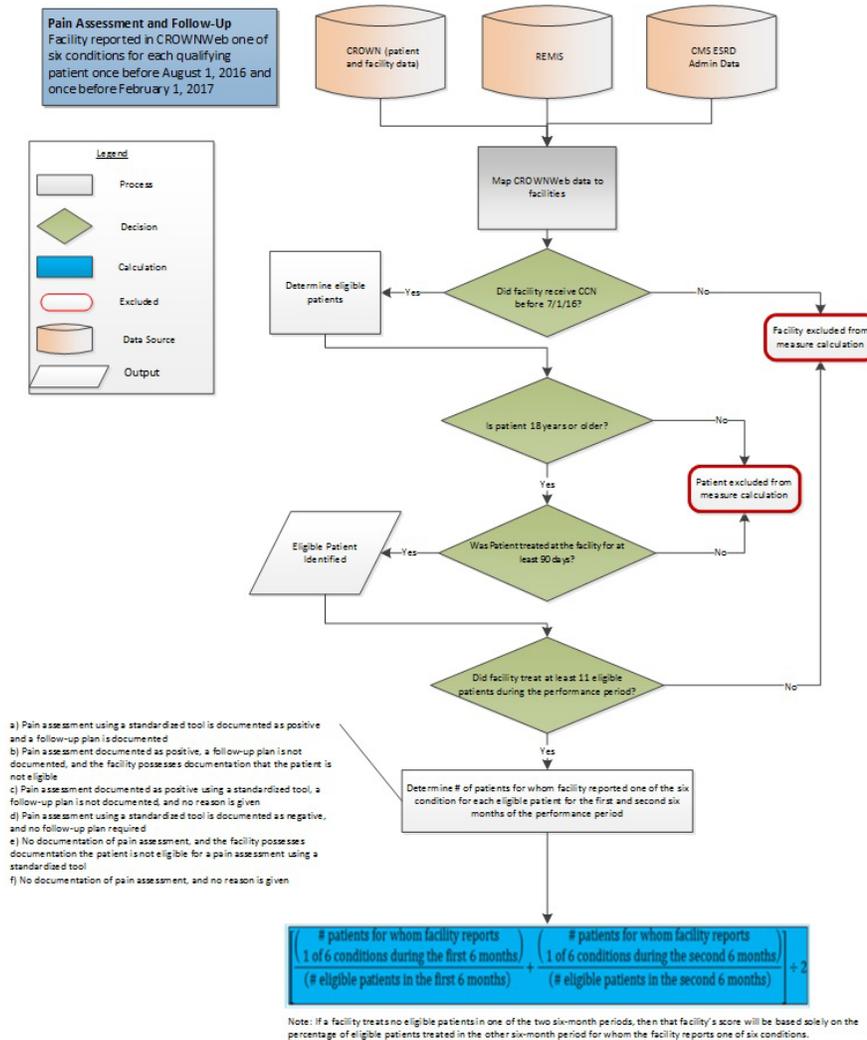
Figure 11. Pain Assessment and Follow-Up Reporting Measure Flowchart for ESRD QIP

2.12 Standardized Readmission Ratio Measure

2.12.1 Introduction

In 2013, CMS rolled out a new approach to ensuring safe and adequate health care delivery to its patients: the CMS Quality Strategy (CMS, 2013). The CMS strategy is designed to align with the six goals of the Department of Health and Human Services' (HHS) National Quality Strategy. The CMS strategy is framed in the following way: "To improve, a broad-based and seamless reform approach is necessary to address challenges in our healthcare system—escalating costs, inadequate coverage and inefficient care of variable quality" (CMS, 2013).

Dialysis patients are a population particularly affected by such issues. Relative to the general population, they experience much higher levels of mortality (de Jager et al., 2009) and morbidity (e.g., hospital readmission; Medicare Payment Advisory Commission (MedPAC), 2007). Both hospitalization and readmission rates reflect morbidity and quality of life of dialysis patients as well as medical costs. For example, in 2011 dialysis patients were admitted to the hospital twice on average and spent an average of 12 days in the hospital, accounting for approximately 38% of Medicare expenditures for ESRD patients (United States Renal Data System, 2013). Furthermore, 36% of hemodialysis patients discharged from the hospital had an unplanned readmission within 30 days (United States Renal Data System, 2013). In other settings (e.g., cardiovascular disease, cancer), some studies show that about 25% of unplanned readmissions are preventable, that preventability vary widely across diagnoses, and that readmissions were more likely to be preventable for patients with more severe conditions (van Walraven et al., 2011).

In the dialysis setting, care coordination strategies, including appropriate hand-off and timely pre- and post-discharge communication among care providers, have emerged as a potentially effective means to reduce unplanned readmission among the ESRD patients. A recent study in the ESRD population found that certain post-discharge assessments and changes in treatment at the dialysis facility may be associated with a reduced risk of readmission (Chan et al., 2009). A recent multi-unit qualitative study by Reilly et al. (2013) found that a lack of care coordination between in- and outpatient dialysis units post-discharge is associated with increased readmission rates. Other articles concerning the dialysis setting (e.g. Castner,2011; Wish, 2014; Plantinga and Jarr, 2009) discuss the importance of dialysis facility and physician communication with the discharging hospital in order to ensure appropriate coordination of care such as reconciliation of post-discharge medications and treatment orders. Clinical studies in the non-ESRD populations have also demonstrated that improved care coordination and discharge planning can reduce readmission rates (e.g., Dunn, 1994; Bostrom, 1996; Dudas, 2001; Azevedo, 2002; Coleman, 2004; Coleman, 2006; Balaban, 2008; Braun, 2009) or a combination of pre- and post-discharge interventions (e.g., Naylor, 1994; McDonald, 2001; Creason, 2001; Ahmed, 2004; Anderson, 2005; Jack, 2009; Koehler, 2009; Parry, 2009).

Readmission measures have been developed in various care settings, including hospitals and skilled nursing facilities. With the U.S. healthcare system moving toward a paradigm of shared accountability across providers from different care settings, a readmission measure that is particularly applicable to ESRD patients will not only encourage improvement in transition of care across various settings, but will also serve as a strong motivation for facilities to coordinate treatment with the discharging hospital to reduce readmission rates. Such a measure should also

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encourage facilities to review readmission practices and identify potential problems. Moreover, measures of the frequency of unplanned readmissions are essential for controlling escalating medical costs in that they can help facilities identify problems and potentially improve care and reduce costs. In 2011, a measure of 30-day readmission was added to the Dialysis Facility Reports, which have been used by dialysis facilities and ESRD Networks for quality improvement, and by ESRD state surveyors for monitoring and surveillance of dialysis facilities.

2.12.2   Methods

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

2.12.2.1   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.

2.12.2.2 Data Sources

Data are derived from an extensive national ESRD patient database, which is primarily based on 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), the Nursing Home Minimum Dataset, the Quality Improvement Evaluation System (QIES) Workbench, which includes data from the Certification and Survey Provider Enhanced Report System (CASPER), 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 types of Medicare Claims.

2.12.2.3 Outcome Definition

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

2.12.2.4 Identifying Patients Treated at Each Facility

We identified each patient's dialysis provider over time 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 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-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 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.

2.12.2.5   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 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 in 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 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 (will begin for DFC on October 2016 release)

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.

2.12.3   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.

- **Age:** We determine each patient's age at index discharge from the birth date provided in the SIMS and REMIS databases.

- **Years on ESRD:** We determine each patient's length of time on ESRD using the first service date from his/her CMS 2728, claims history (all claim types), the SIMS database and the SRTR 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.

2.12.4   Readmission Model and SRR Calculation

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

2.12.4.1   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 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.

2.12.4.2 Calculation of SRR

The equations used in the measure calculation are as follows:

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

2. We use the estimates from this model to calculate the ith 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 ith facility, O_i is the number of observed unplanned readmissions, E_i is the expected number of unplanned readmissions, $H(i)$ is the collection of indices of hospitals from which patients are discharged to the ith facility, and p_{ijk} is the estimated probability of an unplanned readmission under the national norm for each discharge. More specifically,

$$\hat{p}_{ijk} = \frac{\exp(\widehat{\gamma_M} + \widehat{\alpha}_j + \overline{\widehat{\beta^T}} Z_{ijk})}{1 + \exp(\widehat{\gamma_M} + \widehat{\alpha}_j + \widehat{\beta^T} Z_{ijk})} \Bigg|$$

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.

2.12.4.2.2   *Calculation of SRR P-Values and Confidence Intervals*

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 discharges 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.

2.12.5   Flagging Rules for 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."

2.12.6   References

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2.13 Standardized Transfusion Ratio Measure

2.13.1 Introduction

As mandated by the Affordable Care Act (ACA), assuring delivery of high quality and affordable care requires reliable and meaningful quality measures that focus on important outcomes and processes, including patient experience, across the breadth of the healthcare system (CMS, 2013). This view has reinforced CMS' stated goal of providing the highest quality of evidence-based care, which is personalized, prevention-oriented and patient-centered. Achieving this goal requires development of measures that incorporate heterogeneities at both population and individual levels, across traditional institutional or provider domains to address coordination and continuity of care, and focus on outcomes most important to patients. In addition, measures ought to address the efficiency of care delivery at the individual and population levels in order to support value-based purchasing initiatives, and to foster a delivery system that works efficiently for providers by reducing their administrative burdens, while facilitating coordinated care. Most importantly, measures should incorporate the evidence-based results of the latest high quality research and scientific advances in health outcomes research, clinical medicine, public health, and health care delivery. Anemia management in chronic dialysis patients is a complex clinical issue of importance to patients, providers and healthcare administrators. Development of quality measures for this clinical topic reflecting the aforementioned principles is necessary and appropriate in this time of rapidly evolving understanding of the risks and potential benefits of anemia treatments in this population.

