



November 14, 2016

Kate Goodrich, M.D.
Director
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Goodrich,

On behalf of Kidney Care Partners (KCP) and its members, I am writing to share comments on the changes that were presented on October 5th for the methodology and new measures for Star Ratings of dialysis facilities. We appreciate the Agency's efforts to work with the kidney care community to revise the Star Rating methodology and opportunity to comment on measures under consideration for Dialysis Facility Compare (DFC)/ESRD Five Star Rating Program (ESRD Five Star). As you know, the appropriate implementation of ESRD Five Star is a top priority for the members of KCP. It is critically important to create a system that is accurate, transparent, and easy for patients, family members/caregivers, and other consumers to understand.

Therefore, we continue to express our support and appreciation for CMS modifying the ESRD Five Star methodology to recognize improvement, the adoption of the z-score methodology for the rate measures, and the removal of the proposed triggers for rebasing.

The updated methodology represents important progress, as does the improved transparency that Dr. Andress described on the October 5th call. We strongly support having a candidate measure open for comment two years before it is added to DFC/ESRD Five Star, as well as providing facilities a preview year before measures are incorporated. We look forward to working with you to continue improving this program and, as you requested, offer comments on the candidate measures. We also include some suggested refinements to the modified methodology to help address remaining concerns.

I. KCP supports the process for considering candidate measures and facility review and provides comments on the candidate measures.

KCP supports the goal of DFC/ESRD Five Star to provide information about the performance of dialysis facilities to empower patients, family members/caregivers, and consumers. As we have described in the past, the

cornerstone of achieving this goal is to provide for meaningful community input and transparency. Thus, we are pleased that CMS has decided to provide a comment period for candidate measures that could be added to DFC/ESRD Five Star two years before such measures would be added. We also strongly support providing facilities with a preview year before measures are incorporated. We encourage CMS to continue this process going forward.

A. Measures that Matter

As CMS continues to consider modifying the measures in DFC/ESRD Five Star, we ask that the Agency work with KCP to make sure that these programs focus on valid and reliable measures that will have the greatest impact on improving patient outcomes. The number of measures should also be limited to prevent the dilution of their impact on the overall star rating. We echo MedPAC's concerns and its recommendation that "[t]he set of measures should be small to minimize the administrative burden on providers and CMS."¹ We ask that CMS work closely with KCP and others in the kidney care community to create a parsimonious set of measures that will further the Triple Aim, rather than compromise it.

B. KCP supports adding the Pediatric Peritoneal Dialysis Adequacy, Standardized Fistula, and Long-Term Catheter Measures to ESRD Five Star.

KCP supports adding the pediatric peritoneal dialysis and new fistula and long-term catheter measures to ESRD Five Star. We have separately recommended additional refinements to the fistula measure and look forward to working with CMS to improve that measure's risk adjustment in the future.

Specifically, KCP believes the specifications should be clarified as to whether facilities would receive credit for patients using an AVF as the sole means of access, but who also have in place a catheter that is no longer being used. The measure definition of autogenous AVF "as the sole means of vascular access" is imprecise as to whether facilities would receive credit for patients using an AVF as the sole means of access, but who also have in place a catheter that is no longer being used. In previous letters we have described how patients with catheters remain at risk for infection and other adverse sequelae, so credit should not be given when a catheter is present, even if an AVF is being used. A numerator that specifies the patient must be on maintenance hemodialysis "using an AVF with two needles and without a dialysis catheter present" would remove ambiguity. In contrast, removal of an AV graft is complex and not without risk of complications, so KCP believes credit should be received for a patient who is using an AVF as the sole means of access, but who also may have a non-functioning AV graft present.

¹MedPAC, *Report to the Congress*, "Chapter 3: Measuring Quality of Care in Medicare" 41 (June 2014).

We remain supportive of the removal of the 90-day ESRD requirement from the denominator statement. Additionally, we commend the developer for adding an exclusion for patients with limited life expectancy and for now unambiguously identifying the four subcategories, both approaches that KCP had recommended.

While we appreciate that the developer has removed the covariate alcohol dependence from the model's risk variables, we continue to believe two additional vasculature risk variables would strengthen the model: A history of multiple prior accesses and the presence of a cardiac device. The validity testing yielded an overall c-statistic of 0.71, which raises concerns that the model will not adequately discriminate performance—particularly that smaller units might look worse than their actual performance really is. A minimum c-statistic of 0.8 is a more appropriate indicator of the model's goodness of fit and validity to represent meaningful differences among facilities and encourage continuous improvement of the model.

