FORUM OF END STAGE RENAL DISEASE NETWORKS

November 19, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-3346-P
PO Box 8010
Baltimore, MD 21244-1810

Re: CMS-3346-P: Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction

Dear Ms. Verma,

The Forum of ESRD Network's Kidney Patient Advisory Council (KPAC) is composed of patient representatives from each of the 18 ESRD Networks. Our focus is to improve patient's quality of care and quality of life by supporting the ESRD Networks System and the ESRD patient communities throughout the United States and Territories. We appreciate the opportunity to comment on the proposed rule CMS-3346-P.

Below are our comments.

Thank you for your consideration,

Derek Forfang
Chair, Forum Kidney Patient Advisory Council

PO Box 203 • Birchwood, WI 54817 • (715) 354-3735 • Fax: 1 (888) 571-2065
email: forumcoord@centurytel.net • http://www.esrdnetworks.org

E. Transplant Centers

1. Special Requirement for Transplant Centers (§§ 482.68 and 482.70)

Section 482.68 generally describes the requirements that a transplant center must meet in order to participate in the Medicare program; section § 482.70 sets out definitions of terms used in the regulations. Specifically, in addition to meeting all the CoPs as a hospital, a transplant center must meet the CoPs specified in §§ 482.72 through 482.104 in order to be granted approval from CMS to provide transplant services.

2. Data Submission, Clinical Experience, and Outcome Requirements for Re-Approval of Transplant Centers

We propose to remove the requirements at § 482.82 that require transplant centers to submit clinical experience, outcomes, and other data in order to obtain Medicare re-approval. Transplant centers will still be required to comply with the CoPs at §§ 482.72 through 482.104 and the data submission, clinical experience, and outcome requirements for initial Medicare approval under § 482.80.

3. Special Procedures for Approval and Re-Approval of Organ Transplant Centers

Section 488.61 describes the survey, certification, and enforcement procedures for transplant centers, including the periodic review of compliance and approval as set out at § 488.20. Section 488.61(f) through (h) set out the process for our consideration of a transplant center's mitigating factors in initial approval and re-approval surveys, certifications, and enforcement actions for transplant centers. The provisions also set out definitions and rules for transplant systems improvement agreements. We propose to remove the requirements at § 488.61(f) through (h) with respect to the re-approval process for transplant centers. This change corresponds to the proposed removal of the provisions § 482.82, described previously.

KPAC Comments: The Kidney Patients Advisory Council (KPAC) of the National Forum of ESRD Networks supports the proposed changes CMS-3346-P to the transplant centers performance reporting to increase the amount of kidneys transplanted and increase the wait list.

We are hopeful that the changes proposed will change the competitive nature of the Transplant Centers in the United States and just not reward the transplant centers with the best performance outcomes without considering patient centered priorities, such as transparency, allowing for patient willingness to accept risk and shared decision making.

During our discussion of these proposed changes we had several patients share stories where they had problems with their transplant journey. First I shared my story being a higher risk patient due to my comorbidities and high antibody count.

I was turned away from my closest transplant facility and after they had vascular concerns. When a vascular study was done after I was turned down at their facility the vascular surgeon said the study they based my case on was incorrect and I had ample blood supply for transplantation the clinic transplant coordinator refused to reopen my case. I talked to my Nephrologist and appealed my case bringing all my test results with me to a different transplant center and was accepted and listed. I found out later that the center that turned me away had a reputation for not taking higher risk patients. My kidney transplant is over five years out now and still going strong. My concern is another patient would just have taken no for an answer and given up.

We had another KPAC member who asked a center about higher KDPI kidneys and was scared away by the center saying those kidneys have poor success rates and hepatitis C which will have to be treated after transplant. She turned down the option of receiving an extended criteria higher

KDPI option, but luckily went to a different center and is now currently listed willing to accept an expanded criteria higher KDPI kidney after it was better explained.

This lack of transparency is concerning. Not sharing the various type of kidneys that have an expanded criteria higher KDPI. We have several patients in our ESRD Network's Patient Advisory Committees that took older kidneys and other kidneys that are considered high KDPI kidneys who are doing very well.

We are worried that other patients who are not as well informed, as we are, have given up. Not every patient can advocate for themselves and not knowing each transplant center has different criteria for accepting patients leave patients to struggle in navigating the transplant system.

We recommend CMS have centers around the Country standardize transplant patient acceptance criteria in their process to approve transplant facilities. To ensure patients are not mislead or confused about the option of receiving a transplant. This would also hopefully stop the cherry picking that is not only leading to wasted viable kidneys, but also is costing our fellow patients' their lives.

We also strongly recommend that considering criteria for a CMS approved transplant centers have more patient-centered aspects included such as, better education around extended criteria/higher KDPI kidneys, transparency, including transplant patients as well as patients awaiting a transplant be included in transplant center's QAPI program, and improved shared decision making taking in to account a patient's tolerance to risk. For some of us who are vintage dialysis patients, a transplant is the only current renal replacement therapy that can extend our life expectancy.

We are thankful to CMS for putting patients first. The Forum's KPAC appreciates working with CMS to improve patient outcomes and therefore reduce cost to our health care system. The mission of the KPAC mirrors that of the Forum "To support and advocate on behalf of the ESRD Networks and to improve the Quality of Care to Patients with renal disease." The KPAC's vision statement has been since we were formed "Being the Patient Eyes, Ears and Voice for CMS bridging the gap between Patient Experience and Provider Performance.

We are always willing to assist CMS in their quality improvement efforts and appreciate the opportunity to do so.