Anemia is a complication of ESRD, affecting most patients with this condition. Management of anemia in ESRD patients is the responsibility of the patient's dialysis facility as specified in CMS' ESRD Conditions for Coverage and paid for as part of the Medicare ESRD Prospective Payment System. According to Food and Drug Administration (FDA) Prescribing Information, goals of successful treatment should include minimization of blood transfusion risk. According to some, additional potential benefits of anemia treatment may include improvement of the quality of life and health of dialysis patients.

Several recent scientific findings and Medicare ESRD Program policy changes likely impacted anemia management in dialysis facilities. These include identification of safety concerns associated with aggressive ESA use, expansion of the ESRD prospective payment System bundled payment to include payment for ESAs, and the development of the ESRD Quality Incentive Program. Potential unintended consequences of these events include possible underutilization of ESAs by dialysis facilities and, consequently, increasing frequency of red blood cell transfusion in the US chronic dialysis population.

The inverse relationship between achieved hemoglobin and transfusion events has been reported previously for Medicare dialysis patients (Ma, 1999; Collins, 2014) and for non-dialysis chronic kidney disease (CKD) patients treated in the Veterans Administration system (Lawler, 2010). Unpublished analyses of Medicare Claims data presented at CMS Technical Expert Panel in May 2012 demonstrate an inverse association between achieved hemoglobin and subsequent transfusion rise using more recent data from 2008-2011. The Standardized Transfusion Ratios (STrR) is designed to reflect the number of transfusion events for the patients at a dialysis facility, relative to the number of transfusion events that would be expected based on overall national rates and the characteristics of the patients at that facility. Numerically, the STrR is

calculated as the ratio of two numbers: the numerator ("observed") is the actual number of transfusion events over a year period, and the denominator ("expected") is the number of transfusion events that would be expected if patients at that facility experienced transfusion events at the national average rate for patients with similar characteristics.

2.13.2 Methods

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

2.13.2.1 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.

2.13.2.2 Outcome Definition

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

2.13.2.3 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 or value code (inpatient claims) or for outpatient claims, reporting Healthcare Common Procedure Coding System (HCPCS) codes for a revenue center date.

One "transfusion event" is counted per inpatient claim if one or more transfusion-related revenue center or value codes are present. This is the way most inpatient transfusion events are reported on claims (i.e., using revenue center or value codes, not procedure codes). We only count a single transfusion event for an inpatient claim regardless of the number of transfusion revenue center and 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. A small fraction of inpatient transfusion events are identified using specific procedure codes. For these cases, we are able to identify multiple transfusion events for some hospitalizations and count a unique "transfusion event" for each transfusion procedure code listed on an inpatient claim. CMS allows the transfusion procedure to be billed only once per day per visit.

Transfusion events are not common in outpatient settings, but similar rules apply. Multiple HCPCS codes reported for the same revenue center date are counted as a single transfusion event regardless of the number of units of blood recorded. In other words, 3 units of blood reported with the same revenue center date would be counted as a single transfusion event. The detailed procedures to determine unique transfusion events at the claim level are appear below.

2.13.2.4 Cohort Definition

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

2.13.2.4.1 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) 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.

2.13.2.4.2 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.

2.13.2.4.3 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 switches within 60 days of each other), we do not attribute that patient to any facility. Patients are removed from facilities three days prior to transplant in order to exclude the transplant hospitalization. Patients who withdrew from dialysis or recovered renal function remain assigned to their treatment facility for 60 days after withdrawal or recovery.

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

2.13.2.4.4   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.

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-paid 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 month of a month having at least $900 of Medicare–paid dialysis claims or at least one Medicare-paid 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.

2.13.3   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).

- **Years on 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 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.

- **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, 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

2.13.4 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 (365 days) 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 12 describes the inclusion and exclusion period of a hypothetical patient.
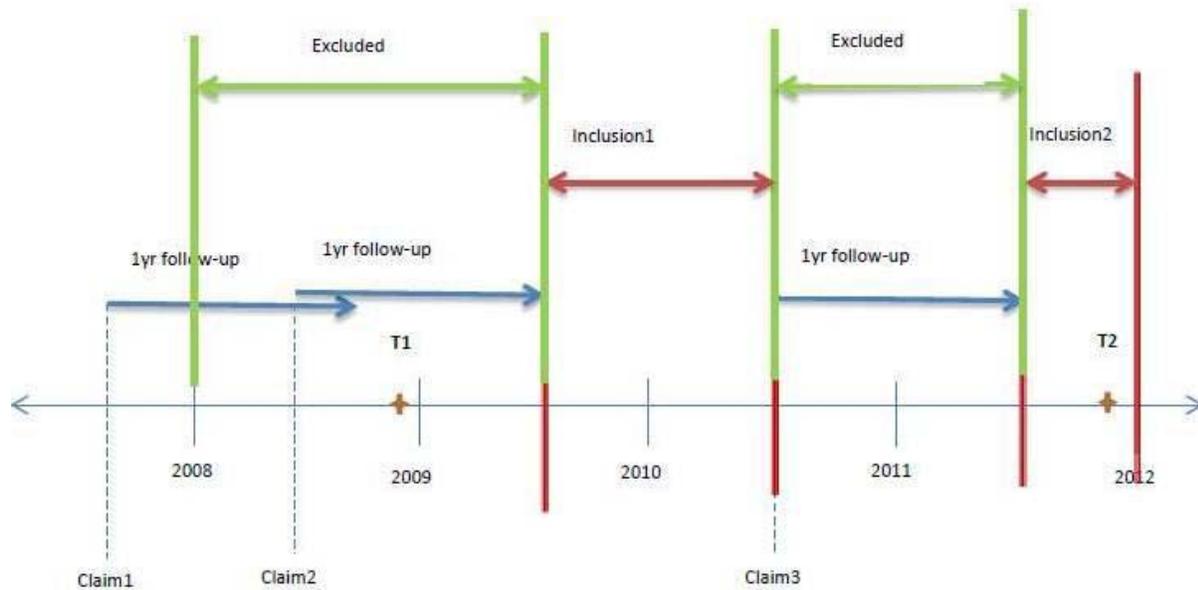
Figure 12. Algorithm for Exclusion of Periods of Time Within 1 Year of an Exclusion Comorbidity

In Figure 12, 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 Appendix) 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 12). 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.

2.13.5   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 kth 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 sth time interval with estimated rate α_s. The corresponding expected number of transfusions in the sth interval for this patient is calculated as:

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

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

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

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

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

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

2.13.6 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.

2.13.7 Calculation of STrR P-Values and Confidence Intervals

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

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

where n_{ik} is the observed number of event for patient i in facility k, E_{ik} is the expected number of events for patient i in facility k and θ_k is the facility-specific intercept. Here, i ranges over the number of patients n_{ik} who are treated in the kth facility. The natural log of the STrR for the kth facility is then given by the corresponding estimate of θ_k. The standard error of θ_k is obtained from the robust estimate of variance arising from the over dispersed Poisson model. Second, we obtain a z-score for each facility by dividing the natural log of its STrR by the standard error from the general linear model described above. These z-scores are then grouped into quartiles based on the number of patient years at risk for Medicare patients in each facility. Finally, using robust estimates of location and scale based on the normal curve fitted to the center of the z-scores for the STrR, we derive the mean and variance of a normal empirical null distribution for each quartile. This empirical null distribution is then used to calculate the p-value for a facility's STrR.

Example

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

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

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

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

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

For example, consider a hypothetical facility whose STrR is 0.927 for which ln STrR = -0.076 with corresponding standard error, SE = 0.118. This facility falls in a quartile where the empirical null has μ = -.143 and σ = 1.479. The corresponding uncertainty interval for the log STrR is

$$-0.076 - (-0.143)*0.118 \pm 1.96 *0.118*1.479 = (-0.401, 0.283).$$

The 95% interval for the true STrR is then 0.67 to 1.33.

2.13.8   Flagging Rules for 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.

2.13.9   References

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2.14 Standardized Hospitalization Ratio Measure

2.14.1 Introduction

In 2013, CMS rolled out a new approach to ensuring safe and adequate health care delivery to its patients: the CMS Quality Strategy (CMS, 2013). The CMS strategy is designed to align with the six goals of the HHS National Quality Strategy. The CMS strategy is framed in the following way: "To improve, a broad-based and seamless reform approach is necessary to address challenges in our healthcare system—escalating costs, inadequate coverage and inefficient care of variable quality" (CMS, 2013).

Dialysis patients are a population particularly affected by such issues. Relative to the general population, they experience much higher levels of mortality (de Jager et al., 2009) and morbidity (e.g., hospital readmission; Medicare Payment Advisory Commission (MedPAC), 2007). On average, dialysis patients are admitted to the hospital approximately twice a year and spend 12 days in the hospital per year (United States Renal Data System, 2013). Measures of the frequency of hospitalization and diagnoses associated with hospitalization help control escalating medical costs, and play an important role in providing cost-effective health care. Hospitalization rates are an important indicator of patient morbidity and quality of life, and hospitalization measures have been in use in the Dialysis Facility Reports (DFRs) since 1995. Dialysis facilities and ESRD Networks use the DFRs for quality improvement, and ESRD state surveyors use the reports for monitoring and surveillance of dialysis facilities.

