July 31, 2025

Thomas J. Engels
Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

Submitted electronically

Re: *Submission to OMB for Review and Approval; Public Comment Request; Process Data for Organ Procurement and Transplantation Network, OMB No. 0906–0001–New*

Dear Administrator Engels:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who are members of the American Society of Nephrology (ASN), thank you for the opportunity to comment on the July 1, 2025 *Submission to OMB for Review and Approval; Public Comment Request; Process Data for Organ Procurement and Transplantation Network, OMB No. 0906–0001–New*. Maximizing patients' access to kidney transplant—and ensuring that access is available to all patients who would benefit—is of utmost priority for ASN.

ASN believes the collection of pre-waitlisting data is a tremendously important step in improving access to kidney transplantation nationwide and commends the administration for advancing this crucial effort. During the comment period on this concept ending January 3, 2025, ASN voiced its support for this data collection while offering suggestions to lessen the administrative burden and improve the feasibility of the proposal. The society's support for pre-waitlisting data collection remains steadfast, and in this comment period, in particular ASN reiterates its initial recommendations for a phased-in approach and leveraging available information technology improvements (IT) to minimize burden on those reporting data.[i]

ASN's early 2025 recommendations to help ensure the success of this endeavor still stand. For brevity, they are summarized here, though the society urges HRSA to revisit the complete January 3, 2025 comments as they remain relevant to the current Federal Register Notice:[ii]

The collection of pre-waitlisting information is necessary and useful for the proper performance of the HRSA's functions. Transplantation is the optimal therapy for most people with kidney failure, and gaining access to the waitlist is a critical gateway step in the process. However, our understanding of how and why some people make it to the waitlist and others do not is limited—restricting our ability to improve access to transplantation through either national policy or local practice changes. Obtaining this information is a significant step forward in understanding (and intervening to address) barriers and is pivotal in allowing the creation of a smooth, transparent patient journey through the transplant process.

Notably, in order to achieve the goal of the Advancing American Kidney Health initiative of increasing transplant rates and having 80% of Americans with incident kidney failure accessing a transplant (or dialyzing at home), ASN believes it is essential to understand and develop policy interventions to address the barriers to referral and evaluation (the gateways to transplantation) that exist for Americans who would benefit and that today stand between them and the attainment of this objective.

Appropriate technology adoption is necessary to support the phased-in data collection, ensure quality and clarity of the information collected, and minimize burden

The transplant system at present does not have the optimal information technology (IT) infrastructure to execute the proposed data collection— but the society strongly supports HRSA and the OPTN working towards the development of the requisite IT systems as swiftly as possible, an effort that aligns with implementation of the 2023 *Securing the U.S. OPTN Act*. These upgrades will not only be essential for more widespread implementation of these data in the future but will also enable a host of other systemic improvements and efficiencies that will ultimately benefit people awaiting a kidney transplant.

The most crucial element for success in the collection of pre-waitlisting data is the use of quarterly batch data.

Transplant centers should not be placed under more strain without being afforded additional Resources: quarterly batch reporting (and ideally, the use of APIs) achieves this goal. Batch reporting also provides greater data accuracy and eliminates the errors that are inherent with manual data entry. Notably, the use of quarterly batch data is very feasible: very few data elements (if any, depending on EMR) in the proposed referral and evaluation forms require manual extraction. Nonetheless, ASN suggests a phased-in approach, allowing for a pilot period to further establish the feasibility of collecting this data through automated means and identify opportunities to further streamline and automate the reporting—again, obviating any need for manual data extraction.

Successful pre-waitlisting data collection should be phased-in

ASN recommends a phased-in approach that supports this technology being adopted and refined by a subset of transplant centers. Among other things, such a phased in-approach permits the administration and early participants to address any challenges with the reporting mechanisms. HRSA and OPTN would have a window to modify the data elements and submission mechanisms if needed. This approach also allows a window for other transplant centers to prepare for this data reporting using quarterly batch data submission, ideally supported through APIs.

ASN expects that many programs would opt to participate in the voluntary data submission period in order to gain experience in advance of an anticipated forthcoming mandatory phase. A second phase could involve mandatory data collection of all data elements that can be reported through batch submission or APIs. A final phase—once the technology is available to support fully automated submission of all data elements irrespective of EMR vendor—would entail mandatory reporting of all data elements.

