ASTS
American Society of Transplant Surgeons

January 2, 2025

HRSA Information Collection Clearance Officer
Room 14NWH04
5600 Fishers Lane
Rockville, MD 20857
paperwork@hrsa.gov

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

Dear Administrator Carole Johnson:

As President of the American Society of Transplant Surgeons (ASTS), I am pleased to have the opportunity to respond to the Information Collection Request referenced above. ASTS is a medical specialty society representing approximately 2,000 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

The Information Collection Request:
This new collection consists of three new data forms as directed by the Secretary of Health and Human Services, which were developed to improve the OPTN organ matching and allocation process and OPTN member compliance with OPTN requirements: one new form will collect data from the point of referral of a patient to an organ procurement organization (OPO) for potential deceased organ donation, and two new forms will expand data collection from the point of patient registration, referral, and evaluation at transplant centers. Our comments are limited to the two forms to be completed by transplant centers, which include a patient referral form and a patient evaluation form.

The Information Collection Request indicates that the data collected on these two forms will provide insight into who gets referred for transplant evaluation and by whom, who gets evaluated, and who gets placed on the organ transplantation waiting list. The data collection is intended to facilitate the OPTN's ability to address disparities in processes of care, improve access to organ transplantation, and assess overall system performance.

The *Information Collection Request* indicates that these forms will be completed by 258 transplant program respondents; that approximately 436,207 forms will be added to those already submitted by transplant centers; and that the completion of these forms will require approximately 160,040 hours (estimated at 35 minutes per referral form and 40 minutes per evaluation form). This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying, processing and maintaining information; training personnel to be able to respond to a

a collection of information; searching data sources; completing and reviewing the collection of information; and transmitting or otherwise disclosing the information.

ASTS Comment:
Please note that ASTS has previously provided guidance regarding data collection in general in our published **ASTS Guiding Principles for the OPTN Modernization Initiative** published and provided to HRSA in September 2023. We now include the pertinent excepts as part of our response to this new *Information Collection Request* at the end of these comments.

While ASTS agrees that it is critical to obtain a better understanding of patients' pre-waitlist experience in order to address disparities and improve the overall access to and equity of the system, we urge HRSA to engage with the patient, transplant and dialysis communities to determine whether there are **alternatives to national collection of pre-waitlist data that might address pre-waitlist obstacles to transplantation more expeditiously** and in a manner that provides actionable data more effectively than a national data collection effort.

We believe that the *Information Collection Request* **significantly underestimates the annualized burden of data collection**, especially in the first year when changes to EMRs and data systems will be necessary to implement the new requirements. But even if the 160,040 hour/year estimate were accurate, implementing the new data collection requirements would require 4001 additional FTEs (generally nurses and LPNs) at a cost of $.54 per minute[1] or $32.40 per hour. Thus, adoption of the new data requirements will cause transplant programs to incur over 9.6 million in labor costs alone, and it is highly likely that annual costs of implementation (including IT and other systems changes) would approximate $10 million every year, or $50 million over a five-year period. These costs will be borne in considerable measure by the Medicare program (through payment of organ acquisition costs) and by transplant programs, which will be forced to reallocate program resources away from direct patient care to fulfill the new data reporting requirements.

We urge HRSA to **explore other more efficient, effective and less costly mechanisms for collecting actionable pre-waitlist data** and believe that the resources that will be expended for this data collection effort could go a long way to addressing waitlist disparities and increasing access. For example, it is our understanding that, in part as the result of CMS incentives encouraging nephrologists and dialysis centers to refer ESRD patients for transplant evaluation, many nephrologists and the major dialysis companies have already instituted new processes to ensure that all clinically appropriate dialysis patients are referred for transplant evaluation in a timely fashion. It is possible, if not likely, that considerable insight into the reasons patients may not follow through on transplant evaluation referrals could be obtained from referring

[1] Based on data relied upon by the Centers for Medicare and Medicaid Services in establishing Medicare payment for physicians' practice expense.

nephrologist and dialysis centers' records; from patient surveys; or from targeted studies of this patient population. Likewise, it seems likely that, to the extent disparities continue to exist due to differences in providers' referrals for transplant evaluation, the problem could be ameliorated considerably through CMS quality incentives or dialysis facility certification requirements that require ESRD and late-stage CKD patients to be referred for transplant evaluation within a year of beginning dialysis unless certain disqualifying conditions are met. Targeted OPTN audits of the waitlist practices of transplant centers whose waitlists are unusually out of line with the demographics of ESRD patient in the program's primary catchment area may yield greater insight than a national data collection effort whose results are likely to take years to analyze. All of these options should be thoroughly explored before the decision is made to implement a costly national data collection effort that is likely to divert resources that could be used for patient care.

If HRSA decides to proceed with national collection of pre-waitlist data, we strongly suggest that HRSA clearly define the questions that it wishes the data collection to answer. Based on our review of the referral and evaluation forms, it is unclear to us what questions HRSA hopes to answer. It is quite evident—without the need for any data collection—that transplant programs' evaluation process and waitlisting decisions are to a large extent driven by program resources that will necessarily vary from program to program and by clinical judgments that will necessarily vary by characteristics of the local population being evaluated. Both the referral and the evaluation forms include "drop down" menus asking respondents to identify the reason(s) for the program's evaluation and waitlist decisions. However, these judgements are multifaceted and are generally based on numerous clinical, behavioral, and other factors which may be weighted differently by different programs. It is unclear from the instructions for the forms whether a transplant program is permitted to report more than one reason for its decision not to evaluate or not to place a candidate on the waitlist. If more than one reason can be reported, it is unclear what conclusions can be drawn from the response: The data, considered in the aggregate, will simply show that decision-making is multi-factorial and personalized to the individual candidate, which we already know. If only one reason can be reported, the data will not capture reality accurately. Either way, the data collection is likely to provide little insight into the barriers to waitlist access and equity.