The Standardized Hospitalization Ratios (SHR) for admissions is designed to reflect the number of hospital admissions for the patients at a dialysis facility, relative to the number of hospital admissions that would be expected based on overall national rates and the characteristics of the patients at that facility. Numerically, the SHR is calculated as the ratio of two numbers: the numerator ("observed") is the actual number of hospital admissions for the patients in a facility over a specified time period, and the denominator ("expected") is the number of hospital admissions that would have been expected for the same patients if they were in a facility conforming to the national norm.

2.14.2 Methods

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

2.14.2.1 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 CMS DFC website.

2.14.2.2   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.

Handling of Hospital Admissions from Medicare Inpatient Claims

In calculating the SHR, Medicare inpatient claims that are adjacent or overlap with another 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.

2.14.2.3   Outcome Definition

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

2.14.2.4   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.

2.14.2.5 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.

2.14.2.6 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 paid 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.

2.14.2.7 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-paid 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-paid 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.

2.14.3   Risk Adjustment

The following subsections describe how the SHR measure is risk-adjusted.

Adjustment in the SHR

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, comorbidity index 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.

- **Comorbidity index at incidence:** Calculated as a weighted linear combination of comorbidities reported on the CMS-2728 namely, alcohol dependence, atherosclerotic heart disease, cerebrovascular disease, chronic obstructive pulmonary disease, congestive heart failure, diabetes, diabetes (currently on insulin), drug dependence, inability to ambulate, inability to transfer, malignant neoplasm, cancer, other cardiac disease, peripheral vascular disease, tobacco use (current smoker) using weights from a Cox model predicting survival among incident dialysis patients. The comorbidity index is included as a linear variable.

- **Calendar year:** The year in which performance is assessed.

- **Categorical indicator variables:** Included as covariates in the stage I model to account for records with missing values for cause of ESRD, comorbidity index, and BMI. These variables have a value of 1 if the patient is missing the corresponding variable and a value of 0 otherwise. Another categorical indicator variable is included as a covariate in the stage 1 model to flag records where the comorbidity index is 0. This variable has a value of 1 if the patient has a comorbidity index of 0 (indicating no comorbidities are recorded as present) and a value of 0 otherwise.

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

- Diabetes as cause of ESRD*Duration of ESRD

- Diabetes as cause of ESRD*Sex

- Diabetes as cause of ESRD*Age

- Age*Sex

2.14.4   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 ith patient in the kth 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 kth 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 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, comorbidity index at incidence, 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. The comorbidity index is included as a linear variable. 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, comorbidity index, 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 categorical indicator variable is included as a covariate in the stage 1 model to flag records where the comorbidity index is 0. This variable has a value of 1 if the patient has a comorbidity index of 0 (indicating no comorbidities are recorded as present) 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 $R_{ik} = \exp(\boldsymbol{\beta}'\boldsymbol{X_{ik}})$ 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 t_{iks} represent the number of days that patient i from facility k is under observation in the sth time interval with estimated rate α_s. The corresponding expected number of hospital admissions in the sth interval for this patient is calculated as

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

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

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

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

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

$$\textbf{SHR = Obs/Exp .}$$

2.14.5   Missing Data

Patients with missing data are not excluded from the model. For the purposes of calculation, missing values for the comorbidity index and 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, comorbidity index, and BMI are also included as covariates in the model.

2.14.6   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

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

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 θ_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 θ_k. The standard error of θ_k is obtained from the robust estimate of variance arising from the over dispersed Poisson model.

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

Example

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

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

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

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

  For example, consider a hypothetical facility whose SHR is 0.927 for which ln SHR = -0.076 with corresponding standard error, SE = 0.118. This facility falls in a quartile where the empirical null has μ = -0.143 and σ = 1.479. The corresponding uncertainty interval for the log SHR is

$$-0.076 - (-0.143)*0.118 \pm 1.96 *0.118*1.479 = (-0.401, 0.283).$$

  The 95% interval for the true SHR is then 0.67 to 1.33.

2.14.7 Flagging Rules for 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. For other purposes (e.g., ESRD QIP) other scoring methods may be used.

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2.15   Standardized Mortality Ratio Measure

2.15.1   Introduction

Standardized Mortality Ratios (SMRs) have been used since at least 1986 (Breslow and Day, 1987; Keiding, 1987) to compare observed mortality for a specific group of people to mortality in a reference group, typically a more general population. Development of the SMR in the ESRD context began with Wolfe et. al.'s (1992) introduction of an SMR to compare mortality rates among subgroups of ESRD patients (e.g., region, dialysis facility) with national mortality rates for ESRD patients. This SMR was calculated using rate tables based on 256 age-sex-race-diagnosis groups.

Since 2001, the SMR has been calculated as the ratio of the actual number of deaths among patients at to the expected number of deaths for the facility, where the expected number of deaths is calculated from a Cox model that takes the particular facility's case mix into account. Currently, the SMR is adjusted for age, race, ethnicity, sex, diabetes as primary cause of ESRD, duration of ESRD, nursing home status in previous year, comorbidities at incidence, body mass index (BMI) at incidence, calendar year, and race-specific state population death rates. The SMR indicates whether patients treated in the facility had higher or lower mortality than expected when adjusted for age, race, ethnicity, sex, diabetes as cause of ESRD, years of ESRD, comorbidities at incidence, BMI at incidence, year, and age-adjusted population death rates.

The SMR has been in use in the Dialysis Facility Reports (DFR) since 1995 and on DFC since 2001, when the Balanced Budget Act (1997) required a system to measure and report the quality of dialysis under Medicare.

2.15.2   Methods

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

2.15.2.1   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 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.

2.15.2.2 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, DFC, and the Social Security Death Master File.

2.15.2.3 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.

2.15.2.4 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.

2.15.2.5 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-paid dialysis claims, the Medical Evidence Form (Form CMS-2728), and paid 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 paid 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.

2.15.2.6 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.

2.15.3 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/PI, 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 outside the range of [10,70) for adults or [5,70) 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*Race: Black

- Ethnicity*Race: Non-White

- 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*Race: Black

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.

2.15.4   Expected Mortality Model and SMR Calculation

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

2.15.4.1   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 ($ß_j$) for the 56 covariates that are measured on individual patients (or patient-records). The coefficients measure the within-facility effects for individual risk factors or comorbidities. Using these coefficients, a relative risk or predicted risk is calculated for each patient-record. Stage 2 adjusts for the differences in mortality rate at the state level. The model of this stage uses only one covariate, the log of the population death rate for that patient's race within the state where the patient is being treated. The predicted value for the patient-record from stage 1 is used as an offset in the stage 2 model and the stage 2 analysis is not stratified. The combined predicted values from stages 1 and 2, and the baseline survival curve from stage 2 of the Cox model are then used to calculate the expected number of deaths for a specific patient-record.

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. 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. The example below shows how these coefficients are used to carry out the calculations. 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 2014 DFR used age-adjusted death rates for 2008-10 from Table 19 of the publication *Health, United States, 2013,* available at http://www.cdc.gov/nchs/data/hus/hus13.pdf.

2.15.4.2   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 [10,70) for adults or [5,70) 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. In the current SMR model, 30597 (3.70%) patients have imputed 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.

2.15.4.3   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 ith 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 (β_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 jth characteristic for the ith patient-record. In stage 1, for patient-record i, we denote the measured characteristics or covariates in a vector form as

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

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, $\beta_1, \beta_2, \ldots, \beta_p$ and the corresponding predicted value for the ith patient-record is given by

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

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 $\mathbf{X_i\beta}$ from equation (1) is used as an offset in the analysis. The Stage 2 Cox model gives rise to an estimate of the regression coefficient β_0 and of the baseline survival function, $S_0(t)$. After stage 2, the linear prediction is

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

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

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

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

Let 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

$$\textbf{SMR = O/E.}$$

2.15.4.4 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 value1.0 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,

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

2.15.4.5 Flagging Rules for 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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2.16   ICH CAHPS

2.16.1   ICH CAHPS

The In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) measure assesses patients' self-reported experience of care. Additional details on the specifications for the ICH CAHPS measure can be found at the following website: https://ichcahps.org/Home.aspx

Program Specific Calculation:

ESRD QIP:

- Measure Description: Percentage of patient responses to multiple testing tools. NQF #0258
  - Composite Score: The proportion of respondents answering each response option by item, summed across all items within a composite. Composites include: Nephrologists' Communication and Caring, Quality of Dialysis Center Care and Operations, and Providing Information to Patients
  - Overall Rating: a summation of responses to the rating items grouped into 3 levels
- 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 after January 1, 2016
  - Facilities not offering In-Center Hemodialysis
  - The following patients are excluded in the count of 30 eligible patients:
    - Patients less than 18 years on the last day of the sampling window 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
- Data Source(s):
  - ICH CAHPS
  - REMIS, CROWNWeb, and other CMS ESRD administrative data (form 2744 to obtain certification date and facility type)

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

2.16.2 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.

