Guide to the Quarterly Dialysis Facility Compare – Preview Report for January 2020 Refresh

Overview, Methodology, and Interpretation

October 2019

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I. Purpose of this Guide and the Quarterly Dialysis Facility Compare Reports

This guide explains in detail the contents of the Quarterly Dialysis Facility Compare (QDFC) reports that were prepared for each dialysis facility under contract to the Centers for Medicare & Medicaid Services (CMS). Included here are the reports' objectives, discussions of methodological issues relevant to particular sections of each report, and descriptions of each data summary.

These reports include information about directly actionable practice patterns such as dose of dialysis, vascular access, mineral metabolism, and anemia management, as well as patient outcomes (such as mortality, hospitalization, hospital readmission and transfusions) that can be used to inform and motivate reviews of practices. The information in the report facilitates comparisons of facility patient characteristics, treatment patterns, and outcomes to local and national averages. Such comparisons help evaluate patient outcomes and account for important differences in the patient mix - including age, sex, and patients' diabetic status - which in turn enhances each facility's understanding of the clinical experience relative to other facilities in the state and nation.

The QDFC report provides facilities with advance notice of their new and updated quality measures that will be reported on the Dialysis Facility Compare (DFC) website, allowing dialysis patients to review and compare characteristics and quality information on dialysis facilities in the United States.

We welcome your participation and feedback concerning the clarity, utility, limitations, and accuracy of this report. You will find information on how to directly provide feedback to us at the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) in Section XI.

II. Overview

The University of Michigan Kidney Epidemiology and Cost Center has produced the QDFC reports with funding from CMS. Each facility's report is available to the facility on the secure Dialysis Reports website (www.DialysisData.org).

Each report provides summary data on each facility's maintenance dialysis patients for the years 2015-2018. These summaries are compiled using the UM-KECC ESRD patient database, which is largely derived from the CMS Consolidated Renal Operations in a Webenabled Network (CROWN/CROWNWeb), which includes Renal Management

Information System (REMIS), the CMS Annual Facility Survey (Form CMS-2744), the CMS Medical Evidence Form (Form CMS-2728), and the Death Notification Form (Form CMS-2746). The UM-KECC ESRD patient database also includes data from Medicare dialysis and hospital payment records; clinical data from the CROWNWeb system, transplant data from the Organ Procurement and Transplant Network (OPTN), the Nursing Home Minimum Dataset; the Quality Improvement Evaluation System (QIES) Workbench, which includes data from the Certification and Survey Provider Enhanced Report System (CASPER); and the Dialysis Facility Compare (DFC). The database is comprehensive for Medicare patients. Non-Medicare patients are included in all sources except for the Medicare payment records. The CROWNWeb system provides tracking by dialysis provider and treatment modality for non-Medicare patients.

This quarter we provided reports for more than 7,500 Medicare-approved dialysis facilities in the United States. We did not create reports for transplant-only facilities or U.S. Department of Veterans Affairs (VA)-only facilities. The Standardized Ratios/Rates for Mortality, Hospitalization, Readmission, Transfusion, Fistula, Transplant Waitlist, and Infection (SMR, SHR, SRR, STrR, SFR, SWR, PPPW, and SIR) were not calculated for facilities with very small numbers of patients. The SMR is not reported for facilities with fewer than 3 expected deaths, the SHR is not reported for facilities with fewer than 5 patient years at risk (or approximately 10 expected admissions), the SRR is not reported for facilities with fewer than 11 hospital discharges, the STrR is not reported for facilities with fewer than 10 patient years at risk (or approximately 4 expected transfusions), the SWR is not reported for facilities with fewer than 2 expected waitlist events or fewer than 11 eligible patients, and the SIR is not reported if there are fewer than 12 complete months of data during the performance year and fewer than 132 eligible patient-months according to NHSN. Percentage of Prevalent Patients Waitlisted PPPW is not reported for facilities with fewer than 11 eligible patients. Statistics produced for such small facilities can be unstable and particularly subject to random variation, and thus difficult to interpret.

This guide discusses the meaning of the data summaries each report provides, and describes the methodology used to calculate each summary (Sections III-IX). Sections V-X are organized according to the order of the summaries in the QDFC report, and may serve as references for their interpretation. Since in many cases, understanding the content of a particular section requires you to understand the issues presented in the previous section, we recommend that you review the sections in order.

The first page provides the purpose and overview of the report, the new activities of this quarter, and how to submit comments. Starting on page 3, the report includes the DFC preview followed by six tables which contain detailed information for your facility as well as regional averages for comparison. Table 1 provides patient mortality (2015 - 2018),

hospitalization (2018), hospital readmission (2018), transfusion (2018), fistula (April 2018-March 2019), transplant waitlist ratio (2015 – 2017), and transplant waitlist percent (April 2018-March 2019) summaries. Note that for the four-year mortality summaries, individual patients typically contribute data for more than one year. Table 2 reports National Healthcare Safety Network bloodstream infection data for your facility for 2018. Table 3 reports hemoglobin for your facility April 1, 2018 – March 31, 2019 as well as for each quarter during the time period. Table 4 reports dialysis adequacy, hypercalcemia, serum phosphorous concentrations, long-term catheter, and pediatric nPCR for your facility for April 1, 2018 – March 31, 2019 as well as for each quarter during the time period. Table 5 contains patient experience of care measures from the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) survey for April 20, 2018 – July 13, 2018 and October 19, 2018 – January 11, 2019. Finally, Table 6 provides an incremental look at how the star rating was calculated from the DFC measures for your facility from 2015 to 2018.

Each row of a table in the report summarizes a data element. Your facility has a column for each time period, and in most cases, two columns for the corresponding geographical summaries, including averages for your facility's state, and the entire nation. Whenever the statistic reported is a count (n), we calculated regional and national averages by taking the average count for all facilities in that area. When the statistic reported for a period included more than one year, we annualized regional and national values to make them comparable to a single-year period. When a statistic is a percent, rate, or ratio, we calculated state and national summaries by pooling together all individual patients in that area to obtain an estimate for that area as if it were one large facility. For the vascular access measures, we calculated state and national summaries by averaging facility level values. We do not report state summary data for dialysis facilities in states or U.S. territories with only one or two dialysis units. We do provide summaries for the nation for facilities in these states or territories.

III. Assigning Patients to Facilities

Patient Assignment Criteria for SMR, SHR, and STrR

This section describes the methods we used to assign patients to a facility in order to calculate the summaries appearing in the Preview Table and Table 1 related to the Standardized Mortality, Hospitalization, and Transfusion Ratios.

Because some patients receive dialysis treatment at more than one facility in a given year, we use standard methods based on assigning person-years to a facility, rather than on assigning a patient's entire follow-up to a facility. We developed conventions which define

the group of patients assigned to a facility at any time during the particular year. This method is described below.

General Inclusion Criteria for Dialysis Patients

We only entered a patient's follow-up into the tabulations after that patient had ESRD for greater 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 assigned patients to a facility only after they had been on dialysis there for at least 60 days. This 60 day period is used both for patients starting renal replacement therapy for the first time and for those who returned to dialysis after a transplant. That is, deaths and survival during the first 60 days do not impact the SMR of that facility.

Identifying Patients Treated at Each Facility

For each patient, we identified the dialysis provider at each point in time using a combination of Medicare dialysis claims, the Medical Evidence Form (Form CMS-2728), and data from CROWNWeb. Starting with day 91 of ESRD, we determined facility treatment histories for each patient, and then assigned each patient to 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. State and Network summaries do not include patients who were not assigned to a facility; these patients are, however, included in the U.S. summaries.

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, we considered the patient lost to follow-up, and did not continue to include that patient in the analysis. If evidence of dialysis re-appeared, the patient was 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 of lost to follow-up were not created in these cases since the instructions for CROWNWeb only require checking patient data for continued accuracy, but do not have a requirement for updating if there are not any changes.

Patient Assignment Criteria for CROWNWeb Measures (Standardized Fistula Rate, Long-Term Catheter Rate, Hypercalcemia, Serum Phosphorus, Kt/V measures and nPCR) and Percentage of Prevalent Patients Waitlisted (PPPW) measure

For each patient, we identified the dialysis provider at each point in time primarily using data from CROWNWeb, the Medical Evidence Form (Form CMS-2728) and Medicare dialysis claims. Both patient assignment to the provider and modality (either hemodialysis or peritoneal dialysis) were determined according to the information reported in the above mentioned data sources. For each reporting month, patients were required to have been indicated as treated by the facility for the complete month in order to be included in the denominator for these measures. 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. However, if the patient received temporary treatment at a different facility, such as in the case of hospitalization or travelling, 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. In addition, please note that the number of sessions are not considered when the patient is attributed to a facility. 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.

IV. Dialysis Facility Compare Preview

The measures included in this table will appear on the DFC website for this facility. Please refer to sections V-X for more information on these measures. Dialysis facilities may submit comments to CMS during the comment period and throughout the year to UM-KECC on the measures included in this report by logging on to the secure section of www.DialysisData.org.

V. Mortality Summary for Medicare Dialysis Patients (2015-2018), Hospitalization Summary for Medicare Dialysis Patients (2018), Readmission Summary for Dialysis Patient Hospitalizations (2018), Transfusion Summary for Adult Medicare Dialysis Patients (2018), Fistula Summary for Adult HD Dialysis Patients (04/01/2018-03/31/2019), and Transplant Waitlist Ratio and Percent Summaries for Dialysis Patients (2015-2017 and 04/01/2018-03/31/2019, respectively).

The first section of Table 1 (rows 1a-1g) provides information about patient mortality for all Medicare dialysis patients treated at your facility between 2015 and 2018. We also reported the averages in your state, and the nation for this combined four-year period. The remainder of Table 1 (rows 1h-1aq) provides information about hospitalization admissions among all Medicare dialysis patients, readmissions of Medicare-covered hospitalizations that ended in 2018, transfusions among all adult Medicare dialysis patients treated at your facility in 2018, rate of fistula use among all adult HD patients assigned to your facility between April 2018-March 2019, transplant waitlist ratio among new dialysis patients assigned to your facility between 2015 and 2017, and transplant waitlist percent summary among all dialysis patients treated at your facility between April 2018-March 2019, along with state and national comparisons for this reporting period.

Standardized Mortality Ratio (SMR) (1a – 1g)

In the first section of the table, we have calculated a relative mortality rate, or Standardized Mortality Ratio (SMR), for Medicare patients in your facility. The SMR compares the observed death rate in your facility to the death rate that was expected based on national death rates during that year for patients with the same characteristics as those in your facility (Wolfe, 1992). The SMR uses expected mortality calculated from a Cox model (SAS Institute Inc., 2000; Andersen, 1993; Collett, 1994), adjusting for calendar year, patient age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, patient

comorbidities at incidence, prevalent comorbidities, body mass index (BMI) at incidence, and population death rates.

The SMR accounts for many patient characteristics known to be associated with mortality, but cannot account for all factors that may explain differences in mortality between facilities. For example, since the SMR accounts for age and diabetes, an older average age or large percentage of diabetic patients at a facility would not elevate the SMR. Other factors, such as nutritional status or factors relating to the process of care are not accounted for. Therefore, if the SMR statistic indicates potential differences in mortality for your facility compared to regional or national averages, please consider the role other important factors play within your facility. As with the hospitalization summaries which are described below, you will find the mortality summaries most informative if you use them as part of an integrated quality assurance process.

