

January 11, 2017

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

RE: CMS-3337-IFC: Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities--Third Party Payment

Dear Administrator Slavitt:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments regarding the December 14, 2016 interim final rule (IFR) "Conditions for Coverage for End-Stage Renal Disease Facilities—Third Party Payment." ASN represents more than 16,000 physicians, scientists, nurses, and other health professionals dedicated to treating and studying kidney diseases to improve the lives of people with kidney diseases. ASN is a not-for-profit organization dedicated to promoting excellence in kidney care. Foremost among the society's concerns is the preservation of equitable patient access to optimal quality chronic kidney disease (CKD) and end-stage renal disease (ESRD) care and the integrity of the patient-physician relationship.

ASN appreciates the Centers for Medicare & Medicaid Services' (CMS) effort to ensure that patients make health care coverage decisions based on their own best interests and agrees that preserving patients' individual decision-making is crucial. ASN observes that the topic of this IFR is a complex matter and that, like many fiduciary issues and as outlined in the IFR, the current third party payment policy is vulnerable to gaming—a concern the society shares with CMS. ASN firmly agrees with CMS that payment of premiums and cost-sharing by third party entities should *only* be used to promote the best interests of the beneficiary.

For many patients in the vulnerable dialysis population, third party assistance currently helps them achieve their goals, be it to work part time, gain access to transplant, or afford medications, and the society is concerned that the proposals in this IFR would inadvertently jeopardize some individuals' access to care. For these reasons, ASN encourages CMS to seek greater stakeholder input to ensure that the concerns that the IFR is attempting to resolve are addressed while appropriate patient access is supported; we encourage CMS to take this step before finalizing this IFR.

As CMS observes in the IFR, the factors informing patient coverage decisions are complex. Dialysis patients are among the most vulnerable populations, with high prevalence rates of cognitive impairment, depression and medical comorbidity and, along with their families, face tremendous social, financial, and medical challenges. These particularly vulnerable individuals often need guidance in navigating an overwhelming healthcare system and selecting the best coverage option for them. For example, variation exists in the range of drug formularies that may be covered by one insurance plan but not another. Responsible clinical practices assist patients with the financial and social challenges they face on a daily basis, and this assistance may include suggesting that a patient evaluate the range of insurance options available to him or her, including Medicare and private insurance.

ASN observes that there are several reasons why it may be in the best interest of some beneficiaries to maintain private insurance coverage. Most notable among these benefits, for some patients, is access to kidney transplantation—the optimal treatment for ESRD. Some kidney transplant centers will not perform kidney transplantation in patients with Medicaid or with Medicare without a secondary payer to assist with medication costs. Transplantation is more likely to occur in individuals with private insurance, and transplant outcomes are better among those patients with private insurance. ASN respectfully disagrees with the statement in the preamble that patients retaining private insurance are less likely to receive a transplant.

In fact, as reported by Johansen and colleagues in the *Clinical Journal of the American Society of Nephrology*, it was noted that individuals under the age of 65 were 50% less likely to be evaluated for transplant if they had public as compared with private insurance and individuals between age 65 and 80 were 10-15% less likely to be assessed. Not surprisingly given that assessment is necessary for listing for transplant, those with Medicare as their primary insurance were approximately 40% less likely to receive a transplant while those with Medicaid as their primary insurance were approximately 50% less likely to receive a transplant.

Additionally, ASN is committed to preserving the integrity of the relationship between patients and their nephrologists, nurses, and other providers; ensuring that patients have choices among health insurance providers is, for many patients, an important aspect of that goal.

ASN recognizes that, as outlined in the IFR, there may be current practices with the potential to harm patients—and the society shares CMS' desire to rectify any and all such harmful practices. However, ASN also stresses that the IFR as drafted is likely to lead to unintended consequences that also bring harm to some dialysis patients. Given the importance of this issue from both patient access and fiduciary perspectives, the society urges the Agency to seek more input from stakeholders on a longer timeline. ASN hopes to have the opportunity to continue to work collaboratively in a comment period to design and implement a rule, with the shared goal to navigate this issue with beneficence and respect for patients.

Again, thank you for the opportunity to comment on this IFR. ASN appreciates CMS's commitment to ensuring the integrity of individual patient choice and to maintaining responsible fiduciary practices. ASN would be pleased to discuss these comments with CMS if it would be helpful and stands ready to assist in any way; please contact ASN Director of Policy and Government Affairs Rachel Meyer at (202) 640-4659 or at rmeyer@asn-online.org.

Sincerely.

Tod Ibrahim

Executive Vice President