Technical Expert Panel Charter

Project Title: Effective Availability and Utilization of Home Dialysis Modalities

TEP Expected Time Commitment and Dates:

The call for nominations period opened on November 16 and closes on December 16, 2020

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan Kidney Epidemiology and Cost Center to develop facility-level measures in the area of modality education for dialysis patients. The contract name is Kidney Disease Quality Measure Development, Maintenance, and Support. The contract number is 75FCMC18D0041, task order number 75FCMC18F0001. As part of its measure development process, the University of Michigan Kidney Epidemiology and Cost Center convenes groups of stakeholders who contribute direction and thoughtful input to the measure developer during measure development and maintenance.

Project Objectives:

UM-KECC has been tasked by CMS to develop dialysis facility quality measures that allow measurement of differences across U.S. dialysis facilities' effectiveness of education of patients about dialysis modality options (i.e. In-center vs. home dialysis) and/or effective utilization of home dialysis modalities in the treatment of chronic kidney failure.

Technical Expert Panel (TEP) Objectives:

The TEP will use existing data and their expert opinion to formulate recommendations to UM-KECC regarding the development of a draft measure that addresses potentially important quality gaps in utilization of home dialysis. Recommended measures should be evidence based, scientifically acceptable (reliable and valid), feasible, and usable by CMS, providers, and the public.

Specifically, the TEP will evaluate the construct validity of a prototype home dialysis utilization quality measure developed over the last year. Additional TEP input will be sought regarding appropriate risk adjustment strategies for the measure and input regarding the usability of the measure from both patients' and providers' perspectives..

TEP Requirements:

A TEP of approximately 11-20 individuals will evaluate the construct validity of a prototype home dialysis utilization quality measure developed over the last year and will provide input regarding appropriate risk adjustment strategies for the measure and input regarding the usability of the measure from both patients' and providers' perspectives.

The TEP will be composed of individuals with differing areas of expertise and perspectives, including:

- · Nephrologists, nephrology trained social workers, and dialysis facility nursing staff
- · Consumer/Patient/Family (caregiver) perspective
- · Performance measurement experts
- · Quality improvement experts
- Purchaser Perspective

Healthcare disparities experts

Scope of Responsibilities:

UM-KECC is seeking balanced representation of dialysis stakeholders and clinical experts representing patients and patient-advocates, dialysis providers, as well as clinical, statistical, and public health experts to evaluate several aspects of a draft quality measure intended to evaluate effective utilization of home dialysis modalities. The TEP will also have the opportunity to advance additional measure concepts via brainstorming sessions, as time allows. It is UM-KECC's intent to facilitate TEP discussion through presentation of background information and a description of the draft quality measure. The TEP will be led by one or two Chairpersons, whose responsibility is to lead the discussion and attempt to develop consensus opinions from TEP membership regarding the topics described in TEP Objectives section above. The TEP is intended to be advisory to UM-KECC, as UM-KECC continues to develop and refine the draft measure described in this document.

The role of each TEP member is to provide advisory input to UM-KECC.

Role of UM-KECC: As the CMS measure developer contractor, UM-KECC has a responsibility to support the development of quality measures for ESRD patients. The UM-KECC moderators will work with the TEP chair(s) to ensure the panel discussions focus on the review of draft measure specifications, as recommended by the contractor. During discussions, UM-KECC moderators may advise the TEP and chair(s) on the needs and requirements of the CMS contract and the timeline, and may provide specific guidance and criteria that must be met with respect to CMS and NQF review of revised candidate measures reflecting prevalent comorbidities.

Role of TEP chair(s): Prior to the TEP meetings, one or two TEP members are designated as the chair(s) by the measure contractor and CMS. The TEP chair(s) are responsible, in partnership with the moderator, for directing the TEP to meet the expectations for TEP members, including provision of advice to the contractor regarding measure specifications.

Duties and Role of TEP members: According to the CMS Measure Management System Blueprint, TEPs are advisory to the measure contractor. In this advisory role, the primary duty of the TEP is to review any existing measures, provide input as to data sources and feasibility, and to suggest measure specifications. TEP members are expected to attend conference calls in 2021 and be available for additional follow-up teleconferences and correspondence as needed in order to support the submission and review of the candidate measure(s) by NQF. Some follow up activities may be needed after testing has occurred.

The TEP will review, edit (if necessary), and adopt a final charter at the first teleconference. A discussion of the overall tasks of the TEP and the goals/objectives of the ESRD Facility Level Measure Development project will be described. TEP members will be provided with a summary of peer reviewed literature and other related quality measures prior to the in-person meeting. TEP members will have the opportunity to submit additional studies to be included in the literature review. A review of the CMS and NQF measure development criteria will also be covered during the teleconference.

During the TEP Meetings: The TEP will review evidence to determine the basis of support for proposed measure(s). The key deliverables of the TEP at the in-person meeting include:

• Recommending draft measure specifications

- Assisting in completing the necessary documentation forms to support submission of the measures to CMS for review, and to the NQF for endorsement
- As needed TEP members may be asked to provide input to UM-KECC as they prepare responses to NQF and public comments

Following the TEP meetings the TEP chair(s) and TEP members will prepare a summary of recommendations. As necessary, the TEP chair(s) will have additional contact with UM-KECC moderators to work through any other issues. This will include votes for draft and final measures. TEP members will review a summary report of the TEP meeting discussions, recommendations, draft measure specifications, and other necessary documentation forms required for submission to the NQF for endorsement.

Guiding Principles:

Participation as a TEP member is voluntary and the participant's input will be recorded in the meeting minutes, which will be summarized in a report that may be disclosed to the public. If a participant has chosen to disclose private, personal data, then related material and communications are not deemed to be covered by patient-provider confidentiality. Patient/caregiver participants may elect to keep their names confidential in public documents. If they chose to participate anonymously their name and information will not be included on any materials provided to the other TEP members or in the public reports. Additionally – they will be assigned a blinded alias which they will be able to use for all virtual conferencing. UM-KECC will answer any additional questions about confidentiality.

The TEP will use both verbal consensus and formal voting by secret ballot for decision-making, depending on the context of the decision. For administrative and other decisions about agenda, direction of discussion, and other minor operational decisions, informal verbal consensus directed by the TEP chairs will be utilized. In order to objectively record TEP recommendations about the validity of the quality measures presented and recommended changes, formal votes utilizing secret ballot will be employed. These techniques have been used for nearly all of clinical TEPs facilitated by the UM-KECC team over the last several years.

The measures evaluation standards included in the CMS Measures Blueprint and reflected in the National Quality Forum (NQF) criteria are presented during an early TEP teleconference, typically during the first call. This is done so that TEP Charter approval and initial direction of the TEP discussion occur after TEP members are informed of the national consensus criteria that will ultimately be used to evaluate the quality measure(s) being considered by the TEP.

All potential TEP members must disclose any significant financial interest or other relationships that may influence their perceptions or judgment. It is unethical to conceal (or fail to disclose) conflicts of interest. However, the disclosure requirement is not intended to prevent individuals with particular perspectives or strong points of view from serving on the TEP. The intent of full disclosure is to inform the measure developer, other TEP members, and CMS about the source of TEP members' perspectives and how that might affect discussions or recommendations.

Estimated Number and Frequency of Meetings:

4 - 6 virtual meetings, each being between 1 to 4 hours long. Meetings are tentatively scheduled in February 2021 and subsequent meetings in March thru June 2021.

Date Approved by TEP:

TBD

TEP Membership:

TBD