KIDNEY CARE PARTNERS

February 13, 2015

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Tavenner,

I am writing on behalf of Kidney Care Partners (KCP) to provide you with recommendations for the ESRD Five Star Technical Expert Panel (TEP) to consider. KCP would like to work with your team and the TEP to identify ways to improve ESRD Five Star so that patients, facilities, and consumers find it a meaningful and accurate tool for evaluating dialysis care.

To develop these recommendations, KCP has convened its own group of kidney care technical experts, including ESRD patient advocates, to advise our membership. These individuals have worked with other experts in the areas of measure development and quality program design to prepare recommendations that have been reviewed by a volunteer work group of KCP members and ultimately by the entire 32-organization KCP membership.

In this letter, we provide specific recommendations about how to address concerns with the three standardized ratio measures that are included in ESRD Five Star. Specifically, we suggest that CMS should:

- Align the standardized ratio measures methodology with that used for other Medicare programs and providers, such as Medicare Advantage (MA) plans and hospitals, by using the CMS claims data available for the hierarchical conditions categories (CMS-HCC);

- Establish the methodology for standardizing comorbidity adjustment for the standardized ratio measures by using a generally accepted methodology, such as the CMS-HCC grouping of diagnosis codes;

- Consider adding the year-over-year difference between normalized (deaths per 100 patient years) for mortality and hospitalization rates currently available from Dialysis Facility Reports data for one to two years until they can be replaced by a standardized mortality *rate* and a standardized hospitalization *rate*; and

- 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.

We also have reiterated our recommendations with regard to the TEP process. Specifically, we describe criteria for selecting members, ensuring the transparency of the process, and establishing clear evaluation criteria.

In a separate letter, we will provide more detailed recommendations about the methodology that builds off of work the KCP provided to CMS after our discussion with you last fall. Specifically, we will provide recommendations about how CMS should:

- Provide a clear definition of quality and performance criteria while continuing to provide patients and consumers with information to allow them to distinguish in a meaningful way among and between facilities;

- Address the statistical uncertainty CMS has identified in the standardized ratio measures, as well as when defining the cut points for stars; and

- Preserve the actual performance distribution without amplifying the differences in a way that misleads patients and consumers.

As KCP developed these recommendations, we have focused on the following principles. We encourage the Agency to use these principles with the TEP as it considers modifications to ESRD Five Star as well. We believe that the program should:

- Accurately reflect actual differences in quality;

- Be transparent and subject to public comment as it evolves;

- Provide meaningful information that empowers patient decision-making;

- Allow consumers to compare facility-level outcomes;

- Clearly define quality care; and

- Reflect performance within the control of dialysis facilities.

KCP has been working to develop these – as well as our forthcoming – recommendations since the end of 2014. We are on track to provide more specific recommendations with regard to the methodology by March 6. We understand from CMS staff that they may not review or seriously consider recommendations provided to them after February 13. While we have been in regular communication with the staff working on Five Star since November, we were given only eight days notice of the hard February 13 deadline. The community is extremely disappointed that public notice of comment deadlines was not

provided and that our request for a few additional weeks was denied. We ask that you direct the staff to take a more open approach than that which has unfolded to date.

I. Recommendations for ESRD Five Star: Reliance upon the Standardized Ratio Measures

In previous letters, KCP has raised concerns about the current standardized ratio measures. CMS has signaled that it is highly unlikely that it will allow the TEP to recommend removing these measures from ESRD Five Star. Thus, despite our serious concerns about the measures' inclusion in Five Star, we have developed the following recommendations in an effort to make their inclusion less problematic.

Recommendation 1: CMS should align the standardized ratio measures methodology with that used for other Medicare programs and providers, such as Medicare Advantage (MA) plans and hospitals, by using the CMS claims data available for the hierarchical conditions categories (CMS-HCC). Currently, the standardized ratio measures rely upon information from CMS Form 2728. Empirical, peer-reviewed studies support the concerns KCP has raised about the validity of using these data.[1] 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 is never updated as the patient progresses in his/her illness.[2] This approach is inconsistent with the Agency's reliance on claims data for risk adjustment in other programs, such as the CMS-HCC system. Second, the form relies in large part on what a patient reports to the physician[3] 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.[4] CMS and its contractor, the University of Michigan's Kidney Epidemiology and Cost Center, determined that CMS Form 2728 should not be used when it constructed the ESRD PPS for these reasons as well.[5]

In its evaluation of CMS Form 2728, the Chronic Disease Research Group (CDRG) found that CMS Form 2728 substantially underestimates the number of comorbidities when compared to USRDS data. This result was true both six months prior to, and twelve months

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[1] *See, 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).

