Guide to the Modified Measures Table for the Quarterly Dialysis Facility Compare Report:

Overview, Methodology, and Interpretation

July 2021

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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.

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 VII.

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 2017-2020. These summaries are compiled using the UM-KECC ESRD patient database, which is largely derived from the CMS Consolidated Renal Operations in a Web-enabled 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 7,800 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, and Transfusion (SMR, SHR, SRR, and STrR) 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). 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 IV, VI). Section VI is organized according to the order of the summaries in the QDFC report, and may serve as a reference for their interpretation. Sections V and VII provide additional information regarding the Preview Period process. 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. On page 3, the report includes a table containing detailed information for your facility as well as regional averages for comparison. This table provides patient mortality (2017 - 2020), hospitalization (2020), hospital readmission (2020), and transfusion (2020) summaries. Note that for the four-year mortality summaries, individual patients typically contribute data for more than one year.

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 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. 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. Data Limitations

Due to the COVID Extraordinary Circumstances Exception (ECE) data policy from CMS and incomplete CROWNWeb data for 2020, the measures shown in this report, calculated for calendar year 2020, have been modified to optimize the available information.
The CMS ECE policy restricts the use of claims data from March through June 2020. Therefore, for SMR, SHR, and STrR, outcome data during March-June 2020 are excluded from all calculations due to data exceptions. This includes all time at risk and events. Determination of past year comorbidities, nursing home status, and Medicare eligibility adjustments will include March-June 2020 claims data. For SRR, index discharges between January 31st - February 29th 2020,

and November-December 2020 are also excluded. In addition, CROWNWeb data incompleteness for the end of 2020 means that we are missing most dialysis patients that are incident during the last three months of the year and cannot attribute patients to dialysis facilities for the last two months of the year. Fortunately, many measures reported in the report do not require incident patients or patient assignment through the end of 2020 in order to be calculated correctly because of the 90-day new patient rule and 60-day facility transfer rules (see Section IV). Information on death, hospitalizations, transplant, and nursing home are available through the end of 2020. A summary of data available for the measures in the report is provided below:

Measure	Data Availability
Standardized Mortality Ratio (SMR) Standardized Hospitalization Ratio (SHR) Standardized Transfusion Ratio (STrR)	January-February, July-December, 2020 (8 months)
Standardized Readmission Ratio (SRR)	January 1 - 30, July-October, 2020 (5 months)

IV. 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 Modified Measures Table 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 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 are 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, if a period of one year passed with neither Medicare dialysis claims nor CROWNWeb information to indicate that a patient was receiving dialysis treatment and if there was no earlier evidence of transfer, recovery, or death, 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 SRR

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.

V. Dialysis Facility Compare Preview

The measures included in the Modified Measures Table will not be reported on the DFC website or included in the star rating at this time. Please refer to section V 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.

VI. Mortality Summary for Medicare Dialysis Patients (2017-2020), Hospitalization Summary for Medicare Dialysis Patients (2020), Readmission Summary for Dialysis Patient Hospitalizations (2020), Transfusion Summary for Adult Medicare Dialysis Patients (2020)

The first section of the Modified Measures table (rows 1.1-1.8) provides information about patient mortality for all Medicare dialysis patients treated at your facility between 2017 and 2020. We also reported the averages in your state, and the nation for this combined four-year period. The remainder of the table (rows 2.1- 4.8) provides information about hospitalization admissions among all Medicare dialysis patients, readmissions of Medicare-covered hospitalizations that ended in 2020, and transfusions among all adult Medicare dialysis patients treated at your facility in 2020, along with state and national comparisons for this reporting period.

Standardized Mortality Ratio (SMR) (1.1 - 1.8)

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 (1.1)

We based the mortality summaries in the first half of the table (rows 1.1-1.8) on the dialysis patients who received treatment in your facility according to the conventions described in Section IV. 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, or that patients are under Medicare Advantage coverage according to the Medicare Enrollment Database. 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 $1,200 of Medicare-paid dialysis claims or at least one Medicare inpatient claim. Patients are also included if they are in the same month of Medicare Advantage coverage.

Patient Years at Risk (1.2)

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 IV) 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 (1.3)

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 (1.4)

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) / height^2(m^2)). We also controlled for age-adjusted population death rates by state and race, based on the U.S. population in 2014-2016 (2017 National Center for Health Statistics, 2018). As with the deaths in 1.3, 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) (1.5)

The SMR equals the ratio of the actual number of deaths (1.3) divided by the expected number of deaths (1.4). It estimates the ratio of facility death rate relative 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 2017 - 2020 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 (rows 1.3/1.4).

Why the National SMR May Not Be Exactly Equal to 1.00

The reported 2017 – 2020 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 section, 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 rate. 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 national death rate. 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 (1.5)

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 (1.6)

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 national 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. 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 (1.7)

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.

Classification Category (1.8)

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 if it is based on fewer than three expected deaths.

Standardized Hospitalization Ratio (SHR): Admissions (2.1 – 2.8)

The SHR (admissions) is calculated by dividing the observed total admissions in 2.3 by the expected total admissions in 2.4. As with the SMR, it enables a comparison of your facility's experience to the national average. A value of less than 1.00 indicates that your facility's total number of admissions was less than expected, based on national rates; whereas a value of greater than 1.00 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 (2.1)
The number of Medicare dialysis patients included in the hospitalization summaries are based on dialysis patients who received treatment in your facility according to the conventions described in Section IV. We also require that patients reach a certain level of Medicare-paid dialysis bills, or that patients have Medicare inpatient claims during the period, or that patients are under Medicare Advantage coverage according to the Medicare Enrollment Database. Specifically, a patient-month within a given dialysis patient-period is included in the SHR calculation 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 $1,200 of Medicare-paid dialysis claims or at least one Medicare inpatient claim. Patients are also included if they are in the same month of Medicare Advantage coverage.

