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advocatehealth.org

December 20, 2024

Amy P. McNulty,  
Deputy Director, Executive Secretariat  
HRSA

HRSA Information Collection Clearance Officer  
Room 14NWH04,  
5600 Fishers Lane,  
Rockville, MD 20857

***Delivered Electronically***

**RE: Agency Information Collection Activities: Proposed Collection: Public Comment Request;  
Information Collection Request Title: Process Data for Organ Procurement and Transplantation  
Network [FR Doc. 2024-25522 Filed 11-1-24; 8:45 am]  
BILLING CODE 4165-15-P**

Dear Dy. Director McNulty,

We are pleased to submit comments on Health Resource and Services Administration's (HRSA) Information Collection Request on Process Data for Organ Procurement and Transplantation Network (OPTN). Our comments and recommendations on the proposed data collection changes are included below. We hope to continue to partner with HRSA on advancing the Agency's priority of updating key data elements to gain insight into clinical factors and patterns of behavior affecting access to transplantation; and we appreciate your consideration of our comments.

**ABOUT ADVOCATE HEALTH**

Advocate Health is a leading nonprofit integrated health system in the United States providing care under the names Advocate Health Care in Illinois; Atrium Health in the Carolinas, Georgia, and Alabama; and Aurora Health Care in Wisconsin. Advocate Health is a national leader in clinical innovation, health outcomes, consumer experience, and value-based care, with Wake Forest University School of Medicine serving as the academic core of the enterprise. Headquartered in Charlotte, North Carolina, Advocate Health serves approximately six million patients and is engaged in hundreds of clinical trials and research studies.

Advocate Health is nationally recognized for its expertise in cardiology, neuroscience, oncology, pediatrics, and rehabilitation, as well as organ transplants, burn treatments, and specialized musculoskeletal programs. Advocate Health employs an estimated 150,000 team members across 69 hospitals and more than 1,000 care locations and offers one of the nation's largest graduate medical education programs with more than 2,000 residents and fellows across more than 200 programs.

Additionally, Advocate has five skilled nursing facilities with 572 licensed beds. Of the 150,000 team members at Advocate Health, 26,000 are staff physicians, 42,000 are staff nurses and 5,000 are advanced practice providers and clinicians. Committed to ensuring access to care for all, Advocate Health provides more than \$6 billion in annual community benefits.

Advocate Health provides adult kidney, kidney-pancreas, liver, and heart transplantation services across 2 hospitals in the Midwest at Advocate Christ Medical Center (ILCH) and Aurora St. Luke's Medical Center (WISL), and 2 hospitals in the Southeast at Carolinas Medical Center (NCCM) and Wake Forest Baptist Medical Center (NCBG). Advocate Health also provides pediatric kidney, liver, and heart transplantation services across the Midwest at Advocate Children's Hospital- Oak Lawn and the Southeast at Levine Children's Hospital. In 2024, Advocate Health is expected waitlist 1,472 patients and transplant 710 organs across these transplant centers combined.

## BACKGROUND

On November 5, 2024, HRSA informed interested stakeholders to provide comments on upcoming OPTN policy and data collection changes. HRSA will be issuing a directive for the OPTN to collect additional data on patients prior to waitlist registration and referrals of potential deceased donor patients to organ procurement organizations (OPOs). This data will facilitate the OPTN's ability to address disparities in processes of care, improve access to organ transplantation, and assess overall system performance. This data will also provide a more objective source of information on procurement practices, the management of potential donor patients, and how these practices inform the supply of deceased donor organs available for transplant. This data may also help to improve monitoring of OPO performance and will facilitate quality assurance and performance improvement efforts to reduce the variation in the quality-of-care OPOs provide to potential donor patients and donor families.

We wish to comment specifically on the proposed policy requirement for pre-waitlist data collection. According to the updated policy on data collection, transplant centers would be required to submit a Pre-Waitlist Transplant Referral Form and a Pre-Waitlist Transplant Evaluation Form for all patients. These forms will be utilized to collect patient data prior to formal listing in the OPTN Computer System for transplant, regardless of candidacy for transplant.

## PRE-WAITLIST TRANSPLANT REFERRAL FORM

With regards to this form, it is unclear where and how the transplant centers will submit data and whether we need to submit data retrospectively for patients currently listed or in the evaluation process. In addition, the targeted start date for such data collection is unclear; as is the timeframe for which the form must be completed relative to the referral date. Finally, the form currently indicates a choice of active referral versus closed referral. This suggests that some patients would have the form filled out more than once: first when they are initially referred and a second time when a decision is made to close a referral.

Accordingly, we urge HRSA to clarify:

- where data will be entered (if not in the OPTN Computer System)
- the expected timeframe for form completion

- any requirements for retrospective data collection
- the targeted implementation date
- if there are instances when the form might be completed more than once

Further, for the OPTN Patient Identification “Organ” field, HRSA must clarify expectations for multi-organ transplant candidate data submission. Specifically, if a separate form will be requested for each organ or if multi-organ transplant “organs” will be created. Additionally, some patients may initially be referred as a single organ transplant candidate and become a multi-organ transplant candidate as the evaluation progresses. Guidance regarding form completion in these instances should be provided.

To reduce administrative burden, granular patient information fields such as “primary phone number, permanent street address, city of permanent residence” should be removed. The social security number (SSN) should be adequate as patient identification data. HRSA should also consider adding a unique data element to identify unhoused or temporarily housed patients.

