



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

CMS ESRD Measures Manual for the 2018 Performance Period / 2020 Payment Year

Final

Version 3.1

March 4, 2019

Table of Contents

1. Introduction	1
2. Measurement Information	2
2.1 Vascular Access Type Clinical Measure: Fistula (ESRD QIP Only)	2
2.1.1 Measure Name	2
2.1.2 Measure Description	2
2.1.3 Measure Rationale	2
2.1.4 Measure Type	2
2.1.5 Improvement Noted as Higher or Lower Rate	2
2.1.6 Risk Adjustment	2
2.1.7 Numerator Statement	2
2.1.8 Facility Exclusions	2
2.1.9 Denominator Statement	2
2.1.10 Denominator Exclusions	3
2.1.11 Mapping Patients to Facilities	3
2.1.12 Calculating Numerators	3
2.1.13 Data Elements and Data Sources	3
2.1.14 Flowchart	5
2.1.15 Selected References	6
2.2 Vascular Access Type Clinical Measure: Catheter \geq 90 Days (ESRD QIP Only)	7
2.2.1 Measure Name	7
2.2.2 Measure Description	7
2.2.3 Measure Rationale	7
2.2.4 Measure Type	7
2.2.5 Improvement Noted as Higher or Lower Rate	7
2.2.6 Risk Adjustment	7
2.2.7 Numerator Statement	7
2.2.8 Facility Exclusions	7
2.2.9 Denominator Statement	7
2.2.10 Denominator Exclusions	8
2.2.11 Mapping Patients to Facilities	8
2.2.12 Calculating Numerators	8
2.2.13 Data Elements and Data Sources	8
2.2.14 Flowchart	9
2.2.15 Selected References	11
2.3 Vascular Access Type Clinical Measure: Hemodialysis Vascular Access: Long-term Catheter Rate (DFC Only)	12
2.3.1 Measure Name	12
2.3.2 Measure Description	12
2.3.3 Measure Rationale	12
2.3.4 Measure Type	12
2.3.5 Improvement Noted as Higher or Lower Rate	12
2.3.6 Numerator Statement	12

2.3.7	Facility Exclusions	13
2.3.8	Denominator Statement	13
2.3.9	Denominator Exclusions	13
2.3.10	Mapping Patients to Facilities	13
2.3.11	Calculating Numerators.....	14
2.3.12	Data Elements and Data Source	14
2.3.13	Flowchart.....	15
2.3.14	Selected References.....	17
2.4	Hemodialysis Vascular Access: Standardized Fistula Rate (DFC Only)	18
2.4.1	Measure Name.....	18
2.4.2	Measure Description.....	18
2.4.3	Measure Rationale	18
2.4.4	Measure Type	18
2.4.5	Improvement Noted as Higher or Lower Rate	18
2.4.6	Risk Adjustment	19
2.4.7	Numerator Statement.....	19
2.4.8	Facility Exclusions	19
2.4.9	Denominator Statement	19
2.4.10	Denominator Exclusions	19
2.4.11	Mapping Patients to Facilities	20
2.4.12	Calculating Numerators.....	20
2.4.13	Statistical Risk Model and Variables	21
2.4.14	Data Elements and Data Sources.....	22
2.4.15	Flowchart.....	25
2.4.16	Selected References.....	26
2.5	Adult Hemodialysis Adequacy Measure (DFC Only).....	27
2.5.1	Measure Name.....	27
2.5.2	Measure Description.....	27
2.5.3	Measure Rationale	27
2.5.4	Measure Type	27
2.5.5	Improvement Noted as Higher or Lower Rate	27
2.5.6	Risk Adjustment	27
2.5.7	Numerator Statement.....	27
2.5.8	Facility Exclusions	27
2.5.9	Denominator Statement	28
2.5.10	Denominator Exclusions	28
2.5.11	Mapping Patients to Facilities	28
2.5.12	Calculating Numerators.....	29
2.5.13	Assigning Patient-Months to Numerators and Denominators.....	29
2.5.14	Data Elements and Data Sources.....	29
2.5.15	Selected References.....	30
2.6	Adult Peritoneal Dialysis Adequacy Measure (DFC Only).....	32
2.6.1	Measure Name.....	32
2.6.2	Measure Description.....	32
2.6.3	Measure Rationale	32
2.6.4	Measure Type	32

2.6.5	Improvement Noted as Higher or Lower Rate	32
2.6.6	Risk Adjustment	32
2.6.7	Numerator Statement.....	32
2.6.8	Facility Exclusions	32
2.6.9	Denominator Statement	32
2.6.10	Denominator Exclusions	33
2.6.11	Mapping Patients to Facilities	33
2.6.12	Calculating Numerators.....	33
2.6.13	Assigning Patient-Months to Numerators and Denominators.....	34
2.6.14	Data Elements and Data Sources.....	34
2.6.15	Selected References.....	35
2.7	Pediatric Hemodialysis Adequacy Measure (DFC Only).....	36
2.7.1	Measure Name.....	36
2.7.2	Measure Description.....	36
2.7.3	Measure Rationale	36
2.7.4	Measure Type	36
2.7.5	Improvement Noted as Higher or Lower Rate	36
2.7.6	Risk Adjustment	36
2.7.7	Numerator Statement.....	36
2.7.8	Facility Exclusions	36
2.7.9	Denominator Statement	36
2.7.10	Denominator Exclusions	37
2.7.11	Mapping Patients to Facilities	37
2.7.12	Calculating Numerators.....	37
2.7.13	Assigning Patient-Months to Numerators and Denominators.....	38
2.7.14	Data Elements and Data Sources.....	38
2.7.15	Selected References.....	39
2.8	Pediatric Peritoneal Dialysis Adequacy Measure (DFC Only).....	40
2.8.1	Measure Name.....	40
2.8.2	Measure Description.....	40
2.8.3	Measure Rationale	40
2.8.4	Measure Type	40
2.8.5	Improvement Noted as Higher or Lower Rate	40
2.8.6	Risk Adjustment	40
2.8.7	Numerator Statement.....	40
2.8.8	Facility Exclusions	40
2.8.9	Denominator Statement	41
2.8.10	Denominator Exclusions	41
2.8.11	Mapping Patients to Facilities	41
2.8.12	Calculating Numerators.....	42
2.8.13	Assigning Patient-Months to Numerators and Denominators.....	42
2.8.14	Data Elements and Data Sources.....	42
2.8.15	Selected References.....	43
2.9	Kt/V Dialysis Adequacy Comprehensive Clinical Measure (ESRD QIP Only)	44
2.9.1	Measure Name.....	44
2.9.2	Measure Description.....	44

2.9.3	Measure Rationale	44
2.9.4	Measure Type	44
2.9.5	Improvement Noted as Higher or Lower Rate	44
2.9.6	Risk Adjustment	44
2.9.7	Numerator Statement	45
2.9.8	Facility Exclusions	45
2.9.9	Denominator Statement	45
2.9.10	Denominator Exclusions	45
2.9.11	Mapping Patients to Facilities	47
2.9.12	Calculating Numerators	47
2.9.13	Assigning Patient-Months to Numerators and Denominators	48
2.9.14	Data Elements and Data Sources	49
2.9.15	Flowchart	51
2.10	nPCR for Pediatric Hemodialysis Patients (DFC only)	52
2.10.1	Measure Name	52
2.10.2	Measure Description	52
2.10.3	Measure Rationale	52
2.10.4	Measure Type	52
2.10.5	Improvement Noted as Higher or Lower Rate	52
2.10.6	Risk Adjustment	52
2.10.7	Numerator Statement	52
2.10.8	Facility Exclusions	52
2.10.9	Denominator Statement	52
2.10.10	Denominator Exclusions	52
2.10.11	Mapping Patients to Facilities	53
2.10.12	Calculating Numerators	53
2.10.13	Data Elements and Data Sources	53
2.10.14	Flowchart	55
2.10.15	Selected References	56
2.11	Hypercalcemia Clinical Measure (ESRD QIP and DFC)	57
2.11.1	Measure Name	57
2.11.2	Measure Description	57
2.11.3	Measure Rationale	57
2.11.4	Measure Type	57
2.11.5	Improvement Noted as Higher or Lower Rate	57
2.11.6	Risk Adjustment	58
2.11.7	Numerator Statement	58
2.11.8	Facility Exclusions	58
2.11.9	Denominator Statement	58
2.11.10	Denominator Exclusions	58
2.11.11	Mapping Patients to Facilities	59
2.11.12	Calculating Numerators	59
2.11.13	Data Elements and Data Sources	60
2.11.14	Flowchart for ESRD QIP	62
2.11.15	Flowchart for DFC	63
2.11.16	Selected References	64

2.12	Anemia Management Reporting Measure (ESRD QIP Only)	66
2.12.1	Measure Name	66
2.12.2	Measure Description	66
2.12.3	Measure Type	66
2.12.4	Facility-Level Exclusions	66
2.12.5	Patient-Level Exclusions	66
2.12.6	Facility-Month-Level Exclusions	66
2.12.7	Determining Successful Reporting for a Patient	67
2.12.8	Calculating Monthly Reporting Percentages	67
2.12.9	Determining Successful Reporting for a Month	67
2.12.10	Determining Requisite Reporting-Months for a Facility	67
2.12.11	Calculating a Facility's Score on the Anemia Management Reporting Measure	68
2.12.12	Data Elements and Data Sources	68
2.12.13	Flowchart	70
2.13	Serum Phosphorus Reporting Measure (ESRD QIP Only)	71
2.13.1	Measure Name	71
2.13.2	Measure Description	71
2.13.3	Measure Type	71
2.13.4	Facility-Level Exclusions	71
2.13.5	Numerator Statement	71
2.13.6	Denominator Statement	71
2.13.7	Patient-Level Exclusions	71
2.13.8	Facility-Month-Level Exclusions	72
2.13.9	Determining Successful Reporting for a Patient	72
2.13.10	Calculating Monthly Reporting Percentages	72
2.13.11	Determining Successful Reporting for a Month	72
2.13.12	Determining Requisite Reporting-Months for a Facility	72
2.13.13	Calculating a Facility's Score on the Serum Phosphorous Reporting Measure	73
2.13.14	Data Elements and Data Sources	73
2.13.15	Flowchart	74
2.14	Clinical Depression Screening and Follow-Up Reporting Measure (ESRD QIP Only)	75
2.14.1	Measure Name	75
2.14.2	Measure Description	75
2.14.3	Measure Type	75
2.14.4	Facility-Level Exclusions	75
2.14.5	Patient-Level Exclusions	75
2.14.6	Determining Successful Reporting for a Patient	75
2.14.7	Calculating a Facility's Score on the Depression Screening and Follow-Up Reporting Measure	77
2.14.8	Data Elements and Data Sources	77
2.14.9	Flowchart	78
2.15	Pain Assessment and Follow-Up Reporting Measure (ESRD QIP Only)	79
2.15.1	Measure Name	79

2.15.2	Measure Description.....	79
2.15.3	Measure Type	79
2.15.4	Facility-Level Exclusions.....	79
2.15.5	Patient-Level Exclusions.....	79
2.15.6	Determining Successful Reporting for a Patient	79
2.15.7	Calculating a Facility’s Score on the Pain Assessment and Follow-Up Reporting Measure	81
2.15.8	Data Elements and Data Sources.....	81
2.15.9	Flowchart.....	81
2.16	Standardized Readmissions Ratio (SRR) Clinical Measure (ESRD QIP and DFC)	83
2.16.1	Measure Name.....	83
2.16.2	Measure Description.....	83
2.16.3	Measure Rationale	83
2.16.4	Measure Type	83
2.16.5	Improvement Noted as Higher or Lower Rate	83
2.16.6	Numerator Statement.....	83
2.16.7	Facility - Level Exclusions.....	83
2.16.8	Denominator Statement	84
2.16.9	Denominator Exclusions	84
2.16.10	Patient Exclusions	84
2.16.11	Mapping Patients to Facilities	84
2.16.12	Calculating Numerators/Outcome Definition	84
2.16.13	Calculation of SRR.....	87
2.16.14	Calculation of SRR P-Values and Confidence Intervals (DFC only)	89
2.16.15	Flagging Rules for Dialysis Facility Compare (DFC only)	89
2.16.16	Data Elements and Data Sources.....	89
2.16.17	Flowchart.....	95
2.16.18	Selected References.....	96
2.17	Standardized Transfusion Ratio (STrR) Clinical Measure (ESRD QIP and DFC)	99
2.17.1	Measure Name.....	99
2.17.2	Measure Description.....	99
2.17.3	Measure Rationale	99
2.17.4	Measure Type	100
2.17.5	Improvement Noted as Higher or Lower Rate	100
2.17.6	Numerator Statement.....	100
2.17.7	Facility Exclusions	100
2.17.8	Denominator Statement	100
2.17.9	Denominator Exclusions	100
2.17.10	Mapping Patients to Facilities	102
2.17.11	Calculating Numerators.....	103
2.17.12	Days at Risk for Medicare Dialysis Patients	104
2.17.13	Risk Adjustment	104
2.17.14	Calculating Expected Number of Transfusions.....	105
2.17.15	Calculation of STrR P-values and Confidence Intervals (DFC Only)	106
2.17.16	Data Elements and Data Sources.....	107
2.17.17	Flowchart.....	109

2.17.18	Determining Transfusion Events Flow Chart.....	111
2.17.19	Selected References.....	114
2.18	Standardized Hospitalization Ratio (SHR) Measure (ESRD QIP and DFC)	116
2.18.1	Measure Name.....	116
2.18.2	Measure Description.....	116
2.18.3	Measure Rationale	116
2.18.4	Measure Type	116
2.18.5	Improvement Noted as Higher or Lower Rate	116
2.18.6	Numerator Statement.....	116
2.18.7	Facility Exclusions	116
2.18.8	Denominator Statement.....	116
2.18.9	Denominator Exclusions	116
2.18.10	Mapping Patients to Facilities	117
2.18.11	Calculating Numerators.....	119
2.18.12	Risk Adjustment.....	119
2.18.13	Calculating Expected Hospital Admissions	120
2.18.14	Calculation of SHR P-Values and Confidence Intervals (DFC Only)	121
2.18.15	Flagging Rules for Dialysis Facility Compare (DFC).....	122
2.18.16	Data Elements and Data Sources.....	122
2.18.17	Flowchart.....	124
2.18.18	Selected References.....	125
2.19	Standardized Mortality Ratio (SMR) Measure (DFC Only).....	126
2.19.1	Measure Name.....	126
2.19.2	Measure Description.....	126
2.19.3	Measure Rationale	126
2.19.4	Measure Type	126
2.19.5	Improvement Noted as Higher or Lower Rate	126
2.19.6	Numerator Statement.....	126
2.19.7	Facility Exclusions	126
2.19.8	Denominator Statement.....	126
2.19.9	Denominator Exclusions	126
2.19.10	Mapping Patients to Facilities	127
2.19.11	Calculating Numerators/Outcome definition	129
2.19.12	Risk Adjustment.....	129
2.19.13	Calculation of Expected Deaths at a Facility	131
2.19.14	Creating Interval Estimates	132
2.19.15	Flagging Rules for Dialysis Facility Compare (DFC).....	133
2.19.16	Data Elements and Data Sources.....	133
2.19.17	Flowchart.....	135
2.19.18	Selected References.....	136
2.20	ICH CAHPS Clinical Measure (ESRD QIP Only)	137
2.20.1	Measure Name.....	137
2.20.2	Measure Description.....	137
2.20.3	Improvement Noted as Higher or Lower Rate	137
2.20.4	Numerator Statement.....	137
2.20.5	Facility Exclusions	137

2.20.6	Denominator Statement	137
2.20.7	Denominator Exclusions	138
2.20.8	Additional Information	138
2.20.9	Data Elements and Data Sources.....	138
2.20.10	Flowchart.....	139
2.20.11	Selected References.....	141
2.21	NHSN Bloodstream Infection in Hemodialysis Patients Clinical Measure (ESRD QIP Only)	142
2.21.1	Measure Name.....	142
2.21.2	Measure Description.....	142
2.21.3	Improvement Noted as Higher or Lower Rate	142
2.21.4	Numerator Statement.....	142
2.21.5	Facility Exclusions	142
2.21.6	Denominator Statement	142
2.21.7	Patient-Level Exclusions	142
2.21.8	Additional Information.....	143
2.21.9	Data Elements and Data Sources.....	143
2.21.10	Flowchart.....	144
2.22	NHSN Health Care Personnel Influenza Vaccination Reporting Measure (ESRD QIP Only)	145
2.22.1	Measure Name.....	145
2.22.2	Measure Description.....	145
2.22.3	Improvement Noted as Higher or Lower Rate	145
2.22.4	Facility Exclusions	145
2.22.5	Additional Information.....	145
2.22.6	Data Elements and Data Sources.....	146
2.22.7	Flowchart.....	146
2.23	NHSN Dialysis Event Reporting Measure (ESRD QIP Only)	148
2.23.1	Measure Name.....	148
2.23.2	Measure Description.....	148
2.23.3	Improvement Noted as Higher or Lower Rate	148
2.23.4	Facility Exclusions	148
2.23.5	Additional Information.....	148
2.23.6	Data Elements and Data Sources.....	148
2.23.7	Flowchart.....	149
2.24	Ultrafiltration Reporting Measure (ESRD QIP Only)	150
2.24.1	Measure Name.....	150
2.24.2	Measure Description.....	150
2.24.3	Measure Rationale	150
2.24.4	Measure Type	150
2.24.5	Numerator Statement.....	150
2.24.6	Facility-level Exclusions	150
2.24.7	Denominator Statement.....	150
2.24.8	Patient-level Exclusions	151
2.24.9	Facility-Month-Level Exclusions.....	151
2.24.10	Determining Successful Reporting for a Patient	151

2.24.11	Calculating Monthly Reporting Percentage	151
2.24.12	Determining Successful Reporting for a Month.....	151
2.24.13	Determining Requisite Reporting-Months for a Facility	152
2.24.14	Calculating a Facility’s Score on the Ultrafiltration Reporting Measure.....	152
2.24.15	Flowchart.....	152
2.24.16	Data Elements and Data Sources.....	154
3.	Cross-Measure Determinations	155
3.1	Determining Patient-Level Exclusions	155
3.1.1	Modality Determination	155
3.1.2	Access Type Determination	160
3.1.3	Time on ESRD Treatment.....	160
3.1.4	Patient Age	162
3.1.5	Determination of Weekly Dialysis and “Frequent Dialysis”	162
3.1.6	Length of Treatment at a Facility	163
3.1.7	Deriving Patient Date of Death	164
3.2	Linking Patient Data	166
3.3	Facility Mapping and Impacts of Change of Ownership.....	169
3.3.1	DFC Specific	169
3.3.2	Overview of Provider Numbers	169
3.3.3	Overview of Main Considerations Associated with Creating a Facility List.....	169
3.3.4	Overview of the Facility List Creation Process.....	171
3.3.5	Additional Rules for Linking Provider Numbers.....	173
3.3.6	Descriptions of the Data Files Used to Create the Facility List	175
3.3.7	ESRD QIP Facility List and Changes of Ownership	176
3.3.8	CROWN Facility Record Consolidation.....	176
3.3.9	CROWN Data Clean-up.....	177
3.3.10	ESRD QIP Eligibility	177
3.3.11	CCN History.....	177
3.4	Extraordinary Circumstance Exception/Extension.....	178
4.	Methodologies for Deriving ESRD QIP Scores.....	179
4.1	Calculating an ESRD QIP Score from a Facility’s Performance Rate on a Clinical Measure	179
4.1.1	Small Facility Adjustment.....	179
4.1.2	Achievement and Improvement Scoring.....	182
4.1.3	Scoring for ICH CAHPS Clinical Measure.....	184
4.1.4	Scoring Measure Topics.....	184
4.2	Calculating a Facility’s Total Performance Score from the Facility’s Measure Scores	187
4.2.1	Calculating the Clinical Measure Domain Score	187
4.2.2	Calculating the Reporting Measure Domain Score	189
4.2.3	Calculating the Safety Measure Domain Score.....	190
4.2.4	Redistributing Weights when a Facility is Not Scored on a Measure.....	191
4.2.5	Calculation of Relative Weights Applied to Measure Scores	191

4.3 Calculating a Facility’s Payment Reduction for the Facility’s TPS193

5. Calculating Star Ratings for DFC 194

5.1 Background and Introduction194

5.2 Summary of Methodology Updates for the October 2018 DFC Release.....195

5.3 DFC Quality Measures Used in Calculating the Star Ratings195

5.3.1 Measures Added, Replaced, or Updated for the 2018 DFC Star Rating System Release.....195

5.4 Final Set of Quality Measures Used in the Clinical Star Rating Calculation196

5.5 ICH CAHPS Star Rating Calculation197

5.6 Development of Measure Domains197

5.7 Measure Scoring in the Initial *Cutoff Year* and a *Current Year*198

5.7.1 *Cutoff Year* Measure Scoring Methodology.....198

5.7.2 *Current Year* Measure Scoring Methodology201

5.7.3 Combining Measure Scores into Final Facility Scores202

5.8 Missing Values.....202

5.9 Translating Facility Final Scores to Star Ratings202

5.9.1 Defining Final Score Cutoffs in the *Cutoff Year*202

5.9.2 Maintaining Longitudinal Continuity in the Star Rating for the October 2018 Release.....203

5.9.3 Assigning Star Ratings in the *Current Year*.....203

5.10 An Illustration of the Star Rating Calculation204

5.10.1 Step 3: Score Values in *Current Year* Based on *Cutoff Year* Standards205

5.10.2 Step 4: Define Final Score Cutoffs in *Cutoff Year*.....206

5.11 Step 5: Apply Final Score Cutoffs in *Current Year*.....207

5.12 Additional Details207

5.12.1 Detailed Example of Scoring Measures in the Standardized Outcomes Domain207

5.12.2 Detailed Example of Scoring Percentage Measures.....208

Acronyms..... 210

Glossary 213

List of Figures

Figure 1: Vascular Access Type: Fistula Measure Rate Flowchart for ESRD QIP.....	5
Figure 2: Vascular Access Type: Catheter Measure Rate Flowchart (ESRD QIP Only).....	10
Figure 3: Vascular Access Type Clinical Measure: Hemodialysis Vascular Access: Long-term Catheter Rate Flowchart (DFC Only).....	16
Figure 4: Hemodialysis Vascular Access: Standardized Fistula Rate (DFC Only).....	25
Figure 5: Kt/V Dialysis Adequacy Comprehensive Clinical Measure Rate Flowchart (ESRD QIP Only).....	51
Figure 6: nPCR for Pediatric Hemodialysis Patients Flowchart Here.....	55
Figure 7: Hypercalcemia Clinical Measure Rate Flowchart (ESRD QIP Only).....	62
Figure 8: Hypercalcemia Clinical Measure Rate Flowchart (DFC Only).....	63
Figure 9: Anemia Management Reporting Measure Flowchart (ESRD QIP Only).....	70
Figure 10: Serum Phosphorus Reporting Measure Flowchart (ESRD QIP Only).....	74
Figure 11: Screening for Clinical Depression and Follow-Up Reporting Measure Flowchart (ESRD QIP Only).....	78
Figure 12: Pain Assessment and Follow-Up Reporting Measure Flowchart (ESRD QIP Only).....	82
Figure 13: Standardized Readmissions Ratio (SRR) Flowchart (ESRD QIP and DFC).....	95
Figure 14: Algorithm for Exclusion of Periods of Time Within 1 Year of an Exclusion Comorbidity.....	102
Figure 15: Standardized Transfusion Ratio Measure Flowchart (ESRD QIP and DFC).....	109
Figure 16: Method of Determining Transfusion Events Flowchart.....	111
Figure 17: Standardized Hospitalization Ratio (SHR) Flowchart (ESRD QIP and DFC).....	124
Figure 18: Standardized Mortality Ratio Flowchart (DFC Only).....	135
Figure 19: ICH CAHPS Survey Flowchart (ESRD QIP Only).....	140
Figure 20: NHSN Bloodstream Infection in Hemodialysis Outpatients Flowchart (ESRD QIP Only).....	144
Figure 21: NHSN HCP Influenza Measure Flowchart (ESRD QIP Only).....	147
Figure 22: NHSN Dialysis Event Reporting Measure Flowchart (ESRD QIP Only).....	149
Figure 23: Ultrafiltration Reporting Measure Flowchart (ESRD QIP Only).....	153
Figure 24: ESRD QIP Derivation of Date of Death.....	165
Figure 25: ESRD QIP Linking Claims and CROWNWeb.....	168
Figure 26: Example of Scoring SMR CY2016 Cutoff Year.....	199
Figure 27: Example of Scoring Kt/V CY2016 Cutoff Year.....	200

List of Tables

Figure 1: Vascular Access Type: Fistula Measure Rate Flowchart for ESRD QIP.....	5
Table 1: Data Elements and Sources for the Vascular Access Type Clinical Measure: Hemodialysis Vascular Access: Long-term Catheter Rate.....	15
Table 2: Data Elements and Sources for Hemodialysis Vascular Access: Standardized Fistula Rate (DFC only).....	23
Table 3: Data Elements and Sources for Standardized Readmissions Ratio (SRR) Clinical Measure (ESRD QIP and DFC).....	91
Table 4: Past Year Comoridities, Grouped by CMS' Condition Categories (CCs) for Standardized Readmissions Ratio (SRR) Clinical Measure (ESRD QIP and DFC)	93
Table 5: Data Elements and Sources for the Standardized Transfusion Ratio (STrR) Clinical Measure (ESRD QIP and DFC).....	108
Table 6: Description of Relevant Revenue Center Codes, Procedure Codes, Value Codes, and HCPCS Codes.....	114
Table 7: Data Elements and Sources for the Standardized Hospitalization Ratio (ESRD QIP and DFC).....	122
Table 8: Data Elements and Sources for the Standardized Mortality Ratio Measure (DFC Only).....	134
Table 9: Modality Types for Revenue Center Codes.....	157
Table 10: Summary of Treatment Time Methods.....	164
Table 11: PY 2020 Clinical Measures and the Defined Lower Threshold, Upper Threshold, Preferred Measures Rate Directionality, and the Measure Unit for Each Measure.....	180
Table 12: Key Achievement and Improvement Scoring Terms	182
Table 13: Clinical Measure/Measure Topic Weights	187
Table 14: Reporting Measure Weights	189
Table 15: Safety Measures Weights	190
Table 16: TPS and Payment Reduction for PY 2020	193
Table 17: Spearman Correlation Matrix, Calendar Year 2016 Data*	197
Table 18: Mean Measure Values and Mean Final Facility Scores Within Each Star Rating Category*.....	203
Table 19: Cutoff Year Measure Values and Standardized Measure Scores	205
Table 20: Current Year Measure Values and Standardized Measure Scores	205
Table 21: Cutoff Year Domain Scores and Final Scores	206
Table 22: Cutoff Values for Star Rating Categories	206
Table 23: Current Year Domain Scores and Final Scores	207
Table 24: Defining Scores for Kt/V in the Cutoff Year (2015).....	208
Table 25: Defining Scores for Kt/V in the Current Year (2016)	209

1. Introduction

The *CMS ESRD Measures Manual (Manual)* Version 3.1 represents an effort to respond to strong stakeholder interest in the detailed specifications that underwrite reporting and clinical performance measures in the Centers for Medicare & Medicaid Services (CMS) End Stage Renal Disease (ESRD) quality programs during the 2018 Performance Period, 2020 Payment Year. CMS, along with its external partners, recognizes that seemingly minor and esoteric aspects of the measure specifications may have a substantial impact on measure scores. Accordingly, the *Manual* provides a transparent and detailed description of how CMS ESRD measures are calculated, offering the public a comprehensive understanding of how CMS evaluates the quality of care provided by dialysis facilities.

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

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

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

Previous versions of the *Manual* will remain posted on the appropriate CMS webpage for review.

2. Measurement Information

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

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

2.1.4 Measure Type

Process

2.1.5 Improvement Noted as Higher or Lower Rate

Higher numbers are better.

2.1.6 Risk Adjustment

None

2.1.7 Numerator Statement

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

2.1.8 Facility Exclusions

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

2.1.9 Denominator Statement

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

2.1.10 Denominator Exclusions

- Patients younger than 18 years old (see Section 3.1.4)
- Patients not on Hemodialysis
- Patients not on ESRD treatment as defined by a completed 2728 medical evidence form, a Renal Management Information System (REMIS) / Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) record, or a sufficient amount of dialysis reported on dialysis facility claims to indicate chronic dialysis (see section 3.1.3)
- 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

2.1.11 Mapping Patients to Facilities

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

2.1.12 Calculating Numerators

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

2.1.13 Data Elements and Data Sources

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

CROWNWeb Data Elements

- Facility CCN
- CROWN Unique Patient Identifier (UPI)
- Patient date of birth
- First date of ESRD (see section 3.1.3)

Claims Based Data Elements

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

- Claim Control Number
- Claim From Date
- Claim Through Date

- Claim NCH 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 Health Insurance Claim Number
- Patient date of birth
- Claim Line Institutional Revenue Center Date
- Claim Line Institutional Revenue Center Codes

2.1.14 Flowchart

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

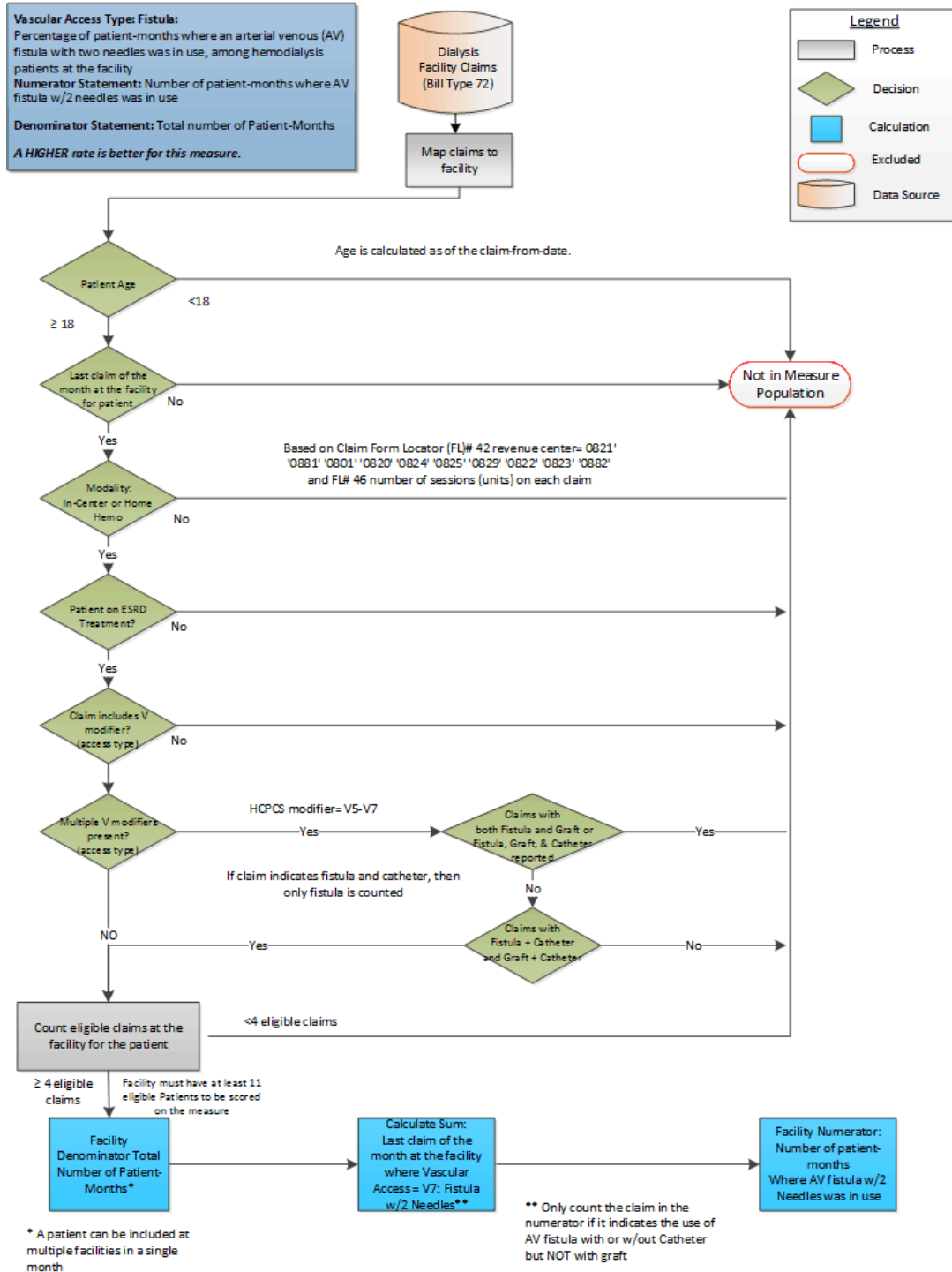


Figure 1: Vascular Access Type: Fistula Measure Rate Flowchart for ESRD QIP

2.1.15 Selected References

- U.S. Renal Data System, USRDS 2009 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2009.
- National Kidney Foundation: DOQI Clinical Practice Guidelines for Vascular Access. http://www.kidney.org/Professionals/kdoqi/guideline_upHD_PD_VA/index.htm

2.2 Vascular Access Type Clinical Measure: Catheter \geq 90 Days (ESRD QIP Only)

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

Based upon data from the CMS Fistula First Breakthrough Initiative (FFBI), a gradual trend towards lower catheter use has been observed among prevalent maintenance HD patients in the US, declining from approximately 28% in 2006 to approximately 24% by May 2007.

Furthermore, the percentage of maintenance HD patients using a catheter for \geq 90 days has declined as well over this time period from nearly 12% to 9.5-10%. Continued monitoring of chronic catheter use is needed to sustain this trend.

2.2.4 Measure Type

Process

2.2.5 Improvement Noted as Higher or Lower Rate

Lower numbers are better

2.2.6 Risk Adjustment

None

2.2.7 Numerator Statement

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

2.2.8 Facility Exclusions

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

2.2.9 Denominator Statement

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

2.2.10 Denominator Exclusions

- Patients not on Hemodialysis
- Patients not on ESRD treatment as defined by a completed 2728 medical evidence form, a REMIS/CROWNWeb record, or a sufficient amount of dialysis reported on dialysis facility claims to indicate chronic dialysis (see section 3.1.3)
- Patients younger than 18 years plus 90 days (see Section 3.1.4)
- 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

2.2.11 Mapping Patients to Facilities

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

2.2.12 Calculating Numerators

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

Measure uses claims data from October, November, and December of the year prior to the performance or comparison period (e.g., October – December 2017 for performance period) to determine catheter history.

2.2.13 Data Elements and Data Sources

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

CROWNWeb Data Elements

- Facility CCN
- CROWN Unique Patient Identifier (UPI)
- Patient date of birth
- First date of ESRD (see section 3.1.3)

Claims Based Data Elements

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

- Patient Health Insurance Claim Number
- Patient date of birth

- Claim Control Number
- Claim From Date
- Claim Through Date
- Claim NCH 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

2.2.14 Flowchart

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

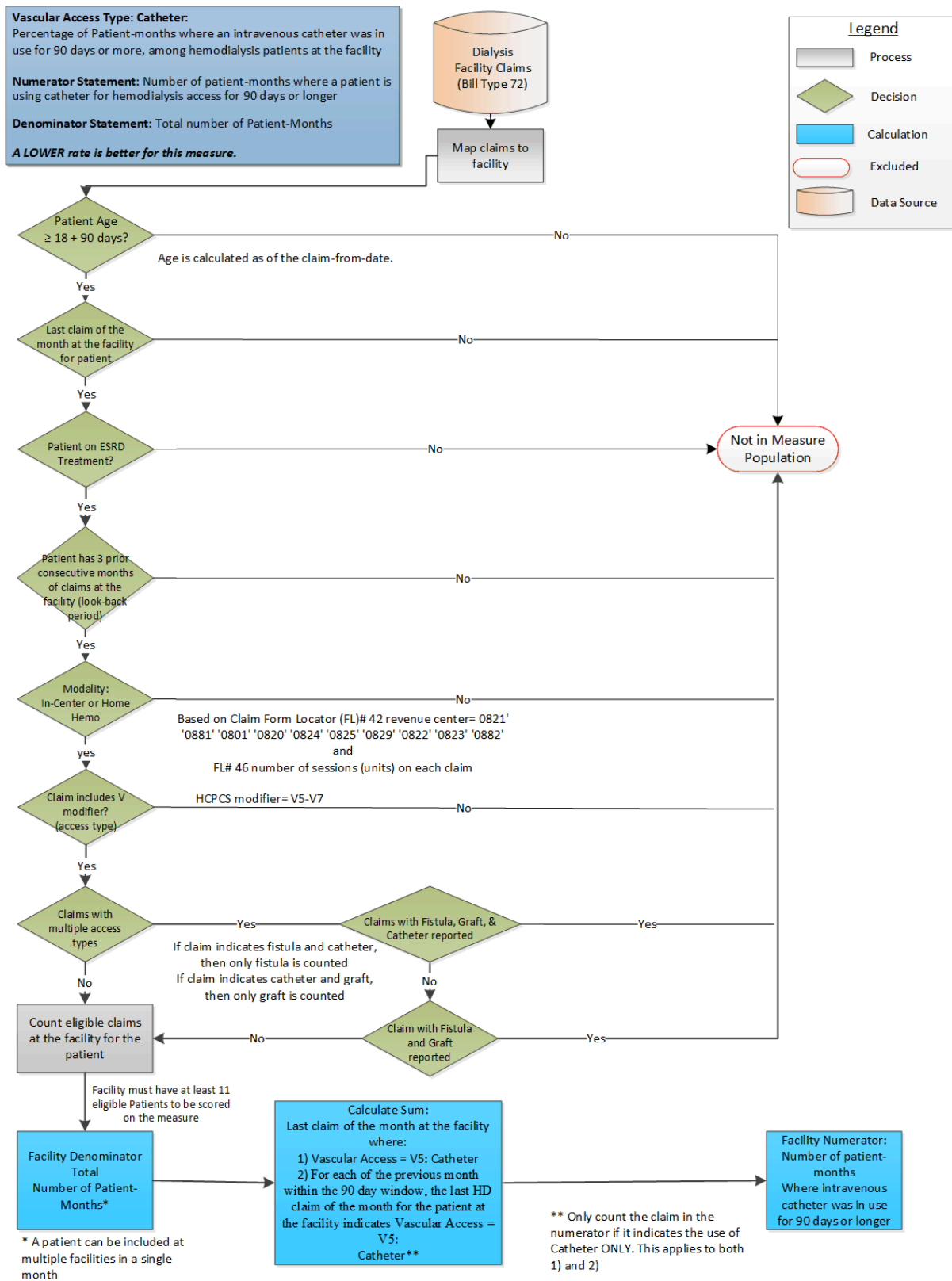


Figure 2: Vascular Access Type: Catheter Measure Rate Flowchart (ESRD QIP Only)

2.2.15 Selected References

- National Kidney Foundation: KDOQI Clinical Practice Guidelines for Vascular Access.
- Fistula First Catheter Last Dashboard August 2015, <http://fistulafirst.esrdncc.org/ffcl/for-ffcl-professionals/archive/>.

2.3 Vascular Access Type Clinical Measure: Hemodialysis Vascular Access: Long-term Catheter Rate (DFC Only)

2.3.1 Measure Name

Hemodialysis Vascular Access: Long-term Catheter Rate

2.3.2 Measure Description

Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access.

2.3.3 Measure Rationale

Based upon data from the CMS Fistula First/Catheter Last initiative, a gradual trend towards lower catheter use has been observed among prevalent maintenance HD patients in the US, declining from approximately 28% in 2006 to approximately 18% by August 2015. Furthermore, the percentage of maintenance HD patients using a catheter for at least three months has declined as well over this time period from nearly 12% to 10.8%. Continued monitoring of chronic catheter use is needed to sustain this trend.

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

2.3.4 Measure Type

Intermediate Clinical Outcome

2.3.5 Improvement Noted as Higher or Lower Rate

Better quality = Lower score

2.3.6 Numerator Statement

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

2.3.7 Facility Exclusions

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

2.3.8 Denominator Statement

All patients at least 18 years old (see Section 3.1.4) as of the first day of the reporting month who are determined to be maintenance hemodialysis patients (in-center and home HD) for the complete reporting month at the same facility.

2.3.9 Denominator Exclusions

Exclusions that are implicit in the denominator definition include:

- Pediatric patients (<18 years old)
- Patients on Peritoneal Dialysis
- Patient-months with in-center or home hemodialysis for less than a complete reporting month at the same facility.

In addition, the following exclusions are applied to the denominator:

Patients with a catheter that have limited life expectancy:

- Patients under hospice care in the current reporting month
- Patients with metastatic cancer in the past 12 months
- Patients with end stage liver disease in the past 12 months
- Patients with coma or anoxic brain injury in the past 12 months

2.3.10 Mapping Patients to Facilities

For each patient, we identify the dialysis provider at each month using a combination of Medicare-paid dialysis claims, the Medical Evidence Form (CMS-2728), and data from CROWNWeb. These sources are used to identify patients that are receiving in-center or home hemodialysis for the entire reporting month. Patients are required to have been treated by the same facility for the complete month in order to be assigned to that facility for the reporting month.

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

The monthly patient count at a facility includes all eligible prevalent and incident patients. The number of patient-months over a time period is the sum of patients reported for the months covered by the time period. An individual patient may contribute up to 12 patient-months per year.

2.3.11 Calculating Numerators

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

For a given month, if any of the following CROWNWeb “Access Type IDs” (16,18,19,20,21,“.”) have been recorded, a catheter is considered in use. If a catheter has been observed for three consecutive months (i.e., in the reporting month and the immediate two preceding months) at the same facility, the reporting month is counted in the numerator. Access Type ID “16” represents AV Fistula combined with a Catheter, “18” represents AV Graft combined with a Catheter, “19” represents Catheter only, “20” represents Port access only, “21” represents other/unknown, and “.” represents missing. In this measure, Access Type IDs “21” and “.” are counted in both the numerator and denominator (meaning, they are counted as catheters).

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

2.3.12 Data Elements and Data Source

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

Variable	Primary Data Source
Facility CCN	CMS data sources ^{*1}
Reporting year and month	CROWNWeb
Vascular Access Type	CROWNWeb
Date of Birth	CMS data sources ^{*1}
Date of First ESRD	Medical Evidence Form (CMS-2728)
Age at the first day of reporting month	CMS data sources ^{*1}
Hospice status in the current month ^{*4}	CMS Hospice file ^{*2}
Metastatic Cancer reported on Medicare Claims in past 12 months ^{*4}	Medicare Claims ^{*3}
End-Stage Liver Disease reported on Medicare Claims in past 12 months ^{*4}	Medicare Claims ^{*3}

Variable	Primary Data Source
Coma or Anoxic Brain Damage reported on Medicare Claims in past 12 months ^{*4}	Medicare Claims ^{*3}

Table 1: Data Elements and Sources for the Vascular Access Type Clinical Measure: Hemodialysis Vascular Access: Long-term Catheter Rate

- *1. This may include information from: Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), Medicare Claims, the Renal Management Information System (REMIS), Medicare Enrollment Database (EDB), Medical Evidence Form (CMS 2728), Medicare Claims, and Organ Procurement and Transplantation Network Database (OPTN).
- *2. Hospice information comes from CMS institutional Medicare Claims files that contain final action claims submitted by Hospice providers (CLM_TYPE=50). Once a beneficiary elects Hospice, all Hospice related claims will be found in this file, regardless if the beneficiary is in Medicare fee-for-service or in a Medicare managed care plan.
- *3. Medicare claims include Part A claims such as inpatient admissions and Part B claims such as outpatient claims (including dialysis claims) and physician services. Claims from providers, such as laboratories, that report diagnosis codes when testing for the presence of a condition are excluded.
- *4. Exclusion factors: A detailed list of ICD-9/ICD-10 diagnostic codes used to identify exclusion comorbidities is included in this file (use the ICD information related to this edition of the Manual, which can be found on the [Measuring Quality](#) page on the ESRD QIP section of CMS.gov)

2.3.13 Flowchart

Figure 3 provides a flowchart that represents the processes used to calculate the Vascular Access Type Clinical Measure: Hemodialysis Vascular Access: Long-term Catheter Rate.