Medicare Patients (1a)

We based the mortality summaries in the first half of the table (rows 1a-1g) on the dialysis patients who received treatment in your facility according to the conventions described in Section III. We also require that patients reach a certain level of Medicare-paid dialysis bills to be included in mortality statistics, or that patients have Medicare inpatient claims during the period. For the purpose of analysis, each patient's follow-up time is broken into periods defined by time since dialysis initiation. For each patient, months within a given period are included if that month in the period is considered 'eligible'; a month is deemed eligible if it is within two months of a month having at least \$900 of Medicare-paid dialysis claims or at least one Medicare inpatient claim.

Patient Years at Risk (1b)

The number of patient years at risk indicates the total amount of time we followed patients in this table's analyses. For all patients, time at risk began at the start of the facility treatment period (see Section III) and continued until the earliest occurrence of the following: one day prior to a transplant; date of death; end of facility treatment; or December 31 of the year. Since a facility may have treated a patient for multiple periods during the same year, patient years at risk includes time at risk for all periods of treatment at your facility.

Deaths (1c)

We reported the number of deaths that occurred among Medicare dialysis patients during the four years. This count 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, we excluded them from the calculations.

Expected Deaths (1d)

We used a Cox model to calculate the expected deaths for each patient based on the characteristics of that patient, the amount of follow-up time (patient years at risk) for that patient during the year, and the calendar year (SAS Institute Inc., 2000; Andersen, 1993; Collett, 1994). We adjusted the Cox model for calendar year, age, race, ethnicity, sex, diabetes, years since start of ESRD, nursing home status, patient comorbidities at incidence, prevalent comorbidities, and patient BMI at incidence (BMI = weight(kg) / height²(m²)). In cases where BMI were missing for a patient, we used the average values of the group of patients with similar characteristics (age, race, ethnicity, sex, and diabetes). We also controlled for age-adjusted population death rates by state and race, based on the U.S. population in 2014-2016 (National Center for Health Statistics, 2019). As with the deaths in 1c, we then summed these expected deaths in order to obtain the total number of deaths expected for each year at your facility, and we summed the annual values to yield the expected number of deaths over the four-year period for each facility.

Standardized Mortality Ratio (SMR) (1e)

The SMR equals the ratio of the actual number of deaths (1c) divided by the expected number of deaths (1d). The SMR estimates the relative death rate ratio for your facility, as compared to the national death rate in the same year. Qualitatively, the degree to which your facility's four-year SMR varies from 1.00 is the degree to which it exceeds (>1.00) or is under (<1.00) the 2015 - 2018 national death rates for patients with the same characteristics as those in your facility. Quantitatively, if your facility's death rates equal the national death rates (in deaths per patient year or per year at risk) times a multiplicative constant, then the SMR estimates that multiplicative constant. If the multiplicative constant varies for different subgroups of patients, then the SMR estimates a weighted average of those constants according to your facility's patient mix. For example, an SMR=1.10 would indicate that your facility's death rates typically exceed national death rates by 10% (e.g., 22 deaths observed where 20 were expected, according to your facility's patient mix). Similarly, an SMR=0.95 would indicate that your facility's death rates are typically 5% below the national death rates (e.g., 19 versus 20 deaths). An SMR=1.00 would indicate that your facility's death rates equal the national death rates.

We calculated the regional summaries as the ratio of the total number of observed deaths among patients from each region to the number of expected deaths among patients from each region (1c/1d).

Why the national SMR may not be exactly equal to 1.00

The reported 2015 - 2018 SMR for the U.S. as a whole may not be precisely equal to 1.00. The SMR value for the U.S. given in the DFC does not include all U.S. dialysis facilities in its calculation. In particular, as discussed in the Overview, transplant-only, VA facilities, and non-Medicare facilities are not included in the geographic summaries.

Random variation

The SMR estimates the true ratio of death rates at your facility relative to the national death rates. An SMR value that differs from 1.00 indicates that your facility's death rates differ from the national death rates. However, the SMR's value varies from year to year above and below the true ratio, due to random variation. Thus, your facility's SMR could differ from 1.00 due to random variation rather than to a fundamental difference between your facility's death rates and the nation's. Both the p-value and the confidence interval, discussed below, will help you interpret your facility's SMR in the face of such random fluctuations. We based our calculations of both items on an assumed Poisson distribution for the number of deaths at your facility.

Confidence Interval (Range of Uncertainty) for SMR (1e)

The 95% confidence interval (or range of uncertainty) gives a range of plausible values for the true ratio of facility-to-national death rates, in light of the observed SMR. The upper and lower confidence limits enclose the true ratio approximately 95% of the time if this procedure were to be repeated on multiple samples. Statistically significant confidence intervals do not contain the ratio value 1.00.

P-value for SMR (1f)

The p-value measures the statistical significance of (or evidence against) the hypothesis that the true death rate for your facility is the same as (neither higher nor lower than) what would be predicted from the overall national death rate. The p-value is the probability that the observed SMR would deviate from 1.00 as much as it does, under the null hypothesis that this ratio is equal to 1.00. A small p-value (often taken as <0.05) suggests the ratio between the observed and expected death rates differs significantly from 1.00. The smaller the p-value, the lower the probability that a facility's death rate is equal to the national death rate. Note that the p-value is less than 0.05 whenever the confidence interval does not include the value 1.00. Because the p-value depends on the facility size, a small p-value in a large facility does not necessarily indicate that the difference between this facility's death rate and the national rate is of clinical importance.

The SMR's actual value can be used to assess the clinical importance of the difference between your facility's and the nation's death rates. An SMR of 1.25, for example, indicates that your facility's death rate is 25% higher than the national average, which may

well be judged to be clinically important. On the other hand, SMR values in the range of 0.95 to 1.05 would generally not be considered to be of clinical interest. With very large facilities, even relatively small differences in the SMR can lead to significant results, so both aspects (the actual value of the SMR and the p-value) are important.

Mortality Rate (per 100 patient-years) and Confidence Interval (Range of Uncertainty) for Mortality Rate (1g)

The mortality rate and confidence interval for the mortality rate are calculated by multiplying the SMR (and confidence interval for SMR) by the national rate of mortality. The national rate of mortality for 2015-2018 is 22.1 deaths per 100 patient-years.

Classified Category

If the facility SMR is less than 1.00 and statistically significant (p<0.05), the classification is "Better than Expected". This classification is based on the measure ratio, not the rate. If the ratio is greater than 1.00 and statistically significant (p<0.05), the classification is "Worse than Expected". Otherwise, the classification is "As Expected" on DFC. Please note that the SMR is not reported on DFC if it is based on fewer than 3 expected deaths.

Standardized Hospitalization Ratio (SHR): Admissions (1h – 1n)

The SHR (admissions) is calculated by dividing the observed total admissions in 1j by the expected total admissions in 1k. As with the SMR, it enables a comparison of your facility's experience to the national average. A value of less than 1.0 indicates that your facility's total number of admissions was less than expected, based on national rates; whereas a value of greater than 1.0 indicates that your facility had a rate of total admissions higher than the national average. Note that this measure is adjusted for the actual patient characteristics of age, sex, diabetes, duration of ESRD, nursing home status, comorbidities at incidence, BMI in your facility, and prevalent comorbidities. Additionally, the estimate is compared to the US hospitalization rates for Medicare dialysis patients for the same year.

Medicare Patients (1h)

The number of Medicare dialysis patients included in the hospitalization summaries (1h) is generally smaller than the number of patients included in the mortality summaries (1a). We calculated hospitalization rates based only on periods in which dialysis patients had satisfied the Medicare payment criterion (described above).

Patient Years at Risk (1i)

The number of patient years at risk indicates the total amount of time we followed patients in this table's analyses. For all patients, time at risk began at the start of the facility treatment period (see Section III) and continued 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. Since a facility may have treated a patient for multiple periods during the same year, patient years at risk includes time at risk for all periods of treatment at your facility.

Total Admissions (1j)

This is the total number of inpatient hospital admissions among the Medicare dialysis patients assigned to this facility. The total number of admissions includes multiple admissions (i.e., second, third, etc. hospitalizations for the same patient). If a patient was admitted near the end of one year and not discharged until the following calendar year (e.g., admitted on 12/28/2013 and discharged on 1/6/2014), the admission would count only in the second year (zero admissions in 2013 and one admission in 2014).

Expected Total Admissions (1k)

We calculated the expected number of hospital admissions among Medicare dialysis patients in a facility based on national rates for hospital admissions in the same year. The expected number of admissions is calculated from a Cox model, adjusting for patient age, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, BMI at incidence, calendar year, and prevalent comorbidities. Duration of ESRD is divided into six intervals with cut points at 6 months, 1 year, 2 years, 3 years, and 5 years and hospitalization rates are estimated separately within each interval. For each patient, the time at risk in each ESRD interval is multiplied by the (adjusted) national admissions rate for that interval, and a sum over the intervals gives the expected number of admissions for each patient. For each patient, the expected number is adjusted for the characteristics of that patient and summing over all patients gives the result.

Standardized Hospitalization Ratio (SHR) for Admissions (11)

The SHR (admissions) is calculated by dividing the observed total admissions in 1j by the expected total admissions in 1k. As with the SMR, it enables a comparison of your facility's experience to the national average. A value of less than 1.0 indicates that your facility's total number of admissions was less than expected, based on national rates; whereas a value of greater than 1.0 indicates that your facility had a rate of total admissions higher than the national average. Note that this measure is adjusted for the actual patient characteristics of age, sex, diabetes, duration of ESRD, nursing home status, comorbidities at incidence, prevalent comorbidities, and BMI in your facility. Additionally, the estimate is compared to the US hospitalization rates for Medicare dialysis patients the same year.

Confidence Interval (Range of Uncertainty) for SHR (11)

The 95% confidence interval (or range of uncertainty) gives a range of plausible values for the true ratio of facility-to-national hospitalization rates, in light of the observed SHR. The upper and lower confidence limits enclose the true ratio approximately 95% of the time if this procedure were to be repeated on multiple samples. Statistically significant confidence intervals do not contain the ratio value 1.00.

P-value for SHR (1m)

The p-value measures the statistical significance of (or evidence against) the hypothesis that the true hospitalization rate for your facility is the same as (neither higher nor lower than) what would be predicted from the overall national hospitalization rate. The p-value is the probability that the observed SHR would deviate from 1.00 as much as it does, under the null hypothesis that this ratio is truly equal to 1.00. A small p-value (often taken as <0.05) indicates that the observed ratio would be highly unlikely under the null hypothesis, and the observed SHR suggests that the ratio between the observed and expected hospitalization rates differs significantly from 1.00. The smaller the p-value, the lower the probability that a facility's hospitalization rate is equal to the national hospitalization rate. Note that the p-value is less than 0.05 whenever the confidence interval does not include the value 1.00. Because the p-value depends on the facility size, a small p-value in a large facility does not necessarily indicate that the difference between this facility's hospitalization rate and the national rate is of clinical importance.

The SHR's actual value can be used to assess the clinical importance of the difference between your facility's and the nation's hospitalization rates. An SHR of 1.25, for example, indicates that your facility's hospitalization rate is 25% higher than the national average, which may well be judged to be clinically important. On the other hand, SHR values in the range of 0.95 to 1.05 would generally not be considered to be of clinical interest. With very large facilities, even relatively small differences in the SHR can lead to significant results, so both aspects (the actual value of the SHR and the p-value) are important.

