January 3, 2025

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Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

Submitted electronically

Re: *Information Collection Request:* Process Data for Organ Procurement and Transplantation Network, OMB No. 0906-xxxx—New.

Dear Administrator Johnson:

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 *Information Collection Request*: Process Data for Organ Procurement and Transplantation Network. 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 supports this proposed rule in concept, while offering suggestions to lessen the administrative burden and improve the feasibility of the proposal. ASN appreciates that this proposal includes capture of data on pre-emptive referrals, which constitute approximately 22 percent of kidney transplant referrals (though pre-emptive referral rates vary regionally), as well as data collection on all organs.[i]

The society addresses the four specific questions HHS and HRSA have posed regarding pre-waitlisting referral and evaluation data collection below. The society acknowledges the importance of the proposed organ procurement organization/ventilated patient deaths-related data collection and conceptually supports it but focuses its comments on the former area given that ASN has more expertise in this aspect of transplant nephrology care.

As an overarching comment, ASN observes that 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 through the OPTN Modernization Initiative. These investments and 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. As this technology is in the process of being adopted, ASN recommends a phased-in approach that, among other things, allows transplant centers to prepare for this data reporting and integrates the use of quarterly batch data submission, among other recommendations described in more detail below. Ideally, in the future, data elements collected across the OPTN should be collected on an automated, efficient basis as technology advances and is supported through the OPTN Modernization Initiative.

(1) the necessity and utility of the proposed information collection for the proper performance of the agency'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. Nationwide, more than 500,000 people are living with kidney failure on dialysis, but fewer than one-fifth of them are actively on the transplant waitlist. The rate at which patients are referred at all, and then drop off, at various stages before actually making it to the waitlist is unknown, as there are no national data regarding this process. Research shows that discrepancies in steps early in the path to transplantation—such as referral and waitlisting—are influenced by multiple factors, including geographic location, insurance status, age, and other characteristics.[ii]

Studies demonstrate that many people with kidney failure who would benefit from transplantation from a clinical standpoint often do not make it to the waitlist. For example, in a recent study, less than half of people under age 40 on dialysis with no other major comorbidities were listed for a kidney transplant within 5 years of initiating dialysis (and just 30% had been added to the waitlist within 1 year of dialysis initiation), indicating major barriers in access to optimal care for reasons other than health status. [iii, iv, v, vi, vii]

The 2022 National Academies of Science, Engineering, and Medicine (NASEM) report on the transplant system highlighted the lack of reliable data on the number of patients who enter the transplant pathway (e.g., patients who might benefit from referral and transplant evaluation). Consequently, the report went on to explain that there are few—if any—ways to properly assess the effect of socioeconomic status on transplant access in particular and recommended collecting this data to identify and ameliorate areas of wide variation.[viii]

While the available data are far from comprehensive, the existing literature consistently shows wide variation in referral and evaluation patterns, suggesting inefficiencies and prime opportunities for quality improvement. For example, in one study, the median within-facility percentage of patients referred within 1 year of starting dialysis was 24.4% and varied from 0% to 75% while in another larger study, referral rates within one year of the onset of kidney failure ranged from 0 to 100% across facilities.[ix] Notably, the barriers associated with being referred versus actually starting an evaluation were not consistent (e.g., greater likelihood of referral did not always translate to greater likelihood of evaluation), underscoring the substantial variability of the process and the importance of obtaining data to improve understanding and access.[x]

The NASEM report also noted that referral and evaluation data collection would help to provide a complete human-centered picture of the patient experience, a recommendation that was echoed during the Scientific Registry of Transplant Recipients (SRTR) Task 5 consensus conference, which prioritized the inclusion of patients and family members, who constituted nearly one-quarter of the participants. One of the consistent themes that emerged from the conference was the desire for more data from the moment of referral through transplantation, a goal that this proposed rule directly advances.[xi]

Although outside the scope of this current effort, the referred patients are the success story but represent only a fraction of the eligible ESRD population.

More recently, ASN was pleased to see the Centers for Medicare and Medicaid Services (CMS) respond to similar calls from advocates, including ASN, and begin to collect more granular

information from dialysis organizations on whether, when, and to which transplant programs referrals for transplant are made. Obtaining this information from the source of the referral is a significant step forward in understanding (and intervening to address) barriers, and is pivotal in allowing the creation of a comprehensive patient journey through the transplant process. The *next* pivotal step is collecting parallel information from transplant centers, as proposed. ASN appreciates that CMS and HRSA are collaborating through the Organ Transplant Affinity Group (OTAG), and has identified "reduc[ing] variation of pre-transplant and referral practices," as a common CMS-HRSA goal; this proposed rule is important for advancing this goal.

