



*Saving and improving lives with transplantation.*

**American Society of Transplant Surgeons®**

September 16, 2019

Tom Duvall, MBA  
Operations Analyst  
Centers for Medicare and Medicaid Innovation (CMMI)  
Centers for Medicare and Medicaid Services (CMS)  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**Re: [CMS-5527-P]; RIN 0938-AT89; Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures (Proposed Rule)**

Dear Mr. Duvall:

On behalf of the American Society of Transplant Surgeons (ASTS), I would like to offer our comments on the Voluntary Kidney Models, as described on the website of the Centers for Medicare and Medicaid Innovation Center (CMMI). ASTS is a medical specialty society representing approximately 1,800 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

ASTS strongly supports increasing the availability of kidney transplantation as a treatment option for ESRD-eligible Medicare beneficiaries, which is one of the primary priorities of the July 10, 2019 Executive Order on Advancing Kidney Health (AKH Executive Order). We applaud CMS' recognition that transplantation is the most clinically and cost effective treatment option for patients with ESRD and the agency's efforts to increase transplantation through the mandatory End-Stage Renal Disease (ESRD) Treatment Choices Model (ETC Model) and the Voluntary Kidney Models. It is in the spirit of overall support for CMMI's efforts to increase transplantation of Medicare patients with ESRD and late stage (4/5) Chronic Kidney Failure (CKF) that we offer these comments and suggestions for requirements that CMMI may wish to consider including in the Voluntary Kidney Model Request for Proposals (RFP). Our suggestions are limited to the Comprehensive Kidney Care Contracting (CKCC) Models.

**I. Require Meaningful Involvement of the Transplant Community as a Condition of Approval of a CKCC Model Application**

We are extremely pleased that each of the Voluntary Kidney Models includes a \$15,000 incentive for the transplantation of aligned Medicare beneficiaries. We believe that a direct payment incentive has the potential to increase efforts to educate ESRD patients about the benefits of transplantation and to increase interest in collaboration and care coordination with area transplant centers, especially with respect to living donor transplantation. However, we are extremely disappointed that the transplant community does not appear to be a more integral focus of the CKCC

**President**

Lloyd E. Ratner, MD, MPH  
Columbia University

**President-Elect**

Marwan S. Abouljoud, MD, CPE, MMM  
Henry Ford Transplant Institute

**Secretary**

A. Osama Gaber, MD  
Houston Methodist Hospital

**Treasurer**

William C. Chapman, MD  
Washington University

**Immediate Past President**

Dixon B. Kaufman, MD, PhD  
University of Wisconsin

**Past President**

Jean C. Emond, MD  
Columbia University Medical Center

**Councilors-at-Large**

Talia B. Baker, MD  
Jonathan P. Fryer, MD  
Alan I. Reed, MD, MBA  
Michael J. Englesbe, MD  
Julie K. Heimbach, MD  
Debra L. Sudan, MD  
Matthew Cooper, MD  
Ryutaro Hirose, MD  
Kenneth Washburn, MD  
Georgeine Smith, MS, MHS, PA-C

**Executive Director**

Daniel D. Garrett, CAE  
daniel.garrett@asts.org

**National Office**

1401 S. Clark St.  
Suite 1120  
Arlington, VA 22202  
703-414-7870  
asts@asts.org  
ASTS.org

**American Transplant Congress**

May 30 – June 3, 2020  
Philadelphia, Pennsylvania

Models. It is our understanding that approval of a CKCC Model application may require no more than the inclusion of one transplant provider of any kind (including, for example, the participation of a single transplant surgeon or physician) on the applicant's governing board, and an agreement to share some savings and losses with any transplant participant. If our understanding is correct, a CKCC Model participant's application may be approved with only nominal involvement of the transplant community.

Our concerns about the structure of CKCC Model Participants are exacerbated by the level of financial risk that successful applicants are required to accept, under both the Professional Model and the Global Model. Providing medically necessary services to the ESRD-eligible patient population is no small undertaking. In fact, as reflected in the Medicare Advantage capitated payment rates, the medically necessary expenditures for services provided to this patient population may be in the range of \$80,000-\$100,000 per year, without risk adjustment. Under these circumstances, few providers are likely to be in the position to take primary responsibility for the financial risk involved in either the CKCC Professional or the CKCC Global Model, and the financing (and therefore likely the governance) of CKCC Model Participants is likely to be dominated by the large public dialysis companies that have already had some experience in taking on financial risk through participation in the Comprehensive ESRD Care (CEC) Model.<sup>1</sup> The likely dominance of dialysis organizations in the funding of CKCC Professional and Global Models contributes to our concerns that the care provided to participating patients will be dialysis centric.

Ideally, from both a clinical and financial perspective, renal transplantation should be the first line renal replacement treatment for ESRD patients, with dialysis available to those for whom transplantation is not a treatment option. Increasing the availability of kidney transplantation as a treatment option for ESRD-eligible Medicare beneficiaries is one of the primary priorities of the July 10, 2019 Executive Order on Advancing Kidney Health (AKH Executive Order) and, in ESRD Treatment Choices Model (ETC Model) Proposed Rule, CMMI recognizes that:

A systematic review of studies worldwide finds significantly lower mortality and risk of cardiovascular events associated with kidney transplantation compared with maintenance dialysis. Additionally, this review finds that beneficiaries who receive transplants experience a better quality of life than treatment with chronic dialysis.