- ICH CAHPS Attestation Indicator
- Patient Medicare Claim Number
- Claim CCN
- 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

2.16.3   Flowchart

Figure 13 provides a flowchart that represents the processes used to calculate the ICH CAHPS Clinical Measure in the ESRD QIP.
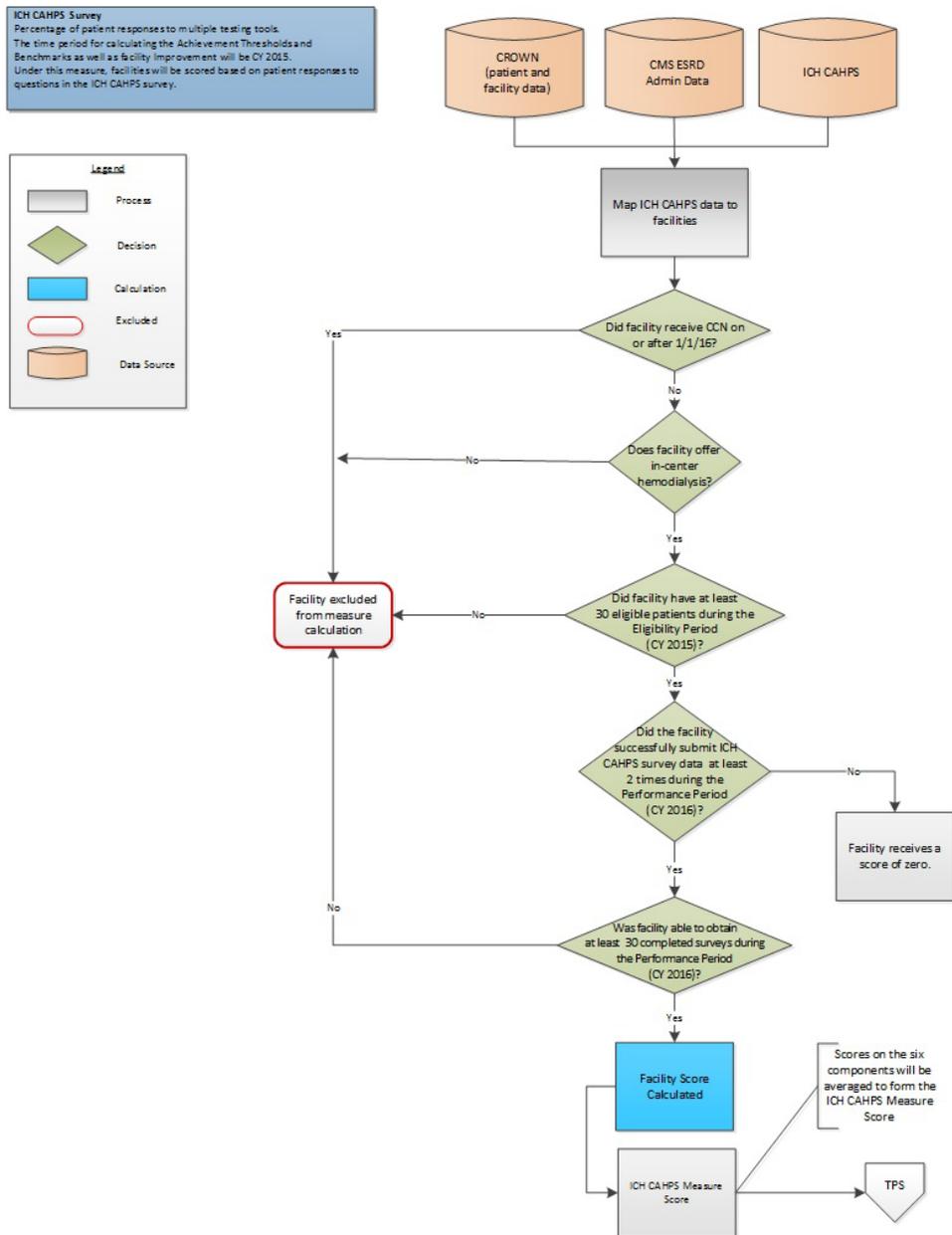
Figure 13. ICH CAHPS Survey Flowchart for ESRD QIP

2.17 NHSN Bloodstream Infection

2.17.1 NHSN BSI

The National Healthcare Safety Network Bloodstream Infection (NHSN BSI) measure assesses facilities' ability to prevent healthcare acquired infections. 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

Program Specific Calculation:

ESRD QIP:

- Measure Description: The Standardized Infection Ratio (SIR) of Bloodstream Infections (BSI) will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers. Based on NQF #1460.

- Numerator Definition: 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.

- Denominator Definition: Number of maintenance in-center hemodialysis patients treated in an outpatient hemodialysis unit, a long-term care facility, or a skilled nursing facility on the first 2 working days of the month.

- Exclusions:
  – Facilities that do not offer in-center hemodialysis
  – Facilities with a CCN certification date after January 1, 2016
  – Facilities that treat fewer than 11 in-center hemodialysis patients during the performance period
  – Facilities with approved Extraordinary Circumstances Exception

- Minimum Data Reported to NHSN: 12 months

- Data Source(s):
  – NHSN (for Risk-Adjusted Standardized Infection Rates)
  – REMIS, CROWNWeb, and other CMS ESRD administrative data (form 2744 to obtain facility type and certification date)
  – Medicare claims and CROWNWeb (to determine patient-minimum exclusion)

- Additional Information:
  – 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.
  – A positive blood culture is considered a new event and counted only if it occurred 21 days or more after a previously reported positive blood culture in the same patient.
  – Patients receiving inpatient hemodialysis are excluded from the measure.
  – Patients receiving only home hemodialysis or peritoneal dialysis are excluded from the measure.

- Facilities that do not submit 12 months of accurately reported data receive zero points for the measure.
- For more information about the methodology used to calculate risk-adjusted standardized infection rates, please see http://www.cdc.gov/nhsn/dialysis/.

2.17.2   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.

- Quarterly reporting compliance indicator (from CDC)
- Standardized Infection Ratio (SIR) for BSI (from CDC)
- Initial Certification Date
- Patient Medicare Claim Number
- Claim CCN
- CROWN Unique Patient Identifier (UPI)
- Admit Date
- Discharge Date
- Primary Type of Treatment ID (CROWNWeb dialysis type)
- Primary Dialysis Setting
- Medicare Certified Services Offered
- Additional Services Offered (Non-Medicare)

2.17.3   Flowchart

Figure 14 provides a flowchart that represents the processes used to calculate the NHSN Bloodstream Infection in hemodialysis outpatient's measure in the ESRD QIP.
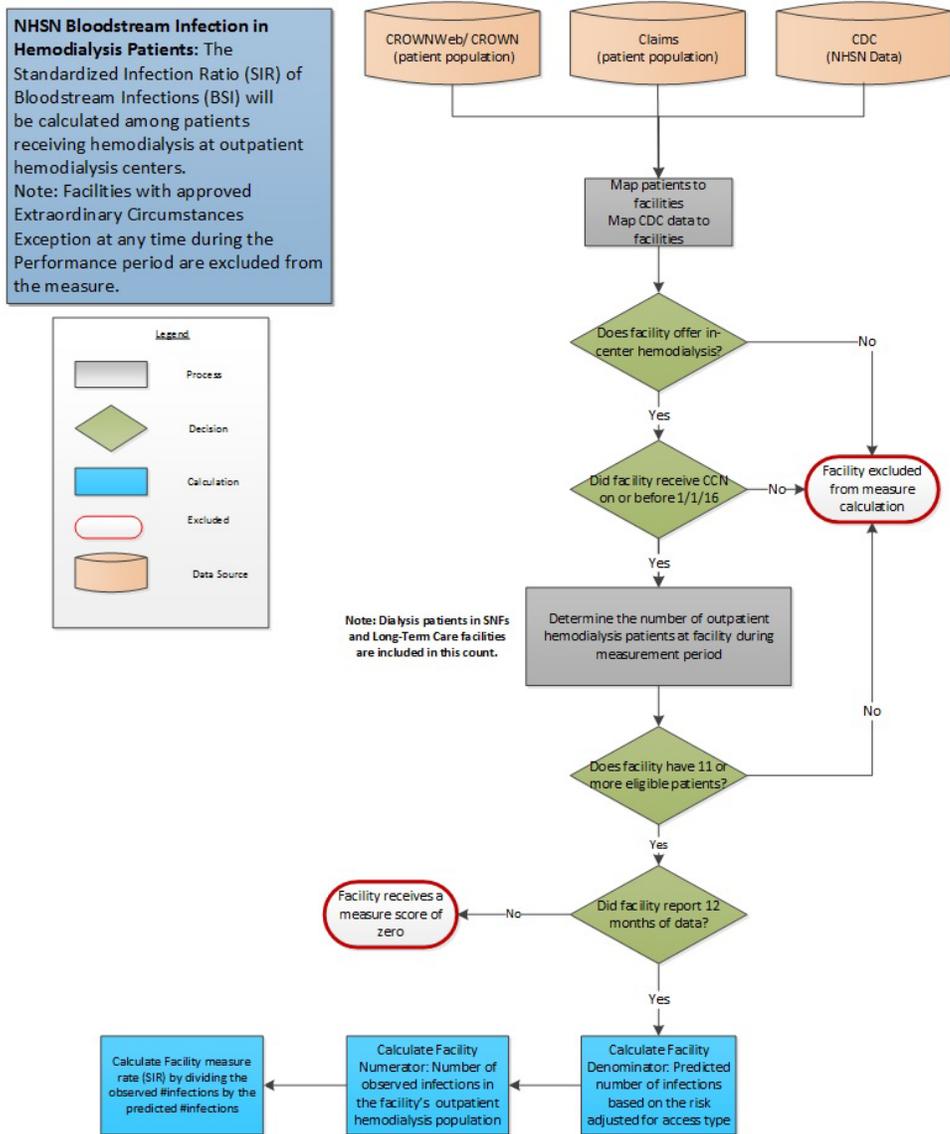
Figure 14. NHSN Bloodstream Infection in Hemodialysis Outpatients Flowchart for ESRD QIP

2.18 NHSN HCP

2.18.1 NHSN HCP

The National Healthcare Safety Network Health Care Personnel (NHSN HCP) Influenza Vaccination measure assesses whether facilities report influenza vaccinations for their staff. 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

Program Specific Calculation:

ESRD QIP:

- Measure Description: 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, 2016. Based on NQF #0431
- Exclusions:
  - Facilities with a CCN certification date after January 1, 2016
- Data Source(s):
  - NHSN
  - REMIS, CROWNWeb, and other CMS ESRD administrative data (form 2744 to obtain facility type and certification date)
- 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, 2015 and March 31, 2016 (designated as the "flu season").
  - NHSN Summary Reports submitted by May 15, 2016 would document actions taken during the flu season that spans October 2015 to April 2016, and would count toward facilities' PY 2018 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.

