



American Society of Transplant Surgeons®

Saving and improving lives with transplantation.

August 23, 2021

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

Re: RIN 0938-AU39/File Code CMS-1749-P. [Medicare Program; End-Stage Renal Disease 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 \("Proposed Rule"\)](#)

Dear Administrator Brooks-LaSure:

On behalf of the American Society of Transplant Surgeons (ASTS), I am pleased to have the opportunity to comment on the modifications of the End-Stage Renal Disease Treatment Choices (ETC Model) described in the Proposed Rule. ASTS is a medical specialty society representing approximately 1,900 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.

The Proposed Rule includes several technical changes to the ETC Model, including changes to the home dialysis rate and transplant rate, the Performance Payment Adjustment (PPA) achievement benchmarking methodology, and the PPA improvement benchmarking and scoring methodology. CMS is also proposing to add processes and requirements for ETC Participants to receive certain data from CMS and to include certain additional waivers and flexibilities as part of the ETC Model test.

As indicated in the 2019 comments filed for the record when the ETC Model was first proposed, we do not believe that the ETC Model will significantly "move the needle" to increase the availability of transplantation or the number of transplants actually performed. For significant progress to be made in attaining these goals, a new model of care would need to be designed with the active input and involvement of the transplant community: The ETC Model was not designed with the input of transplant providers, it does not involve transplant providers as participants, and none of the proposed technical changes include those suggested by ASTS. To the extent that CMS seeks to increase the availability of transplantation and the number of Medicare beneficiaries transplanted, we encourage the agency to incorporate the changes suggested by ASTS in 2019 (see attachment) and to coordinate with the transplant community, including ASTS, in future proposals in this area.

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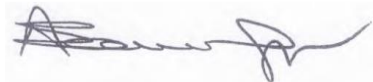
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ASTS advises CMS that true increase in transplant opportunities for patients will follow increased reimbursement for more costly transplants. Also, financial incentives for nephrologists and transplant centers to refer and list patients pre-emptively before starting dialysis will both lead to more transplantations and lower overall ESRD cost to CMS.

If you have any questions regarding ASTS' position on these issues, please do not hesitate to contact Jennifer Nelson-Dowdy, ASTS Advocacy Manager, at Jennifer.Nelson-Dowdy@asts.org or by calling (703) 414-7870.

Respectfully,

A handwritten signature in black ink, appearing to read "A. Osama Gaber", written over a light gray rectangular background.

A. Osama Gaber, MD, FACS
President
American Society of Transplant Surgeons



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September 16, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue S.W.
Room 314G
Washington, DC 20201

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

Dear Administrator Verma:

On behalf of the American Society of Transplant Surgeons (ASTS), I am pleased to have the opportunity to comment on the End-Stage Renal Disease (ESRD) Treatment Choices Model (ETC Model) described in the Proposed Rule. 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 appreciate CMS recognition, as set forth in the Proposed Rule, 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.”

As we understand it, CMS is proposing that the ETC Model apply to approximately 50 percent of adult ESRD beneficiaries in the country—those whose ESRD-related services are provided in randomly select Hospital Referral Regions (HRRs). The ETC Model would include two types of payment adjustments, which would apply to the dialysis-related claims filed by Clinicians (Nephrologists) and Facilities (Dialysis Facilities). The two types of adjustments are the Home Dialysis Payment Adjustment (HDP) and the Performance Payment Adjustment (PPA). Since the HDP relates to home dialysis, it is beyond the scope of these comments. By contrast, we are pleased to comment on the Performance Payment Adjustment (PPA), which is designed in part to increase transplantation.

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More specifically, the PPA for ETC Participants will be based on the Participant's Modality Performance Score (MPS). While two thirds of the MPS score will be based on the higher of the Participant's home dialysis achievement or performance score, one-third will be based on the higher of the Participant's transplant achievement or performance score.

Preliminary Observations

The ETC Model includes as Participants only Nephrologist/Clinicians and Dialysis Facilities. Transplant centers, transplant physicians and surgeons, Organ Procurement Organizations, donor hospitals, and other providers integral to the performance of transplantation are not included as Participants in the ETC Model. Under these circumstances, we believe it extremely unlikely that the ETC Model will affect the availability of deceased donor transplantation, and the impact of the ETC Model on living donor transplantation is likely to be far more modest than it could be if the transplant community were more integrally involved. For this reason, we believe that, while the ETC Model is a reasonable first step in achieving more value based care for ESRD-eligible Medicare beneficiaries, much more can and should be done to reform the dialysis-centric care paradigm in this area.