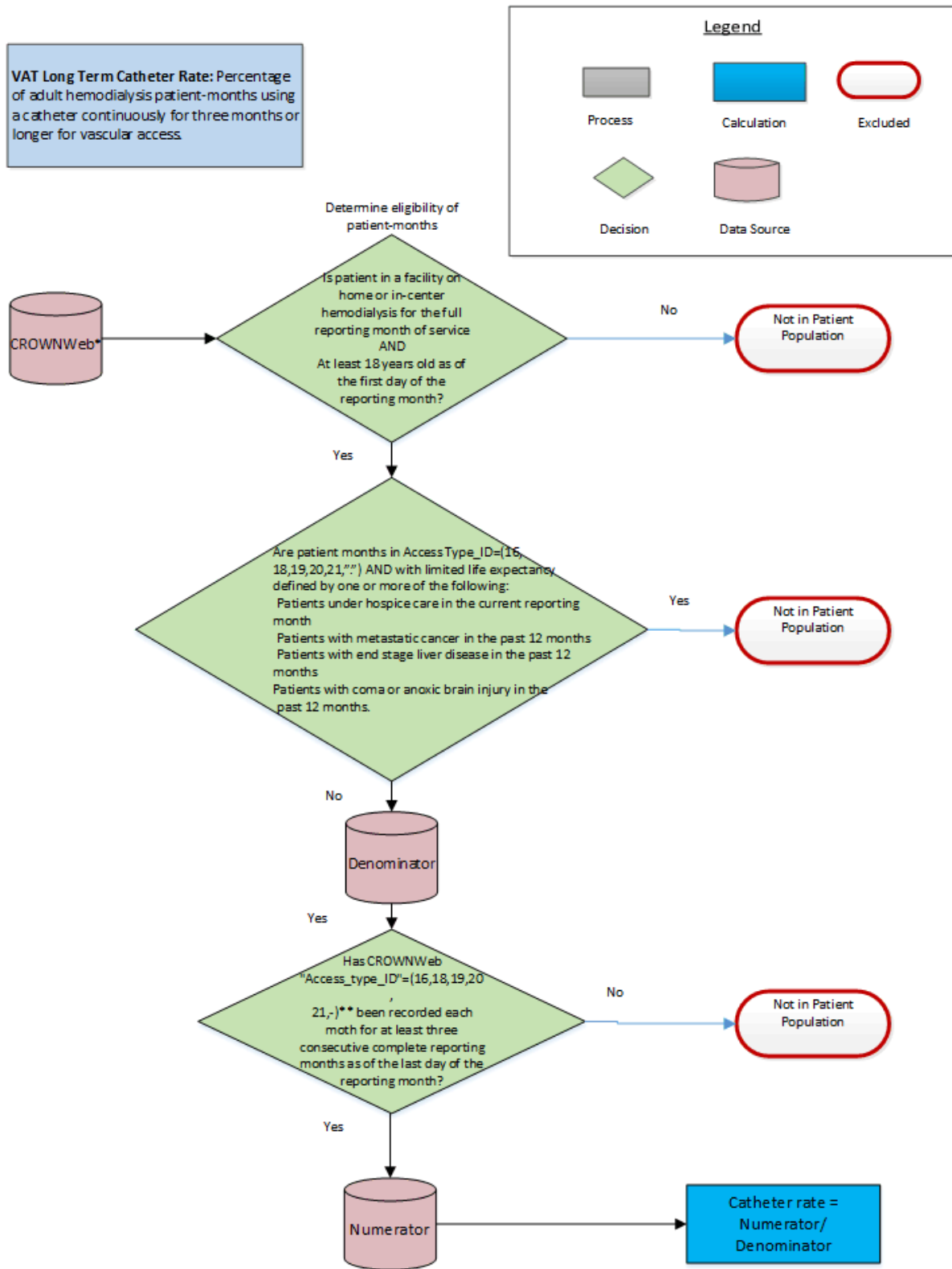


Figure 3: Vascular Access Type Clinical Measure: Hemodialysis Vascular Access: Long-term Catheter Rate Flowchart (DFC Only)

2.3.14 Selected References

- National Kidney Foundation: DOQI Clinical Practice Guidelines for Vascular Access, http://www.kidney.org/professionals/KDOQI/guidelines_commentaries.
- Grubbs V, Wasse H, Vittinghoff E, et al. Health status as a potential mediator of the association between hemodialysis vascular access and mortality. *Nephrol Dial Transplant*. 2014 Apr;29(4):892-8. doi: 10.1093/ndt/gft438. Epub 2013 Nov 13.
- ESRD Vascular Access TEP Summary Report, https://dialysisdata.org/sites/default/files/content/ESRD_Measures/ESRD_Vascular_Access_TEP_Summary_Report.pdf.

2.4 Hemodialysis Vascular Access: Standardized Fistula Rate (DFC Only)

2.4.1 Measure Name

Hemodialysis Vascular Access: Standardized Fistula Rate

2.4.2 Measure Description

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

2.4.3 Measure Rationale

The NKF K/DOQI guidelines state the following: 1) AV fistulas have the lowest rate of thrombosis and require the fewest interventions, 2) cost of AV fistula use and maintenance is the lowest, 3) fistulas have the lowest rates of infection, and 4) fistulas are associated with the highest survival and lowest hospitalization rates. Indeed, a number of epidemiologic studies consistently demonstrate the reduced morbidity and mortality associated with greater use of AV fistulas for vascular access in maintenance hemodialysis.

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

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

2.4.4 Measure Type

Intermediate Clinical Outcome

2.4.5 Improvement Noted as Higher or Lower Rate

Higher numbers are better

2.4.6 Risk Adjustment

Statistical risk model

2.4.7 Numerator Statement

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

2.4.8 Facility Exclusions

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

2.4.9 Denominator Statement

All patients at least 18 years old (see Section 3.1.4) as of the first day of the reporting month who are determined to be maintenance hemodialysis patients (in-center and home HD) for the entire reporting month at the same facility.

2.4.10 Denominator Exclusions

Exclusions that are implicit in the denominator definition include:

- Pediatric patients (<18 years old)
- Patients on Peritoneal Dialysis
- Patient-months with in-center or home hemodialysis for less than a complete reporting month at the same facility

In addition, patients with a catheter that have the following limited life expectancy are excluded from the denominator:

- Patients under hospice care in the current reporting month
- Patients with metastatic cancer in the past 12 months
- Patients with end stage liver disease in the past 12 months
- Patients with coma or anoxic brain injury in the past 12 months

Use the ICD information related to this edition of the Manual, which can be found on the [Measuring Quality](#) page on the ESRD QIP section of CMS.gov for a list of codes used to identify these exclusions.

Determination of peritoneal dialysis treatment modality is derived from a combination of Medicare-paid dialysis claims, the Medical Evidence Form (CMS-2728), and data from CROWNWeb. These sources also determine patient assignment to the facility. Patients not treated by the facility for the entire month are excluded for that reporting month.

The patient's age is determined by subtracting the patient's date of birth from the first day of the reporting month. Patients that are <18 years old as of the first day of the reporting month are excluded.

For the exclusion of catheter patients with limited life expectancy, catheter use in the reporting month is defined as the CROWNWeb “Access Type ID” having any of the following values: (16,18,19,20,21,“.”), where Access_Type_ID “16” represents AV Fistula combined with a Catheter, “18” represents AV Graft combined with a Catheter, “19” represents Catheter only, “20” represents Port access only, “21” represents other/unknown, and “.” represents missing.

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

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

Diagnoses of metastatic cancer, end stage liver disease, or coma in the past 12 months were determined from Medicare claims. Medicare claim types include inpatient admissions, outpatient claims (including dialysis claims) and physician services. Claims from providers, such as laboratories that report diagnosis codes when testing for the presence of a condition are excluded. Use the ICD information related to this edition of the Manual, which can be found on the [Measuring Quality](#) page on the ESRD QIP section of CMS.gov for a detailed list of ICD-9/ICD-10 diagnostic codes used to identify these comorbidities.

2.4.11 Mapping Patients to Facilities

For each patient, we identify the dialysis provider at each month using a combination of Medicare dialysis claims, the Medical Evidence Form (CMS-2728), and data from CROWNWeb. These sources are used to identify patients that are on in-center or home hemodialysis for the entire reporting month. Patients are required to have been treated by the same facility for the complete month in order to be assigned to that facility for the reporting month.

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

The monthly patient count at a facility includes all eligible prevalent and incident patients. The number of patient-months over a time period is the sum of patients reported for the months covered by the time period. An individual patient may contribute up to 12 patient-months per year.

2.4.12 Calculating Numerators

The numerator is determined by number of patient-months using an AVF as the sole means of vascular access at a given facility, adjusted for patient-mix.

An AVF is considered in use if the CROWNWeb “Access Type IDs” of 14 or 22 has been recorded for a given month, where “14” represents AV fistula only (with 2 needles) and “22” represents AV fistula only with an approved single needle device.

2.4.13 Statistical Risk Model and Variables

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

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

- Age
- BMI at incidence
- Nursing home status in previous year
- Nephrologist's care prior to ESRD
- Duration of ESRD
- Inability to ambulate/transfer at ESRD incidence Medical Evidence Form (CMS-2728)
- Diabetes as primary cause of ESRD Medical Evidence Form (CMS-2728)
 - Comorbidities either at ESRD incidence Medical Evidence Form (CMS-2728) or the Medicare eligible months (below) together with prevalent comorbidities based on Medicare claims filed in prior 12 months. Use the ICD information related to this edition of the Manual, which can be found on the [Measuring Quality](#) page on the ESRD QIP section of CMS.gov for list of codes used to identify these conditions.
 - Diabetes (NOT as primary cause of ESRD)
 - Heart diseases
 - Peripheral vascular disease
 - Cerebrovascular disease
 - Chronic obstructive pulmonary disease
 - Anemia (unrelated to ESRD/CKD)
 - Non-Vascular Access-Related Infections
 - Drug dependence
- Indicator for Medicare coverage for at least 6 months during the past 12 months

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

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

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

The model is fitted using Generalized Estimating Equations (GEE; Liang and Zeger, 1986) in order to account for the correlation within-patient across months. With 6,000 facilities, it is difficult to estimate all parameters (i.e., including the facility indicators) simultaneously.

Therefore, we break the fitting process into two stages. At the first stage, we estimate the β vector by averaging 10 random subgroups of approximately 600 facilities each. At the second stage, we then estimate the α_i ($i=1, \dots, 6000$) by fitting facility-specific intercept-only GEE models, with the linear predictor from the first stage, $\beta'x_{ijm}$, serving as an offset. Per well-established GEE results (e.g., Liang and Zeger, 1986), the estimator of α_i is consistent for its target value, and follows a normal distribution with standard error given by the robust 'sandwich' estimator computed via GEE. We can then compute SFR_i for each facility i as follows:

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

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

2.4.14 Data Elements and Data Sources

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

Variable	Primary Data Source
Facility CCN	CMS data sources* ¹
Reporting year and month	CROWNWeb
Vascular Access Type	CROWNWeb
Date of Birth	CMS data sources* ¹
Date of First ESRD	Medical Evidence Form (CMS-2728) CROWNWeb Patient Events Medicare Claims* ³ OPTN
Age at the first day of reporting month	CMS data sources* ¹
BMI at incidence	Medical Evidence Form (CMS-2728)
Nursing home status (in the previous calendar year)	CMS Minimum Data Set
Nephrologist's Care prior to ESRD	Medical Evidence Form (CMS-2728)
Diabetes - Primary cause of ESRD	Medical Evidence Form (CMS-2728) REMIS CROWNWeb
Diabetes –Not as primary cause of ESRD * ⁵	Medicare Claims* ³ Medical Evidence Form (CMS-2728)
Heart Failure * ⁵	Medicare Claims* ³ Medical Evidence Form (CMS-2728)

Variable	Primary Data Source
Other Heart Diseases ^{*5}	Medicare Claims ^{*3} Medical Evidence Form (CMS-2728)
Peripheral Vascular Disease ^{*5}	Medicare Claims ^{*3} Medical Evidence Form (CMS-2728)
Cerebrovascular Disease ^{*5}	Medicare Claims ^{*3} Medical Evidence Form (CMS-2728)
Chronic Obstructive Pulmonary Disease ^{*5}	Medicare Claims ^{*3} Medical Evidence Form (CMS-2728)
Drug Dependence ^{*5}	Medicare Claims ^{*3} Medical Evidence Form (CMS-2728)
Inability to ambulate/transfer	Medical Evidence Form (CMS-2728)
Anemias (unrelated to ESRD/CKD) ^{*5}	Medicare Claims ^{*3}
Non-Vascular Access-Related Infections: Pneumonias/ Hepatitis/HIV/AIDS/Tuberculosis ^{*5}	Medicare Claims ^{*3}
Not having at least 6-month Medicare eligible in past 12 months	Medicare Claims ^{*3}
Hospice status in the current month ^{*4}	CMS Hospice file ^{*2}
Metastatic Cancer reported on Medicare Claims in past 12 months ^{*4}	Medicare Claims ^{*3}
End-Stage Liver Disease reported on Medicare Claims in past 12 months ^{*4}	Medicare Claims ^{*3}
Coma or Anoxic Brain Damage reported on Medicare Claims in past 12 months ^{*4}	Medicare Claims ^{*3}

Table 2: Data Elements and Sources for Hemodialysis Vascular Access: Standardized Fistula Rate (DFC only)

- *1. This may include information from the: Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) Patient List, Medicare Claims, the Renal Management Information System (REMIS), Medicare Enrollment Database (EDB), Medical Evidence Form (CMS 2728), Medicare Claims, and Organ Procurement and Transplantation Network Database (OPTN) (DFC only). Unique patients are identified by using a combination of SSN, first name, surname, sex, Patient Health Insurance Claim Number and birth date. DFC runs a matching process to ensure that minor typos and misspellings do not cause a patient record to fall out of their history. The matching process is able to successfully match 99.5% of patients. The remaining patients have incomplete or incorrect data that does not allow them to be matched.
- *2. Hospice information comes from CMS institutional Medicare Claims files that contain final action claims submitted by Hospice providers (CLM_TYPE=50) . Once a beneficiary elects Hospice, all Hospice related claims will be found in this file, regardless if the beneficiary is in Medicare fee-for-service or in a Medicare managed care plan.
- *3. Medicare claims include Part A claims such as inpatient admissions and Part B claims such as outpatient claims (including dialysis claims) and physician services. Claims from providers, such as laboratories, that report diagnosis codes when testing for the presence of a condition are excluded.

Final

- *4. Exclusion factors: A detailed list of ICD-9 diagnostic codes and HCPCS CPT codes used to identify comorbidities in this edition of the Manual, can be found on the [Measuring Quality](#) page on the ESRD QIP section of CMS.gov
- *5. Comorbidities were identified by combining prevalent comorbidities reported on all Medicare Claims in past 12 month and incident comorbidities reported on the Medical Evidence Form (CMS-2728). A detailed list of ICD-9/ICD-10 diagnostic codes and HCPCS CPT codes used to identify comorbidities from Medicare Claims related to this edition of the Manual, can be found on the [Measuring Quality](#) page on the ESRD QIP section of CMS.gov

2.4.15 Flowchart

Figure 4 provides a flowchart that represents the processes used to calculate the Standardized Fistula Rate.

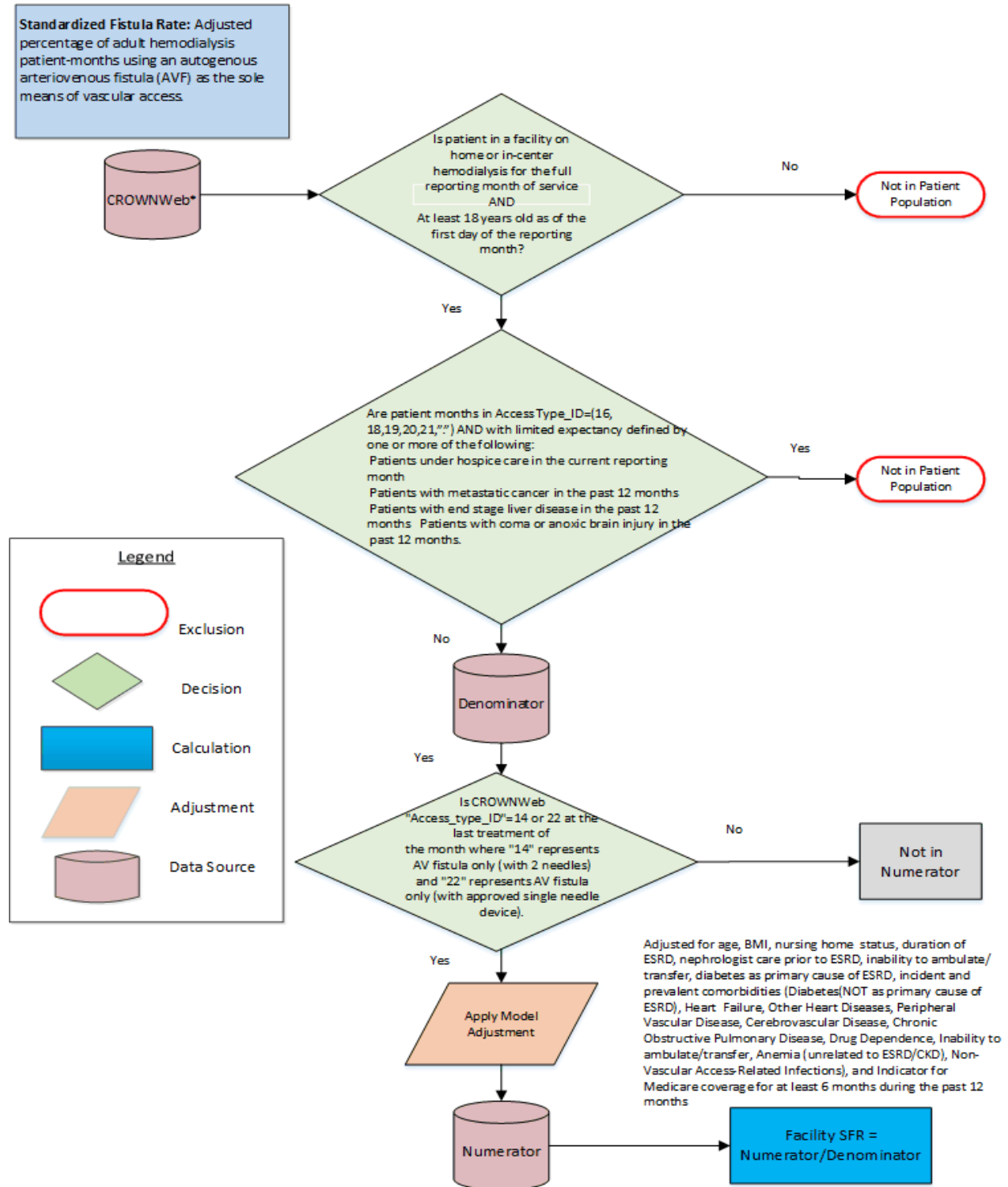


Figure 4: Hemodialysis Vascular Access: Standardized Fistula Rate (DFC Only)

* Multiple data sources include CMS Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), the CMS Annual Facility Survey (CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN) (DFC only), the Death Notification Form (CMS-2746), the Dialysis Facility Compare (DFC) and the Social Security Death Master File (DFC only).

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

2.4.16 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).
http://www.kidney.org/professionals/KDOQI/guidelines_commentaries

2.5 Adult Hemodialysis Adequacy Measure (DFC Only)

2.5.1 Measure Name

Delivered Dose of Hemodialysis Above Minimum – NQF# 0249

2.5.2 Measure Description

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

2.5.3 Measure Rationale

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

2.5.4 Measure Type

Intermediate outcome

2.5.5 Improvement Noted as Higher or Lower Rate

Higher rates are better

2.5.6 Risk Adjustment

None

2.5.7 Numerator Statement

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

2.5.8 Facility Exclusions

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

2.5.9 Denominator Statement

All patient-months for adult (≥ 18 years old, see Section 3.1.4) patients in the sample for analysis who have had ESRD for 91 days or more and dialyzing greater than 2 and less than 4 times weekly the entire month.

2.5.10 Denominator Exclusions

- Patients not assigned to the facility for the entire month
- Patients younger than 18 years old as of the first day of the month (or as of the claim-from date if claims data are used)
- Patients not on hemodialysis the entire month
- Patients who were on ESRD treatment for less than 91 days as of the first of the month (see Section 3.1.3)
- Patients not dialyzing greater than 2 and less than 4 times weekly (see Section 3.1.5)
 - If the patient is identified as not dialyzing greater than 2 and less than 4 times weekly anytime during the month, then the entire patient-month is excluded from the calculations. See Section 3.1.5 below for more details regarding the determination of weekly and frequent dialysis

2.5.11 Mapping Patients to Facilities

A patient may only be assigned to **one** dialysis facility each month.

For each patient, the dialysis provider at each point in time was identified primarily using data from CROWNWeb, the Medical Evidence Form CMS-2728) and Medicare dialysis claims. Both patient assignment to the provider and modality (either hemodialysis or peritoneal dialysis) were determined according to the information reported in the above mentioned data sources. For each reporting month, patients were required to have been indicated as treated by the facility for the complete month in order to be included in the denominator. If a patient transferred in or out of the facility, discontinued dialysis, recovered renal function or died anytime during the month, the entire patient-month is excluded. Please note that the number of sessions are not considered and the patient may not have received treatment at the facility for the entire month to be included. For example, if a patient is hospitalized or travels during the month, the patient may still be included in the facility's measure if they are indicated as the facility's patient that month according to the data as described above. Additionally, patients for whom the only evidence of dialysis treatment is the existence of Medicare claims were considered lost to follow-up and removed from a facility's analysis one year following the last claim, if there was no earlier evidence of transfer, recovery, or death. In other words, if a period of one year passed with neither Medicare dialysis claims nor CROWNWeb information to indicate that a patient was receiving dialysis treatment, we considered the patient lost to follow-up, and did not use him or her in the analysis.

2.5.12 Calculating Numerators

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

- If a patient has multiple Kt/V values in CROWNWeb during a month, then the last non-missing reported value is selected.
- If an in-range value was not found in CROWNWeb for the patient during the month then the last reported non-missing value reported on the last eligible Medicare claim for the patient during the month was selected (when available).
 - A claim was considered eligible if it was from a HD patient who had ESRD for at least 91 days and was at least 18 years old (as of the claim-from date), and the claim was neither a “frequent” dialysis claim nor an “infrequent” dialysis claim as described in Section 3.1.5.
 - When there were multiple claims in a month, the Kt/V value from the last eligible claim with an in-range (less than or equal to 5.0) and not expired Kt/V value was selected. For in-center HD patients, a Kt/V with an occurrence date from a previous month is defined as expired. For home HD patients, a Kt/V with an occurrence date more than four months prior to the claim through date is defined as expired.

2.5.13 Assigning Patient-Months to Numerators and Denominators

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

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

2.5.14 Data Elements and Data Sources

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

CROWNWeb Data Elements

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

- Additional Services Offered (Non-Medicare)
- Kt/V Method
- Kt/V value
- Modality to determine frequent dialysis
- First date of ESRD (see section 3.1.3)

Claims Based Data Elements

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

- Patient Health Insurance Claim Number
- Patient Date of Birth
- Patient Date of Death
- Claim Related Condition Code
- Claim Control Number
- Claim From Date
- Claim Through Date
- Claim NCH Daily Process Date
- Claim Link Number
- Claim Occurrence Date
- Claim Occurrence Code
- Claim CCN
- Claim Value Code D5
- Claim Value Amount
- Claim Value Sequence Number
- Claim Line Institutional Revenue Center Codes
- Claim Line Institutional Revenue Center Date

2.5.15 Selected References

- Wolfe RA, Hulbert-Shearon TE, Ashby VB, Mahavadevan S, Port FK: Improvements in dialysis patient mortality are associated with Urea Reduction Ratio and Hematocrit, 1999 to 2002. *Am J Kidney Dis* 45(1):127-135, 2005.
- Wolfe RA, Ashby VB, Daugirdas JT, Agodoa LY, Jones CA, Port FK: Body size, dose of hemodialysis, and mortality. *Am J Kidney Dis* 35:80-88, 2000.
- Port FK, Ashby VB, Dhingra RK, Roys EC, Wolfe RA: Dialysis dose and body mass index are strongly associated with survival in hemodialysis patients. *J Am Soc Nephrol* 13:1061-1066, 2002.

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- 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.

2.6 Adult Peritoneal Dialysis Adequacy Measure (DFC Only)

2.6.1 Measure Name

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

2.6.2 Measure Description

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

2.6.3 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.

2.6.4 Measure Type

Intermediate Outcome

2.6.5 Improvement Noted as Higher or Lower Rate

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

2.6.6 Risk Adjustment

None

2.6.7 Numerator Statement

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

2.6.8 Facility Exclusions

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

2.6.9 Denominator Statement

All patient-months for adult (≥ 18 years old) patients in the sample for analysis who have had ESRD for 91 days and receiving peritoneal dialysis the entire month.

2.6.10 Denominator Exclusions

- Patients not assigned to the facility for the entire month
- Patients younger than age 18 years old as of the first day of the month (Section 3.1.4)
- Patients not on peritoneal dialysis the entire month
- Patients on ESRD treatment for fewer than 91 days as of the first day of the month (see section 3.1.3)

2.6.11 Mapping Patients to Facilities

A patient may only be assigned to **one** dialysis facility each month.

For each patient, the dialysis provider at each point in time was identified primarily using data from CROWNWeb, the Medical Evidence Form (CMS-2728) and Medicare dialysis claims. Both patient assignment to the provider and modality (either hemodialysis or peritoneal dialysis) were determined according to the information reported in the above mentioned data sources. For each reporting month, patients were required to have been indicated as treated by the facility for the complete month in order to be included in the denominator. If a patient transferred in or out of the facility, discontinued dialysis, recovered renal function or died anytime during the month, the entire patient-month is excluded. Please note that the number of sessions are not considered and the patient may not have received treatment at the facility for the entire month to be included. For example, if a patient is hospitalized or travels during the month, the patient may still be included in the facility's measure if they are indicated as the facility's patient that month according to the data as described above. Additionally, patients for whom the only evidence of dialysis treatment is the existence of Medicare claims were considered lost to follow-up and removed from a facility's analysis one year following the last claim, if there was no earlier evidence of transfer, recovery, or death. In other words, if a period of one year passed with neither Medicare dialysis claims nor CROWNWeb information to indicate that a patient was receiving dialysis treatment, we considered the patient lost to follow-up, and did not use him or her in the analysis.

2.6.12 Calculating Numerators

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

- If a patient has multiple Kt/V values in CROWNWeb during a month, then the last reported value is selected.
- If an in-range value was not found in CROWNWeb for the patient during the month then the last reported non-missing value reported on the last eligible Medicare claim for the patient during the month was selected (when available).
 - A claim was considered eligible if it was from a PD patient who had ESRD for at least 91 days and was at least 18 years old (as of the claim-from date).

- The last eligible claim with an in-range (less than or equal to 8.5) and not expired (Kt/V occurrence date more than four months prior to the claim through date) Kt/V value reported was selected when there were multiple claims reported in a month.

2.6.13 Assigning Patient-Months to Numerators and Denominators

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

- If the selected Kt/V value is missing or not in the valid range (> 8.5), include patient-month in the denominator but not the numerator.
- If selected Kt/V value is in valid range (≤ 8.5) and meets the Kt/V value threshold (≥ 1.7), then include the patient-month in denominator and the numerator

2.6.14 Data Elements and Data Sources

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

CROWNWeb Data Elements

- CROWN Unique Patient Identifier (UPI)
- Facility CCN
- Patient Date of Birth
- Patient Date of Death
- Primary type of treatment ID (CROWNWeb dialysis type)
- Medicare Certified Services Offered as of 12/31 of the performance period
- Additional Services Offered (Non-Medicare) as of 12/31 of the measurement period
- Kt/V
- First date of ESRD (see Section 3.1.3)

Claims Based Data Elements

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

- Claim Related Condition Code
- Claim Control Number
- Claim From Date
- Claim Through Date
- Claim NCH Daily Process Date
- Claim Link Number
- Claim Occurrence Code
- Claim Occurrence Date

- Claim CCN
- Claim Value Code D5
- Claim Value Amount
- Claim Value Sequence Number
- Claim Line Institutional Revenue Center Codes
- Claim Line Institutional Revenue Center Date
- Patient Health Insurance Claim Number
- Patient Date of Death
- Patient Date of Birth

2.6.15 Selected References

- Paniagua R, Amato D, Vonesh E, et al. “Effects of increased peritoneal clearances on mortality rates in peritoneal dialysis: ADEMEX, a prospective, randomized, controlled trial.” *Journal of the American Society of Nephrology: JASN* (2002) 13:1307-20. PMID: 11961019.
- Lo WK, Lui SL, Chan TM, et al. “Minimal and optimal peritoneal Kt/V targets: Results of an anuric peritoneal dialysis patient’s survival analysis.” *Kidney international* (2005) 67:2032-8. PMID: 15840054.

2.7 Pediatric Hemodialysis Adequacy Measure (DFC Only)

2.7.1 Measure Name

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

2.7.2 Measure Description

Percentage of all pediatric (≤ 18 years old) patient-months in the sample for analysis who were on ESRD treatment for 91 days or more, and dialyzing greater than 2 and less than 4 times weekly whose delivered dose of hemodialysis (calculated from the last measurements of the month using the Urea Kinetic Modeling (UKM) or Daugirdas II formula) was a spKt/V ≥ 1.2 during the study period.

2.7.3 Measure Rationale

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

2.7.4 Measure Type

Intermediate Outcome

2.7.5 Improvement Noted as Higher or Lower Rate

Higher rates are better

2.7.6 Risk Adjustment

None

2.7.7 Numerator Statement

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

2.7.8 Facility Exclusions

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

2.7.9 Denominator Statement

All pediatric (<18 years old) patient-months in the sample for analysis who have had ESRD for 91 days or more and dialyzing greater than 2 and less than 4 times weekly the entire month.

2.7.10 Denominator Exclusions

- Patients not assigned to the facility for the entire month
- Patients 18 years and older as of the first day of the month (see Section 3.1.4)
- Patients not on in-center hemodialysis the entire month
- Patients on ESRD treatment for fewer than 91 days as of the first day of the month (see section 3.1.3)
- Patient not dialyzing greater than 2 and less than 4 times weekly (see Section 3.1.5)

If the patient is identified as not dialyzing greater than 2 and less than 4 times weekly anytime during the month, then the entire patient-month is excluded from the calculations. See Section 3.1.5 below for more details regarding the determination of weekly and frequent dialysis.

2.7.11 Mapping Patients to Facilities

A patient may only be assigned to one dialysis facility each month.

For each patient, the dialysis provider at each point in time was identified primarily using data from CROWNWeb, the Medical Evidence Form (CMS-2728) and Medicare dialysis claims. Both patient assignment to the provider and modality (either hemodialysis or peritoneal dialysis) were determined according to the information reported in the above mentioned data sources. For each reporting month, patients were required to have been indicated as treated by the facility for the complete month in order to be included in the denominator. If a patient transferred in or out of the facility, discontinued dialysis, recovered renal function or died anytime during the month, the entire patient-month is excluded. Please note that the number of sessions are not considered and the patient may not have received treatment at the facility for the entire month to be included. For example, if a patient is hospitalized or travels during the month, the patient may still be included in the facility's measure if they are indicated as the facility's patient that month according to the data as described above. Additionally, patients for whom the only evidence of dialysis treatment is the existence of Medicare claims were considered lost to follow-up and removed from a facility's analysis one year following the last claim, if there was no earlier evidence of transfer, recovery, or death. In other words, if a period of one year passed with neither Medicare dialysis claims nor CROWNWeb information to indicate that a patient was receiving dialysis treatment, we considered the patient lost to follow-up, and did not use him or her in the analysis.

2.7.12 Calculating Numerators

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

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

- If an in-range value was not found in CROWNWeb for the patient during the month then the last reported non-missing value reported on the last eligible Medicare claim for the patient during the month was selected (when available).
 - A claim was considered eligible if it was from an HD (in-center) patient who had ESRD for at least 91 days and was under 18 years old (as of the claim-from date), and the claim was neither a “frequent” dialysis claim nor an “infrequent” dialysis claim as described in Section 3.1.5.
 - When there were multiple claims in a month, the Kt/V value from the last eligible claim with an in-range (less than or equal to 5.0) and not expired Kt/V value was selected. A Kt/V with an occurrence date from a previous month is defined as expired.

2.7.13 Assigning Patient-Months to Numerators and Denominators

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

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

2.7.14 Data Elements and Data Sources

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

CROWNWeb Data Elements

- CROWN Unique Patient Identifier (UPI)
- Facility CCN
- Patient Date of Birth
- Patient Date of Death
- Primary type of treatment ID (CROWNWeb dialysis type)
- Number of dialysis sessions per week
- Medicare certified services offered as of 12/31 of the performance period
- Additional services offered (Non-Medicare) as of 12/31 of the measurement period
- Kt/V
- Kt/V method
- Modality to determine frequent dialysis
- First date of ESRD (see section 3.1.3)

Claims Based Data Elements

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

- Claim Related Condition Code
- Claim Control Number
- Claim From Date
- Claim Through Date
- Claim NCH Daily Process Date
- Claim Link Number
- Claim Occurrence Date
- Claim Occurrence Code
- Claim CCN
- Claim Value Code D5
- Claim Value Amount
- Claim Value Sequence Number
- Claim Line Institutional Revenue Center Codes
- Claim Line Institutional Revenue Center Date
- Patient Health Insurance Claim Number
- Patient Date of Death
- Patient Date of Birth

2.7.15 Selected References

- Frankenfield DL, Neu AM, Warady BA, Watkins SL, Friedman AL, Fivush BA: Adolescent hemodialysis: results of the 2000 ESRD Clinical Performance Measures Project. *Pediatr Nephrol* 17:10-15, 2002.
- Leonard MB, et al. Racial and center differences in hemodialysis adequacy in children treated at pediatric centers: a North American Pediatric Renal Transplant Cooperative Study (NAPRTCS) report. *J Am Soc Nephrol*. 2004 Nov;15(11):2923-32.

2.8 Pediatric Peritoneal Dialysis Adequacy Measure (DFC Only)

2.8.1 Measure Name

Delivered Dose of Pediatric Peritoneal Dialysis (PD) Above Minimum

2.8.2 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.

2.8.3 Measure Rationale

Dialysis dose is an intermediate clinical outcome. The dose of dialysis is used to estimate the ability of peritoneal dialysis to clear the blood of accumulated toxins. In the adult population, clinical practice guidelines have established an association between dose of peritoneal dialysis 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.

2.8.4 Measure Type

Intermediate outcome

2.8.5 Improvement Noted as Higher or Lower Rate

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

2.8.6 Risk Adjustment

None

2.8.7 Numerator Statement

Patient-months in the denominator for patients whose delivered dose of peritoneal dialysis was equal to or greater than 1.8 Kt/V (dialytic+ residual, measured in the last 6 months). Kt/V must also be in range ($Kt/V \leq 8.5$).

2.8.8 Facility Exclusions

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

2.8.9 Denominator Statement

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

2.8.10 Denominator Exclusions

- Patients not assigned to the facility for the entire month
- Patients age 18 years and older as of the first day of the month (see Section 3.1.4)
- Patients not on peritoneal dialysis the entire month
- Patients on ESRD treatment for fewer than 91 days as of the first day of the month (see section 3.1.3)

2.8.11 Mapping Patients to Facilities

A patient may only be assigned to one dialysis facility each month.

For each patient, the dialysis provider at each point in time was identified primarily using data from CROWNWeb, the Medical Evidence Form (CMS-2728) and Medicare dialysis claims. Both patient assignment to the provider and modality (either hemodialysis or peritoneal dialysis) were determined according to the information reported in the above mentioned data sources. For each reporting month, patients were required to have been indicated as treated by the facility for the complete month in order to be included in the denominator. If a patient transferred in or out of the facility, discontinued dialysis, recovered renal function or died anytime during the month, the entire patient-month is excluded. Please note that the number of sessions are not considered and the patient may not have received treatment at the facility for the entire month to be included. For example, if a patient is hospitalized or travels during the month, the patient may still be included in the facility's measure if they are indicated as the facility's patient that month according to the data as described above. Additionally, patients for whom the only evidence of dialysis treatment is the existence of Medicare claims were considered lost to follow-up and removed from a facility's analysis one year following the last claim, if there was no earlier evidence of transfer, recovery, or death. In other words, if a period of one year passed with neither Medicare dialysis claims nor CROWNWeb information to indicate that a patient was receiving dialysis treatment, we considered the patient lost to follow-up, and did not use him or her in the analysis.

2.8.12 Calculating Numerators

Number of patients in denominator whose delivered dose of peritoneal dialysis (dialytic + residual, calculated from the last measurements of the six-month study period) was a $Kt/V \geq 1.8$ and $Kt/V \leq 8.5$.

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

2.8.13 Assigning Patient-Months to Numerators and Denominators

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

- If the selected Kt/V value is missing or not in the valid range (> 8.5), include patient-month in the denominator but not the numerator.
- If selected Kt/V value is in valid range (≤ 8.5) and meets the Kt/V value threshold (≥ 1.8), then include the patient-month in denominator and the numerator.

2.8.14 Data Elements and Data Sources

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

CROWNWeb Data Elements

- CROWN Unique Patient Identifier (UPI)
- Facility CCN
- Patient Date of Birth
- Patient Date of Death
- Primary type of treatment ID (CROWNWeb dialysis type)
- Medicare certified services offered as of 12/31 of the performance period
- Additional services offered (Non-Medicare) as of 12/31 of the measurement period
- Kt/V
- First date of ESRD (see section 3.1.3)

Claims Based Data Elements

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

- Claim Related Condition Code
- Claim Control Number
- Claim From Date
- Claim Through Date
- Claim NCH Daily Process Date
- Claim Link Number
- Claim Occurrence Date
- Claim Occurrence Code
- Claim CCN
- Claim Value Code D5
- Claim Value Amount
- Claim Value Sequence Number
- Claim Line Institutional Revenue Center Codes
- Claim Line Institutional Revenue Center Date
- Patient Health Insurance Claim Number
- Patient Date of Death
- Patient Date of Birth

2.8.15 Selected References

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

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

2.9.1 Measure Name

Kt/V Dialysis Adequacy Comprehensive Clinical Measure

2.9.2 Measure Description

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

2.9.3 Measure Rationale

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

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

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

2.9.4 Measure Type

Intermediate outcome

2.9.5 Improvement Noted as Higher or Lower Rate

Higher rates are better

2.9.6 Risk Adjustment

None

2.9.7 Numerator Statement

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

- Hemodialysis (all ages): $spKt/V \geq 1.2$ (calculated from the last measurement of the month using UKM or Daugirdas II)
- Peritoneal dialysis (pediatric < 18 years old, see Section 3.1.4): $Kt/V \geq 1.8$ (dialytic + residual, measured within the past 6 months)
- Peritoneal dialysis (adult ≥ 18 years old): $Kt/V \geq 1.7$ (dialytic + residual, measured within the past 4 months)

2.9.8 Facility Exclusions

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

2.9.9 Denominator Statement

- All adult hemodialysis patients who received dialysis greater than two and less than four times a week (adults, ≥ 18 years old), and all pediatric in-center hemodialysis patients who received dialysis greater than two and less than four times a week (pediatric, < 18 years old), and did not indicate frequent dialysis.
- All patients (both hemodialysis and peritoneal dialysis) who are assigned to the facility for the entire month, and have had ESRD for 90 days or more (see Section 3.1.6).
- Note, patient age is determined as of the first of the month for CROWNWeb, and as of the claim-from date for claims.

2.9.10 Denominator Exclusions

- Hemodialysis patients receiving dialysis less than or equal to 2 times weekly or greater than or equal to 4 times weekly (see Section 3.1.5)
- Pediatric home hemodialysis patients. When Kt/V is reported in CROWNWeb, pediatric patients are defined as patients < 18 years old as of the first day of the reporting month. If Kt/V is obtained from claims, pediatric patients < 18 years old as of the claim from date are excluded.
- Patients on ESRD treatment for fewer than 90 days at the beginning of the reporting month when using CROWNWeb as the data source. If claims are used as the data source, the 90 days on ESRD treatment is determined based on the claim-from date, representing the start of when care was provided.
- Patients who changed dialysis modality during the month. Note: For adult HD patients, a change from in-center to home HD (or vice versa) is not considered a modality change. Modality determination is described in section 3.1.1.

Final

- Patients who were not assigned to the facility for the entire month due to death or discharge for one of the following reasons: discontinued, involuntary discharge, transplant, or other reasons for leaving dialysis (see Section 3.1.6)
- Patients who were not assigned to the facility for the entire month due to transfer to a different facility.
- Criteria for selecting claims and their Kt/V values:
 - An HD claim is considered eligible if it is for an in-center HD (adult or pediatric) or adult home HD patient and meets all three of the following condition:
 - The patient has had ESRD for at least 90 days as of the claim-from date;
 - The home HD patient is at least 18 years old as of the claim-from date; and
 - The claim is neither a “frequent” dialysis claim nor an “infrequent” dialysis claim, as described in Section 3.1.5.
 - A PD claim is considered eligible if it is from a PD patient who had ESRD for at least 90 days.
 - If there are multiple claims for a patient during a month, the last claim is the claim with the latest claim-from date.
 - For an HD patient, if a multiple Kt/V values are reported on the last eligible claim, then the following decision rules are used to select the Kt/V value:
 - First, select the highest numeric Kt/V value that is not 8.88 or 9.99
 - Second, select 8.88 if reported and no other valid value is reported
 - Third, select 9.99 if reported and no other value is reported.
 - For HD patients, the reported spKt/V should not include residual renal function.
 - For a PD patient, the last eligible claim with a Kt/V value that is not expired (i.e. the Kt/V occurrence date is less than or equal to four months prior to the end of the claim for an adult, six months prior to the end of the claim for pediatric) is selected when there are multiple claims reported in a month. If multiple valid claims are submitted for a patient in the same month and there is at least one Kt/V=9.99 and at least one Kt/V not equal to 9.99 then the claims with Kt/V 9.99 are considered invalid.

2.9.11 Mapping Patients to Facilities

A patient may only be assigned to **one** dialysis facility each month.

For each patient, the dialysis provider at each point in time was identified primarily using data from CROWNWeb, the Medical Evidence Form (CMS-2728) and Medicare dialysis claims. Both patient assignment to the provider and modality (either hemodialysis or peritoneal dialysis) were determined according to the information reported in the above-mentioned data sources. For each reporting month, patients were required to have been indicated as treated by the facility for the complete month in order to be included in the denominator. If a patient transferred in or out of the facility, discontinued dialysis, recovered renal function or died anytime during the month, the entire patient-month is excluded. Please note that the number of sessions provided to the patient are not considered and the patient may not have received treatment at the facility for the entire month to be included. For example, if a patient is hospitalized or travels during the month, the patient may still be included in the facility's measure if they are indicated as the facility's patient that month according to the data as described above. Additionally, patients for whom the only evidence of dialysis treatment is the existence of Medicare claims were considered lost to follow-up and removed from a facility's analysis one year following the last claim, if there was no earlier evidence of transfer, recovery, or death. In other words, if a period of one year passed with neither paid Medicare dialysis claims nor CROWNWeb information to indicate that a patient was receiving dialysis treatment, we considered the patient lost to follow-up, and did not use him or her in the analysis.

2.9.12 Calculating Numerators

2.9.12.1 Adult HD Kt/V:

Number of patient-months in denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a $spKt/V \geq 1.2$. Patient age is determined as of the first of the month for CROWNWeb, and as of the claim-from date for claims.

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

2.9.12.2 Adult PD Kt/V:

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

Patient age is determined as of the first of the month for CROWNWeb, and as of the claim-from date for claims.

- If a patient has multiple Kt/V values in CROWNWeb during the month under consideration or in the 3 months prior, then the last reported value is selected.
- If a value is not found in CROWNWeb for the patient during the four-month study period, then the last reported non-missing value reported on the last eligible Medicare claim for the patient during the four-month study period is selected (when available).
- Note, the length of the study period is based on patient age determination.

2.9.12.3 Pediatric HD Kt/V:

Number of patient-months in denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a $spKt/V \geq 1.2$. Patient age is determined as of the first of the month for CROWNWeb, and as of the claim-from date for claims.

- If a patient has multiple Kt/V values in CROWNWeb during a month, then the last reported value is selected.
- If a Kt/V value is not found in CROWNWeb for the patient during the reporting month, the following logic applies to selecting a Kt/V value from claims, if possible.
 - For in-center HD pediatric patients, the system will select the appropriate non-missing Kt/V value reported on the last eligible Medicare claim for the patient during the month.

2.9.12.4 Pediatric PD Kt/V:

Number of patient-months in denominator whose delivered dose of peritoneal dialysis (dialytic + residual, calculated from the last measurements of the six-month study period) was a $Kt/V \geq 1.8$. Patient age is determined as of the first of the month for CROWNWeb, and as of the claim-from date for claims.

