



October 1, 2020

Alex M. Azar II  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Azar:

On behalf of the more than 37 million Americans living with kidney diseases as well as the more than 21,000 nephrologists, scientists, and other kidney health care professionals who are members of the American Society of Nephrology (ASN), thank you for leadership in helping to transform our nation's approach to ensuring kidney health.

In particular, ASN is grateful for the recent finalization of several policies that comprise the Advancing American Kidney Health Initiative, including the ESRD Treatment Choices (ETC) and Kidney Care Choices (KCC) Models, which realign the incentives for the provision of kidney care to be person-centered and value-based. ASN is also appreciative of the National Living Donor Assistance Center (NLDAC) final rule, which removes financial disincentives to living organ donation.

ASN believes the entire Advancing American Kidney Health Initiative, including these policies, is an essential tool to build a future where every American with kidney diseases receives care that is timely, innovative, and focused around the needs and choices of each individual. As such, ASN urges you to formalize and enact policies described in the December 17, 2019, Organ Procurement Organizations (OPOs) Conditions for Coverage Proposed Rule with utmost expediency.

In a February 21, 2020, comment letter, ASN reiterated support for the proposed rule, particularly its proposal to institute objective and verifiable metrics to assess the performance of OPOs. Specifically, ASN supported:

- Using the inclusionary Cause, Age, and Location Consistent (CALC) metric described in the Proposed Rule, as opposed to the proposed denominator that uses exclusionary diagnosis.
- Avoiding penalties for "zero organ donors."
- Opposing risk adjustment based on race and ethnicity.
- Creating a system that transparently evaluates OPO performance with clear pathways to addressing improvement and consequences for not improving.
- Reporting outcome measures of organ transplant rates by type of organ.



- Taking future steps in other proposed rules to address waitlist criteria, less than ideal organs and patients, and payment issues for less than ideal patients.<sup>1</sup>

Particularly, in light of the appropriate emphasis on increasing access to transplantation in the ETC final rule and KCC models, ASN believes ensuring the performance of OPOs is measured in a transparent and accountable process is all the more urgent for the success of these models. ASN applauds the advancements made to support living donors through the expansion of NLDAC reimbursements, which will be crucial to support the transplant goals, yet these changes alone will not be sufficient to bridge the organ gap. The society urges HHS to make similar advancements by finalizing and implementing the OPO rule as expeditiously as possible.

Further, the confluence of the COVID-19 pandemic and disparities in health faced by Black and Hispanic/Latinx Americans have created a renewed urgency among ASN's membership to ensure our nation's kidney transplantation system is providing equitable care at a time when receiving a kidney transplant is more critical than ever. In 2019, nearly 50% of White Americans on the transplant waitlist received a kidney, yet in the same year, only 26% of Black Americans received a transplant.

Research has pointed to factors directly within the control of OPOs as responsible for part of this inequity, such as providing fewer opportunities for the families of potential organ donors to consider organ donation and not making OPO representatives available for consultation at the time of potential donation.<sup>2</sup> Evaluating the performance of OPOs utilizing objective and verifiable metrics as outlined in the proposed rule will increase transparency and accountability in the US transplant system and increase equity in organ donation. In fact, an internal quality control study of one OPO found organ donation authorizations among Black and Hispanic/Latinx families doubled when protocol was correctly followed.<sup>3</sup>

Again, thank you for your efforts to help transform kidney care through the Advancing American Kidney Health Initiative. Encouraged to see the finalization of critical parts of this groundbreaking initiative, ASN hopes that the move toward objective, verifiable, and standardizable metrics for OPOs will soon join this constellation of policies, increasing accountability and transparency in our organ transplant system.

To discuss this letter, ASN's support for efforts to advance American kidney health, or the society's imploration that you formalize and enact policies described in the December 17, 2019,

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<sup>1</sup> ASN. Public Comment Letter to Administrator Verma Re CMS-3380-P. February 21, 2020. Retrieved September 28, 2020 from [https://www.asn-online.org/policy/webdocs/ASN\\_Comment\\_Final\\_Comment\\_Letter\\_CMS-3380-P.pdf](https://www.asn-online.org/policy/webdocs/ASN_Comment_Final_Comment_Letter_CMS-3380-P.pdf)

<sup>2</sup> Siminoff, L A, Lawrence, R H, Arnold, R M. Comparison of black and white families' experiences and perceptions regarding organ donation requests. 2003, Crit Care Med. doi: 10.1097/00003246-200301000-00023.

<sup>3</sup> Siminoff, L A, Shafer, T J. Public Comment Re CMS-3380-P: Proposed Rule on OPO Conditions of Coverage. February 18, 2020. Retrieved September 30, 2020 from <https://www.dropbox.com/s/ppnjkdhxav64gkm/Comments%20-%20CMS%20Proposed%20OPO%20Outcome%20Measurements.pdf?dl=0>



Organ Procurement Organizations (OPOs) Conditions for Coverage Proposed Rule with utmost expediency, please contact David White, ASN Regulatory and Quality Officer, at (202) 640-4635 or [dwhite@asn-online.org](mailto:dwhite@asn-online.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Anupam Agarwal", with a long horizontal line extending to the right.

Anupam Agarwal, MD, FASN  
President

cc: Seema Verma