C. KCP supports including the ICH CAHPS measure on a separate DFC webpage and keeping it out of the star ratings, but also encourages CMS to address the burden of implementing the ICH CAHPS measure on patients.

KCP has consistently supported using the ICH CAHPS measure as a reporting measure for the Quality Incentive Program (QIP); we similarly support providing the results of the ICH CAHPS survey on DFC, so long as it is not included in the ESRD Five Star overall rating and so long as CMS includes the response rate (*i.e.*, how many patients were eligible to respond and how many actually responded) with the results. The response rate is critically important to allow patients and caregivers to understand and interpret the information they are seeing. Before it can be included in the ratings, the burden it places on patients needs to be resolved to ensure that the majority of patients are able and willing to complete the survey tool. Therefore, we ask that CMS work with KCP and the kidney care community.

In previous letters, we have suggested that CMS decrease the burden on patients and facilities of the twice-yearly administration. The American Institutes for Research/RAND *et al.* have described in detail the difficulties in translating the results from ICH CAHPS into interventions resulting in meaningful improvement when administered more frequently than once a year.² We continue to believe that reducing the frequency and eliminating Network duplication in administration will decrease the burden on patients, increase their participation and survey completeness rates, decrease costs, and increase facilities' capacity to respond to

² American Institutes for Research, RAND, Harvard Medical School, Westat, Network 15. Using the CAHPS® In-center Hemodialysis Survey to Improve Quality: Lessons Learned from a Demonstration Project. Rockville, MD: Agency for Healthcare Research and Quality (Dec. 2006).

survey results. Given our previous recommendations, we would like to better understand why CMS considers administering the survey once each year inadequate so that we can work to find a viable solution.

In previous letters, we have raised concerns about patients being unable to finish the complete survey because of its length and recommended that CMS divide the survey into the three sections that were already independently validated. If there is a reason why this suggestion is not workable, we would like to better understand the concern and work with CMS to find another alternative that promotes the completion of the survey by patients.

We also recommend that CMS ensure the accuracy of the administration of the survey. First, it is critically important to have a mechanism, which does not appear to exist currently, for facilities to ensure that patients' contact information is as accurate and up-to-date as possible. Because response rates necessarily depend on accurate contact information, we recommend inclusion of an opportunity for facilities to ensure that the primary survey and/or any follow-up is delivered to the most current contact (phone or mail) given the penalty that applies for non-responsiveness. Similarly, CMS should review the lingual translations of the surveys to ensure that they are accurate. Several translation errors have been reported to us, and the Agency has a responsibility to ensure that the information gleaned from all foreign-language speakers is accurate and meaningful.

As we have noted previously, we also suggest that the Agency update the survey to include home dialysis patients as well.

KCP agrees that it is important to provide information about patient satisfaction. While ICH CAHPS may not be perfect, it is an appropriate tool to use at the present time, if the concerns KCP and most significantly patients have raised with the burden of completing the survey and the accuracy in its administration. We are sincere in our request to work with CMS to resolve these problems in the near term.

D. KCP continues to have significant concerns about the reliability of the Standardized Mortality Ratio (SMR), Standardized Hospitalization Ratio (SHR), Standardized Transfusion Ratio (STrR), and Standardized Readmission Ratio (SRR).

KCP applauds CMS for moving away from ratios and transition to rates. We were also pleased to see prevalent co-morbidities incorporated into the SMR and SHR measures as well.

Despite these positive steps forward, KCP remains concerned about the reliability of these measures. It is simply not clear what value these measures provide patients when a clear majority of measure's reliability score is due to random chance. For example, CMS's testing data indicates 60-70 percent of a small facility's score is due to chance. Similarly for the SHR, 43 percent of a medium-sized facility's score is due to noise and not a signal of quality; 54 percent is due to noise for small facilities. Similar poor reliability exists for the 4-year SMR, where 55-70 percent of a facility's score is due to differences in performance for small- and medium-sized facilities. Rather than providing the accurate information patients, family members/caregivers, and consumers need to make decisions, these measures present random data that can be misleading and confuse patient decision-making. We recommend that CMS describe how it will address these short-comings before adding these measures to the ESRD Five Star ratings.

Additionally, concerns about several of the technical details of the SMR, SHR, STrR, and SRR unfortunately remain unresolved. We have conveyed those concerns separately and have included them in the appendix to this letter.