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. Achieving this objective would require aligning the financial incentives of all of the providers and other institutions involved (e.g., transplant centers, OPOs, dialysis facilities, and donor hospitals), establishing appropriate and internally consistent quality metrics for all providers, and waiving certain regulatory restrictions and requirements that inhibit the efficient retrieval and utilization of available organs. ASTS's proposed demonstration project to accomplish these objectives was previously submitted to the CMS Innovation Center (CMMI) and has been the subject of a number of discussions with the agency.

In short, in order to significantly "move the needle" toward a transplant-centric ESRD care model, it will be necessary to both increase the availability of transplantable organs and reduce organ discards, both of which are complex tasks, and neither of which is the focus of the ETC Model. To address the former challenge, the AKH Executive Order calls for new proposed OPO metrics that would encourage underperforming OPOs to improve organ retrieval. With respect to the latter objective—reducing organ discards—ASTS urges CMS to:

- *Finalize the deletion of one-year outcomes requirements for Medicare recertification of transplant centers.*
- *Partner with HRSA to eliminate even more stringent one-year outcomes requirements imposed by the OPTN.*
- *Partner with HRSA to modify the current SRTR "five star ratings," which strongly encourage risk-averse patient and organ selection by transplant centers.*

Along with these regulatory actions, we urge CMMI to establish a demonstration program that provides additional Medicare payment for transplants that involve the use of non-standard organs that meet specifically defined criteria and that are currently discarded and that waives otherwise applicable outcomes requirements imposed by CMS and the OPTN for transplants that meet these requirements. The Inpatient Prospective Payment Rate for kidney transplantation in 2020 is less than \$20,000, and the use of non-standard organs has the potential to increase hospital costs substantially. For example, transplant center inpatient hospital costs are increased when deceased donors are older, when organs are donated after cardiovascular death, or when the donor had history of illnesses such as diabetes or

hypertension. Additional costs may arise as the result of increased length of stay, increased risk of complications, including delayed graft function, infection and rejection, and decreased graft survival, all of which may result in greater need for inpatient dialysis early after transplant and an increase in other hospital costs.¹

If the objective is to reduce discards of potentially transplantable organs, these costs should be reimbursed. Instituting a separate demonstration program along these lines has the potential to contribute significantly to the availability of transplantation as a treatment option for those with ESRD, an objective that the ETC Model is not designed to achieve.

Recommendation: *We recommend that CMMI supplement the ETC Demonstration with a demonstration that more specifically focuses on increasing the availability of transplantation as a treatment option for those patients with ESRD and CKD 4/5.*

Specific Comments on the PPA

Comments that specifically address the ETC Model design are set forth below.

First, we note that the PPA transplant-related metrics focus on an ETC Participant's achievement and improvement in getting assigned beneficiaries transplanted and not simply getting them waitlisted. A number of complex and highly variable factors contribute to whether or not a beneficiary referred for a transplant evaluation ultimately becomes a transplant recipient, including, for example, availability of a living donor, the waitlist practices of area transplant centers, and local OPO performance. For this reason, we certainly understand the position of those groups that may argue that it is unfair to measure the performance of ETC Participants on the basis of the number or percentage of their patients who are ultimately transplanted.

However, we believe that measuring the actual transplantation rate of the patient population assigned to an ETC Participant is preferable to measuring the proportion of the Participant's assigned patient population referred for transplant evaluation or the proportion actually waitlisted. Measuring the actual transplant rate of the assigned population provides the strongest incentive for effective care coordination between and among nephrologists, dialysis facilities, and transplant centers; provides a strong incentive for ETC Participants to maintain the health of their patients who are on the transplant waiting list; provides an extremely strong incentive for ETC Participants to educate and provide support to their patients about living donation; and provides an incentive for ETC Participants to educate themselves and their patients about the potential benefits of patients' multiple listing at a number of Transplant Centers. For this reason, we support using actual transplant rates as the basis for measuring performance in the PPA transplant-related domain.