<u>Hospitalization Rate (per 100 patient-years) and Confidence Interval (Range of Uncertainty)</u> for Hospitalization Rate (1n)

The hospitalization rate and confidence interval for the hospitalization rate are calculated by multiplying the SHR (and confidence interval for SHR) by the national rate of hospitalization. The national rate of hospitalization for 2018 is 188.8 hospitalizations per 100 patient-years.

Classified Category

If the facility SHR is less than 1.00 and statistically significant (p<0.05), the classification is "Better than Expected". This classification is based on the measure ratio, not the rate. If the ratio is greater than 1.00 and statistically significant (p<0.05), the classification is "Worse than Expected". Otherwise, the classification is "As Expected" on DFC. Please note that the SHR is not reported on DFC if the facility has less than 5 patient years at risk.

Standardized Hospital Readmission (SRR) Summary for Dialysis Patients (10-1t)

Hospital readmission rates are an important indicator of patient morbidity and quality of life. Relative to the general population, dialysis patients experience much higher levels of

mortality (de Jager et al., 2009) and morbidity (e.g., hospital readmission; MedPAC, 2007). Both hospitalization and readmission rates reflect morbidity and quality of life of dialysis patients as well as medical costs. For example, during the calendar year 2012, dialysis patients were admitted to the hospital twice on average and spent an average of 11 days in the hospital. This is indicative of a poorer quality of life for dialysis patients and also accounts for approximately 37% of Medicare expenditures for ESRD patients (USRDS, 2014). Furthermore, 35% of hemodialysis patients discharged from the hospital had a readmission within 30 days (USRDS, 2014). In other settings (e.g., cardiovascular disease, cancer), studies show that about 25% of unplanned readmissions are preventable, that preventable for patients with more severe conditions (van Walraven et al., 2011). Readmission summaries for dialysis patients are reported in the third section of Table 1.

This report includes summaries of unplanned readmission rates among Medicare dialysis patients in your facility, along with regional and national hospitalization rates for comparison. These summaries are based on administrative data obtained primarily from Medicare claims and are risk adjusted for the discharging hospital and for patient-level factors. This readmission rate, as well as the SHR, can be viewed as giving a partial assessment of hospital resource utilization across facilities.

Like the SMR and SHR, the SRR compares your facility's observed number of unplanned readmissions with the number that would be expected if patients at your facility were instead subject to the national average readmission rate. The expected number is computed given the number and characteristics of the hospital discharges during the year. The probability that a given discharge results in a readmission is based on a hierarchical logistic model that adjusts for the discharging hospital of the index hospitalization and for the patient characteristics of age, sex, diabetes, duration of ESRD at index hospital discharge, comorbidities in the year preceding the index hospital discharge, the presence of a high-risk diagnosis at index hospital discharge, length of stay of the index hospital discharge, and BMI at onset of ESRD.

Identifying Patients Treated at Each Facility

We identified each patient's dialysis provider over time using a combination of Medicare dialysis claims, the Medical Evidence Form (Form CMS-2728) and data from CROWNWeb. We determined these facility treatment histories as of day 1 of ESRD and used them to identify a patient's dialysis treatment facility at the time of each index discharge.

We remove a patient from a facility upon receiving a transplant, withdrawing from dialysis or recovering renal function. Additionally, we considered a patient lost to follow-up for

whom the only evidence of dialysis treatment is the existence of Medicare claims, and we removed them 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 continue to include that patient in the analysis. If evidence of dialysis re-appeared, the patient re-entered the analysis. Finally, we extended all CROWNWeb records noting continuing dialysis until the appearance of any evidence of recovery, transfer or death. We did not create periods of lost to follow-up in these cases since the instructions for CROWNWeb only require checking patient data for continued accuracy and do not require updating if there are no changes.

Differences in Inclusion Criteria for SRR Measure

The inclusion criteria and facility assignment methods for the SRR described above are somewhat different than those for the SMR, SHR and STrR. First, patients are included in the SRR as of the first day of ESRD treatment. Second, patients are included in the SRR for a facility as soon as the patient begins treatment at the facility. This is in contrast to the other standardized measures, which require a patient to have ESRD for greater than 90 days and be in a facility for at least 60 days before he or she is included in the measure. The last difference is that patients are removed from the SRR analysis at withdrawal or lost to follow-up rather than 60 days later as is done for the other standardized measures.

Index discharges (10)

Index discharges are those hospitalizations that serve as starting points for identifying readmissions. This is the number of Medicare-covered hospital discharges occurring at acute-care hospitals in the calendar year for dialysis patients treated at your facility. Note that this does not include discharges from long-term care hospitals (LTCHs) or skilled nursing facilities (SNFs). An index discharge is attributed to the dialysis facility to which the patient is assigned as of his/her discharge date.

Total readmissions (1p)

The number of readmissions for the facility is defined as the number of index discharges followed by an unplanned readmission within 4-30 days of discharge—in other words, the number of index discharges for which the next admission was unplanned and occurred within 4-30 days of the index discharge. Like index discharges, those hospitalizations considered as potential readmissions are restricted to hospitalizations for inpatient care at acute care hospitals. Note that a hospitalization identified as a readmission may also be an index discharge.

Hospital admissions were classified as being planned or unplanned according to the algorithm developed for CMS' hospital-wide readmission measure (Horwitz et. al., 2012). A detailed description of this algorithm is available at www.dialysisdata.org.

The readmission is assigned to the index discharge dialysis facility regardless of the treatment facility at the time of readmission. In other words, if a patient is discharged from a hospital while assigned to Facility A, transfers to Facility B on her 15th day after hospital discharge, then is readmitted to the hospital on the 20th day after discharge while in Facility B, that readmission will be attributed to Facility A, not to Facility B.

Expected total readmissions (1q)

We calculated the number of hospital readmissions that would be expected given the set of index discharges of dialysis patients in your facility based on national rates for hospital readmissions in the same year. The expected number of readmissions is calculated from a hierarchical logistic model, adjusted for the discharging hospital of the index hospitalization and for the patient characteristics of age, sex, diabetes, duration of ESRD at index hospital discharge, comorbidities in the year preceding the index hospital discharge, the presence of a high-risk diagnosis at index hospital discharge, length of stay of the index hospital discharge, and BMI at onset of ESRD. For each patient, the expected number is adjusted for the characteristics of that patient.

Standardized Readmission Ratio (SRR) (1r)

We calculated the SRR by dividing the observed total readmissions in 1m by the expected total readmissions in 1n. As with the SMR and SHR, the SRR compares your facility's experience to what should be expected on the basis of the national norm. A value of less than 1.0 indicates that your facility's total number of readmissions is less than expected, based on national rates; whereas a value of greater than 1.0 indicates that your facility had a rate of total readmissions higher than would be expected given national rates. Note that this measure is adjusted for the discharging hospital of the index hospitalization and for the patient characteristics described above in section 1n. In addition, the estimate is compared with the US readmission rates for the same year.

Confidence Interval (Range of Uncertainty) for SRR (1r)

The 95% confidence interval (or range of uncertainty) gives a range of plausible values for the true ratio of facility-to-national readmission rates, in light of the observed SRR. The upper and lower confidence limits enclose the true ratio approximately 95% of the time if this procedure were to be repeated on multiple samples. Statistically significant confidence intervals do not contain the ratio value 1.00.

P-value for SRR (1s)

The p-value measures the statistical significance of (or evidence against) the hypothesis that the true readmission rate for a facility is the same as what would be predicted from the

overall national rate. The p-value is the probability that the observed SRR would deviate from 1.00 as much as it does, under the null hypothesis that the ratio is truly equal to 1.00. A smaller p-value indicates that the observed SRR is not likely due to chance and occurs when the observed SRR differs markedly from 1.00. A p-value of less than 0.05 suggests that the ratio between the observed and expected readmission rates differs significantly from 1.00. The smaller the p-value, the lower the probability that a facility's readmission rate is equal to the national readmission rate. A small p-value helps rule out the possibility that an SRR's deviance from 1.00 could have arisen by chance. However, a small p-value does not indicate the degree of importance of the difference between your facility's readmission rate and the nation's.

The SRR's actual quantitative value reflects the clinical importance of the difference between your facility's and the nation's readmission rates. An SRR of 1.25, for example, indicates that your facility's readmission rate is 25% higher than the national average, which may well be judged to be clinically important. On the other hand, SRR values in the range of 0.95 to 1.05 would generally not be considered to be of clinical interest. With very large facilities, even relatively small differences in the SRR can lead to significant results, so both aspects (the actual value of the SRR and the p-value) are important.

Readmission Rate (percentage of hospital discharges) and Confidence Interval (Range of Uncertainty) for Readmission Rate (1t)

The readmission rate and confidence interval for the readmission rate are calculated by multiplying the SRR (and confidence interval for SRR) by the national rate of readmission (26.8% of index discharges in 2018).

Standardized Transfusion Ratio (STrR) (1u - 1aa)

Blood transfusion may be an indicator for underutilization of treatments to increase endogenous red blood cell production (e.g. erythropoiesis-stimulating agents (ESAs), iron). In addition, dialysis patients who are eligible for kidney transplant are at some risk of becoming sensitized to the donor pool through exposure to tissue antigens in blood products, thereby making transplant more difficult to accomplish. Blood transfusions also carry a small risk of transmitting blood borne infections and the development of a reaction to the transfusion. 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 differences in dialysis facility anemia treatment

patterns. This is of particular importance due to recent FDA guidance regarding the use of ESAs and new economic incentives to minimize ESA use introduced by Medicare bundling payment for ESAs. In early 2012, a highly publicized United States Renal Data System (USRDS) study presented at the National Kidney Foundation (NKF) clinical meeting reported increased dialysis patient transfusion rates in 2011 compared to 2010. 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 over-use of blood transfusions to treat ESRD-related anemia.

This report includes summaries of the transfusion rates among adult Medicare dialysis patients in your facility, along with comparative state and national data. Because the intention behind the measure is to detect the possibility of underutilization of alternatives to transfusion, patients' time at risk and transfusion events are not included if they occur within one year of diagnoses contraindicating the use of ESAs. In particular, patients' time at risk is excluded beginning with a Medicare claim for hemolytic or aplastic anemia, solid organ cancer, lymphoma, carcinoma in situ, coagulation disorders, multiple myeloma, myelodysplastic syndrome and myelofibrosis, leukemia, head and neck cancer, other cancers (connective tissues, skin, and others), metastatic cancer, and sickle cell anemia. Once a patient is diagnosed with one of these comorbidities, a patient's time at risk is included only after a full year free of claims that list any diagnosis on the exclusions list.

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

Like the SMR, SHR, and SRR, the STrR is intended to compare your facility's observed number of transfusions to the number that would be expected if patients at your facility were instead subject to the 2018 national average transfusion rates, adjusted by patient characteristics, as described here. The expected national rates are calculated from Cox models (SAS Institute Inc., 2000; Andersen, 1993; Collett, 1994) which make adjustments

for patient age, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, BMI at incidence, and calendar year.

In 2017, the specifications for the Standardized Transfusion Ratio have been revised. We developed a more conservative definition of transfusion events. The revised definition excludes inpatient transfusion events for claims that include only 038 or 039 revenue codes without an accompanying procedure or value code. This more conservative definition of transfusion events is used to calculate the restricted STrR. This more restricted definition of transfusion events results in a reduced total number of events identified as well as the range of total events for dialysis facilities.

