

November 19, 2018

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

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

Dear Administrator Verma:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments regarding the September 17, 2018 proposed rule to lift unnecessary regulations and ease burden on providers. ASN represents more than 20,000 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 kidney disease care and the integrity of the patient-physician relationship.

The Centers for Medicare and Medicaid Services (CMS) proposed “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.” CMS will maintain requirements for data submission, clinical experience, and outcome requirements for a transplant center’s initial Medicare approval.

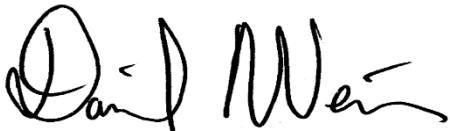
In a CMS statement on the proposed rule, CMS wrote “[a] key provision would reduce burden and promote efficiency to support patients who need organ transplants. The rule would eliminate a duplicative requirement on transplant programs to submit data and other information more than once for ‘re-approval’ by Medicare. Re-approval has led to transplant programs avoiding performing transplants for certain patients, causing some organs to go unused. CMS will maintain other requirements in order to continue to monitor outcomes and quality of care in transplant programs after initial Medicare approval.”

ASN applauds CMS for taking this step to reverse the unintended consequences that have arisen due to the Medicare re-approval process for transplant centers and for maintaining the standards applied for original Medicare approval of transplant centers. These changes may increase transplantation and result in lower discard rates in the United States.

ASN understands that the Scientific Registry of Transplant Recipients (SRTR) will continue its role providing statistical and epidemiological analysis related to solid organ allocation and transplantation in support of the Department of Health and Human Services and its agents in their oversight of the national organ transplantation system.

Again, thank you for the opportunity to provide comment on the proposed burden reduction rule. ASN would be pleased to discuss these comments with CMS if it would be helpful. To discuss ASN's comments, please contact ASN Director of Policy and Government Affairs Rachel Meyer at (202) 640-4659 or at rmeyer@asn-online.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Dan E. Weiner". The signature is fluid and cursive, with "Dan" and "E." on the first line and "Weiner" on the second line.

Daniel E. Weiner, MD, FASN
Quality Committee, Chair