KIDNEY CARE PARTNERS

August 8, 2014

Dr. Patrick Conway
Chief Medical Officer
Director, Center for Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Conway:

I am writing on behalf of Kidney Care Partners (KCP) to share our comments about the release of the End-Stage Renal Disease Five-Star Rating System (ESRD Five Star). As you know, KCP is an alliance of members of the kidney care community that serves as a forum for patient advocates, dialysis care professionals, providers, and manufacturers to advance policies that support the provision of high-quality care for individuals with both chronic kidney disease (CKD) and End-Stage Renal Disease (ESRD).

We agree that ESRD quality initiatives (1) should promote transparency of meaningful quality information based upon metrics that measure the actions dialysis facilities undertake while caring for patients and (2) should compare facility-level outcomes to appropriate benchmarks. Such initiatives should recognize attainment and improvement. KCP supports efforts to increase transparency and provide meaningful quality data to empower patient and caregiver decision-making.

An example of our commitment to quality is the Performance, Excellence, and Accountability in Kidney Care (PEAK) Quality Initiative. The PEAK Campaign was a voluntary community initiative designed to highlight proven practices with the goal of improving the survival of kidney failure patients new to dialysis. Available data at the time indicated that overall survival rates for patients with end-stage renal disease had been improving, but, by comparison, the first-year mortality rate had remained relatively stagnant. During this initiative, the 90-day mortality rate declined 25 percent.[1] In addition to PEAK, we have worked closely with the Agency to implement the ESRD Quality Incentive Program (QIP), which is the first value-based purchasing program in Medicare. These activities include assisting in the refinement of the methodology and harmonizing measures developed through the Kidney Care Quality Alliance (KQCA) with measures developed by CMS.

Given this history of working constructively with the Agency, we strongly urge CMS to avoid rushing the rollout of ESRD Five Star without input from the kidney care

[1]Shailender Swaminathan, PhD & Vincent Mor, PhD, "Performance Excellence and Accountability in Kidney Care: Final Report" (Sept. 2013) *available at http://kidneycarepartners.com/images/final-report.pdf.*

community. We are disappointed that the Agency chose not to consult with patients, clinical experts, or others in the kidney care community before designing and implementing the Five Star program, despite repeated assurances from CMS staff that the community would be provided with an opportunity to engage and provide meaningful input. Instead, we have been told repeatedly that CMS has sufficient experience to rollout ESRD Five Star without such input, but as described in this letter, the current design of ESRD Five Star does not recognize quality attainment or improvement by facilities caring for Medicare beneficiaries.

As KCP members have reviewed the methodology and measures, we are concerned that ESRD Five Star will simply not meet CMS's intended goal, or that of the kidney care community, to empower consumers by increasing the transparency of quality information. Specifically, as currently designed, ESRD Five Star will not provide accurate quality information about individual facilities because it relies upon:

(1) a bell curve to award stars that distorts actual quality performance;
(2) standardized ratio measures with values that cannot be transformed into rankings given the inherent structure of the measures; and
(3) certain measures that are not actionable by facilities and/or are based upon data that are not reliable.

Given these shortcomings, we do not believe that ESRD Five Star will provide the desired clarity for consumers. It has already created substantial confusion and concern among medical directors, who do not understand the rationale for rolling out a suboptimal program without taking the opportunity to resolve the problems. The community as a whole, including patient organizations, will not support a flawed program. That said, we believe these problems can be overcome if CMS will work with the community to address them before the rollout of the program.

Specifically, we ask that CMS hold off from launching this flawed program in October. Instead, we recommend that the Agency work with the kidney care community to address the core problems with ESRD Five Star as currently defined. KCP believes that with the assistance of the kidney care community, CMS could identify an appropriate benchmark methodology to replace the bell curve. We also believe that the problems described below with the standardized ratio measures are not insurmountable and could be addressed as well. Our intent would be to find solutions in an efficient manner so that ESRD Five Star could be launched in a reasonable timeframe.

I. Patients and Their Advocates are Concerned that ESRD Five Star Is Misleading and Will Create Unnecessary Concerns and Doubts among Patients.