We report the modified transfusion summaries for January 1 – December 31, 2018 only.

Adult Medicare Patients (1u)

The number of adult Medicare dialysis patients included in the transfusion summaries (1u) is generally smaller than the number of patients included in the mortality and hospitalization summaries ((1a) and (1h)) because of the exclusion criteria. See above.

Patient Years at Risk (1v)

The number of patient years at risk indicates the total amount of time patients were followed in this table's analyses. For all patients, time at risk began at the start of the facility treatment period (see Section III) and continued until the earliest occurrence of the following: a Medicare claim indicating a diagnosis on the exclusions list, three days prior to a kidney transplant, death, end of facility treatment, or December 31 of the year. Patients whose time at risk was terminated due to a comorbidity on the exclusions list will have future time at risk included beginning after a full year free of claims with diagnoses on the exclusions list. Since a facility may have treated a patient for multiple periods during the same year, patient years at risk includes time at risk for all periods of treatment at your facility.

Total Transfusion (1w)

This is the total number of transfusion events during eligible time-at-risk among the adult Medicare dialysis patients assigned to this facility. The total number of transfusion events includes multiple transfusions (i.e., second, third, etc. transfusions for the same patient).

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

claims) or for outpatient claims, reporting Healthcare Common Procedure Coding System (HCPCS) codes with at least one revenue center codes.

One "transfusion event" is counted per inpatient claim if one or more transfusion-related procedure or value codes are present. We only count a single transfusion event for an inpatient claim regardless of the number of transfusion revenue center, 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. A detailed list of procedure codes, value codes, and System HCPCS codes used to identify transfusion events is included in a separate document available at www.DialysisData.org under the Methodology heading.

Expected Total Transfusion (1x)

We calculated the expected number of transfusion events among Medicare dialysis patients in a facility based on national rates for transfusion events in the same year. The expected number of transfusion events is calculated from a Cox model, adjusting for patient age, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, BMI at incidence, and calendar year. Duration of ESRD is divided into six intervals with cut points at 6 months, 1 year, 2 years, 3 years, and 5 years and transfusion rates are estimated separately within each interval. For each patient, the time at risk in each ESRD interval is multiplied by the adjusted national transfusion rate for that interval, and a sum over the intervals gives the expected number of transfusions for each patient. For each patient, the expected number is adjusted for the characteristics of that patient and summing over all patients gives the result reported in 3.4.

Standardized Transfusion Ratio (STrR) (1y)

The STrR is calculated by dividing the observed total transfusions in s by the expected total transfusions in 1x. As with the SMR and SHR, the STrR enables a comparison of your facility's experience to the national average. A value of less than 1.0 indicates that your facility's total number of transfusion events was less than expected, based on national rates; whereas a value of greater than 1.0 indicates that your facility had a rate of total transfusion events higher than the national average. Note that this measure is adjusted for the actual patient characteristics of age, diabetes, duration of ESRD, nursing home status,

comorbidities at incidence, and BMI in your facility. Additionally, the estimate is compared to the US transfusion rates for the same year.

Confidence Interval (Range of Uncertainty) for STrR (1y)

The 95% confidence interval (or range of uncertainty) gives a range of plausible values for the true ratio of facility-to-national transfusion rates, in light of the observed STrR. The upper and lower confidence limits enclose the true ratio approximately 95% of the time if this procedure were to be repeated on multiple samples. Statistically significant confidence intervals do not contain the ratio value 1.00.

P-value for STrR (1z)

The p-value measures the statistical significance of (or evidence against) the hypothesis that the true transfusion rate for a given facility is the same as (neither higher nor lower than) what would be predicted from the overall national transfusion rate. The p-value is the probability that the observed STrR would deviate from 1.00 as much as it does, under the null hypothesis that this ratio is truly equal to 1.00. A small p-value (often taken as <0.05) suggests the ratio between the observed and expected transfusion rates differs significantly from 1.00. The smaller the p-value, the lower the probability that a facility's transfusion rate is equal to the national transfusion rate. Note that the p-value is less than 0.05 whenever the confidence interval does not include the value 1.00. Because the p-value depends on the facility size, a small p-value in a large facility does not necessarily indicate that the difference between this facility's transfusion rate and the national rate is of clinical importance.

The STrR's actual value can be used to assess the clinical importance of the difference between your facility's and the nation's transfusion rates. A STrR of 1.25, for example, indicates that your facility's transfusion rate is 25% higher than the national average, which may well be judged to be clinically important. On the other hand, STrR values in the range of 0.95 to 1.05 would generally not be considered to be of clinical interest. With very large facilities, even relatively small differences in the STrR can lead to significant results, so both aspects (the actual value of the STrR and the p-value) are important.

<u>Transfusion Rate (per 100 patient-years) and Confidence Interval (Range of Uncertainty)</u> for Transfusion Rate (1aa)

The transfusion rate and confidence interval for the transfusion rate are calculated by multiplying the STrR (and confidence interval for STrR) by the national rate of transfusion. The national rate of transfusion for 2018 is 21.1 transfusions per 100 patient-years.

Classified Category

If your facility's transfusion rate is less than the national rate and statistically significant (p<0.05), the classification is "Better than expected". If your facility's transfusion rate is greater than the national rate and statistically significant (p<0.05), the classification is

"Worse than expected". Otherwise, the classification is "As expected" on DFC. Please note that the STrR is not reported on DFC if there are fewer than 10 patient years at risk in your facility in the year.

Standardized Fistula Rate (SFR) (1ab – 1af)

Standardized Fistula Rate (SFR) is an adjusted percentage of adult hemodialysis patientmonths using an autogenous arteriovenous (AV) fistula as the sole means of vascular access.

SFR is intended to be jointly reported with Hemodialysis Vascular Access: Long-term Catheter Rate. These two vascular access quality measures, when used together, consider 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 AV fistula or have comorbidities that may limit the success of AV fistula creation, joint reporting of the measures accounts for all three vascular access options: fistula, graft, and catheter. 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.

The statistics in the table are based on information collected in CROWNWeb from April 1, 2018 – March 31, 2019. SFR is calculated for a rolling 12 month period and is updated quarterly.

Eligible adult hemodialysis (HD) patients (1ab)

The number of eligible adult patients (18 years or older as of the first day of the reporting month) who are determined to be on hemodialysis (includes in-center and home HD) for at least one whole calendar month is reported in row 1ab.

Patient months at Risk (1ac)

The number of patient-months at risk for eligible adult HD patients is reported in row 1ac.

To be included for a particular reporting month, the patient must be receiving home or incenter 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 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.

In addition, patients with a catheter that have limited life expectancy, including under hospice care in the current reporting month, or with metastatic cancer, end stage liver disease, coma or anoxic brain injury in the past 12 months, were excluded.

Total Fistula months (1ad)

This row reports the patient-months in 1ac in which the patient received dialysis through an AV fistula. The last non-missing vascular access type collected during the reporting month for the patient was selected to determine whether an AV fistula was in use. An AV fistula 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.

Standardized Fistula Rate (SFR) (1ae)

The SFR measure is a standardized rate, in that each facility's percentage of AV fistula use is adjusted to the national distribution of covariates (risk factors), with 'national' 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. Risk adjustment is based on a multivariate logistic regression model. The adjustment is made for age, BMI at incidence, nursing home status, nephrologist's care prior to ESRD, duration of ESRD, diabetes as primary cause of ESRD and a set of combined incident and prevalent comorbidities, and an indicator for Medicare coverage for at least 6 months during the past 12 months. This model includes the facility indicators and assumes that the regression coefficients of risk factors are the same across all facilities. Common risk effects are assumed in order to improve computational stability in estimating facility-specific effects.

SFR is not reported on DFC if there are fewer than 11 eligible adult patients in that facility during the 12 month period.

Confidence Interval (Range of Uncertainty) for SFR (1ae)

The 95% confidence interval (or range of uncertainty) gives a range of plausible values for the true standardized fistula rate. The upper and lower confidence limits enclose the true rate approximately 95% of the time if this procedure were to be repeated on multiple samples.

P-value for SFR (1af)

The p-value measures the statistical significance of (or evidence against) the hypothesis that the true fistula rate for a facility is the same as (neither higher nor lower than) that from the overall national fistula rate. The p-value is the probability that the observed SFR

would deviate from the national rate as much as it does, under the null hypothesis that the two rates are equal. A small p-value (often taken as <0.05) indicates that the observed rate would be highly unlikely under the null hypothesis. The smaller the p-value, the lower the probability that a facility's SFR is equal to the national rate. Note that the p-value is less than 0.05 whenever the confidence interval does not include the national rate. Because the p-value depends on the facility size, a small p-value in a large facility does not necessarily indicate that the difference between one facility's SFR and the national rate is of clinically meaningful difference.

Classified Category

If one facility's SFR is greater than the national rate and statistically significant (p<0.05), then classified as "Better than expected". If one facility's SFR is less than the national rate and statistically significant (p<0.05), then classified as "Worse than expected". Otherwise, the classification is "As expected" on DFC.

Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) (1ag - 1al)

The SWR measure tracks the number of incident patients at a dialysis facility who are under the age of 75 and were listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant within the first year of initiating dialysis. For each facility, the Standardized Waitlist Ratio (SWR) is calculated to compare the observed number of waitlist events in a facility to its expected number of waitlist events. The SWR uses the expected waitlist events calculated from a Cox model (SAS Institute Inc., 2004; Andersen, 1993; Collett, 1994), adjusted for age and patient comorbidities at incidence. For this measure, patients are assigned to the facility based on the facility information entered on the Medical Evidence 2728 form.

Eligible patients (1ag)

The SWR includes ESRD patients, under the age of 75, who have initiated dialysis during the reporting period. The exclusion criteria applied in the calculation of the SWR are as follows: i) patients who were listed on the kidney or kidney-pancreas transplant waitlist prior to the start of dialysis; ii) patients who were admitted to a skilled nursing facility (SNF) at incidence or previously, according to Question 17u and 22 on the CMS Medical Evidence Form and the CMS Long Term Care Minimum Data Set (MDS); iii) active hospice patients at time of dialysis initiation, based on Medicare final action claims data.

Patient-years at risk (1ah)

For patients in the SWR analysis, time at risk began at the incidence of dialysis and continued until the earliest occurrence of the following: date of listing on the kidney or kidney-pancreas transplant waitlist; date of receiving a living donor transplant; date of death; or one year after the start of treatment, whichever comes first. In addition, all patients' time at risk are included under the calendar year heading corresponding to the year in which chronic dialysis was initiated on the Medical Evidence Form, even if a portion of the follow-up time occurs in the following year.

<u>Transplant waitlist event or receipt of a living-donor transplant (1ai)</u>

This is the total number of patients on the transplant waitlist or in receipt of a living-donor transplant among new dialysis patients during their first year of dialysis. It is also the numerator of the SWR.

Expected number of transplant waitlist or living-donor transplant events (1aj)

The expected number of waitlist or living donor transplant events was calculated using a Cox model, adjusted for patients' age and comorbidities at incidence (SAS Institute Inc., 2000; Andersen, 1993; Collett, 1994). All expected events at the same facility are summed up to obtain the total number of expected events in the reporting period.