2.18.2 Data Elements and Data Sources

These data elements have yet to be determined.

2.18.3 Flowchart

Figure 15 provides a flowchart that represents the processes used to calculate the NHSN clinical measure in the ESRD QIP.

NHSN Healthcare Personnel Influenza Vaccination
Facility submits Healthcare Personnel influenza Vaccination Summary Report to CDC NHSN system, according to the specifications of the Healthcare Personnel Safety Component Protocol, by May 15, 2016

CROWN (patient and facility data)

CDC NHSN

Claims (patient population)

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

Map patients to facilities
Map CDC data to facilities

Facility CCN certification date on or before 01/01/16 — No → Facility excluded from measure calculation

Yes

Eligible Facility

NHSN Summary Report Submitted by 05/15/2016?

Yes — Facility receives score of ten (10).

No — Facility receives a score of zero (0).

TPS

Figure 15. NHSN HCP Influenza Measure Flowchart for 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

Program Specific Calculation:

DFC:

- − 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:

- − In cases where a dialysis patient receives treatment using more than one dialysis treatment modality in a month, 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.

    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 Table 1 in ***bold italic***):

                o Hemodialysis—0821, 0881

                o Other Peritoneal Dialysis—0831

                o 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 Table 1 without bold/non italic.

        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.

Table 1: Modality Types for Revenue Center Codes

Modality Type	Revenue Center Codes (Composite codes in ***Bold Italic*** otherwise non-composite codes)
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

  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 Table 1 in ***bold italic***):
         - 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 Table 1 without bold/non italic

   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 Table 1 without bold/non-italic), 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. 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:
  o 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.
  o If the **Primary Single Claim** has a claim-related condition code of 74 or 75 then switch the primary modality to **Home Hemodialysis**.
  o If the **Primary Single Claim** does not have a claim-related condition code of 74 or 75 then the modality remains **In-center Hemodialysis**.
  o 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. Time on ESRD treatment is defined as the length of time from the initiation of ESRD date and the claim start date, as reported on the claim used for the patient-month.

- The date regular chronic dialysis began from the earliest completed Medical Evidence (CMS 2728) form. If this date is missing, the earliest date of these four other dates on the form is used: physician's signature date, date of return to regular dialysis after transplant failure, date dialysis training began, and transplant date.
- Earliest CROWNWeb admit date from any facility.
- 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, REMIS, and CROWNWeb admissions to transplant facilities.

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, as reported on the claim used for the patient-month.

3.1.5   Sessions per Week and "Frequent Dialysis"

The number of days the claim covers was calculated by: days = (clm_thru-(clm_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: the patient was identified in CROWNWeb as undergoing frequent dialysis that month or 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 for adult HD Kt/V or 5 for pediatric HD Kt/V or more sessions per week

- Short claim (less than 7 days) with 4 for adult HD Kt/V or 5 for pediatric HD Kt/V 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

The next section provides an overview of the facility mapping that is used for creating a master facility list for the Dialysis Facility Reports (DFR). 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.

3.2.1 Overview of Provider Numbers

The DFRs 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

This information is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R146CP.pdf

3.2.2   Overview of Main Issues 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 dialysis 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 sources 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) but this has yet to be seen in the files.

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 3.2.5).

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 <u>not</u> manually linked to the old provider number(s). Instead, the new CCN is treated as a new facility and separate DFRs are created for both the old and new provider numbers if the time of change happened within the

four-year DFR period. 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 were 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). Prior to 2008, CMS approved such requests.

For more issues and rules associated with creating the facility list, please refer to Section 3.2.4.

3.2.3   Overview of the Facility List Creation Process

Two primary data sources are used to create the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) facility list; the CROWNWeb facility directory file and CASPER provider of services (POS) files. The 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 anytime during the current four-year reporting period will receive a Dialysis Facility Report (DFR). Facilities certified after the last day of the current four-year reporting period will not receive a DFR. All active facilities receive a QDFC Preview report each quarter, including those certified on or after the last day of the current four-year reporting period

In the past, the ESRD number was used as the DFR report number. For an open facility, beginning in 2012, the provider number reported on DFC is used as the main provider number for the DFR and QDFC reports. For hospital-based or satellite facilities, this is either the ESRD or hospital provider number. For a closed facility, the ESRD provider number is used as the DFR reporting number.

For DFR production, CMS data released between April-July are used for reports.

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 paid 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 of the four year DFR reporting period. 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., Veteran's Administration (VA) facilities).
2. Identify ESRD and HOSPITAL provider numbers for hospital based facilities.
3. Select records for active facilities for DFR and DFC.

   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 were active anytime over the four-year DFR period, 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 a closed date (*dateclosed)* on and after January 1, 2011 are selected. In addition, the middle 2 digits of the CCN must be one of the values shown in Section I. Facilities certified (*certdate*) on or after January, 1, 2015 receive a QDFC Preview report only (and not a DFR). 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 provider 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 during the four-year DFR period 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 each 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 for DFR. Transplant facilities and other facilities invalid for DFR purpose are output to other data files for data checking purposes.

   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 provider numbers that were active anytime over the current four-year DFR reporting period (*osc_TRMNTN_EXPRTN_DT* $\geq$ January 01, 2011**or** the termination date (*osc_TRMNTN_EXPRTN_DT*) is missing and has claims. That is, 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 DFR and/or DFC 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 (Appendix A). 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 DFR/QDFC reporting purpose and update the usage variables, variable labels, and formats.
d. Create the lookup file used to link all alternate/related provider numbers to the DFR/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, Large Dialysis Organization (LDO), 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.

3.2.4   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 (as of June 9, 2015). We consider there to be evidence of change of ownership (CHOW) when multiple records match on facility characteristics (name, address, etc.) and <u>also have</u> one of the following reported for one of the records: (1) a closed date, (2) new certification date, or (3) a name change indicating strong evidence of CHOW (i.e., different LDO 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 numbers were 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.

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

3.2.5.1   Facility Directory File

The facility directory file is extracted from CROWNWEB, a web-based data collection system that allows authorized used to securely submit, update, and verify data provided to Medicare on a monthly basis. 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

3.2.5.2   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 KECC-processed facility directory file for DFR during data processing.

3.2.5.3   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.

3.2.5.4   Dialysis Facility Compare File

The DFC project covers all open facilities at a given time. The Dialysis Facility Compare is extracted from CROWNWeb. We receive the DFC facility list file quarterly and in May. 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.

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. For facilities receiving a performance rate on a clinical measure in the ESRD QIP, receives 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 facilities measure score.

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 will be 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.

- The system will store both the unadjusted and adjusted measure rates, for each facility for each measure to which the adjustment was applied.

Table 2 lists each PY 2018 Clinical Measure and the defined Lower Threshold, Upper Threshold, Preferred Measure Rate Directionality, and the Measure Unit for each measure.

Table 2: PY 2018 Clinical Measures and the defined Lower Threshold, Upper Threshold, Preferred Measure Rate Directionality, and the Measure Unit for each Measure

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 and Risk
VAT: Catheter	11	25	Lower Rate indicates better performance	Eligible Patients
VAT: Fistula	11	25	Higher Rate indicates better performance	Eligible Patients
Kt/V Dialysis Adequacy: Adult Hemodialysis	11	25	Higher Rate indicates better performance	Eligible Patients
Kt/V Dialysis Adequacy: Peritoneal Dialysis	11	25	Higher Rate indicates better performance	Eligible Patients
Kt/V Dialysis Adequacy: Pediatric Hemodialysis	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

Small Facility Adjustment Calculation:

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) 2018

Table 3 defines key achievement and improvement scoring terms.

Table 3. Key Achievement and Improvement Scoring Terms

Term	Definition
Achievement threshold	The 15th percentile of performance rates nationally during 2014**
Benchmark	The 90th percentile of performance rates nationally during 2014**
Improvement threshold	Your facility's performance rate during 2015
Performance period	All of calendar year 2016*
Performance standard	The 50th percentile of performance rates nationally during 2014**
Facility performance rate	The percentage of a facility's patients either meeting or falling short of a measure's requirements during the performance period

NOTES:

* For the NHSN HCP Influenza measure, the performance period is October 1, 2015 through March 31, 2016.

** For ICH CAHPS, the period for calculating the achievement threshold, benchmark, and performance standard is calendar year 2015.

A higher measure rate does not necessarily indicate a better score. See the respective measure chapters for details on preferred directionality of each measure.

A facility's score for each clinical measure is calculated using the achievement and improvement scoring methodology. The score is based on the facility's performance rate during the performance period compared to two ranges.

The **achievement range** is the scale running from the achievement threshold to the benchmark

(15th Percentile – 90th percentile of performance rates nationally during 2014).

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 2015 – 90th 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.

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.

4.1.3   Exception to PY 2018 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 four-dialysis adequacy, and 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	Kt/V Adult Hemodialysis Measure Score	
b	Kt/V Adult Peritoneal Dialysis Measure Score	
c	Kt/V Pediatric Hemodialysis Measure Score	
d	Kt/V Pediatric Peritoneal Dialysis Measure Score	

2) Next, determine the total number of patients for weighting the denominator. This number is calculated by taking the sum of all eligible patients' included in each measure within the measure topic.