[2] *See, e.g.,* Layton, *supra* note 1.

[3] *Id.*

[4] *See* Longenecker *supra* note 1.

[5] Richard A. Hirth, Ph.D., Robert A. Wolfe, Ph.D., et al., " Is Case-Mix Adjustment Necessary for an Expanded Dialysis Bundle?" 24 Health Care Fin. Rev. 77-88, 79 (2003).

after, the initiation date for comorbidities. The percentage of the underestimate is as high as 50 percent in many instances.[6]

To address this problem, CMS should rely on information used for the CMS-HCC. This approach would align the measures with other providers such as hospitals[7] and MA plans.[8]

Recommendation 2. CMS should establish the methodology for standardizing comorbidity adjustment for the standardized ratio measures by using a generally accepted methodology, such as the CMS-HCC grouping of diagnosis codes. The CMS-HCC grouping of diagnosis codes could be used for statistical adjustment for mortality and hospitalization because the methodology aligns with other non-ESRD programs. Since CMS has decided to hold dialysis facilities accountable for coordinating care, it is important that the methodology align across the various providers who touch ESRD.

If for some reason CMS is not able to apply the CMS-HCC grouping of diagnosis codes for dialysis, then standardized ratio measures, when possible, should follow the same methodology and include the same adjustors. For example, CMS should add a race and ethnicity adjustor to the standardized hospitalization ratio measure since it is already included in the standardized mortality ratio adjustors. For the standardized ratio measure, some customization is appropriate. Specifically, the standardized transfusion ratio measure should include additional adjustors that are specifically related to transfusions, such as comorbid disorders that lead to repeated transfusions as is the case for patients with chronic GI bleeds. CMS should provide the microspecifications for these measures along with detailed flowcharts or computer code to allow the public to replicate the mathematics used. Finally, CMS should 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 ERSD status the same way.

Recommendation 3: CMS should consider adding the year-over-year difference between normalized (deaths per 100 patient years) for mortality and hospitalization rates currently available from Dialysis Facility Reports data to Five Star for one to two years until they can be replaced by a standardized mortality *rate* and a standardized hospitalization *rate*. 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. This

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[6] Chronic Disease Research Group, Burden of Comorbidities in the ESRD Population, 2007-2009 (2014) *available upon request.*

[7] CMS Fact Sheet, "Methodology for Determining Shared Savings and Losses under the Medicare Shared Savings Program," *available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO_Methodology_Factsheet_ICN907405.pdf*

[8] MedPAC, "Payment Basics: Medicare Advantage Payment System," *available at* http://medpac.gov/documents/payment-basics/medicare-advantage-program-payment-system-14.pdf?sfvrsn=0.

metric would ideally just 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 allow consumers to make local purchasing decisions among providers in their local markets.

Recommendation 4: CMS should 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. Our final recommendation with regard to the standardized ratio measures relates to the ability of facilities to change their behavior as appropriate. For example, dialysis facilities are not able to access and are not 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 the January 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. 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, we also do not have access to hospitalization, readmission, and morality data and request that CMS also provide these data points.

II. Recommendations for the TEP Process

On December 19, 2014, KCP provided recommendations to Dr. Conway about how the TEP process could be improved upon at the behest of CMS staff. In developing our recommendations, KCP discussed the process with a variety of individuals who have participated in previous CMS TEPs. A consistent theme we heard from each TEP member was that the TEP must be more than a rubberstamp for predetermined policies. It also must be an open and transparent process that takes into account not only theoretical and academic issues, but also acknowledges practical and operational realities. As a threshold matter, CMS should provide a timeline that clearly describes each step in the TEP process and when it will occur. Additionally, KCP recommends that CMS take steps to: (1) improve the membership of the TEP panels to ensure that it is reflective of all constituencies within the community; (2) create an open and transparent process; and (3) establish clear evaluation criteria for TEP members to apply to the evaluation of measure and structural proposals.

