KIDNEY CARE PARTNERS

June 30, 2016

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UM-KECC
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Dear Dr. Messana,

On behalf of Kidney Care Partners (KCP), I want to thank you for the opportunity to respond to questions that UM-KECC has posed related to patient-reported outcomes measures (PROMs). As we discussed this morning, we look forward to working with you and your team as UM-KECC prepares the white paper requested by CMS. This letter sets forth our written answers to the questions on which you requested comments.

I. Adoption of Guiding Principles

Since the creation of the Kidney Care Quality Alliance (KCQA), KCP has supported the development of quality measures and linking payment to performance. In our work, we identified a set of guiding principles that should be followed when developing any type of measure. In particular for PROMs we highlight the following principles:

- Be patient-centered.
- Reflect patient values and needs.
- Allow for appropriate variations in individual patient care regimens.
- Be equitable and ensure that sicker patients continue to receive high quality care.
- Be consistent with the patient-physician relationship, as well as the relationship between patients, providers, facilities, and other health care professionals.
- Reflect an array of aspects of care.
- Encourage improved quality and effective practices.
- Focus on improving the safety, effectiveness, and efficiency of care.
- Be public to ensure integrity and allow for understanding of reported data by patients and their families.
- Produce consistent and credible results.
- Be reliable, valid, precise, based on sound scientific evidence, and predictive of overall quality performance.
- Be standardized, transparent, explicit, and measurable.

- Be based on standardized definitions, technical specifications, and methodologies.
- Allow for mastering benchmarks and demonstrating improvement.
- Facilitate meaningful comparisons at the facility-level and be risk adjusted or risk stratified when appropriate.
- Be based on KCQA's prioritization of the Blueprint's domains/subdomains.
- Be based on a strong consensus.

These principles are consistent with those the National Quality Forum (NQF) has set forth in its report on PROMs.

- Conceptual and measurement model documented
- Reliability
- Validity
- Interpretability of Scores
- Burden
- Alternative modes and methods of administration
- Cultural and language adaptations
- Electronic health record capability

II. Response to UM-KECC Questions

1. What patient reported outcomes/patient centered outcome measures are meaningful to patients and health care providers?

There are very few validated PROMs in the ESRD space. The ICH-CAHPS for ESRD and the KDQOL instruments are two examples of PROMs that are in use today.

ICH CAHPS: KCP believes that it is critically important to evaluate patients' experiences when receiving dialysis. The current ICH CAHPS survey is one tool that if adjusted could be considered for a PROM, but as currently designed and implemented in the ESRD Quality Incentive Program (QIP) it is burdensome for the patients and the dialysis facilities.

The complete survey contains 56 questions and requires the patients to answer all of the questions in a single setting. The length can be very taxing on patients who are battle kidney failure and trying to maintain as normal a life as possible. The Agency for Healthcare Research and Quality (AHRQ) also understood this concern and conducted validity and reliability testing for the survey in total, as well as in three independent sections, to allow providers to divide the survey among different patients and reduce the burden.

In addition to the burden on patients, there is also the administrative burden

on facilities, as the measure is currently implemented in the ESRD QIP. In this program, facilities must administer the survey twice each year, rather than once a year as others have recommended. 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]

KDQOL: PROMs may also focus on quality of life (QOL) and functional status. These patient-reported outcomes can be measured for individual patients through standardized instruments, such as the Kidney Disease Quality of Life Survey (KDQOL) or the Short Form Health Survey (SF-36). We also note that KDQOL was originally validated on 165 patients in 1997.[2] As dialysis patients are known to have a different disease burden today than 17 years ago, we believe the instrument should be validated and modified as necessary just as other clinical measures are, in a larger, more contemporary dialysis population. Moreover, while the KDQOL is useful as a tool to assess individual patients, it does not adequately identify patients' underlying goals and values that would permit a truly patient-centered approach to improving QOL; additional research and development in this area could improve care plans, QOL, and patient satisfaction and experience with care.

It is also important to recognize the distinctions among satisfaction, functional status/QOL, and patient engagement in the context of PROMs. Engagement in a patient's own care is still a very difficult thing to measure despite concepts like the Patient Activation Measure.

2. What data may be available to support development and testing of these measures

As noted above, we believe that additional research needs with regard to the KDQOL to identify patients' goals and values to make sure the instrument is patient-centered, as well as to validate the measure.

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[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.

[2] Mayne T, Dunn D, Marlowe G, Schatell D. Revalidation of the Kidney Disease Quality of Life Questionnaire (KDQOL). *Davita, Inc. Denver, CO; MEI, Madison, WI.* Abstract presented at ASN's 2010 Renal Week. https://www.asn-online.org/. *Last accessed January 16, 2014.*

III. Conclusion

Again, KCP appreciates the opportunity to provide comments in response to the questions UM-KECC has raised. We also look forward to finding a way to collaborate as KCP pursues its work on PROMs as well. If you have further questions, please do not hesitate to contact Kathy Lester at klester@lesterhealthlaw.com or (202) 534-1773.

Sincerely,

Frank Maddux, M.D.
Chairman
Kidney Care Partners

cc: Claudia Dahlerus, Ph.D., M.A.
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