- If a patient has multiple Kt/V values in CROWNWeb during the month under consideration or in the 5 months prior, then the last reported value is selected.
- If a value is not found in CROWNWeb for the patient during the six-month study period then the last reported non-missing value reported on the last eligible Medicare claim for the patient during the six-month study period (reporting month and five prior months) is selected (when available).
- Note, the length of the study period is based on patient age determination.

2.9.13 Assigning Patient-Months to Numerators and Denominators

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

- If selected Kt/V value is missing or 9.99 (i.e. when using claims), include patient-month in the denominator, but not in the numerator.

- If selected Kt/V value meets the Kt/V value threshold (≥ 1.2 for HD, ≥ 1.7 for adult PD, or ≥ 1.8 for pediatric PD), then include patient month in denominator and numerator.

2.9.14 Data Elements and Data Sources

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

CROWNWeb Data Elements

- Facility CCN
- Patient Date of Birth
- Patient Date of Death
- CROWN Unique Patient Identifier (UPI)
- Primary type of treatment ID (CROWNWeb dialysis type)
- Number of prescribed dialysis sessions per week
- Medicare Certified Services Offered as of 12/31 of the performance period
- Additional Services Offered (Non-Medicare) as of 12/31 of the measurement period
- Kt/V method
- Kt/V value
- Reporting/clinical month
- Modality (to determine look-back period and assess if modality changed during the month)

Claims Based Data Elements

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

- Patient Health Insurance Claim Number
- Patient date of birth
- Patient date of death
- Claim Related Condition Code
- Claim Control Number
- Claim From Date
- Claim Through Date
- Claim NCH Daily Process Date
- Claim Link Number
- Claim Occurrence Date
- Claim Occurrence Code
- Claim CCN
- Claim Value Code D5

- Claim Value Amount
- Claim Value Sequence Number
- Claim Line Institutional Revenue Center Codes
- Claim Line Institutional Revenue Center Dates
- Calculated start of ESRD date (see section 3.1.3)

2.9.15 Flowchart

Figure 5 provides a flowchart that represents the processes used to calculate the Kt/V Dialysis Adequacy Comprehensive Clinical Measure Rate.

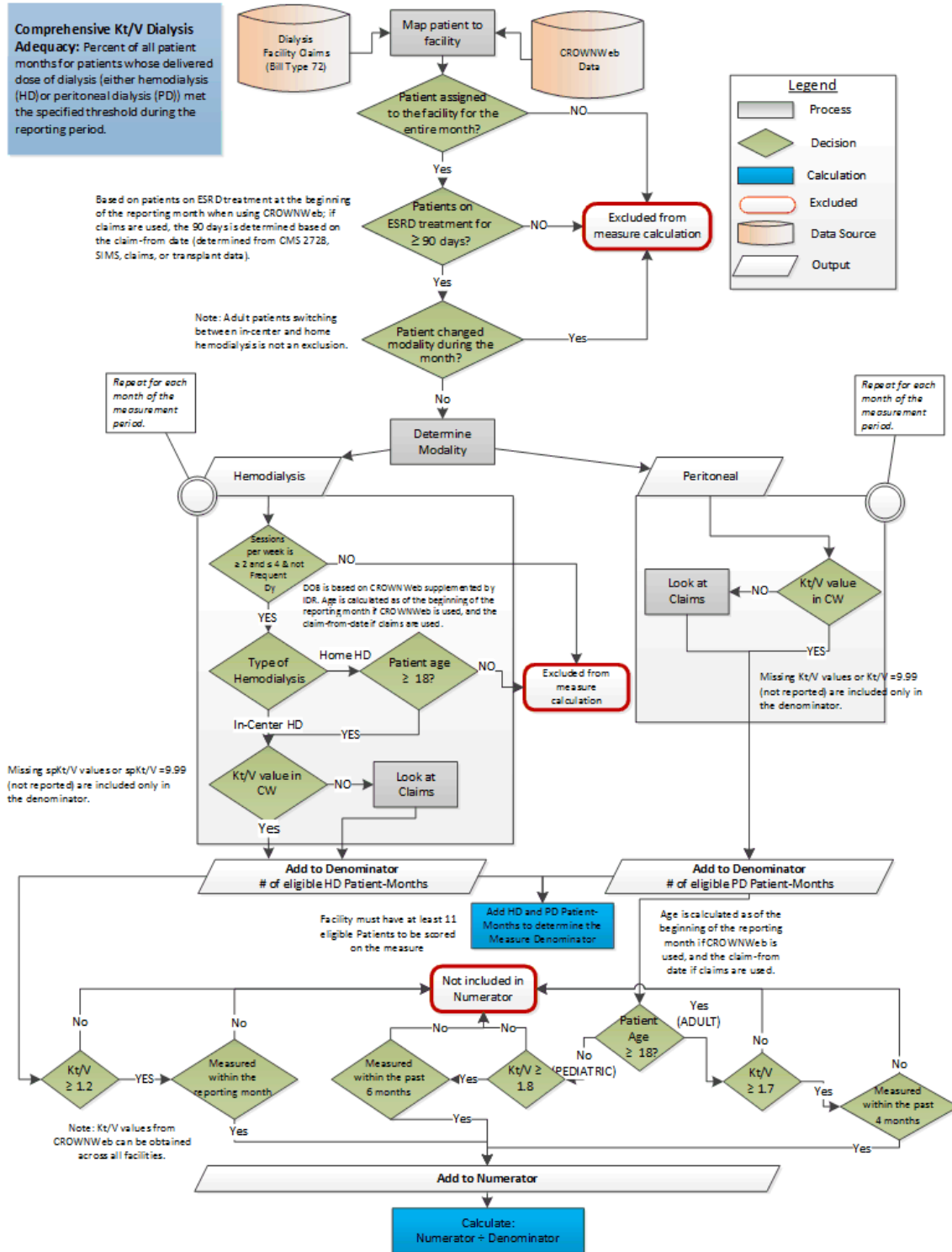


Figure 5: Kt/V Dialysis Adequacy Comprehensive Clinical Measure Rate Flowchart (ESRD QIP Only)

2.10 nPCR for Pediatric Hemodialysis Patients (DFC only)

2.10.1 Measure Name

Measurement of nPCR for Pediatric Hemodialysis Patients

2.10.2 Measure Description

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

2.10.3 Measure Rationale

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

2.10.4 Measure Type

Process

2.10.5 Improvement Noted as Higher or Lower Rate

Higher numbers are better

2.10.6 Risk Adjustment

None

2.10.7 Numerator Statement

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

2.10.8 Facility Exclusions

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

2.10.9 Denominator Statement

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

2.10.10 Denominator Exclusions

Exclusions that are implicit in the denominator definition include:

- Pediatric patients (\geq 18 years old) (see Section 3.1.4)
- Patients not assigned to the facility for the entire month

- Home hemodialysis patients

2.10.11 Mapping Patients to Facilities

A patient may only be assigned to one dialysis facility each month.

For each patient, the dialysis provider at each point in time was identified primarily using data from CROWNWeb, the Medical Evidence Form (CMS-2728) and Medicare dialysis claims. Both patient assignment to the provider and modality (either hemodialysis or peritoneal dialysis) were determined according to the information reported in the above mentioned data sources. For each reporting month, patients were required to have been indicated as treated by the facility for the complete month in order to be included in the denominator. If a patient transferred in or out of the facility, discontinued dialysis, recovered renal function or died anytime during the month, the entire patient-month is excluded. Please note that the number of sessions are not considered and the patient may not have received treatment at the facility for the entire month to be included. For example, if a patient is hospitalized or travels during the month, the patient may still be included in the facility's measure if they are indicated as the facility's patient that month according to the data as described above. Additionally, patients for whom the only evidence of dialysis treatment is the existence of Medicare claims were considered lost to follow-up and removed from a facility's analysis one year following the last claim, if there was no earlier evidence of transfer, recovery, or death. In other words, if a period of one year passed with neither Medicare dialysis claims nor CROWNWeb information to indicate that a patient was receiving dialysis treatment, we considered the patient lost to follow-up, and did not use him or her in the analysis.

2.10.12 Calculating Numerators

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

2.10.13 Data Elements and Data Sources

CROWNWeb Data Elements

- CROWN Unique Patient Identifier (UPI)
- Facility CCN
- Patient Date of Birth
- Patient Date of Death
- Primary type of treatment ID (CROWNWeb dialysis type)
- Number of dialysis sessions per week
- Medicare Certified Services Offered as of 12/31 of the performance period
- Additional Services Offered (Non-Medicare) as of 12/31 of the measurement period

- BUN pre-dialysis
- BUN post-dialysis
- Pre-dialysis weight
- Pre-dialysis weight unit of measure
- Post-dialysis weight
- Post-dialysis weight unit of measure
- Delivered minutes of BUN hemodialysis session
- Intradialytic time
- First date of ESRD (see section 3.1.3)

Claims Based Data Elements

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

- Claim Related Condition Code
- Claim Control Number
- Claim From Date
- Claim Through Date
- Claim NCH Daily Process Date
- Claim Link Number
- Claim Occurrence Code
- Claim Occurrence Date
- Claim CCN
- Claim Value Code D5
- Claim Value Amount
- Claim Value Sequence Number
- Claim Line Institutional Revenue Center Codes
- Claim Line Institutional Revenue Center Date
- Patient Health Insurance Claim Number
- Patient Date of Death
- Patient Date of Birth

2.10.14 Flowchart

Figure 6 provides a flowchart that represents the processes used to calculate the nPCR for Pediatric Hemodialysis Patients Rate.

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

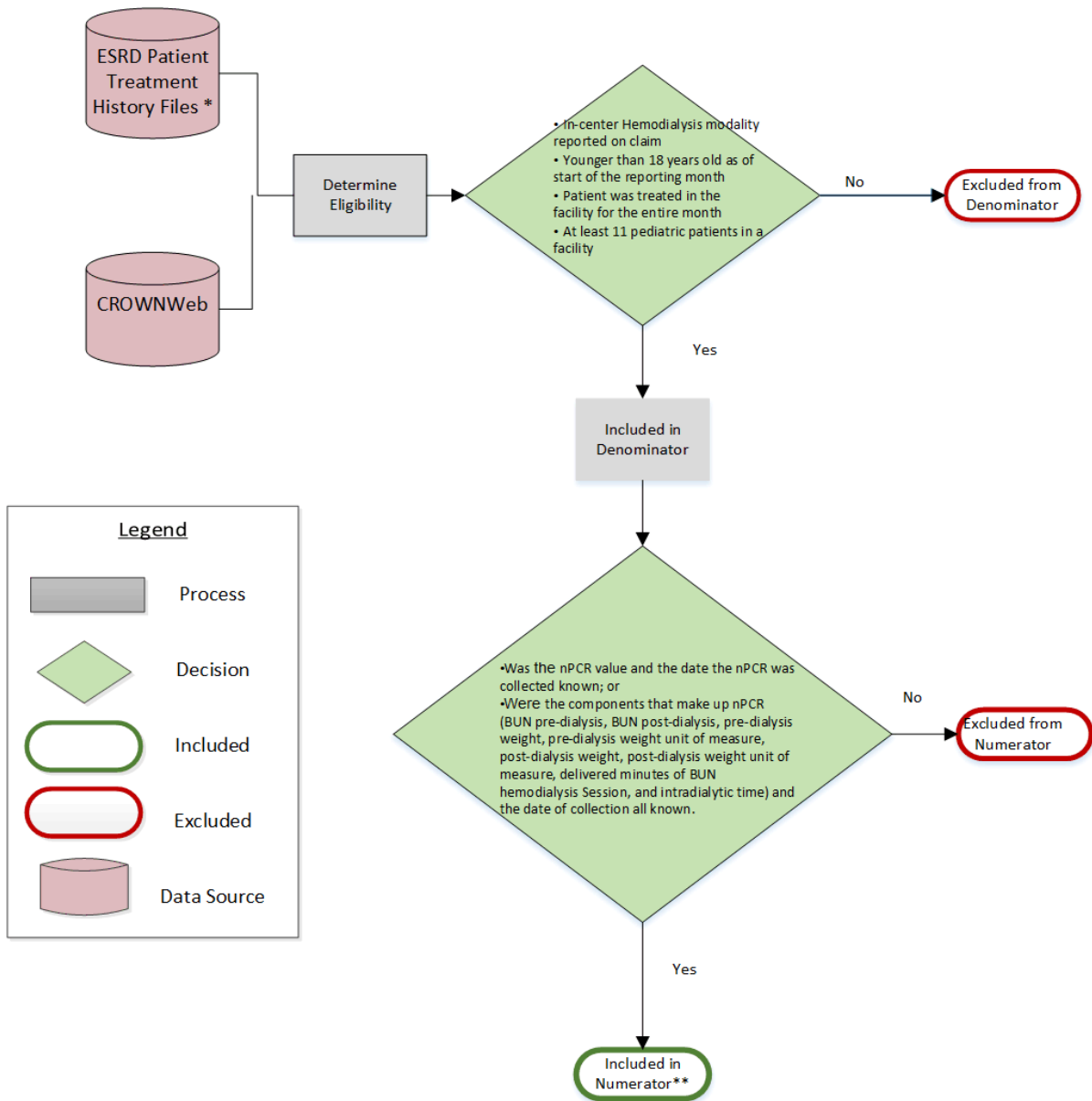


Figure 6: nPCR for Pediatric Hemodialysis Patients Flowchart Here

* Multiple data sources include CMS Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN) (DFC only), the Death Notification Form (CMS-2746), the Dialysis Facility Compare (DFC) and the Social Security Death Master File (DFC only).

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

2.10.15 Selected References

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

2.11 Hypercalcemia Clinical Measure (ESRD QIP and DFC)

2.11.1 Measure Name

Proportion of Patients with Hypercalcemia – NQF #1454

2.11.2 Measure Description

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

2.11.3 Measure Rationale

The hypercalcemia measure was developed in 2010 based on the recommendations of a clinical technical expert panel's (TEP) consideration of the multiple large, risk-adjusted observational studies (referenced below) demonstrating a consistent relationship between presence of hypercalcemia and patient mortality. TEP members felt that while small, the population of patients with hypercalcemia was at increased risk of cardiovascular events and therefore the condition 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, the measure remains an important intermediate outcome and patient safety measure, even in light of the lack of interventional trials supporting a specific threshold. Nevertheless, the number of large, risk-adjusted observational studies (referenced below) with consistent direction of association between hypercalcemia and mortality cannot be ignored.

Given this, several NQF standing committee reviewers agreed with the prior TEPs' opinions that the measure represented an appropriate safety-net. As an additional concern, the Protecting Access to Medicare Act of 2014 mandated the implementation of conditions treated through oral-only medications in the ESRD Quality Incentive Program (QIP) as a safety measure against over-use of oral-only medications following changes to the ESRD prospective payment system (PPS) bundle payment. Congress likely recognized the need for more safety measures in the ESRD program, particularly in the area of drug overuse, following similar concerns for the use of erythropoiesis stimulating agents (ESAs) in treating anemia in the same population.

2.11.4 Measure Type

Intermediate Outcome

2.11.5 Improvement Noted as Higher or Lower Rate

Lower rates are better

2.11.6 Risk Adjustment

None

2.11.7 Numerator Statement

Number of patient-months in the denominator with 3-month rolling average of total uncorrected (indicates that albumin is not considered in the calculation) serum or plasma calcium greater than 10.2 mg/dL. Patient-months with missing values in the reporting month and the two months prior are included in the numerator to minimize any incentive favoring non-measurement of serum calcium during the preceding three months.

2.11.8 Facility Exclusions

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

2.11.9 Denominator Statement

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

2.11.10 Denominator Exclusions

- Patient younger than age 18 years old as of the first day of the reporting month (see Section 3.1.4)
- Patient on ESRD treatment for fewer than 90 days as of the first day of the reporting month.
- Patients who died prior to the last day of the reporting month.

DFC only:

- Out of range uncorrected serum calcium or plasma value (values < 0.1 and value > 20) are considered as missing.
- Patients not assigned to the facility for the entire reporting month.

ESRD QIP only:

- Patients for whom the facility reported fewer than 3 months of calcium values in CROWNWeb during the measurement period, plus the two months prior (i.e. November and December of the previous year will be used in calculating the three-month rolling average for January and February of the baseline and performance period)
- Patient was at the facility for fewer than 30 days (either consecutive or non-consecutive) during the reporting month and the two months prior (the 3-month calculation period).

- Patient was discharged from the facility prior to the last day of the reporting month.
- Patient was not on ESRD treatment during the month.

2.11.11 Mapping Patients to Facilities

ESRD QIP:

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

DFC:

- Patients can be attributed to only one facility per month.
- For each patient, the dialysis provider at each point in time was identified primarily using data from CROWNWeb, the Medical Evidence Form (CMS-2728) and Medicare dialysis claims. Both patient assignment to the provider and modality (either hemodialysis or peritoneal dialysis) were determined according to the information reported in the above mentioned data sources. For each reporting month, patients were required to have been indicated as treated by the facility for the complete month in order to be included in the denominator. If a patient transferred in or out of the facility, discontinued dialysis, recovered renal function or died anytime during the month, the entire patient-month is excluded. Please note that the number of sessions are not considered and the patient may not have received treatment at the facility for the entire month to be included. For example, if a patient is hospitalized or travels during the month, the patient may still be included in the facility's measure if they are indicated as the facility's patient that month according to the data as described above. Additionally, patients for whom the only evidence of dialysis treatment is the existence of Medicare claims were considered lost to follow-up and removed from a facility's analysis one year following the last claim, if there was no earlier evidence of transfer, recovery, or death. In other words, if a period of one year passed with neither Medicare dialysis claims nor CROWNWeb information to indicate that a patient was receiving dialysis treatment, we considered the patient lost to follow-up, and did not use him or her in the analysis.

2.11.12 Calculating Numerators

A patient-month is included in the numerator if the average calcium level is greater than 10.2 mg/dL or missing. Any value reported during the two months prior to the reporting month will only be used to calculate the 3-month rolling average if applicable.

- The last calcium value reported in the month is used for calculation.
- The calcium value reported by the facility is used. The facility may obtain this value from an external source.
- No interpolation between calcium values for peritoneal dialysis patients.

- “Uncorrected” indicates albumin is not considered in the calculation.
- A one-, two-, or three-month average can be calculated as long as there is a calcium value reported during the three-month window.
- Patient-months with missing values in the reporting month and the two months prior are included in the denominator and the numerator to minimize any incentive favoring non-measurement of serum calcium in the preceding three months.

ESRD QIP:

- November and December of the year before the performance period may be used in calculating the three-month rolling average for January and February of the performance period.
- November and December of the year before the improvement baseline period may be used (if reported) in calculating the three-month rolling average for January and February in the Improvement Threshold rate.
- The monthly rolling average for each patient with an average calcium greater than 10.2 mg/dL is rounded to one decimal place (XX.X), with half rounded up, prior to comparing the average to the threshold rate (10.2 mg/dL).

2.11.13 Data Elements and Data Sources

The data elements used for this measure are listed below. A complete description of the data elements can be found at the [ESRD section of QualityNet.org](https://www.qualitynet.org/essrd).

CROWNWeb Data Elements:

- Facility CCN
- Initial Certification Date
- Patient Date of Birth
- Patient Date of Death
- 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
- First date of ESRD (see section 3.1.3)

Claims Based Data Elements:

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

- Claim Control Number
- Claim From Date

- Claim Through Date
- Patient Health Insurance Claim Number
- Patient date of birth
- Patient date of death
- Claim CCN

2.11.14 Flowchart for ESRD QIP

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

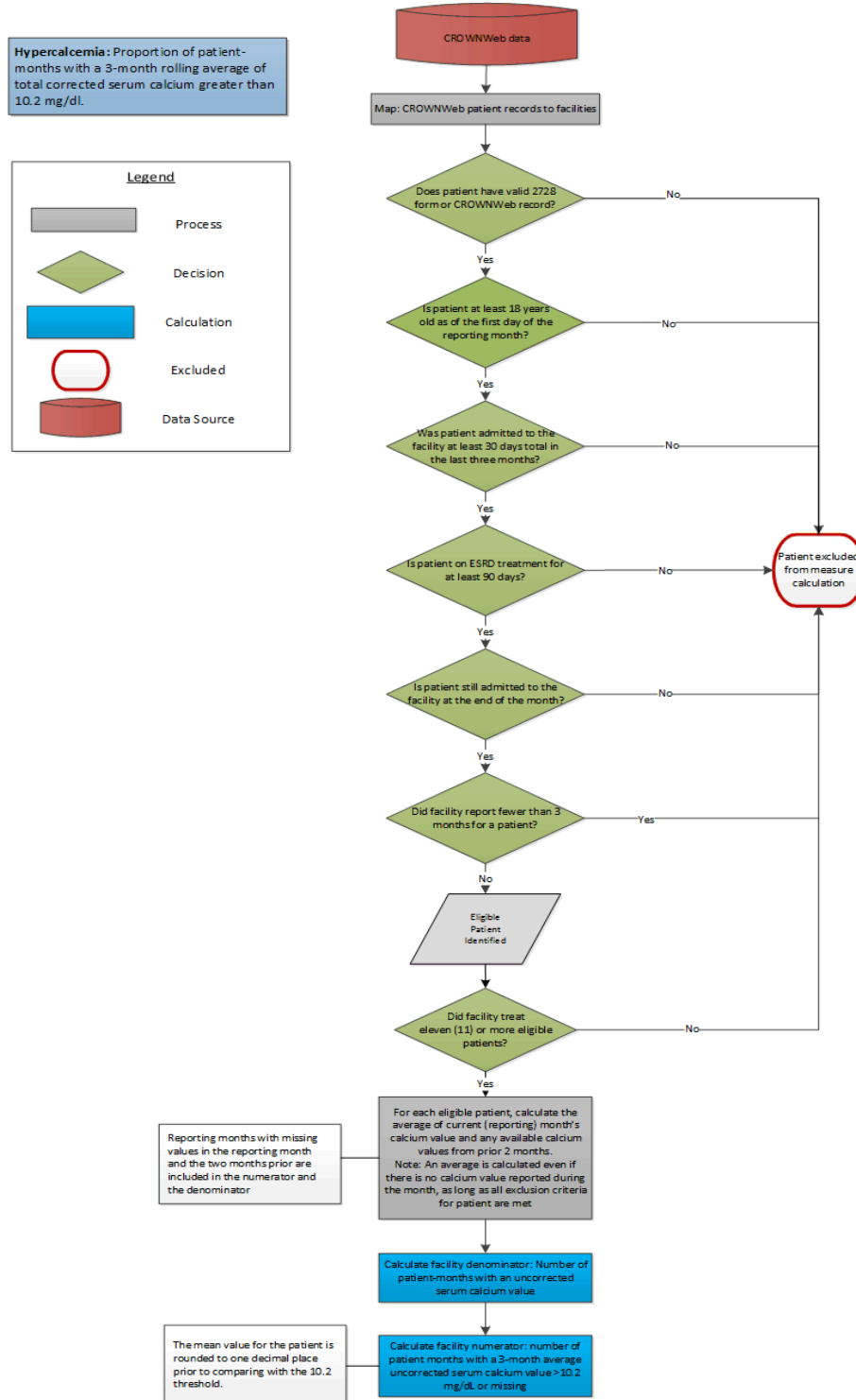


Figure 7: Hypercalcemia Clinical Measure Rate Flowchart (ESRD QIP Only)

2.11.15 Flowchart for DFC

Figure 8 provides a flowchart that represents the processes used to calculate the Hypercalcemia Clinical Measure Rate for DFC.

Hypercalcemia (DFC): Percentage of adult dialysis patients with a 3-month rolling average of total uncorrected calcium (Serum or plasma) greater than 10.2 mg/dL (hypercalcemia)

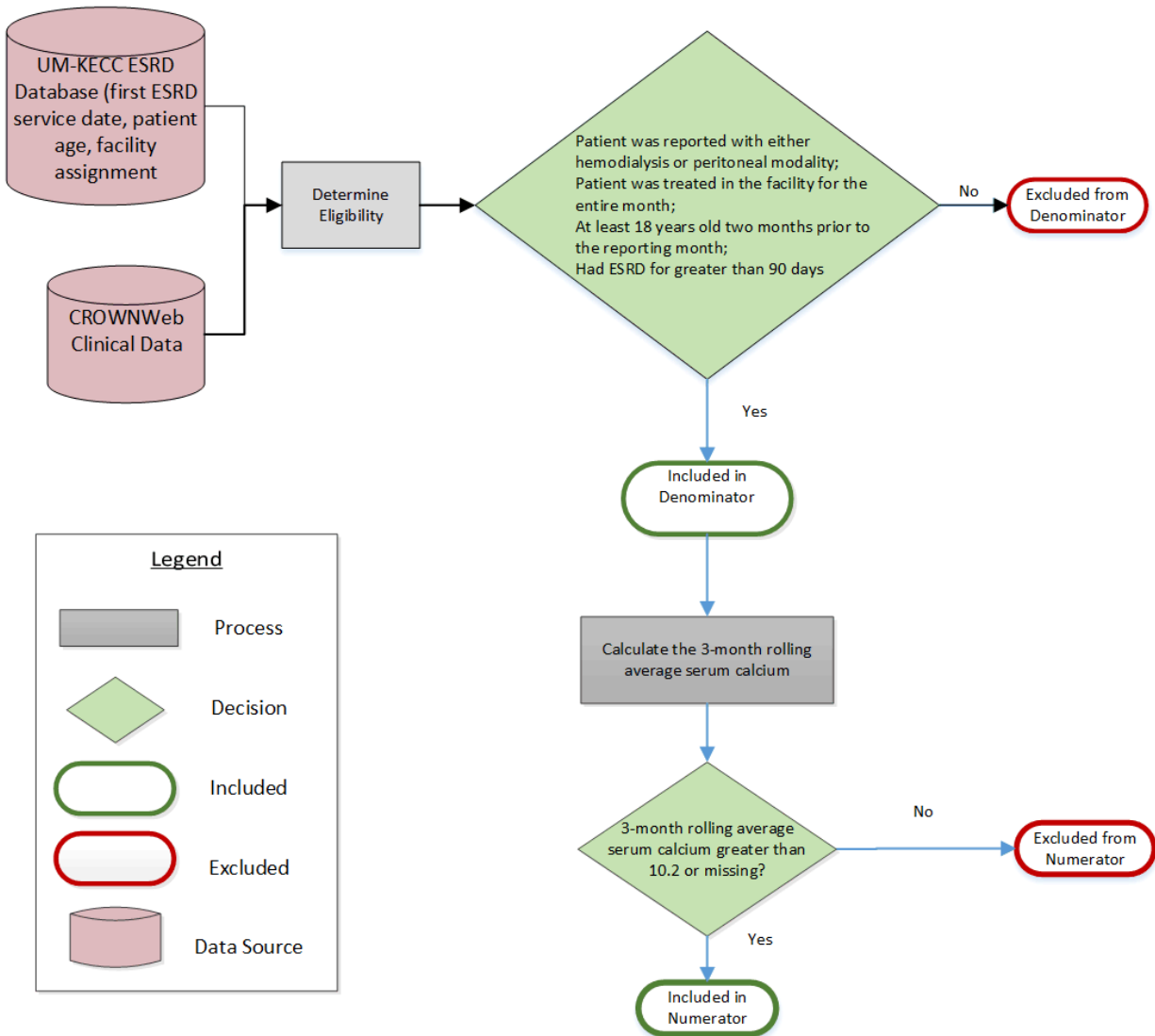


Figure 8: Hypercalcemia Clinical Measure Rate Flowchart (DFC Only)

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2.12 Anemia Management Reporting Measure (ESRD QIP Only)

2.12.1 Measure Name

Anemia Management Reporting Measure

2.12.2 Measure Description

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

2.12.3 Measure Type

Reporting measure

2.12.4 Facility-Level Exclusions

- Facilities with fewer than 11 eligible patients during the performance period.
- Facilities with a CMS certification number (CCN) certification date on or after July 1, 2018.

2.12.5 Patient-Level Exclusions

- In-center hemodialysis patients treated at a facility fewer than 7 times during claim month.
- Home dialysis patients for whom a facility does not submit a claim during the claim month.
- Patients with other-peritoneal dialysis, missing or undetermined modality. Modality determination for each claim is described in Section 3.1.1
- Patients not on ESRD treatment as defined by a completed 2728 form or a REMIS/CROWNWeb record, or a sufficient amount of dialysis reported on dialysis facility claims

2.12.6 Facility-Month-Level Exclusions

- No eligible patients in the reporting month
- Certification date on or after the 1st day of the reporting month (the scenario can only occur during January, 2018 through June, 2018)

2.12.7 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.

No ESA dosage need be recorded if patient is not treated with ESAs. ESA dosage must be reported via HCPCS codes and corresponding units, as applicable.

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

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

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

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

2.12.8 Calculating Monthly Reporting Percentages

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

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

2.12.9 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) 2018

2.12.10 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, 2018, then the facility is required to report data for the entirety of the performance period (i.e. all 12 months in 2018).

If the facility's certification date was between January 1, 2018 and June 30, 2018, then the facility is required to report on the first day after the month in which the facility is certified to participate in Medicare. For example, if the facility certification date is in March of 2018, then reporting requirements begin on April 1, and the facility is required to report nine months of data.

If the facility's certification date was after June 30, 2018, 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 domain score and one reporting measure domain score to receive a Total Performance Score).

2.12.11 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, an eligible facility's score on the Anemia Management reporting measure is calculated according to the following equation:

$$\left[\frac{(\# \text{ Months Successfully Reporting Data})}{(\# \text{ Eligible Months})} \times 12 \right] - 2$$

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.

2.12.12 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](https://www.qualitynet.org/ESRD).

CROWNWeb Data Elements

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

Claims Based Data Elements

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

- Claim Related Condition Code
- Claim Control Number
- Claim From Date

- Claim Through Date
- Claim Line Institutional Revenue Center Codes
- Claim Line Institutional Revenue Center Dates
- Claim Value Code 48 or 49
- Claim Value Amount
- Claim Value Sequence Number
- Patient Health Insurance Claim Number
- Claim CCN
- Claim HCPCS code

2.12.13 Flowchart

Figure 9 provides a flowchart that represents the processes used to calculate the Anemia Management Reporting Measure Rate.

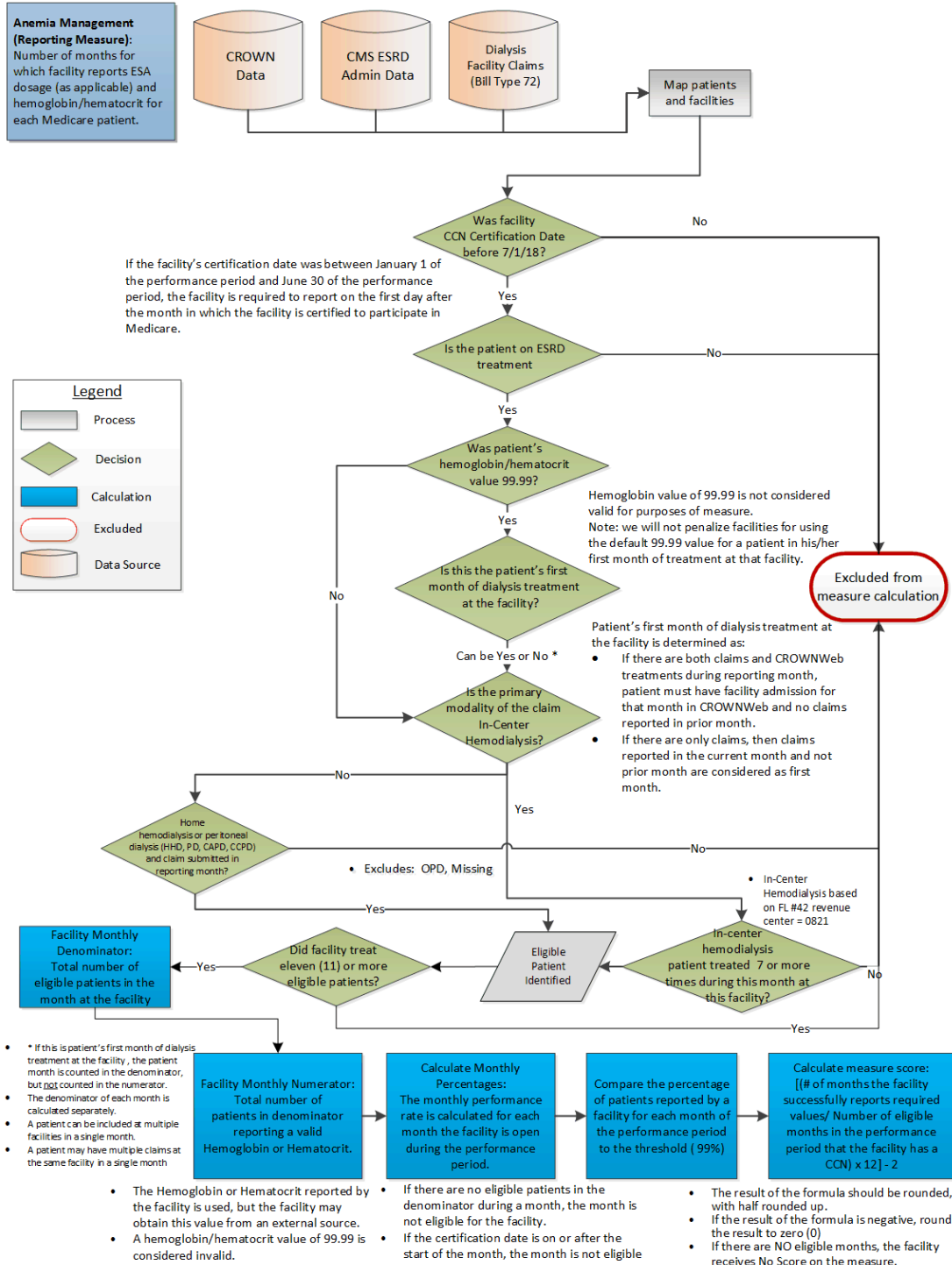


Figure 9: Anemia Management Reporting Measure Flowchart (ESRD QIP Only)

2.13 Serum Phosphorus Reporting Measure (ESRD QIP Only)

2.13.1 Measure Name

Serum Phosphorus Reporting Measure – NQF #0255

2.13.2 Measure Description

Number of months in which a facility reports serum or plasma phosphorus in CROWNWeb at least once during the reporting month for adult (≥ 18 years of age) peritoneal dialysis and hemodialysis patients. **NQF #: 0255.**

2.13.3 Measure Type

Reporting measure

2.13.4 Facility-Level Exclusions

- Facilities with fewer than 11 eligible patients during the performance period (see Section 2.13.6).
- Facilities with a CMS certification number (CCN) certification date on or after July 1 of the performance period.

2.13.5 Numerator Statement

Number of months the facility successfully reports serum or plasma phosphorus in CROWNWeb at least once during the reporting month.

2.13.6 Denominator Statement

Number of eligible months the facility treats at least one adult (≥ 18 years of age) peritoneal dialysis or hemodialysis patient during the performance period..

2.13.7 Patient-Level Exclusions

- Patients not at the facility for the entire month ("Admit Date" greater than the first day of the month and "Discharge Date" is less than the last day of the month)
- Home dialysis patients for whom a facility does not submit a claim during the claim month
- Patients not on ESRD treatment as defined by a completed 2728 form or a REMIS/CROWNWeb record, or a sufficient amount of dialysis reported on dialysis facility claims
- Patients whose age is less than 18 years (see Section 3.1.4)
- Kidney transplant recipients with a functioning graft whose "Primary Type of Treatment" = 'Hemodialysis', 'CAPD', or 'CCPD' on the last day of the reporting month

- Patients with other peritoneal dialysis, missing or undetermined modalities. Modality determination is described in Section 3.1.1

2.13.8 Facility-Month-Level Exclusions

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

2.13.9 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.

2.13.10 Calculating Monthly Reporting Percentages

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

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

2.13.11 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) 2018

The serum or plasma phosphorus values reported by the facility are used. The facility may obtain these values from an external source.

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

If the facility's certification date was between January 1 of the performance period, and June 30 of the performance period, the facility is required to report on the first day after the month in which the facility is certified to participate in Medicare. For example, if the facility certification date is in March of the performance period, 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 of the performance period, then the facility is exempt from all reporting measures and will not receive a Total Performance Score (because a facility must be eligible for at least one measure in the Clinical Measure Domain, and one measure in the Reporting Measure Domain to receive a Total Performance Score).

2.13.13 Calculating a Facility's Score on the Serum Phosphorous Reporting Measure

Once numbers have been calculated for months of successful reporting and requisite reporting months, an eligible facility's score on the Serum Phosphorous reporting measure is calculated according to the following equation:

$$\left[\frac{(\# \text{ Months Successfully Reporting Data})}{(\# \text{ Eligible Months})} \times 12 \right] - 2$$

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.

2.13.14 Data Elements and Data Sources

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

CROWNWeb Data Elements

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

Claims Based Data Elements

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

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

2.13.15 Flowchart

Figure 10 provides a flowchart that represents the processes used to calculate the Serum Phosphorous Reporting Measure Rate.

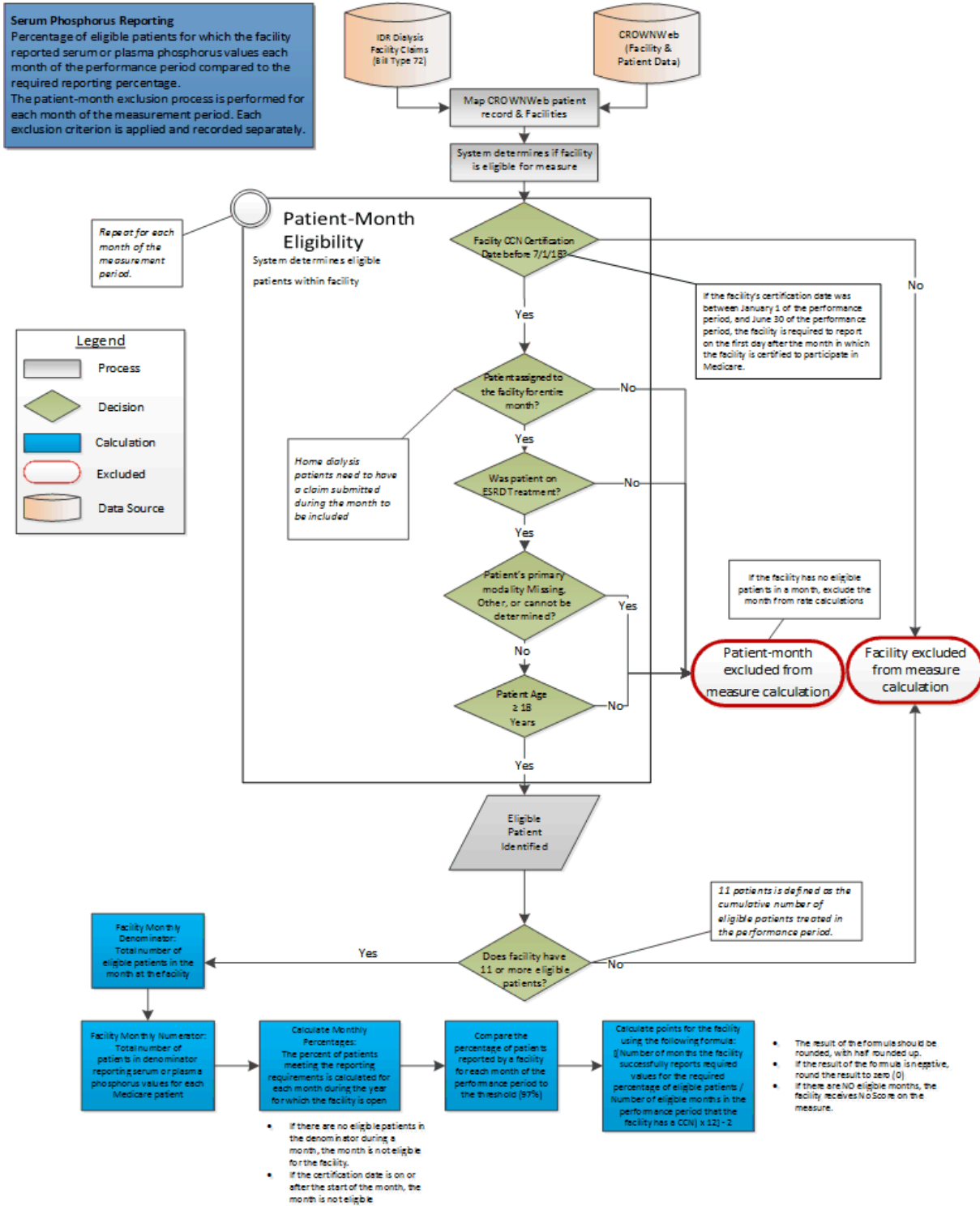


Figure 10: Serum Phosphorous Reporting Measure Flowchart (ESRD QIP Only)

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

2.14.1 Measure Name

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

2.14.2 Measure Description

Facility reports in CROWNWeb one of the six conditions below for each qualifying patient once before the close of the December clinical month.

2.14.3 Measure Type

Reporting measure

2.14.4 Facility-Level Exclusions

- Facilities with fewer than 11 eligible patients during the performance period (see Section 2.14.5 below)
- Facilities with a CCN certification date on or after July 1 of the performance period.

2.14.5 Patient-Level Exclusions

- Patients who are younger than 12 years old (see Section 3.1.4) as of October 31 of the performance period.
- Patients who are treated at the facility for fewer than 90 days (days do not have to be consecutive) between January 1 and December 31 of the performance period. (see Section 3.1.6)

2.14.6 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 the close of the December clinical month. If a patient is eligible at more than one facility, then each facility must report for the patient in order to receive credit on the measure.

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

- Screening for clinical depression not documented, but the facility possesses documentation stating the patient is not **eligible** (see 5 below).
- Clinical depression screening not documented, and no reason is given.

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

1. **Screening for clinical depression** – Completion of a clinical or diagnostic standardized tool used to identify people at risk of developing or having a certain disease or condition, even in the absence of symptoms. A standardized tool is an assessment tool that has been appropriately normalized and validated for the population in which it is used. Facilities are not required to use a particular tool, but should choose one that is appropriate for their patient population. Example tools include, but are not limited to: Adolescent Screening Tools (12-17 years) Patient Health Questionnaire for Adolescents (PHQ-A), Beck Depression Inventory-Primary Care Version (BDI-PC), Beck Depression Inventory-Primary Care Version (BDI-PC), PRIME MD-PHQ2, Mood Feeling Questionnaire (MFQ); Adult Screening Tools (18 years and older) Patient Health Questionnaire (PHQ-9), Beck Depression Inventory (BDI or BDI-II), Center for Epidemiologic Studies Depression Scale (CES-D), PRIME MD-PHQ2, Depression Scale (DEPS), Duke Anxiety-Depression Scale (DADS), Geriatric Depression Scale (GDS). **The name of the standardized assessment tool used must be documented in the medical record.**
2. **Positive** – Based on the scoring and interpretation of the specific standardized tool used, and through discussion during the patient visit, the provider should determine if the patient is deemed positive for signs of depression. **Justification for or against a positive screening should be documented in the medical record.**
3. **Follow-Up Plan** – A documented outline of care for a positive depression screening.
4. **Not eligible** – A patient may not be eligible for Follow-Up Plan, or it may not be appropriate for a patient to undergo treatment or therapy for pain because such treatments are medically contraindicated. **Justification for a patient’s ineligibility for follow-up treatment should be documented in the patients’ medical record.**
5. **Not eligible** – A patient is not eligible for Depression Screening if one or more of the following reasons are documented in the patient’s medical record:
 - Patient refuses to participate
 - Patient is in an urgent or emergent situation where time is of the essence and to delay treatment would jeopardize the patient’s health status
 - Situations where the patient’s motivation to improve may impact the accuracy of results of nationally recognized standardized depression assessment tools. For example: certain court appointed cases
 - Patient was referred with a diagnosis of depression
 - Patient has been participating in on-going treatment with screening of clinical depression in a preceding reporting period

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

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

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

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

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

2.14.8 Data Elements and Data Sources

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

CROWNWeb Data Elements:

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

2.14.9 Flowchart

Figure 11 provides a flowchart that represents the processes used to calculate the Screening for Clinical Depression and Follow-Up Reporting Measure Rate.