Patient Years at Risk (2.2)
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 IV) 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 (2.3)
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 (2.4)
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, Medicare Advantage coverage, 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 (2.5)

The SHR (admissions) is calculated by dividing the observed total admissions in 2.3 by the expected total admissions in 2.4. As with the SMR, it enables a comparison of your facility's experience to the national average. A value of less than 1.00 indicates that your facility's total number of admissions was less than expected, based on national rates; whereas a value of greater than 1.00 indicates that your facility had a rate of total admissions higher than the national average. Additionally, the estimate is compared to the US hospitalization rates for Medicare dialysis patients the same year.

Confidence Interval (Range of Uncertainty) for SHR (2.5)

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 (2.6)

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 national 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.

Hospitalization Rate (per 100 patient-years) and Confidence Interval (Range of Uncertainty) for Hospitalization Rate (2.7)

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.

Classification Category (2.8)

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 if the facility has less than 5 patient years at risk.

Standardized Hospital Readmission (SRR) Summary for Dialysis Patients (3.1 – 3.7)

Unplanned readmission rates are an important indicator of patient morbidity and quality of life. On average, dialysis patients are admitted to the hospital nearly twice a year and hospitalizations account for approximately 38% of total Medicare expenditures for dialysis patients (U.S. Renal Data System, 2018). In 2010, 37% of dialysis patient discharges from an all-cause hospitalization were followed by an unplanned readmission within 30 days (U.S. Renal Data System, 2018). Measures of the frequency of unplanned readmissions, such as SRR, help efforts to control escalating medical costs, play an important role in providing cost-effective health care, and support coordination of care across inpatient and outpatient settings. Preventive interventions such as fluid weight management, management of mineral and bone disease, anemia management as well as post-discharge processes of care (medication reconciliation) by dialysis facilities, and coordination of care with other providers in the pre and post-discharge periods (communication with the dialysis provider; medication reconciliation) have the potential to prevent hospital readmissions for ESRD dialysis patients. Preventing hospital readmissions is regarded as a shared responsibility that can be impacted by both dialysis providers and hospitals.

Readmission summaries for dialysis patients are reported in the third section of the Modified Measures Table.

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, age and diabetes interaction, 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 a nursing home stays 365 days prior to discharge, Medicare Advantage status at time of discharge, length of stay of the index hospital discharge, and BMI at onset of ESRD.

Index Discharges (3.1)

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 (3.2)

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.

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 his or her 15^{th} day after hospital discharge, then is readmitted to the hospital on the 20^{th} day after discharge while in Facility B, that readmission will be attributed to Facility A, not to Facility B.

Expected Total Readmissions (3.3)

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, age and diabetes interaction, 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 a nursing home stays 365 days prior to discharge, Medicare Advantage status at time of 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) (3.4)

We calculated the SRR by dividing the observed total readmissions in 3.2 by the expected total readmissions in 3.3. 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 1.00 indicates that your facility's total number of readmissions is less than expected, based on national rates; whereas a value of greater than 1.00 indicates that your facility had a rate of total readmissions higher than

would be expected given national rates. In addition, the estimate is compared with the US readmission rates for the same year.

Confidence Interval (Range of Uncertainty) for SRR (3.4)

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 (3.5)

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 national 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 (3.6)

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.

Classification Category (3.7)

If the facility SRR 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 SRR is not reported if the facility has fewer than 11 index discharges.

Standardized Transfusion Ratio (STrR) (4.1 – 4.8)

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 also 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 $1200 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 2020national 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.

Please note that the specifications for the Standardized Transfusion Ratio have been revised this year. 1) Patient time at risk excludes time during which a patient is enrolled in Medicare Advantage, according to the Medicare Enrollment Database. 2) We used a broader definition of transfusion events. The revised definition includes inpatient transfusion events for claims that include only 038 or 039 revenue codes without an accompanying procedure or value code. This broader definition of transfusion events results in an increased total number of events identified as well as the range of total events for dialysis facilities.

Adult Medicare Patients (4.1)

The number of adult Medicare dialysis patients included in the transfusion summaries (4.1) is generally smaller than the number of patients included in the mortality and hospitalization summaries ((1.1) and (2.1)) because of the exclusion criteria. See above.

Patient Years at Risk (4.2)

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 IV) 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 Transfusions (4.3)

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 https://dialysisdata.org/sites/default/files/content/CodesForDFC_0.pdf .

Expected Total Transfusion (4.4)

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 4.4.

Standardized Transfusion Ratio (STrR) (4.5)

The STrR is calculated by dividing the observed total transfusions in 4.3 by the expected total transfusions in 4.4. 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 1.00 indicates that your facility's total number of transfusion events was less than expected, based on national rates; whereas a value of greater than 1.00 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 (4.5)

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 (4.6)

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 national 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.

Transfusion Rate (per 100 patient-years) and Confidence Interval (Range of Uncertainty) for Transfusion Rate (4.7)
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.

Classification Category (4.8)
Classification is based on the STrR, not the transfusion rate. If your facility's STrR is less than 1.00 and statistically significant ($p<0.05$), the classification is "Better than Expected". If the STrR 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 STrR is not reported if there are fewer than 10 patient years at risk in your facility in the year.

VII. Please Give Us Your Comments

We welcome questions or comments about this report's content. Comments can be submitted via www.DialysisData.org July 15th through August 15th 2021. If you have questions after the comment period is closed, please contact UM-KECC directly using the contact information provided below. Please include your contact information and the facility's CMS certification number (CCN).

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