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American Society of Transplant Surgeons®

Via Electronic Submission

September 10, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: File code CMS-1691-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, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Amounts; 42 CFR 413; RIN: 0938-AT28

Dear Administrator Verma:

On behalf of the American Society of Transplant Surgeons (ASTS), I am pleased to have the opportunity to submit these comments in response to 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.

ASTS applauds CMS for focusing on the critical role of transplantation in the care of ESRD patients and for spotlighting the importance of dialysis facility referrals of appropriate patients for transplant evaluation. As noted in the Preamble of the Proposed Rule, despite the benefits of timely kidney transplantation and requirements that Medicare-certified dialysis facilities evaluate all patients for transplant suitability and make appropriate referrals, the percentage of dialysis patients waitlisted for a kidney has recently declined.

Strengthening CMS requirements in this area has the potential to significantly mitigate this trend: In light of the need for patients with ESRD to receive life-saving services from their dialysis facilities frequently and for lengthy periods, dialysis facilities are necessarily in a strong position to evaluate the clinical and

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psychological condition of ESRD patients and are well positioned to encourage their patients to explore transplantation as an alternative to continued dialysis. At the same time, those ESRD patients most likely to be suitable candidates for transplantation are also more likely to be younger, healthier, and privately insured—the very patients who contribute disproportionately to dialysis facility profit margins. We support addressing this inherent conflict of interest through increased focus on dialysis facility referral processes and outcomes as part of the Medicare certification process and value-based payment system.

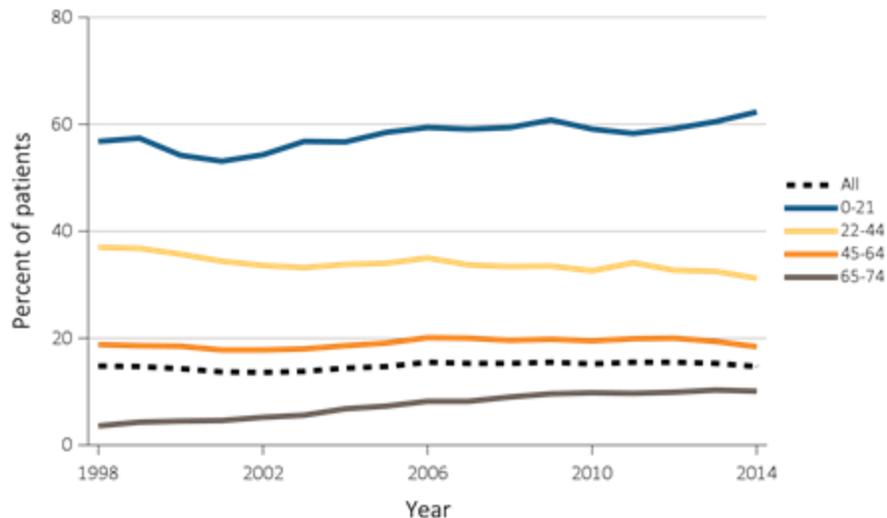
Inclusion of Transplant-Related Quality Measure in ESRD QIP

We believe that adding the Proposed Percentage of Patients Waitlisted (PPPW) to the ESRD QIP, as proposed in the Proposed Rule, would constitute an effective first step in addressing these issues. The PPPW measure tracks the percentage of patients attributed to each dialysis facility during a 12-month period who were on the kidney or kidney-pancreas transplant waiting list. This measure has a number of significant advantages. First, substantial clinical literature indicates that an ESRD patient's time on dialysis is a relatively reliable predictor of transplant outcomes: Positive transplant outcome is strongly correlated with less time on dialysis. By focusing on wait-listing dialysis patients quickly, the PPPW measure focuses on a clinically meaningful indicia of quality care. Second, by focusing on the proportion of a dialysis facility's patients who are actually waitlisted and not on the number of patients referred, this measure maximizes the likelihood that dialysis facilities will refer for evaluation only those ESRD patients who are clinically appropriate for transplantation.

Recommendation: ASTS supports the inclusion of the PPPW measure into the ESRD QIP; however, we urge CMS to incorporate this measure into the ESRD QIP in 2019, rather than waiting until Payment Year 2022, as set forth in the Proposed Rule.

While we strongly urge the inclusion of this quality measure in the ESRD QIP and suggest that it be added as soon as practicable, it should be recognized that waitlist practices vary substantially from one geographic region (and one Transplant Center) to another. In addition, while waitlists are long, a substantial number of ESRD patients who are likely to be appropriate candidates for transplantation are never referred for evaluation. There are over 600,000 ESRD patients in the United States and only approximately 100,000 waitlisted. In light of the progress that has been made in the field of transplantation, we believe it likely that a significantly greater percentage of ESRD patients should be referred for transplant evaluation.

vol 2 Figure 6.3 Percentage of incident patients who were wait-listed or received a kidney transplant within one year of ESRD initiation, by age, 1998-2014



Data Source: Reference Table E.5(2). Waiting list or transplantation among incident ESRD patients by age (0-74 years). Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014. Abbreviation: ESRD, end-stage renal disease.

