August 28, 2017

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 445-G
Washington, DC 20201

Re: 42 CFR Parts 413 and 414; [CMS–1674–P]; RIN 0938–AT04; Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program (ESRD Proposed Rule)

Dear Administrator Verma:

On behalf of the American Society of Transplant Surgeons, I am pleased to have this opportunity to comment on the ESRD 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 leadership, advocacy, education, and training.

We are writing to you to urge that CMS include a specific quality measure related to access to transplantation in the ESRD Quality Incentive Program. While we understand that the ESRD Conditions of Participation require dialysis facilities provide transplant education[1], as a practical matter, we believe that ESRD facilities generally fail to provide comprehensive information on the benefits of transplantation or otherwise ensure that appropriate referrals for transplant evaluations are made as part of the process of designing ESRD patients' plans of care. We believe that including a specific quality measure related to access to transplantation would help improve ESRD facilities' focus on this critical area.

[1]The CoPs require that patients be informed about transplantation as a modality (42 CFR § 494.70(a)(7)) and the "Plan of care" condition (42 CFR § 494.90(d)) requires that patients and caregivers be provided with education and training on several topics, including transplantation.

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ESRD facility referrals for transplant evaluation are critically important. The average kidney transplant recipient lives more than twice as long as he/she would if remaining on dialysis (USRDS data) and enjoys markedly improved quality of life and longevity: Life expectancy after starting dialysis is 5.7 years and after kidney transplantation is 15.8 years. Thus, to the extent that ESRD facilities fail to refer Medicare beneficiaries for transplant evaluation on a timely basis, this lapse has the potential to significantly and adversely impact the life expectancy and quality of life of these Medicare patients.

In addition, since transplantation is by far the most cost-effective treatment option for patients with ESRD, to the extent that ESRD facilities fail to educate their patients regarding transplantation options and refer their patients for transplant evaluation as clinically appropriate, this failure has the potential to increase ESRD costs of care. Kidney transplantation is associated with a cost savings of as much as $200,000 per transplant over the first 5 years after transplantation. (Examination of Medicare spending reveals the breakeven point for transplantation vs. dialysis is 2.3 years for patients who undergo living donor transplantation and 3.6 years for recipients of deceased donor transplantation.)

The Healthy People (HP) 2020 initiative includes a number of goals related to transplantation that have not been met (See Attachment A). Under-referral for transplant evaluation clearly contributes to the problem. A study published in the August 11, 2015 issue of JAMA (Vol 314, No. 6) (http://jama.jamanetwork.com/article.aspx?articleid=2425745), examined United States Renal Data System (USRDS) data from a cohort of patients (18-69 years) with ESRD from 308 Georgia dialysis facilities from January 2005 to September 2011. That study found that less than 25% of ESRD patients in Georgia during the study period were referred by their dialysis facilities for transplant evaluation overall and that 5% of dialysis facilities did not refer any patients for evaluation. Clearly, then, the available data suggests that under-referral of dialysis patients to transplant centers for evaluation may be a widespread problem

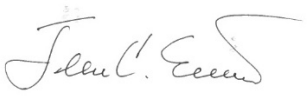
We are especially concerned about potential disincentives for ESRD facilities to refer patients for transplant evaluations in light of the expansion of the Comprehensive ESRD Care (CEC) demonstration program and the further expansion of this program that is likely to occur in light of CMS' decision to treat this demonstration program model as an Advanced Alternative Payment Model under the Merit-based Incentive Payment System (MIPS). The CEC demonstration project essentially implements ESRD-specific ACOs, under which participating entities (ESCOs) share savings (and, in some cases, losses) as compared with a baseline. However, as we understand it, if a beneficiary assigned to an ESCO receives a transplant, the ESCO is no longer eligible for shared savings/losses. Thus, ESCOs have an incentive to refer for evaluation only those ESCO-aligned Medicare beneficiaries for whom they do not believe savings are achievable (i.e., sicker patients who consume relatively more Part A and Part B medical services).

In light of the current and growing incentive for ESRD facilities to refrain from referring for transplant evaluations, we believe that it would be useful for the ESRD Quality Incentive Program to include a quality measure related to referrals for transplantation. CMS has contracted with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to develop Access to Kidney Transplantation measures. The measures developed by UM-KECC (Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) and Percentage of Prevalent Patients Waitlisted (PPPW)) focus on the proportion of a facility's patients who are waitlisted or are transplanted (using either deceased or living donors) within a

year of beginning dialysis.[2] See comments on the proposed measure summarized at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/End-Stage-Renal-Disease-Access-to-Kidney-Transplantation-Measure-Development-Public-Comment-Summary-Report.pdf.We believe that adoption of this, or a similar quality measure related to access to transplantation, should be included in the ESRD Quality Incentive Program. We would be pleased to work with you to design an appropriate measure.

We appreciate the opportunity to comment on the ESRD Proposed Rule. If you have any questions regarding these comments, please do not hesitate to contact ASTS Executive Director Kim Gifford at kim.gifford@asts.org or 703-414-7870.

Sincerely yours,



Jean C. Emond
President

[2] In its comments on these proposed measures, ASTS recommended focusing on the proportion of a dialysis facility's patients referred for transplant evaluation, rather than the proportion of a dialysis facility's patients actually waitlisted, since transplant centers' waitlist criteria vary substantially. However, we recognize that both methods have drawbacks. Measuring the proportion of a facility's patients who are referred for transplant evaluation is subject to "gaming" (e.g. the referral of patients who clearly do not meet the transplant center's waitlist criteria or are otherwise clearly unsuitable candidates for transplantation), while measuring only the proportion of a facility's patients who are actually waitlisted fails to take into account variation in TCs' waitlist criteria and practices and therefore may be unfair to dialysis facilities in the areas served by transplant centers with more restrictive criteria.

Attachment A

HP2020 kidney transplant goals

USRDS 2015 Annual Report

HP2020 CKD-12 Increase the proportion of dialysis patients waitlisted and/or receiving a deceased donor kidney transplant within 1 year of end-stage renal disease (ESRD) start (among patients under 70 years of age): Target 18.4% of dialysis patients

2000 (%)	2001 (%)	2002 (%)	2003 (%)	2004 (%)	2005 (%)	2006 (%)	2007 (%)	2008 (%)	2009 (%)	2010 (%)	2011 (%)	2012 (%)	2013 (%)
15.2	14.5	14.5	14.5	15.5	15.6	16.9	17.0	16.7	17.2	16.9	17.5	17.7	***18.0***

HP2020 CKD-13.1 Increase the proportion of patients receiving a kidney transplant within 3 years of end-stage renal disease (ESRD): Target 19.7%

1998 (%)	1999 (%)	2000 (%)	2001 (%)	2002 (%)	2003 (%)	2004 (%)	2005 (%)	2006 (%)	2007 (%)	2008 (%)	2009 (%)	2010 (%)
19.9	19.4	19.1	18.5	18.5	18.0	18.2	17.6	17.1	16.6	15.6	14.6	***14.1***

HP2020 CKD-13.2 Increase the proportion of patients who receive a preemptive transplant at the start of ESRD: No applicable target

2001 (%)	2002 (%)	2003 (%)	2004 (%)	2005 (%)	2006 (%)	2007 (%)	2008 (%)	2009 (%)	2010 (%)	2011 (%)	2012 (%)	2013 (%)
3.3	3.5	3.4	3.7	3.9	4.1	4.1	4.0	3.8	3.9	4.0	3.7	***3.7***