

July 25, 2025

Abe Sutton

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Deputy Administrator for the Centers for Medicare and Medicare Services  
7500 Security Boulevard  
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Tom Duvall

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Re: Increasing Organ Transplant Access (IOTA) Model

Dear Director Sutton and Mr. Duvall:

On behalf of the American Society of Nephrology (ASN) and its more than 21,000 members, thank you for your leadership on kidney health, supporting the more than 37 million Americans with kidney diseases.

Dedicated to maximizing access to kidney transplantation, ASN has been a strong proponent of the principles tested in the Increasing Organ Transplant Access (IOTA) model for more than a decade. The society appreciated the opportunity to provide input to CMMI as it considered a kidney transplant model at the conceptual stage as well as during proposed rulemaking. The society was pleased that a majority of its seven initial key recommendations, as well as numerous others, were instituted in the final rule.<sup>1</sup> Since the model was finalized, ASN has worked to provide education and guidance about IOTA participation within the kidney community.

ASN will be closely monitoring the model's success following its July 1, 2025 start date and engaging with ASN members and other stakeholders participating in the model to understand its strengths and opportunities for improvement. In the meantime, the society also offers eight recommendations along these lines for CMMI's more immediate consideration.

### **1. Sharing, prospectively, the methodology related to calculating savings**

ASN urges CMMI to prospectively share with IOTA participants and the broader kidney community how it will be calculating savings in the model. Recently, the society was deeply gratified to see substantial gains in key transplant-related metrics in the Comprehensive Kidney Care Choices (CKCC) model, including a 22% increase in living donation and a 69% increase in pre-emptive kidney transplantation. Not only do these gains represent increased access to optimal care for people with kidney failure, as you are aware, they also represent optimal value as compared to dialysis. In the context of this remarkable success, the society and many CKCC participants were dismayed that preliminary findings from CKCC did not provide any indication of the financial impact of these gains or how they were calculated—and that the kidney transplant component of CKCC was sunset.

**Thus, the society strongly urges CMMI to transparently share with the community how it will be calculating the financial impact of IOTA and the cost-related effect of increases in transplantation (deceased, living, and pre-emptive), what the time horizons for these calculations will be, and when it will be releasing findings.**

Over time and with an appropriate economic model, ASN believes that IOTA will be successful in reducing costs versus maintenance dialysis. Robust research shows that kidney transplantation is cost-effective across all donor types even when considering higher costs for marginal organs and innovative living donor practices—both of which are anticipated to be used increasingly amongst IOTA participants.<sup>ii</sup>

Crucially, the upfront cost of transplant is higher than the cost of annual dialysis, but this cost attenuates significantly over time. (This higher up-front cost may have contributed to the perception that gains in transplant rates hurt the financial viability within CKCC, though a) we do not know since the savings/losses methodology has not been shared and b) we may have been too early in the lifespan of CKCC for the cost savings that increased living donor and pre-emptive transplant rates typically confer over time.) In the first year, IOTA may yield no cost savings (or higher costs), but it will be crucial for CMMI to be patient and allow for a couple of years of the model to begin to show cost savings.

While certain transplant types begin to yield savings more quickly (for example, data show that savings from pre-emptive transplantation—infrequent but optimal—begin to accrue within six months compared to maintenance dialysis, with a cost differential of \$288,111 over a 36-month time horizon) other transplant types take longer to accrue (such as the most common type, deceased donor kidney transplants, particularly if more marginal organs are utilized).<sup>iii, iv</sup>

For example, depending on the type of transplant performed, it may make sense to allowing a model to persist for five years before assessing whether patients treated in the model's first year had experienced more cost-effective care than their peers. Moreover, building in time for transplant centers' new approaches and interventions to take effect before some patients' care is meaningfully impacted (such that cost savings might be realized), then waiting even six to seven years may be most appropriate to fully identify costs and savings from averted dialysis expenses. These time horizons are simply examples, not ASN recommendations per se, but illustrate the kind of medium and long-term approach ASN believes is needed. Moreover, increased access to transplantation will confer a dramatic improvement in quality of life early that is going to exceed the standard benchmarks for cost effectiveness. Both aspects of success, financial and patient quality of life benefit, should to be included as measures of success of the model.

ASN is concerned that first year or two of IOTA shows increased costs (which would have been anticipated, reflecting the upfront cost of transplant surgery), the model will be deemed unsuccessful, similar to what happened with CKCC. ASN would be pleased to offer the expertise of its members in providing input and collaborating on how to design and optimize such a long-term cost-savings model.

## **2. Addressing issues with the rolling composite graft survival rate**

ASN commends CMMI for streamlining the Quality Domain, concentrating it on the rolling composite graft survival rate. As noted earlier, the society strongly supports this important step towards greater, more appropriate, emphasis on long-term graft survival, a particularly important outcome from the patient perspective. The IOTA model's pioneering use of this measure is a key

milestone that will hopefully portend greater focus on long-term outcomes throughout the transplant system even beyond IOTA, though ASN notes a crucial opportunity to improve the measure.