In light of the likely central role of dialysis facilities in CKCC Model Participant governance and financial structures, we recommend that CMMI require Participants to comply with a number of transplant-related requirements:

***Recommendation:*** *To ensure that care pathways made available to Medicare beneficiaries assigned to the CKCC Models are structured to increase the availability of transplantation to clinically appropriate patients, we recommend that transplant providers constitute a third of the members of the governing board of any approved CKCC Model. Assuming that representation of the transplant community is expanded as we recommend, we believe that the term "transplant provider" should be defined to include clinical practitioners specializing in transplantation (e.g., nurses, advanced practice providers), transplant coordinators, and transplant physicians and surgeons whose primary employment or affiliation is with a UNOS accredited kidney transplant program.*

---

<sup>1</sup> In fact, these companies have sought enactment of legislation that would require the establishment of a capitated payment model quite similar to the CKCC Global Model. See Dialysis PATIENTS Demonstration Act of 2017.

***Recommendation:*** We recommend that CKCC Model Participants be required to refer for transplant evaluation any patient with an Estimated Post Transplant Survival (EPTS) Score of 75% or below. The EPTS Score is a numerical measure that UNOS/OPTN assigns to all potential kidney transplant candidates. It takes into account four patient variables – duration of dialysis, current diagnosis of diabetes, history of previous transplants, and the candidate’s age. A lower score typically denotes a younger, healthier, first-time transplant candidate. Please note that the OPTN EPTS calculator can be found at <https://optn.transplant.hrsa.gov/resources/allocation-calculators/epts-calculator> and includes all patients age 70 years or less who are first time transplant candidates and who are either not yet on dialysis or are just starting dialysis.

***Recommendation:*** We recommend that CMMI consider a higher transplant bonus for pre-emptive transplants since these result in better clinical outcomes and increased savings to the system.

## **II. Maintain Patient Access to Multiple Listing at a Number of Transplant Centers**

The available data suggests that an ESRD patient’s inclusion on the waiting lists of multiple Transplant Centers can significantly increase the patient’s opportunity to obtain a renal transplant. For this reason, it is our view that it is critical that the CKCC Professional and Global Models be designed in a manner that encourages, rather than discourages, multiple listing.

***Recommendation:*** All transplant and transplant-related services be covered and reimbursed directly to the providers who provide the services (and not to the CKCC Contracting Organization).

***Recommendation:*** CKCC Model Organizations should be required to inform patients of the advantages of multiple listings at several area Transplant Centers.

## **III. Consider Inclusion of Cross-Cutting Population-based ESRD Quality Measures**

There is a pressing need for revised quality/outcomes measures that better encourage care coordination among the various providers involved in providing services to ESRD and late-stage CKD patients. We encourage CMMI to test the viability of cross-cutting population based measures that encourage care coordination in the context of the CKCC Model. For example, one recent article suggested the use of risk adjusted mortality measures to ensure that all providers involved in the care of these patients are focused on decreasing mortality in this patient population.<sup>2</sup> It also may be possible to construct a measure intended to encourage Demonstration Participants to provide access to transplant-related education through trained transplant professionals and living donor advocates.

***Recommendation:*** We encourage CMMI to consider using the CKCC Model structure to test potential cross-cutting quality measures that are not currently used to assess the performance of ESRD care providers.

---

<sup>2</sup> See J.D. Schold, L.D. Buccini, MP Phelan, et al. “Building an Ideal Quality Metric for ESRD Health Care Delivery.” Clin J. Am Soc Nephrol 12:1351-1356, 2017; doi: <https://doi.org/10.2215/CJN.01020117>.

**IV. Require CKCC Model Participants to Comply with Capital and Other Requirements Applicable to Special Needs Medicare Advantage Plans**

Finally, we note that CKCC Model Participants will be responsible for the care of an extremely vulnerable patient population whose medical needs may be unpredictable and whose clinical condition may involve multiple co-morbidities. Under the Global Model, CKCC Model Participants essentially assume full financial risk and under the Professional Model, CKCC Model Participants will assume half of the financial risk involved in providing comprehensive health care services to these patients. To the extent that CKCC Model Participants are not regulated entities (i.e., health insurers), we believe that it is critical that they at a minimum meet the financial, administrative, governance and other requirements imposed on Medicare Advantage Special Needs Plans that undertake to bear similar financial and clinical risk.

***Recommendation:*** *We recommend that CKCC Participants be required to meet the requirements applicable to Medicare Advantage Special Needs Plans.*

We hope that this input on the RFP requirements for CKCC Model Participants is useful to you. If you have any questions or would like any further information about ASTS' position with respect to the Voluntary Kidney Models, please do not hesitate to contact Jennifer Nelson-Dowdy at [Jennifer.Nelson-Dowdy@asts.org](mailto:Jennifer.Nelson-Dowdy@asts.org).

Sincerely yours,

A handwritten signature in blue ink, appearing to read "L. Ratner", is positioned above the typed name.

Lloyd E. Ratner, MD, MPH  
President  
American Society of Transplant Surgeons