Lastly, and perhaps most importantly when considering how essential this data collection is for the agency to fulfill its function, we must return to the 2019 Executive Order on Advancing American Kidney Health. ASN believes that in order to achieve the ambitious 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), 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 goal.[xii]

(2) the accuracy of the estimated burden;

Despite the society's robust conceptual support and conviction that it is critical to obtain and use this data, ASN has serious reservations about the transplant system's ability to collect the data without significant—but achievable—modifications to the process as proposed.

It is not possible to proceed with collecting this data with manual review and extraction.

The burden estimates appear to be predicated on manual data review and extraction. Because the society believes that this important effort is unworkable with a manual, non-automated approach—and below makes recommendations to collect it through more automated means—it is impossible to comment meaningfully on the accuracy of the estimated burden as proposed.

Transplant centers should not be placed under more strain without being afforded additional resources. While aspects of care pertaining to the pre-transplant period are reportable on the Organ Acquisition Cost Center (OACC) report and could help offset some of the burden of any new manual data reporting requirements, the reality is that the hospitals and health systems that house transplant centers see that only a percentage of the costs of data abstraction are reimbursed. ASN wishes to ensure that other aspects of patient care are not disadvantaged because of increased reporting burden. These dynamics underscore the imperative for any pre-waitlisting referral and evaluation data collection to be minimally burdensome, such as collected via quarterly batch submission and supported by APIs.

The society asserts that the burden estimates would be substantially lower and vastly more feasible if predicated on a more automated data reporting approach, such as quarterly batch submission. ASN observes that very few data elements (if any, depending on EMR) in the proposed referral and evaluation forms require manual extraction. Transplant centers using EPIC would not require any manual extraction. In certain EMRs, such as Cerner, there are some data elements that might be more challenging. For example, certain pull-down menus would need to be revised and standardized (such as the "reason denied waitlist")—a not insurmountable challenge, but one that will take some time. Recognizing these and other challenges articulated elsewhere in this letter, ASN recommends that this data collection begin with voluntary data submission efforts. Such efforts would further establish the feasibility of

collecting this data through automated means and identify opportunities to further streamline and automate the reporting—as well as provide more accurate estimations of the burden associated with the effort (and reveal opportunities to mitigate the burden). Therefore, ASN recommends beginning a phased-in approach along these lines. (Table 1)

Table 1. Successful Pre-Waitlisting Data Collection Should Be Done in a Phased Manner

Phase	Data Collection
1	Start with limited, voluntary batch data submission for one year
2	Proceed to mandatory reporting of elements that require no manual data entry (for most centers, no elements would require manual data entry)*
3	Eventually, institute mandatory reporting of all elements, supported by technology

ASN recommends that the OPTN DAC be responsible for identifying the data elements that are universally submittable via batch submission.

Table 2. Appropriate Technology Adoption Necessary to Support the Phased Data Collection

- Identification of workable patient-level identifiers to support batch submission at OPTN

- Modification of EMRs at vendor level to facilitate automated upload (local and/or EMR-level modifications to do so)

- Implementation of patient-level identifiers at OPTN

- Shift to an OPTN that collects all data in an automated fashion, obviating the need for any manual data entry or form submission

Building on learnings from the voluntary data submission phase of a limited number of essential data elements (such as the date of referral and evaluation), HRSA and OPTN could modify the data elements and submission mechanisms if needed. 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.

As noted earlier, state and regional efforts to collect this data for research purposes have been conducted successfully for many years.[xiii] ASN recognizes that its proposed timeline constitutes a multi-year process and is contingent on investments in IT, including through Congressional appropriations and supportive oversight. However, the society believes that the crucial nature of this data collection dictates that it be done in a maximally feasible, minimally burdensome manner—which ASN believes is fully possible over time.

(3) ways to enhance the quality, utility, and clarity of the information to be collected

ASN appreciates HHS and HRSA's attention to data quality and utility with respect to this proposed data collection effort. As has been documented more generally, underlying IT shortcomings and a history of lack of attention to or investment in data audits and data hygiene have led to significant challenges with the utility of information elsewhere in the OPTN.[xiv] ASN strongly supports OPTN Modernization efforts to overcome these issues and improve the data environment across the transplant system.

