Technical Expert Panel (TEP) Charter

Project Title: Assessment of Patient Autonomy for Clinical Outcomes used in Quality of Care Outcomes Reported for U.S. Chronic Dialysis Facilities and Providers

TEP Expected Time Commitment and Dates:

Participate in 2-3 virtual meetings, approximately 2-3 hours in duration. The meetings will take place between February 2025- March 2025.
All meetings will be held virtually, via a Zoom video conferencing platform.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) contracted University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to collect stakeholder feedback for the assessment of patient autonomy in ESRD treatment decision making. The contract name is Kidney Disease Quality Measure Development, Maintenance, and Support. The contract number is 75FCMC18D0041 and the task order number is 75FCMC23F0001. As part of its measure development process, University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) convenes groups of stakeholders who contribute direction and thoughtful input to the measure developer during measure development and maintenance.

In our society, there is a fundamental expectation that health care providers respect patient autonomy or choice in the process of shared decision-making. In practice, clinicians are trained that the informed consent process is one way in which we document our adherence to this critically important ethical principle. Addressing patient autonomy, patient choice, and informed consent during the measure development and maintenance process will be essential if new and pre-existing clinical outcome quality measures are to be truly patient centered and judged valid by the dialysis community.

What is somewhat less emphasized is the principle that informed consent and patient choice is very dependent on the quality and quantity of information provided about the risks, benefits, and alternatives available for treatment. Multiple barriers may affect shared decision making and informed consent, including inadequate education by the healthcare team, healthcare provider bias, limited understanding of medical concepts by the patient due to cognitive or educational limitations, and potential limitations of the provider-patient relationship. These can undermine the development of true informed consent for medical care as well as well-informed patient decisions about their care, and therefore, provide potential challenges to successful adherence to the principle of patient autonomy. In addition, financial or other incentives may sway healthcare providers to direct patients towards a particular type of treatment. It is often very difficult to determine how many of these issues are present in any given treatment choice. When present, it is also difficult to determine if the issue influences the appropriate use of informed consent principles and practice regarding patient autonomy in treatment choices.

Identification of a method for assessing the contribution of patient choice in medical decisions is critical. In addition, quality improvement programs generally provide incentives for providers to deliver ESRD care in ways supported by evidence. These incentives may not be aligned with patient choice for those who choose an alternative treatment paradigm. Many clinicians and patients involved in the consensus endorsement process have voiced concerns that implementation of quality metrics failing to explicitly address patient choice may result in unacceptable consequences for members of the dialysis community.

Project Objectives:
Develop a strategy for defining and measuring the contributions of "patient choice" to both the health outcomes and intermediate outcomes used to assess clinical quality in U.S. dialysis facilities. The project objective assumes that at least a partially operational shared decision model is currently present in the U.S dialysis system

Technical Expert Panel (TEP) Objectives:
Develop recommendations for the most effective means of measuring the contributions of "patient choice" to both the health outcomes and intermediate outcomes used to assess clinical quality in U.S. dialysis facilities. A TEP of approximately *10-20* individuals will *1) Consider whether the shared decision model currently reflects the majority of treatment decisions made in U.S. chronic dialysis programs, 2) Review the types of and extent to which patient choices impacts clinical quality outcomes in a shared decision environment, and 3) Develop recommendations for the most effective means of measuring the contributions of "patient choice" to both the health outcomes and intermediate outcomes used to assess clinical quality in U.S. dialysis facilities*

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

- Patients 18 years or older who are receiving long-term dialysis in the United States/ US Territory;
- Dialysis care providers including nephrologists, nurses, social workers, and administrative staff;
- Individuals with consumer/patient/family perspective and consumer and patient advocates; specifically, patients with long-term dialysis;
- Individuals with perspectives on healthcare disparities in ESRD;
- Expertise in performance measurement and quality improvement;
- Expertise in patient reported outcomes and instrument development or implementation;
- Expertise in medical ethics

Scope of Responsibilities:

UM-KECC is seeking balanced representation of members of the ESRD community, clinical, and ethical experts. This would include patients, patient-advocates, dialysis providers, and medical ethics experts, to

gather feedback about patient autonomy in ESRD treatment and decision-making. It is UM-KECC's intent to facility a Technical Expert Panel (TEP) discussion through presentation of background information and a description of the quality measure. The TEP will be led by one or two Chairperson(s), whose responsibility is to lead the discussion and attempt to develop consensus opinions from TEP membership regarding the topics described in the TEP Objects section above. The TEP is intended to be advisory to UM-KECC.

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 moderator(s) will work with the TEP chairperson(s) to ensure the panel discussions focus on the review of the assessment of patient autonomy in ESRD treatment decision-making developed by the contractor. During discussions, UM-KECC moderator(s) may advise the TEP and chairperson(s) on the needs and requirements of the CMS contract and the timeline, may provide specific guidance and criteria that must be met with respect to CMS and the Consensus Based Entity (CBE) review of candidate measures.

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

Duties and role of TEP members: According to the CMS Measure Management System Blueprint, TEPs are advisory to UM-KECC, as the measure contractor. In this advisory role, the primary duty of the TEP is to discuss the impact of patient autonomy in ESRD treatment decision-making and quality measure outcomes, with particular emphasis on 1) importance of patient choice exclusions in assessment of clinical outcomes and 2) discussion and input regarding how to assess patient choice influence on dialysis facility outcomes. TEP members are expected to attend the virtual meetings in February and/or March 2025 and be available for any follow-up teleconferences and correspondence as needed in order to support the submission and review of the TEP Report to CMS. Some follow up activities may be needed after post-TEP work has occurred. TEP members will review the proposed charter prior to the planned teleconference along with any supporting documents. Any comments or concerns with the charter should be provided to the TEP chairperson(s) and UM-KECC prior to the planned teleconference. TEP members who choose to participate in the meetings are providing their implicit agreement to the TEP charter content in its final form as of the first TEP meeting. UM-KECC and the chairperson(s) will provide descriptions of the overall tasks of the TEP and the goals/objectives at the first TEP meeting. TEP members will also be provided with background information about the discussion topics and will be asked to contribute additional literature or other pertinent background for TEP consideration as appropriate.

During the TEP Meetings:

- TEP members will discuss the clinical relevance of this topic and how implementation of TEP recommendations might improve interpretation of clinical quality measures used in U.S. dialysis facility quality reporting programs.

Following the TEP meetings, UM-KECC will prepare a summary of recommendations in a TEP Report. The summary report will include TEP meeting discussions and recommendations. As necessary, UM-KECC

will have additional contact with the TEP chairperson(s) and TEP members to ensure that the TEP deliberations and recommendations are accurately reflected in the TEP Report. As needed, TEP members may be asked to provide input to UM-KECC as they prepare responses to CMS and public comments.

Guiding Principles:

Participation as a TEP member is voluntary and the measure developer records the participant's input in the meeting minutes, which the measure developer will summarize in a report that they may disclose to the public. If a participant has chosen to disclose private, personal data, then related material and communications are not covered by patient-provider confidentiality. Patient/caregiver participants may elect to keep their names confidential in public documents. TEP organizers will answer any questions about confidentiality.

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, there is no intent for the disclosure requirement 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.

The TEP may 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 the agenda, direction of discussion, and other minor operational decisions, informal verbal consensus directly by the TEP chairs will be utilized. In order to objectively record TEP recommendations, formal votes utilizing secret ballot may be employed.

Estimated Number and Frequency of Meetings:

Attend 2-3 virtual meetings, approximately 2-3 hours in duration. The meetings will take place between February-March, 2025.

Date Approved by TEP:

TBD.

TEP Membership:

TBD.