Standardized Waitlist Ratio (1ak)

The SWR equals the ratio of the observed number of transplant waitlist events or receipt of a living-donor transplant (1ai) divided by the expected number of transplant waitlist events or living donor transplant events (1aj). For regional and national summaries, we calculated the SWR as the ratio of the total number of observed events among patients from each region (or the U.S.) to the number of expected events among patients from each region (or the U.S.). Please note that facilities with less than 11 patients or less than 2 expected events for the reporting period are included in the State and US summaries. However, their SWR values, p-values and 95% confidence intervals are suppressed at facility level for the relevant years.

Confidence interval for SWR (1ak)

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

P-value for SWR (1al)

The p-value measures the statistical significance (or evidence) of the hypothesis that the true transplant waitlist rate for a given facility is different from what would be predicted from the overall national rate. The p-value is the probability that the calculated SWR would deviate from 1.00 as much as it does, under the null hypothesis that this ratio is truly equal to 1.00. A smaller p-value tends to occur when the ratio differs greatly from 1.00 and/or when one uses more patient data to calculate the SWR value. A p-value less than 0.05 suggests that the ratio between the observed and expected waitlist event rates differs significantly from 1.00. The smaller the p-value, the lower the probability that a facility's waitlist event rate is equal to the national waitlist event rate. A small p-value helps rule out the possibility that an SWR's deviance from 1.00 could have arisen by chance. However, a small p-value does not indicate the degree of importance of the difference between the facility waitlist event rate and the national rate.

Classification Category

When a facility's SWR is greater than 1.00 and statistically significant (p-value < 0.05), it is classified as "Better than expected". When a facility's SWR is less than 1.00 and statistically significant (p-value < 0.05), it is classified as "Worse than expected". When a facility's SWR is not significantly different from 1.00, it is classified as "As expected". Please note that the classification of SWR is reported as "Not available" on DFC for facilities with less than 11 patients or less than 2 expected events for the relative reporting year.

Percentage of Prevalent Patients Waitlisted (PPPW) (1am - 1aq)

The PPPW measure tracks the percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist. It is an adjusted percentage of waitlist events among dialysis patients. Results are averaged across patients who were assigned to the dialysis facility as of the last day of each month during the reporting year, adjusted for age.

Eligible patients and Patient-months at risk (1am – 1an)

The total number of dialysis patients included in the PPPW calculation is reported in row 1 am. The total number of patient-months at risk is the sum of patient-months belonging to patients who are under the age of 75 on the last day of each month and who are assigned to the dialysis facility according to the methods described in Section III as of the last day of each month during the reporting year. A patient could be counted up to 12 times per

year. The following patients or patient-months were excluded from the analysis: i) patient months that the patients were admitted to a skilled nursing facility (SNF) any number of days during the month of evaluation according to CMS Long Term Care Minimum Data Set (MDS) file; ii) patients who were admitted to a SNF previously, according to Question 17u and 22 on the CMS Medical Evidence Form; iii) active hospice patients during the month of evaluation, based on Medicare final action claims data.

Total waitlisted months (1ao)

This is the count of patient-months in which the patient at the dialysis facility is on the kidney or kidney-pancreas transplant waiting list as of the last day of each month during the reporting period.

Percentage of Prevalent Patients Waitlisted (1ap)

The Percentage of Prevalent Patients Waitlisted (PPPW) measure is a directly standardized percentage, in the sense that each facility's percentage waitlisted is adjusted to the national age distribution (with 'national' here referring to all-facilities-combined). The PPPW for each facility is an estimate of what the facility's percentage of prevalent patients would equal if the facility's patient mix was equal to that of the nation as a whole. The model is fitted using Generalized Estimating Equations (GEE; Liang and Zeger, 1986) in order to account for the within-patient correlation across months. Please note that the PPPW calculation is restricted to facilities with 11 or more eligible patients during the reporting time period.

Confidence interval for PPPW (1ap)

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

P-value (1aq)

We use a two-sided Wald test (0.05 significance level) to measure the statistical significance of (or evidence against) the hypothesis that the PPPW for a facility is the same as (neither higher nor lower than) that from the national average percentage waitlisted. Note that the Wald test is based on the logit of PPPW, which is much more likely to follow a normal distribution than PPPW itself, due to the symmetry and lack of range restrictions of the transformed version. A p-value of less than 0.05 is usually taken as evidence that the facility PPPW differs from the national PPPW.

Classification Category

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

VI. Facility Bloodstream Infection Summary for Hemodialysis Patients Based on the National Healthcare Safety Network (NHSN), (01/01/2018-12/31/2018)

Table 2 displays bloodstream infection (BSI) information for hemodialysis outpatients as reported by dialysis facilities to the National Healthcare Safety Network (NHSN). Data are reported according to the NHSN Dialysis Event Surveillance Protocol. The surveillance population is hemodialysis outpatients. The measures reported in Table 2 have been developed and calculated by NHSN.

Eligible patient-months (2a)

The number of eligible patient-months is the sum of patients who received hemodialysis in-center on the first two working days of each month, during the performance year. These data are reported to NHSN on the monthly "Denominators for Dialysis Event Surveillance" form.

Observed Bloodstream infections (2b)

The number of observed bloodstream infections is the total number of positive blood cultures that were reported by the facility for the performance year. This includes positive blood cultures collected from a patient under surveillance on the day of or the day following admission to a hospital. These data are reported to NHSN on the "Dialysis Event" form.

Predicted Bloodstream infections (2c)

The predicted number of bloodstream infections is calculated by multiplying the national aggregate BSI Rates Stratified by Vascular Access Type from NHSN Dialysis Event Data 2018* by the facility's number of patient-months for each vascular access category. The number of patient-months is equal to the summed number of patient-month denominators reported by the facility to NHSN during the performance year. The total number of patients at a facility and the number of patients in different vascular access categories factor into the calculation. For example, a facility with many patients will tend to have more predicted BSIs than a facility with few patients.

*The 2018 national aggregate NHSN Dialysis Event Surveillance BSI rates are the aggregate pooled means from over 6,000 outpatient hemodialysis facilities that reported to NHSN in 2018. These data are referred to as the "baseline."

Standardized Infection Ratio (SIR) (2d)

The SIR is a facility-level measure that is calculated by dividing the observed number of bloodstream infections (2b) by the predicted number of bloodstream infections (2c). As a ratio, the SIR (with its confidence interval) is interpreted relative to the number 1. If a facility reports an observed number of BSIs exactly equal to their predicted number of BSIs, the SIR is equal to 1. If a facility observed more BSIs than were predicted, the SIR is greater than 1. If a facility observed fewer BSIs than were predicted, the SIR is less than 1.

The measure accounts for the vascular access types of patients treated at the facility. The SIR is not reported if there are fewer than 12 complete months of data and fewer than 132 eligible patient-months reported to NHSN during the performance year.

Confidence Intervals (Range of Uncertainty) for SIR (2d)

The confidence interval (or range of uncertainty) provides an estimated range of probable values for the SIR. The lower and upper confidence limits enclose the true SIR approximately 95% of the time if this procedure were to be repeated on multiple samples.

If the SIR's confidence interval contains 1, the facility's number of observed BSIs is not statistically different from their number of predicted BSIs, and the SIR will be categorized "as expected." If the SIR's lower confidence limit is greater than 1, the facility had a statistically significant result indicating more infections than predicted and the SIR will be categorized as "worse than expected." If the SIR's upper confidence limit is less than 1, the facility had a statistically significant result indicating fewer infections than predicted and the SIR will be categorized as "better than expected."

VII. Facility Hemoglobin for Medicare Dialysis Patients based on Medicare Dialysis Claims, 04/01/2018 – 03/31/2019

Table 3 reports information on facility practice patterns. Medicare claims are identified as dialysis claims if they are bill type '72' or they are an outpatient claim with a dialysis revenue center code between the following ranges: 800-809 or 820-889. We restricted hemoglobin information to patients who have had ESRD for at least 91 days. The inclusion criteria are described in more detail below. The statistics are reported for each quarter between April 1, 2018 – March 31, 2019 and the entire year along with comparative

regional and national data for the year. Note that State and U.S. averages may differ from values in the DFR due to the difference in number of facilities receiving a report and difference in time periods.

Hemoglobin (3a-3c)

We based the hemoglobin information reported in rows 3a to 3c on all Medicare dialysis claims submitted by your facility that indicated the use of an ESA, specifically, the use of epoetin alfa, epoetin beta, darbepoetin alfa, or peginesatide (Omontys®). Hemoglobin was calculated as hematocrit divided by three for claims that report hematocrit but not hemoglobin, rounding to the nearest tenth of a g/dL. Neither patient claims starting before, or on, day 90 of ESRD nor claims with hemoglobin values less than 5 g/dL or greater than 20 g/dL were included. For each patient, the last claim reported for a month at a facility satisfying the above mentioned criteria was included in the summaries.

The rolling year summary in row 3a reports the number of patients for whom at least four claims fulfilling these criteria were submitted by the facility for the year. The quarterly summaries report the number of patients with at least one claim fulfilling these criteria. A patient treated at more than one facility during the year was included in the report for each.

For each patient in row 3a, the average hemoglobin reported on claims submitted by the facility was calculated. Rows 3b and 3c present the percentage of patients from 3a with an average hemoglobin less than 10g/dL, and greater than 12 g/dL, respectively. A slightly different group of patients are included in the DFC calculation of the percent of patients that have an average hemoglobin greater than 12, compared to the corresponding measure in the CMS ESRD Quality Incentive Program (QIP). The QIP calculations are restricted to adult patients while DFC includes all patients.

VIII. Mineral and Bone Disorder for Adult Dialysis Patients, Dialysis Adequacy for All Dialysis Patients, Long-term Catheter for Adult HD Patients, and nPCR for Pediatric HD Patients based on CROWNWeb, 04/01/2018 – 03/31/2019

Table 4 reports information primarily from CROWNWeb. Each section of the table includes a slightly different group of patients described in more detail below. All measures are restricted to patients who have had ESRD for greater than 90 days (except phosphorus and long-term catheter) and received dialysis at the facility for at least one entire month during the reporting period. Hypercalcemia, serum phosphorus concentrations, long-term

catheter and nPCR are obtained from CROWNWeb only while Kt/V is supplemented with Medicare claims data when values are missing or out of range.

Mineral and Bone Disorder (4a-4f)

Hypercalcemia (4a -4c)

This measure derives its information primarily from CROWNWeb (04/01/2018 - 03/31/2019). The measure is restricted to patients who have had ESRD for greater than 90 days and received dialysis at the facility for at least one entire month during the reporting period.

Hypercalcemia is averaged from uncorrected serum or plasma calcium values over a rolling 3-month period. The percentage for a given month uses the average of the last reported uncorrected serum or plasma calcium value and the last reported values for the previous 2 months (if available). The acceptable range for calcium is 0.1 - 20 mg/dL. Values outside of this range are considered missing. For example, the percentage calculated for April would be based on the average of uncorrected serum calcium values submitted in April, March and/or February.

Eligible adult hypercalcemia patients and patient-months (4a – 4b)

The number of adult patients (18 years or older two months prior to the reporting month) who had ESRD for greater than 90 days and treated in the facility the entire reporting month is reported in row 4a. Patients with missing or out of range values who meet the criteria above are included in the denominator. The number of patient-months is reported in row 4b. An individual patient may contribute up to 3 patient-months per quarter and up to 12 patient-months per year.

