



July 20, 2023

Partnership for Quality Measurement
Battelle
505 King Avenue
Columbus, Ohio 43201

RE: Battelle Clinical Quality Measure Endorsement and Maintenance Process Public Comments

Kidney Care Partners (KCP) is a non-profit coalition of more than thirty organizations comprising the full spectrum of stakeholders related to dialysis care—patients and advocates, dialysis professionals, physicians, nurses, researchers, therapeutic innovators, transplant coordinators, and manufacturers. KCP is committed to advancing policies that improve the quality of care and life for individuals at every stage along the chronic kidney and end stage renal disease care continuum, from prevention to dialysis, transplant, and post-transplant care. KCP applauds Battelle and the Partnership for Quality Measurement (P4QM) for its commitment to serve as the new Consensus Based Entity (CBE) for the Centers for Medicare and Medicaid Services (CMS), and we appreciate the opportunity to comment on the new Endorsement and Maintenance (E&M) Process. We offer the following comments.

EXPEDITED TIMELINES

KCP appreciates Battelle’s focus on accelerating and streamlining the prior E&M consensus processes. Given today’s rapidly evolving clinical, legislative, and regulatory environments, a commitment to meeting stakeholders’ needs in a timelier manner is paramount. However, sufficient time must be provided for stakeholders to review and develop thoughtful comments and positions on endorsement recommendations—and for measure developers to appropriately respond to feedback and questions during the submission and review process. We urge Battelle to acknowledge this reality and to ensure that the quality of the process is not compromised in the interest of expediency.

SCIENTIFIC METHODS PANEL ROLE

KCP welcomes Battelle’s proposal to provide opportunities for Measure Developer support throughout the submission and endorsement review processes. In particular, we applaud the revised role of the Scientific Methods Panel (SMP), wherein its members’ considerable expertise can be better leveraged on a measure-by-measure basis to assist developers struggling with methodological challenges. We have long advocated for this more fluid use of the SMP. In contrast to the prior resource-intensive, siloed development and endorsement processes, this revised approach is a more iterative, collaborative process between developers, the SMP, and the E&M Committees that we believe will better meet the needs of all parties, will conserve limited measure development resources, and will result in stronger, more meaningful measures.

APPEALS PROCESS

Battelle notes in its E&M Guidebook that it will enact a more robust and transparent appeals process. However, the proposed Appeals Panel will consist of the internal Battelle E&M team, the Chairs of the E&M Committee that initially voted to endorse the measure in question, and “others, requested as needed.” As described, we are concerned that this process may neither be robust nor transparent; we request additional details for clarity. For instance, is there an opportunity for new nominations to Appeals Panels to better engage stakeholders in the process and to provide new opinions and diverse

points of view? At current, we fear the described revised appeals process may prove to be little more than a rehash of prior positions from individuals involved in the original decision in favor of the measure.

NOVEL HYBRID DELPHI AND NOMINAL GROUPS TECHNIQUE

Battelle proposes a novel hybrid Delphi and nominal groups multistep process to increase engagement of all committee members and structure facilitation by using standard measure evaluation criteria and practices. While we are pleased by the proposal for expert facilitation to better ensure an equitable sharing of ideas and opinions among committee members, we have serious reservations with the process as currently specified.

We note that it appears each E&M project will now have two committees—a Foundational Advisory Group to review and make recommendations on all candidate measures, and a Recommendations Reconciliation Group to make final recommendations on measures for which there was not consensus within the Advisory Group. Additionally, there now appears to be only five E&M projects which have absorbed the many project committees that had been created under NQF. As such, although it is not entirely clear in the Guidebook, we believe that the Renal Standing Committee will no longer exist.

Instead, renal measures will now be reviewed under two larger projects, “Management of Acute Events, Chronic Disease, Surgery, and Behavioral Health” and “End-of-Life Care, Rescue, Specialized Interventions”. Given the large number of topics being covered and the target rosters of 45 and 15 members, respectively, we gather that there will be only one or two individuals with renal-related expertise on each of the Advisory and Recommendations Groups. We have grave concerns with this proposal and feel the end result will be a tremendous loss of experiential and clinical expertise within all clinical areas. We note that the dialysis facility, in particular, is a unique care setting guided by unique Federal regulations and a unique punitive payment system. ESRD Quality Incentive Program (QIP) penalties often disproportionately and paradoxically impact the most financially vulnerable facilities treating the most socially and medically disadvantaged patients.¹

The Renal Standing Committee was constructed to ensure that measures being considered for the QIP are technically appropriate for use in this singular patient population and specialized care setting and will not inadvertently perpetuate the very disparities CMS and Battelle are working to address. As proposed, these committees will not have the requisite clinical or experiential knowledge to provide meaningful input in the wide array of topic areas. Likewise, clinicians, patients, and advocates with expertise in a particular area will now be asked to review measures outside that realm of expertise, squandering their insights, talents, and time. The end result will likely be the adoption of a significant number of new measures into the QIP for which there was no input from providers with knowledge of the inner workings of dialysis facilities—or from the patients and families that will ultimately be impacted by those metrics.

We believe this loss of expert input contradicts CMS’s “Measures that Matter” priorities and anticipate it will have a profoundly deleterious impact on the quality of the QIP. We urge Battelle to reconsider this approach and to reinstate individual Advisory Groups addressing specific clinical foci. Barring that, we urge Battelle to invite appropriate subject matter experts or sitting Standing Committee members to participate in measures’ reviews.

Finally, and importantly, we have profound concerns with renal measures falling under the “End-of-Life Care” Project. We note that patients, care-partners, and advocates working with KCP are in fact offended by this proposal. As Battelle knows, many dialysis patients lead long, active, and fulfilling lives for 5, 10, or even 20 or more years. Individuals with chronic and end-stage renal disease—including those on dialysis—do not consider themselves to be dying, but rather living, with kidney failure. Moreover,

¹ Sheetz KH, Gerhardinger L, Ryan AM, Waits SA. Changes in dialysis center quality associated with the End-Stage Renal Disease Quality Incentive Program: An observational study with a regression discontinuity design. *Ann Intern Med.* 2021 Aug;174(8):1058-1064. doi: 10.7326/M20-6662. Epub 2021 Jun 1. PMID: 34058101.

splitting the renal topic area into two projects will further dilute the clinical expertise required to review these complex measures. We strongly suggest Battelle revise the proposal to allow for review of all renal-related measures within the Chronic Care Project.

KCP again thanks you for the opportunity to comment on the Battelle Clinical Quality Measure Endorsement and Maintenance Process. If you have any questions, please do not hesitate to contact Lisa McGonigal, MD, MPH (lmcgon@msn.com).

Sincerely,

Kidney Care Partners

Akebia Therapeutics, Inc.
American Kidney Fund, Inc.
American Nephrology Nurses Association
American Society of Nephrology
American Society of Pediatric Nephrology
Ardelyx
AstraZeneca
Atlantic Dialysis Management Services, LLC
Baxter International, Inc.
Cara Therapeutics, Inc.
Centers for Dialysis Care
CorMedix Inc.
CSL Vifor
DaVita, Inc.
Dialysis Care Center
Dialysis Patient Citizens, Inc.
Fresenius Medical Care
Greenfield Health Systems
Kidney Care Council
North American Transplant Coordinators Organization
Nephrology Nursing Certification Commission
Renal Healthcare Association
Renal Physicians Association
Renal Support Network
Rogovin Institute
Satellite Healthcare, Inc.
U.S. Renal Care, Inc.
Unicycive Therapeutics, Inc.