



August 13, 2014

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

Re: Dialysis Facility Compare Five-Star Rating System

Dear Dr. Conway:

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with renal disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with kidney disease. We are writing to express our concerns regarding CMS' proposed application of the Five-Star Rating System to ESRD facilities via Dialysis Facility Compare, and to urge the Agency to delay its implementation until the kidney community has a meaningful opportunity to engage in a dialogue with the agency around this program.

RPA's concerns about the Dialysis Facility Compare Five-Star System (DFCFSS) come from our perspective as the leading U.S. nephrology organization on kidney disease quality measurement and implementation. RPA was the lead organization of the Kidney Disease Workgroup of the AMA's Physician Consortium for Performance Improvement (PCPI) which developed 6 ESRD (adult) measures, 6 CKD measures, and 2 ESRD (pediatric) measures. RPA also has developed three evidence-based clinical practice guidelines: (1) the RPA Clinical Practice Guideline on Adequacy of Hemodialysis published in 1993; (2) the RPA Clinical Practice Guideline on Appropriate Patient Preparation for Renal Replacement Therapy was published in 2002; and (3) the RPA Clinical Practice Guideline on Shared Decision Making in the Appropriate Initiation of and Withdrawal from Dialysis initially published in 2000, revised and expanded for the second edition published in October 2010. In early 2015 RPA will also be launching a specialty specific registry to assist nephrologists with participating in Medicare's incentive programs and continually improving kidney patient care and outcomes.

As a result of RPA's commitment to quality measurement in kidney disease and our content knowledge and depth of experience in this area, we are deeply concerned that the DFCFSS is

simply not ready for rollout in a way that will be constructive for kidney patients. Our specific concerns focus on:

- Absence of Meaningful Public Review and Comment Process
- Assignment of the Star Ratings
- Premature Use of Standardized Ratio Measures
- Potential Disruptions in Continuity of Kidney Patient Care

Absence of Meaningful Public Review and Comment Process

Given the current movement toward transparency across all sectors and activities in the U.S. healthcare spectrum, RPA finds it surprising and disheartening that the timeline between first open, public discussion of the DFCFSS and implementation is less than two months. We recognize that the use of five-star systems in healthcare is not novel, and that CMS is under legislative mandate to pursue their implementation. However, dialysis organizations, the individual ESRD facilities, and the medical directors of those facilities take their responsibilities in the quality of care realm very seriously, with few exceptions, and we believe this program has the potential to alter perceptions of care inappropriately and without foundation.

Further, it is not as if there is no quality assessment structure in place for dialysis facilities. The kidney disease care community has worked hard with CMS to develop and refine the ESRD Quality Incentive Program (QIP) and while it is not perfect, it has strived to be as evidence-based as possible and has the 'buy-in' of the kidney community at large. RPA believes that to precipitously impose a system as the DFCFSS with far-reaching potential in the absence of robust feedback from the kidney care community will unnecessarily result in ongoing confusion and misperceptions for patients, dialysis providers, and administrative leaders in the field. We therefore urge the Agency to delay implementation of the DFCFSS until meaningful input from the kidney community has been considered carefully.

Assignment of the Star Ratings

CMS' rollout of the DFC Five Star System indicates that the ratings will have a symmetrical bell-curve distribution of 10%-20%-40%-20%-10%, so that when the ratings are released 30% of all dialysis facilities nationwide will have a rating that is at least perceived to be below average. Acknowledging that in any population of participants in any field of endeavor there will be high performers, mid-range performers, and low performers, RPA believes that to impose a rating stratification as proposed on all dialysis facilities providing care to the most vulnerable Medicare beneficiary sub-population nationwide is arbitrary and counterproductive.

In its presentation on the DFCFSS, CMS staff indicated that the star ratings "generally" aligned with the QIP Total Performance Scores, but not always. RPA believes that this is unacceptable. In developing a ratings system that will be used by kidney patients and their families to determine where they will receive life-sustaining dialysis treatment, 'general' alignment with what is considered to be the gold standard in dialysis facility assessment is insufficient. We

therefore strongly urge CMS to work with the kidney care community on a ratings system that does have community buy-in, is as un-arbitrary as possible, and serves the needs of kidney patients and their families.

Premature Use of Standardized Ratio Measures

RPA shares the concerns of Kidney Care Partners (KCP) regarding the use of standardized ratio measures in the DFCFSS. We recognize that standardized ratio measures have been a part of the quality measurement equation for some time, but we would offer that their utilization in previous contexts does not necessarily make them appropriate or ready for use in a rankings system such as DFCFSS. It is our understanding that within the confidence intervals of the standardized ratio measures there can be substantial variability or 'play' such that two facilities may have no difference in quality delivered specific to the measure but will have significant differences in rankings due to inherent inconsistencies within the measure. Since these rankings will be of exceptional importance to the facilities being ranked, we believe that it is incumbent upon to CMS to resolve operational issues with the DFCFSS in areas such as the use of standardized ratio measures before implementation.

Potential Disruptions in Continuity of Kidney Patient Care

The quality of care provided to Medicare beneficiaries with kidney disease is of course the issue of greatest importance in the discussion of proposals such as the DFCFSS. RPA shares CMS' commitment to ensuring that the care delivered is of the highest quality possible, and we steadfastly support the Agency's mission and responsibility to assess and publicly report on quality of care delivered by Medicare providers.

However, it is also quite likely that implementation of programs such as the DFCFSS without appropriate vetting will cause substantial disruptions in the continuity of patient care in many facilities adversely affected by the rankings. It is not difficult to envision scenarios where facilities may be providing care that under the QIP achieve perfectly acceptable total performance scores but in the DFCFSS receive star ratings of two stars or less. To the extent that the number of stars assigned to a dialysis center compels patients to change their facility based not on the actual quality of care provided but on the vagaries of the ratings system, RPA would posit that the DFCFSS was not improving patient care but rather undermining it. Further, unintended misperceptions on the part of patients not only have the potential to damage or at a minimum tarnish relationships between the patients and their facilities, but will be even more detrimental to patients who have only one choice of dialysis provider.

RPA would like to emphasize that we support the use of incentives to improve patient care, and we are not inherently or adamantly opposed to a star ratings system per se. However, we believe it should be pursued with care, appropriate refinement and alignment with other quality programs, and with the active and consequential participation of the kidney community. To do so otherwise would be to invite unnecessary problems for the Agency itself, the kidney care provider community, and most importantly, Medicare beneficiaries with ESRD.

As always, RPA welcomes the opportunity to work collaboratively with CMS in its efforts to improve the quality of care provided to the nation's kidney patients, and we stand ready as a resource to CMS in its future endeavors. Any questions or comments regarding this correspondence should be directed to RPA's Director of Public Policy, Robert Blaser, at 301-468-3515, or by email at rblaser@renalmd.org.

Thank you,

A handwritten signature in black ink that reads "Rebecca Schmidt, DO". The signature is written in a cursive style with a large, stylized initial 'R'.

Rebecca Schmidt, DO
President