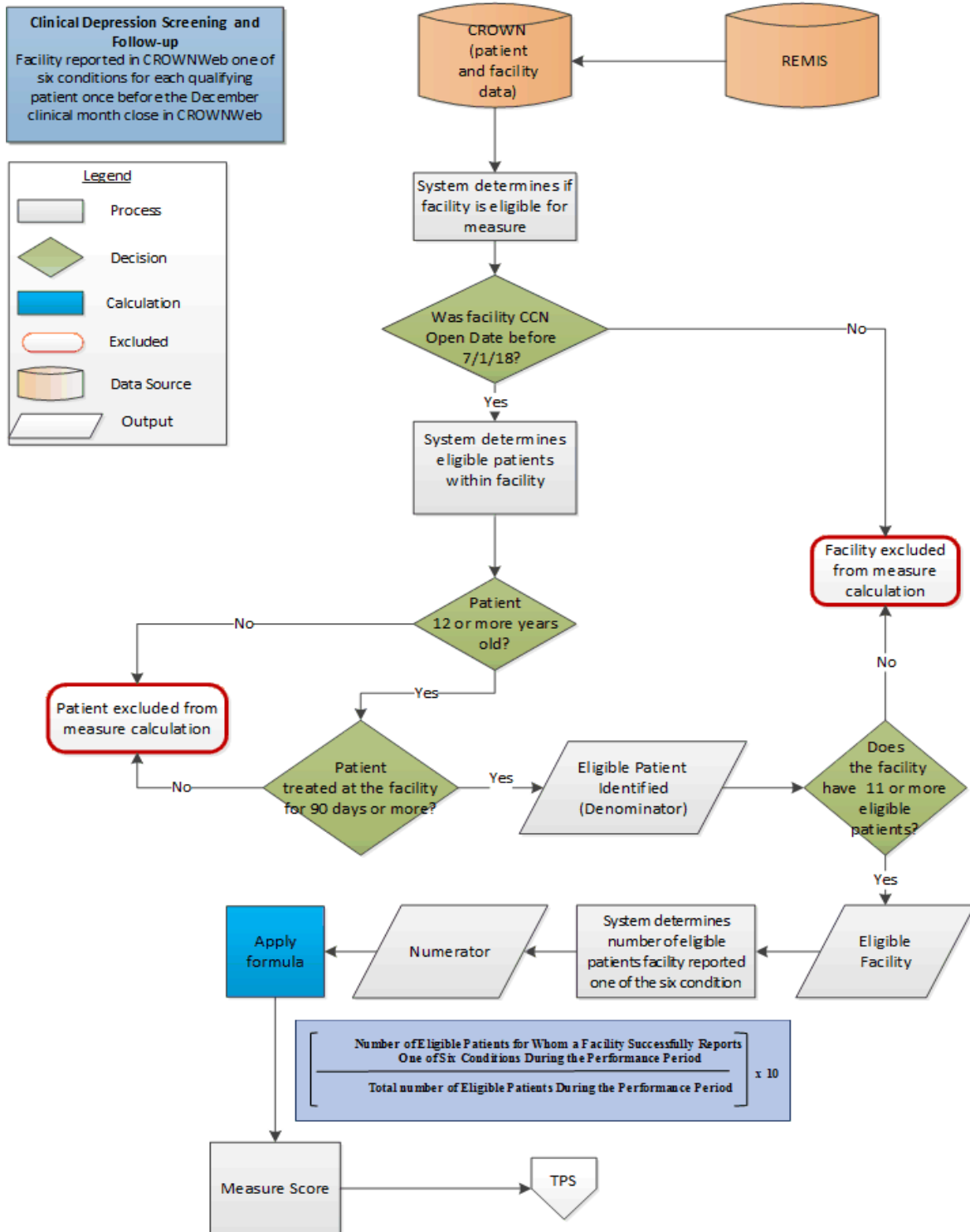


Figure 11: Screening for Clinical Depression and Follow-Up Reporting Measure Flowchart (ESRD QIP Only)

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

2.15.1 Measure Name

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

2.15.2 Measure Description

Facility reports in CROWNWeb one of the six conditions below for each qualifying patient twice during the performance period. For the first assessment period (January 1 through June 30), the facility must report prior to the close of the June clinical month. For the second assessment period (July 1 through December 31), the facility must report prior to the close of the December clinical month.

Please note that CROWNWeb will allow facilities to report for multiple assessment periods during the months of July and August and the months of January and February after the performance period if there are no conditional deadline extensions.

2.15.3 Measure Type

Reporting measure

2.15.4 Facility-Level Exclusions

- Facilities with fewer than 11 eligible patients during the performance period (see Section 2.15.5 below).
- Facilities with a CCN certification date on or after July 1 of the performance year.

2.15.5 Patient-Level Exclusions

- Patients who are younger than 18 years old (see Section 3.1.4) as of April 30, for the first assessment period, and as of October 31, for the second assessment period
- Patients who are treated at the facility for fewer than 90 days (days do not have to be consecutive) during the first assessment period or fewer than 90 days during the second assessment period. (See Section 3.1.6)

2.15.6 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 to receive credit on the measure.

- **Pain assessment** (see 1 below) using a standardized tool is documented as **positive** (see 2 below) and a **follow-up plan** (see 3 below) is documented

- Pain assessment documented as **positive** (see 2 below), a follow-up plan is not documented and the facility possesses documentation that the patient is **not eligible** (see 4 below).
- Pain assessment documented as **positive** (see 2 below) using a standardized tool, a follow-up plan is not documented and no reason is given.
- Pain assessment using a standardized tool is documented as negative and no follow-up plan required.
- No documentation of pain assessment and the facility possesses documentation the patient is **not eligible** (see 5 below) for a pain assessment using a standardized tool
- No documentation of pain assessment and no reason is given.

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

1. **Pain assessment** – Documentation of a clinical assessment for the presence or absence of pain using a standardized tool. A standardized tool is an assessment tool that has been appropriately normalized and validated for the population in which it is used. Facilities are not required to use a particular tool, but should choose one that is appropriate for their patient population. Example tools include, but are not limited to: Brief Pain Inventory (BPI); Faces Pain Scale (FPS); McGill Pain Questionnaire (MPQ); Multidimensional Pain Inventory (MPI); Neuropathic Pain Scale (NPS); Numeric Rating Scale (NRS); Oswestry Disability Index (ODI); Roland Morris Disability Questionnaire (RMDQ); Verbal Descriptor Scale (VDS); Verbal Numeric Rating Scale (VNRS); and Visual Analog Scale (VAS). **The name of the standardized assessment tool used must be documented in the medical record.**
2. **Positive** – Based on the scoring and interpretation of the specific standardized tool used, and through discussion during the patient visit, the provider should determine if the patient is deemed positive for pain. **Justification for or against a positive screening should be documented in the medical record.**
3. **Follow-Up Plan** – A documented outline of care for a positive pain assessment.
4. **Not eligible** – A patient may not be eligible for Follow-Up Plan, or it may not be appropriate for a patient to undergo treatment or therapy for pain because such treatments are medically contraindicated. **Justification for a patient's ineligibility for follow-up treatment should be documented in the patients' medical record.**
5. **Not eligible** – A patient is not eligible for Pain Assessment if one or more of the following reasons is documented in the patient's medical record:
 - Severe mental and/or physical incapacity where the person is unable to express himself/herself in a manner understood by others. For example, cases where pain cannot be accurately assessed through use of nationally recognized standardized pain assessment tools.
 - Patient is in an urgent or emergent situation where time is of the essence and to delay treatment would jeopardize the patient's health status.

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

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

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

Number of Eligible Periods

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

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.

2.15.8 Data Elements and Data Sources

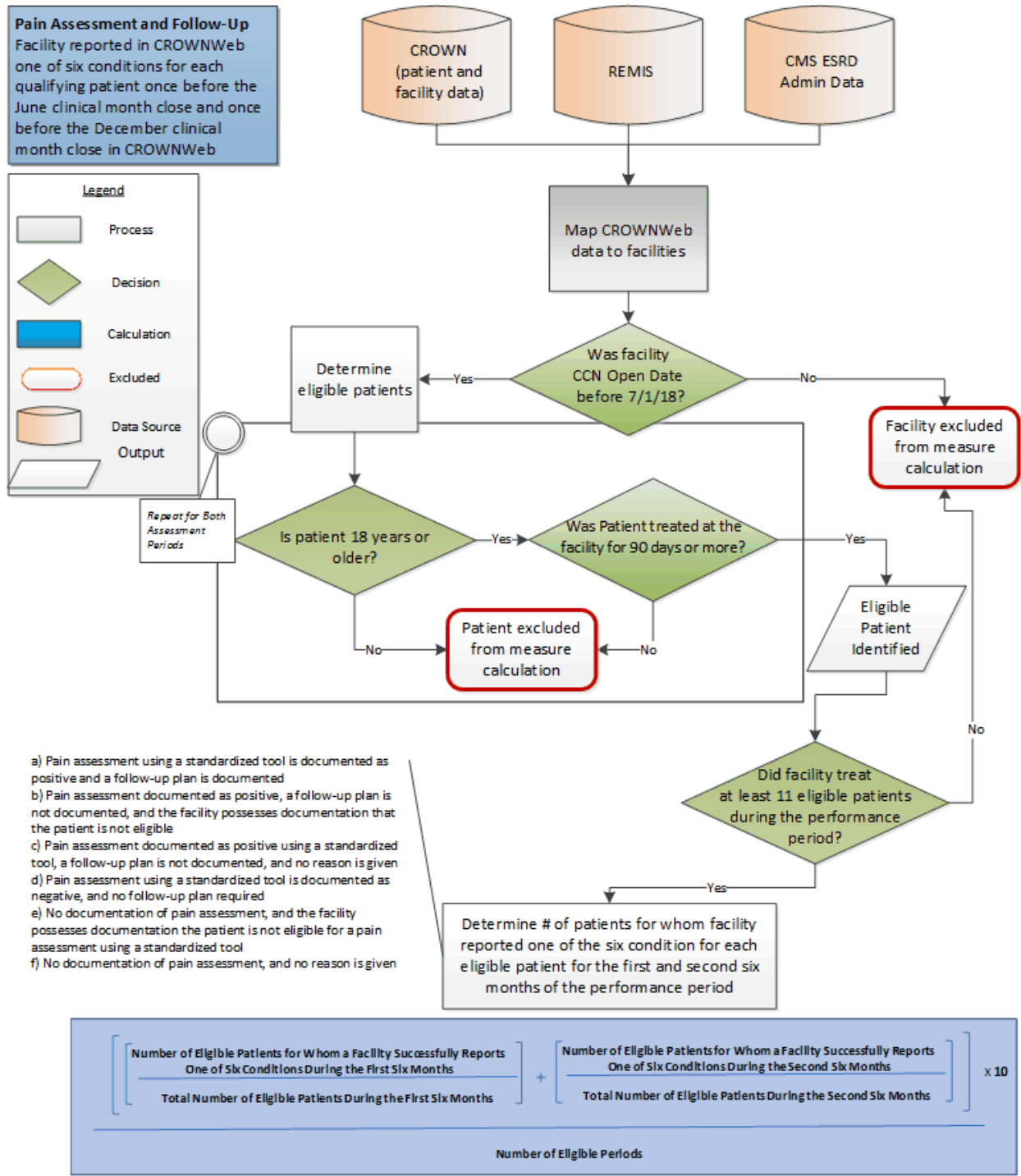
The data elements used for this measure are listed below. A complete description of the data elements can be found at the [ESRD section of QualityNet.org](https://www.qualitynet.org/ESRD).

CROWNWeb Data Elements:

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

2.15.9 Flowchart

Figure 12 provides a flowchart that represents the processes used to calculate the Pain Assessment and Follow-Up Reporting Measure Rate for both assessment periods.



Note: If a facility treats no eligible patients in one of the two six-month assessment 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.

Figure 12: Pain Assessment and Follow-Up Reporting Measure Flowchart (ESRD QIP Only)

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

2.16.1 Measure Name

Standardized Readmission Ratio for Dialysis Facilities (NQF #2496)

2.16.2 Measure Description

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

2.16.3 Measure Rationale

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

2.16.4 Measure Type

Outcome

2.16.5 Improvement Noted as Higher or Lower Rate

Better quality = Lower score

2.16.6 Numerator Statement

Number of unplanned 30-day hospital readmissions that are followed by an unplanned hospital readmission within 4-30 days of discharge

2.16.7 Facility - Level Exclusions

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

2.16.8 Denominator Statement

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

2.16.9 Denominator Exclusions

The measure excludes index hospital discharges from the denominator that:

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

2.16.10 Patient Exclusions

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

2.16.11 Mapping Patients to Facilities

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

2.16.12 Calculating Numerators/Outcome Definition

Index discharges are restricted to Medicare-covered hospitalizations for inpatient care at short-term acute care hospitals and critical access hospitals. Discharges from skilled nursing facilities (SNFs), long-term care hospitals (LTCHs), rehabilitation hospitals and prospective payment system (PPS)-exempt cancer hospitals - as well as those from separate dedicated units for hospice, rehabilitation and psychiatric care - are excluded. To be counted as an index discharge, the patient must be receiving dialysis treatment for ESRD at the time of discharge.

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

Potential readmissions are restricted to:

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

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

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

* Planned readmissions are determined using the algorithm developed by Yale New Haven Health Services Corporation/Center for Outcomes Research & Evaluation (YNHHSC/CORE) for the Centers for Medicare and Medicaid Services (CMS). 2013 Measure Updates and Specifications Report: Hospital-Wide All-Cause Unplanned Readmission Measure.
https://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228890434757&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3DDryRun_HWR_TechReport_081012%2CO.pdf&blobcol=urldata&blobtable=MungoBlobs

Risk Adjustment

The risk adjustment approach used in the model for the SRR was adapted from CMS' Standardized Hospitalization Ratio (SHR) and CMS' Hospital-Wide Readmission (HWR) measure. The regression model used to compute a facility's "expected" number of readmissions for the SRR measure contains many factors thought to be associated with readmission event rates. Specifically, the model adjusts for age, sex, diabetes, duration of end-stage renal disease (ESRD), body mass index (BMI) at start of dialysis, past-year comorbidities, length of the index

discharge hospital stay, and the presence of a high-risk diagnosis (defined below) at index discharge. In addition, the model adjusts for the effect of the discharging hospital (via random effects).

Below are details on the SRR's risk adjustors:

- **Sex:** Determined from CROWNWeb.
- **Age at Index Discharge:** Determined from the birth date provided in CROWNWeb, Medicare Claims, and the Medical Evidence Form (CMS-2728).
- **Years on ESRD:** Determined using the first service date from patient's Medical Evidence Form (CMS-2728), claims history (all claim types with evidence of dialysis), and CROWNWeb. DFC also uses the Scientific Registry of Transplant Recipients (SRTR) database.
- **Diabetes as cause of ESRD:** Primary cause of ESRD determined from patient's Medical Evidence Form (CMS-2728), REMIS, and CROWNWeb. When primary cause of ESRD is missing, we assume diabetes is not the cause of ESRD.
- **BMI at incidence:** Calculated based on the height and weight provided on patient's Medical Evidence Form (CMS-2728). When height and/or weight are missing, BMI is imputed for the patient based on the average BMI of all patients - specific to sex, race, diabetic status and age at ESRD incidence - with at least one eligible index discharge in the calendar year.
- **Days hospitalized during index hospitalization:** Each hospitalization's length is determined by taking the difference between the date of admission and the date of discharge available on the inpatient claim. For patients who are transferred between one acute care hospital and another, the measure considers these multiple contiguous hospitalizations as a single acute episode of care, and the length is calculated by taking the difference between the date of admission for the first hospitalization and the date of discharge from the last hospitalization included.
- **Past-year comorbidities (risk variables):** Determined by identifying unique ICD-9-CM and ICD-10 diagnosis codes for each patient reported on Medicare claims in the 365 days preceding (and inclusive of) the index discharge date. Five claim types are examined: inpatient, outpatient, skilled nursing facility, hospice, and home health claims. Diagnosis codes are grouped using CMS' Condition Categories (CCs; see https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/evaluation_risk_adj_model_2011.pdf). The HWR measure has determined that a subset of these diagnosis areas is appropriate to use in accounting for case mix; see Section 2.16.16 for a list of the CCs included in these areas.
- **Discharged with high-risk condition:** A *high-risk* diagnosis is any diagnosis area (grouped by the AHRQ Clinical Classification Software (CCS)) that was rare in the population but had a 30-day readmission rate of at least 40%. Note that high-risk diagnosis groups related to cancer or mental health are excluded from index discharges. The CCS areas identified as high-risk are:
 - **CCS 5:** HIV infection
 - **CCS 6:** Hepatitis
 - **CCS 56:** Cystic fibrosis

- CCS 57: Immunity disorders
- CCS 61: Sickle cell anemia
- CCS 190: Fetal distress and abnormal forces of labor
- CCS 151: Other liver diseases
- CCS 182: Hemorrhage during pregnancy; abruptio placenta; placenta previa
- CCS 186: Diabetes or abnormal glucose tolerance complicating pregnancy; childbirth; or the puerperium
- CCS 210: Systemic lupus erythematosus and connective tissue disorders
- CCS 243: Poisoning by nonmedicinal substances

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

2.16.13 Calculation of SRR

The expected number of readmissions in the denominator of the SRR is calculated based on a statistical model for the probability that a given hospital discharge will give rise to an unplanned readmission within the next 4–30 days. This model is technically termed a hierarchical logistic model and takes into account the patient characteristics or covariates discussed above. In addition, our model includes a random effect term for hospital of discharge and so makes an adjustment in patient outcomes for the potential effect of the care received at the hospital. This adjustment acknowledges the fact that there is a shared responsibility between the dialysis facility and the discharging hospital for patient care. At the same time, the model retains an incentive for facilities and hospitals to coordinate care in order to improve outcomes with respect to readmissions. Facility effects are also estimated in the model, and the number of readmissions in each facility is compared to the number that would be expected at a facility under the national norm (i.e. with median facility effect) given the patient characteristics. There are a number of technical details associated with this computation that are not dealt with in this summary. The interested reader is referred to He et al. (2013).

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

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

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

The equations used in the measure calculation are as follows:

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

(1)

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

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

1. We use the estimates from this model to calculate the i^{th} facility's SRR:

(2)

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

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

More specifically,

(3)

$$\tilde{p}_{ijk} = \frac{\exp(\widehat{\gamma}_M + \widehat{\alpha}_j + \widehat{\beta}^T Z_{ijk})}{1 + \exp(\widehat{\gamma}_M + \widehat{\alpha}_j + \widehat{\beta}^T Z_{ijk})}$$

estimates the probability that a discharge from hospital j to facility i of a patient with characteristics Z_{ijk} would result in an unplanned readmission; this probability is being estimated assuming that the facility's effect corresponds to the median of national facility

effects, denoted by $\hat{\gamma}M$. Here, $\hat{\alpha}_i$ 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.

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

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

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

2.16.15 Flagging Rules for Dialysis Facility Compare (DFC only)

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

2.16.16 Data Elements and Data Sources

Data are derived from an extensive national ESRD Patient database based on data from the CMS REMIS and CROWNWeb systems, Medicare dialysis and hospital payment records, the Organ

Procurement and Transplant Network (OPTN) (DFC only), the CMS Nursing Home Minimum Dataset, and the Social Security Death Master File (DFC only) (CMS-2744), the CMS Medical Evidence Form (CMS-2728), and the Death Notification Form (CMS-2746) come from CROWNWeb (Table 3). The database is comprehensive for Medicare-covered ESRD patients. Information on hospitalizations is obtained from Medicare Inpatient Claims Standard Analysis Files (SAFs) and past-year comorbidity is obtained from multiple types (inpatient, outpatient institutional, physician/supplier, home health, hospice, skilled nursing facility claims) of Medicare Claims SAFs.

The data are comprehensive for Medicare patients. Non-Medicare patients are included in all sources except for the Medicare claims, which do include non-traditional Medicare such as the Part A shadow records for Medicare Advantage patients. CROWNWeb provides tracking by dialysis provider and treatment modality for non-Medicare patients. Information on hospitalizations is obtained from Part A Medicare Inpatient Claims, and information on past-year comorbidities is obtained from multiple Part A claim types (inpatient, home health, hospice, skilled nursing facility claims) and Part B outpatient institutional Medicare Claims.

Two grouping systems are used in the risk adjustment model to identify comorbidities and high risk conditions. For past year comorbidity adjustment, the measure groups diagnosis codes by diagnosis area using HHS' Hierarchical Condition Categories (CCs); (Table 4) see <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/HealthCareFinancingReview/downloads/04summerpg119.pdf>. To identify high-risk conditions, the measure groups diagnosis codes using the Agency for Healthcare Research and Quality (AHRQ) Clinical Classification Software (CCs); see <https://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccs.jsp>.

Variable	Primary Data Source
Facility CCN	Multiple data sources* ¹
Date of Birth	Multiple data sources* ¹
Sex	Multiple data sources* ¹
Date of First ESRD	Multiple data sources* ¹
Date of Death	Multiple data sources* ¹
Dates of Transplant	Multiple data sources* ¹
BMI at incidence	Medical Evidence Form (CMS-2728)
Diabetes - Primary cause of ESRD	Medical Evidence Form (CMS-2728) REMIS CROWNWeb
High-risk diagnoses	Medicare Claims* ²
Planned readmissions	Medicare Claims* ²

Final

Variable	Primary Data Source
Hospital admissions	Inpatient Medicare claims
Discharge Status	Inpatient Medicare claims

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

*1. This may include information from the: Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), Medicare Claims, the Renal Management Information System (REMIS), Medicare Enrollment Database (EDB), Medical Evidence Form (CMS 2728), Medicare Claims, and Organ Procurement and Transplantation Network Database (OPTN) (DFC only).

Unique patients are identified by using a combination of SSN, first name, surname, sex, patient Health Insurance Claim Number and birth date. DFC’s patient-matching process is performed to ensure that minor typos and misspellings do not cause a patient record to fall out of their history. The matching process is able to successfully match 99.5% of patients. The remaining patients have incomplete or incorrect data that does not allow them to be matched.

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

Description	CC	Detailed Description (if applicable)
Severe infection	1, 3–5	
	1	HIV/AIDS
	3	Central nervous system infection
	4	Tuberculosis
	5	Opportunistic infections
Other infectious disease & pneumonias	6, 111–113	
	6	Other infectious disease
	111	Aspiration and specified bacterial pneumonias
	112	Pneumococcal pneumonia, emphysema, lung abscess
	113	Viral and unspecified pneumonia, pleurisy
Metastatic cancer/acute leukemia	7	
Severe cancer	8–9	
	8	Lung, upper digestive tract, and other severe cancers
	9	Other major cancers
Other major cancers	10–12	
	10	Breast, prostate, colorectal and other cancers and tumors

Final

Description	CC	Detailed Description (if applicable)
	11	Other respiratory and heart neoplasms
	12	Other digestive and urinary neoplasms
End-stage liver disease	25–26	
	25	End-Stage Liver Disease
	26	Cirrhosis of Liver
Other hematological disorders	44	
Drug and alcohol disorders	51–52	
	51	Drug/alcohol psychosis
	52	Drug/alcohol dependence
Psychiatric comorbidity	54–56, 58, 60	
	54	Schizophrenia
	55	Major depressive, bipolar, and paranoid disorders
	56	Reactive and unspecified psychosis
	58	Depression
	60	Other psychiatric disorders
Hemiplegia, paraplegia, paralysis	67–69, 100–101	
	67	Quadriplegia, other extensive paralysis
	68	Paraplegia
	69	Spinal cord disorders/injuries
	100	Hemiplegia/hemiparesis
	101	Diplegia (upper), monoplegia, and other paralytic syndromes
Amputation	177–178	
	177	Amputation status, lower limb/amputation
	178	Amputation status, upper limb
Seizure disorders and convulsions	74	
Chronic obstructive pulmonary disease	108	
Fibrosis of lung or other chronic lung disorders	109	

Description	CC	Detailed Description (if applicable)
Ulcers	148–149	
	148	Decubitus ulcer
	149	Decubitus ulcer or chronic skin ulcer
Septicemia/shock	2	
Cardio-respiratory failure or cardio-respiratory shock	79	
Pancreatic disease	32	
Rheumatoid arthritis and inflammatory connective tissue disease	38	
Respirator dependence/tracheostomy status	77	
Major organ transplant status	174	
Coagulation defects and other specified hematological disorders	46	
Hip fracture/dislocation	158	

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

* **Note.** For the SRR based on 2015 claims data that include ICD-10 codes, we use CMS' 2016 ICD9-to-ICD10 General Equivalence Mapping (GEM) to associate CCs with ICD10 codes. A list of codes is available here: <https://dialysisdata.org/sites/default/files/content/Methodology/CodesForDFC.pdf>.

This grouping of CCs is based on the HWR measure; we removed or modified the following risk variable areas:

Removed

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

Modified

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

2.16.17 Flowchart

Figure 13 provides a flowchart that represents the processes used to calculate the Standardized Readmissions Ratio (SRR).

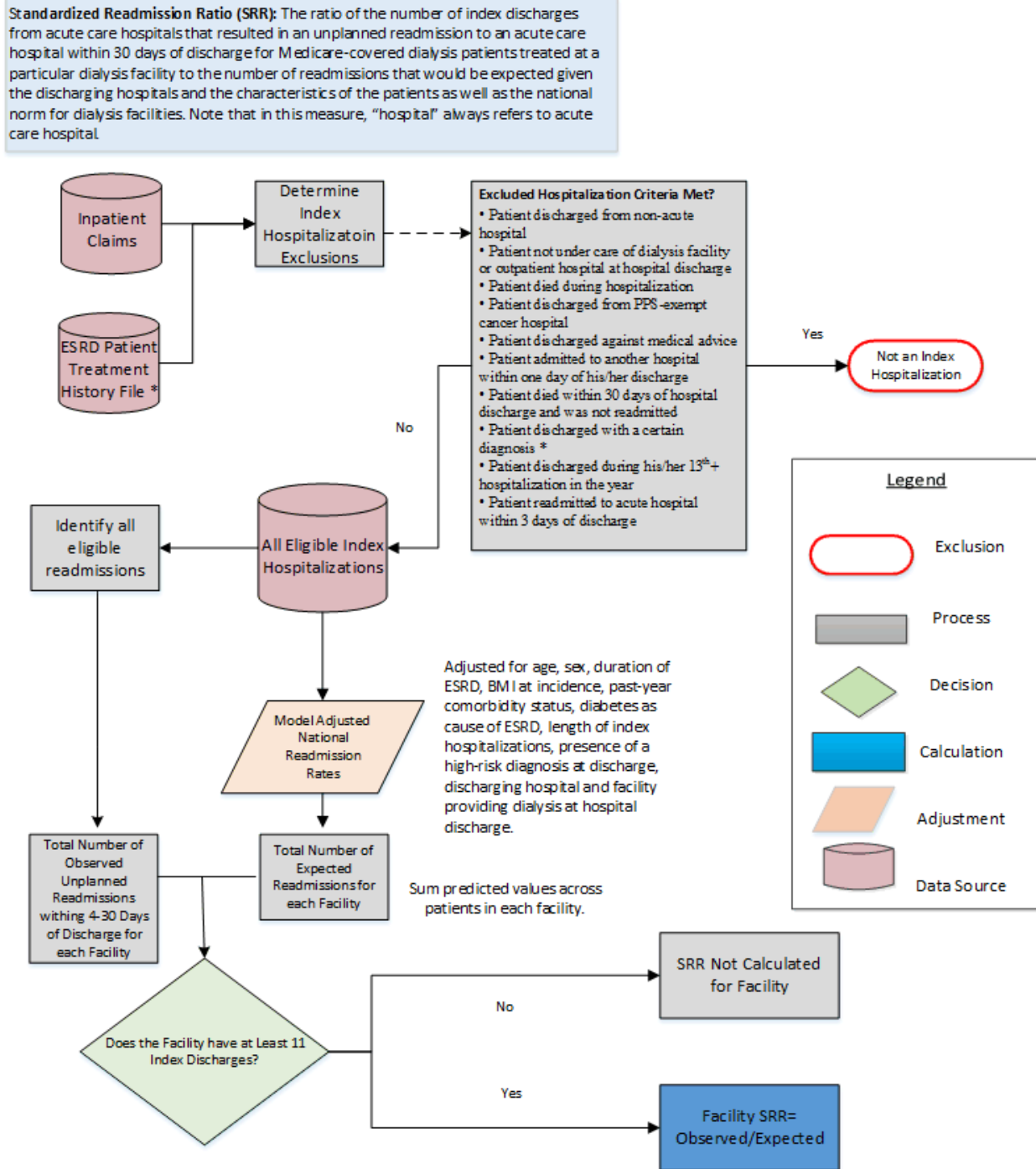


Figure 13: Standardized Readmissions Ratio (SRR) Flowchart (ESRD QIP and DFC)

From Figure 13:

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

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

2.17.1 Measure Name

Standardized Transfusion Ratio for Dialysis Facilities

2.17.2 Measure Description

The risk adjusted facility level transfusion ratio “STrR” is specified for all adult Medicare dialysis patients. It is a ratio of the number of eligible red blood cell transfusion events observed in patients dialyzing at a facility, to the number of eligible transfusion events that would be expected under a national norm, after accounting for the patient characteristics within each facility. Eligible transfusions are those that do not have any claims pertaining to the comorbidities identified for exclusion, in the one year look back period prior to each observation window.

This measure is calculated as a ratio, but can also be expressed as a rate.

2.17.3 Measure Rationale

Several changes in the ESRD system are likely to impact anemia management. These include identification of safety concerns associated with aggressive erythropoiesis-stimulating agent (ESA) use, expansion of the ESRD Prospective Payment System bundled payment, and the development of the ESRD Quality Incentive Program. There are concerns that these changes could result in underutilization of ESAs, with lower achieved hemoglobin values that may increase the frequency of red blood cell transfusion in the US chronic dialysis population.

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

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

2.17.4 Measure Type

Outcome

2.17.5 Improvement Noted as Higher or Lower Rate

Lower rates are better

2.17.6 Numerator Statement

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

2.17.7 Facility Exclusions

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

2.17.8 Denominator Statement

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

2.17.9 Denominator Exclusions

For all patients, time at risk begins at the start of the facility treatment period and continues until the earliest occurrence of the following: three days prior to a transplant; date of death; end of facility treatment; or December 31 of the year. This convention is used with other dialysis facility measures developed and previously endorsed by NQF (like SHR NQF #1463 <http://www.qualityforum.org/QPS/1463>). Patient time at risk is excluded for:

- Patients less than 18 years old (see Section 3.1.4)
- Patients on ESRD treatment for fewer than 90 days
- Patients treated at the facility for fewer than 60 days
- Patients who receive a transplant (excluded 3 days prior)
- Patients who have not been treated by any facility for a year or longer
- Patients with a Medicare claim (Part A inpatient, home health, hospice, and skilled and nursing facility claims; Part B outpatient and physician supplier) for one of the following conditions in 1-year look back period:
 - hemolytic and aplastic anemia
 - solid organ cancer (breast, prostate, lung, digestive tract and others)
 - lymphoma

- carcinoma in situ
- coagulation disorders
- multiple myeloma
- myelodysplastic syndrome and myelofibrosis
- leukemia
- head and neck cancer
- other cancers (connective tissue, skin, and others)
- metastatic cancer
- sickle cell anemia

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

Since these comorbidities are associated with higher risk of transfusion and require different anemia management practices that this measure is not intended to address, every patient's risk window is modified to have at least 1 year free of claims that contain diagnoses on the exclusion list. We assessed the predictive power of comorbidities on future transfusions, as a function of the time interval between development of the comorbidity and the occurrence of the transfusion by performing multivariate logistic regression with transfusion count as the dependent variable. Results showed that 1-year look back period for each of the above mentioned comorbidities was the most predictive of one or more RBC transfusions.

Figure 14 describes the inclusion and exclusion period of a hypothetical patient.

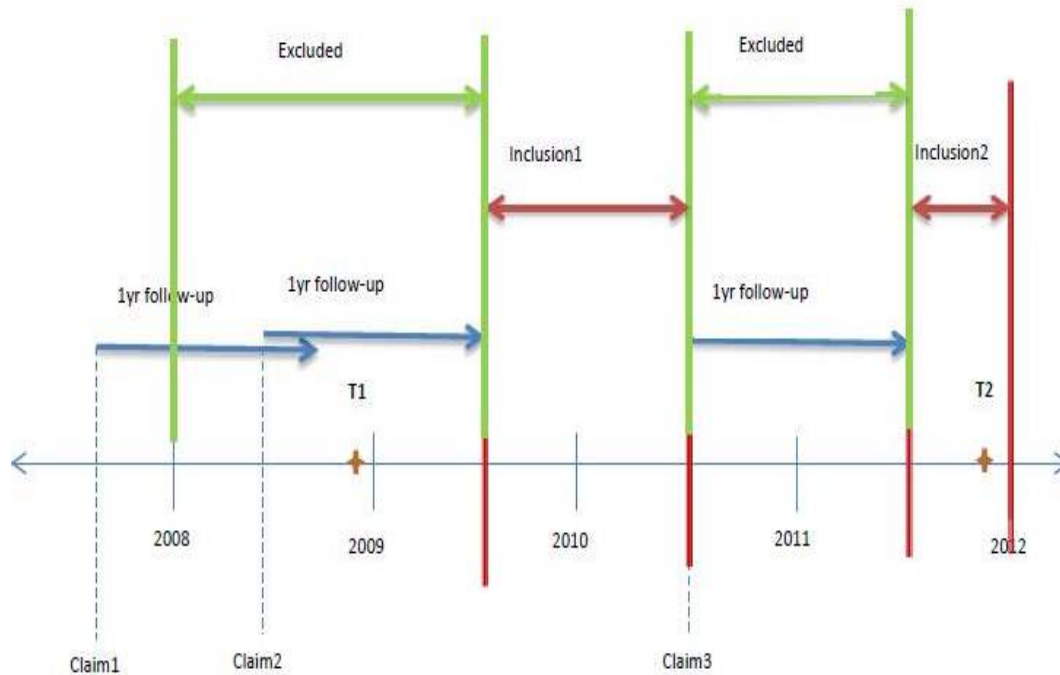


Figure 14: Algorithm for Exclusion of Periods of Time Within 1 Year of an Exclusion Comorbidity

In the Figure 14, a hypothetical patient has patient years at risk at a facility from 1/1/2008 to 12/31/2011. Review of Medicare claims identified presence of one or more exclusion comorbidities in 2007 (Claim1), 2008 (Claim2) and 2010 (Claim3). Each claim is followed by a one year exclusion period. The revised inclusion periods are defined as risk windows with at least 1 year of claim-free period (Inclusion1 and Inclusion2 in figure). The patient has two transfusion events, marked as T1 and T2 in late 2008 and late 2011 respectively. However, since T1 falls in the exclusion period, it will not be counted towards the facility's transfusion count as presence of exclusion comorbidity claims within a year might have increased the risk of transfusion unrelated to dialysis facility anemia management practice. However, T2, which occurs in late 2011 and in Inclusion2 period, will be counted since there is at least a year gap between this transfusion event and the last claim observed.

2.17.10 Mapping Patients to Facilities

Starting with day 91 after onset of ESRD, a patient is attributed to a facility according to the following rules. A patient is attributed to a facility once the patient has been treated there for 60 days. When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 60 days and then is attributed to the destination facility. In particular, a patient is attributed to their current facility on day 90 of ESRD if that facility had treated him or her for at least 60 days. If on day 90, the facility had treated a patient for fewer than 60 days, we wait until the patient reaches day 60 of treatment at that facility before attributing the patient to that facility. When a patient is not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we do not attribute that patient to any

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

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

2.17.11 Calculating Numerators

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

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

Transfusion events are not common in outpatient settings, but similar rules apply. One or more transfusion-related HCPCS codes with at least one transfusion-related revenue center codes, or one or more transfusion-related value codes listed on an outpatient claim are counted as a single transfusion event regardless of the number of units of blood recorded. In other words, 3 units of blood would be counted as a single transfusion event.

Because we identify transfusions only if they appear in Medicare inpatient and outpatient claims, we only want to include patients during time periods in which all of the patient’s transfusions are included in Medicare billing records. To achieve this goal, we require that patients either reach a certain level of Medicare-paid dialysis bills or have Medicare-paid inpatient claims during the period. Specifically, months within a given dialysis patient-period are used for STrR calculation when they meet the criterion of being within two months after a month with either: (a) \$900+ of Medicare-paid dialysis claims OR (b) at least one Medicare-paid inpatient claim. The intention of this criterion is to assure completeness of information on transfusions for all patients included in the analysis.

The detailed procedures to determine unique transfusion events at the claim level are presented in a flow chart later in this section.

* Note: For the ESRD QIP, one "transfusion event" is counted per inpatient claim if one or more transfusion-related revenue center, procedure or value codes are present. Revenue center codes only can be used to identify a transfusion (without an accompanying ICD-9 or ICD-10 code).

2.17.12 Days at Risk for Medicare Dialysis Patients

After patient treatment histories are defined as described in the Denominator Exclusions Section, periods of follow-up in time since ESRD onset are created for each patient. In order to adjust for duration of ESRD appropriately, we define 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.

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.

2.17.13 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 as cause of ESRD, duration of ESRD, nursing home status, BMI at incidence, comorbidities at incidence, and calendar year. This model allows the baseline transfusion rates to vary between strata (facilities), but assumes that the regression coefficients are the same across all strata; this approach is robust to possible differences between facilities in the patient mix being treated.

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

- **Age:** Determine each patient's age for the birth date provided in the SIMS and REMIS databases, CROWNWeb, Medicare Claims, and the Medical Evidence Form (CMS-2728). Patients are grouped into the following categories: 18-24 years old, 25-44 years old, 45-59 years old, 60-74 years old, or 75+ years old.
- **Diabetes as cause of ESRD:** Determine each patient's primary cause of ESRD from his/her CMS-2728, CROWNWeb and REMIS.
- **Duration of ESRD:** Determine each patient's length of time since start of ESRD treatment using patient's CMS-2728, claims history (all claim types), the CROWNWeb patient events file, and OPTN (DFC only). Duration is categorized as 90 days- < 6 months, 6 months- < 1 year, 1- < 2 years, 2- < 3 years, 3- < 5 years, or 5+ years as of the period start date.
- **Nursing home status:** Using the Nursing Home Minimum Dataset, determine if a patient was in a nursing home the previous year.
- **BMI at incidence:** Calculate each patient's BMI as the height and weight provided on his/her CMS 2728. BMI is included as a log-linear term.
- **Comorbidities at incidence** are determined using a selection of comorbidities reported on the CMS-2728 namely, alcohol dependence, atherosclerotic heart disease, cerebrovascular disease, chronic obstructive pulmonary disease, congestive heart failure, diabetes (includes currently on insulin, on oral medications, without medications, and diabetic retinopathy), drug dependence, inability to ambulate, inability to transfer, malignant neoplasm, cancer, other cardiac disease, peripheral

vascular disease, and tobacco use (current smoker). Each comorbidity is included as a separate covariate in the model.

- Calendar year

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

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

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

2.17.14 Calculating Expected Number of Transfusions

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

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

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

where \mathbf{X}_{ik} is the vector of covariates for the (i,k) th patient and $\boldsymbol{\beta}$ is the vector of regression coefficients. The baseline rate function $r_{0k}(t)$ is assumed specific to the k^{th} facility, which is assumed to be a step function with break points at 6 months, 1 year, 2 years, 3 years and 5 years since the onset of dialysis. This model allows the baseline transfusion rates to vary between strata (facilities), but assumes that the regression coefficients are the same across all strata; this approach is robust to possible differences between facilities in the patient mix being treated. The stratification on facilities is important in this phase to avoid bias due to possible confounding between covariates and facility effects.

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

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

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

where $R_{ik} = \exp(\beta' X_{ik})$ is the estimated relative risk for patient i in facility k estimated from the stage 1. In our computation, we assume the baseline to be a step function with 6 unknown parameters, $\alpha_1, \dots, \alpha_6$, to estimate. These estimates are used to compute the expected number of transfusions given a patient's characteristics.

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

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

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

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

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

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

2.17.15 Calculation of STrR P-values and Confidence Intervals (DFC Only)

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

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

where \mathbf{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 \mathbf{n}_{ik} who are treated in the k th facility. The natural log of the STrR for the k th facility is then given by the corresponding estimate of θ_k . The standard error of θ_k is obtained from the robust estimate of variance arising from the overdispersed Poisson model.

Second, we obtain a z-score for each facility by dividing the natural log of its STrR by the standard error from the general linear model described above. These z-scores are then grouped into quartiles based on the number of patient years at risk for Medicare patients in each facility. Finally, using robust estimates of location and scale based on the normal curve fitted to the

center of the z-scores for the STrR, we derive the mean and variance of a normal empirical null distribution for each quartile. This empirical null distribution is then used to calculate the p-value for a facility’s STrR.

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

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

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

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

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

2.17.16 Data Elements and Data Sources

Table 5 shows the CMS data sources^{*1} are used as the data sources for establishing the denominator. Medicare claims is the data source for establishing the numerator. CMS Medical Evidence form 2728 is data sources for the risk adjustment factors. Medicare claims are used for the exclusion criteria.

Variable	Primary Data Source
Facility CCN	CMS data sources ^{*1}
Date of Birth	CMS data sources ^{*1}
Date of First ESRD	Medical Evidence Form (CMS-2728) CROWNWeb Patient Event OPTN Data (DFC only) Medicare Claims ^{*2}
BMI at incidence	Medical Evidence Form (CMS-2728)
Nursing home status (in the previous calendar year)	CMS Minimum Data Set
Diabetes - Primary cause of ESRD	Medical Evidence Form (CMS-2728) REMIS CROWNWeb
Incident Comorbidities as the risk adjustment factors ^{*3}	Medical Evidence Form (CMS-2728)
Transfusion events ^{*4}	Medicare Claims ^{*2}

Variable	Primary Data Source
Prevalent comorbidities used for exclusion ^{*5}	Medicare Claims ^{*2}

Table 5: Data Elements and Sources for the Standardized Transfusion Ratio (STrR) Clinical Measure (ESRD QIP and DFC)

- *1. This may include information from: Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), Medicare Claims, the Renal Management Information System (REMIS), Medicare Enrollment Database (EDB), Medical Evidence Form (CMS 2728), Medicare Claims, and Organ Procurement and Transplantation Network Database (OPTN) (DFC only).
- For DFC, unique patients are identified by using a combination of SSN, first name, surname, sex, Patient Health Insurance Claim Number and birth date. The DFC patient-matching process is performed to ensure that minor typos and misspellings do not cause a patient record to fall out of their history. The matching process is able to successfully match 99.5% of patients. The remaining patients have incomplete or incorrect data that does not allow them to be matched (see Section 3.2).
- *2. Medicare claims include Part A claims such as inpatient admissions and Part B claims such as outpatient claims (including dialysis claims) and physician services. Claims from providers, such as laboratories, that report diagnosis codes when testing for the presence of a condition are excluded.
- *3. Incident Comorbidities as the risk adjustment factors: Comorbidities at incidence are determined using a selection of comorbidities reported on the Medical Evidence Form (CMS 2728) namely, alcohol dependence, atherosclerotic heart disease, cerebrovascular disease, chronic obstructive pulmonary disease, congestive heart failure, diabetes (includes currently on insulin, on oral medications, without medications, and diabetic retinopathy), drug dependence, inability to ambulate, inability to transfer, malignant neoplasm, cancer, other cardiac disease, peripheral vascular disease, and tobacco use (current smoker). Each comorbidity is included as a separate covariate in the model.
- *4. Details in Determining Transfusion Events Flow Chart (Figure 16)
- *5. Prevalent comorbidities used for exclusion: Patient time at risk is excluded if there is a Medicare claim (Part A inpatient, home health, hospice, and skilled and nursing facility claims; Part B outpatient and physician supplier) for hemolytic and aplastic anemia, solid organ cancer (breast, prostate, lung, digestive tract and others), lymphoma, carcinoma in situ, coagulation disorders, multiple myeloma, myelodysplastic syndrome and myelofibrosis, leukemia, head and neck cancer, other cancers (connective tissue, skin, and others), metastatic cancer, or sickle cell anemia within one year of their patient at risk time.

2.17.17 Flowchart

Figure 15 provides a flowchart that represents the processes used to calculate the Standardized Transfusion Ratio (STrR).

Standardized Transfusion Ratio: The risk adjusted facility level transfusion ratio “STrR” is specified for all adult Medicare dialysis patients. It is a ratio of the number of eligible red blood cell transfusion events observed in patients dialyzing at a facility, to the number of eligible transfusion events that would be expected under a national norm, after accounting for the patient characteristics within each facility. Eligible transfusions are those that do not have any claims pertaining to the comorbidities identified for exclusion, in the one year look back period prior to each observation window.

