



November 6, 2015

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Chief Medical Officer
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Dear Dr. Conway:

On behalf of Kidney Care Partners (KCP), I am writing to thank you for the opportunity to provide comments on Dialysis Facility Compare (DFC)/ESRD Five Star. KCP supports initiatives to improve quality and provide patients, their families, and caregivers with accurate information about dialysis facility performance. We appreciate the opportunity to provide comments on the next iteration of DFC/ESRD Five Star and would welcome the opportunity to discuss these in further detail with you and your team.

In sum, KCP supports modifying the measures used in DFC/ESRD Five Star by addressing problems with some of the current measures, especially the standardized ratio measures, and incorporating the proposed new measures if they are modified as described below. KCP continues to believe that it is important that DFC/Five Star accurately assess the quality of care being provided in dialysis facilities. To that end, any and all measures used in DFC/ESRD Five Star should focus on practices and outcomes that are within the control of the facility. In addition, we echo the concerns raised by the ESRD Five Star TEP patient work group and reiterate our concerns with the decision to make ESRD Five Star a relative ranking system rather than a rating system.

I. KCP Supports Modifying the Measures Used in DFC/ESRD Five Star.

KCP appreciates the Agency's decision to allow public comment on the measures included in DFC/ESRD Five Star. Given that the stated goal for the program is to provide information that is useful to patients and consumers, it is important that the measures included are meaningful and provide accurate information.

A. KCP Supports the Inclusion of Some New Measures on ESRD/Five Star with Modifications.

KCP appreciates the opportunity to provide comments on the four measures CMS is considering adding to DFC/ESRD Five Star in 2016. As we have noted previously, it is important to maintain a balanced approach when adding quality measures to ensure that the impact of any one measure is not diluted by the ongoing desire to add more measures to a program. Consistent with recommendations from the Medicare Payment Advisory Commission (MedPAC), KCP encourages CMS to include fewer, more targeted measures in its quality programs.

1. Bloodstream Infection in Hemodialysis Outpatients (NQF #1460)

In previous comment letters, KCP has supported the inclusion of the NHSN Bloodstream Infection measure (NQF #1460) as a reporting measure. Our concerns about the measure more generally have related to the addition of the Adjusted Ranking Metric (ARM) and the lack of transparency in the methodology and, in particular, the lack of validation surrounding it. The NQF Renal Standing Committee initially recommended against endorsement of the modified NHSN Bloodstream Infection measure because of this lack of information and only recommended it without the ARM. We understand that the Agency does not plan to apply the ARM for PY 2019 in the ESRD Quality Incentive Program (QIP) and assume that this decision should apply to prior years, as well as to its potential inclusion in DFC/ESRD Five Star. To the extent CMS includes the previously endorsed NHSN Bloodstream Infection measure that does not include the ARM, KCP supports its inclusion in DFC/ESRD Five Star. As we understand it, CMS has adopted these changes in the recently released final rule for the ESRD QIP and, thus, recommend aligning the DFC/ESRD Five Star measure as well.

Additionally, we ask CMS to address the concerns the community has brought forth regarding the potential for a bimodal distribution of this measure. We also ask that CMS and the CDC release the Standardized Infection Ratio (SIR) distribution to validate if the NHSN data collection reflects differing comprehensiveness of data collection between all blood cultures for a patient and only those cultures from the ESRD reference lab. In that scenario the diligent get punished (by having a higher infection rate), while less diligent clinics will benefit from an artificially lower infection rate.

2. CAHPS (Consumer Assessment of Healthcare Providers) In-Center Hemodialysis Survey (NQF #0258)

KCP agrees that it is critically important to evaluate patients' experiences when receiving dialysis. We support including the ICH-CAHPS measure in

Patrick Conway, M.D.

November 6, 2015

Page 3 of 11

DFC/ESRD Five Star to the extent it can be modified to address concerns about the burden on patients and to align the specifications with those that Agency for Healthcare Research and Quality (AHRQ) relied on when it tested the measure, as well as to ensure the accuracy of its fielding. We also appreciate CMS' willingness to consider expanding the ICH CAHPS survey to include peritoneal dialysis and home hemodialysis patients in the future.

As noted in our recent ESRD QIP letter, KCP would like to work with CMS to identify ways to address the burden and cost issues associated with administering the survey.