There are two levels at which IT modernization will be necessary to support this data collection, both of which should be piloted and refined during the phased-in approach:

1. **OPTN IT,** which will need to be updated in some manner to allow patient identification prior to waitlisting.

2. **Individual transplant centers**, some of which will have to make modifications to local level IT/EMR systems to ready them to do batch submission for this data. A phased-in approach would provide a window to perfect best practices as well as appropriate lead time for centers to

make these changes (which will compete for time and resource with other IT/electronic medical record changes deemed necessary by a given hospital or health system).

While virtually all of the data elements on the proposed data collection form can be reported through batch submission, updates to allow the OPTN to accept batch data and link it to the waitlist are essential. The adoption of this capability should be swiftly prioritized as part of implementation of the *Securing the U.S. OPTN Act.*

Comments on draft forms

While the current federal register notice does not explicitly seek input on the data collection forms, ASN registers three important points, below. Two fields were removed from what had been outlined in the Data Advisory Committee (DAC) workgroup recommendations to HRSA, without an explanation. ASN believes these fields are important information to capture and urges HRSA to reinstate them (and/or share rationale as to why they have been apparently eliminated). Lastly, ASN also encourages the capture of the CCN number.

Reinstate "Initial evaluation appointment date" field

Originally, the forms were to have included a field for patient's initial evaluation appointment date. At this time, that field appears to have been removed, though it is unclear why HRSA may have thought this information is not relevant or necessary. ASN believes that understanding when an evaluation begins, and how long it takes to go from referral to evaluation, is of great relevance. Many patients get stuck in a phase wherein they have been referred—but not evaluated—for weeks to months while a transplant center attempts to sort out their insurance coverage. With the growth of ESRD patient enrollment in Medicare Advantage plans, information would be particularly important to know. ASN urges the reinstatement of the "initial evaluation appointment date" field.

Reinstate "Evaluation Status: Evaluation Cancellation Reason" field

Originally, the forms were to have included a field for the reason a patient's evaluation was cancelled. Technically, according to Centers for Medicare and Medicaid Services (CMS) regulations, every patient for whom an evaluation is initiated is considered by the transplant selection committee—even if the patient elects to drop out of consideration for transplant partway through the process. However, it is unclear how often this step of the process is actually completed. Thus, keeping this field in the form may still be of value to paint a complete picture of all patient journeys.

Add a CMS Certification Number (CCN) field

ASN recommends that HRSA add a CMS Certification Number (CCN) field. Without CCN information, it will be challenging to link the OPTN data here to the dialysis facility, hospital, or other site from which a patient's referral originated. This information will be very important to identify where these referrals are coming from the transplant center perspective (and allow comparisons with the information CMS is collecting on the 2728 form about referrals). It is also likely that the data would be valuable to CMS for purposes such as like quality metrics for dialysis facilities.
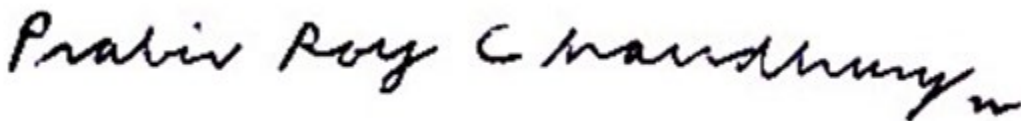
Conclusion

Lastly, ASN reiterates its recommendation that HHS and HRSA ensure the enabling of bidirectional communication between the pre-waitlisting data collected by OPTN and the data the Centers for Medicare and Medicaid (CMS) collects regarding transplant referrals from dialysis facilities via the 2728 form. Making these two datasets compatible and linkable is essential to create a complete picture of the patient journey and identify barriers that can be overcome through future policy or practice changes.

In summary, ASN continues to support the collection of pre-waitlisting referral and evaluation data. This effort should be advanced in a phased-in fashion and that the technology upgrades to allow automated submission of batch data should be vetted and completed before the entirety of the proposed data collection elements are implemented on a mandatory basis.

To discuss these recommendations further, or if ASN can provide any additional information, please contact ASN Strategic Policy Advisor Rachel Meyer at rmeyer@asn-online.org.

Sincerely,

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[i] ASN comments re: Information Collection Request: Process Data for Organ Procurement and Transplantation Network, OMB No. 0906-xxxx—New. January 3, 2025. https://www.asn-online.org/policy/webdocs/25.1.3FINAL_ASN_Comments_re._OMB_No._0906-xxxx—New.pdf
[ii] *Ibid.*