Average uncorrected serum or plasma calcium > 10.2 mg/dL (4c)

The percentage of all eligible patient-months (row 4b) with a 3-month rolling average uncorrected serum or plasma calcium greater than 10.2 or missing is reported in 4c.

Eligible adult phosphorous patients and patient-months (4d-4e)

The number of adult patients with ESRD treated in the facility the entire reporting month is reported in row 4d. The number of patient-months is reported in row 4e. An individual patient may contribute up to 3 patient-months per quarter and up to 12 patient-months per year.

Serum Phosphorous Categories (4f)

The percentage of all eligible patient-months is characterized into five mutually exclusive categories: less than 3.5 mg/dL, 3.5-4.5 mg/dL, 4.6-5.5 mg/dL, 5.6-7.0 mg/dL, and greater than 7.0 mg/dL.

Hypercalcemia is not reported on DFC if there are fewer than 11 eligible patients in that facility during the 12 month period.

Dialysis Adequacy: Kt/V (4g-4v)

Kt/V is defined as: K-dialyzer clearance of urea; t-dialysis time; V-patient's total body water. This section of the table is primarily based on information collected in CROWNWeb. If Kt/V is missing or out of range in CROWNWeb during the reporting month, the last valid Kt/V value collected for the patient during the reporting month according to paid, type-72 Medicare dialysis claims was selected (if available). Additional details are provided below.

Eligible adult hemodialysis (HD) patients and patient-months (4g-4h)

Eligible patients were adults (≥18 years) who had ESRD for greater than 90 days, were receiving hemodialysis at the facility for at least one whole calendar month during the reporting period (i.e., 'assigned' facility), and dialyzed thrice weekly (4g). Patient-months were excluded from the denominator if there was evidence the patient was not dialyzing thrice weekly anytime during the month. A patient may only be assigned to one dialysis facility each month and may not switch modalities during the month. The corresponding number of eligible patient-months is reported in row 4h. Patients may be counted up to 12 times per year.

Determination of thrice weekly dialysis

A patient-month was excluded from the hemodialysis Kt/V patient counts described above if the prescribed number of sessions reported in CROWNWeb by the patient's 'assigned' facility was not equal to 3 and/or the patient was identified in CROWNWeb as undergoing 'frequent' dialysis anytime during the reporting month. If information regarding the frequency of dialysis was not available for the reporting month in CROWNWeb by the patient's 'assigned' facility, session information submitted by other dialysis facilities where the patient received treatment was considered.

If the dialysis frequency was not reported in CROWNWeb for the reporting month, eligible hemodialysis Medicare claims submitted by the patient's 'assigned' facility during the reporting month were considered. A claim was considered eligible if it was for an adult (≥18 years old) HD patient (or pediatric in-center HD for pediatric HD measure) with ESRD for greater than 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).

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

The number of dialysis sessions per week on a claim was calculated as a rate: 7*(# of HD sessions/# of days). This rate was only calculated for claims that covered at least seven days. A claim was identified as indicating "frequent" dialysis if any of the following criteria were met:

- (a) reported a Kt/V value of 8.88,
- (b) covered seven or more days and had a rate of four or more sessions/week, or
- (c) covered fewer than seven days and had four or more total sessions indicated

A claim was identified as indicating "infrequent" dialysis if it covered at least seven days and had a rate of two or fewer sessions/week. No short claims (less than 7 days) were considered as indicating "infrequent" dialysis.

Adult hemodialysis: $Kt/V \ge 1.2$ (4i-4j)

Summaries are calculated using CROWNWeb as the primary data source. The last Kt/V collected (from any facility) during the reporting month for the patient was selected. If Kt/V was missing or out of range (Kt/V > 5.0) in CROWNWeb, then the Kt/V (based on the value code 'D5: Result of last Kt/V') reported on the last eligible Medicare claim for the patient during the reporting month was selected when available.

A claim was considered eligible if it was from a HD patient who had ESRD for greater than 90 days, was at least 18 years old, and the claim was neither a "frequent" dialysis claim nor an "infrequent" dialysis claim as described above. The last eligible claim with an in-range (less than or equal to 5.0) and not expired (in-center HD with Kt/V reported from a previous claim, or home HD with Kt/V reported from more than four months prior) Kt/V value reported was selected when there were multiple claims reported in a month.

Patients with missing or out of range Kt/V (Kt/V > 5.0) values from either data source (CROWNWeb or Medicare claims) (4i) are included in the denominator but not the numerator and therefore may result in a lower percentage than expected. The percentage of patient-months reported in 4h with a Kt/V value greater than or equal to 1.2 is reported in 4i.

Eligible adult peritoneal dialysis (PD) patients and patient-months (4k-4l)

Eligible patients were adults (≥18 years) who had ESRD for greater than 90 days and were receiving peritoneal dialysis at the facility for at least one whole calendar month during the reporting period (4k). A patient may only be assigned to one dialysis facility each month and may not switch modalities during the month. The corresponding number of eligible patient-months is reported in row 4l. Patients may be counted up to 12 times per year.

Adult Peritoneal Dialysis: $Kt/V \ge 1.7$ (4m-4n)

Kt/V values are only required to be reported every four months for adult PD patients. Therefore, if Kt/V was missing for the reporting month, the most recent available value collected up to 3 months prior was selected when available. If all values in a 4-month lookback period were missing, then the PD Kt/V value was considered missing for that reporting month.

Summaries are calculated using CROWNWeb as the primary data source. The last Kt/V collected (from any facility) during the reporting month for the patient was selected. If Kt/V was missing or out of range (Kt/V > 8.5) in CROWNWeb, then the Kt/V (based on the value code 'D5: Result of last Kt/V') reported on the last eligible Medicare claim for the patient during the reporting month was selected when available.

A claim was considered eligible if it was from a PD patient who had ESRD for greater than 90 days and was at least 18 years old. The last eligible claim with an in-range (less than or equal to 8.5) and not expired (Kt/V reported from more than four months prior) Kt/V value was selected when there were multiple claims reported in a month.

Patients with missing or out of range Kt/V (Kt/V > 8.5) values from either data source (CROWNWeb or Medicare claims) (4m) are included in the denominator but not the numerator and therefore may result in a lower percentage than expected. The percentage of patient-months reported in 4l with a Kt/V value greater than or equal to 1.7 is reported in 4n.

Eligible pediatric hemodialysis (HD) patients and patient-months (40-4p)

Eligible patients were pediatric (<18 years) patients who had ESRD for greater than 90 days, were receiving in-center HD at the facility for at least one whole calendar month during the reporting period (i.e., 'assigned' facility), and dialyzed thrice weekly (40). Patient-months were excluded from the denominator if there was evidence the patient was not dialyzing thrice weekly anytime during the month. A patient may only be assigned to one dialysis facility each month and may not switch modalities during the month. The corresponding number of eligible patient-months is reported in row 4p. Patients may be counted up to 12 times per year.

CROWNWeb and eligible (pediatric, in-center, ESRD for greater than 90 days) paid type-72 Medicare dialysis claims were used to determine dialysis frequency for each patientmonth. For detailed description regarding the determination of thrice weekly dialysis, and the calculation of "frequent" and" infrequent" dialysis in Medicare dialysis claims, please refer to the 'Eligible adult HD' section above.

Pediatric Hemodialysis: $Kt/V \ge 1.2$ (4q-4r)

Summaries are calculated using CROWNWeb as the primary data source. The last Kt/V collected (from any facility) during the reporting month for the patient was selected. If Kt/V was missing or out of range (Kt/V > 5.0) in CROWNWeb, then the Kt/V (based on the value code 'D5: Result of last Kt/V') reported on the last eligible Medicare claim for the patient during the reporting month was selected when available.

A claim was considered eligible if it was from a HD patient who did not indicate home HD, had ESRD for greater than 90 days, was younger than 18 years old, and the claim was neither a "frequent" dialysis claim nor an "infrequent" dialysis claim as described above. The last eligible claim with an in-range (less than or equal to 5.0) and not expired (Kt/V reported from a previous claim) Kt/V value was selected when there were multiple claims reported in a month.

Patients with missing or out of range Kt/V (Kt/V > 5.0) values from either data source (CROWNWeb or Medicare claims) (4q) are included in the denominator but not the numerator and therefore may result in a lower percentage than expected. The percentage of patient-months reported in 4p with a Kt/V value greater than or equal to 1.2 is reported in 4r.

Eligible pediatric peritoneal dialysis (PD) patients and patient-months (4s-4t)

Eligible patients were pediatric (< 18 years) patients who had ESRD for greater than 90 days and were receiving peritoneal dialysis at the facility for at least one whole calendar month during the reporting period (4s). A patient may only be assigned to one dialysis facility each month and may not switch modalities during the month. The corresponding number of eligible patient-months is reported in row 4t. Patients may be counted up to 12 times per year.

Pediatric Peritoneal Dialysis: $Kt/V \ge 1.8$ (4u-4v)

Kt/V values are only required to be reported every six months for pediatric PD patients. Therefore, if Kt/V was missing for the reporting month, the most recent available value collected up to 5 months prior was selected when available. If all values in a 6-month lookback period were missing, then the PD Kt/V value was considered missing for that reporting month.

Summaries are calculated using CROWNWeb as the primary data source. The last Kt/V collected (from any facility) during the reporting month for the patient was selected. If Kt/V was missing or out of range (Kt/V> 8.5) in CROWNWeb, then the Kt/V (based on the value code 'D5: Result of last Kt/V') reported on the last eligible Medicare claim for the patient during the reporting month was selected when available.

A claim was considered eligible if it was from a PD patient who had ESRD for greater than 90 days and was younger than 18 years old. The last eligible claim with an in-range (Kt/V less than or equal to 8.5) and not expired (Kt/V reported from more than six months prior) Kt/V value was selected when there were multiple claims reported in a month.

Patients with missing or out of range Kt/V (Kt/V > 8.5) values from either data source (CROWNWeb or Medicare claims) (4u) are included in the denominator but not the numerator and therefore may result in a lower percentage than expected. The percentage of patient-months reported in 4r with a Kt/V value greater than or equal to 1.8 is reported in 4v.

Kt/V measures are not reported on DFC if there are fewer than 11 eligible patients in that facility during the 12 month period.

Hemodialysis Vascular Access: Long-Term Catheter Rate (4w – 4y)

This measure reports the percentage of all eligible patient-months where a long-term catheter was in use, i.e., a catheter was reported for three consecutive months (the reporting month and preceding two months) in the same facility. Patients are included in the measure denominator if the patient was on hemodialysis (home or in-center) at the facility for the entire reporting month and was at least 18 years old as of the first day of that month.

This measure is paired with the Hemodialysis Vascular Access- Standardized Fistula Rate. These two vascular access quality measures, when used together, consider arteriovenous (AV) fistula use as a positive outcome and prolonged use of a tunneled catheter as a negative outcome. With the growing recognition that some patients have exhausted options for an AV fistula, or have comorbidities that may limit the success of AV fistula creation, pairing the measures accounts for all three vascular access options: fistula, graft, and catheter.

Eligible adult hemodialysis (HD) patients (4w)

The number of eligible adult patients (18 years or older as of the first day of the reporting month) who are determined to be on hemodialysis (includes in-center and home HD) for at least one whole calendar month is reported in row 4w.