In talking with patients, it is clear that having an easily understandable system to identify high quality facilities is important. KCP members agree. However, the ESRD Five Star program does not achieve this goal.

Probably the most critical issue with the current design of ESRD Five Star is the decision to use a bell curve to force a defined number of facilities into each star category. The bell curve forces at least 30 percent of all facilities into the 1 and 2 star rating categories. This is especially problematic for measures where facilities have attained the desired quality outcome, such as the dialysis adequacy quality measure. In the QIP, 43 percent of facilities are in the top performance tier and receive no penalty, while in ESRD Five Star only 10 percent of facilities could qualify for five stars. Most facilities that are not penalized are placed in the three star category, yet this also includes some facilities with a 0.5 percent or 1.0 percent reduction. CMS staff noted that the QIP Total Performance Scores "generally" aligned with the star rates, but not always. "Generally" is an inappropriate, undefined standard. The stars simply do not reflect the actual quality of care being provided.

The bell curve methodology is also inconsistent with how other consumer star rating programs for everything from other health care programs to car safety, movies, hotels, and restaurants work. In these systems, a benchmark of quality is defined, and organizations are rated against it. For example, the National Highway Traffic Safety Administration's star rating for vehicle safety, upon which millions of Americans rely, evaluates cars against transparent benchmarks. The Leapfrog Group's hospital grading program also relies on benchmarks. Consumers will assume that ESRD Five Star is like these and other star rating programs. Thus, if CMS gives a facility one star, consumers will not understand that the rating is on a bell-curve. They will assume that it is a low-quality facility.

The situation created by the inconsistencies in ESRD Five Star and the QIP can be compared to a classroom. In our classroom, everyone has earned grades ranging from A+ to B. The teacher, then, determines that the range is not large enough and so decides to establish a bell curve to increase the differences among the students. This means that students whose actual performance earned a B+ or B would now receive a D or F. There is no doubt that the students would view this system as unfair and not representative of their work. More importantly, they would carry the artificially lowered grades on their transcripts as they applied to colleges. The college application committees would see only the D or F and not know that the students' actual performance earned them a B+ or B. These college applications committees would perceive the students to be underachievers. Whether CMS intends it or not, the forced distribution is unfairly and inappropriately labeling facilities as having poor quality.

We understand that CMS intends to clarify the language on the ESRD Five Star website. That is important, but will simply not be enough to address this critical flaw in ESRD Five Star. The very thing that makes using star ratings attractive – namely that they are used in many consumer evaluation systems – makes it less likely that consumers will feel that they need to read the methodology or clarifying language. Consumers will assume that ESRD Five Star relies upon benchmarks like other star rating systems. A much better approach would be to get the system right rather than try to explain it away.

Patients and consumers will act upon the ratings. Patients in one star facilities may seek to change to five star facilities. If there is not a five star facility in the area, their anxiety may increase, which could lead to depression and poorer outcomes. If there is a five star

facility available, it may not be as convenient. In these instances, a patient may agree to travel farther to the five star facility or accept less convenient session times, both of which could lead to missed appointments and significant health complications. We agree that patients should have the opportunity to select high-quality facilities. However, that only works if the quality information that is presented to them is meaningful. The forced distribution will mislead patients by failing to present actual performance data.

In addition, there is already a Congressionally mandated public reporting program, the ESRD QIP, that requires facilities to post certificates in their buildings and CMS to put QIP total performance scores in an easily understandable format on a website. Because the measures, the benchmarks, and the methodology significantly differ between these programs, many facilities that receive no penalty will receive lower rankings in ESRD Five Star. The chart below shows the differences created by the forced bell curve.

	QIP Penalty					
Stars	**0%**	**0.5%**	**1.0%**	**1.5%**	**2%**	**Total**
1	468	47	21	6	9	**551**
2	1,019	48	17	8	9	**1,101**
3	2,155	38	6	0	3	**2,202**
4	1,091	9	0	0	0	**1,100**
5	552	0	0	0	0	**552**
Total	**5,285**	**142**	**44**	**14**	**21**	**5,506**

This is simply confusing. Consumers want a single definition of quality that is aligned across programs. The decision to use such a dramatically different quality definition for ESRD Five Star begs the question as to how CMS believes a quality dialysis facility should be defined. The differing definitions of quality and forced distribution will mislead patients and negate the actual intent of the program.