If HRSA does decide to proceed with the proposed pre-waitlist data collection, we request that the following issues be addressed:

- Currently, other than heart-lung and kidney-pancreas, there is no option to select other multi-organ combinations. We recommend that the data collection forms be modified to collect all transplant data for a patient using the same form (i.e. a single form for the same patient referred for a heart transplant in January and a kidney transplant in March).
- The time allowed between adoption of these new forms and implementation should be sufficient for transplant programs to partner with the EMR vendors

to update software to accommodate the new information required to be reported.

- Data collection should be prospective only. **The burden of providing referral and evaluation data retroactively would be extraordinary.**
- The transplant evaluation form should include an option for a transplant program to report deferral of a decision and reasons for the deferral.
- The data should be uploaded by transplant programs on a quarterly basis: real-time submission is not necessary and should not be required.
- Transplant programs should be provided with options with respect to data submission: (a) Transplant programs should be authorized to utilize either the UNet integration process with the variety of EMR vendors for form autocompletion; (b) a secure portal could be developed to facilitate data submission or (c) data could be submitted in conjunction with the OPTN audit process.
- The forms should be stackable to avoid the need to enter duplicate information about OPTN Patient Identification more than once for multiple forms.
- Specific information on the drop-down menu for Referral Closure Reason that is requested on the Pre-Waitlist Transplant Referral Form appears to align better with the Pre-Waitlist Transplant Evaluation form:
    - "Evaluation Started – Patient began testing for evaluation"
    - "Evaluation Started – Patient completed the initial visit for evaluation." We suggest revising this language to "Initial Visit Completed – Patient completed the initial visit for evaluation" for accuracy and clarity.
- The options provided to capture reasons a program may not move forward with a referral or evaluation are reasonable; however, they do not include one critical operational factor: state, local, or national emergencies, as well as capacity issues. The impact of the COVID-19 pandemic on transplant program operations highlighted how such emergencies can significantly disrupt normal processes.
    - Adding this category would ensure the capture of data reflecting on external challenges that can affect program operations and provide valuable insights for planning and response in similar future scenarios. Including this mechanism would enhance the directive's comprehensiveness and utility.

We hope that these comments are helpful and look forward working with HRSA to discuss alternatives to the proposed data collection that have the potential to address waitlist access and equity in a manner that is both more effective and more efficient that national data collection. If you have any questions, please do not hesitate to contact Emily Besser, MA, CAE, Associate Director, Advocacy & Professional Practices,

at Emily.Besser@asts.org with questions.

Respectfully,

Ginny L. Bumgardner, MD, PhD, FACS
President

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American Society of Transplant Surgeons (ASTS) Statement of Principles: OPTN Modernization Initiative {EXCERPT}

Data and Transparency

- New and continuing OPTN data collection activities should comply with the following principles:
    - Data collection should be clearly tied to, and necessary for the achievement of, a clearly stated goal or objective that is one of the National Transplantation Goals.
    - New data collection should be authorized only if the data is unavailable from any existing data source.
    - Transplant centers should not be responsible for new data collection requirements unless funding sources outside the transplant centers are identified.
    - Every attempt should be made to automate clinical data submission by centers directly from EHRs and this should lead to efforts by SRTR to provide better risk-adjustment methodologies.
    - The appropriate audience for the data should be clearly identified and consulted about the utility of the proposed data collection before date collection is instituted.
    - The potential inadvertent repercussions of data dissemination should be thoroughly considered in advance.

- HRSA and CMS should collaborate to establish a single, comprehensive public-facing integrated website that provides educational information to candidates, waitlisted patients, recipients, donors, and donor and recipient families regarding transplantation, including data collected from SRTR to help guide candidates choosing a transplant center.

- The risk-adjusted transplant program-specific outcomes data required to be included on the SRTR website under the Final Rule should be presented in the context of comparison to outcomes of alternative forms of treatment for that specific end-organ disease process.

- Any public metrics that are established should focus primarily on encouraging optimal utilization of organs, maximizing aggregate life-years saved including decreasing waiting times, decreasing disparities and waste, while providing patients with easy-to-understand risk adjusted outcomes data.

- The outcomes metrics used under the current five-star rating system for transplant programs should be eliminated. This rating system strongly disincentivizes transplant programs from utilizing hard-to-place organs and does not predict future outcomes. The current system is severely flawed

methodologically and therefore grossly misinforms potential recipients.

- Public-facing data should be responsive to patients expressed need for use friendly information that provide them with an accurate approximation of whether they are likely to meet a transplant program's waitlist candidate criteria and how long they are likely to remain on the waitlist and the impact on survival, considering the selected transplant program's historical performance for patients with similar demographic, clinical, and other profiles.

- Data collected to facilitate transplant center quality improvement and self-improvement should be clearly distinguished from public-facing data and should be shared with transplant programs on a confidential basis.

- Data utilized by OPTN Committees and the Board for the purposes of assessing or modifying OPTN policies, including allocation policy changes, should be shared with stakeholders in a user-friendly format prior to Board or Committee review of such data and prior to deliberations utilizing those data.

- The role of the SRTR in data analysis and dissemination should be clearly defined and distinguished from the data-related role(s) of the OPTN and a written document should be drafted to outline each entity's responsibilities and role with respect to data dissemination to the public. Historically, the suggestions of the SRTR contractor are often accepted for implementation by the committees without to help assess the analyses provided by the SRTR contractor for the OPTN.