Patient-months at Risk (4x)

The number of patient-months at risk for eligible adult HD patients is reported in row 4x.

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 3 patient-months per quarter and up to 12 patient-months per year.

In addition, patients with a catheter that have limited life expectancy, including under hospice care in the current reporting month, or with metastatic cancer, end stage liver disease or coma or anoxic brain injury in the past 12 months, were excluded.

Long-Term Catheter Rate (4y)

This row reports the percentage of patient-months in 4x in which the patient received dialysis through a catheter for at least three consecutive months (the reporting month and preceding two months) in the same facility.

The last vascular access type listed in CROWNWeb during each of these three complete months for the patient was selected to determine whether a catheter was in use. Before indicating that a catheter was present for three consecutive months, we checked that the access type reported on the last day of the month that was three months before the reporting month was also a catheter. A catheter was considered in use if the CROWNWeb "Access Type IDs" of 16, 18, 19, 20, and 21 had been recorded for a given month, where "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. If there was no CROWNWeb vascular access type entry for a given month, we counted the vascular access type for that month as a catheter. If a patient changes dialysis facilities, the counting of the three consecutive complete months restarts at the new facility.

Long-Term Catheter Rate is not reported on DFC if there are fewer than 11 eligible adult patients in that facility during the 12 month period.

Percentage Reporting nPCR (4z – 4ab)

In the pediatric population, the assessment of dialysis adequacy requires an evaluation of both small solute clearance and nutritional status. This is because both adequate solute clearance and nutrition are essential for growth and visceral weight gain. Whereas there are several potential measures of nutritional status, these are outside the scope of hemodialysis adequacy measures with the exception of nPCR (normalized protein catabolic rate), a value that is a fundamental component of and already readily available from urea kinetics. This allows the use of nPCR along with spKt/V as measures of dialysis adequacy.

nPCR provides an estimate of dietary protein intake and has been shown to provide additional information to spKt/V. In malnourished adolescent patients who achieved target spKt/V levels, nPCR, but not serum albumin, was associated with nutritional status. In adolescent patients, nPCR levels < 1 gram/kg/day were found to be an earlier and more sensitive marker than serum albumin levels in predicting malnutrition and sustained weight loss. Additionally, monitoring of nPCR continues to be recommended as part of evaluation of Protein Energy Wasting (PEW) in children on dialysis. There is currently no evidence that supports specific nPCR targets, although age-specific protein intake targets exist. The same data needed for Kt/V calculation can be used for nPCR calculation. Thus, nPCR can be monitored monthly along with Kt/V to follow up protein intake for a particular patient.

Eligible pediatric in-center hemodialysis (HD) patients and patient-months (4z - 4aa)

Eligible patients were pediatric patients (<18 years) who were receiving in-center hemodialysis at the facility for at least one whole calendar month during the reporting period. The number of the eligible patients is reported in row 4z. The corresponding number of eligible patient-months is reported in row 4aa. An individual patient may contribute up to 3 patient-months per quarter and up to 12 patient-months per year.

Percentage of pediatric in-center hemodialysis (HD) patients with documented monthly nPCR measures (4ab)

Summaries are calculated using CROWNWeb as the primary data source. To be included in the denominator for a particular month, the patient must be on in-center hemodialysis for the entire month, be < 18 years old at the beginning of the month, and must be assigned to that facility for the entire month.

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 used to calculate nPCR (BUN predialysis, 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.

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 is reported in 4ab.

Percentage Reporting nPCR is not reported on DFC if there are fewer than 11 eligible patients in that facility during the 12 month period.

IX. Patient Experience of Care based on ICH CAHPS survey 04/20/2018 – 07/13/2018 and 10/19/2018 – 01/11/2019

Overview

The ICH CAHPS Survey is intended to measure in-center hemodialysis patients' perspectives on the care they receive at dialysis facilities. The survey is administered twice a year (once in the spring and once in the fall). It contains a total of 62 questions. Questions were chosen to reflect aspects of the in-center dialysis experience that are important to patients. Table 5 reports the results for three rating measures and three multi-item or "composite" measures. The data include the two most recent semi-annual surveys. The measures reported in Table 5 have been developed and calculated by RTI. A copy of the questionnaire can be found on the ICH CAHPS Survey web site, https://ichcahps.org.

The ICH CAHPS Survey of Patients' Experiences Star Rating will be calculated and reported as a separate Star Rating from the Quality of Patient Care Star Rating. Current measure specifications are available at:

https://ichcahps.org/SurveyandProtocols.aspx

The ICH CAHPS Star Rating Technical Notes are available at: https://ichcahps.org/ICHCAHPS_Star_Rating_Methodology_Report.docx

Which patients are included?

Dialysis facility patients are eligible to participate if they meet the following criteria:

- 18 years or older on the last day of the sampling window for the semiannual survey;
- Still living as of the last day of the sampling window for the semiannual survey;
- Received in-center hemodialysis on an outpatient basis from their current facility for three months or longer; not currently residing in an institution, such as a residential nursing home or other long-term care facility, or a jail.

The ICH CAHPS survey is administered either to a random sample of adult patients or to all patients at each dialysis facility, depending upon the total number of patients at the facility. Only patients who get in-center hemodialysis can participate in the survey; home or peritoneal dialysis patients are excluded from the survey.

How are scores calculated?

The rating scores are based on single items in the survey, each of which has a response set from 0 to 10. Scores are calculated based on the proportion of patients that answered with

the two most favorable responses, "9" or "10", two middle favorable responses "7" or "8" and seven least favorable responses "0-6". These results are publicly reported at the level of the dialysis facility.

The calculation for the composite scores is more complex. The scores for a facility are the average of the proportion of respondents who provided the most favorable (top box), least favorable (bottom box) or mid-range responses to each question included in each composite. The responses that are coded as the most favorable, least favorable, and mid-range will vary by question.

Number of Completed Surveys (5a)

The number of completed surveys from patients at the facility who met the inclusion criteria detailed above. Patients are assigned to the facility based on information in CROWNWeb. If the data in CROWNWeb show that a patient only visited one in-center hemodialysis facility during the sampling window, the patient is assigned to that facility. Patients who had visits to more than one facility during the sampling window are assigned to a facility using a variety of rules which take into account the number of visits the individual made to each facility and consider whether the facility is in the same state as the state in which the respondent lives.

Response Rate (5b)

The proportion of patients who completed the survey (5a) out of those who were offered the survey.

Percent of Patients reporting- Nephrologists' communication and caring (5c)

The proportion of patients who provided the most [middle or least] favorable responses to questions included in this composite measure are shown in the Always [Sometimes or Never, respectively] category. The scores for a facility are the average of the proportion of respondents who provided the most [middle or least] favorable responses to each question included in each composite (survey questions 3, 4, 5, 6, 7, 9).

Percent of Patients reporting- Quality of dialysis center care and operations (5d)

The proportion of patients who provided the most [middle or least] favorable responses to questions included in this composite measure are shown in the Always [Sometimes or Never, respectively] category. The scores for a facility are the average of the proportion of respondents who provided the most [middle or least] favorable responses to each question included in each composite (survey questions 10, 11, 12, 13, 14, 15, 16, 17, 21, 22, 24, 25, 26, 27, 33, 34, 43).

Percent of Patients reporting- Providing information to patients (5e)

The proportion of patients who provided the most [least] favorable responses to questions included in this composite measure are shown in the Yes [No] category. The scores for a facility are the average of the proportion of respondents who provided the most [least]

favorable responses to each question included in each composite (survey questions 19, 28, 29, 30).

Percent of Patients reporting- Rating of the nephrologist (5f)

The proportion of patients who provided the most (9 or 10) [middle (7 or 8) or least (0-6)] favorable response to question 8 on the survey receive a measure rating of Always [Sometimes or Never, respectively].

Percent of Patients reporting- Rating of the dialysis center staff (5g)

The proportion of patients who provided the most (9 or 10) [middle (7 or 8) or least (0-6)] favorable response to question 32 on the survey receive a measure rating of Always [Sometimes or Never, respectively].

Percent of Patients reporting- Rating of the dialysis facility (5h)

The proportion of patients who provided the most (9 or 10) [middle (7 or 8) or least (0-6)] favorable response to question 35 on the survey receive a measure rating of Always [Sometimes or Never, respectively].

Overall Star Rating (5i)

The Overall Star Rating for ICH CAHPS Survey of Patients' Experiences calculated as a separate star rating from the Quality of Patient Care Star Rating (5i). Current measure specifications are available at: https://ichcahps.org/SurveyandProtocols.aspx. The ICH CAHPS Star Rating Technical Notes are available at:

https://ichcahps.org/ICHCAHPS_Star_Rating_Methodology_Report.docx.

X. Facility Star Rating Calculation

Overview

Table 6 reports the star rating, ranging from one to five stars, associated with the facility. The October 2019 DFC release includes the use of a baseline period (April 2018 QDFC) and an evaluation period (January 2018 – December 2018), calculation of measure scores in the evaluation data period compared against relative scoring in a fixed baseline period, and assignment of star ratings in an evaluation data period based on relative cutoffs for final facility scores set in the same fixed baseline period. Such a methodology allows users to compare dialysis facilities and observe changes in facility performance over time. Eleven of the fifteen Quality Measures (QMs) reported on the Medicare DFC website were used in the algorithm to calculate the star rating. Methods will be described briefly below and detailed information on the Star Rating methodology is available in the Technical Notes on the Updated Dialysis Facility Compare Star Rating Methodology for the October 2018

<u>release</u>. You may also view the 'Star Rating Measure Scoring Tables and Instructions' on the Methodology page of DialysisData.org to help in calculating individual measure scores.

The eleven QMs used in the calculation are grouped into different QM domains. Specifically, domains are empirically derived using factor analysis and assessing correlations among the QMs. Factor analysis detects underlying latent factors that are the source of correlations between variables. The method led to the creation of three domains of QMs. The first domain comprises the standardized measures for hospitalizations, mortality, transfusions, and readmissions (STrR, SMR, SRR, and SHR) and is named "Standardized Outcomes (SHR, SMR, STrR, SRR)". The standardized fistula rate (SFR) and long-term catheter measures form the second domain which is named "Other Outcomes 1 (SFR, Catheter)." All Kt/V and Hypercalcemia QMs form the third domain and is named "Other Outcomes 2 (Total Kt/V, Hypercalcemia)." These domains are equally weighted in determining the final facility score for the star rating.

As the DFC QMs have different distributions, scales, and direction of better performance, the measure values are transformed into measure scores in order to make the metrics comparable. Transformation of measure values into measure scores are described below for baseline year and the current data period.

Baseline Period

Percentage Measures

The four percentage QMs (Total Kt/V, Hypercalcemia, Long-Term Catheter Rate, and SFR) vary in their distributions. These measures are scored with 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.

Standardized Ratio Measures

The four standardized ratio QMs are scored differently than the four percentage QMs since the quality associated with a unit change in a ratio measure is not equally spaced. Probit scoring better reflects spacing differences than z-scores, which assume equal spacing. In addition, since the probit function maps percentiles of the standardized ratio measures to a distribution with mean 0 and variance 1, this type of scoring can be easily combined with the percentage measures.