E. Because the data show that the NHSN Blood Stream Infection Measure is not valid, KCP cannot support including it in DFC/ESRD Five Star.

Finally, as we have communicated in our most recent letter, KCP recognizes the vital importance of reducing infections and strongly supports efforts to do so. However, we cannot support use of the NHSN BSI Measure for inclusion on DFC and in ESRD Five Star because the Centers for Disease Control and Prevention's (CDC) research and CMS's data have demonstrated that the measure is not valid. For example, CMS has stated that its review of data reported for the PY 2015 NHSN Dialysis Event Reporting Measure and results from the PY 2014 NHSN data validation feasibility study suggest that as many as 60-80 percent of dialysis events are under-reported.³ Simply put, this high under-reporting rate demonstrates the measure is not valid. A lack of validity means that we cannot be certain that the measure results in accurate findings. Reporting inaccurate findings on Dialysis Facility Compare and including it in the Five Star ratings misleads patients who are trying to use measures to make informed decisions about their care.

³ESRD QIP Proposed Rule Display Copy 90.

II. KCP commends CMS for modifying the methodology to move away from the forced distribution and seeks clarity regarding rebasing to ensure that the problems of the past do not recur.

KCP continues to believe that ESRD Five Star ratings should align as closely as possible with actual facility performance. Therefore, we were pleased when CMS announced the revised ESRD Five Star methodology that moves to a z-score model to score most of the individual measures, as KCP had suggested previously and patient organizations strongly support.

Additionally, we are pleased that CMS has changed the methodology to use fixed performance benchmarks for the Star Rating cut points. This will allow facilities to demonstrate performance changes over time and eventually would allow the distribution of Star Ratings to shift based on overall improvement trends. Both of these results are aligned to the overall program goals on conveying accurate information to consumers.

We remain concerned, however, that the improvements in the methodology could be undermined by using the 10-20-40-20-10 distribution when the stars are “rebased.” We ask that CMS provide more information about how it views rebasing. Specifically, it is not clear whether CMS plans to return star ratings to the 10-20-40-20-10 distribution when it adds new measures. We strongly urge CMS not to use this distribution and instead continue to rely upon the fixed performance benchmarks to address the concerns expressed by the kidney care community and, in particular, the patient organization participants in the ESRD Star Rating Technical Expert Panel (TEP).

Our previous comment letter raised concern about “using rebasing triggers that seem likely to result in the rebasing the star ratings every year.” The final methodology released by CMS makes a clear distinction between rebasing individual measures and rebasing the overall Star Rating distribution. Therefore, we interpret that the final methodology permits rebasing of one and not the other. We support this interpretation. The less frequently the program is rebased, the more it will display for consumers the ongoing improvements in quality among dialysis facilities.

The final methodology also provides for rebasing when the program “becomes ineffective at communicating differences in outcomes between facilities due to shifting to the extreme.” We request that CMS clarify this criterion so that the ESRD community can better anticipate potential changes and updates to the program. We recommend that CMS work with KCP to more clearly articulate the rebasing process.

III. Conclusion

Once again, we want to thank you and your team for addressing some of the concerns we have raised in previous letters. We reiterate our commitment to working with you to resolve the outstanding issues that will allow the Star Rating program to achieve the Agency's goal and be a useful tool for patients, caregivers, and consumers. Please do not hesitate to contact Kathy Lester at klester@lesterhealthlaw.com or (202) 534-1773 if you have questions or would like to discuss these recommendations.

Sincerely,

A handwritten signature in black ink that reads "Frank Maddux M.D." with a stylized flourish at the end.

Frank Maddux, M.D.
Chairman
Kidney Care Partners

Appendix: Technical Comments on Selected Candidate Measures

STANDARDIZED MORTALITY RATIO (NQF #0369)

KCP recommends working with the kidney care community to address concerns about the current Standardized Mortality Ratio (SMR) measure.

KCP believes mortality is an important outcome to measure, but has on several occasions expressed concern about the current SMR. We appreciate the CMS's recognition in 2013 that it needed to "properly take into account the effect that comorbidities have on hospitalization and mortality rates in the ESRD population,"⁴ as well as its movement away from exclusively relying on the 2728 data. However, we remain concerned about the testing data, which indicate significant reliability issues with the SMR for small- and medium-sized facilities—even with the 4-year measure. Empirical testing has demonstrated that for the 4-year SMR, on average, less than 60% of a facility's score is attributable to between-facility differences; testing results specifically for small- and medium-sized facilities indicate very poor reliability, with IURs of 0.30 and 0.45, respectively. Given the poor reliability testing results, KCP believes the specifications must explicitly require a minimum sample as identified through the developer's empirical testing.

