Rogosin Institute

July 28, 2023

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

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

The Rogosin Institute was established in 1983 as an independent, not-for-profit institution for the research, treatment and prevention of kidney disease. Our founder, Dr. Albert Rubin and his colleagues performed the first hemodialysis treatment in New York City in 1962 and the first kidney transplant in New York City in 1963.

Today, the Rogosin Institute remains a not-for-profit corporation whose mission includes medical research, education and health care concentrating on kidney disease through our affiliations with Weill Cornell Medicine and the New York-Presbyterian Hospital. Rogosin administers a nephrology practice which provides more than 20,000 patient visits for all manner of kidney disease at three locations in New York City. We also administer ten dialysis centers in Brooklyn, the Bronx, Manhattan and Queens, New York where we care for approximately 1,400 patients with end-stage kidney disease (ESKD). More than 15% of our patients treat by peritoneal dialysis and home hemodialysis.

The Rogosin Institute was a pioneer participant in the End-Stage Renal Disease Seamless Care Organization (ESCO) demonstration project and continues to participate in the ETC model. Through our Program to Educate Patients with Advanced Kidney Disease (PEAK), we have achieved outcomes far better than local and national benchmarks. Approximately 12.5% of patients participating in the program receive pre-emptive kidney transplants compared to 2.5% of patients entering the Medicare ESRD program. Of those who receive dialysis, 20% of PEAK participants initiate dialysis with home modalities compared to 2% across New York City. Of those starting with in-center hemodialysis, more than 60% begin as outpatients with permanent vascular access compared to less than 20% of their counterparts nationally. Currently, we are expanding our PEAK program to northern Manhattan and the southern Bronx and to Brooklyn. These data reflect our belief in providing all patients with the treatment that is right for them at the location that best suits them.

Achieving the highest quality of care is the driving force behind all of our work. The 2024 update to CMS' Care Compare website is currently under preview. All of our eight rated facilities achieved ratings of four or five stars with an average rating of 4.625 stars for Quality of Patient Care. For Patient Experience, our average score increased from 3.50 to 3.625; three of our facilities achieved five star ratings for Patient Experience.

We appreciate the opportunity to comment on Battelle's Clinical Quality Measure Endorsement and Maintenance Process. We applaud Battelle and the Partnership for Quality Measurement (P4QM) for its commitment to serve as the new Consensus Based Entity for the

Centers for Medicare and Medicaid Services (CMS). We offer the following comments based on the publicly available information about P4QM's new processes.

Expedited Timelines

While we appreciate P4QM's focus on accelerating and streamlining the E & M consensus process, we are concerned that the accelerated timeline will make it difficult for stakeholders to review and provide comments on proposed measures. In the present rapidly evolving clinical and regulatory environment, a streamlined process is vital; however, sufficient time is required for measure developers to respond to feedback and concerns submitted during the public comment period which P4QM emphasizes will be critical to development of consensus by the new committees which are currently in formation. It will be critical to monitor the quality of the process as it is implemented to be sure that the emphasis on expediency does not compromise a careful consideration of the measures.

Scientific Methods Panel

The Scientific Methods Panel has provided invaluable support for the E & M consensus process. Employing their expertise to help the consensus committees understand issues like reliability and validity of measures has been critical to the committees' endorsement of standardized measures capable of measuring providers' performance. We support the more collaborative approach in the proposed process which will assist developers in ensuring that methodological challenges are addressed before the measure is presented to the committee. However, we urge P4QM to monitor the deliberations of its committees to ensure there is adequate understanding of all of the important aspects of the measures under consideration.

Appeals Process

Battelle intends to enhance the appeals process after measures undergo consideration by its E & M committees. We have concerns that the appeals panel consisting of the internal Battelle E & M team and the chairs of the E & M committee that initially considered the measure will revisit the measure with a preformed opinion of it. P4QM notes that others will be requested to join the appeals panel as needed but we are concerned that failure to include such experts from the outset of the appeals process will not improve the transparency of the process and will not make it more robust.

Committee Structure

P4QM proposes a novel process to increase engagement of all committee members. We support the proposal to facilitate expert involvement and ensure more equitable sharing of ideas among committee members, we are concerned that the new process may not achieve these goals.

The prior process had disease-specific E & M committees made up of expert stakeholders. The Renal Standing Committee included health care professionals, patient representatives and experts in the science of quality measurement all with experience and expertise in kidney disease and the operations of dialysis facilities. I served as a member of the Renal Standing Committee from 2020 until Battelle assumed the CMS contract for E & M in 2023. The process proposed by the P4QM replaces disease-specific committees with

committees that evaluate measures by patient experience or life journey. As a result, measures related to kidney disease will be divided into two larger projects: “Management of Acute Events, Chronic Disease, Surgery and Behavioral Health” and “End-of-Life Care, Rescue and Specialized Interventions”. P4QM proposes a target of as many as 45 members for each of these committees. Since each committee will be responsible for many areas of medicine, it is likely that each will have a small number of individuals (perhaps one or two) with expertise in kidney disease on each of the advisory and recommendation groups.

We are very concerned that this proposal will dilute the expertise of the E & M committee evaluating measures related to kidney disease. The dialysis facility is a unique care setting guided by a unique Federal program with a Quality Incentive Program (QIP) that penalizes underperforming facilities. We support the program’s process of evaluating and comparing dialysis facilities based on clearly structured, objective quality measures but we note that the QIP often disproportionately impacts financially vulnerable facilities treating the most socially and medically disadvantaged patients.

We are also concerned that the division of the committees into a Foundational Advisory Group members of which will be responsible for reviewing measures and submitting their recommendations individually and a Recommendations Reconciliation Group members of which will only discuss those measures for which consensus was not reached by the Foundational Advisory Group. We are concerned that this structure will impact the committee members’ opportunity for discussion of the measures. Without this discussion, we are concerned that measures might receive endorsement without due consideration of the ability of dialysis facilities to collect the data and without due consideration of unintended consequences the new measures may have on patients.

The Renal Standing Committee developed to ensure that measures under evaluation for inclusion in the QIP are technically appropriate for use in the unique patient population who receive care in these specialized settings. We are concerned that the proposed committees will lack the clinical knowledge and specialized experience to evaluate potential unintended consequences of new measures. We are concerned that this will result in adoption of new measures into the QIP without input from subject matter experts with knowledge of the processes of dialysis facilities or the patients who would be impacted by them.

CMS has a goal of limiting quality measurement to “Measures that Matter”. We are concerned that P4QM’s new process will negatively impact the quality of the QIP by adding measures that are of lower importance to patients and those who care for them. We urge P4QM to reinstate clinically focused committees including the Renal Standing Committee.

Thank you again for the opportunity to comment on the Battelle Clinical Quality Measure Endorsement and Maintenance Process.

Sincerely,

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