Second, we believe that it may be prudent to consider exempting from the transplant measures additional groups of patients who are highly unlikely to meet transplant criteria. While the proposed measures exclude patients who are seventy five years or older from the transplant measure, patients who meet the following criteria also should be excluded, since they are rarely appropriate for transplantation. For example, we recommend the exclusion of patients who have untreatable

¹ The Changing Financial Landscape of Renal Transplant Practice: A National Cohort Analysis. Axelrod DA, Schnitzler MA, Xiao H, Naik AS, Segev DL, Dharnidharka VR, Brennan DC, Lentine KL. Am J Transplant. 2017 Feb;17(2):377-389. doi: 10.1111/ajt.14018. Epub 2016 Oct 4. PMID: 27565133

cardiopulmonary, cardiovascular, peripheral vascular disease or cancer, significant physical disability (Karnofsky Score <40%), active malignancies, severe pulmonary issues, severe morbid obesity (BMI>50), or recurrent chronic infections.

Recommendation: We urge CMMI to finalize its proposal to assess performance on transplant measures based on actual transplantation rates but to exempt additional categories of patients from the measure, as specified above.

Third, it is not at all clear whether or to what extent the proposed incentives are sufficient to significantly impact the clinical practices of ETC Participants. For example, under the proposed scoring methodology, an ETC Participant whose performance is at the 75th percentile (or greater) of comparable geographic areas with respect to home dialysis would not be subject to a PPA adjustment so long as that Participant scored at the 30th percentile or higher with respect to transplantation. Even further, we believe that the scoring system used for the PPA should be revamped to ensure that it does not inadvertently create an incentive for home dialysis over transplantation. In this regard, it is important to note that the ESRD patients who are the most clinically appropriate for home dialysis are those who are also likely to be the best candidates for transplantation. Yet, the Proposed Rule weights a Participant's performance with respect to home dialysis at twice the weight afforded to performance on the transplantation measure(s), thereby creating a significant incentive for Participants to place (or retain) patients on home dialysis who would be good candidates for both home dialysis and transplantation. We strongly believe that this feature of the proposed scoring system should be corrected.

Recommendation: We urge CMMI to increase the weight accorded to a Participant's performance on the transplant measure(s) to at least equal the weight accorded to performance on the home dialysis measure, or to score the measures separately such that a Participant's score on the home dialysis measure(s) does not impact the Participant's incentive to increase its transplantation rate.

Fourth, we recommend that 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.

Recommendation: We would suggest that, to maximize the likelihood that the ETC Model will increase transplantation rates, Participants be required to refer any patient with an EPTS score of 75% and below for a transplant evaluation.

Finally, to the extent that the ETC Model does incentivize changes in clinical practice, we would anticipate that those changes may consist of increasing the amount of attention that ETC Participants provide to educating their patients about living donor transplantation. While we strongly support increasing living donor transplantation, living donation is not without risks, and the decision to provide financial incentives to nephrologists and dialysis facilities that are designed to increase living donation should be accompanied by a requirement that potential living donors receive full and complete counseling, through the independent living donor advocates and transplant center personnel most knowledgeable about the potential risks involved.

Recommendation: We urge CMMI to make a payment mechanism available for transplant personnel to conduct transplant-related patient education activities through multiple venues inclusive of dialysis units, since these activities are most likely to provide accurate information about the benefits and risks of transplantation if they are conducted by transplant center personnel. We would be delighted to work with you to establish appropriate metrics to ensure that dialysis patients and those who might benefit from pre-emptive transplantation have appropriate access to transplant-related education in all necessary settings.

Conclusion

Ultimately, in light of the severe organ shortage, ETC Participants are likely to have little or no control over whether their patients receive a deceased donor kidney transplant. While the ETC Model may increase the number of appropriate—and inappropriate—referrals for transplant evaluation, waitlist practices among transplant programs differ, as does the performance of area OPOs, and both of these factors—as well as a myriad of others—are likely to have a significant impact on an ETC Participant’s deceased donor transplant rate. However, the ETC Model does have some potential to increase care coordination and patient education with respect to living donor transplantation, and we are hopeful that some improvement in living donor transplantation may result.

ASTS firmly believes, however, that substantial improvement in renal transplantation rates is not possible without the direct involvement of the transplant community. Ultimately, deceased donor transplantation cannot be expanded sufficiently to meet the need without increasing the supply of transplantable organs and decreasing the number of transplantable organs that are discarded. Both of these objectives require the full participation and dedication of the transplant community, as well as the coordinated action of both CMS and HRSA. While we applaud the establishment of the Learning Cooperative to disseminate best practices in this area, we anticipate that more aggressive action will be needed. We look forward to working with CMS to accomplish the goals described in the AKH Executive Order through this and future initiatives.

Sincerely yours,



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