A. Membership

To create community support, it is important to make sure that the TEP is representative of the entire community. We are pleased that CMS has adopted many of the recommendations KCP requested with respect to the type of experience TEP members should have. Because it is not clear from the TEP call for nominations, we want to emphasize again the importance of not only including nephrologists, nurses, and clinicians, but also those individuals who have experience operating dialysis facilities. We believe that CMS may have meant to incorporate this experience into the perspective labeled as "dialysis facility quality improvement," but it is not completely clear. It is important that CMS make sure that at least a few TEP members have a clear understanding of the operational implications of the proposals that are discussed.

We also encourage CMS to consult with the kidney care community before finalizing the TEP membership to ensure an appropriate balance in the make up of the participants. This step would be similar to that used by the National Quality Forum and the Institute for Medicine, which post their rosters to stakeholders for comment. We ask that this process be undertaken in a public way with sufficient notice to allow the entire kidney care community to provide comments.

Finally, CMS should also clarify the role of the contractor. Specifically, the contractor should serve as the facilitator and not a content participant. This clarity would help ensure that the discussions are facilitated in a fair and open manner that results in recommendations that take into account the views of the TEP members.

B. Transparency

KCP also recommends that CMS break from the historic approach to TEPs, which has been closed and secretive, and instead establish an open and transparent process. We believe that a more collaborative approach would allow all interested parties to provide input earlier in the process and arguably lead to a better end product. To achieve transparency, KCP recommends that CMS take the following steps:

- The TEP participants should be permitted to talk with others in the community and not be prohibited from discussing the TEP or sharing the materials.

- All materials that the TEP will consider should be available at least a week prior to the TEP meeting/call. These materials, as well as dial-in information, should also be available to other interested parties via the CMS website and a CMS or Arbor listserv with enough notice for them to review the material and plan to participate.

- Non-TEP members should be allowed to listen to TEP meetings/calls and provide comments at appropriate times during/calls prior to decisionmaking

and/or votes. Questions or comments could also be submitted to CMS staff prior to the discussions to ensure they can be answered.

- All comments received should be publicly available along with the response to each in a fashion similar to that deployed by CMS during rulemaking and NQF during its review of measures.

- A governance process for establishing consensus among TEP members should be standardized and articulated during the chartering of the TEP. We have heard from multiple TEP participants in the absence of such a process, the contractor, in creating the final report and recommendation, makes the final recommendation. This very issue became important enough for the chair of the ESRD re-hospitalization TEP to publically distance himself from the final report.

We have previously described to your staff how these steps are aligned with the way the Kidney Care Quality Alliance (KCQA) operates. In addition to including a list of all KCQA members and ad hoc work groups, the KCQA posts all final documents (*e.g.,* approved recommendations, Guiding Principles, and minutes of meetings) on its website. All KCQA meetings and conference calls are open to members of the public, and time on the agenda is provided for public comment. Draft specifications are also posted for public comment. Additionally, there is an appeals process that allows anyone to request reconsideration of an endorsed voluntary consensus recommendation within 15 days of public notification of the recommendation.

An open and transparent process promotes collaboration. Most importantly, it would allow all interested stakeholders, not only those selected by CMS, to participate in the dialogue. This could lead to greater support for ESRD Five Star, specifically, and Agency efforts more generally.

C. Evaluation

Finally, we recommend that once the TEP members are selected, they should be provided with clear grading criteria for evaluating the various options being reviewed – both in terms of measures being considered to be added to Five Star and the structural modification proposals.

As a threshold matter, a measure should: (1) have a verified entity responsible to maintain and update it on a schedule commensurate with the rate of clinical innovation (at least every three years); and (2) be fully and clearly specified and tested for reliability and validity. Additionally, measures should also be evaluated on the ability to implement them in the dialysis setting. The TEP should also rely upon the NQF criteria, which require that a measure be evaluated as:

- Having a high impact on an aspect of dialysis care, address a demonstrated performance gap and present an opportunity for improvement in dialysis care, and

be grounded in evidence supporting the relationship of the outcome to a process or structure of care **(Impact, Opportunity and Evidence)**;

- Containing data elements that produce the same results a high proportion of the time when assessed in the same population in the same time period; having specifications that are consistent with the evidence to support the focus of the measure; having been the subject of testing validating that the data elements and measure scoring are correct; containing necessary exclusions supported by clinical evidence or sufficient observation; for outcomes-based measures, including a specified evidence-based risk-adjustment strategy; demonstrating that methods for scoring and analysis are statistically significant; and allowing for identification of disparities if identified through stratification of results **(Reliability and Validity)**;