These two factors suggest that (a) a quality measure that focuses exclusively on the proportion of a dialysis facility's patients waitlisted as compared with national norms may result in little change in practice in regions where area transplant centers include patients on their waitlists liberally and places a difficult burden for those in regions where area transplant centers are more conservative; and (b) that comparing a dialysis facility's performance in this area with current waitlist practices fails to address the overall need to increase appropriate referrals for transplant evaluations. At the same time, we do not believe that it would be practicable for CMS to include a measure focused on a dialysis facility's referrals for transplant evaluation, unless the measure is appropriately calibrated to ensure that ESRD patients who are clearly inappropriate for transplantation are not referred for evaluation. Little would be gained and potentially much valuable time and resources would be wasted if every dialysis facility were required to refer some designated proportion of their patients for transplant evaluation, regardless of the patient's clinical circumstances.

To address these complex issues, CMS may wish to consider (in addition to the PPPW measure) a quality measure that focuses on the proportion of a dialysis facility's patients who are waitlisted as compared with its prior performance in this area. Such a measure would encourage dialysis facilities in all areas to improve—regardless of the waitlist practices of their area transplant center(s). In addition, it may be possible to develop an age-related transplant referral quality measure by establishing minimal referral standards by age group, as a rough proxy for a patient's clinical condition. (For example, such a standard

could provide that nearly 100% of those under 21 should be referred for transplant evaluation within six months of the initiation of dialysis; 80% of more of those aged 22 to 44 should be referred for transplant evaluation within six months of transplant initiation; and approximately 70% of those aged 45 to 64 should be referred for transplant evaluation within six months of the initiation of dialysis.)

ESRD Facility Conditions of Coverage

CMS also seeks additional input on ways to increase kidney transplant referrals and improve the tracking process. Specifically, CMS asks:

- Are there ways to ensure facilities are meeting the Conditions for Coverage (CfC) requirements, in addition to the survey process?
- Are the current dialysis facility CfC requirements addressing transplantation support services adequately, or should additional requirements be considered?

We believe that a number of ideas should be considered to ensure that Medicare-certified dialysis facilities encourage transplantation and to expand transplant referral to emerging areas of CKD care. As an example, in recent years dialysis providers have expanded their reach to persons with CKD and established multiple initiatives for pre-dialysis education with some of the stated purposes to increase transplant referrals and promote pre-dialysis transplantation.^{1,2} However, the existing system has not had an impact on increased access to pre-dialysis transplantation. In the 2017 Annual Report of the United States Renal Data System (USRDS), only 1.3% of patients registered as preemptive kidney transplant recipients at ESRD service initiation.³ The data also shows that during the first three months of the transition to ESRD, and despite a high death rate of about 10% for new dialysis patients, only 2.5% received a kidney transplant.³ CMS could include a quality monitor for increasing transplant referrals as part of pre and early ESRD care.

In addition, While current regulations (at 42 CFR§490.70) require dialysis facilities to inform patients about treatment modalities, ensure patient access to resource information, assess patient abilities and preferences, identify a plan of care, and provide education and training, we commonly find that those ESRD patients who make their way to Transplant Centers for assessment do so by seeking out information on the advantages of transplantation themselves, or through research conducted by family

¹ Kidney Smart(r) Class. 2018 [cited 2018 April 24]; Available from: <https://www.davita.com/services/education-classes>

² Beyond dialysis: other options to consider. 2018 [cited 2018 April 24]; Available from: <https://www.freseniuskidneycare.com/about-chronic-kidney-disease>

³Vol 1. Chapter 8. Transition of care in chronic kidney disease. In United States Renal Data System. 2017 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2017. In 2015, 87.3% of incident individuals began renal replacement therapy with hemodialysis (HD), 9.6% started with peritoneal dialysis (PD), and 2.5% received a preemptive kidney transplant (Figure 1.2).

member. It appears clear to us that current regulatory requirements are insufficient to ensure that ESRD patients are appropriately educated on transplant options by their dialysis facilities.

We would suggest that, to address this issue, each Medicare certified dialysis facility be required to have an agreement with at least one area transplant center setting forth a plan to ensure that ESRD patients are adequately educated about their transplant options and to facilitate appropriate referrals for assessments. Such a plan should, at a minimum, provide for quarterly educational sessions on transplantation, the distribution of patient-friendly educational materials, and the designation of an individual at the dialysis facility and at the transplant center to take responsibility for implementation of the educational and referral processes.

We appreciate the opportunity to comment on these important issues and would be pleased to have the opportunity to meet with you to engage in further discussions of ways to increase access to transplantation for clinically appropriate Medicare beneficiaries.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Dixon Kaufman". The signature is fluid and cursive, with the first name "Dixon" and last name "Kaufman" clearly distinguishable.

Dixon B. Kaufman, MD, PhD

President

American Society of Transplant Surgeons