For referral details requirements, we are concerned that referring provider NPI is not routinely captured in the referral process and could cause significant administrative (likely requiring staff to search the internet or call outside offices/dialysis centers to obtain accurate NPI numbers for referring providers). Some patients also have more than one referring provider (i.e. patients who have a community physician following but are referred for inpatient evaluation by a different inpatient provider), are self-referred, or are not referred by a physician at all (i.e. referral from dialysis center). Therefore, we ask that HRSA consider requesting referral source rather than specific physician NPI to track referral origination, and to provide additional guidance on reporting more than one referral source. If NPI is to be used, HRSA must account for extra time to obtain NPIs.

There are numerous reasons to decline a transplant and many cannot be captured within the 20 or so reasons proposed under the new form. Additionally, decisions are sometimes multi-factorial. Accordingly, the options on the new form should:

- be more open
- have more options for medical co-morbidities leading to closure
- include an option to multi-select if closed for more than one reason, and
- include an “Other-specify” option for cases that meet none of the choices

HRSA should also consider making reasons align with “Selection Committee Decision/Decline Reason” on the Pre-Waitlist Transplant Evaluation Form.

#### **PRE-WAITLIST TRANSPLANT EVALUATION FORM**

Like the previous form, it is unclear where and how the transplant centers will submit data and whether there are requirements to submit data retrospectively for patients currently listed or in the evaluation process, the targeted start date and the timeframe the form should be completed relative to evaluation date. Some patients take months to years to get through the process. Much of the required data on patient demographic, contact, and financial information is redundant if the referral form is completed.

Hence, we again urge HRSA to clarify:

- where data will be entered, if not in the OPTN Computer System.
- if any retrospective data collection will be required
- the targeted implementation date
- expected timeframe for completion

HRSA must also consider an autocomplete option for data already submitted.

Further, we would like to reiterate our above comments on patient information reporting, referral details, evaluation reporting and closure reasons.

**HEAVY BURDEN ON TRANSPLANT CENTERS**

These updated data reporting requirements will pose heavy administrative burden, especially on smaller transplant centers with minimal or no dedicated staff for data entry.

We would like to highlight that this HRSA proposal does not include some of the feedback from the OPTN Data Advisory Committee (DAC) and two OPTN workgroups that offered recommendations to HRSA regarding this initiative. Those recommendations can be found on the OPTN website.<sup>1</sup> Additionally, the DAC and workgroups tended to include members representing larger, well-resourced transplant centers, and thus, feedback from smaller centers with less staff and access to resources would be very important for HRSA to consider during this public comment period.

Advocate Health’s transplant programs range from small to high volume in size with differing staffing models and resources for data entry. Some do not have dedicated data entry staff and have clinical staff submit the already numerous forms to the OPTN on waitlisted and transplanted patients and living donors. It is expected that the new directive will result in a high number of additional forms with associated time burden to complete them. The table below shows an estimate of additional form volume and additional hours to complete them for all of the Advocate Health transplant centers. This was generated using our 2024 annualized volumes for referrals and evaluations, not accounting for programmatic growth. We expect that across the enterprise, we will complete an additional 3157.6 hours of data entry annually, which translates to 60.7 additional hours per week. **For transplant centers that use clinical staff for data entry, this will pull time away from patient care management.**

	Estimated Additional Forms	Estimated Additional Hours*
<b>Abdominal Transplant</b>	<b>7752</b>	<b>2850.6</b>
<b>Kidney, Kidney-Pancreas, Liver</b>		
Pre-Waitlist Transplant Referral Form	5004	1751.4
Pre-Waitlist Transplant Evaluation Form	2748	1099.2
<b>Thoracic Transplant</b>	<b>825</b>	<b>307</b>
<b>Heart</b>		
Pre-Waitlist Transplant Referral Form	460	161

<sup>1</sup> <https://optn.transplant.hrsa.gov/about/committees/data-advisory-committee/departement-of-health-and-human-services-data-directive/>



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Pre-Waitlist Transplant Evaluation Form	365	146.0
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*\*Time in hours is using estimated burden hours cited in the policy proposal*

UTILIZATION OF THE COLLECTED DATA

We appreciate the intent that this data collection will shed light on referral and evaluation patterns, specifically when it comes to access and barriers to transplantation. We would ask for further clarification on how this data will be used in the future. We are interested to know if this data be publicly available, made available for transplant center use, and if the data will be used to establish metrics to which transplant centers will be held accountable for.

CONCLUSION

Thank you for the opportunity to provide our feedback on HRSA’s Information Collection Request on Process Data for OPTN. If you have any questions about our comments or need any additional information, please do not hesitate to contact Sabra Rosener, VP, Federal Affairs and Government Policy (Sabra.Rosener@aah.org). We stand ready to serve as a resource as the Agency continues its important efforts to improve care quality, data accuracy and reporting on this important public health issue.

Sincerely,

Heather Genna  
Heather Genna, Transplant Administrator, NCCM

Date: 12/23/2024 | 7:13:27 PM EST

Michele Martin  
Michele Martin, Transplant Administrator, ILCH

Date: 12/26/2024 | 10:15:02 AM CST

Ayanna Powell-Lee  
Ayanna Powell-Lee, Transplant Administrator, WISL

Date: 12/23/2024 | 8:23:27 PM EST

Carrie Lynn Simpkins  
Carrie Lynn Simpkins, Transplant Administrator, NCBG

Date: 12/24/2024 | 10:37:10 AM EST