#	Calculation Definition	Value
	Measure Weight Calculation	
e	Number of patients included in Kt/V Adult Hemodialysis Measure Score calculation	
f	Number of patients included in Kt/V Adult Peritoneal Dialysis Measure Score calculation	
g	Number of patients included in Kt/V Pediatric Hemodialysis Measure Score calculation	
h	Number of patients included in Kt/V Pediatric Peritoneal Dialysis Measure Score	
i	Determine total number of patients for weighting denominator *Add e + f + g + h*	

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

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

#	Calculation Definition	Value
	Measure Topic Score Calculation	
j	Weight the Kt/V Adult Hemodialysis Measure Score *Calculate a x (e ÷ i)*	
k	Weight the Kt/V Adult Peritoneal Dialysis Measure Score *Calculate b x (f ÷ i)*	
l	Weight the Kt/V Pediatric Hemodialysis Measure Score *Calculate c x (g ÷ i)*	
m	Weight the Kt/V Pediatric Peritoneal Dialysis Measure Score *Calculate c x (g ÷ i)*	
n	Combine Measure Scores ***Add j + k + l + m and round***	
o	**Kt/V Dialysis Adequacy Measure Topic Score (from k)**	

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

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

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

To qualify a Total Performance Score (TPS) the facility must have earned a score on at least one clinical and one Reporting measure. 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 three categories. As seen in Table 4 below, each individual clinical measure or measure topic is assigned a specific weight within its respective subdomain.

Table 4. Clinical Measure/Measure Topic Weights

PY 2018 Measures/Measure Topics by Subdomain	PY 2018 Measure Weights in the Clinical Measure Domain Score
Safety Subdomain	**20%**
NHSN Bloodstream Infection measure	20%
Patient and Family Engagement/Care Coordination Subdomain	**30%**
ICH CAHPS measure	20%
SRR measure	10%
Clinical Care Subdomain	**50%**
STrR measure	7%
Dialysis Adequacy measure topic	18%
Vascular Access Type measure topic	18%
Hypercalcemia measure	7%

In order to calculate the Clinical Measure Domain Score, each individual measure, or measure topic score is converted to a weighted measure score within its respective Subdomain. These scores are then summed to make up the weighted subdomain score. Each subdomain score is then summed to make up the Clinical Measure Domain Score. See the example below for a hypothetical scenario of the Clinical Measure Domain Score calculation.

Example I: Eligible for All Measures

Scoring Example: Facility A

Clinical Measure	Measure Score
NHSN Bloodstream Infection (BSI)	8
ICH CAHPS	9
SRR	9
STrR	10
Dialysis Adequacy measure topic	10
Vascular Access measure topic	9
Hypercalcemia	10

Reporting Measure	Measure Score
Mineral Metabolism	8
Anemia Management	8
Pain Assessment and Follow-Up	10
Clinical Depression Screening and Follow-Up	10
NHSN HCP	10

Safety Subdomain formula

(NHSN BSI) x 10

Patient and Family Engagement/ Care Coordination Subdomain formula

$$\left[(.666 \times [\text{ICH CAHPS}]) + (.334 \times [\text{SRR}]) \right] \times 10$$

Clinical Care Subdomain formula

$$\left[(.14 \times [\text{STrR}]) + (.36 \times [\text{Dialysis Adequacy measure topic score}]) + (.36 \times [\text{Vascular Access measure topic score}]) + (.14 \times [\text{Hypercalcemia}]) \right] \times 10$$

Safety Subdomain formula

$$8 \times 10 = 80$$

Patient and Family Engagement/ Care Coordination Subdomain formula

$$\left[\frac{.666 \times 9}{+} .334 \times 9 \right] \times 10 = 90$$

Clinical Care Subdomain formula

$$\left[.14 \times 10 + .36 \times 10 + .36 \times 9 + .14 \times 10 \right] \times 10 = 96.4$$

Clinical Measure Domain Score formula

(.2 x [Safety Subdomain score])
+
(.3 x [Patient and Family Engagement/
Care Coordination Subdomain score])
+
(.5 x [Clinical Care Subdomain score])

Scoring Example: Facility A

Subdomain	Subdomain Score
Safety	80
Patient and Family Engagement/Care Coordination	90
Clinical Care	96.4

Clinical Measure Domain Score example for Facility A

16 + 27 + 48.2 = 91.2

Note: Although the example includes a step for calculating the subdomain scores, it is important to note that this calculation is not necessary. Clinical domain scores can be calculated solely based on the individual measure weights.

Example II: Eligible for All But One Subdomain

Scoring Example: Facility B

Clinical Measure	Measure Score
NHSN Bloodstream Infection (BSI)	N/A
ICH CAHPS	9
SRR	9
STrR	10
Dialysis Adequacy	10
Vascular Access measure topic	9
Hypercalcemia	10

Safety Subdomain formula

Not Eligible for NHSN

**Patient and Family Engagement/
Care Coordination Subdomain formula**

[(.666 x [ICH CAHPS])
+
(.334 x [SRR])] x 10

Clinical Care Subdomain formula

[(.14 x [STrR])
+
(.36 x [Dialysis Adequacy])
+
(.36 x [Vascular Access measure topic score])
+
(.14 x [Hypercalcemia])] x 10

Safety Subdomain formula

$$\boxed{\text{Not Eligible}} = \text{N/A}$$

Patient and Family Engagement/ Care Coordination Subdomain formula

$$\left[\begin{array}{c} .666 \times 9 \\ + \\ .334 \times 9 \end{array} \times 10\right] = 90$$

Clinical Care Subdomain formula

$$\left[\begin{array}{c} .14 \times 10 \\ + \\ .36 \times 10 \\ + \\ .36 \times 9 \\ + \\ .14 \times 10 \end{array} \times 10\right] = 96.4$$

Clinical Measure Domain Score formula

(Not eligible for the Safety Subdomain score)

(.4 x [Patient and Family Engagement/ Care Coordination Subdomain score])
+
(.6 x [Clinical Care Subdomain score])

Note: Weight of safety subdomain is distributed equally to remaining subdomains

Scoring Example: Facility B

Subdomain	Subdomain Score
Safety	N/A
Patient and Family Engagement/Care Coordination	90
Clinical Care	96.4

Clinical Measure Domain Score example for Facility B

$$36 + 57.84 = 93.84$$

Note: Although the example includes a step for calculating the subdomain scores, it is important to note that this calculation is not necessary. Clinical domain scores can be calculated solely based on the individual measure weights.

4.2.2   Calculating the Reporting Measure Domain Score

The reporting measure domain score is calculated by taking the sum of the facilities score on all eligible measure scores and dividing by the total possible score. See the examples below for examples.

Example I - Eligible for all Reporting Measures

Scoring Example: Facility A

Clinical Measure	Measure Score
NHSN BSI	8
ICH CAHPS	9
SRR	9
STrR	10
Dialysis Adequacy measure topic	10
Vascular Access measure topic	9
Hypercalcemia	10

Reporting Measure	Measure Score
Mineral Metabolism	8
Anemia Management	8
Pain Assessment and Follow-Up	10
Clinical Depression Screening and Follow-Up	10
NHSN HCP	10

Reporting Measure Domain Score formula

Mineral Metabolism score
+
Anemia Management score
+
Pain Assessment score
+
Depression Screening score
+
NHSN HCP score

Reporting Measure Domain Score example for Facility A

8 + 8 + 10 + 10 + 10 =
46/50 or 92%

Example II - Eligible for All But One Reporting Measures

Scoring Example: Facility B

Clinical Measure	Measure Score
NHSN BSI	8
ICH CAHPS	9
SRR	9
STrR	10
Dialysis Adequacy measure topic	10
Vascular Access measure topic	9
Hypercalcemia	10

Reporting Measure	Measure Score
Mineral Metabolism	N/A
Anemia Management	8
Pain Assessment and Follow-Up	10
Clinical Depression Screening and Follow-Up	10
NHSN HCP	10

Reporting Measure Domain Score formula

Mineral Metabolism score
+
Anemia Management score
+
Pain Assessment score
+
Depression Screening score
+
NHSN HCP score
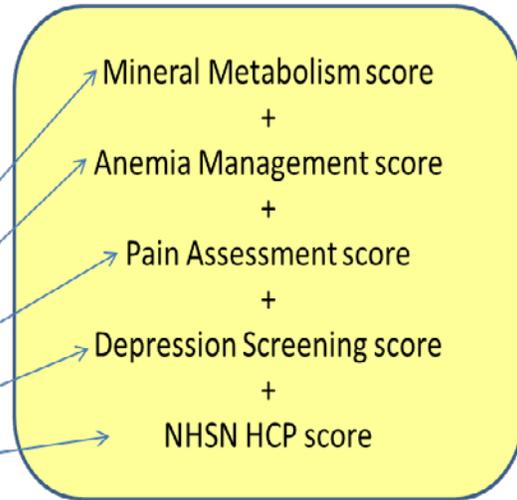
Reporting Measure Domain Score example for Facility B

8 + 10 + 10 + 10 = **38/40 or 95%**

4.2.3 Redistributing Weights when a Facility Is Not Scored on a Measure

If a facility does not meet the eligibility requirements for a clinical measure within a subdomain, the facility is not scored on the measure and the corresponding measure weight will be reallocated equally across all remaining clinical measures.

If a facility does not meet the eligibility requirements for all clinical measures within a subdomain, the weight of the subdomain is reallocated equally to all other eligible subdomains.