II. CMS Should Not Rush to Implementation Because the ESRD Five Star Standardized Ratio Measures Have Not Been Vetted Properly.

In addition to the confusion of having two different public reporting programs and a misleading methodology, the decision to use the standardized ratio measures along with the core QIP measures for ESRD Five Star is problematic. First, CMS acknowledges that each of the standardized ratio measures is constructed in a way that creates a 95 percent confidence interval. This means that results for 95 percent of facilities fall within what is expected for facilities. All values within this range are statistically equivalent to 1.0 and do not imply that the low end and the high end within those boundaries differ significantly.

Within that 95 percent confidence limit, if one facility's score comes out at two and the lower end of the facilities within that interval are ten, the two and ten may be part of the same value because the estimated number of deaths or number of hospitalizations are not exact. When CMS currently releases these data on the Dialysis Facility Compare, it describes the results as "expected," "worse than expected," or "better than expected." However, in ESRD Five Star CMS intends to transform these designations into a ranking system. Thus, a facility that has a rank of one may be no different or even worse than other facilities that are ranked at ten, but now CMS will report the facilities to have different levels of quality.

Taking this step will further mislead patients and other consumers who may not realize that the forced ranking is actually meaningless statistically speaking. Similar to our objections with the "bell curve" approach with the overall star ratings, KCP has serious concerns about the approach to standardize and rank facilities on the individual measures if there is no statistical difference in quality because of intrinsic uncertainties in the measurement. To analogize to grading systems, this would be like taking all the students who receive 95 percent on a test and then ranking them and assigning grades A through D. The result would be completely unfair and misleading.

In addition to this concern, KCP members remain deeply troubled by the three standardized ratio measures specifically. First and foremost, the Standardized Transfusion Ratio (STrR) measure has not been endorsed by the National Quality Forum (NQF). Using the STrR with no external review is inappropriate. It is one thing for CMS to use a measure not endorsed by NQF, but one that at least had a rigorous level of review so that all parties are aware of its strengths and weaknesses. It is highly problematic, however, to use a measure, such as the STrR, which has had no review by an NQF renal endorsement Steering Committee.

KCP also has additional concerns about the STrR, which we have noted in previous comments during the Technical Expert Panel process (TEP). As currently specified, the STrR does not adjust for hospital- or physician-related factors. The literature notes that both impact transfusion rates in other areas and there is no reason to think transfusions in ESRD patients are any different. The documentation for the measure also does not demonstrate that it accurately predicts and identifies those patients who have had transfusions. Before this measure is used, additional analytic rigor must be brought to bear. As currently specified, this measure will not provide meaningful information to patients or consumers.

In terms of the Standardized Hospitalization Ratio (SHR), KCP remains concerned about the fact that the specifications are not limited to appropriate DRGs for dialysis access-related infections and fluid overload. If it were, we would support the measure. However, as constructed, it is too expansive in scope to achieve its purpose. It is also not clear how CMS plans to calculate "expected" hospitalizations. Another concern is that the SHR relies upon the 2728 data that are not validated or updated to reflect additional patient comorbidities over time.

Another concern about the use of both the STrR and SHR is that there is a very high correlation between measures (0.4). This correlation is consistent with current practice, which indicates that transfusions are almost exclusively given in hospitals. Thus, the metrics are measuring essentially the same thing. Therefore, it would be inappropriate to include both. If the SHR is refined as described above, it would be the better measure at this time.

For both the SHR and SMR, there should be greater transparency in the methodology. We also have concerns about the inadequacy of the risk adjustment methodologies to robustly account for case-mix.

Finally, KCP has concerns about the variation in measure specifications CMS has published and is using and/or proposes to use. We compared the specifications CMS provided for ESRD Five Star, the Payment Year (PY) 2016 QIP, the PY 2017 QIP, and NQF endorsement. In no case are the specifications for a measure the same for all four. The variation means that there is no consistency even among measures that are used in the same or other quality programs. This inconsistency is completely inappropriate.