Evaluation Period

Percentage Measures

The purpose of scoring measures relative to the baseline period data is to map each measure value to the same score that the measure value would have been mapped to if it had been observed in the baseline period. Z-scores in the evaluation data period are therefore calculated by subtracting the mean and dividing by the standard deviation of the measure in the baseline period. These z-scores are then truncated at the same values as truncated in the baseline period and re-standardized using the mean and the standard deviation of the truncated z-scores in the baseline period.

Standardized Ratio Measures

Evaluation period facility ratios are first multiplied by the adjustment factor (described in the Technical Notes on the Updated Dialysis Facility Compare Star Rating Methodology for the October 2018 release) to create individual facility adjusted ratios. Each adjusted ratio is mapped to the same percentile that the ratio would have been mapped to if it had been observed in the baseline period. The cutoffs used for the percentiles are determined by the best measure value within each percentile in the baseline period.

Further details of the calculation are presented in the row descriptions below.

Standardized Outcomes Domain

Standardized Outcomes Score (6a)

The score for this domain is between -2.58 and 2.58 and was computed by averaging the measure scores for measures within the Standardized Outcomes domain. Suppressed measures were treated as missing when calculating the domain score. If there was at least one non-missing measure in the domain, the missing measures in the domain were given the average measure score to limit the non-missing measures from being too influential. If all measures within the domain were missing, then the domain did not receive a score.

Standardized Mortality Ratio (SMR) (6b)

The SMR equals the ratio of the observed number of deaths at your facility divided by the expected number of deaths, as compared to the national death rate in the same year, adjusted for facility patient case mix, including incident patient comorbidities. A lower ratio is better. Please see Section V of this guide for more information about the SMR. The time period used for the current star rating calculation is January 1, 2015 – December 31, 2018.

Measure Score: SMR (6c)

This measure is scored using percentile ranking and probit scoring technique in order to accommodate for the unequal spacing with a unit change in a ratio measure. Percentiles ranging from 0.5 to 99.5 in increments of 0.5 are used, resulting in 199 distinct percentiles. The associated minimum probit score is -2.58 and the maximum probit score is 2.58.

Standardized Hospitalization Ratio (Admissions) (SHR) (6d)

The SHR (admissions) is calculated by dividing the observed total admissions by the expected number of admissions. As with the SMR, it enables a comparison of your facility's experience to the national average. A lower ratio is better. Please see Section V of this guide for more information about the SHR. The time period used for the current star rating calculation is January 1, 2018 – December 31, 2018.

Measure Score: SHR (6e)

Same method as for SMR. Please see "Measure Score: SMR" above for description.

Standardized Readmission Ratio (SRR) (6f)

The SRR is calculated by dividing the total number of unplanned hospital readmissions by the expected number of admissions. As with the SMR, it enables a comparison of your facility's experience to the national average. A lower ratio is better. Please see Section V of this guide for more information about the SRR. The time period used for the current star rating calculation is January 1, 2018 – December 31, 2018.

Measure Score: SRR (6g)

Same method as for SMR. Please see "Measure Score: SMR" above for description.

Standardized Transfusion Ratio (STrR) (6h)

The STrR is calculated by dividing your facility's observed total transfusions by the expected number of transfusions. As with the SMR and SHR, the STrR enables a comparison of your facility's experience to the national average. A lower ratio is better. Please see Section V of this guide for more information about the STrR. The time period used for the current star rating calculation is January 1, 2018 – December 31, 2018.

Measure Score: STrR (6i)

Same method as for SMR. Please see "Measure Score: SMR" above for description.

Other Outcomes 1 Domain

Other Outcomes 1 Score (6j)

The score for this domain is between -2.58 and 2.58 and was computed by averaging the measure scores for measures within this domain. Suppressed measures were treated as missing when calculating the domain score. If there was at least one non-missing measure in the domain, the missing measures in the domain were given the average measure score to limit the non-missing measures from being too influential. If all measures within this domain were missing, then the domain did not receive a score. Note however that facilities which service only peritoneal dialysis patients are not expected to have measures in this domain and, therefore, this domain is not included in the calculation of the star rating for these PD-only facilities.

Standardized Fistula Rate (SFR) (6k)

Adjusted percentage of adult hemodialysis patient-months using an arteriovenous fistula (AVF) as the sole means of vascular access (higher is better). The time period used for the current star rating calculation is January 1, 2018 – December 31, 2018. Percentages based on 10 or fewer patients are shown in this table but will be reported as 'Not Available' on DFC.

Measure Score: SFR (61)

This measure is scored with truncated z-scores. Truncated z-scores represent the number of standard deviations away from the mean, truncated at a maximum/minimum allowed value. The upper and lower truncation bounds are different for each measure and are chosen so that all final measure scores have a maximum range of -2.58 to 2.58.

Long-Term Catheter Rate (6m)

Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access (lower is better). The time period used for the current star rating calculation is January 1, 2018 – December 31, 2018. Percentages based on 10 or fewer patients are shown in this table but will be reported as 'Not Available' on DFC.

Measure Score: Catheter (6n)

This measure is scored with truncated z-scores. Truncated z-scores represent the number of standard deviations away from the mean, truncated at a maximum/minimum allowed value. The upper and lower truncation bounds are different for each measure and are chosen so that all final measure scores have a maximum range of -2.58 to 2.58.

Other Outcomes 2 Domain

Other Outcomes 2 Score (60)

The score for this domain is between -2.58 and 2.58 and was computed by averaging the measure scores for measures within this domain. Suppressed measures were treated as missing when calculating the domain score. If there was at least one non-missing measure in the domain, the missing measures in the domain were given the average measure score to limit the non-missing measures from being too influential. If all measures within this domain were missing, then the domain did not receive a score.

Adult HD: $Kt/V \ge 1.2$ (6p)

Percentage of adult hemodialysis patients who had enough wastes removed from their blood during dialysis: Kt/V greater than or equal to 1.2 (higher is better). The time period used for the current star rating calculation is January 1, 2018 – December 31, 2018. Percentages based on 10 or fewer patients are shown in this table but will be reported as 'Not Available' on DFC.

Adult PD: $Kt/V \ge 1.7$ (6q)

Percentage of adult peritoneal dialysis patients who had enough wastes removed from their blood during dialysis: Kt/V greater than or equal to 1.7 (higher is better). The time period used for the star rating calculation is January 1, 2018 – December 31, 2018. Percentages based on 10 or fewer patients are shown in this table but will be reported as 'Not Available' on DFC.

Pediatric HD: Kt/V ≥1.2 (6r)

Percentage of pediatric hemodialysis patients who had enough wastes removed from their blood during dialysis: Kt/V greater than or equal to 1.2 (higher is better). The time period used for the star rating calculation is January 1, 2018 – December 31, 2018. Percentages based on 10 or fewer patients are shown in this table but will be reported as 'Not Available' on DFC.

Pediatric PD: Kt/V ≥1.8 (6s)

Percentage of pediatric peritoneal dialysis patients who had enough wastes removed from their blood during dialysis: Kt/V greater than or equal to 1.8 (higher better). The time period used for the star rating calculation is January 1, 2018 – December 31, 2018. Percentages based on 10 or fewer patients are shown in this table but will be reported as 'Not Available' on DFC.

Total $Kt/V \ge$ specified threshold (6t)

The individual Kt/V measures were combined into one overall measure for calculation of the domain score. The percentage of patients that achieve Kt/V greater than the specified thresholds for the respective modality and adult or pediatric age group was weighted based on the number of patient-months of data available. The resulting combined measure (Total Kt/V) represents the percentage of total dialysis patients who had enough wastes removed from their blood (Kt/V greater than or equal to specified threshold). If the overall Kt/V percentage is based on 10 or fewer patients, then it is reported as 'Not Available' in this table.

Measure Score: Overall Kt/V (6u)

Same method as for Catheter. Please see "Measure Score: Catheter" above for description.

Serum calcium > 10.2 mg/dL (6v)

Percentage of adult dialysis patients who had an average calcium over the past three months greater than 10.2 mg/dL (hypercalcemia) (lower is better). The time period used for the current star rating calculation is January 1, 2018 – December 31, 2018.

Measure Score: Hypercalcemia (6w)

Same method as for Catheter. Please see "Measure Score: Catheter" above for description.

Final Score and Overall Star Rating

Final score (6x)

The measure scores are combined to create a final facility score for each facility. First, each facility is given domain scores between -2.58 and 2.58 by averaging the measure scores within each of the three domains: Standardized Outcomes, Other Outcomes 1, and Other Outcomes 2. Facilities are then given a final score between -2.58 and 2.58 by averaging the domain scores. Facilities are given final scores as long as they have at least one measure in each domain. Note again that facilities which only service peritoneal dialysis patients are not expected to have measures in the Other Outcomes 1 Domain and therefore this domain is not included in the calculation of the star rating for these PD-only facilities. These facilities will still receive a final score based on the average of the other two domains, provided those domains have at least 1 non-missing measure in each of them.

Missing values for facilities that qualify for ratings are assigned the mean of the scores given to that measure. In the baseline period, the missing value is imputed with the mean of the measure in the *baseline period*. And in the evaluation period, the missing value is imputed with the mean of the measure in the *evaluation period*. This method of imputation ensures that one measure does not exert too much influence on the domain score, and in turn, the final score used to determine the Star Rating. For example, if one facility had the maximum measure score of 2.58 for STrR and had missing values for SMR and SHR, it would not be appropriate to assume that the Standardized Ratio Measure Domain should be given the maximum score of 2.58 for the two missing measures (i.e., SMR and SHR) based on the one available measure for that domain (i.e., STrR).

Overall Star Rating (6y)

The final score cutoffs for the star rating are defined using the *baseline year* data. Final score cutoffs for the baseline period (April 2018 QDFC) are set so that approximately 3%, 8%, 35%, 27%, 26% facilities are assigned 1-, 2-, 3-, 4-, 5-stars, respectively, in order to maintain the longitudinal continuity of the star ratings. The final score cutoffs calculated based on these proportions are retained and used to define star rating categories in the October 2018 star ratings and for future star ratings until a new baseline year is established.

The final score cutoffs defined using the *baseline period* data are used to assign star ratings to facilities for the *evaluation period*. If the population of facilities improves in their measure performance from the *baseline period*, more facilities are likely to be in the higher star rating categories compared to the baseline period. That is because they are being compared to the lower of average performance that prevailed in the earlier baseline year, rather than relative to the average performance of other facilities in the *evaluation period*. When facilities move up in star ratings other facilities will not necessarily move down into

lower star rating categories, unless their individual performance declined compared to the *baseline period*.

Some facilities will not receive a star rating if they are missing (or had suppressed) all measures in at least one domain (excepting PD-only facilities) or if they are new facilities. Facilities that only service peritoneal dialysis patients will not have measures in the Other Outcomes 1 domain but will still receive a star rating based on the average of the other two domains, provided those domains have at least 1 non-missing measure in each of them. If a star rating is not provided, the table will say "Not Available" along with an explanation indicated by a footnote.

XI. Please Give Us Your Comments

We welcome questions or comments about this report's content, or any suggestions you may have for future reports of this type. Improvements in the content of future reports will depend on feedback from the nephrology community. Comments can be submitted via www.DialysisData.org November 1st-15th. If you have questions after the comment period is closed, please contact UM-KECC directly using the contact information provided below. Please note "Dialysis Facility Compare Reports – Preview for January 2020" as the topic of your correspondence, and include your contact information and facility's CMS certification number (CCN).

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