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August 11, 2025

Mehmet Oz, MD, MBA; Administrator

Centers for Medicare & Medicaid Service

Department of Health and Human Services

P.O. Box 8010 Baltimore, MD 21244–8010

**Attention: CMS–1830–P**

Dear Dr. Oz:

The non-profit Medical Education Institute (MEI) is pleased to have the opportunity to comment on the proposed rule for the End-Stage Renal Disease (ESRD) Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model, Docket Number CMS–2025–0240–0002.

MEI’s mission is to *empower people with chronic disease to manage and improve their health*. To fulfill this mission, MEI develops free or low-cost evidence-based patient education in a variety of formats, grounded in motivational theory, and written at a 5th-6th grade level.

The ESRD Treatment Choices Model did not achieve the Advancing American Kidney Health **goal to** **increase patient access to home dialysis and transplantation**. MEI is submitting this comment to recommend how these goals *could* be achieved.

**Recommendation: CMS should establish a Clinical Outcomes Measure for Patient Choice of ESRD Treatment**

*Active*, *informed patient participation* in their choice of treatment needs to be encouraged. A Cochrane review of 209 studies of 107,698 patients found that use of a decision-aid extended communications **by just 1.5 minutes**—and had these benefits vs. usual care (assessing risk, providing general information, and using professional guidelines): [[1]](#endnote-1)

* Increasing patient involvement in decision-making
* Improving patient knowledge of benefits and risks of each treatment option
* Helping patients make decisions *based on what is important to them*

Due to Medical Education Institute advocacy in 2007, the 2008 *ESRD Conditions for Coverage* states under the Condition for Patients’ rights at §494.70(a): *The patient has the right to:*

*(7)* ***Be informed about all treatment modalities and settings, including but not limited to, transplantation, home dialysis modalities (home hemodialysis, intermittent peritoneal dialysis, continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis), and in-facility hemodialysis. The patient has the right to receive resource information for dialysis modalities not offered by the facility, including information about alternative scheduling options for working patients****.[[2]](#endnote-2)*

The 2019 *Advancing American Kidney Health* Executive Order*[[3]](#endnote-3)* set a goal to:

*(a)  prevent kidney failure whenever possible through better diagnosis, treatment, and incentives for preventive care;*

*(b)  increase patient choice through affordable alternative treatments for ESRD by encouraging higher value care, educating patients on treatment alternatives, and encouraging the development of artificial kidneys; and*

*(c)  increase access to kidney transplants by modernizing the organ recovery and transplantation systems and updating outmoded and counterproductive regulations.*

Patients who choose work-friendly treatment options, for example, are better able to keep their jobs and health plans. **If each dialysis facility offers eligible patients an** **evidence-based decision aid that informs them about ALL treatment options and allows them to rate how well each option fits their values, CMS could reduce costs—while improving patient outcomes**. The non-profit Medical Education Institute has developed ***My Kidney Life Plan***([www.mykidneylifeplan.org](https://www.mykidneylifeplan.org))*,* a FREE, values-based decision aid written at a 5th grade reading level, in English and Spanish, that meets all the International Patient Decision Aid Standards (IPDAS) criteria.  ***My Kidney Life Plan* is the *only* evidence-based decision aid that helps patients match their values and lifestyle preferences to the impact of all nine treatment options for kidney failure**:

1. Kidney transplant
2. Standard in-center hemodialysis
3. Nocturnal in-center hemodialysis
4. Standard home hemodialysis
5. Short daily home hemodialysis
6. Nocturnal home hemodialysis
7. Continuous ambulatory peritoneal dialysis
8. Automated peritoneal dialysis
9. Active medical management without dialysis (referred to as Comfort Care)

What follows is a suggested Clinical Outcomes measure.

**Measure Name/Title:**

*Matching ESRD Treatment Option Choices to Patient Values*

**Description of the Proposed Measure**

Percent of eligible patients in the performance period who initiate an ESRD treatment consistent with one of the choices they rated most highly on an evidence-based ESRD treatment decision aid that contains all of the ESRD treatment options, such as *My Kidney Life Plan*.

**Measure Type**

Clinical Outcomes

**Numerator Statement**

The number of eligible patients for which a facility reports condition A in the table below under “additional Information” in EQRS before the close of the clinical month of December.

**Denominator Statement**

Number of patients in the performance period who do not have any of the following exclusions:

**Facility Exclusions**

1. Facilities with a CMS Certification Number (CCN) certification date on or after September 1 of the performance period.
2. Facilities treating fewer than 11 eligible patients during the performance period.
3. Calculations will exclude the months covered by a granted Extraordinary Circumstance Exception (ECE).

**Patient Exclusions**

1. Patients who are younger than 12 years.
2. Patients treated at the facility for fewer than 30 days during the performance period.
3. Patients for whom there are no dialysis claims during the performance period.
4. The patient lacks decisional capacity *and has no proxy with a durable power of attorney* who has legal authority to make decisions about the patient’s treatment option.
5. One or more of the following conditions are documented during the performance period:
6. Patient has one or more clinical contraindications limiting treatment options to one.
7. Facility has documentation that the patient chose not to use an evidence-based ESRD treatment decision aid.

**Data Source(s)**

1. EQRS
2. Enrollment Data Base (EDB) and other CMS ESRD administrative data

**Additional Information**

For this Clinical Outcomes measure, facilities will select one of the following conditions. Each patient in condition A, B, or C is eligible to be counted in the denominator.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Documented Patient Eligibility | | Documented screening for choice of ESRD treatment using an evidence-based decision aid | | Documented  Follow-up Plan | |
|  | **Yes** | **No** | **Yes** | **No** | **Yes** | **No** |
| A | **X** |  | **X** |  | **X** |  |
| B | **X** |  | **X** |  |  | **X** |
| C | **X** |  |  | **X** |  | **X** |
| D |  | **X** |  | **X** |  | **X** |

In dialysis facilities, we recommend that the decision aid be administered within the first 30 days of dialysis and repeated annually and when any treatment option is failing. We thank CMS for considering this recommendation to help promote greater patient participation in care.



Dori Schatell, MS

Executive Director

Medical Education Institute

1. Stacey, D., Lewis, K. B., Smith, M., Carley, M., Volk, R., Douglas, E. E., Pacheco-Brousseau, L., Finderup, J., Gunderson, J., Barry, M. J., Bennett, C. L., Bravo, P., Steffensen, K., Gogovor, A., Graham, I. D., Kelly, S. E., Légaré, F., Sondergaard, H., Thomson, R., Trenaman, L., … Trevena, L. (2024). Decision aids for people facing health treatment or screening decisions. *The Cochrane database of systematic reviews*, *1*(1), CD001431. <https://doi.org/10.1002/14651858.CD001431.pub6> [↑](#endnote-ref-1)
2. https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/esrdpgmguidance.pdf [↑](#endnote-ref-2)
3. <https://trumpwhitehouse.archives.gov/presidential-actions/executive-order-advancing-american-kidney-health/> [↑](#endnote-ref-3)