In previous letters, we have also raised concerns about patients being unable to finish the complete survey because of its length and recommended that CMS divide it into the three sections that were independently tested. Given that the Agency has not yet made this modification, we ask that CMS work with us and the patient organizations to find another alternative that promotes the completion of the survey by patients. Similarly, we have raised concerns about the requirement to administer the survey twice each year. We would like to better understand why administering the survey once each year is inadequate. In fact, 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.¹ We also recommend that CMS coordinate with the Networks to reduce duplication in its administration.

It is important that if CMS plans to use ICH-CAHPS in DFC/ESRD Five Star that the Agency ensure the accuracy of the administration of the survey. 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 providing 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). 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.

We are disappointed that CMS has not addressed these concerns in the ESRD QIP and strongly encourage the Agency to resolve them in DFC/ESRD Five Star.

¹ See, 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," (December 2006).

3. Ultrafiltration rate greater than 13 ml/kg/hr

KCP believes fluid management is a critical area to address through performance measurement and strongly supports and recommends NQF #2701, *Avoidance of Utilization of High Ultrafiltration Rate* (developed by the Kidney Care Quality Alliance [KCQA]) be used in DFC/ESRD Five Star.

As noted in previous letters, KCP remains deeply concerned about the measure developed by UM-KECC for CMS because it relies on a single data point per month, whereas NQF #2701 relies on an average across all treatments provided over the course of a week (*i.e.*, the week the Kt/V is performed). Simply put, relying on a single data point is a significant threat to the validity of the measure CMS proposes to use in DFC/ESRD Five Star. Specifically, relying on a single data point disadvantages those facilities on a Monday/Tuesday blood draw schedule, since patients typically have more fluid at the first treatment of the week after a two-day gap in treatment. KCQA documented this issue in its submission to NQF and also provided the data to CMS in April 2015—*i.e.*, that Monday/Tuesday facilities are indeed disadvantaged merely because of the timing of the sampling. A single data point also is easier to game.

The CMS measure also lacks a time component, which in contrast is specified in NQF #2701. This measure includes patients in the numerator only if they have an average dialysis time of <240 minutes for the calculation period. The inclusion of the time component is critical to avoid an unintended adverse consequence that could result from the cascading effect of extending an individual's treatment time, given the upper rate of fluid removal is limited by the measure. Specifically, if an individual goes beyond his/her stated treatment time such that the following patient must start later, the second patient is likely to expect and want treatment to end at the "usual" time and, thus, be under-treated. Including the time component is important to mitigate a very real potential for unintended harm to this "third-party" individual due to measurement-related actions for other patients.

The NQF Renal Standing Committee, in its recent review of both ultrafiltration measures, also supported NQF #2701 and did not support the CMS measure; at this time the NQF Members and governance bodies also have approved NQF #2701 and the measure is in the appeals phase. We note that while the NQF Committee acknowledged that high ultrafiltration rates and short dialysis session times are independently associated with increased morbidity and mortality, it noted that the time component strengthens the KCQA measure because it acts as a "safety valve" to the ultrafiltration component. The NQF Committee noted that the KCQA measure allows a second path to meet the dialysis goal and is, because of this, at the same time more patient-centric. In contrast, the CMS measure can address intradialytic weight gain only in terms of the ultrafiltration rate—*i.e.*, if a patient is

unwilling or unable to extend the time of his/her session, there is no alternative way to meet dialysis goals for that patient for that session. Thus, we are pleased that CMS has not adopted the CMS measure for the ESRD QIP. However, we continue to believe that this measure is critically important and, therefore, KCP supports inclusion of the NQF #2701, the KCQA ultrafiltration measure, in DFC/ESRD Five Star.

4. Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V

KCP believes including pediatric patients in the scope of DFC/ESRD Five Star is important and supports use of *Pediatric Peritoneal Dialysis Adequacy*.

B. KCP Recommends Modifications to the Current DFC/ESRD Five Star Measures as well.

In addition to the proposed new measures, KCP urges the Agency respond to comments about the current measures that have not been addressed, including those recommendations that the Agency has yet to resolve in the context of the ESRD QIP.