The society offers several suggestions to improve the quality, utility, and clarity of the data collected through this effort:

- Provide the OPTN Data Advisory Committee (DAC) with the resources to conduct data quality monitoring during and after implementation. Having their expertise to evaluate the quality, utility, and clarity of the data consistently over time will provide invaluable quality control as well as the capability to recommend modifications if needed. This DAC data monitoring should happen as quickly as possible as the data are collected and available.

- 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.

- Collect this pre-waitlisting data exclusively through batch submission. As noted elsewhere in this comment letter, batch submission of this data is essential on a nationwide basis for many reasons, including its ability to provide greater accuracy and eliminate the errors that are inherent with manual data entry.

- Encourage EMR vendors to use the same data standards and elements to eliminate some of the variation in terms and definitions and regarding readiness for 100% batch submission. More generally, the OPTN Modernization Initiative should also support the development and adoption of a standardized data dictionary for transplant nephrology (and all solid organ transplantation), together with key stakeholders in the community, the Assistant Secretary for Technology Policy, and others.

- Sunset, or transition to automated reporting of, forms that are not currently used for valuable quality improvement or health services research efforts, such as the Transplant Recipient Follow-Up forms.

(4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

As noted, it appears the burden estimates are predicated on manual data review and extraction on an individual patient level, but ASN strongly recommends that this data collection effort proceed *only* through batch data submission, such as on a quarterly timeline, and ideally supported through APIs.

There are two levels at which IT modernization will be necessary to support this data collection:

1. **OPTN IT** which, as discussed below, 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. Appropriate lead time will need to be provided to allow for these changes, which will compete for time and resource with other IT/EMR 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 OPTN Modernization. Ideally, OPTN should move towards automated, efficient collection of these data elements as technology capabilities become available through the modernization initiative.

A key component of this step is finding a patient identifier mechanism to link this information to the waitlist. Some of the proposed data collection elements are currently entered directly onto the waitlist (another process that should be modernized), and the waitlist uses social security numbers (SSNs) as the primary identifier. The Medicare ESRD program also has authority to collect SSNs for people on dialysis—though this does not encompass every person who is referred for transplant evaluation given than many referrals are pre-emptive and has no relevance for non-kidney referrals. Meanwhile, many hospitals and health systems nationwide have stopped collecting SSNs due to privacy concerns unless they are adding people to the waitlist. Additionally, some patients do not have a SSN entered in the system, though the reasons it is missing are typically unclear. (For example, a multi-region transplant data registry indicates that 19% of patients are missing SSN, but that omission could be due to a variety of factors, including that the patient either was not a dialysis patient in one of the four ESRD Network regions included in the registry; they were preemptive and not yet a dialysis patient; or a transplant center did not provide a SSN.)[xv] In sum, it is at present unclear whether a SSN is the optimal long-term patient identifier for the purpose of collecting pre-waitlisting referral and evaluation data via batch submission.

Ideally, if SSNs are used, HRSA would require health systems to collect SSNs earlier in the process than the moment of waitlisting, e.g. as close to the initiation of the evaluation process as possible. This approach would still be unable to identify the patients who didn't make it to the point in the process where they were evaluated, but would be superior to waiting until people are waitlisted.

Another possible approach is using a patient's medical record number (MRN) together with a center identifier to identify them. A drawback of this approach is tracking individuals who are referred to and evaluated at multiple centers: it would be difficult to discern that the same person is being seen is several places, information that would be important in understanding that person's ultimate outcome. ASN considered whether patients could be identified through OACC reports to CMS, but since that data is aggregated it appears nonviable for this purpose.
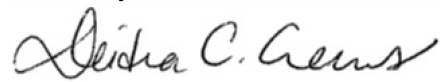
ASN firmly believes a path forward to identify patients in conjunction with pre-waitlisting data collection is feasible, but determining the best possible approach will require additional consideration from HRSA, ideally under advisement from the DAC.

Conclusion

Lastly, while HHS and HRSA have not explicitly asked for feedback on the data elements included on the proposed referral and evaluation forms at this time, ASN looks forward to providing additional input during the subsequent comment period.

In summary, ASN supports the collection of pre-waitlisting referral and evaluation data but believes it should be advanced in a phased-in fashion and that the technology upgrades to allow automated submission of batch data should be expedited 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,

Deidra C. Crews, MD, ScM, FASN
Past-President

CC: Chiquita Brooks-LaSure

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