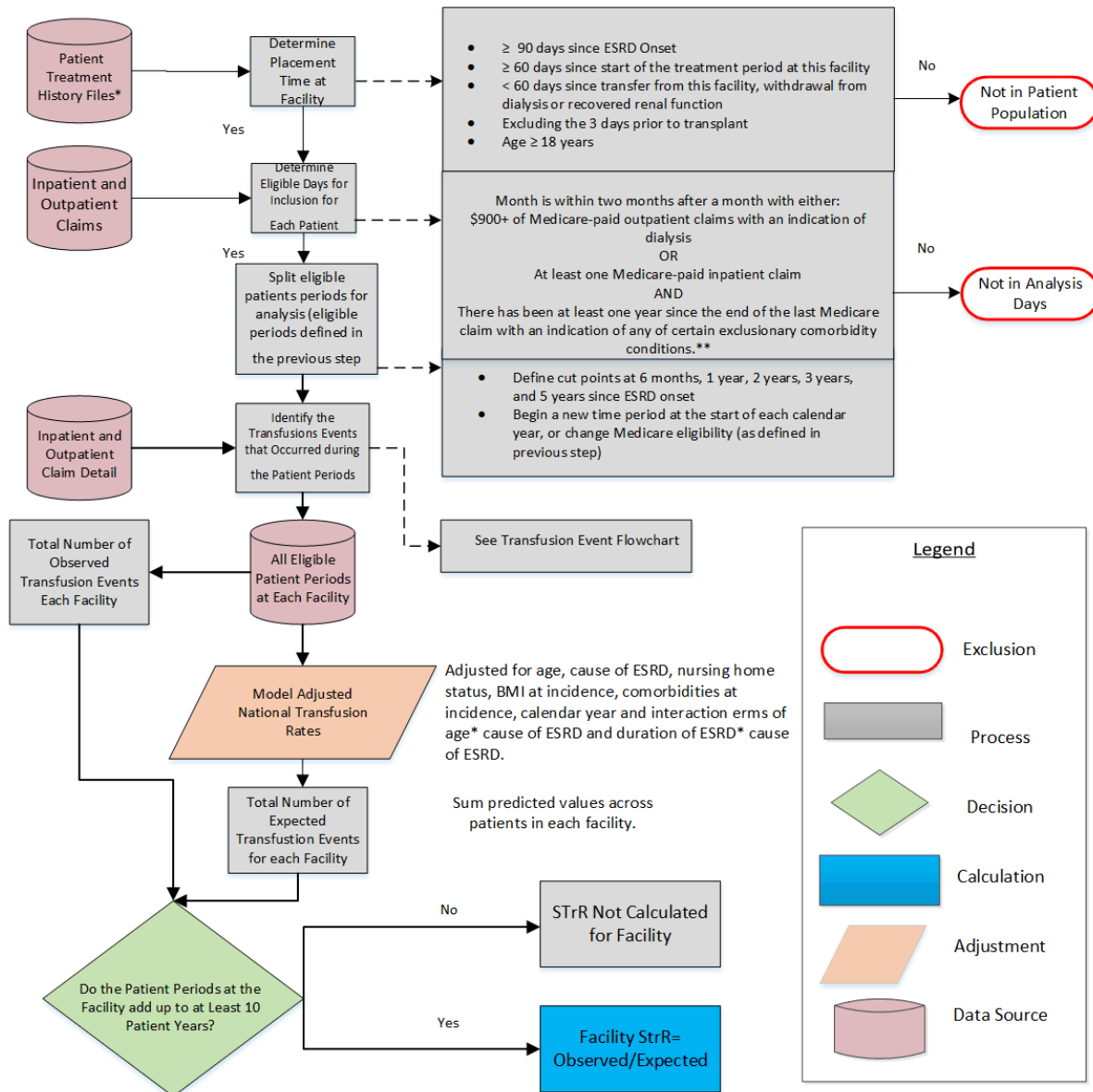


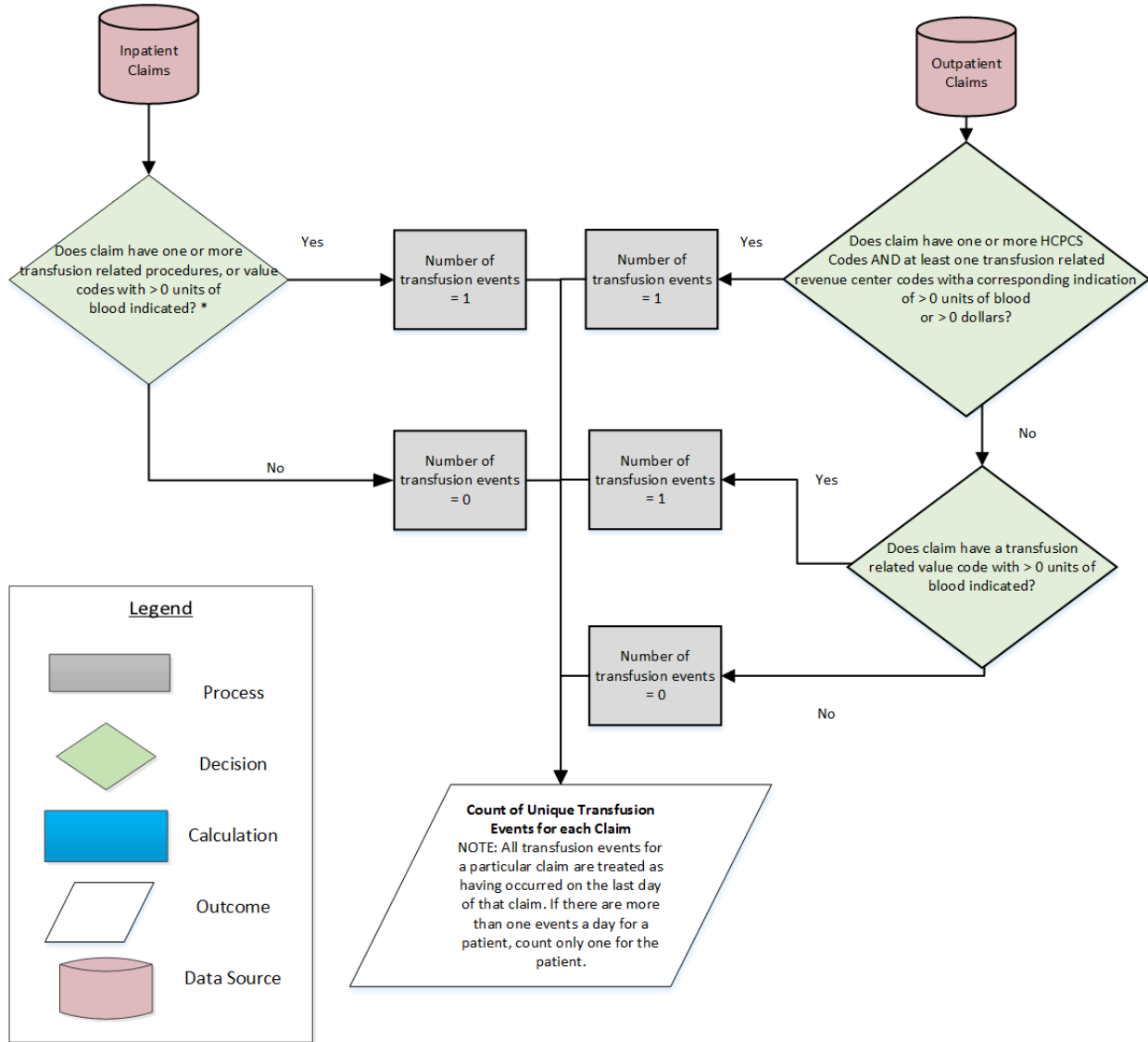
Figure 15: Standardized Transfusion Ratio Measure Flowchart (ESRD QIP and DFC)

From Figure 15:

- * = Multiple data sources include CMS Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment 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 Dialysis Facility Compare (DFC) and the Social Security Death Master File. Also see Section 3.1.7
- ** = Exclusionary comorbidity conditions: hemolytic and aplastic anemia, solid organ cancer (breast, prostate, lung, digestive tract and others), lymphoma, carcinoma in situ, coagulation disorders, multiple myeloma, myelodysplastic syndrome and myelofibrosis, leukemia, head and neck cancer, other cancers (connective tissue, skin, and others), metastatic cancer, sickle cell anemia.

2.17.18 Determining Transfusion Events Flow Chart

Figure 16 shows the method of determining transfusion events.



* For the ESRD QIP, one "transfusion event" is counted per inpatient claim if one or more transfusion-related revenue center, procedure or value codes are present. Revenue center codes only can be used to identify a transfusion (without an accompanying ICD-9 or ICD-10 code).

Figure 16: Method of Determining Transfusion Events Flowchart

Table 6 below gives the description of Relevant Revenue Center Codes, Procedure Codes, Value Codes, and HCPCS Codes.

ICD Version	Code	Description	Field
	0380	Blood - General Classification	Revenue Center Codes
	0381	Blood - Packed Red Cells	Revenue Center Codes
	0382	Blood - Whole Blood	Revenue Center Codes
	0389	Blood - Other Blood	Revenue Center Codes
	0390	Blood Storage and Processing - General Classification	Revenue Center Codes
	0391	Blood Storage and Processing - Administration	Revenue Center Codes
	0392	Blood Storage and Processing - Blood Processing and Storage	Revenue Center Codes
	0399	Blood Storage and Processing - Other Storage & Processing	Revenue Center Codes
9	9903	Other Transfusion Of Whole Blood	Procedure Codes
9	9904	Transfusion Of Packed Cells	Procedure Codes
10	30230H1	Transfusion of Nonautologous Whole Blood into Peripheral Vein, Open Approach	Procedure Codes
10	30233H1	Transfusion of Nonautologous Whole Blood into Peripheral Vein, Percutaneous Approach	Procedure Codes
10	30233P1	Transfusion of Nonautologous Frozen Red Blood Cells into Peripheral Vein	Procedure Codes
10	30240H1	Transfusion of Nonautologous Whole Blood into Central Vein, Open Approach	Procedure Codes
10	30243H1	Transfusion of Nonautologous Whole Blood into Central Vein, Percutaneous Approach	Procedure Codes
10	30250H1	Transfusion of Nonautologous Whole Blood into Peripheral Artery, Open Approach	Procedure Codes
10	30253H1	Transfusion of Nonautologous Whole Blood into Peripheral Artery, Percutaneous Approach	Procedure Codes

Final

ICD Version	Code	Description	Field
10	30260H1	Transfusion of Nonautologous Whole Blood into Central Artery, Open Approach	Procedure Codes
10	30263H1	Transfusion of Nonautologous Whole Blood into Central Artery, Percutaneous Approach	Procedure Codes
10	30230N1	Transfusion of Nonautologous Red Blood Cells into Peripheral Vein, Open Approach	Procedure Codes
10	30230P1	Transfusion of Nonautologous Frozen Red Cells into Peripheral Vein, Open Approach	Procedure Codes
10	30233N1	Transfusion of Nonautologous Red Blood Cells into Peripheral Vein, Percutaneous Approach	Procedure Codes
10	30240N1	Transfusion of Nonautologous Red Blood Cells into Central Vein, Open Approach	Procedure Codes
10	30240P1	Transfusion of Nonautologous Frozen Red Cells into Central Vein, Open Approach	Procedure Codes
10	30243N1	Transfusion of Nonautologous Red Blood Cells into Central Vein, Percutaneous Approach	Procedure Codes
10	30243P1	Transfusion of Nonautologous Frozen Red Cells into Central Vein, Percutaneous Approach	Procedure Codes
10	30250N1	Transfusion of Nonautologous Red Blood Cells into Peripheral Artery, Open Approach	Procedure Codes
10	30250P1	Transfusion of Nonautologous Frozen Red Cells into Peripheral Artery, Open Approach	Procedure Codes
10	30253N1	Transfusion of Nonautologous Red Blood Cells into Peripheral Artery, Percutaneous Approach	Procedure Codes
10	30253P1	Transfusion of Nonautologous Frozen Red Cells into Peripheral Artery, Percutaneous Approach	Procedure Codes
10	30260N1	Transfusion of Nonautologous Red Blood Cells into Central Artery, Open Approach	Procedure Codes
10	30260P1	Transfusion of Nonautologous Frozen Red Cells into Central Artery, Open Approach	Procedure Codes
10	30263N1	Transfusion of Nonautologous Red Blood Cells into Central Artery, Percutaneous Approach	Procedure Codes

ICD Version	Code	Description	Field
10	30263P1	Transfusion of Nonautologous Frozen Red Cells into Central Artery, Percutaneous Approach	Procedure Codes
	37	Pints of blood furnished	Value Code
	P9010	Whole blood for transfusion	HCPCS Codes
	P9011	Blood split unit	HCPCS Codes
	P9016	RBC leukocytes reduced	HCPCS Codes
	P9021	Red blood cells unit	HCPCS Codes
	P9022	Washed red blood cells unit	HCPCS Codes
	P9038	RBC irradiated	HCPCS Codes
	P9039	RBC deglycerolized	HCPCS Codes
	P9040	RBC leukoreduced irradiated	HCPCS Codes
	P9051	Blood, l/r, cmv-neg	HCPCS Codes
	P9054	Blood, l/r, froz/degly/wash	HCPCS Codes
	P9056	Blood, l/r, irradiated	HCPCS Codes
	P9057	Red blood cells, frozen/deglycerolized/washed, leukocytes reduced, irradiated, each unit	HCPCS Codes
	P9058	RBC, l/r, cmv-neg, irrad	HCPCS Codes
	36430	Current Procedural Terminology (CPT) code (transfusion, blood or blood components)	HCPCS Codes

Table 6: Description of Relevant Revenue Center Codes, Procedure Codes, Value Codes, and HCPCS Codes

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2.18 Standardized Hospitalization Ratio (SHR) Measure (ESRD QIP and DFC)

2.18.1 Measure Name

Standardized Hospitalization Ratio for Dialysis Facilities

2.18.2 Measure Description

Risk-adjusted standardized hospitalization ratio of the number of observed hospitalizations to the number of expected hospitalizations for dialysis facility patients. This measure is calculated as a ratio but can also be expressed as a rate. (NQF# 1463)

2.18.3 Measure Rationale

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

2.18.4 Measure Type

Outcome

2.18.5 Improvement Noted as Higher or Lower Rate

Lower numbers are better.

2.18.6 Numerator Statement

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

2.18.7 Facility Exclusions

The standardized hospitalization ratio is only calculated for facilities with at least 5 patient years at risk. (See Section 2.18.10.1)

2.18.8 Denominator Statement

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

2.18.9 Denominator Exclusions

Patient Time at Risk Exclusions:

- First 90 days of ESRD treatment

- Time during which patients were treated at the facility for fewer than 60 days
- Time during which patient has a kidney transplant (exclusion begins 3 days prior to the date of transplant)
- Time at risk once a patient has not been treated by any facility for a year or longer.
- Months which are not within or in the two months following a month in which the patient has \$900 of Medicare-paid dialysis claims or at least one Medicare inpatient claim.

2.18.10 Mapping Patients to Facilities

SIMS/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 additional sources including the CMS Medical Evidence Form (CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN) (DFC only), the Death Notification Form (CMS-2746) and the Social Security Death Master File (DFC only). Also see Section 3.1.7. Additionally, for DFC, a new treatment history record is created for each patient each time he/she changes facility or treatment modality. Each record represents a time period associated with a specific modality and dialysis facility.

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

We only include a patient's follow-up after that patient has received chronic dialysis 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 any time a patient begins therapy at a new facility whether the patient transferred from another facility, started ESRD for the first time, or returned to dialysis after a transplant. That is, hospitalizations during the first 60 days of dialysis at a facility do not affect the SHR of that facility.

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

- A patient is attributed to a facility once the patient has been treated there for the past 60 days. When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 60 days and then is attributed to the destination facility.
- In particular, a patient is attributed to his or her current facility on day 91 of ESRD if that facility had treated him or her for the past 60 days. If on day 91, the facility had not treated a patient for the past 60 days, we wait until the patient reaches day 60 of continuous treatment at that facility before attributing the patient to that facility.

- When a patient is not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we do not attribute that patient to any facility.
- Patients are no longer attributed 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, the patient is designated lost to follow-up and is not included in the analysis. If dialysis claims or other evidence of dialysis reappears, the patient is re-entered into analysis after 60 days of continuous therapy at a single facility.

2.18.10.1 Days at Risk for Medicare Dialysis Patients

After patient treatment histories are defined as described above, periods of follow-up in time since ESRD onset are created for each patient. In order to adjust for duration of ESRD appropriately, we define 6 time intervals with cut points at 6 months, 1 year, 2 years, 3 years and 5 years. A new time period begins each time the patient is determined to be at a different facility or crosses any of the above cut points, and at the start of each calendar year.

Because we identify hospitalizations only if they appear in Medicare inpatient claims, we only want to include patients during time periods in which all of the patient's hospitalizations are included in Medicare billing records. To achieve this goal, we require that patients either reach a certain level of Medicare-paid dialysis bills or have Medicare-paid inpatient claims during the period. Specifically, months within a given dialysis patient-period are used for SHR calculation when they meet the criterion of being during or within two months after a month with either: (a) \$900+ of Medicare-paid dialysis claims OR (b) at least one Medicare-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 facility-year time periods is used to calculate the expected number of hospital admissions for the patient during that period. The SHR for a facility is the ratio of the total number of observed hospitalizations to the total number of expected hospitalizations during all time periods at the facility. Based on a risk adjustment model for the overall national hospitalization rates, we compute the expected number of hospitalizations that would occur for each month that each patient is attributed to a given facility. The sum of all such expectations for patients and months yields the overall number of hospital admissions that would be expected given the specific patient mix and this forms the denominator of the measure.

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

2.18.11 Calculating Numerators

The numerator is calculated through use of Medicare claims. When a claim is made for an inpatient hospitalization, the patient is attributed to a dialysis facility following rules discussed above. The numerator is the count of all such hospitalizations over the reporting period.

2.18.12 Risk Adjustment

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

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

- Age: Determine each patient's age for the birth date provided by multiple data sources* group patients into the following categories: 0-14 years old, 15-24 years old, 25-44 years old, 45-59 years old, 60-74 years old, or 75+ years old.
- Sex: Determine each patient's sex from multiple sources*.
- Diabetes as cause of ESRD: Determine each patient's primary cause of ESRD from Medical Evidence Form (CMS-2728), REMIS, and CROWNWeb.
- Duration of ESRD: Determine each patient's length of time on dialysis using the first service date from multiple data sources* and categorize as 90 days- < 6 months, 6 months- < 1 year, 1- < 2 years, 2- < 3 years, 3- < 5 years, or 5+ years as of the period start date.
- Nursing home status: Using the Nursing Home Minimum Dataset, determine if a patient was in a nursing home the previous year.
- BMI at incidence: Calculate each patient's BMI as the height and weight provided on his/her CMS 2728. BMI is included as a log-linear term. Comorbidities at incidence are determined using a selection of comorbidities reported on Medical Evidence Form (CMS-2728) namely, alcohol dependence, atherosclerotic heart disease, cerebrovascular disease, chronic obstructive pulmonary disease, congestive heart failure, diabetes (includes currently on insulin, on oral medications, without medications, and diabetic retinopathy), drug dependence, inability to ambulate, inability to transfer, malignant neoplasm, cancer, other cardiac disease, peripheral vascular disease, and tobacco use (current smoker). Each comorbidity is included as a separate covariate in the model.
- Prevalent comorbidities: Identify a patient's prevalent comorbidities based on claims from the previous calendar year. The specific list of ICD codes used for adjustment

related to this edition of the Manual, which can be found on the [Measuring Quality](#) page on the ESRD QIP section of CMS.gov.

- Calendar year

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

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

Beside main effects, two-way interaction terms between age, sex and duration and cause of ESRD are also included. Interactions between the following pairs of variables are included:

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

2.18.13 Calculating Expected Hospital Admissions

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

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

where X_{ik} is the vector of covariates for the i^{th} patient in the k^{th} facility and β is the vector of regression coefficients. Time t is measured from the start of ESRD. The baseline rate function $r_{0k}(t)$ is specific to the k^{th} facility, and is assumed to be a step function with break points at 6 months, 1 year, 2 years, 3 years and 5 years since the onset of dialysis. This model allows the baseline hospitalization rates to vary between strata (facilities), but assumes that the regression coefficients are the same across all strata; this approach is robust to possible differences between facilities in the patient mix being treated. The stratification on facilities is important in this phase to avoid bias due to possible confounding between covariates and facility effects.

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

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

where $R_{ik} = \exp(\beta'X_{ik})$ is the estimated relative risk for patient i in facility k obtained from the stage 1. In our computation, we assume the baseline to be a step function with 6 unknown

parameters, $\alpha_1, \dots, \alpha_6$, to estimate. These estimates are used to compute the expected number of admissions given a patient's characteristics.

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

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

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

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

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

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

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

2.18.14 Calculation of SHR P-Values and Confidence Intervals (DFC Only)

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

$$\log(E[\mathbf{n}_{ik}]) = \log(\mathbf{E}_{ik}) + \boldsymbol{\theta}_k,$$

where \mathbf{n}_{ik} is the observed number of events for patient i in facility k , \mathbf{E}_{ik} is the expected number of events for patient i in facility k and $\boldsymbol{\theta}_k$ is the facility-specific intercept. Here, i ranges over the number of patients N_k who are treated in the k^{th} facility. The natural log of the SHR for the k^{th} facility is then given by the corresponding estimate of $\boldsymbol{\theta}_k$. The standard error of $\boldsymbol{\theta}_k$ is obtained from the robust estimate of variance arising from the over dispersed Poisson model.

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

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

- From the general linear model we obtain the natural log of the SHR (ln SHR) as well as its standard error, (SE). From the empirical null, we obtain a mean (μ) and a standard

deviation (σ). The 95% uncertainty interval for the ‘true’ log standardized hospitalization ratio for this facility is

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

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

2.18.15 Flagging Rules for Dialysis Facility Compare (DFC)

As currently implemented for DFC, for reporting purposes we identify outlier facilities from amongst those with at least 5 patient-years at risk during the time period. If the 95% interval lies entirely above the value of 1.00 (i.e. both endpoints exceed 1.00), the facility is said to have outcomes that are “worse than expected”. On the other hand, if the 95% interval lies entirely below the value 1.00, the facility is said to be better than expected. If the interval contains the value 1.00, the facility is said to have outcomes that are “as expected”.

2.18.16 Data Elements and Data Sources

Variable	Primary Data Source
Facility CCN	Multiple data sources ^{*1}
Date of Birth	Multiple data sources ^{*1}
Sex	Multiple data sources ^{*1}
Date of First ESRD	Multiple data sources ^{*1}
Date of Death	Multiple data sources ^{*1}
Dates of Transplant	Multiple data sources ^{*1}
BMI at incidence	Medical Evidence Form (CMS-2728)
Nursing home status (in the previous calendar year)	Nursing Home Minimum Data Set
Diabetes - Primary cause of ESRD	Medical Evidence Form (CMS-2728) REMIS CROWNWeb
Incident Comorbidities	Medical Evidence Form (CMS-2728)
Prevalent comorbidities	Medicare Claims ^{*2}
Hospital admissions	Inpatient Medicare claims

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

- *1. This may include information from: Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), Medicare Claims, the Renal Management Information System (REMIS), Medicare Enrollment Database (EDB),

Final

Medical Evidence Form (CMS 2728), Medicare Claims, and Organ Procurement and Transplantation Network Database (OPTN) (DFC only). Also see Section 3.1.7

Unique patients are identified by using a combination of SSN, first name, surname, sex, Patient Health Insurance Claim Number and birth date. DFC runs a matching process is performed to ensure that minor typos and misspellings do not cause a patient record to fall out of their history. The matching process is able to successfully match 99.5% of patients. The remaining patients have incomplete or incorrect data that does not allow them to be matched. Also see Section 3.2

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

2.18.17 Flowchart

Figure 17 provides a flowchart that represents the processes used to calculate the Standardized Hospitalization Ratio (SHR).

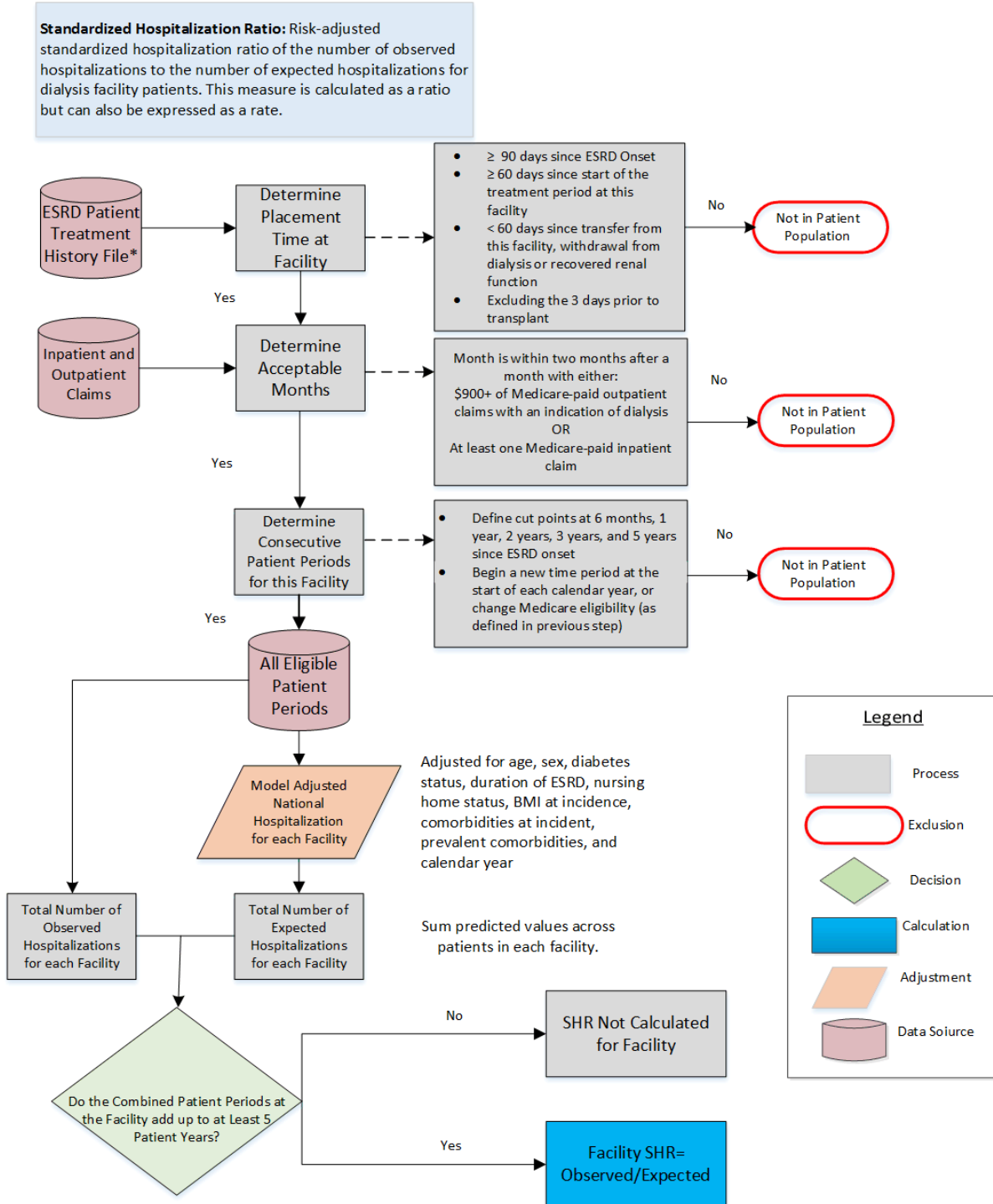


Figure 17: Standardized Hospitalization Ratio (SHR) Flowchart (ESRD QIP and DFC)

From Figure 17:

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

2.18.18 Selected References

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

2.19.1 Measure Name

Standardized Mortality Ratio for Dialysis Facilities

2.19.2 Measure Description

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

2.19.3 Measure Rationale

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

2.19.4 Measure Type

Outcome

2.19.5 Improvement Noted as Higher or Lower Rate

Lower numbers are better

2.19.6 Numerator Statement

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

2.19.7 Facility Exclusions

The standardized mortality ratio is only calculated for a facility if there are at least 3 expected deaths for the time period.

2.19.8 Denominator Statement

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

2.19.9 Denominator Exclusions

N/A

2.19.10 Mapping Patients to Facilities

2.19.10.1 Assignment of Patients to Facilities

The treatment history file provides a complete history of the status, location, and dialysis treatment modality of an ESRD patient from the date of the first ESRD service until the patient dies or the data collection cutoff date is reached. For each patient, a new record is created each time he/she changes facility or treatment modality. Each record represents a time period associated with a specific modality and dialysis facility. SIMS/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 additional sources including the CMS Medical Evidence Form (CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (CMS-2746).

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

The denominator is based on expected mortality calculated from a Cox model (Cox, 1972; SAS Institute Inc., 2004; Kalbfleisch and Prentice, 2002; Collett, 1994). The model used is fit in two stages. The stage 1 model is a Cox model stratified by facility and adjusted for patient age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities, calendar year, and 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 and these provide an estimate of the relative risk for each patient. This is based on a linear predictor that arises from the Cox model, and is then used as an offset in the stage 2 model, which is unstratified and includes an adjustment for the race-specific age-adjusted state population death rates.

2.19.10.2 General Inclusion Criteria for Dialysis Patients

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

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

2.19.10.3 Identifying Facility Treatment Histories for Each Patient

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

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

Using CROWNWeb data and dialysis claims to determine whether a patient has transferred to another facility, we attributed patient outcomes to the patient's original facility for 60 days after transfer out. On day 61 after transfer from a facility, we placed the patient in the new facility once the patient had been treated at the new facility for 60 days. When a patient was not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we did not attribute that patient to any facility. Patients were removed from facilities upon receiving transplants. Patients who withdrew from dialysis or recovered renal function remained assigned to their treatment facility for

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

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

2.19.10.4 Days at Risk for Each Patient-Record

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

the sum of all time spent at the facility for the year so that a given patient can generate only one patient-record per year at a given facility. For example, consider a patient who spends two periods of 100 days assigned to a facility, but is assigned to a different facility for the 165 days between these two 100-day periods. This patient will give rise to one patient-record of 200 days at risk at the first facility, and a separate patient-record of 165 days at risk at the second facility.

This measure is limited to Medicare dialysis patients. We require that patients reach a certain level of Medicare-paid dialysis bills to be included in the mortality statistics, or that patients have Medicare-paid inpatient claims during the period. Specifically, months within a given dialysis patient-period are used for SMR calculation when they meet the criterion of being within two months after a month with either: (a) \$900+ of Medicare-paid dialysis claims OR (b) at least one Medicare-paid inpatient claim.

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

2.19.11 Calculating Numerators/Outcome definition

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

2.19.12 Risk Adjustment

The SMR is based on expected mortality calculated from a Cox model (Cox, 1972; SAS Institute Inc., 2004; Kalbfleisch and Prentice, 2002; Collett, 1994). The model used is fit in two stages. The stage 1 model is a Cox model stratified by facility and adjusted for patient age, race, ethnicity, sex, diabetes as cause of ESRD, duration of ESRD, nursing home status from previous year, patient comorbidities at incidence, prevalent comorbidities, calendar year and 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 patient characteristics included in the stage 1 model as covariates are:

- Age: Determine each patient's age for the birth date provided in the CROWNWeb, Medicare Claims, and the Medical Evidence Form (CMS-2728). Age is included as a piecewise continuous variable with different coefficients based on whether the patient is 0-13 years old, 14-60 years old, or 61+ years old.
- Sex: Determine each patient's sex from CROWNWeb.

- Race (White, Black, Asian/PI, Native American or other): We determine race from CROWNWeb, Medical Evidence Form (CMS-2728), the REMIS patient identification, and the CMS Medicare Enrollment Database file.
- Ethnicity (Hispanic, non-Hispanic or unknown): Determine ethnicity from CROWNWeb, patient's CMS-2728, the REMIS Patient Identification, and the CMS Medicare Enrollment Database File.
- Diabetes as cause of ESRD: Determine each patient's primary cause of ESRD from patient's CMS-2728, the REMIS Patient List, and CROWNWeb.
- Duration of ESRD: We determine each patient's length of time on dialysis using the first service date from patient's CMS-2728, CROWNWeb, Medicare claims history (all claim types), OPTN data (DFC only). The data is categorized as less than one year, 1-2 years, 2-3 years, or 3+ years as of the period start date.
- Nursing home status in previous year: Using the Nursing Home Minimum Dataset, determine if a patient was in a nursing home the previous year.
- BMI at incidence: Calculate each patient's BMI as the height and weight provided on patient's CMS-2728. BMI is included as a log-linear term. The logarithm of BMI is included as a piecewise continuous log-linear term with different coefficients based on whether the log of BMI is greater or less than 3.5.
- Comorbidities at incidence: Determine each patient's comorbidities at incidence from patient's CMS-2728 namely, alcohol dependence, atherosclerotic heart disease, cerebrovascular disease, chronic obstructive pulmonary disease, congestive heart failure, diabetes (includes currently on insulin, on oral medications, without medications, and diabetic retinopathy), drug dependence, inability to ambulate, inability to transfer, malignant neoplasm, cancer, other cardiac disease, peripheral vascular disease, and tobacco use (current smoker). Each comorbidity is included as a separate indicator in the model, having a value of 1 if the patient has that comorbidity, and a value of 0 otherwise. Another categorical indicator variable is included as a covariate in the stage 1 model to flag records where patients have at least one comorbidities. This variable has a value of 1 if the patient has at least one comorbidity and a value of 0 otherwise.
- Prevalent comorbidities: We identify a patient's prevalent comorbidities based on claims from the previous calendar year. The specific list of ICD codes used for adjustment related to this edition of the Manual, can be found on the [Measuring Quality](#) page on the ESRD QIP section of CMS.gov.
- Calendar year

Categorical indicator variables are included as covariates in the stage 1 model to account for records with missing values for cause of ESRD, comorbidity at incidence (missing Medical Evidence Form (CMS-2728)), 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 to 70 for adults or 5 to 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 and Race: Black
- Ethnicity and Race: Non-White
- Diabetes as cause of ESRD and Race
- Diabetes as cause of ESRD and Vintage
- Duration of ESRD: less than or equal to 1 year and Race
- Duration of ESRD: less than or equal to 1 year and Sex
- Diabetes as cause of ESRD and Sex
- Sex and Race: Black

2.19.13 Calculation of Expected Deaths at a Facility

Using the estimates of the regression coefficients from stage 1, we estimate the relative risk for each patient-record. The predicted value for the patient-record from stage 1 is then used as an offset in the stage 2 model, which is unstratified and includes an adjustment for the race-specific age-adjusted state population death rates.

Age-adjusted population death rates (per 100,000) by state and race are obtained from the U.S. Centers for Disease Control National Center for Health Statistics. The 2018 DFC used age-adjusted death rates for 2012-2014 from Table 16 of the publication Health, United States, 2015, available at <http://www.cdc.gov/nchs/data/hus/hus15.pdf>.

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

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

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

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

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

$$X_i\beta = \beta_1x_{i1} + \beta_2x_{i2} + \dots + \beta_px_{ip}. \quad (1)$$

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

$$A_i = \beta_0x_{i0} + X_i\beta = \beta_0x_{i0} + \beta_1x_{i1} + \beta_2x_{i2} + \dots + \beta_px_{ip}$$

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

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

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

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

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

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

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

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

$$SMR = Obs/Exp.$$

2.19.14 Creating Interval Estimates

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

computed from the Cox model and described in the previous section. Accordingly, if the observed number, O , is greater than E , then

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

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

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

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 $\leq 5\%$, then the 95% confidence interval does not include the value 1.0 that corresponds to the null hypothesis that this facility has death rates identical to the national norm.

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

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

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

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

2.19.15 Flagging Rules for Dialysis Facility Compare (DFC)

As currently implemented for DFC, for reporting purposes we identify outlier facilities from amongst those with at least 5 patient-years at risk during the time period. If the 95% interval lies entirely above the value of 1.00 (i.e. both endpoints exceed 1.00), the facility is said to have outcomes that are “worse than expected”. On the other hand, if the 95% interval lies entirely below the value 1.00, the facility is said to be better than expected. If the interval contains the value 1.00, the facility is said to have outcomes that are “as expected.”

2.19.16 Data Elements and Data Sources

Variable	Primary Data Source
Facility CCN	CMS data sources ^{*1}
Race	CMS data sources ^{*1}
Ethnicity	CMS data sources ^{*1}
Date of Birth	CMS data sources ^{*1}

Variable	Primary Data Source
Gender	CMS data sources ^{*1}
Date of First ESRD	Medical Evidence Form (CMS-2728) CROWNWeb Patient Event OPTN Data Medicare Claims
BMI at incidence	Medical Evidence Form (CMS-2728)
Nursing home status (in the previous calendar year)	CMS Minimum Data Set
Diabetes - Primary cause of ESRD	Medical Evidence Form (CMS-2728)
Race-Specific Age adjusted State Death Rate	Health, United States, 2015 ^{*2} Medicare Claims ^{*3}
Diabetes –Not as primary cause of ESRD	Medical Evidence Form (CMS-2728)
Incident Comorbidities	Medical Evidence Form (CMS-2728)
Prevalent comorbidities	Medicare Claims ^{*3}
Not having at least 6-month Medicare eligible in past 12 months	Medicare Claims ^{*3}

Table 8: Data Elements and Sources for the Standardized Mortality Ratio Measure (DFC Only)

- *1. This may include information from the: Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) Patient List, Medicare Claims, the Renal Management Information System (REMIS), Medicare Enrollment Database (EDB), Medical Evidence Form (CMS 2728), Medicare Claims, and Organ Procurement and Transplantation Network Database (OPTN) (DFC only). Unique patients are identified by using a combination of SSN, first name, surname, sex, Patient Health Insurance Claim Number and birth date. DFC runs a matching process to ensure that minor typos and misspellings do not cause a patient record to fall out of their history. The matching process is able to successfully match 99.5% of patients. The remaining patients have incomplete or incorrect data that does not allow them to be matched.
- *2. Table 16 of the publication Health, United States, 2015, available at <http://www.cdc.gov/nchs/data/hus/hus15.pdf>
- *3. Medicare claims include Part A claims such as inpatient admissions and Part B claims such as outpatient claims (including dialysis claims) and physician services. Claims from providers, such as laboratories, that report diagnosis codes when testing for the presence of a condition are excluded.

2.19.17 Flowchart

Figure 18 provides a flowchart that represents the processes used to calculate the Standardized Mortality Ratio.

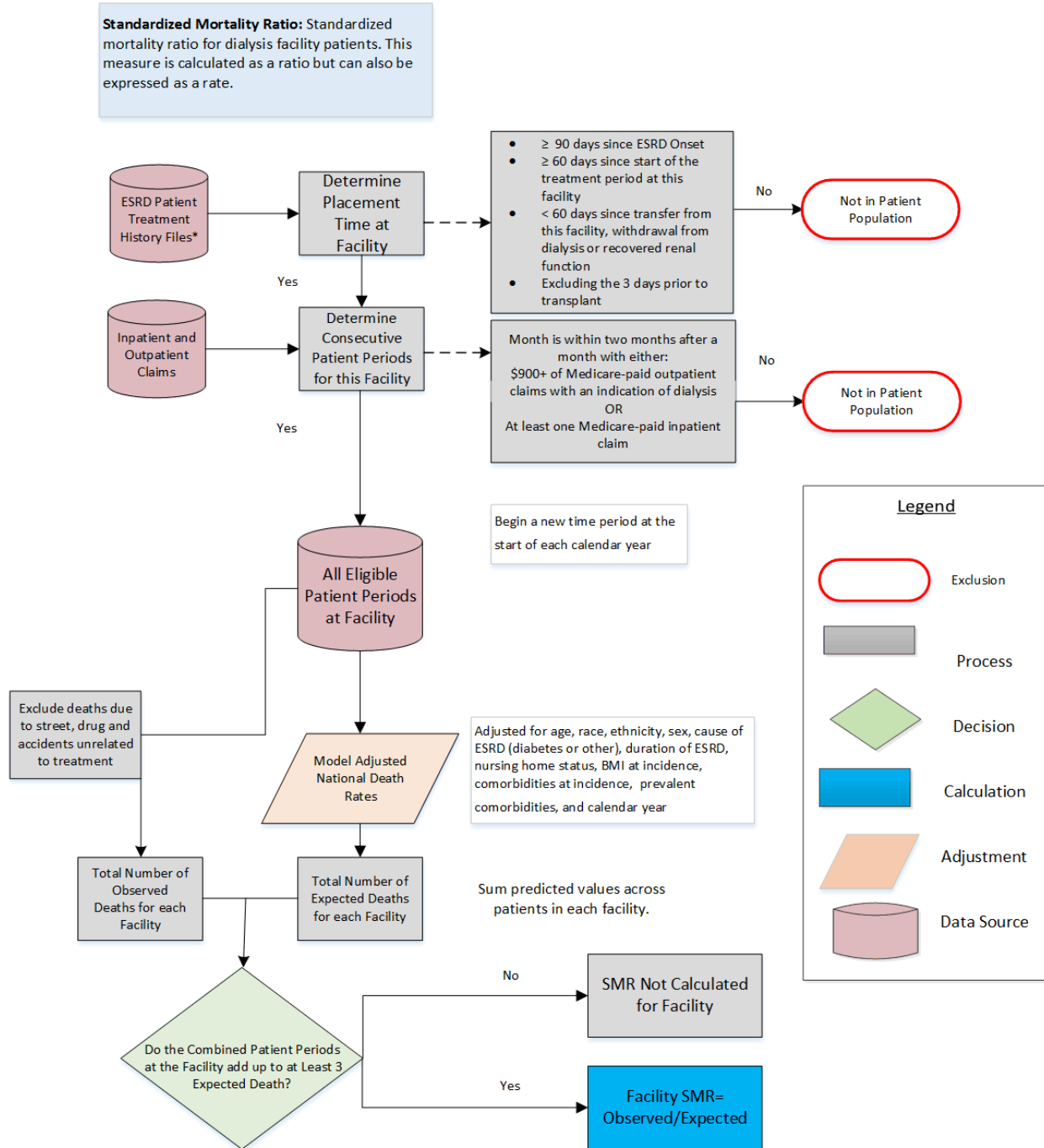


Figure 18: Standardized Mortality Ratio Flowchart (DFC Only)

From Figure 18:

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

2.19.18 Selected References

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2.20 ICH CAHPS Clinical Measure (ESRD QIP Only)

2.20.1 Measure Name

In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) - NQF #0258

2.20.2 Measure Description

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

2.20.3 Improvement Noted as Higher or Lower Rate

Higher rate is better.

2.20.4 Numerator Statement

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

2.20.5 Facility Exclusions

- Facilities treating fewer than 30 eligible in-center hemodialysis adult patients during the "eligibility period," which is defined as the year prior to the performance period
- Facilities that treat 30 or more eligible in-center hemodialysis adult patients during the "eligibility period," but are unable to obtain at least 30 completed surveys during the performance period
- Facilities with a CCN certification date on or after January 1, 2018
- Facilities not offering in-center hemodialysis as of December 31 of the performance period

Note: Adult and pediatric facilities that treat fewer than 30 eligible patients during the eligibility period must attest to this in 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 if they obtain at least 30 completed surveys.

2.20.6 Denominator Statement

Patients with ESRD receiving in-center hemodialysis at sampled facility for the past 3 months or longer are included in the sample frame. The denominator for each question is the sample patients that responded to the particular question.

2.20.7 Denominator Exclusions

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

- Patients less than 18 years old (see Section 3.1.4) on the last day of the sampling window ((see <https://ichcahps.org> for dates) for the semiannual survey
- Patients receiving hemodialysis from their current facility for less than 90 days
- Patients receiving hospice care
- Patients currently residing in an institution, such as a residential nursing home or other long-term care facility, or a jail or prison

2.20.8 Additional Information

- Facilities are required to register on the <https://ichcahps.org> website in order to authorize a CMS-approved vendor to administer the survey and submit data on their behalf.
- Facilities are required to administer the survey twice during the performance period, using a CMS-approved vendor.
- Facilities are required to ensure that vendors submit survey data to CMS by the date specified at <https://ichcahps.org>.
- Facilities that do not administer two surveys during the performance period will receive a score of 0 on the measure.
- Facilities that administer two surveys during the performance period but less than 30 completed surveys will be excluded from the measure.
- Additional specifications may be found at <https://ichcahps.org>.