1. Adequacy Measures

KCP continues to support several of the measures used in DFC/ESRD Five Star, including: (1) Percentage of adult hemodialysis (HD) patients who had enough wastes removed from their blood during dialysis; (2) Percentage of pediatric hemodialysis (HD) patients who had enough wastes removed from their blood during dialysis; and (3) Percentage of adult peritoneal dialysis (PD) patients who had enough wastes removed from their blood during dialysis. Patients should be able to understand how a dialysis facility performs the most critical aspect of care – cleaning patients' blood. We ask, however, that CMS align the specifications for the adequacy measures with those used in the ESRD Quality Incentive Program (QIP). Currently, the QIP requires seven treatments for inclusion in the measure, but DFC/Five Star requires only two treatments. We recommend that CMS use the QIP specifications to address the issues of transient patients.

2. Vascular Access Measures

We also support the continued inclusion of Percentage of adult dialysis patients who received treatment through arteriovenous (AV) fistula and Percentage of adult patients who had a catheter left in vein longer than 90 days for their regular hemodialysis treatment. However, as in previous comment letters, we strongly recommend that CMS weight the removal of the catheter measure greater than the fistula measure to compensate for the lack of a graft measure. We are pleased that

CMS has convened a technical expert panel (TEP) to consider development of a graft measure and look forward to the completion of its work.

3. Hypercalcemia Measure

During the April ESRD Five Star TEP, the patient TEP members recommended that the hypercalcemia measure be removed from DFC/ESRD Five Star.² KCP supports their recommendation. In previous comment letters, KCP has raised concerns and indicated that this metric is not the best measure in the bone mineral metabolism domain to impact patient outcomes. Additionally, the NQF has concluded that the hypercalcemia measure is topped out and the likely outcome will be endorsed with Reserve Status because of high facility performance and minimal room for improvement.

4. Standardized Ratio Measures

Generally speaking, rather than rely upon standardized ratios, CMS should consider establishing rate measures, which would allow patients and facilities to see year-over-year differences between normalized rates (deaths per 100 patient years) for mortality and hospitalization. These rates are currently available from Dialysis Facility Reports data and should be used in DFC/ESRD Five Star.

Given that CMS has indicated that it wants to provide patients and consumers with more information rather than less, we strongly recommend that CMS add the mortality and hospitalization rates from Dialysis Facility Reports to the Five Star grouping in which the standardized measures are included until the standardized rates can be used. These metrics would ideally reflect a directional change like positive, negative, or neutral. Over time, the rates should be risk standardized, but it is important to include the year-over-year rate difference at this time to allow patients, consumers, and the program to acknowledge improvement as well as attainment. Adding these measures will allow patients and consumers to identify the year-over-year change, which is also important to evaluating dialysis facility quality. Providing these rates will also inform consumers in making choices among providers in their local markets.

In addition, we recommend that as long as CMS relies upon standardized ratio measures, the Agency provide raw transfusion, hospitalization, readmissions, and mortality data directly to facilities on a quarterly basis by using Dialysis Facility Report calculations and the six month lagged data file. Dialysis facilities cannot access this information, which is critically important to understanding the measures. For example, dialysis facilities are not able to access and are not

² UM-KECC, "End Stage Renal Disease Dialysis Facility Compare Star Ratings Technical Expert Panel Summary Report" 35 (2015).

provided with any data about patients' transfusions from other healthcare providers such as hospitals or infusion centers. We are aware of numerous attempts to gather these and other hospital data, which have not met with success. We understand from CMS staff comments during a previous National Provider Call that CMS has decided not to dedicate any resources to providing facilities with this information. However, if this measure is viewed as important, it is equally important to provide facilities with the data to allow them to better understand their own patient population so that they can focus their quality improvement efforts. Providing these data should not be difficult. For example, as the Center for Medicare (CM) was implementing the ESRD Prospective Payment System (PPS), the chief medical officer of CM reached out to dialysis facilities directly to share transfusion data with them obtained from the six-month lagged claims file. It was a very straight-forward process. Similarly, facilities also do not have access to hospitalization, readmission, and morality data and request that CMS also provide these data files.

Additionally, we are pleased that CMS has convened a TEP to evaluate the potential prevalent comorbidity adjustments in the Standardized Hospitalization Ratio (SHR) and the Standardized Mortality Ratio (SMR). As you are aware these measures currently rely upon information from CMS Form 2728. Empirical, peer-reviewed studies support the concerns KCP has raised about the validity of using these data.³ CMS Form 2728 is not an appropriate source of data for two reasons. First, by relying solely on CMS Form 2728 instead of claims data, CMS does not have access to current patient comorbidities, because the form only represents apparent comorbid conditions at the start of the course of dialysis and is not updated thereafter as the patient progresses in his/her illness.⁴ Second, the form relies in large part on what a patient reports to the physician⁵ and, as such, these self-reported data have not been validated. This fact was less important when CMS Form 2728 was used for its original purpose, namely to obtain information for future research. It is inappropriate to use it as a source of data to risk adjust quality measures.⁶ We recommend that a more appropriate source of data be used to risk adjust these measures.