4.2.4 Calculation of Relative Weights Applied to Measure Scores

- The Total Performance score is comprised of the two measure categories below.
  - **Clinical measure Domain** 90%
  - **Reporting measure Domain:** 10%

The Total Performance Score (TPS) for the facility is then calculated by multiplying the Clinical Domain score by 0.9 and the Reporting Domain score by 0.1 and adding the results, as follows:

$$TPS = (0.9 * Clinical\ Domain\ Score) + (0.1 * Reporting\ Domain\ Score)$$

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

Table 5. TPS and Payment Reduction for PY 2018

Total Performance Score	Payment Reduction
Score meets or exceeds minimum Total Performance Score (100–49)	No reduction
1 to 10 points below minimum Total Performance Score (48–39)	0.5%
11 to 20 points below minimum Total Performance Score (38–29)	1.0%
21 to 30 points below minimum Total Performance Score (28–19)	1.5%
31 or more points below minimum Total Performance Score (18–0)	2.0%
No Score calculated	No reduction

5. Calculating Star Ratings for DFC

The following subsections describe how the DFC calculates Star Ratings.

5.1 Introduction

CMS, through a contract with University of Michigan Kidney Epidemiology and Cost Center (UM-KECC), developed a Star Quality Rating System to rate the quality of care provided by dialysis facilities. The goal of the Star Ratings is to provide patients, their families, and caregivers information that they can use to easily compare dialysis facilities as well as be aware of areas of care delivery where the quality of care is rated lower. This document describes an overall quality rating system that gives each facility a rating between one and five stars. Facilities with five stars are considered to deliver much above average quality of care and those with one star are considered to deliver care that is rated much below average quality, compared to other dialysis facilities in the nation.

5.2 Overview of Measures

A set of DFC Quality Measures (QMs) has been developed over the past 10 years. These are currently implemented on DFC and are used to rate the quality of care at all Medicare certified facilities. We used nine of the eleven QMs reported on the Medicare DFC website in the algorithm to determine the Star Rating for facilities using January 2013 release data.[1] The Urea Reduction Ratio (URR) a measure of dialysis adequacy, and hemoglobin (measure of anemia management) measures were not used in this rating system because most patients achieve the goal values (national averages are 99% and 0% respectively) resulting in very little variability across facilities. Additionally, the three QMs measuring Kt/V levels are combined resulting in seven final measures used to rate facilities.

Quality Measures Used in Star Rating Calculation

- Standardized Transfusion Ratio (STrR) (lower is better, updated yearly)

- Standardized Mortality Ratio (SMR) (lower is better, updated yearly)

- Standardized Hospitalization Ratio (SHR) (lower is better, updated yearly)

- Percentage of adult hemodialysis patients who had enough wastes removed from their blood during dialysis: Kt/V greater than or equal to 1.2 (higher is better, updated quarterly).

- Percentage of pediatric hemodialysis patients who had enough wastes removed from their blood during dialysis: Kt/V greater than or equal to 1.2 (higher is better, updated quarterly).

- Percentage of adult peritoneal dialysis patients who had enough wastes removed from their blood during dialysis: Kt/V greater than or equal to 1.7 (higher is better, updated quarterly).

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[1] SMR is based on previous 4 years of data. All other measures are based on previous year of data.

- Percentage of adult patients who received treatment through arteriovenous fistula (AVF) (higher is better, updated quarterly).

- Percentage of adult patients who had a catheter (tube) left in a vein longer than 90 days, for their regular hemodialysis treatment (catheter > 90) (lower is better, updated quarterly).

- 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).

There are currently three separate measures that report on a facility's achievement of removing enough wastes from the blood using Kt/V measurements for different types of patients, either based on modality, or for pediatric patients with hemodialysis (HD) as their modality. These are, respectively, measures for adult HD, adult peritoneal dialysis (PD), and pediatric HD patients. However, many facilities do not have peritoneal dialysis patients and/or have few to no pediatric hemodialysis patients. To improve the ability to compare facilities with these different patient types, these three Kt/V measurements were combined into one measure. The percentage of patients that achieve Kt/V greater than the specified thresholds for each of the three respective patient types (adult PD patients, adult HD patients, and pediatric HD patients), was weighted based on the number of patient-months of data available. The resulting pooled measure (all Kt/V) represents the percentage of total dialysis patients who had enough wastes removed from their blood (Kt/V greater than or equal to specified threshold). After these measures were combined, there were seven final measures used to rate the dialysis facilities.

5.3 Developing Quality Measure Domains

The following subsections describe how quality measure domains are constructed in DFC Star Ratings.

5.3.1 Analytic Approach

A straight forward way of constructing an overall rating would be to use the un-weighted average of the seven final QMs. The correlation structure of the QMs (Table 6) reveal some measures are more correlated than with the others, which might cause issues with the equal weighting. Specifically, if some correlated QMs measure a similar aspect of quality of a facility and fewer QMs measure a different quality of a facility, equal weighting would artificially count the preceding quality as more important. We addressed this problem by grouping QMs in an unbiased manner by using factor analysis.

Factor analysis is a method for reducing a set of variables into groupings or latent factors that measure similar qualities based on the observed covariance structure (Johnson & Wichern, 2007). By grouping QMs into different domains, we can develop a final score based on equal weights of these latent factors which can be used to partition facilities into 5 different "star" levels. Equal weighting of these domains rather than the individual QMs avoids overweighting large groups of associated measures.

5.3.2   Standardization of Measures

The DFC QMs are noticeably different in distributions as well as scales. In order to make measures comparable across facilities and to reduce the impact of few possible outliers, we standardize the measures by using their ranks (instead of the original values) and align all the measures in the same direction. Specifically, for each QM, the facility performances are separated into 100 groups or "percentile ranks" ranging from 0.5 to 99.5 increasing by 1 where higher rank indicates a better score on a measure. To further differentiate facilities that performed exceptionally well or poorly, these percentile ranks (pRanks) were "normalized" or mapped from the uniform percentile rank distribution to a normal distribution (nRanks).

By using the transformation:

$$nRanks = \Phi{-}1(pRanks \div 100) \times 19.4112 + 50 \, ,$$

the 0.5 and 99.5 percentile were first mapped to z-scores of the standard normal distribution. Scaling these 0 centered z-scores by a factor of 19.4112 and shifting by a value of 50, the normalized percentile ranks were centered at 50, with the lowest value achieving 0 and the highest 100.

Example: Suppose one of the QMs which measure the percentage of patients within a facility "passing" a threshold is right skewed (Figure 16). Using normal ranks allows many facilities to fall around the middle of the distribution, making extreme values more difficult to obtain. This method allows all measures to be scored in the same manner preventing different weighting on measures due to diverse distributions and scales. This method also manages to control outliers from having scores that differ extremely from the other facilities while recognizing that exceptionally high or low values should be distinguished.
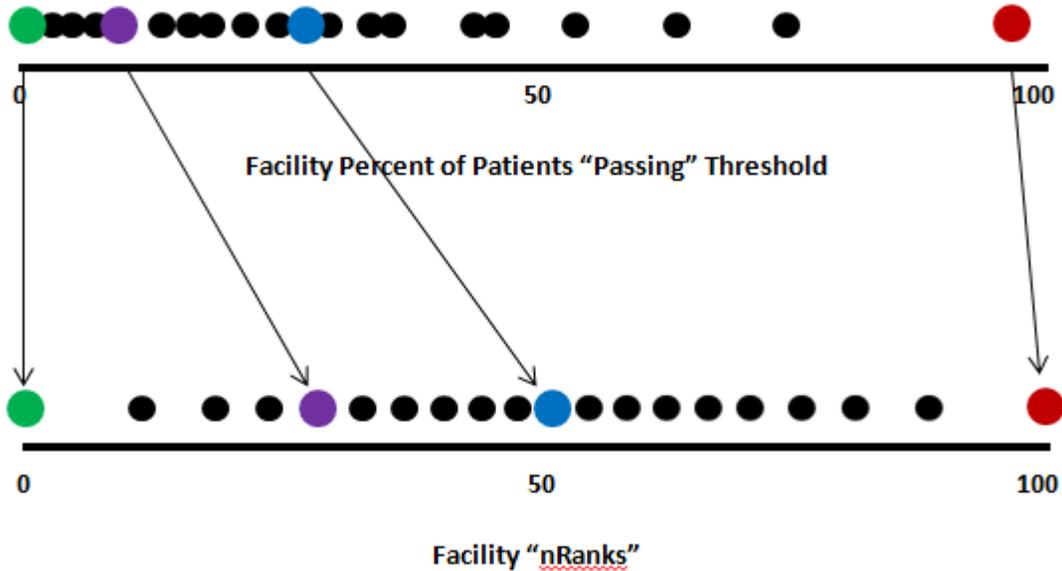
Figure 16. Depiction of Normalization Algorithm

Table 6. Correlation of Normalized Measures

Measures	STrR	SHR	SMR	All Kt/V	Hypercalcemia	AVF	Catheter > 90
STrR	1.0000	*0.40139*	*0.21471*	0.08497	-0.00204	0.11354	0.15369
SHR		1.00000	*0.26229*	0.11016	0.00509	0.12759	0.18672
SMR			1.00000	0.07859	0.05328	0.16660	0.11062
All Kt/V				1.00000	*0.18577*	0.06416	0.13376
Hypercalcemia					1.00000	0.08786	0.04866
AVF						1.00000	*0.44751*
Catheter > 90							1.00000

Based on January 2014 DFC data

5.4 Factor Analysis

When performing a factor analysis, we specify that our statistical software uses the method of principal components to extract the factors with loadings based on eigenvalue-eigenvector pairs of the sample covariance matrix. The resulting procedure is called the principal factor analysis, a common way of conducting factor analysis. We specify the prior communality estimates to substitute into the diagonal of the correlation matrix. The principal factor analysis uses squared multiple correlations (SMC) as priors. Finally, a rotation must be specified to obtain interpretable factor loadings (SAS/STAT 9.22 User's Guide).