While we recognize some changes to specifications result from implementation after NQF endorsement, CMS should be vigilant about ensuring the most up-to-date specifications are available through the NQF maintenance process. We are most concerned, however, about specifications that differ across CMS' own programs. Such a situation can result in different benchmarks and different scoring of facilities, which could translate to a different ranking under the CMS system. In other words, depending on which CMS specifications are being used, a facility may look "average" for ESRD Five Star in an area, but "very good" in the QIP for that measure—all because CMS has used different specifications between the programs. For example, for *NQF 0257: Maximizing Placement of AVF*, the description for DFC/ESRD Five Star states "Minimum claims = 1," yet the specifications for the QIP for PY 2016 and PY 2017 state this is 4 months. A single claim (or even if 1 *month* was intended) is significantly different from 4 months.

Again, we emphasize that KCP supports promoting transparency in an easily understood fashion for patients and their loved ones, but we also strongly believe that the metrics used must be standardized and consistent across programs, evidence-based, and scientifically valid and reliable.

We acknowledge that CMS believes these measures are not "new" and should raise little concern. As noted, we have raised concerns about these measures each time we have had an opportunity to comment. Additionally, Dialysis Facility Compare currently provides the values and compares them against a national average benchmark. The transformation of them into the ranking is new and extremely problematic as noted. Nursing Home Five Star does not include standardized ratio measures either. Thus, we strongly urge CMS not to use the standardized ratio measures as part of ESRD Five Star and to work with the community to refine these measures so that they are representative of meaningful differences in quality.

III. Conclusion

As described, the problems with ESRD Five Star raise serious concerns about its ability to provide meaningful information to patients and consumers. Patients should not be misled by forcing facility performance into arbitrary, pre-determined tiers. Instead, facilities should be measured against transparent quality benchmarks that describe attainment and improvement. As designed, ESRD Five Star is not structured to describe actual and meaningful differences between facility performance levels. It is important to have a consistent definition of quality across all ESRD initiatives and programs.

Similarly, it is important that any quality initiative provide transparency for consumers and incentives for facilities. Measures that extend beyond the sphere of influence of a facility cannot be acted upon. Because they are not actionable at the facility level, such measures provide no information to consumers about facility performance. They also do not create incentives for improvement because facilities cannot control the actions that would lead to change. The three standardized ratio measures are problematic for these reasons. Additionally, they simply cannot be transformed in a meaningful manner, as the Agency has attempted to do.

These problems, however, are not insurmountable. KCP is ready to work with CMS to implement ESRD Five Star with a revised methodology and appropriate measures. There is no statutorily mandated deadline for implementing ESRD Five Star. We reiterate that with the assistance of the kidney care community, CMS could identify an appropriate benchmark methodology to replace the bell curve. Thus, CMS should work with the community to ensure that the program works and not rush an October implementation. However, if CMS believes an October launch is necessary, it should rely upon the percentage measures and QIP benchmarks to establish the first iteration of star ratings. From there, we could work together to determine how future iterations should be designed.

We appreciate your consideration of our comments. Please do not hesitate to contact Kathy Lester at (202) 534-1773 or klester@lesterhealthlaw.com if you have any questions or to begin discussions about how to address these concerns.

Sincerely,

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

cc: Kate Goodrich, Director, Quality Measurement and Health Assessment Group

Appendix A: Members of Kidney Care Partners

AbbVie
Akebia Therapeutics, Inc.
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
Centers for Dialysis Care
DaVita Healthcare Partners, Inc.
Dialysis Patient Citizens
Dialysis Clinic, Inc.
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Greenfield Health Systems
Hospira
Keryx Biopharmaceuticals, Inc.
Kidney Care Council
National Kidney Foundation
National Renal Administrators Association
Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage Medical
Renal Physicians Association
Renal Support Network
Renal Ventures Management, LLC
Rogosin Institute
Sanofi
Satellite Healthcare
U.S. Renal Care