2.20.9 Data Elements and Data Sources

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

CROWNWeb Data Elements:

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

ICH CAHPS Data Elements

- Reporting Compliance Indicator
- 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

2.20.10 Flowchart

Figure 19 provides a flowchart that represents the processes used to calculate the ICH CAHPS Clinical Measure.

Final

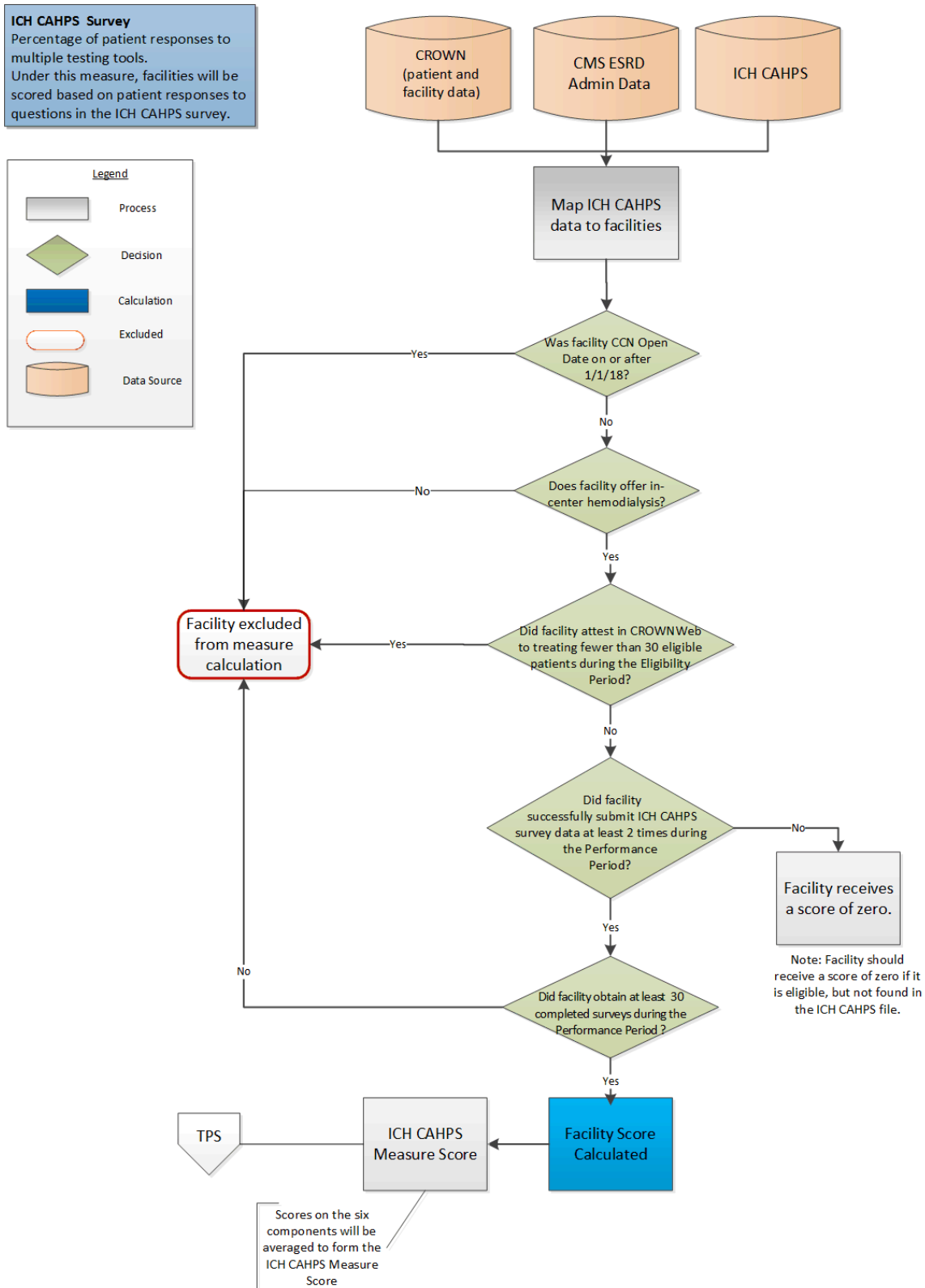


Figure 19: ICH CAHPS Survey Flowchart (ESRD QIP Only)

2.20.11 Selected References

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

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

2.21.1 Measure Name

The National Healthcare Safety Network (NHSN) Standardized Infection Ratio (SIR) of Bloodstream Infections (BSI) – NQF #1460

2.21.2 Measure Description

The Standardized Infection Ratio (SIR) of Bloodstream Infections (BSI) will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.

2.21.3 Improvement Noted as Higher or Lower Rate

Lower ratio is better.

2.21.4 Numerator Statement

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

2.21.5 Facility Exclusions

- Facilities that do not offer in-center hemodialysis as of December 31 of the performance period
- Facilities with a CCN certification date on or after January 1 of the performance year
- Facilities that treat fewer than 11 in-center hemodialysis patients during the performance period

2.21.6 Denominator Statement

Expected number of positive blood culture events in maintenance in-center hemodialysis patients treated in the outpatient hemodialysis facility on the first 2 working days of the month.

2.21.7 Patient-Level Exclusions

- Patients receiving inpatient hemodialysis
- Patients receiving only home hemodialysis or peritoneal dialysis

2.21.8 Additional Information

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

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

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

2.21.9 Data Elements and Data Sources

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

CDC Data Elements:

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

CROWNWeb Data Elements:

- Certification Date
- CROWN Unique Patient Identifier (UPI)
- CROWN Provider ID
- Admit Date
- Discharge Date
- Primary Type of Treatment ID (CROWNWeb dialysis type)
- Primary Dialysis Setting
- Medicare Certified Services Offered as of 12/31 of the performance period
- Additional Services Offered (Non-Medicare) as of 12/31 of the measurement period

Claims Based Data Elements:

- Patient Health Insurance Claim Number
- Claim CCN

2.21.10 Flowchart

Figure 20 provides a flowchart that represents the processes used to calculate the NHSN Bloodstream Infection in hemodialysis outpatient’s measure in the ESRD QIP.

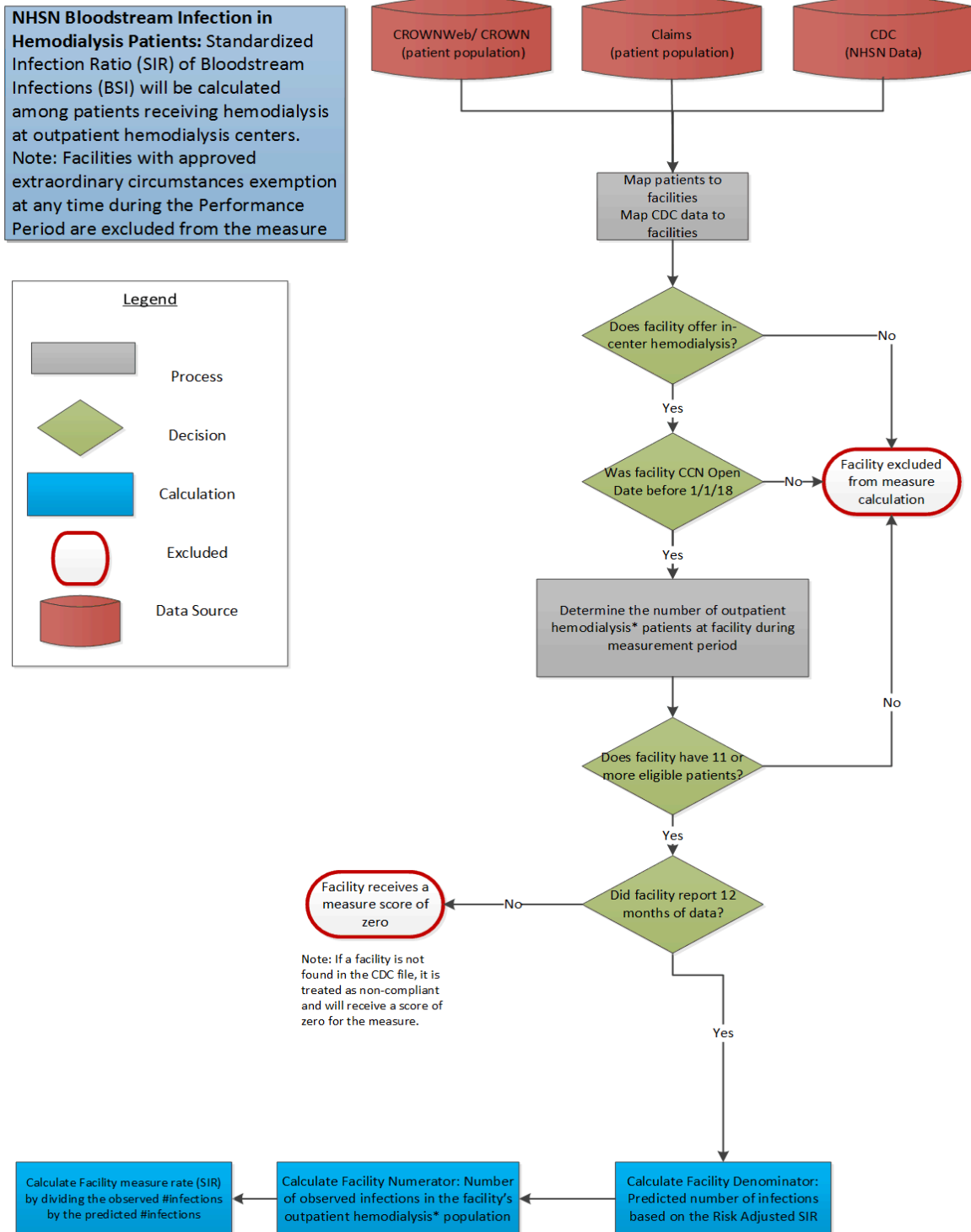


Figure 20: NHSN Bloodstream Infection in Hemodialysis Outpatients Flowchart (ESRD QIP Only)

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

2.22.1 Measure Name

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

2.22.2 Measure Description

Measure assesses whether facilities report influenza vaccinations for their staff. Facility must submit the 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, 2018.

2.22.3 Improvement Noted as Higher or Lower Rate

Higher rate is better.

2.22.4 Facility Exclusions

Facilities with a CCN certification date on or after January 1, 2018

2.22.5 Additional Information

- A “qualifying healthcare personnel” is defined as an employee, licensed independent practitioner, or adult student/trainee/volunteer who works in a facility for at least one day between October 1, 2017 and March 31, 2018 (designated as the “flu season”).
- NHSN Summary Reports submitted by May 15, 2018 document actions taken during the flu season that spans October 1, 2017 to March 31, 2018, and would count toward facilities’ PY 2020 NHSN Healthcare Personnel Influenza Vaccination reporting measure scores.
- Additional information about the Protocol and Summary Report can be found at: <http://www.cdc.gov/nhsn/PDFs/HPS-manual/vaccination/HPS-flu-vaccine-protocol.pdf>.
- Additional details on the specifications for the NHSN HCP Influenza Vaccination measure can be found at the following website: <http://www.cdc.gov/nhsn/dialysis/hcp-vaccination/index.html>

2.22.6 Data Elements and Data Sources

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

CROWNWeb Data Elements:

- Facility CCN
- Initial Certification Date

CDC Data Elements:

- NHSN performance year
- NHSN yearly compliance indicator (as calculated by CDC)

2.22.7 Flowchart

Figure 21 provides a flowchart that represents the processes used to calculate the NHSN HCP Influenza measure.

Final

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, 2018

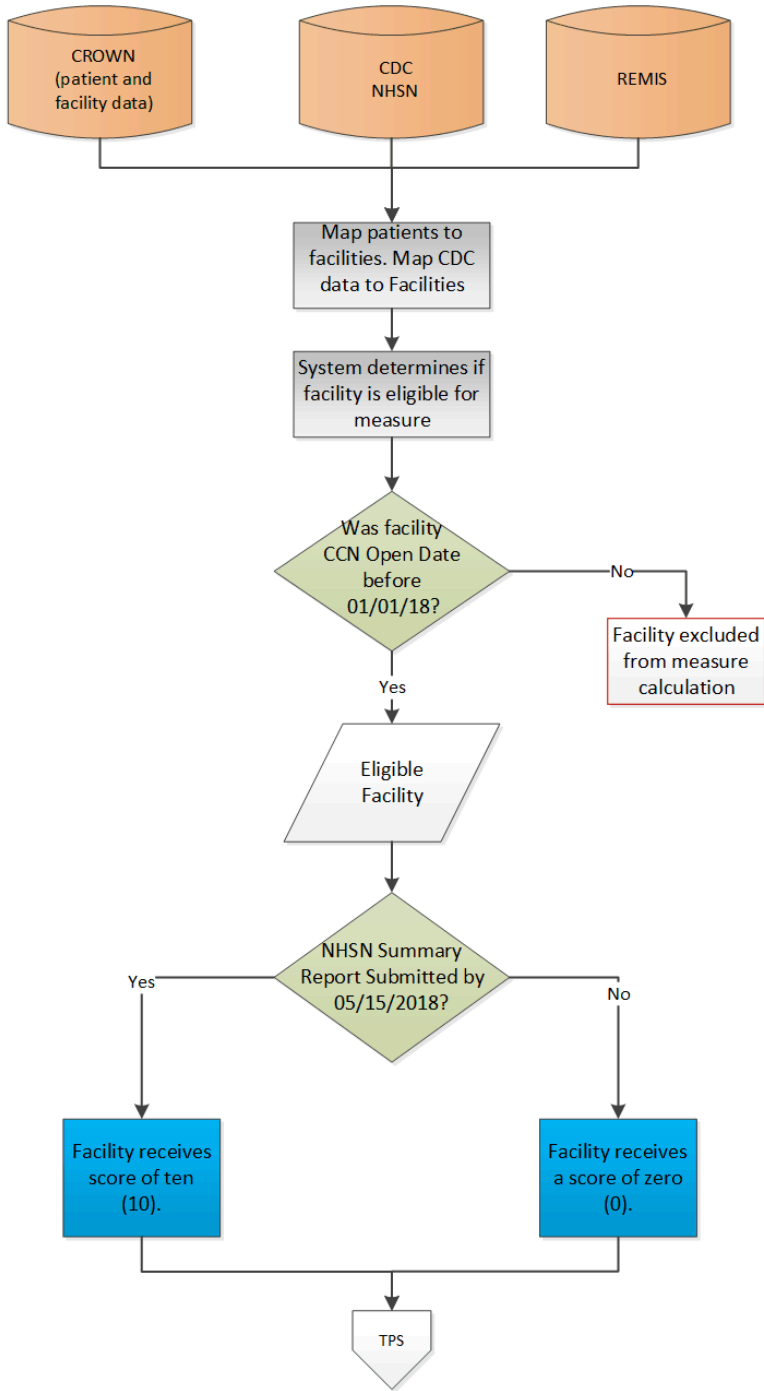
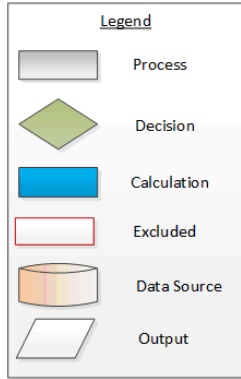


Figure 21: NHSN HCP Influenza Measure Flowchart (ESRD QIP Only)

2.23 NHSN Dialysis Event Reporting Measure (ESRD QIP Only)

2.23.1 Measure Name

The National Healthcare Safety Network (NHSN) Dialysis Event Reporting

2.23.2 Measure Description

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

There are three types of dialysis events reported by users: IV antimicrobial start; positive blood culture; and pus, redness, or increased swelling at the vascular access site.

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

2.23.3 Improvement Noted as Higher or Lower Rate

A higher rate is better.

2.23.4 Facility Exclusions

- Facilities that do not offer in-center hemodialysis as of December 31 of the performance period
- Facilities with a CMS certification date on or after January 1, 2018.
- Facilities treating fewer than 11 in-center hemodialysis patients

2.23.5 Additional Information

Scoring Distribution for the NHSN Dialysis Event Reporting Measure:

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

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

2.23.6 Data Elements and Data Sources

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

CROWNWeb Data Elements:

- Facility CCN
- Initial Certification Date

CDC Data Elements:

- NHSN performance year
- NHSN yearly compliance indicator (as calculated by CDC)

2.23.7 Flowchart

Figure 22 provides a flowchart that represents the processes used to calculate the NHSN Dialysis Event Reporting measure.

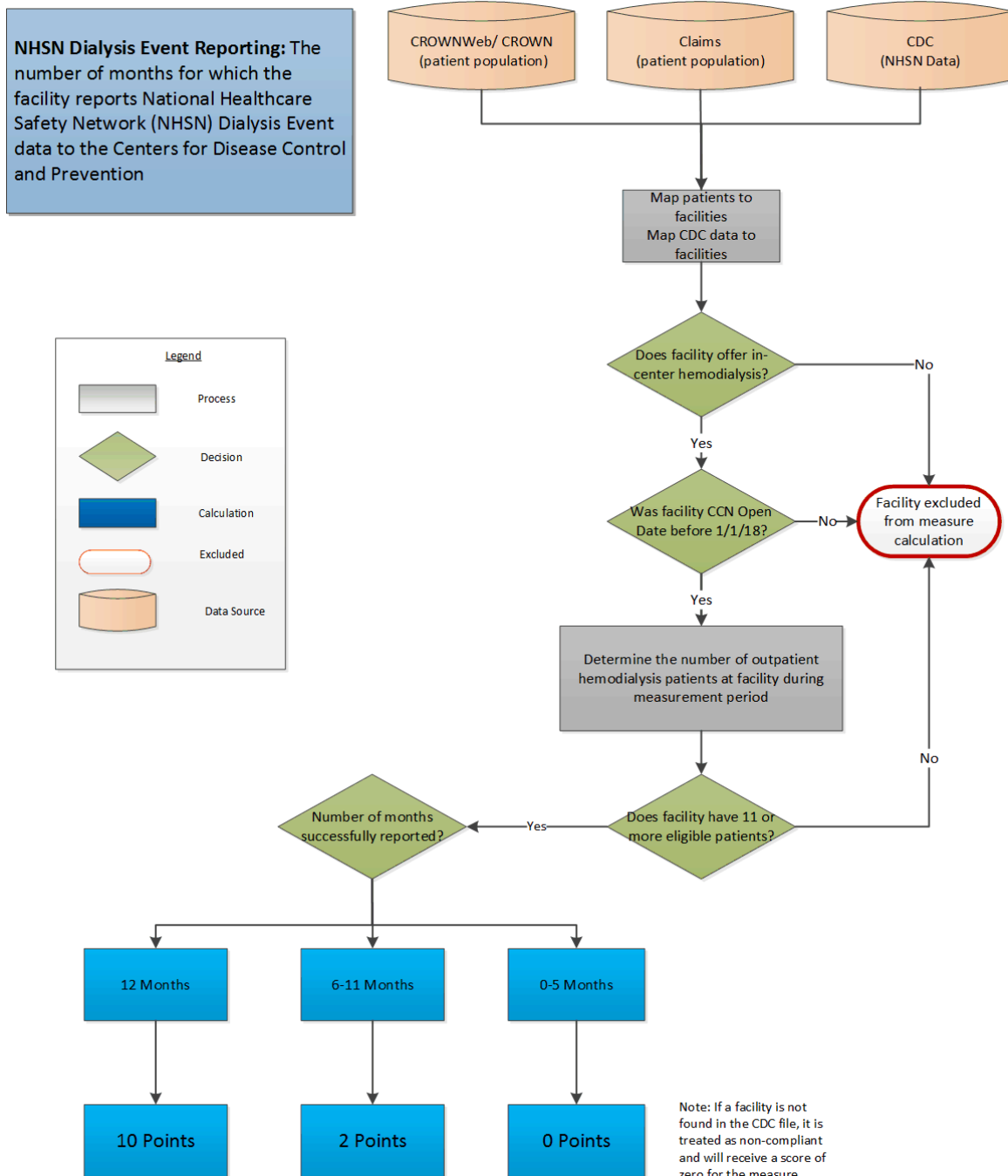


Figure 22: NHSN Dialysis Event Reporting Measure Flowchart (ESRD QIP Only)

2.24 Ultrafiltration Reporting Measure (ESRD QIP Only)

2.24.1 Measure Name

Ultrafiltration Reporting Measure

2.24.2 Measure Description

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

2.24.3 Measure Rationale

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

2.24.4 Measure Type

Process

2.24.5 Numerator Statement

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

*See Section 2.24.10 for further detail on required data

2.24.6 Facility-level Exclusions

- Facilities with a CCN open date on or after July 1, 2018
- Facilities treating fewer than 11 eligible patients during the performance period

2.24.7 Denominator Statement

The number of eligible months the facility treats at least one eligible Medicare or non-Medicare dialysis patient.

2.24.8 Patient-level Exclusions

- Patients less than 18 years of age (see Section 3.1.4) at the beginning of the reporting month
- Patients not assigned to the facility for the entire reporting month
- Patients not on in-center hemodialysis during the reporting month
- Patients on ESRD treatment (as defined by a completed 2728 form or a REMIS/CROWNWeb record) for less than 90 days at the beginning of the reporting month

2.24.9 Facility-Month-Level Exclusions

- No eligible patients in the reporting month

2.24.10 Determining Successful Reporting for a Patient

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

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

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

(Note: For a patient prescribed hemodialysis three times per week, the first four listed data elements are reported 3 times during the week of the monthly Kt/V draw (4 x 3 = 12) and the final element is reported once per month, for a total of 13 data elements per patient per month).

2.24.11 Calculating Monthly Reporting Percentage

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

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

2.24.12 Determining Successful Reporting for a Month

A facility is considered to have successfully reported for a month if the reporting requirements are met for 100% of eligible patients treated at the facility during the reporting month.

2.24.13 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, 2018, then the facility is required to report data for the entirety of the performance period (i.e., all 12 months in 2018).

If the facility's certification date was between January 1, 2018, and June 30, 2018, the facility is required to report on the first day after the month in which the facility is certified to participate in Medicare. For example, if the facility certification date is in March of 2018, 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, 2018, 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).

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

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

$$\left[\frac{(\# \text{ Months Successfully Reporting Data})}{(\# \text{ Eligible Months})} \times 12 \right] - 2$$

2.24.15 Flowchart

Figure 23 provides a flowchart that represents the processes used to calculate the Ultrafiltration Reporting Measure.

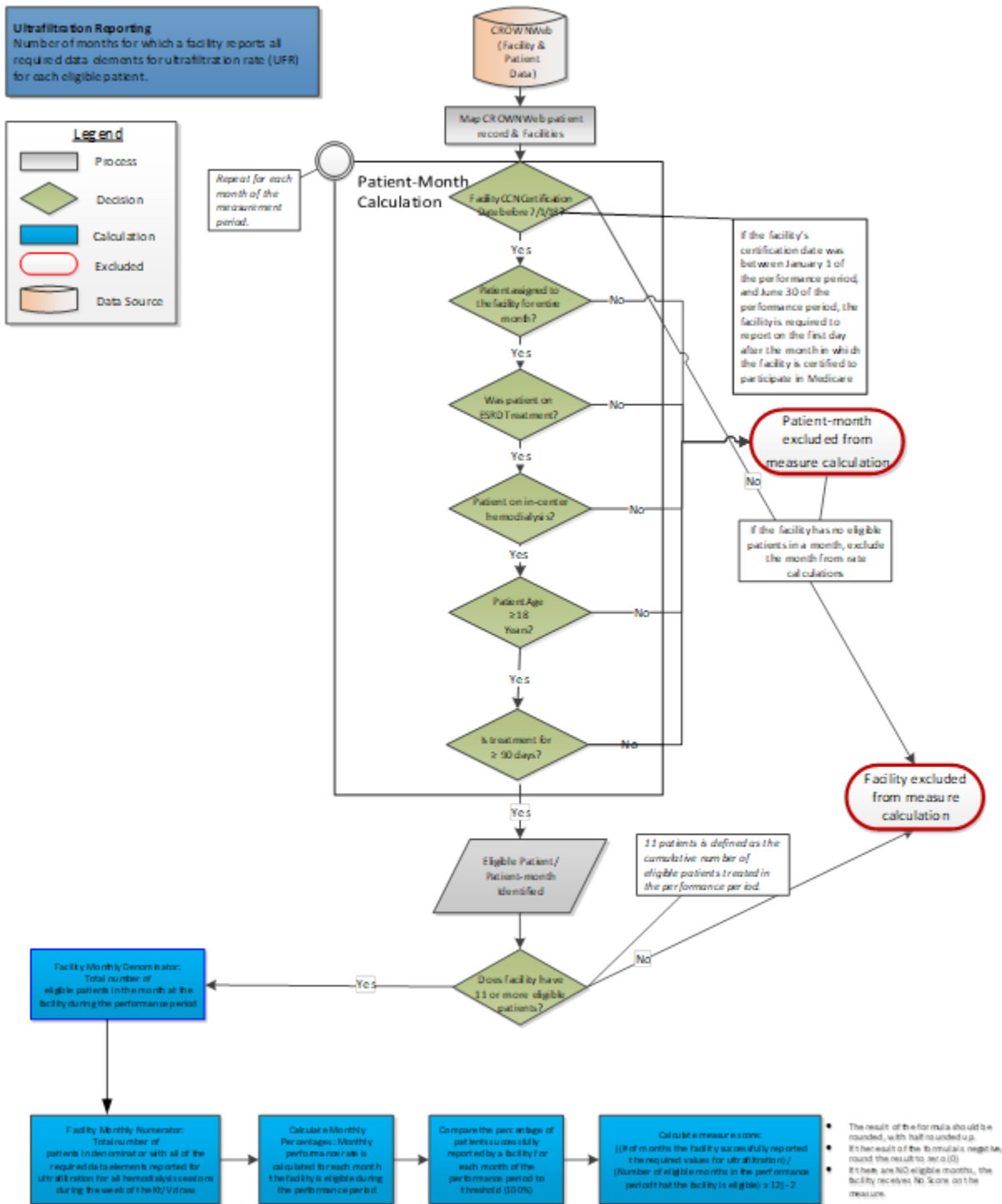


Figure 23: Ultrafiltration Reporting Measure Flowchart (ESRD QIP Only)

2.24.16 Data Elements and Data Sources

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

CROWNWeb Data Elements

- Initial Certification Date
- CROWN Unique Patient Identifier (UPI)
- Facility CCN
- Admit Date
- Date of Month/Year associated with CROWNWeb Clinical Record
- Patient Date of Birth
- Patient Date of Death
- Primary type of treatment ID (CROWNWeb dialysis type)
- Number of prescribed dialysis sessions during the clinical month
- Medicare Certified Services Offered as of 12/31 of the performance period
- Additional Services Offered (Non-Medicare) as of 12/31 of the measurement period
- Kt/v reading date
- Session UF Date
- Pre-Dialysis Weight (entered for Kt/V and UF session)
- Pre-Dialysis Weight Unit of Measure (entered for Kt/V and UF session)
- Post-Dialysis Weight (entered for Kt/V and UF session)
- Post-Dialysis Weight Unit of Measure (entered for Kt/V and UF session)
- Delivered Minutes (entered for Kt/V and UF session)

3. Cross-Measure Determinations

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

3.1 Determining Patient-Level Exclusions

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

3.1.1 Modality Determination

DFC Only:

- A patient is defined as a hemodialysis patient if their modality reported in Medicare claims is any of the following: ‘Hemodialysis’, ‘Center self hemo’, ‘Home hemo’ or ‘Hemo Training’
- A patient is defined as a peritoneal patient if their modality reported in claims is any of the following: ‘CAPD’, ‘CAPD Training’, ‘CCPD’, ‘CCPD Training’, ‘Other PD’ where CAPD is continuous ambulatory peritoneal dialysis and CCPD is continuous cycling peritoneal dialysis.

ESRD QIP Only:

- For the comprehensive Kt/V measure, modality is determined using either CROWNWeb treatment records or claims, with preference given to CROWNWeb. The system tracks if a patient changed modality during the month to implement that exclusion, with the exception that switching between in-center hemodialysis and home hemodialysis is not considered a modality change for adults over age 18 years. Patient modality is derived from CROWNWeb as follows:
 - In-Center Hemodialysis:
 - Dialysis Type= Hemodialysis
 - Dialysis Setting= Dialysis Center
 - Home Hemodialysis:
 - Dialysis Type = Hemodialysis
 - Dialysis Setting= SNF/LTC or Home
 - Peritoneal Dialysis:
 - Dialysis Type=CAPD or CCPD
 - Other:
 - Dialysis Type= Other
- Patient modality for Kt/V is derived from claims by considering revenue center codes for In-Center HD, with condition codes used to identify home HD, and Peritoneal Dialysis. Claims with revenue center codes indicating a mix of modalities are flagged as Multiple.
- Patient modality is derived from claims for all measures except comprehensive Kt/V as follows: In cases where a dialysis patient receives treatment with more than one dialysis treatment modality in a month, for some measures the system must determine

the patient's primary treatment modality for that month. The system will use the logic described in this section to determine patient's primary treatment modality for single or a multiple-claim patient-month by facility. For measures requiring modality determination at the level of detail corresponding to the individual claim, the portions of this process related to a single claim are followed.

1. For each claim, determine the presence of dialysis-related revenue center codes:
 - a. Determine if any of the following dialysis-related **composite** revenue center codes (also known as primary codes) are on the claim:
 - Composite revenue center codes (shown in the second column of Table 9):
 - Hemodialysis - 0821, 0881
 - Other Peritoneal Dialysis - 0831
 - Peritoneal - CAPD (0841) or CCPD (0851)
 - b. If only the following dialysis-related **non-composite** revenue center codes are present, skip to step 5.
 - Non-composite revenue center codes are shown in the third column of Table 9.
 - c. When there are revenue center codes with the same line item date, use Table 9 (below) to determine modality type for each revenue center code.
 - If the modality types are the same, only count once when determining modality and number of sessions.
 - If the modality types are different, do not count either when determining modality and number of sessions.
 - If there are both composite and non-composite revenue center codes, only the composite codes will be counted when determining modality and number of sessions.

Modality Type	Revenue Center Codes Composite	Revenue Center Codes Non-Composite
In-Center Hemodialysis	0821, 0881	0801, 0820, 0824, 0825, 0829
HHD – Home Hemodialysis		0822, 0823, 0882
Peritoneal Dialysis	0841, 0851	0803, 0804, 0840, 0842, 0843, 0844, 0845, 0849, 0850, 0852, 0853, 0854, 0855, 0859
OPD – Other Peritoneal Dialysis	0831	0802, 0830, 0832, 0833, 0834, 0835, 0839
Undetermined		0800, 0809, 0880, 0889

Table 9: Modality Types for Revenue Center Codes

- d. If no dialysis-related revenue center codes are present, set the Primary Modality to **Undetermined**.
2. For months where the facility has submitted multiple claims for the patient:
 - a. Determine the presence of dialysis-related revenue center codes across all claims and combine into one list.
 - b. Determine if any of the following dialysis-related **composite** revenue center codes (also known as primary codes) are on any of the claims:
 - Composite revenue center codes (shown in the second column of Table 9):
 - Hemodialysis - 0821, 0881
 - Other Peritoneal Dialysis - 0831
 - Peritoneal - CAPD (0841) or CCPD (0851)
 - c. If only dialysis-related **non-composite** revenue center codes are present, skip to step 5.
 - Non-composite revenue center codes are shown in the third column of Table 9
 - d. When there are revenue center codes with the same line item date, use Table 9 (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:
- Count sessions per modality type using revenue center codes as follows:
 - a. HD sessions = count incidences of revenue center codes 0821 and 0881
 - b. Other PD sessions = count incidences of revenue center code 0831
 - c. CAPD sessions = count incidences of revenue center code 0841
 - d. CCPD sessions = count incidences of revenue center code 0851
 - Sum HD sessions
 - Sum Other PD, CAPD, and CCPD sessions and convert to PD hemo-equivalent sessions. PD (hemo-equivalent) sessions = $(OPD+CAPD+CCPD)*3/7$
4. Compare HD and PD (hemo-equivalent) dialysis sessions, determine the primary modality.
- a. If there are more HD sessions set primary modality to **In-center Hemodialysis** and continue to step 6
 - b. If there are more PD sessions
 - Sum Other PD sessions
 - Sum CAPD and CCPD sessions
 - If there are more Other Peritoneal sessions, set primary modality to **OPD**
 - If there are more CAPD and CCPD sessions, set primary modality to **Peritoneal Dialysis**
 - c. If there is a tie between the highest counts of two or more of different modality types, set primary modality to **Undetermined**
5. If the only dialysis-related codes on the claim are non-composite revenue center codes (shown in the third column of Table 9), set the primary modality according to which modality type code set occurs most frequently:
- a. Count the non-composite codes of each type and set the Primary Modality according to which code occurs most frequently as shown in Table 9 (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 9 (above) to determine modality type:
 - If the modality types are the same, only count once when determining modality and number of sessions
 - If the modality types are different, do not count either when determining modality and number of sessions
 - c. Determine primary modality:
 - Sum HD code counts (one code=one session)
 - Sum PD and Other PD code counts (sessions) and convert to PD hemo-equivalent sessions. PD (hemo-equivalent) sessions = $(PD+OPD)*3/7$
 - Compare HD and PD (hemo-equivalent) dialysis sessions, determine the primary modality:
 - If there are more HD sessions, set primary modality to **In-center Hemodialysis** and continue to step 6
 - If there are more PD sessions, set primary modality to **Peritoneal Dialysis**
 - If there is a tie of the highest counts of two or more modality types, set primary modality to **Undetermined**.
6. Determine if the patient was receiving Home Hemodialysis:
- a. For patient months that have a single claim:
 - If the patient's primary modality is set to **In-Center Hemodialysis**, change to **Home Hemodialysis** if the Claim Related Condition Code is 74 or 75 (which correspond to 'Home - Billing is for a patient who received dialysis services at home' and 'Home 100% reimbursement - (not to be used for services after 4/15/90) The billing is for home dialysis patient using a dialysis machine that was purchased under the 100% program' claims).
 - b. For months where the facility has submitted multiple claims for the patient:
 - If the patient's primary modality is set to **In-Center Hemodialysis**, and any one of the multiple claims have Claim Related Condition Code of 74 or 75:
 - Set the claim with the highest number hemodialysis revenue center codes (shown in Table 9 with Modality Type In-center Hemodialysis) as the **Primary Single Claim**.
Note: Count all dialysis-related codes for this purpose, including

those occurring on the same date and both composite and non-composite codes if both are present.

- If the **Primary Single Claim** has a claim-related condition code of 74 or 75 then switch the primary modality to **Home Hemodialysis**.
 - If the **Primary Single Claim** does not have a claim-related condition code of 74 or 75 then the modality remains **In-center Hemodialysis**.
 - If no Primary Single Claim can be determined (because there is a tie between two or more claims containing the highest number of hemodialysis revenue center codes), then:
 - ◆ If all claims with the highest number of hemodialysis revenue center codes also have a Claim Related Condition Code of 74 or 75, then switch the primary modality to **Home Hemodialysis**.
 - ◆ If any of the claims with the highest number of hemodialysis revenue center codes does not have a Claim Related Condition Code of 74 or 75, then the modality remains **In-center Hemodialysis**.
7. If the primary modality is **In-center Hemodialysis** or **Home Hemodialysis**, save the count of revenue center codes (determined in Steps 2 or 5) as the number of sessions in the patient month.

3.1.2 Access Type Determination

The follow modifiers are used to determine access type for the claims based vascular access measures in the ESRD QIP:

- 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 transplant standard analysis file (constructed from multiple sources), the CROWNWeb events file, and CMS Institutional Claims. Patients often have data concerning their ESRD service from more than one of these sources. The earliest reported source is taken as the official first service date (FSD). If multiple data sources occur on the FSD, they are sorted as follows: (1) CROWNWeb, (2) medical evidence, (3) claims, and (4) transplant.
- If the first ESRD service date was selected from a dialysis claim and there is a 2728 AND a CROWNWeb event that occur within 30 days of each other that are > 90 days AFTER the dialysis claim date, with NO transplants in between, then the first ESRD service date is moved to the next closest date, either the 2728 or the CROWNWeb event, whichever was earlier.
- If first ESRD service date has been set to the 2728 date but there is a CROWNWeb event of "new patient" more than 1 year later, and that date is earlier than any other CROWNWeb event, transplant, or claim, then the first ESRD service date is changed to the CROWNWeb event date.
- If the ESRD first service date is not before the claim “from” date, then the claim is excluded from the measure calculations.

ESRD QIP:

A patient’s initiation of ESRD date is the earliest among the four dates listed below. If multiple data sources have the earliest ESRD date, the source is identified by the following priority: (1) Medical Evidence form, (2) CROWNWeb, (3) claims, and (4) transplant. Time on ESRD treatment is defined as the length of time from the initiation of ESRD date and the claim start date, as reported on the claim used for the patient-month.

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

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.

3.1.4 Patient Age

Patient age was defined as the length of time between the patient's date of birth and the claim "from" date (the start date for when care was provided), as reported on the claim used for the patient-month. If CROWNWeb was the data source, such as for Comprehensive Kt/V, patient age was as of the first day of the month.

3.1.5 Determination of Weekly Dialysis and "Frequent Dialysis"

A patient was defined as not dialyzing greater than 2 and less than 4 times weekly if the prescribed number of sessions reported in CROWNWeb by the patient's "assigned" facility was not greater than 2 and less than 4 times and/or the patient was identified in CROWNWeb as undergoing "frequent" dialysis anytime during the reporting month. If information regarding the frequency of dialysis was not available for the reporting month in CROWNWeb by the patient's "assigned" facility, session information submitted by other dialysis facilities where the patient received treatment was considered.

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

If the prescribed dialysis information was not available for the patient during the reporting month in either data source (CROWNWeb or Medicare claims), the patient-month was excluded from the denominator.

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

The number of days the claim covers was calculated by: $\text{days} = (\text{clm_thru} - (\text{claim_from} - 1))$. For claims covering more than 7 days, the number of dialysis sessions per week is calculated as a rate: $7 * (\# \text{ of HD sessions} / \# \text{ of days})$. For claims covering 7 or fewer days, no dialysis sessions per week rate is calculated.

Frequent dialysis is defined as follows if any claim starting during the month met any of the following criteria:

- Hemodialysis claim with Kt/V value of 8.88
- Hemodialysis claim with rate of 4 or more sessions per week

- Short hemodialysis claim (7 days or fewer) with 4 or more total sessions

A hemodialysis 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.

3.1.6 Length of Treatment at a Facility

This section (Table 10) summarizes the approaches to length of treatment. The following table indicates where treatment time is discussed, by measure.

Measure	Measure Subsection	Method Summary
Vascular Access Type Clinical Measure: Fistula (ESRD QIP only)	2.1.11	Review of claims by patient month
Vascular Access Type Clinical Measure: Catheter \geq 90 Days (ESRD QIP only)	2.2.11	Review of claims by patient month
Vascular Access Type Clinical Measure: Long-term Catheter Rate (DFC only)	2.3.10	For each month of treatment, dialysis provider is determined using CROWNWeb admissions, form CMS-2728 and claims
Vascular Access Type Clinical Measure: Standardized Fistula Rate (DFC only)	2.4.11	For each month of treatment, dialysis provider is determined using CROWNWeb admissions, form CMS-2728 and claims
Adult Hemodialysis Adequacy Measure (DFC Only)	2.5.11	For each month of treatment, dialysis provider is determined using CROWNWeb admissions, form CMS-2728 and claims
Adult Peritoneal Dialysis Adequacy Measure (DFC Only)	2.6.11	For each month of treatment, dialysis provider is determined using CROWNWeb admissions, form CMS-2728 and claims
Pediatric Hemodialysis Adequacy Measure (DFC Only)	2.7.11	For each month of treatment, dialysis provider is determined using CROWNWeb admissions, form CMS-2728 and claims
Pediatric Peritoneal Dialysis Adequacy Measure (DFC Only)	2.8.11	For each month of treatment, dialysis provider is determined using CROWNWeb admissions, form CMS-2728 and claims
Kt/V Dialysis Adequacy Comprehensive Clinical Measure (ESRD QIP Only)	2.9.11	For each month of treatment, dialysis provider is determined using CROWNWeb admissions, form CMS-2728 and claims
nPCR for Pediatric Hemodialysis Patients (DFC Only)	2.10.11	For each month of treatment, dialysis provider is determined using CROWNWeb admissions, form CMS-2728 and claims
Hypercalcemia Clinical Measure (ESRD QIP and DFC)	2.11.11	Review dialysis facility calcium values during a three-month window

Measure	Measure Subsection	Method Summary
Anemia Management Reporting Measure (ESRD QIP Only)	2.12	Review hemoglobin or hematocrit values for the billing provider on the patient's claims during the month with special consideration for the first month a facility submits claims for a patient
Serum Phosphorus Reporting Measure (ESRD QIP Only)	2.13.6	Comparison of admit and discharge dates in CROWNWeb, combined with billing provider on the patient's claims
Clinical Depression Screening and Follow-Up Reporting Measure (ESRD QIP Only)	2.14.5	Comparison of admit and discharge dates in CROWNWeb. For patients with a death date, when calculating length of treatment at the facility, the system will use the death date as the end of treatment when CROWNWeb discharge date is later than date of death or is blank
Pain Assessment and Follow-Up Reporting Measure (ESRD QIP Only)	2.15.5	Comparison of admit and discharge dates in CROWNWeb. For patients with a death date, when calculating length of treatment at the facility, the system will use the death date as the end of treatment when CROWNWeb discharge date is later than date of death or is blank
Standardized Readmissions Ratio (SRR) Clinical Measure (ESRD QIP and DFC)	2.16.11	For each day of treatment, dialysis provider is determined using CROWNWeb admissions, form CMS-2728 and claims
Standardized Transfusion Ratio (STrR) Clinical Measure (ESRD QIP and DFC)	2.17.10	For each day of treatment, dialysis provider is determined using CROWNWeb admissions, form CMS-2728 and claims
Standardized Hospitalization Ratio (SHR) Measure (DFC Only)	2.18.10	For each day of treatment, dialysis provider is determined using CROWNWeb admissions, form CMS-2728 and claims
Standardized Mortality Ratio (SMR) Measure (DFC Only)	2.19.10	For each day of treatment, dialysis provider is determined using CROWNWeb admissions, form CMS-2728 and claims
Ultrafiltration Rate Reporting Measure (ESRD QIP Only)	2.24.7	For each month of treatment, dialysis provider is determined using CROWNWeb admissions, form CMS-2728 and claims

Table 10: Summary of Treatment Time Methods

3.1.7 Deriving Patient Date of Death

Because multiple sources report death information for the same patient, one patient may have several reported dates. Patient date of death is derived from multiple sources for both DFC and ESRD QIP, using a prioritized hierarchy.

For DFC, the death date is based on the hierarchy order below, with lower numbers having a higher priority:

1. CMS 2746 Death Notification form
2. CMS Medicare Enrollment Database
3. CROWNWeb Events
4. SRTR Transplant data
5. CMS 2728 Medical Evidence form (only available on 2728 forms prior to 2005)
6. REMIS, CROWNWeb, and SRTR Patient Lists
7. CMS Institutional Claims
8. Social Security Death Master File

ESRD QIP relies upon slightly different data sources, but takes the same prioritized approach. This is illustrated in Figure 24.