The screen plot displayed in Figure 17 shows the eigenvalues associated with the correlation matrix of the measures in the December 2013 release dataset. One method of choosing the number of factors for data reduction is to take the factors before a breaking point in the plot (relatively large drop), and another, the positive eigenvalues (UCLA: Statistical Consulting Group). While there is a noticeable drop after the first eigenvalue (a global factor), a multiple factor solution allows the measurement of subgroups within the QMs. We observe a second, smaller break after the third eigenvalue which happens to be the cutoff between positive and negative eigenvalues. We investigate the three factor solution here for interpretable results.
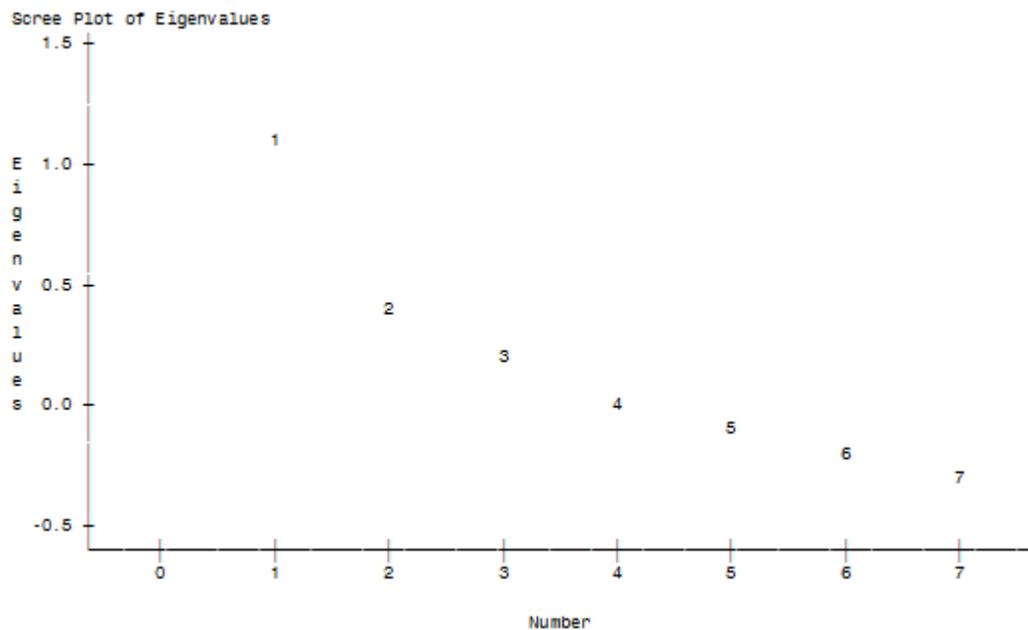
Figure 17. Screen Plot of Eigenvalues

Both the orthogonal and oblique rotations were fit. The factor loadings from both methods were similar and yield the same interpretable results as to which QMs were associated with which domains. If results had been different, the orthogonal rotation would have been the better method if the oblique solution had shown little correlation between factors. The QMs that are loaded highly on each of the three factors were allocated into 3 domains.

5.5   Quality Measure Domains

With the obtained factor loadings, the three respective empirically derived groups (domains) were also determined to correspond to related outcomes at the facility level. The three outcome measures for transfusions, mortality and hospitalization formed the first grouping which was named the "Standardized Outcomes (SHR, SMR, STrR)". The arteriovenous fistula and catheter measures formed the second grouping which was named "Other Outcomes 1 (AV fistula, tunneled catheter)" The All Kt/V and hypercalcemia QMs formed the third grouping which was named "Other Outcomes 2 (Kt/V, hypercalcemia)". Together, these empirically derived groupings contain measures that are most correlated with one another, as indicated in the cells with the bolded correlation coefficients in Table 6. This is further evidence that grouped measures provide information on similar qualities about a facility.

5.6   Overall Star Rating for Each Facility

To create the Star rating system, each domain is first given a score between 0 and 100 by averaging the normalized scores for measures within that domain. Facilities are given ratings as long as they have at least one measure in each domain. Facilities that served PD patients only (N=92 in the January 2014 data) do not have values for the two measures in the Other Outcomes 1 (AV fistula, tunneled catheter) Domain. These facilities were not excluded and instead were

rated based on the average scores for the other domains. Among the 6,033 facilities in the January 2014 dataset, 542 (9% were unrated). In Table 7, the number and percentage of facilities with missing data is shown by the number of measures missing. Most facilities (81%) had all seven measures. Table 8 shows the number of facilities with missing data for each measure. The STrR measure was missing the most often in facilities.

Table 7. Number and Percent of Facilities Overall and Those Unrated by the Number of Measures Missing

# Measures Missing	# Facilities (%)	# Facilities Unrated (%)
0	4,903(81)	0 (0)
1	400 (7)	0 (0)
2	180 (3)	42 (23)
3	144 (2)	109 (76)
4	79 (1)	69 (87)
5	50 (1)	45 (90)
6	47 (1)	47 (100)
7	230 (4)	230 (100)
Total	6,033	542 (9)

Based on January 2014 DFC data

Table 8. Number and Percent of Facilities with Missing Data by Each Measure

Measures	# Facilities with Missing Data (%)
STrR	804 (13)
SHR	430 (7)
SMR	468 (8)
All Kt/V	386 (6)
Hypercalcemia	650 (11)
AVF	456 (8)
Catheter > 90 days	456 (8)

Based on January 2014 DFC data

After factor analysis is performed, missing values for facilities that qualified for ratings are assigned median pRanks and nRanks of 50. This method of imputation ensures that one measure is not too influential in the final rating. For instance, if one facility had an nRank of 100 for the catheter > 90 day measure and had no report of arterial venous fistula (AVF), it would be

unreasonable to assume that the Other Outcomes 1 (AV fistula, tunneled catheter) Domain should be given an average score of 100. By imputing 50 (the average) for the AVF measure, we instead give the domain a score of 75, still well above average, but conservative enough to limit catheter > 90 days measure from being too influential.

A final score between 0 and 100 is then created by averaging the three domain scores.

Finally, to recognize high and low performances, facilities receive stars in the following way:

- Facilities with top 10% final scores were given a rating of 5 stars.
- Facilities with the next 20% highest final scores were given a rating of 4 stars.
- Facilities within the middle 40% of final scores were given a rating of 3 stars.
- Facilities with the next 20% lowest final scores were given a rating of 2 stars.
- Facilities with bottom 10% final scores were given a rating of 1 star.

A 1- or 2-star rating does not mean that you will receive poor care from a facility. It only indicates that measured outcomes were below average compared to those for other facilities.

In the January 2014 release dataset, we observed a noticeable systematic improvement of all average measure values with higher star rating (Table 9).

Table 9. Average Measure Values Within Overall Star Rating

Measure	★	★★	★★★	★★★★	★★★★★
STrR	1.50	1.20	1.00	0.81	0.63
SHR	1.28	1.12	0.99	0.86	0.75
SMR	1.34	1.11	1.02	0.93	0.84
All Kt/V	75.5	81.8	86.8	89.5	92.3
Hypercalcemia	5.7	4.6	3.4	2.3	1.8
AVF	48.6	56.0	62.1	67.3	73.2
Catheter > 90	20.3	14.7	10.6	7.6	5.2

Based on January 2014 DFC data

5.7   Conclusions

This methodology report presents an overview of the DFC Star Rating of facilities based on the groupings of correlated quality measures that are currently reported on the Medicare DFC website. In future years, when reported DFC measures change, the general algorithm described here will be used to update measure domains used to produce the rating. For the implementation

of the Star System with January 2014 data, average measure values are consistently better with higher Overall Star Rating (Table 9). The analysis of ratings over time was limited because data for some measures have only been available recently. However, the data available showed evidence that the ratings would not behave erratically over time. An advantage to the Star Rating, is the grouping of QMs based on systematic empirical methods, specifically, factor analysis. This method limits the possibility of overweighting QMs that measure similar qualities of facility care. Finally, the Star Rating is updated annually, to align with the annual updates of the standardized measures.

5.8   References

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- SAS/STAT(R) 9.22 User's Guide. Retrieved April 26, 2014, from http://support.sas.com/documentation/cdl/en/statug/63347/HTML/default/viewer.htm#statug_factor_sect029.htm

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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	Bloodstream 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 Medicare & Medicaid Services
CROWN	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	Department of Health and Human Services
HIV	Human Immunodeficiency Virus

Acronym	Definition
HWR	Hospital-Wide Readmission Measure
ICH CAHPS	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems
KDOQI	Kidney Disease Outcomes Quality Initiative
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 Bloodstream 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
REBUS	Renal Beneficiary and Utilization System
REMIS	Renal Management Information System
SAF	Standard Analysis File
SHR	Standardized Hospitalization Ratio
SMR	Standardized Mortality Ratio
SNF	Skilled Nursing Facility
SRR	Standardized Readmission Ratio
STrR	Standardized Transfusion Ratio
TEP	Technical Evaluation Panel
TPS	Total Performance Score
UKM	Urea Kinetic Modeling

Acronym	Definition
UM – KECC	University of Michigan Kidney Epidemiology and Cost Center
URR	Urea Reduction Ratio
USRDS	United States Renal Data System
VA	Veterans Administration
VAT	Vascular Access Type