Additionally, we note the SMR specifications indicate the measures can be expressed as a rate, but is calculated as a ratio. KCP continues to support the use of rate measures because they allow patients and facilities to see year-over-year differences between normalized rates (deaths per 100 patient years) for mortality and hospitalization. We believe comprehension, transparency, and utility to all stakeholders is superior with a scientifically valid *rate* methodology.

STANDARDIZED HOSPITALIZATION RATIO (NQF #1463)

KCP would like to support the Standardized Hospitalization Ratio (SHR), but cannot until its reliability has been demonstrated.

KCP concurs that hospitalization is an important quality domain, and we appreciate and approve that the SHR now accounts for prevalent comorbidities. We would like to support a hospitalization measure, but continue to be concerned about the significant reliability issues for the 1-year SHR for small facilities and do not support incorporation of the SHR until its reliability at the proposed facility size is demonstrated.

Specifically, for facilities with ≤ 50 patients, more than half (54%) of a facility's score is due to random noise; even for medium facilities, 43% of a facility's score

⁴ "End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Proposed Rule" 78 *Fed. Reg.* 40836, 40861 (July 8, 2013).

attributable to random noise and is not a signal of quality. Given the poor reliability testing results, KCP also did not support CMS's proposal to include it in the Quality Incentive Program (QIP) for Payment Year 2020.

Additionally, we are concerned that only facilities with <5 patient-years at risk during the performance period are not eligible for the measure. As we have noted elsewhere, KCP believes the standardized ratio measures should be harmonized—currently the SHR uses a <5 patient-years at risk threshold, but the standardized mortality ratio and standardized transfusion ratio use <10 patient-years at risk.

Finally, the SHR specifications indicate the measures can be expressed as a rate, but is calculated as a ratio. KCP continues to support the use of rate measures because they allow patients and facilities to see year-over-year differences between normalized rates (hospitalizations per 100 patient years) for mortality and hospitalization. We believe comprehension, transparency, and utility to all stakeholders is superior with a scientifically valid *rate* methodology.

STANDARDIZED TRANSFUSION RATIO (NQF #2979)

KCP continues to have significant concerns about the reliability of the Standardized Transfusion Ratio (STrR) measure.

KCP again expresses our concern about the reliability of the STrR for small facilities. Specifically, testing yielded IURs of 0.30-0.41 for small facilities for each of 2011, 2012, 2013, and 2014, indicating approximately 60-70% of a small facility's score is due to random noise. KCP believes the specifications must specifically require a minimum sample as identified through the developer's empirical testing. Additionally, we again note that physicians independently (or following hospital protocols) make decisions about whether or not to transfuse a specific patient; the measure does not adjust for such hospital- and physician-related transfusion practices.

Finally, while KCP is pleased that CMS has decided to evaluate the impact of the STrR on access to care through the SRR/Standardized Transfusion Ratio Impact Study, we again question the appropriateness of using the measure until the results of the study are known remains. If CMS is unclear about whether these measures will have a positive or negative impact on dialysis patients and the care they receive, the Agency should not use these measures until it has such clarity. We again also recommend evaluating the effectiveness of the STrR in measuring the actual care provided in dialysis facilities.

STANDARDIZED READMISSION RATIO (NQF #2496)

KCP continues to have significant concerns about the reliability of the inclusion of the Standardized Readmission Ratio (SRR) measure.

KCP again expresses our concern about the reliability of the SRR. CMS presented reliability data to NQF for which even for large facilities with >121 patients, the IUR was only 0.61. Additionally, for SRR implementation in the QIP, CMS proposes an adjuster of 11-41 index discharges, but offers no rationale for this value. This lack of transparency undermines our ability to assess the proposed use of the measures. KCP believes that the values are too low, and will result in random volatility that the Small Facility Adjuster, as proposed, cannot fully offset.

Finally, while KCP is pleased that CMS has decided to evaluate the impact of the SRR on access to care through the SRR/Standardized Transfusion Ratio Impact Study, we again question the appropriateness of using the measure until the results of the study are known remains. If CMS is unclear about whether these measures will have a positive or negative impact on dialysis patients and the care they receive, the Agency should not use these measures until it has such clarity. We again also recommend evaluating the effectiveness of the SRR in measuring the actual care provided in dialysis facilities.