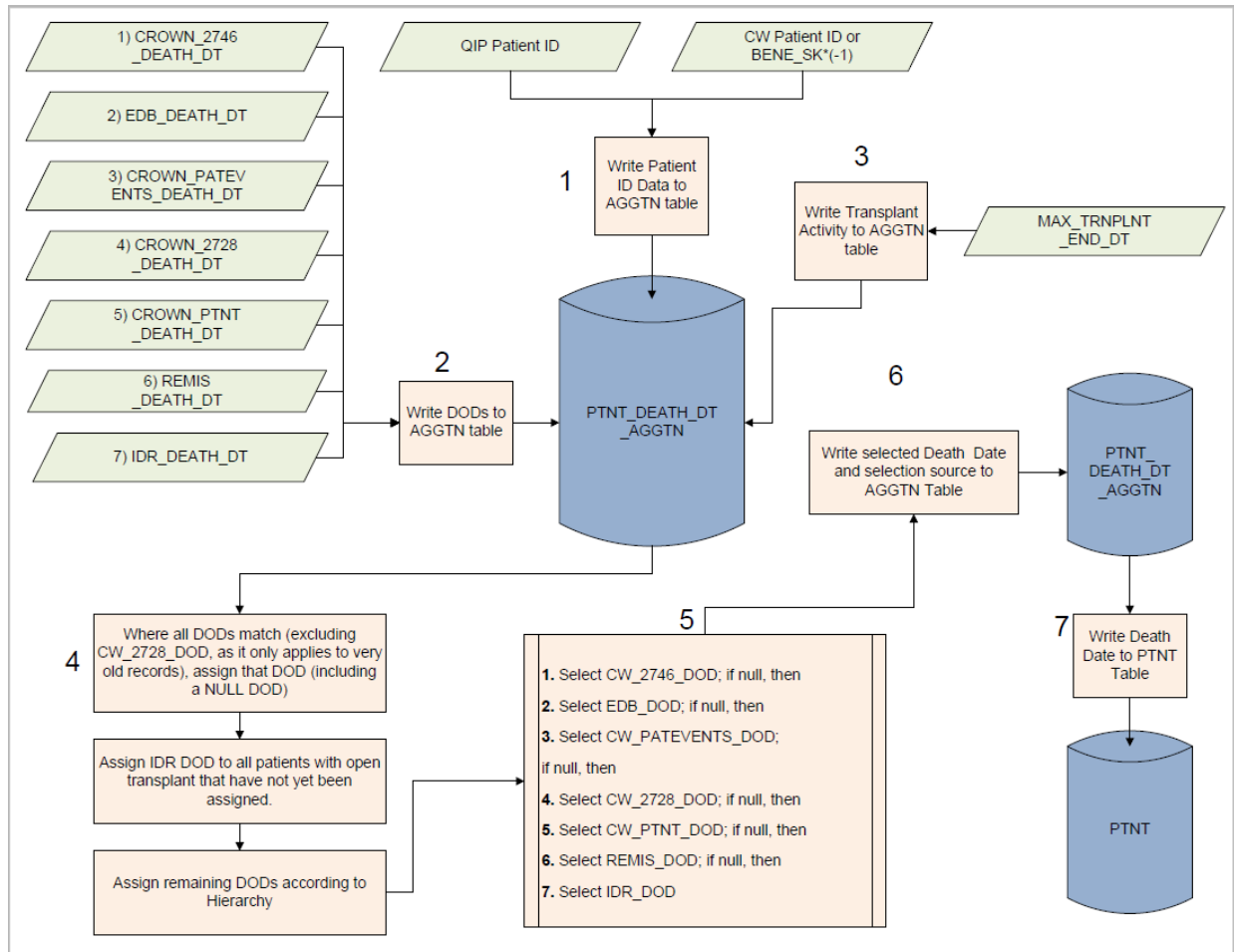


Figure 24: ESRD QIP Derivation of Date of Death

3.2 Linking Patient Data

Quality measures regularly combine information on the same patient from different data sources. In the absence of a national patient identifier, patients are matched across data sources using the identifying information available in each of those sources. There can be inconsistencies, so several logical tests are applied to determine if a patient matches across data sources.

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

Match method components:

1. Candidate search and selection
2. Match quality evaluation

Patient variables used to match:

1. Medicare claim number
2. Social security number
3. Last name
4. First name
5. Birthdate
6. Sex

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

- First 9 characters of Medicare ID
- SSN and first 9 characters of current Medicare ID
- SSN
- First name and surname
- First 9 characters of Medicare ID or SSN with first 9 characters of previous Medicare ID(s)
- Surname and first initial
- Surname and first initial compared with first name and first character of surname
- Birth date

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

- Exact match
- Very confident match
- Somewhat less confident match

Final

Centers for Medicare & Medicaid Services

- Questionable match
- Non-match
- No match candidates found

Matches that are “Questionable” or below are rejected.

For ESRD QIP, the CROWNWeb and Medicare claims must be linked. Figure 25 describes the process.

Final

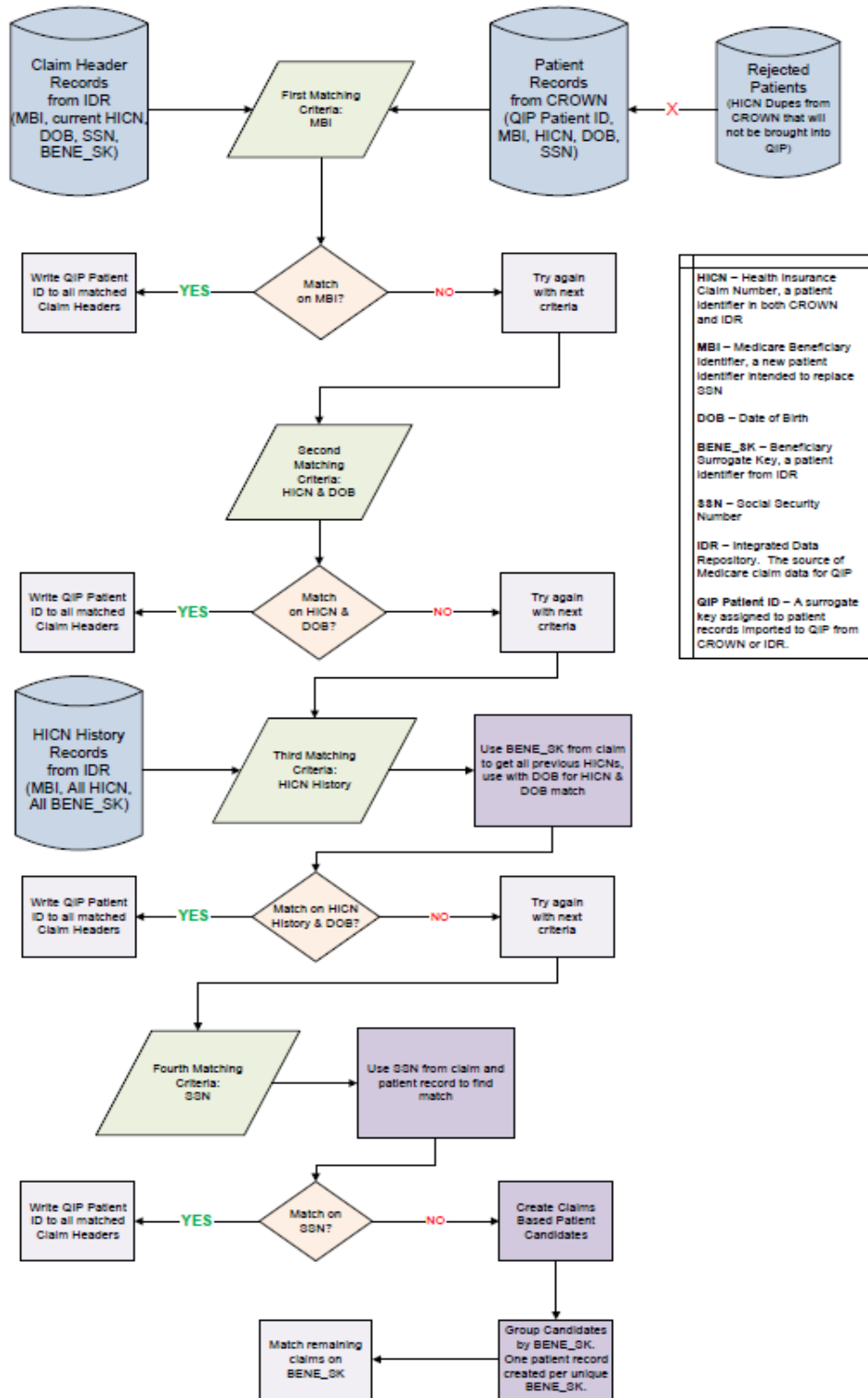


Figure 25: ESRD QIP Linking Claims and CROWNWeb

3.3 Facility Mapping and Impacts of Change of Ownership

3.3.1 DFC Specific

The next section provides an overview of the facility mapping that is used for creating a master facility list for the Quarterly Dialysis Facility Compare (QDFC) Preview Reports. Facility mapping refers to the process by which provider numbers, in this case CMS Certification Numbers, are grouped together to define a single facility for quality measurement purposes.

3.3.2 Overview of Provider Numbers

The QDFCs use the CMS Certification Number (CCN) as a primary provider identifier for quality measurement purposes. A valid CCN must be exactly 6 characters long. All of the digits must be a number except for the 6th digit, which can be ‘F’ indicating special purpose facilities. The middle 2 digits of the provider number indicate the type of the facility. Invalid provider numbers are deleted.

A **hospital based facility** or **satellite facility** has two provider numbers associated with it. Besides its own provider number, it also has a hospital number that has ‘00’ – ‘08’ (Short Stay Hospitals), ‘13’ (Critical Access Hospitals), ‘20’ – ‘22’ (Long Term Hospital) or ‘33’ (Children’s Hospitals) as the middle 2 digits.

A dialysis service provider falls into one of the three main categories:

(1) Freestanding (D25)

- 25 – 28 Non-Hospital Renal Disease Treatment Centers
- 29 Independent Special Purpose Renal Dialysis Facilities

(2) Hospital based (D23)

- 23 – 24 Hospital-Based Chronic Renal Care Facilities

(3) Hospital satellites (D35)

- 35- 36 Renal Disease Treatment Center (Hospital Satellites)
- 37 Hospital-based Special Purpose Renal Dialysis Facilities

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

3.3.3 Overview of Main Considerations Associated with Creating a Facility List

Issue 1: Various Data Sources Use Different Provider Numbers for the Same Facility

Provider numbers are used in various data files such as the medical evidence form, patient events file, the annual facility survey, facility cost reports, facility directory file, CMS survey and certification files, and Medicare claims. A major problem observed in these data sources is that hospital-based facilities (and hospital-satellite facilities) often utilize different provider numbers (ESRD or hospital) for different purposes. For example, a patient’s medical evidence form may be filed under the hospital provider number, ‘210056’, while Medicare dialysis claims were

submitted under the ESRD provider number '212306'. The list below briefly describes many of the data sources that store one or more provider number fields.

Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb): There are two fields, PROVNUM and ALTPROVNUM. For hospital-based dialysis facilities, either the ESRD provider number or the hospital provider number may be found in PROVNUM. Also, the ALTPROVNUM may be missing for hospital-based provider types. The following data are collected through CROWNWeb and will have the same PROVNUM that is used in CROWNWeb.

- **Annual Facility Survey (AFS) (CMS-2744)**
- **Medical Evidence Form (CMS-2728)**
- **Death Notification Form (CMS-2746)**

Facility Directory file

- **Certification and Survey Provider Enhanced Report (CASPER) System:** ESRD provider numbers are stored in OSC_PROV_NUM. Any related or old provider numbers (ESRD or hospital) are stored in OSC_RELATED_PROV_NUM.
- **Medicare Claims:** For hospital-based dialysis facilities, either the ESRD provider number or the hospital provider number may be used. CMS has instructed dialysis facilities to submit claims under their ESRD provider number. (rather than hospital provider number)

Solution: Find all provider numbers that are associated with a given dialysis facility and create a lookup file that links all provider numbers (i.e., Medicare CCN numbers) that may be reported in the various data sources described above by a facility. This look up file is largely based on the CROWNWeb facility directory file and CASPER provider of services files (See Section 3.2.6).

Issue 2: Change of Ownership (CHOW)

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

Solution (CHOW rule): If a facility changes ownership and obtains a new Medicare provider number, the new provider number is treated as a new facility and is not manually linked to the old provider number(s). Instead, the new CCN is treated as a new facility and a QDFC Preview Report is created for the new provider number only. If the provider number is retained (a new CCN is not issued), all information reported under this provider number, under the prior ownership, are also retained.

In some cases, errors are identified by facilities during the comment period, at which time they would request that the old provider number(s) be linked to the new provider number(s).

For more issues and rules associated with creating the facility list, please refer to Section 3.3.4.

3.3.4 Overview of the Facility List Creation Process

Two primary data sources are used to create the facility list; the CROWNWeb facility directory file and CASPER provider of services (POS) files. The Dialysis Facility Compare (DFC) file, which is also extracted from CROWNWeb, is also used to obtain newly certified facilities that will receive a Quarterly Dialysis Facility Compare (QDFC) Preview report. These files are described in more detail in Section 3.3.6.

All facilities active as of the most recent data available will receive a Quarterly Dialysis Facility Compare (QDFC) Preview Report.

The provider number reported on DFC is used as the main provider number for the QDFC reports. For hospital-based or satellite facilities, this is either the ESRD or hospital provider number.

Step 1: Create provider number usage file.

Summary: This file summarizes the number of instances a provider number is reported in various CMS data files, such as the number of Medicare dialysis claims, medical evidence forms, the number of patients reported on the annual facility survey, and number of patient events (i.e., new ESRD patient, transfer in, transfer out, deaths), each year. The provider number usage file is used to help with the data cleaning process. In particular, this file is useful in determining which facility is utilizing the hospital CCN when a hospital number is associated with multiple ESRD facilities, or when a facility closed and/or changes ownership.

Step 2: Process the Dialysis Facility Compare file.

Summary: Process the DFC file received from CMS and append the current DFC data to the cumulative DFC file.

Step 3: Process the facility directory and services files.

Summary: Clean the provider number fields (PROVNUM & ALTPROVNUM) stored in the facility directory file as needed.

1. Eliminate invalid values for both PROVNUM and ALTPROVNUM.
 - a. A valid value must be exactly 6 characters long.
 - b. All of the digits must be a number except for the 6th digit, which can be 'F'. Note: We do not create reports for the latter (i.e., Veterans Affairs(VA) facilities).
2. Identify ESRD and HOSPITAL provider numbers for hospital-based facilities.
3. Select records for active facilities.

The Facility Directory File is not restricted to dialysis facilities. It includes all types of outside organizations that are under the Networks. To select dialysis facilities that are active, the following variables may be used: *Facilityid*, *provtype*, *factype*, *dateclosed*, *certdate(facility_code)*. We create variables *current_record* and

current_idprov to select the records for active facilities. Records with provider type (*provtype*) reported as “MEDICARE”, “OTHER”, “PENDING CERT” or missing; facility type (*factype*)=”Dialysis”, and missing a closed date (*dateclosed*) are selected. In addition, the middle 2 digits of the CCN must be one of the values shown in Section I. Variable *facility_code* indicates the type of facility certification and is retained for possible use in the future. Facilities missing *provtype* or certification date (but not both) are contacted by the ESRD helpdesk for this information in order to be included in the facility list.

There are cases of multiple records in CROWNWeb for a single facility and we employ different ways of handling different scenarios. One such scenario is when a facility’s Medicare provider number changed for any reason. A provider number could be changed at any point in time hence, a facility may have used more than one provider number resulting in two reports. A particular example of this is a change of ownership and issuance of a new provider number; the old and new provider numbers will be treated as separated entities and a report will be generated for the active facility only using its corresponding reported data. However, when there is a change of ownership but the same provider number is retained, only one report will be created using all the data reported under that provider number.

Another scenario is when a provider number is associated with different CROWNWeb facility ID. This has occurred when 1) a facility is shared by adult and pediatric units, or 2) by a hemodialysis and peritoneal units, or 3) a transplant facility and a dialysis facility, or 4) a permanent and temporary facility. The duplicates records with the same ESRD provider numbers are deleted and only one report is created.

In this step, data are output that identifies the active facilities. Transplant facilities and other facilities do not receive a QDFC report and are output to other data files for data checking purposes only.

Step 4: Process and merge CASPER POS files (active and terminated) into one file to serve as a lookup file for the ESRD and hospital provider numbers of hospital-based dialysis facilities with missing ESRD or hospital provider numbers in the Facility Directory File.

Summary: Create a file that contains all active provider numbers. Note, there may be provider numbers listed in CASPER but not CROWNWeb. Some variables are cleaned and corrected during the data creation processes.

Step 5: Create facility list and provider number lookup file.

Summary: Make a clean working copy of the CROWNWeb facility directory file restricted to facilities receiving a QDFC report. Then, for the hospital-based providers that are missing their

hospital number or ESRD number, search for the missing CCN in the CASPER POS. These missing numbers may be reported in CASPER only (and not in CROWNWeb).

- a. For hospital-based facilities with missing hospital CCN, search for the ESRD CCN in the CASPER POS file.
- b. For hospital-based facilities with missing ESRD CCN, search for the hospital CCN in the CASPER POS file. Also, from the CASPER POS file, obtain dialysis numbers that are not kept in the CROWNWeb facility directory file (i.e. CASPER only provider numbers). Since more than one ESRD number could be associated with the same hospital, we also review the facility information (address, facility name, etc.) in order to determine which CCN is affiliated with the hospital. If there is an exact match on all the facility characteristics, the ESRD and hospital provider numbers are automatically linked, otherwise, we output the records for manual review. Records are grouped by Facility ID, address, name, and hospital number.
- c. Create a unique provider variable used for QDFC reporting and update the usage variables, variable labels, and formats.
- d. Create the lookup file used to link all alternate/related provider numbers to the QDFC provider number.
- e. Manually link provider numbers previously requested by facilities that were approved by CMS.

Step 6: Create the Facility Information file.

Summary: This file includes the facility provider number(s), provider name, address, network, region, Dialysis Organization (DO), certification date, open date, and services provided from the DFC file (created in step 2) or facility services file (i.e., closed facilities that aren't in the DFC file) received quarterly along with the CROWNWeb facility directory file. All related provider numbers from these files (created in step 5 above) are aggregated to a single record.

3.3.5 Additional Rules for Linking Provider Numbers

In step 5b described above, a file is output for review from which the following scenarios are observed. In any of the cases described below, no two numbers will be linked together if both are reported on DFC. We consider there to be evidence of change of ownership (CHOW) when multiple records match on facility characteristics (name, address, etc.) and also have one of the following reported for one of the records: (1) a closed date, (2) new certification date, or (3) a name change indicating strong evidence of CHOW (i.e., different Dialysis Organization inserted in name).

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

Solution(s): If there is evidence of CHOW, two reports are created. Otherwise, the two numbers are combined into a single report.

Issue 2: A record in CROWNWeb matches on facility characteristics to a record reported in CASPER and all claims were submitted under the CASPER CCN.

Solution(s): If there is evidence of CHOW, two reports are created. Otherwise, the two numbers are combined into a single report.

Issue 3: Extra provider numbers.

As described above in step 3, if a second provider number of the same type (or any additional number for a freestanding facility) was reported as an alternate provider number in CROWNWeb, it was stored as an 'extra' provider number.

Case 1: The alternate/extra provider number is not associated with any other facilities or reported on a separate record in CROWNWeb.

Solution: Keep the alternate and main provider numbers linked in the report.

Case 2: The alternate/extra provider number is reported on a separate record in CROWNWeb.

Solution: If there is evidence of CHOW, do not link the alternate and main provider number. Otherwise, keep the alternate and main provider numbers linked in the report.

Case 3: The alternate provider number reported in CROWNWeb for a freestanding provider is a hospital number. (i.e., PROVNUM = Freestanding & ALTPROVNUM= Hospital Number).

Solution(s):

- a. If the hospital number was reported on DFC, a report is created for both the freestanding facility and hospital.
- b. If a hospital-based or hospital-satellite ESRD CCN is found associated with the hospital CCN, then the alternate number is not linked to the freestanding provider number.
- c. If no other ESRD numbers are found associated with the hospital CCN then the alternate provider number remains linked to the main number. If there were a separate record for the hospital CCN only and it is not reported on DFC then we would ignore the record (i.e., no separate report for hospital number).

Issue 4: Multiple ESRD provider numbers may be associated with the same hospital provider number.

Solution: Search all data sources for all associated ESRD provider numbers and generate a report that includes the ESRD number usage, open and closed dates, certification dates, facility names, notes, etc. Generally, a hospital-based facility will be linked to the hospital number by definition (case 1). However, if there are multiple hospital satellite facilities associated with the same hospital, the usage file is helpful. For example, if one hospital satellite facility has no usage under their ESRD number and the other hospital satellite facility does, we would link the hospital number to the first facility (case 2).

Case 1: Both hospital-based and hospital satellite and/or freestanding facilities are associated with the same hospital number.

Solution: Link to the hospital-based facility by definition.

Case 2: Multiple hospital-based provider numbers are associated with the same hospital number.

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

Case 3: Multiple hospital-satellite facilities ('35') (and no hospital-based facilities) are associated with the same hospital number in CROWNWeb.

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

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

3.3.6.1 Facility Directory File

The facility directory file is extracted from CROWNWeb. The facility directory files are received quarterly via CROWN RDS. The facility directory files include information such as the facility name, address, and telephone number, etc. Dialysis providers can be categorized into the following groups based on different criteria included in this file. Here are the most common:

- Active (open) or Closed Facilities
- Dialysis Facility or Transplant-only Facility
- Medicare Certified or Non-Medicare Certified Facility
- VA or Non-VA Facility
- Adult Facility or Pediatric Facility
- Permanent Facility or Temporary Facility

3.3.6.2 Facility Service File

This file is received quarterly along with the facility directory file; also extracted from CROWNWeb. The original facility service file only has two columns which are used, *facilityid* and *service*. The variable *facilityid* is the link between the facility directory file and the facility

service file. The service information will be merged to the facility directory file for DFC during data processing.

3.3.6.3 Provider of Service File (POS)

The POS file is downloaded from the Quality Improvement Evaluation System (QIES) Workbench, which includes data from the Certification and Survey Provider Enhanced Report System (CASPER) is used by the State Surveyors for recording results of surveys for certification or subsequent inspection of dialysis facilities. CASPER POS file is more “official” than CROWNWeb facility directory file in the sense that it is tied to the certification process, but new facilities or changes to existing facilities may show up in CROWNWeb before they show up in CASPER. These files are downloaded monthly.

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

3.3.6.4 Dialysis Facility Compare (DFC) File

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

3.3.7 ESRD QIP Facility List and Changes of Ownership

- CROWN assigns a facility ID to each physical building and sub-unit providing dialysis. When data is extracted from CROWN, the system automatically supplies the current CCN for each facility ID. This needs to be converted to CCN in effect as of the date the care was provided for ESRD QIP.
- For hospital-based facilities, the primary CCN is set to the dialysis facility and the alternate CCN is set to the hospital.
- Historical facility ownership changes are documented and used to assign patients to facility CCNs for measures requiring attribution of patient care to facilities.
- ESRD QIP evaluates all facility records in CROWN and determines which are eligible to receive ESRD QIP reports and which may be used in the statistical modeling to support the standardized ratio measures (but not receive a ESRD QIP report).
- ESRD QIP relies primarily on CROWN as data source as it is the facility information system of record. Potential issues are identified by comparison with the DFC facility list through the ESRD QIP Validation process. Research of those issues is supported through Provider of Services, contact with Networks, and other supporting information, such as newspaper articles and press releases regarding changes to facilities.

3.3.8 CROWN Facility Record Consolidation

CROWN assigns different facility IDs to units that share a CCN. This happens most frequently when there are adult and pediatric units, or hemodialysis and peritoneal dialysis units. For these cases, data for these multiple CROWN facility IDs needs to be consolidated under a single CCN

for ESRD QIP. In the ESRD QIP system, one of the “merged” facilities becomes the primary source and is used for the basis for attributes such as name and address.

3.3.9 CROWN Data Clean-up

- CROWN data entry errors, or other inaccuracies, need to be corrected for ESRD QIP until the facility or network updates the information in CROWN. An example might be errors in dates. The date a facility was certified or the date it was closed could have digits transposed, wrong month, etc.
- ESRD QIP reports the dialysis facility CCN as primary when associated with an alternate CCN. ESRD QIP forces this order through a data quality update process if it is not what is observed in CROWN.
- CROWN has duplicate CCNs which cause no problems internally to CROWN but can cause duplication and distortion of ESRD QIP data. The ESRD QIP data quality update process is also used to ensure there are no duplicated CCNs.

3.3.10 ESRD QIP Eligibility

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

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

3.3.11 CCN History

Facility ownership changes that result in a change of CCN are treated as if the facility closed then re-opened in ESRD QIP, severing the past performance under the prior CCN from current ESRD QIP data submitted with the new CCN. CMS intends that when a CCN changes, care provided under the prior management does not influence the new management’s ESRD QIP scores, preventing the prior management impacting the new management’s payment reduction (if any). For the standardized ratio measures, patient events (hospitalizations for SRR and transfusions for STrR) are assigned to the facility responsible for their care at the time of the hospitalization or transfusion. If that care was provided under the prior management, the new management will not held responsible for that care.

3.4 Extraordinary Circumstance Exception/Extension

CMS offers a process for dialysis facilities to request, and for CMS to grant, exemptions when extraordinary circumstances occur beyond the control of the facility. In this way, CMS ensures that facility performance during the extraordinary circumstance does not factor into ESRD QIP scores.

In the event of such circumstances, dialysis facilities must submit an Extraordinary Circumstances Exceptions (ECE) Request Form. The facility may request consideration for an exemption from the ESRD QIP for that payment year. The form must be signed by the dialysis facility's chief executive officer (CEO) or designee, and submitted via email to the ESRD QIP Mailbox at ESRDQIP@cms.hhs.gov. This form must be submitted within 90 days of the extraordinary circumstances event for the ESRD QIP.

For QIP, dialysis facilities granted an ECE will be exempt from all reporting requirements of the ESRD QIP clinical and reporting measures for the months covered by the ECE. QIP calculations will ignore the ECE months.

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

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

For DFC, there is no ECE. Facilities can request suppression during the preview period and those requests are evaluated on a case by case basis.

4. Methodologies for Deriving ESRD QIP Scores

The services for which quality is measured under the ESRD QIP are renal dialysis services defined in section 1881(b)(14)(B) of the Social Security Act (SSA). Prior to January 1, 2017, these services could only be covered and reimbursed under Medicare if they were furnished to individuals with ESRD, but with the passage of the Trade Preferences Extension Act of 2015 (TPEA), these services are now also covered and reimbursed if they are furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the SSA to individuals with Acute Kidney Injury (AKI) (see section 1861(s)(2)(F) and 1834(r) of the Act). In response to stakeholder concerns regarding the impact that AKI patients may have on ESRD QIP measure scores, and because CMS would like to learn more about this population and ensure AKI patients are included only as clinically appropriate, CMS has decided to exclude data from AKI patients from all of its measure score calculations for the ESRD QIP and DFC, pending future consideration of their inclusion on a measure-by-measure basis.

4.1 Calculating an ESRD QIP Score from a Facility's Performance Rate on a Clinical Measure

A measure rate of “No Rate” is assigned for measures from which a facility has been excluded from rate calculations, as defined by each measure's specifications. Scoring methodologies for reporting measures in ESRD QIP are described in the sections of the manual that cover those measures. Facilities receiving a performance rate on a clinical measure in the ESRD QIP will receive a small facility adjustment to the Performance Period rate (if applicable), and then the achievement and improvement scoring methodology is employed.

4.1.1 Small Facility Adjustment

Facilities with a low patient census or nominal amounts of certain clinical events may be eligible to receive a favorable adjustment to their achievement score. This adjustment, known as the Small Facility Adjuster, is applied to account for one patient or event skewing a facility's measure score. A small facility adjustment may be applied to all clinical measures except ICH CAHPS.

The value of a facility's small facility adjustment for a measure depends on that facility's number of measure units for the measure, as well as that facility's unadjusted measure rate. The adjustment will be added to measure rates for which a higher rate indicates better performance and subtracted from those for which a lower rate indicates better performance. That is, the adjustment will always be applied to improve the facility's performance rate.

- The small facility adjustment will be applied to each clinical measure rate, for each eligible facility, for the Performance Period. This adjusted rate will then be used to calculate both the facility's achievement and improvement scores for the measure. Please note that there is no adjustment made to the ICH CAHPS clinical measure.
- A facility having between the lower and upper threshold (inclusive) of eligible patients (or other appropriate unit) —and thus being eligible for the small facility adjustment— will be determined independently for each measure. See Table 11 below.

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

Measure	Lower Threshold (L)	Upper Threshold (C)	Preferred Measure Rate Directionality	Measure Unit
Standardized Readmission Ratio	11	41	Lower Ratio indicates better performance	Index Discharges
Standardized Transfusion Ratio	10	21	Lower Ratio indicates better performance	Patient-years at Risk
Standardized Hospital Ratio	5	14	Lower Rate indicates better performance	Patient-years at Risk
VAT: Catheter	11	25	Lower Rate indicates better performance	Eligible Patients
VAT: Fistula	11	25	Higher Rate indicates better performance	Eligible Patients
Dialysis Adequacy: Comprehensive Kt/V	11	25	Higher Rate indicates better performance	Eligible Patients
Hypercalcemia	11	25	Lower Rate indicates better performance	Eligible Patients
NHSN Bloodstream Infection in Hemodialysis Outpatients	11	25	Lower Rate indicates better performance	Eligible Patients

Table 11: PY 2020 Clinical Measures and the Defined Lower Threshold, Upper Threshold, Preferred Measures Rate Directionality, and the Measure Unit for Each Measure

The following describes the steps the ESRD QIP system will take to calculate a small facility adjustment for a facility's clinical measure rate:

- 1) The ESRD QIP system will perform exclusions for the measure to determine the number of measure units (MUs) at the facility during the performance period.
- 2) The ESRD QIP System will calculate the Benchmark (B), which is set to 90th percentile for each clinical measure using the applicable performance period data.
- 3) The ESRD QIP system will calculate the facility's unadjusted measure rate (UMR) for the measurement period.
- 4) The ESRD QIP system will determine the number of unique, eligible MUs at the facility during the Performance period (n). If the facility's number of MUs is greater than or equal to the lower threshold (L) AND less than or equal to the upper threshold (C), the system will begin the small facility adjustment process:
 - a) The ESRD QIP system will calculate the weighted coefficient for a given clinical measure (w) by dividing the number of MUs during the Performance period (n) by the defined upper threshold 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 Comprehensive 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: Subtract 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) 2020

Table 12 defines key achievement and improvement scoring terms.

Term	Definition
Achievement threshold	The 15th percentile of performance rates nationally during 2016
Benchmark	The 90th percentile of performance rates nationally during 2016
Improvement threshold	Your facility's performance rate during 2017
Performance period	All of calendar year 2018*
Performance standard	The 50th percentile of performance rates nationally during 2016
Facility performance rate	The percentage of a facility's patients either meeting or falling short of a measure's requirements during the performance period

Table 12: Key Achievement and Improvement Scoring Terms

NOTES:

* For the NHSN HCP Influenza measure, the performance period is October 1, 2017 through March 31, 2018.

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 2016).

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 2017 – 90th percentile of performance rates nationally during 2016).

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.

Final

Note: for measures with a lower desired directionality, “meet or exceeds” indicates a rate that is less than or equal to the achievement benchmark.

If facility’s performance rate is below the achievement threshold, a facility receives 0 points for achievement and no achievement score is calculated.

Note: for measures with a lower desired directionality, facility will receive a zero if their performance rate is greater than the achievement threshold.

If a facility's performance rate falls within the achievement range (i.e., between the achievement threshold and the benchmark), then the facility score is calculated using the following equation:

$$9 \times \left[\frac{\text{Facility's Performance Period Rate} - \text{Achievement Threshold}}{\text{Benchmark} - \text{Achievement Threshold}} \right] + 0.5$$

The score is then rounded to the nearest integer, with halves rounded up, resulting in an achievement score of 1 to 10.

Note: Measure rates, achievement thresholds, and benchmarks, are all rounded to the same degree of precision when calculating achievement scores.

4.1.2.2 Calculating an Improvement Score

If the facility’s performance rate is below the facility improvement threshold, the facility receives 0 points for improvement and no improvement score is calculated.

Note: for measures with a lower desired directionality, facility will receive a zero if their performance rate is greater than the achievement threshold.

If a facility's performance rate or improvement threshold meets or exceeds the benchmark, no improvement score is calculated.

Note: for measures with a lower desired directionality, meet or exceeds indicates a rate that is less than or equal to the benchmark.

If a facility's performance rate falls between the improvement threshold and the benchmark, the following equation is used to calculate the facility's improvement score:

$$10 \times \left[\frac{\text{Facility's Performance Period Rate} - \text{Improvement Threshold}}{\text{Benchmark} - \text{Improvement Threshold}} \right] - 0.5$$

The score is then rounded to the nearest integer, with halves rounded up.

Note: Unlike the achievement score, the facility can only earn a maximum of 9 points for improvement.

If a facility does not have sufficient data to calculate a measure improvement rate during 2017, but does have sufficient information to calculate an achievement rate during 2018, then the facility score for that measure is based solely on achievement.

Note: Measure rates, achievement thresholds, and benchmarks, are all rounded to the same degree of precision when calculating improvement scores.

4.1.3 Scoring for ICH CAHPS Clinical Measure

- The In-Center Hemodialysis - Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) survey is scored based on three composite measures and three global ratings
- 3 Composite measures
 - Nephrologists' Communication and Caring (6 questions)
 - Quality of Dialysis Center Care and Operations (12 questions)
 - Providing Information to Patients (9 questions)
- 3 Global ratings (Scale of 0-10)
 - Overall rating of nephrologists
 - Overall rating of the dialysis center staff
 - Overall rating of the dialysis facility
- Each composite measure/global rating is scored via achievement and improvement methods, with facilities receiving the better result for each.
- Scores on the six components will be averaged to form the ICH CAHPS measure score.

If the facility does not meet the survey administration and reporting requirements, the facility will receive a zero on the ICH CAHPS clinical measure, regardless of how many surveys were returned.

Note: The ICH CAHPS survey is administered twice within a single performance period. All calculations will be conducted using a single data set that is compiled from the aggregation of the two surveys submissions.

4.1.4 Scoring Measure Topics

After scores are calculated for each individual measure, certain groups of measures are then combined to form a single measure topic score. This process is applied to the two NHSN measures within the Safety Domain (NHSN BSI and NHSN Dialysis Event Reporting) and the two vascular access type clinical measures (VAT Fistula and VAT Catheter). The scores for these measure topics are discussed below in the example table templates.

4.1.4.1 NHSN BSI Measure Topic

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

#	Calculation Definition	Value
Safety Measure Domain Scores		
a	NHSN BSI Clinical Measure Score	
b	NHSN Dialysis Event Reporting Measure Score	

- 2) Next, calculate the weighted topic score

#	Calculation Definition	Value
Measure Topic Score Calculation		
c	Weight the NHSN BSI Clinical Score <i>Calculate a x (.60)</i>	
d	Weight the NHSN Dialysis Even Reporting score <i>Calculate b x (.40)</i>	
e	Combine Measure Scores <i>Add c + d and round</i>	
f	NHSN BSI Measure Topic Score (from e)	

- 3) 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.

4.1.4.2 VAT Measure Topic

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

Example #1

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

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

Final

#	Calculation Definition	Value
Measure Weight Calculation		
c	Number of patients included in VAT Fistula Measure Score calculation	
d	Number of patients included in VAT Catheter Measure Score calculation	
e	Determine total number of patients for weighting denominator <i>Add c and d</i>	

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

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

#	Calculation Definition	Value
Measures Topic Score Calculation		
f	Weight the VAT Fistula Measure Score <i>Calculate $a \times (c \div e)$</i>	
g	Weight the VAT Catheter Measure Score <i>Calculate $b \times (d \div e)$</i>	
h	Combine Measure Scores <i>Add $f + g$ and round</i>	
i	Vascular Access Type Measure Topic Score (from h)	

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

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

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

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

4.2.1 Calculating the Clinical Measure Domain Score

The Clinical Measure Domain is comprised of subdomains that group clinical measures into two categories. As seen in Table 13 below, each individual clinical measure or measure topic is assigned a specific weight within its respective subdomain.

PY 2020 Measures/Measure Topic by Subdomain	Measure Weight in the Clinical Measure Domain Score
Patient and Family Engagement/ Care Coordination Subdomain	40%
ICH CAHPS measure	25%
SRR measure	15%
Clinical Care Subdomain	60%
STrR measure	11%
Dialysis Adequacy measure topic	18%
Vascular Access Type measure topic	18%
Hypercalcemia measure	2%
SHR measure	11%

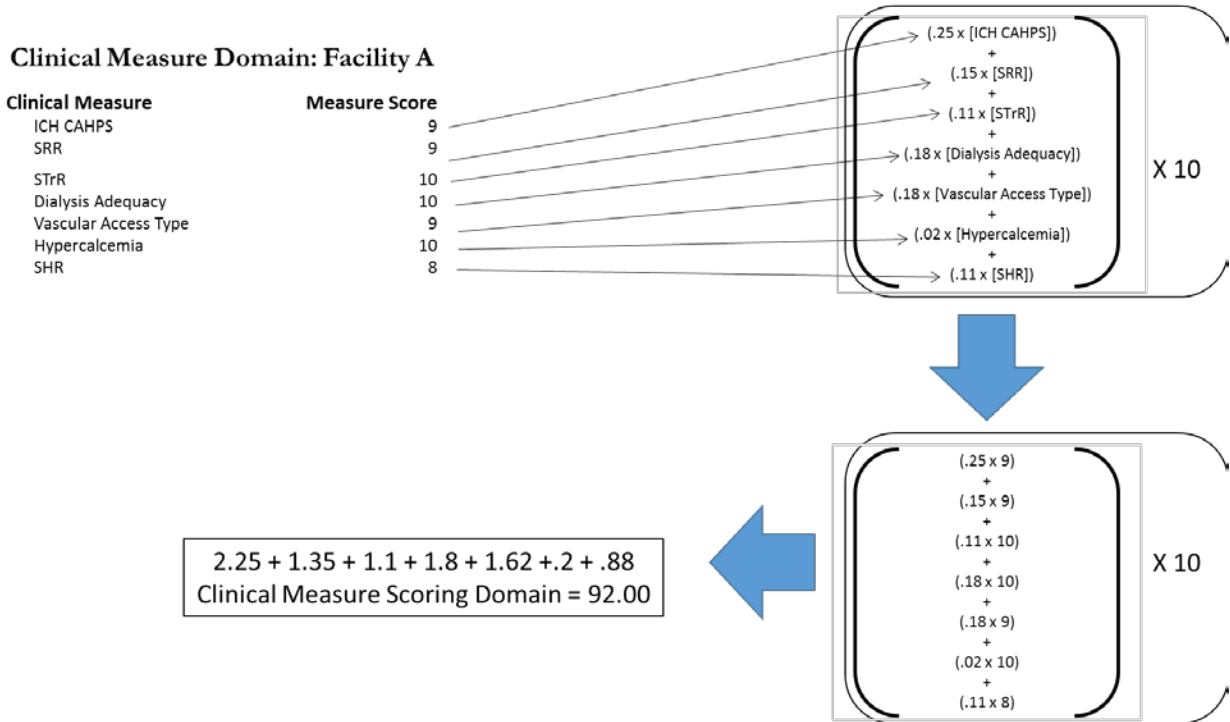
Table 13: Clinical Measure/Measure Topic Weights

In order to calculate the Clinical Measure Domain Score, each individual measure, or measure topic score is converted to a weighted measure score. These scores are then summed up and multiplied by 10 to equal the Clinical Measure Domain score. The clinical subdomain scores can also be determined by summing the weighted scores within each of the respective subdomains. See the example below for a hypothetical scenario of the Clinical Measure Domain Score calculation.

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

Example I: Eligible for all measures in the Clinical Domain for PY 2020

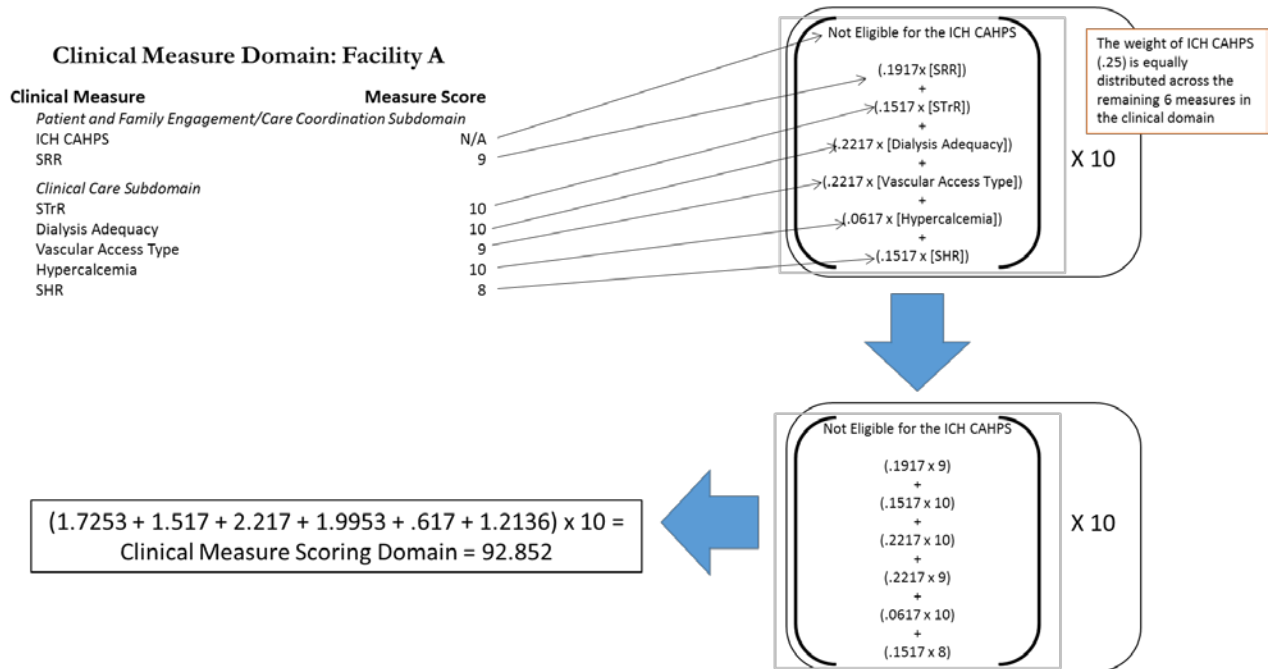
PY 2020 Scoring Example



Example II: Eligible for all but one measure in the Clinical Domain for PY 2020

PY 2020 Scoring Example

Eligible for all but 1 measure



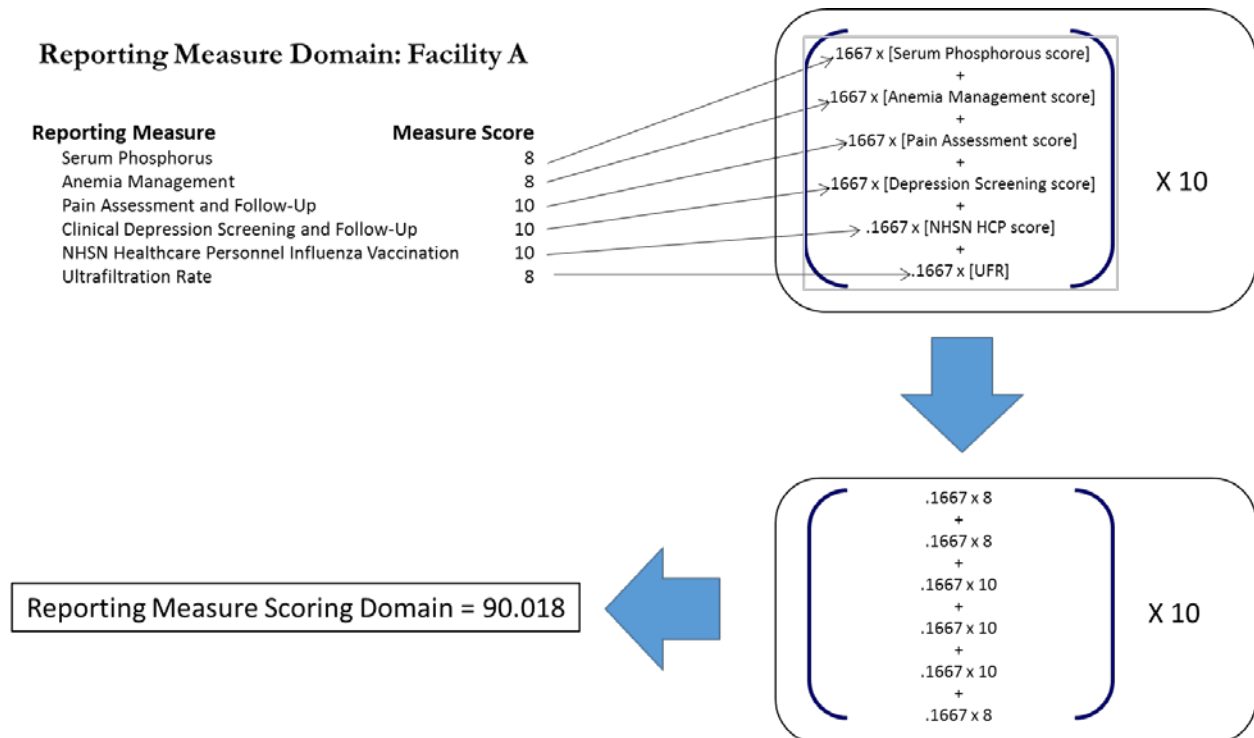
4.2.2 Calculating the Reporting Measure Domain Score

In order to calculate the Reporting Measure Domain Score, each individual measure is converted to a weighted measure score. As seen in Table 14 below, each individual measure is assigned a specific weight. These weighted scores are then summed to make up the Reporting Measure Domain score.