- Demonstrating that the intended audience (beneficiaries, purchasers, providers, and policymakers) can understand the results and find them useful for decision-making **(Usability)**;

- Having data that are readily available or could be captured without undue burden **(Feasibility)**; and

- Being harmonized with related measures or justifying the differences in the specifications **(Comparison to Related or Competing Measures).**[9]

Similarly, methodological options should also be evaluated using clear criteria. These would include:

- Ensuring that the methodology results in information that is accurate and meaningful. Methodology options that distort the relationship among facilities should always be rejected.

- Creating a clear and consistent definition of quality performance to avoid ambiguity that may arise from inconsistent definitions and that could lead to unintended negative consequences.

Ensuring that the methodology adjusts for uncertainties inherent in the data being used.

III. A Preview of Methodological Recommendations

In our March letter, KCP will provide concrete suggestions about how CMS should modify the methodology for determining the star ratings. The concerns we have raised with the Agency since the summer of 2014 remain unchanged. KCP members continue to be troubled by the fact that ESRD Five Star is based upon a methodology that is misleading

[9]For a complete description of the NQF measure evaluation criteria, *see* http://www.qualityforum.org/docs/measures_evaluation_criteria.aspx.

about the actual performance of dialysis facilities. We have always understood the Agency's goals as providing consumers with information that "is most important [to them] in a way they can understand" and to "report only valid data."[10] We agree with these principles, but urge the Agency to re-examine the methodology to ensure that it does not force facilities into a predetermined set of star categories.

The kidney care community is not the only group subject to stars that has raised concerns about the way CMS has "transformed" measures so that they fall into a normal distribution and then sets cut points based on the percentage of facilities in each category. We understand that CMS originally used bell curves for some of the categories of the nursing home star ratings. These providers also raised concerns about this methodology because it also meant that no matter how good a nursing home's performance was, only 10 percent of nursing homes could receive five stars and 23.3 percent could receive four stars. After nursing homes raised concerns, CMS changed the methodology in a way that resulted in 53 percent of nursing homes receiving four and five stars. The nursing home industry's concerns parallel those raised by KCP and others about ESRD Five Star. Just as it did for the nursing homes, CMS should also eliminate the fixed bell curve methodology for dialysis facilities.

It is also important to recognize that the majority of the measures used in ESRD Five Star are measures that dialysis facilities have been reporting for 20 years or more. Thus, it should not be surprising if these measures show that dialysis facilities are meeting the standard of care set by CMS. If they did not, the Agency should question whether monitoring quality truly works.

In the coming days, KCP will provide additional methodological recommendations and share them with CMS. We would welcome the opportunity to have our analysts speak with the CMS contractor directly to help expedite the review process. We strongly encourage you to ensure that the TEP (the call for nominations was announced only last week) has an opportunity to review these recommendations, along with those in this letter.

IV. Conclusion

KCP has never asked CMS to cease the ESRD Five Star program. Instead, we have focused our discussions and recommendations on ways to improve the program. KCP supports quality measurement and transparency and historically has worked well with CMS to ensure the smooth implementation of the first value-based purchasing program in Medicare. We encourage you now to work with the kidney care community by allowing the TEP to conduct an open and transparent review of the current Five Star methodology and to have a meaningful discussion with us about the recommendations (these and those that we will share during the next few weeks) that KCP provides.

[10]CMS, National Provider Call "Dialysis Facility Compare Star Rating System" (July 10, 2014).

Thank you for working with KCP on this and other important programs over the years. Kathy Lester will be contacting CMS staff to schedule a meeting with your team to answer any questions about the recommendations and to discuss the rationale for their acceptance and the importance of their implementation.

Sincerely,

Edward R. Jones, M.D.
Chairman
Kidney Care Partners

cc: Andrew Slavitt, Principle Deputy Administrator, CMS
Patrick Conway, M.D., Deputy Administrator for Innovation & Quality, CMS Chief Medical Officer, Director of the Center for Clinical Standards and Quality
Kate Goodrich, M.D., Director of the Quality Measurement and Health Assessment Group
Elena Balovlenkov, R.N., Technical Lead for Dialysis Facility Compare
Joel Andress, Ph.D., Center for Quality Measurement in the Health Assessment Group

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