³See, e.g., Jane Paik Kim, Manisha Desai, *et al.*, "Validation of Reported Predialysis Nephrology Care of Older Patients Initiating Dialysis," 23 *J Am Soc Nephrol* 1078-1085 (2012); J. Bradley Layton, Susan L. Hogan, *et al.*, "Discrepancy between Medical Evidence Form 2728 and Renal Biopsy for Glomerular Diseases," 5 *Clin J Am Soc Nephrol* 2046-2052 (2010); Eduardo Lacson, Jr, MD, MPH, Ming Teng, MD, *et al.*, "Limitations of the Facility-Specific Standardized Mortality Ratio for Profiling Health Care Quality in Dialysis," 37 *Am. J. Kid. Dis.* 267-275 (2001); J. Craig Longenecker, Josef Coresh, *et al.*, "Validation of Comorbid Conditions on the End-Stage Renal Disease Medical Evidence Report: The CHOICE Study," 11 *J Am Soc Nephrol* 520-529 (2000).

⁴ See, e.g., Layton, *supra* note 3.

⁵ *Id.*

⁶See Longenecker *supra* note 3.

a. Standardized Transfusion Ratio Measure (STrR)

KCP agrees that proper anemia management is a critical component of high-quality dialysis care, but like many of the patient members of the ESRD Five Star TEP, KCP remains concerned that the STrR measure as currently specified may not be the best way to address this important issue. The NQF Renal Steering Committee also raised concerns about the measure reflecting the transfusion practices and behaviors at the hospital level and not for dialysis facilities. In addition, the Committee raised concerns about the potential for coding inconsistencies threatening the validity of the measure. Because of these concerns, the Committee recommended against endorsing the measure and it advanced no further.

The NQF Committee correctly noted that because transfusions do not occur in the dialysis facilities, it is difficult for facilities to influence whether or not a patient receives a transfusion, but more importantly, facilities often do not know if a patient has received a transfusion. Patient members of the ESRD Five Star TEP echoed this concern. One TEP member noted succinctly that patients are “not interested” unless the “event was directly caused by the facility.” Providing patient transfusion data would help facilities know when transfusions occur and give them the opportunity to try to determine the reason for the transfusions. CMS should provide transfusion data (from the Quarterly Standard Analytics File (SAF)) directly to facilities on a quarterly basis by using Dialysis Facility Report calculations and the six-month lagged data file.

As we noted in previous letters, data confirm the relevance of the NQF Committee’s concerns about inconsistency in coding. In 2011-12, short-term, critical access, and long-term hospitals administered 98.5 percent of transfusions in the inpatient setting and 82.9 percent of transfusions in the outpatient setting. Transfusions are coded by hospitals and coding varies nationwide and even within hospitals—specifically, coding is inconsistent between type and screens (*i.e.*, preparing for a transfusion) and actual transfusions. Some coding variations potentially overestimate the number of transfusions, which would inappropriately penalize facilities in those areas. To address this issue, CMS should conduct an audit of the transfusion data to determine the extent of the problem and adjust the measure accordingly to address any problems it discovers.

In addition, the measure could be improved by incorporating hospital- or physician-related factors into the risk model. Because physicians independently or following hospital protocols make decisions about whether or not to transfuse a specific patient, it is important to account for the variability these factors create.

We also urge CMS, as part of the upcoming ESRD Measures Manual, to provide the microspecifications for the measure along with detailed flowcharts or

computer codes to allow the public to replicate the mathematics used. Ideally, this information would be provided through rulemaking prior to adopting any measure as well.