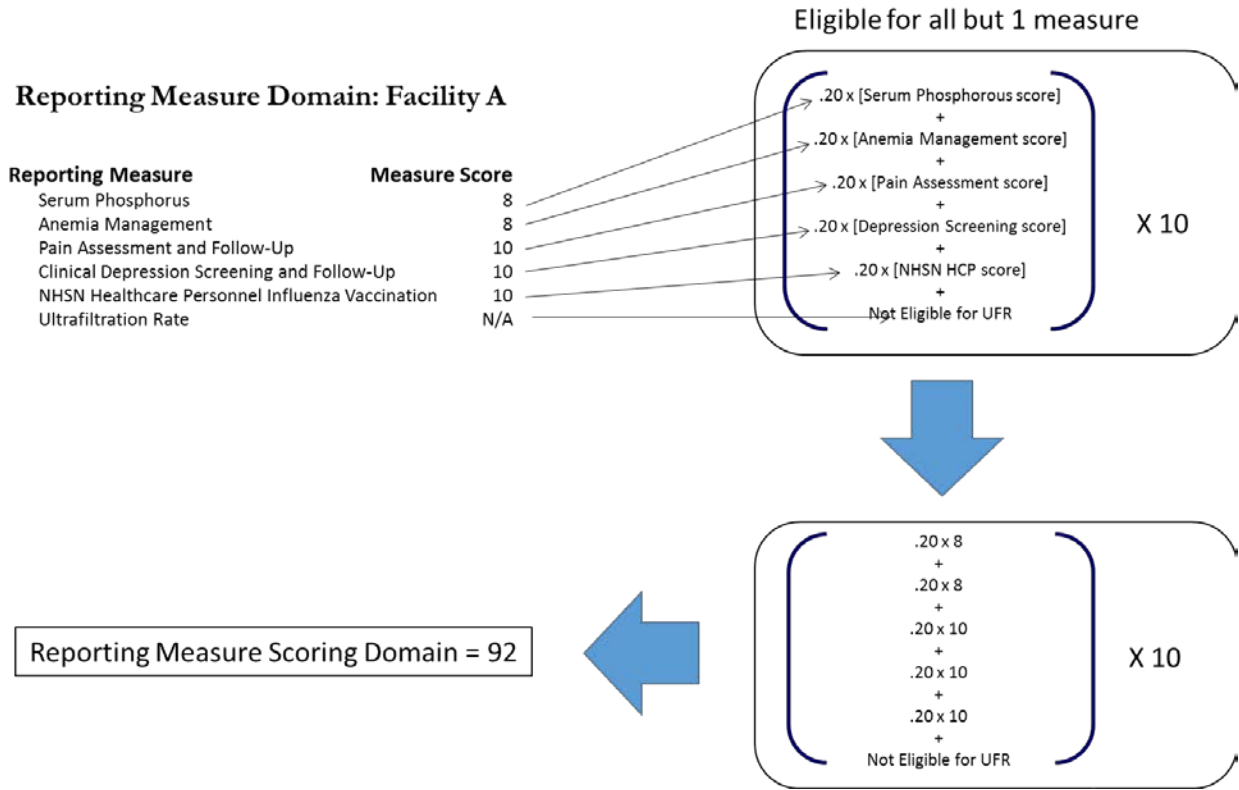
PY 2020 Reporting Measure	Measure Weight in the Reporting Measure Domain Score
Serum Phosphorus	16.67%
Anemia Management	16.67%
Pain Assessment and Follow-Up	16.67%
Clinical Depression Screening and Follow-Up	16.67%
NHSN Healthcare Personnel Influenza Vaccination	16.67%
Ultrafiltration	16.67%

Table 14: Reporting Measure Weights

Example I - Eligible for all Reporting Measures in PY 2020



Example II - Eligible for all but one Reporting Measures in PY 2020



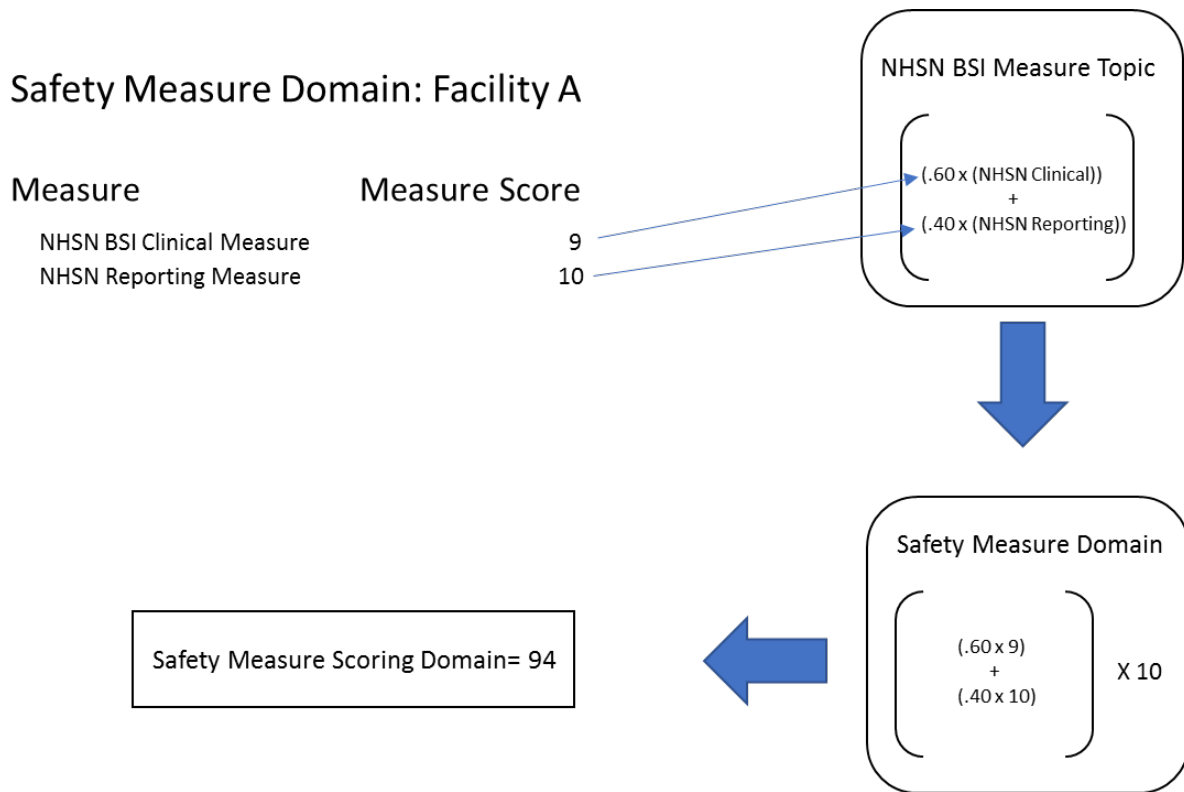
4.2.3 Calculating the Safety Measure Domain Score

In order to calculate the Safety Measure Domain Score, each individual measure is converted to a weighted measure score. As seen in Table 15 below, each individual measure is assigned a specific weight. These weighted scores are then summed to make up the Safety Measure Domain score.

PY 2020 Safety Measure	Measure Weight in the Safety Measure Domain Score
NHSN BSI Clinical Measure	60%
NHSN Dialysis Event Reporting Measure	40%

Table 15: Safety Measures Weights

Example I – Calculating the safety measure domain in PY 2020



4.2.4 Redistributing Weights when a Facility is Not Scored on a Measure

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

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

The safety domain is handled slightly differently in that if a facility is not eligible to be scored in the safety domain, then this domain will be reallocated such that 60% is assigned to the Clinical Domain and 40% assigned to the Reporting Domain. This equates to 9% of the TPS (NHSN BSI Clinical) redistributed to the Clinical Domain and 6% of the TPS (NHSN Event Reporting) redistributed to the Reporting Domain.

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

4.2.5 Calculation of Relative Weights Applied to Measure Scores

The Total Performance Score is comprised of the three measure domains below:

- Clinical measure Domain 75%**
- Reporting measure Domain: 10%**
- Safety measure Domain: 15%**

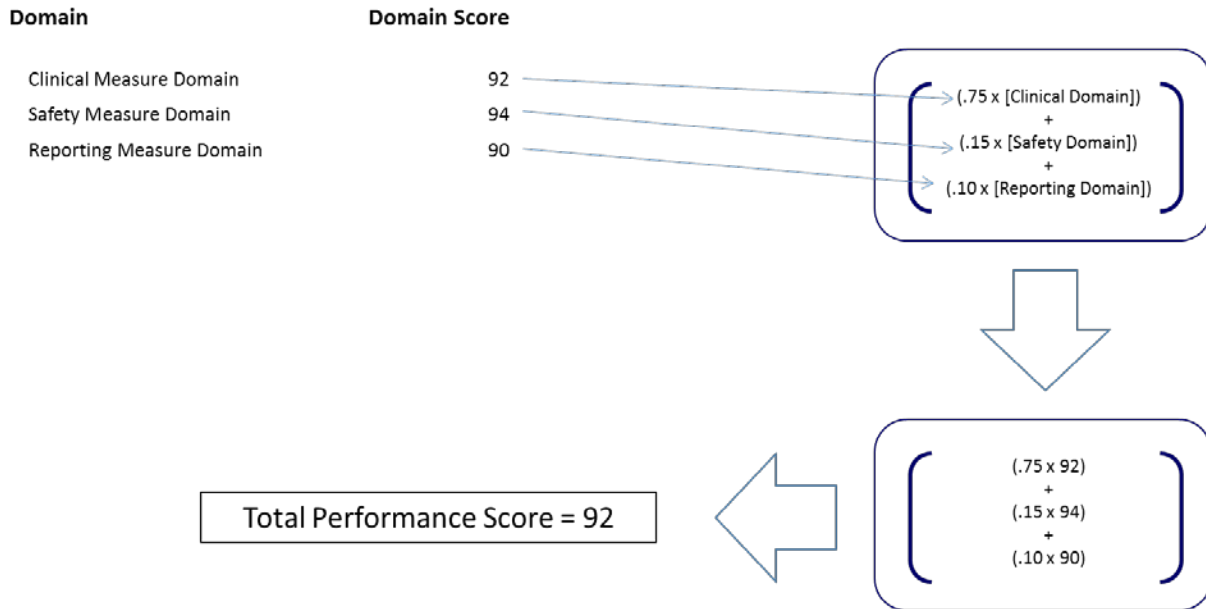
The Total Performance Score (TPS) for the facility is then calculated by multiplying the Clinical Domain score by 0.75, the Reporting Domain score by 0.10, and the Safety Domain score by 0.15 adding the results, as follows:

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

Note, when safety domain is missing, the clinical domain weight is 84% and reporting domain weight is 16% of the TPS. A facility is eligible for receiving TPS if it is eligible for both clinical domain and reporting domain, regardless of the eligibility of the safety domain.

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

Total Performance Score: Facility A



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

Total Performance Score	Payment Reduction
100-59 (Score meets or exceeds minimum TPS)	No reduction
58-49 (1 to 10 points below minimum TPS)	0.5%
48-39 (11 to 20 points below minimum TPS)	1.0%
38-29 (21 to 30 points below minimum TPS)	1.5%
28-0 (28 or more points below minimum TPS)	2.0%
No Score calculated	No reduction

Table 16: TPS and Payment Reduction for PY 2020

5. Calculating Star Ratings for DFC

5.1 Background and Introduction

The Centers for Medicare & Medicaid Services (CMS) developed the Dialysis Facility Compare (DFC) Star Rating System to rate the overall quality of care provided by dialysis facilities. The goal of the Star Rating System is to provide patients, their families, and caregivers information that they can use to easily compare dialysis facilities, as well as be aware of areas of care delivery where the quality of care differs. Each facility is rated between one and five stars. Facilities with five stars are considered to deliver much above average quality of care and those with one star are considered to deliver care that is rated much below average quality.

The original DFC Star Rating System was implemented in January 2015 on the Medicare DFC website. The technical report for the original Star Rating methodology is available at:

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

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

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

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

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

This technical report describes the updated methodology developed for the DFC Star Rating System, which will be implemented for the October 2018 Star Rating release. The report highlights changes to the methodology since the October 2016 Star Rating methodology update.

Specifically, this technical report includes: (1) summary of methodology changes beginning with the October 2018 DFC release, (2) DFC Quality Measures used in calculating the Star Ratings, (3) development of measure domains, (4) measure scoring in a *cutoff year* and in a *current year*, (5) translation of facility final scores to Star Rating categories, and (6) an example Star Rating calculation.

5.2 Summary of Methodology Updates for the October 2018 DFC Release

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

1. For the October 2018 Star Rating release the measures used in this update to the DFC Star Rating System methodology include DFC measures implemented in the original 2015 release of the Star Rating System, updated or replaced versions of several of the original DFC measures, and measures new to the Star Rating. See the next section which lists all the measures.
2. In order to maintain the longitudinal continuity of the current Star Rating distribution, the October 2018 release will use the 2017 DFC Star Rating distribution to establish a new set of cutoffs for the Star Rating categories. This will be applied to the final scores calculated for the October 2018 release, and in determining the Star Ratings.
3. The CAHPS In-Center Hemodialysis Survey (ICH CAHPS) measure will be calculated and reported as separate Star Ratings.

5.3 DFC Quality Measures Used in Calculating the Star Ratings

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

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

5.3.1.1 New Measures

- Standardized Readmission Ratio for Dialysis Facilities (SRR, [NQF #2496](#))
- Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V (Pediatric PD Kt/V, [NQF #2706](#))
- CAHPS® In-Center Hemodialysis Survey (ICH CAHPS, [NQF #0258](#))

5.3.1.2 Replaced Measures

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

5.3.1.3 Updated Measures

- Standardized Mortality Ratio for Dialysis Facilities (SMR, [NQF #0369](#)), Updating existing

[NQF #0369](#)

- Standardized Hospitalization Ratio for Dialysis Facilities (SHR, [NQF #1463](#)), Updating existing [NQF #1463](#)
- Standardized Transfusion Ratio for Dialysis Facilities (STrR, [NQF #2979](#)), Updating existing [NQF #2979](#)
- Proportion of Patients with Hypercalcemia (Hypercalcemia, [NQF #1454](#)), Updating existing [NQF #1454](#)

Full documentation for all NQF endorsed measures can be viewed at:

<http://www.qualityforum.org/QPS/> by entering the measure's NQF number into the *Measure Search* toolbar.

5.4 Final Set of Quality Measures Used in the Clinical Star Rating Calculation

The final set of quality measures used in the clinical start rating calculation include:

- Standardized Transfusion Ratio for Dialysis Facilities (STrR, [NQF #2979](#))*
- Standardized Mortality Ratio for Dialysis Facilities (SMR, [NQF #0369](#))*
- Standardized Hospitalization Ratio for Dialysis Facilities (SHR, [NQF #1463](#))*
- Standardized Readmission Ratio for Dialysis Facilities (SRR, [NQF# 2496](#))*
- Total Kt/V Measure[§]:
 - Delivered Dose of Hemodialysis Above Minimum (Adult HD Kt/V, [NQF #0249](#))^{&, II}
 - Minimum spKt/V for Pediatric Hemodialysis Patients (Pediatric HD Kt/V, [NQF #1423](#))^{&, II}
 - Delivered Dose of Peritoneal Dialysis Above Minimum (Adult PD Kt/V, [NQF #0318](#))^{&, II}
 - Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V (Pediatric PD Kt/V, [NQF# 2706](#))[&]
- Hemodialysis Vascular Access: Standardized Fistula Rate (SFR, [NQF #2977](#))[§]
- Hemodialysis Vascular Access: Long-Term Catheter Rate (Catheter, [NQF #2978](#))[†]
- Proportion of Patients with Hypercalcemia (Hypercalcemia, [NQF #1454](#))[†]

* Lower is better, updated yearly

§ Higher is better, individual measure updated quarterly

† Lower is better, updated quarterly

& The four Kt/V measurements are combined into a single, Total Kt/V measure. The average percentage of patients achieving Kt/V greater than the specified thresholds for each of the four respective patient populations (Adult HD, Adult PD, Pediatric HD, and Pediatric PD), was weighted based on the number of patient-months of data available for each patient population. The resulting measure (Total Kt/V) represents the percentage of

total dialysis patients eligible for the measure who had enough wastes removed from their blood (Kt/V greater than or equal to the specified threshold). After combining these measures, eight final Quality Measures are used to calculate the clinical Star Rating.

" No changes to measure specifications

5.5 ICH CAHPS Star Rating Calculation

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

The ICH CAHPS Star Rating will be calculated and reported as separate Star Ratings. Current measure specifications are available at: <https://ichcahps.org/SurveyandProtocols.aspx>

The ICH CAHPS Star Rating Technical Notes are available at: <https://ichcahps.org>

5.6 Development of Measure Domains

The correlation structure of the measures (Table 17) reveals that some measures are more closely correlated than others. If more correlated measures capture an aspect of facility care quality, while fewer measures capture a different aspect of quality, equal weighting of all measures in the final facility score would artificially attribute greater weight to that aspect of quality being captured by more correlated measures. To address this, the measures are grouped into domains in an empirical, data-driven manner using factor analysis. Equal weighting of these domains, rather than the individual measures, avoids overweighting particular measures that may represent a similar aspect of quality as other measures in the Star Rating.

	STrR	SHR	SMR	SRR	SFR	Catheter Hypercal.	Total Kt/V
STrR	1.00	0.23	0.14	0.13	0.06	0.09	0.11
SHR	0.23	1.00	0.26	0.44	0.12	0.15	0.22
SMR	0.14	0.26	1.00	0.10	0.04	0.04	0.13
SRR	0.13	0.44	0.10	1.00	0.08	0.07	0.13
SFR	0.06	0.12	0.04	0.08	1.00	0.42	0.22
Catheter	0.09	0.15	0.04	0.07	0.42	1.00	0.27
Hypercalcemia	0.02	0.12	0.05	0.07	0.20	0.28	0.47
Total Kt/V	0.11	0.22	0.13	0.13	0.22	0.27	1.00

* Correlations were statistically significant at $p \leq 0.001$ (for SMR and Catheter $p = 0.003$), except for the correlation between Hypercalcemia and STrR ($p = 0.1965$).

Table 17: Spearman Correlation Matrix, Calendar Year 2016 Data*

Analyses of calendar year 2016 data, and the expanded measure set, informed the creation of three measure domains that will be used beginning with the October 2018 Star Rating release. Four standardized outcome measures form the first domain, which is named “Standardized

Outcomes (SHR, SMR, STrR, and SRR).” The Standardized Fistula Rate and Long-Term Catheter Rate measures form the second domain, “Other Outcomes 1 (SFR, Catheter).” The Total Kt/V and Hypercalcemia measures form the third domain, “Other Outcomes 2 (Total Kt/V, Hypercalcemia).”

5.7 Measure Scoring in the Initial *Cutoff Year* and a *Current Year*

The DFC clinical quality measures have different distributions and scales, therefore we first transform the values of individual measures to measure scores in order to make them comparable in terms of scale and direction (scoring methodology is described further below). In this report, the term *measure value* refers to the original value that a facility obtains on a quality measure (e.g. percent of patients with Kt/V > 1.2). The term *measure score*, which is used to generate the DFC Star Rating, refers to the score associated with a specific *measure value*. In addition, *current year* refers to the calendar year of data that are being reported on DFC. The implementation of the *current year* and *cutoff year* for scoring measures and assigning star ratings are described in more detail in later sections.

5.7.1 *Cutoff Year* Measure Scoring Methodology

This section outlines how the CY2016 data are used to define cutoffs for measure scores. The October 2016 DFC Star Rating release used CY2014 data as the *baseline year*. This allowed facilities to maintain or improve their Star Rating if they maintained or improved performance on the quality measures compared to their *baseline year* score. As new measures are added, and several measures are updated for the October 2018 release, one cannot directly compare cutoff scores to the Star Rating cutoffs established using CY2014. Therefore, the October 2018 release has updated the Star Rating final score cutoffs (determined using calendar year 2016 data) based on the CY2016 Star Rating distribution, in order to maintain continuity of facility Star Rating distribution as the measure set undergoes transition.

The measure values in the current DFC Star Rating are either standardized ratios or percentages. As described below, different scoring methods are applied, based on the measure scales, in developing scores for the CY2016 *cutoff year*.

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

The standardized ratio measures are scored differently from the percentage measures since the quality associated with a unit change in a ratio measure is not equally spaced. For example, the quality difference between an SMR of 0.5 versus 1.0 is not the same as the quality difference between an SMR of 1.0 versus 1.5. Despite both covering an interval of 0.5, the former represents a two-fold difference, while the latter represents a difference in mortality that is only 1.5 times higher. Probit scoring, a ranking approach described below, better accounts for these spacing differences than z-scores, which assume equal spacing. In addition, since the probit function maps percentile ranks of the standardized ratio measures to a distribution with mean 0 and variance 1, this type of scoring can be easily combined with z-scores for the percentage measures, which also have mean 0 and variance 1. Therefore, probit scoring is used for the ratio measures to define scores in the *cutoff year*.

To calculate probit scores, we input a “percentile rank/100” into the probit function, Φ^{-1} , the inverse cumulative distribution function for the standard normal distribution. This produces the normal quantile associated with the input percentile rank. Minimum and maximum values of probit scores are determined by precision of the percentile input into the probit function. The DFC Star Rating uses percentiles ranging from 0.5 to 99.5 in increments of 0.5, resulting in 199 distinct percentiles. The associated minimum probit score is $\Phi^{-1}(0.5/100) = -2.58$, and the maximum probit score is $\Phi^{-1}(99.5/100) = 2.58$.

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

Probit scoring algorithm in the *cutoff year*:

- Percentile ranks are calculated for the *cutoff year* measure values, to then be fed into the probit function.
- The percentile ranks are realigned so that the highest value (99.5) represents care much above average and the lowest value (0.5) represents care much below average. This is to ensure the same directionality before combining measures.
- The percentiles are then mapped to the probit scores: probit score = $\Phi^{-1}(\text{percentile rank} / 100)$. All scored measures now have mean 0 and variance 1 at this step.

Figure 26 shows the distribution of measure values for SMR on the left (where lower values are better) and the distribution of probit measure scores for SMR on the right (where higher scores are better).

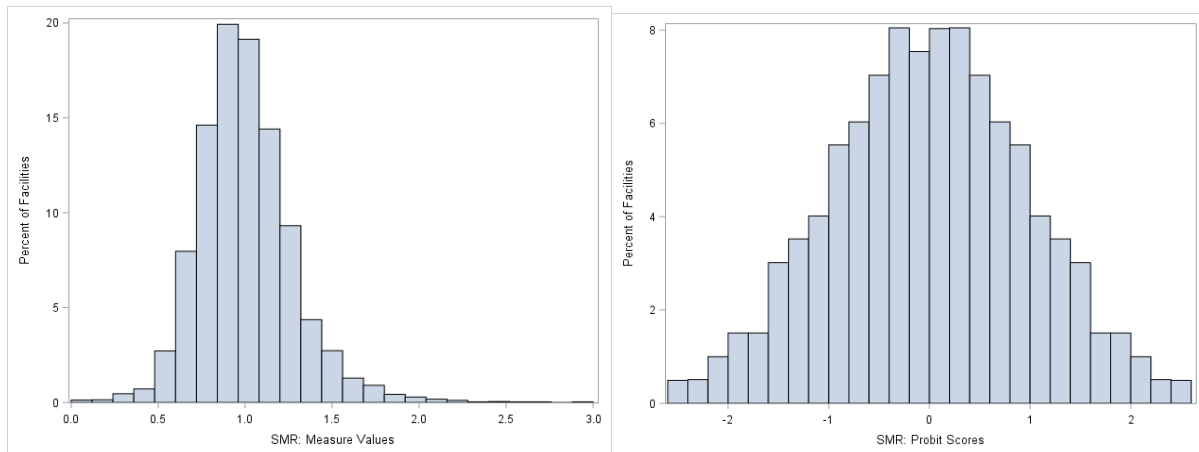


Figure 26: Example of Scoring SMR CY2016 Cutoff Year

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

The percentage measures vary in distribution and are scored using truncated z-scores. Truncated z-scores represent the number of standard deviations away from the mean, truncated at a maximum/minimum allowed value. During the truncation process, these measures are iteratively re-scored to ensure a final mean of 0 and variance of 1.

The scoring algorithm is as follows:

- Percentage measures in the *cutoff year* are realigned so that the highest value (100) represents care much above average and the lowest value (0) represents care that is much below average. This is to ensure scored measures have the same directionality before they are combined.
- Z-scores are calculated. All z-scored measures now have mean of 0 and variance of 1 at this step. Variance stabilization ensures that measures are given equal influence if equally weighted in the rating.
- Z-scores are truncated at upper and lower bounds on the z-score distribution for each measure.
- These truncated scores are then re-standardized to ensure the final truncated z-scores still have mean of 0 and variance of 1. The upper and lower truncation bounds are different for each measure, and chosen so that all final measure scores have a maximum range of -2.58 to 2.58.

A detailed example of this calculation is shown in Section 5.12.2. Highly skewed measures have the potential to result in large z-scores for facilities in the tail of the measure. These large scores may exert too much influence on the Star Rating. Limiting the range of the scores through truncation ensures that a facility's Star Rating is not determined primarily by outlier performance on a single measure. Figure 27 shows the distribution of measure values for Kt/V (left) and the distribution of measure z-scores for Kt/V (right).

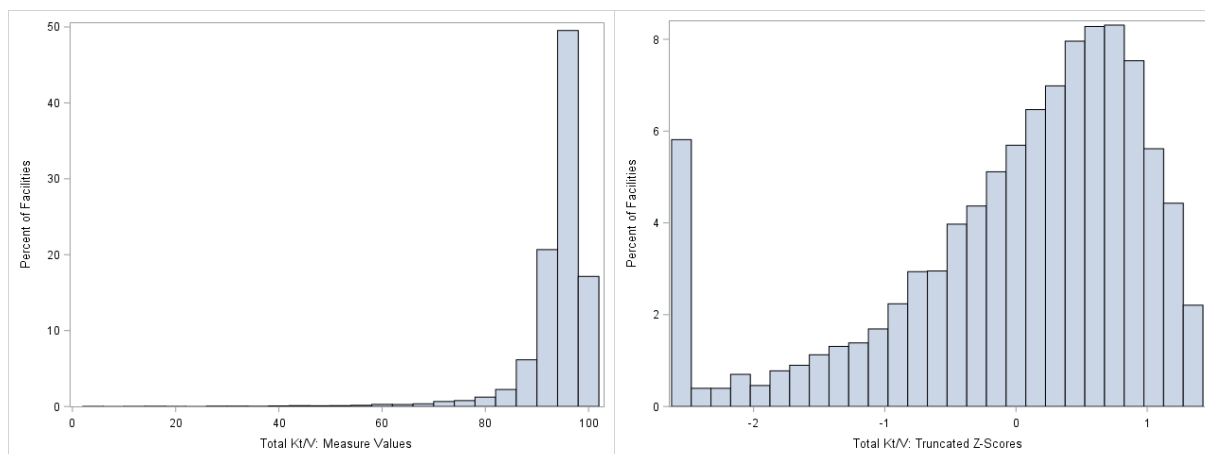


Figure 27: Example of Scoring Kt/V CY2016 Cutoff Year

5.7.2 Current Year Measure Scoring Methodology

For the October 2018 DFC release, the Star Rating System has new, replaced, and updated measures in the measure set, therefore it would not be appropriate to directly compare this current year's data to the original baseline year criteria (CY2014), initially established for the October 2016 release of the updated Star Rating. Instead, the October 2018 Release will use the prior year's DFC Star Rating distribution (CY2016) to establish a new set of cutoffs for the October 2018 release of the DFC Star Rating. This will maintain the longitudinal continuity of the current Star Rating distribution, while using the appropriate score cutoffs established for the new measure set.

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

The standardized ratio measures represent ratios (observed events/expected events) based on expected events relative to the *current year*. Before applying scores to standardized ratio measures in the *current year*, we multiply these ratios by an adjustment factor. The adjustment factor, which accounts for differences in population event rates between the CY2016 and CY2017 data, is applied so that an adjusted *current year* ratio value reflects the same value it would have taken in CY2016. The adjustment factor multiplied by the standardized ratio is the same for all facilities in the *current year*, for that particular measure. It is the average national observed event rate in the *current year* divided by the average national observed event rate in the *cutoff year*. For the October 2018 Star Rating release, the *current year* will be data from CY2017.

We provide an example using CY2016 data as the *current year*, adjusted to the CY2015 data event rates. As an illustration, the example below shows the adjustment that would be made for data collected in 2016 (i.e., *current year*):

$$\text{STrR Adjustment Factor} = \frac{\text{Current Year (CY2016) Transfusions per Patient-Year}}{\text{Cutoff Year (CY2015) Transfusions per Patient-Year}} = \frac{0.218294}{0.247761} = 0.881068$$

Since transfusion rates were lower in 2016 than in 2015, the expected number of events for the average facility is lower in 2016. By multiplying STrR in 2016 by a factor of 0.88 to calculate an adjusted STrR to use in the Star Rating, these facilities are effectively being measured by 2015 criteria, i.e., *cutoff year* criteria. This is interpreted as how the facility performed in the *current year* relative to the typical facility in a pre-established prior year. For example, if the *current year* is 2018 and the *cutoff year* is 2016, a facility's values and ratings will reflect how well its *current year* performance would have been rated in comparison to two years earlier.

Current year facility ratios are first multiplied by the adjustment factor (as described earlier) in order to calculate individual facility adjusted ratios. Each adjusted ratio is mapped to the same percentile rank that the ratio would have been mapped to if it had been observed in the *cutoff year*. The cutoffs used for the percentile ranks are determined by the best measure value within each percentile rank in the *cutoff year*. More detail is provided in Section 5.12.

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

Each measure value is mapped to the same score that the measure value would have been mapped to if it had been observed in the *cutoff year* (CY 2016). Z-scores in the *current year* are

therefore calculated by subtracting the mean and dividing by the standard deviation of the measure in the *cutoff year*. These z-scores are then truncated at the same values as truncated in the *cutoff year* and re-standardized using the mean and the standard deviation of the truncated z-scores in the *cutoff year*. A detailed example is shown in Table 24: Defining Scores for Kt/V in the Cutoff Year (2015) and Table 25: Defining Scores for Kt/V in the Current Year (2016) in Section 5.12.2.

5.7.3 Combining Measure Scores into Final Facility Scores

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

5.8 Missing Values

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

5.9 Translating Facility Final Scores to Star Ratings

To translate the final facility scores into five Star Rating categories, four cutoffs for the final facility scores are determined by data from the *cutoff year*, i.e., the prior year’s Star Rating distribution (see Section 4).

5.9.1 Defining Final Score Cutoffs in the *Cutoff Year*

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

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

This release of the Star Rating system will incorporate the new, replaced, and updated measures described earlier in this report, with new Star Rating category cutoff values. The new cutoff values will preserve the star rating distribution from the previous year's Star Rating. CY 2016 will be used as the year in which these cutoffs are established. The final facility score distribution will use the cutoff thresholds that are the same as reported in the CY2016 data DFC release. These cutoff thresholds will then be applied to the facility Star Rating scores for the October 2018 DFC release.

5.9.3 Assigning Star Ratings in the *Current Year*

The final score cutoffs that are defined using the CY2016 data Star Rating distribution are used to assign Star Ratings to facilities for the *current year*. If the population of facilities improves in their measure performance from the year in which the cutoffs are established, more facilities could be in the higher Star Rating categories compared to the *cutoff year*, as they are being compared to prior measure performance in the earlier year.

Table 18 below reports an example distribution of average *measure values* for facilities within each Star Rating category. As is shown, better measure values and final scores correspond with higher Star Rating categories. Note: This table uses the currently available CY 2016 DFC data in order to illustrate this example. An updated version of this technical report, to be released prior to the July 2018 preview period, will use updated data.

Measure	★	★★	★★★	★★★★	★★★★★
Facility N (%)	405	804 (12%)	2824 (41%)	1715 (25%)	1133 (16%)
SMR	1.24	1.10	1.04	0.97	0.89
SHR	1.26	1.16	1.06	0.93	0.79
STrR	1.43	1.17	0.96	0.75	0.52
SRR	1.16	1.11	1.03	0.94	0.81
Total Kt/V	81.24	91.63	93.55	96.17	97.38
Hypercalcemia	17.44	6.16	4.08	2.23	1.42
SFR	45.74	54.05	59.73	66.01	72.25
Catheter	27.17	19.04	13.85	10.42	7.62
Final Facility	-1.12	-0.42	0.07	0.46	0.84

* 2016 Current Year Results, 2015 Cutoff Year

Table 18: Mean Measure Values and Mean Final Facility Scores Within Each Star Rating Category*

5.10 An Illustration of the Star Rating Calculation

This section illustrates the updated Star Rating methodology that will be implemented beginning with the October 2018 DFC Star Rating release. The calculation is illustrated using two sample facilities: (1) A *Standard* facility, denoted as *Facility A*, which provides a combination of in-center hemodialysis, home hemodialysis, and/or peritoneal dialysis, and (2) A *PD-Only* facility, denoted as *Facility B*, which provides only peritoneal dialysis services. This illustrates how PD-only versus all other facilities are treated in the Star Rating calculation. Note that these examples use currently available data, where CY2015 is the *cutoff year*, and CY2016 is the *current year* to illustrate this example. An updated version of this technical report, to be released prior to the July 2018 preview period, will use updated data.

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

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

- **Step 2: Define Scores in a Cutoff Year**

- Standardized Ratio Measures: Apply probit scoring to each measure
 - Generate 199 percentile ranks for each measure (0.5 to 99.5)
 - Generate probit scores where the score = $\phi^{-1}(\text{percentile rank} / 100)$
- Percentage Measures: Apply iterative truncated Z-score algorithm to each realigned measure
 - Let the measure of interest be m and first standardize m to get z
 - Iteratively truncate z at δ^+ , δ^- to get t and standardize t to get w

The *cutoff year measure values* and *standardized measure scores* are reported in Table 19 below. Here, *measure value* refers to the value as reported for DFC. *Standardized measure scores* (Std. Score) refers to the transformed measure values for each individual metric, after applying Step 2, which are used to calculate a facility's final score and subsequent Star Rating:

Measure	Facility A (A Standard Facility)		Facility B (A PD-Only Facility)	
	Measure Value	Std. Score	Measure Value	Std. Score
STrR	0.4826	0.7554	1.0744	-0.3451
SHR	0.9100	0.2275	1.2605	-1.1031
SMR	1.0602	0.3319	1.0188	-0.1637
SRR	0.8999	0.3451	1.0407	-0.1637
SFR	47.1398	1.6255	N/A	N/A

Measure	Facility A (A Standard Facility)		Facility B (A PD-Only Facility)	
	Measure Value	Std. Score	Measure Value	Std. Score
Catheter	11.3420	0.4566	N/A	N/A
Total Kt/V	95.6855	0.7080	71.5434	-2.5798
Hypercalcemia ^a	3.8356	0.3514	2.4116	0.7037

Table 19: Cutoff Year Measure Values and Standardized Measure Scores

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

- Standardized Ratio Measures
 - Apply adjustment factor to *current year* measure values.
 - Assign probit scores in the *current year* using bounds defined in the *cutoff year*
- Percentage Measures
 - Standardize *current year* measure values using *cutoff year* $sd(m)$ and $mean(m)$
 - Truncate standardized measure scores at (δ^+, δ^-) from *cutoff year*
 - Re-standardize truncated scores by $sd(t)$ and $mean(t)$ from *cutoff year*

In our example, the *current year* measure values and standardized measure scores are reported in Table 20.

Measure	Facility A		Facility B	
	Measure Value	Std. Score	Measure Value	Std. Score
STrR	0.6786	0.3451	0.0000	2.5800
SHR	0.8262	0.5828	1.2006	-0.8965
SMR	0.9819	-0.0125	1.0004	-0.0878
SRR	0.9439	0.2019	1.4543	-1.5548
SFR	45.8396	-1.7495	N/A	N/A
Catheter	15.0546	-0.0980	N/A	N/A
Total Kt/V	97.0257	0.9759	82.3315	-1.9615
Hypercalcemia	1.7685	0.8628	2.3679	0.7145

Table 20: Current Year Measure Values and Standardized Measure Scores

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

- Determine which facilities will be rated in the *cutoff year* based on the suppression criteria outlined in step 1
- Score the facility in the *cutoff year*
 - Average standardized measure scores within each domain to obtain domain scores
 - Average domain scores to obtain a final score
- Define Star Ratings in *cutoff year* based on the defined Star Rating proportions (i.e., the prior year's Star Rating distribution)
- Define the Star Rating cutoffs as the average of the greatest lower bound and the least upper bound between two adjacent Star Rating categories

For our example facilities, the *cutoff year* domain scores and final scores are reported in Table 21 below; the Star Rating cutoffs are reported in Table 22. Note that Cutoff 1 is defined to be the average score between the highest scoring facility in the 1-Star category and the lowest scoring facility in the 2-Star category. Cutoffs for categories 2-4 are defined similarly.

Measure	Facility A	Facility B
Domain 1	0.2491	-0.4439
Domain 2	-0.5844	N/A
Domain 3	0.5297	-0.9380
Final Score	0.0648	-0.6910

Table 21: Cutoff Year Domain Scores and Final Scores

Cutoff	Cutoff between 1-Star & 2-Stars	Cutoff between 2-Stars & 3-Stars	Cutoff between 3-Stars & 4-Stars	Cutoff between 4-Stars & 5-Stars
Value	-0.6901	-0.2294	0.3015	0.6329

Table 22: Cutoff Values for Star Rating Categories

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

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

For our example facilities, the *current year* domain scores and final scores are reported in Table 23 below. Using the cutoffs reported in Table 22, the *Standard* facility would be assigned 3-Stars while the *PD-Only* facility would be assigned 2-Stars.

Measure	Facility A	Facility B
Domain 1	0.2793	0.0102
Domain 2	-0.9238	N/A
Domain 3	0.9194	-0.6235
Final Score	0.0916	-0.3066
Star Rating	3-Star	2-Star

Table 23: Current Year Domain Scores and Final Scores

5.12 Additional Details

5.12.1 Detailed Example of Scoring Measures in the Standardized Outcomes Domain

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

5.12.2 Detailed Example of Scoring Percentage Measures

Here we show how truncated z-scores are defined in the *cutoff year* and applied in the *current year*. Table 24 shows how scoring is defined in the *cutoff year*. In the first row, we display Kt/V and its summary statistics for CY 2015. In the second row, the z-score is obtained by subtracting each Kt/V value by its mean (91.69) and dividing by its standard deviation (6.91). In the third row, initial truncated z-scores are calculated by truncating the z-score at a lower bound (-1.80) and upper bound (here no truncation needed for the upper bound of Kt/V since it is already below 2.58). Finally, in the fourth row, the initial Kt/V truncated z-score is re-standardized by subtracting each value by its mean (0.07) and dividing by its standard deviation (0.72). Note that the truncation bounds in row 2 are chosen by an iterative algorithm that ensures that the re-standardized measure lies within -2.58 and 2.58. The summary statistics in this table are then used to calculate the scores in the *current year* (2016).

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

Table 24: Defining Scores for Kt/V in the Cutoff Year (2015)

Table 25 shows how scoring is defined in the *current year*. The first row reports Kt/V and its summary statistics in CY2017. In the second row, the z-score is obtained by subtracting each Kt/V value by the *cutoff year* mean (91.69) and dividing by the *cutoff year* standard deviation (6.91) in Table 24. In the third row, initial truncated z-scores are formed by truncating the z-score at the lower bound (-1.80) and upper bound (no bound needed for Kt/V) used in the *cutoff year*. Finally, in the fourth row, the initial Kt/V truncated z-score is re-standardized by subtracting each value by the mean (0.07) and dividing by the standard deviation (0.72) of the initial truncated z-scores in the *cutoff year*. Using the summary statistics from the *cutoff year*, the Kt/V values are scored by criteria defined in the *cutoff year*. Note that the mean of the re-standardized score in Table 25 is greater than 0, indicating improvement in the population average of Kt/V from the *cutoff year*.

Variable	Mean	SD	Minimum	Maximum
Kt/V Measure Value	94.01	6.77	2.50	100.00
Kt/V Z-Score	0.60	0.86	-11.00	1.36
Initial Kt/V Truncated Z-Score	0.64	0.62	-2.58	1.36

Final

Centers for Medicare & Medicaid Services

Variable	Mean	SD	Minimum	Maximum
Final Kt/V Truncated Z-Score (Re-Standardized)	0.80	0.86	-2.58	1.80

Table 25: Defining Scores for Kt/V in the Current Year (2016)

Acronyms

Acronym	Definition
AFS	Annual Facility Survey
AHRQ	Agency for Healthcare Research and Quality
AKI	Acute Kidney Injury
AV	Arterial Venous
AVF	Arterial Venous Fistula
BMI	Body Mass Index
BSI	Blood Stream Infections
CAPD	Continuous Ambulatory Peritoneal Dialysis
CASPER	Certification and Survey Provider Enhanced Report System
CC	HHS Hierarchical Condition Categories
CCN	CMS Certification Number
CCPD	Continuous Cycling Peritoneal Dialysis
CCS	AHRQ Clinical Classification Software
CHOW	Change of Ownership
CKD	Chronic Kidney Disease
CMS	Centers for Medicaid and Medicare Services
CROWNWeb	Consolidated Renal Operations in a Web-enabled Network
CY	Calendar Year
DFC	Dialysis Facility Compare
DFR	Dialysis Facility Reports
EDB	Enrollment Database
ESA	Erythropoiesis Stimulating Agents
ESRD	End Stage Renal Disease
FDA	Food and Drug Administration
FSD	First Service Date
HCP	Healthcare Personnel
HCPCS	Healthcare Common Procedure Coding System
HD	Hemodialysis

Acronym	Definition
HHS	Health and Human Services
HIV	Human Immunodeficiency Virus
HWR	Hospital-wide Readmission Measure
ICH CAHPS	In Center Hemodialysis - Consumer Assessment of Healthcare Providers and Systems
KDOQI	Kidney Disease Outcomes Quality Initiative
Kt/V	K (dialyzer clearance of urea)* t (dialysis time)/ V (patient's total body water)
LDO	Large Dialysis Organization
LTCH	Long Term Care Hospitals
MedPAC	Medicare Payment Advisory Commission
NCH	National Claims History database
NHSN	National Healthcare Safety Network
NHSN BSI	National Health Safety Network Blood Stream Infection
nPCR	Normalized protein catabolic rate
NQF	National Quality Foundation
OPTN	Organ Procurement and Transplant Network
PD	Peritoneal Dialysis
PMMIS	Program Management and Medical Information System
POS	Provider of Service
PPS	Prospective Payment System
PY	Payment Year
QDFC	Quarterly Dialysis Facility Compare
QIES	Quality Improvement Evaluation System
QIP	Quality Incentive Program
QM	Quality Measure
RDS	Renal Data Systems
REBUS	Renal Beneficiary and Utilization System
REMIS	Renal Management Information System
SAF	Standard Analysis File
SHR	Standardized Hospitalization Ratio

Acronym	Definition
SIMS	Standard Information Management System
SMR	Standardized Mortality Ratio
SNF	Skilled Nursing Facility
spKt/V	“Single pool” Kt/V as it assumes that excess water and urea are removed from only one body compartment, and does not reflect rebound of water and waste products contributed by other body compartments.
SRR	Standardized Readmission Ratio
STrR	Standardized Transfusion Ratio
TEP	Technical Expert Panel
TPS	Total Performance Score
UKM	Urea Kinetic Modeling
URR	Urea Reduction Ratio
USRDS	United States Renal Data System
VA	Veterans Affairs
VAT	Vascular Access Type

Glossary

CMS Certification Number (CCN) Open Date

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

B. Clarification of ESRD QIP Terminology: “CMS Certification Number (CCN) Open Date”

Some stakeholders have expressed confusion about the use of the term “CMS Certification Number (CCN) Open Date” under the ESRD QIP (for example, see 79 FR 66186). We interpret this term to mean the “Medicare effective date” under 42 CFR 489.13, which governs when the facility can begin to receive Medicare reimbursement for ESRD services under the ESRD PPS. Thus, a facility is eligible, with respect to a particular payment year, to receive scores on individual measures and participate in general in the ESRD QIP based on the facility’s CCN Open Date (*i.e.*, Medicare effective date)