Finally, we ask that CMS provide a clear and consistent definition of when patients are no longer considered ESRD and, thus, are excluded from the measure calculations. For example, it is important to ensure that all facilities define returning renal function, selecting hospice care/withdrawal from dialysis, or other patient choices affecting ESRD status the same way.

b. Standardized Mortality Ratio (SMR)

KCP has on several occasions expressed concern about the SMR because of a lack of transparency in the methodology and lack of published validation studies. We appreciate the Agency's recognition in 2013 that CMS needed to "properly take into account the effect that comorbidities have on hospitalization and mortality rates in the ESRD population,"⁷ as well as its movement away from exclusively relying on the 2728 data as noted above. We agree with patients that mortality is an important measure, but it is critically important that the measure be tailored to the actions of the dialysis facility. For example, it does not help patients or consumers to have mortality from automobile accidents included with mortality due to infection. Therefore, we recommend that CMS work more closely with the kidney care community to establish an appropriate mortality rate measure that focuses on year-over-year, facility-specific improvement for inclusion in DFC/ESRD Five Star.

c. Standardized Hospitalization Ratio for Admissions (SHR)

KCP has on several occasions expressed concern about the SHR measure because of a lack of transparency in the methodology and published validation studies. As with the SMR measure, it is important to make sure that the impact of comorbidities are taken into account, as well as the effect of local hospital practices—*i.e.*, community resources may have an impact that may not be comparable. KCP believes that this measure may be useful for a descriptive purpose, but given the lack of validation, has concerns about its use as a performance measure. We recommend instead a metric that focuses on year-over-year, facility-specific improvement.

⁷ "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).

Additionally, as with the SMR, we ask that CMS provide the quarterly SAF data to dialysis facilities so that they can identify the number and types of admissions.

II. KCP Recommends that CMS Address the Concerns Raised by Patient Organizations and Members of the ESRD Five Star TEP and Modify the Methodology for 2016.

While we understand that CMS has focused the comment period on measures, we urge the Agency to listen to the numerous comments it has received from patient organizations, other stakeholders, and the members of the ESRD Five Star TEP patient work group which have called upon the Agency to adopt a rating, rather than a relative ranking, methodology.

While the ESRD Five Star TEP methodology work group indicated that the probit methodology was adequate to establish a relative ranking, it was not asked if a relative ranking itself was the most appropriate methodology. Most importantly, the patient ESRD Five Star TEP repeatedly raised serious concerns with the decision to use relative rankings rather than ratings. The patient TEP members unanimously recommended that CMS eliminate the relative ranking methodology and instead rely upon performance standards to rate facilities. The patients were clear that the current methodology was not useful to them.

These concerns are documented in the recently released report on the ESRD Five Star TEP. Most notably, it states: “The workgroup stated that the methodology used for the star ratings is difficult to understand for intended users (patients and other consumers), and not consistent with other online public rating systems.”⁸ It is extremely disappointing that despite numerous letters and suggestions by KCP, its members, and other members of the kidney care community that CMS has decided to leave in place a methodology that is not meeting the needs of patients and consumers. We agree with the patient TEP members that a rating methodology would make it easier for patients, their families, and caregivers to understand, evaluate, and choose quality dialysis providers.

We were also troubled by the discussion in the ESRD Five Star methodology TEP, as were members of the TEP, because the discussion was limited to evaluating whether the probit model could be used to establish a relative ranking. When comparing this methodology to a Z-score methodology, the contractor raised concerns about outliers under the Z-score, but never described to the group that this “problem” could easily be addressed by simply truncating the scores. The TEP members simply did not receive a complete analysis.

⁸UM-KECC, *supra* note 2 at 34.

Patrick Conway, M.D.

November 6, 2015

Page 11 of 11

Perhaps most importantly, while the methodology work group focused primarily on the current methodology and whether it was statistically appropriate, the methodology TEP members when asked by the patient TEP members also indicated that it would be possible to develop a methodology consistent with the patient TEP members' recommendations.

As evidenced by multiple letters, meetings, and discussions, many in the kidney care community question why in a system designed to make it easier for patients and families to understand, evaluate, and choose quality dialysis providers, quality performance should be "translated" in a way that is counter-intuitive and results in finding that a three star facility is in the top 31 percent of all facilities.

III. Conclusion

As always, KCP appreciates the efforts CMS has made in working to recognize high quality care attainment and improvement in the Medicare ESRD Program. It is important that the kidney care community and CMS work together to refine ESRD Five Star so that this program also becomes a meaningful tool for patients and consumers. As the patient TEP members noted, ESRD Five Star's methodology should be modified to describe the actual differences among facilities based upon performance benchmarks and include measures that describe the actual care provided by dialysis facilities. We would welcome the opportunity to continue working with you and your team to revise the ESRD Five Star.

Sincerely,



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