At the same time, the society reiterates its original recommendation that CMMI integrate modest risk adjustment into the measure. This change would strengthen the domain's contributions to the model's goals by providing IOTA participants some reassurance that key drivers of variation in successful outcomes have been accounted for. This reassurance is important, as it would create more latitude for participants to transplant patients or kidneys that may once not have been considered. As IOTA participants transplant patients who are increasingly complex, or utilize increasingly complex donor kidneys—which would be successes of the model that policy should seek to encourage—it will be all the more important to have some mechanism of risk adjustment. Specifically, ASN recommends adjusting for age, ESRD vintage, and diabetes mellitus (y/n), which would leverage currently available data and remain easily measurable and understood.

### **3. Emphasizing long-term graft survival**

ASN supports CMMI's focus on the outcome of kidney transplants as a major focus of the proposed model, versus on processes along the way. However, ASN recommends that future iterations of the model place greater emphasis on, and investment in, supporting patients' longer-term (post one-year and longer) outcomes post-transplant. ASN and CMMI clearly share the goals of increased access to transplantation and improved long-term success of those transplants. We anticipate that under IOTA more marginal kidneys will be used and higher-risk patients will be transplanted; these are among the intended outcomes of IOTA, are aligned with kidney patients' expressed wishes, and are consistent with ASN's and CMMI's shared goals of promoting access to kidney transplantation. In this case, we should anticipate the current 95%+ success rates seen in the first-year post-transplant may decrease. This predictable tradeoff is aligned with kidney patients' expressed wishes for improved transplant access among many patient groups, and ASN is aligned with patients in this, recognizing the OPTN Medical Professional Standards Committee (MPSC) metrics will still be providing a backstop on quality and safety.

ASN appreciates the revisions made to streamline the components of the Quality domain in the final rule, which is now focused on the rolling composite graft survival metric, versus the proposed rule. However, the society remains concerned that with 60 points on Achievement and just 20 points on Quality, in the context of resource-scarce kidney transplant programs, resources may be pulled from efforts to help patients succeed in the long-term (post one-year) period in order to deliver success on increasing transplant rates. The society recommends that CMMI more closely align the points assigned to each domain in the performance score: 50 for the Achievement domain and 30 for the Quality domain. Additional rationale for this recommendation is included in ASN's July 16, 2024 proposed rule comment letter.

However, ASN emphasizes that the risk adjustment discussed above is a crucial change to institute should CMMI increase the points on this domain. Data shows that historically, centers at risk of being flagged as low performing decreased transplant rates and increase waitlist removals—counter to IOTA's goals.<sup>v</sup> Risk adjustment would be crucial if greater weight is placed on this domain to avoid creating a similar, counterproductive, dynamic.

#### **4. Exploring ways to ensure adequate post-transplant care**

Despite the crucial importance of lifelong care and management of kidney transplant recipients—provided by transplant nephrologists as well as general nephrologists—there are both vastly fewer resources available to support this work during the pre-and post-transplant phases (relative to the immediate peri-operative phase) and a growing shortage of transplant nephrologists to perform it. This latter dynamic will, somewhat paradoxically, be exacerbated to the extent IOTA is successful in achieving its goal of increasing access to kidney transplantation. As outlined in ASN's July 2024 comments, the relative underfunding of pre- and post-transplant care is a longstanding challenge.<sup>1</sup>

Reflecting ASN's belief that IOTA is likely to achieve success and will coincide with the fruition of other systemic improvements designed to bolster access to kidney transplantation, ASN believes developing mechanisms to ensure adequate post-transplant care is an urgent matter. Future iterations of the model should incentivize systems or partnerships that ensure longitudinal continuity of care for transplant recipients in the community, especially after they leave the transplant center's direct care. Long-term transplant success often depends on effective coordination between transplant centers, nephrologists, primary care providers, and other specialists. ASN recognizes that CMMI established the IOTA "collaborators" option to help facilitate this goal but suggests that more explicit incentives may be needed—particularly given that at present, dialysis is more lucrative than post-transplant care for community nephrologists.

ASN outlined two recommendations to alleviate these workforce-related challenges in its July 16, 2024 proposed rule comment letter, below, and recommends CMMI revisit them at this time:

- Create, within the model, a Monthly Capitated Payment (MCP) for post-transplant care. With a secure, regular revenue stream for post-transplant care as there is in dialysis care, community nephrologists will be more able to dedicate time to the essential post-transplant care of stable kidney transplant recipients.
- Establish an RVU adjustment for the care of transplant patients attributed to the model regardless of the nephrologist type, providing the care (e.g. transplant or general nephrologist). ASN would be pleased to work with CMMI and the broader kidney care community to help specify what this upward adjustment would appropriately entail to reflect the complexity and uniqueness of post-transplant care provided in the community setting.

#### **5. Stratify growth expectations by kidney transplant volume**

ASN encourages CMMI to revisit a recommendation originally made by ASN in July 2024: Stratifying growth expectations by kidney transplant volume. ASN appreciates the significant changes CMMI already made to temper growth expectations and make them more realistically feasible for transplant centers. This recommendation would complement those steps CMMI has already taken.

The dynamics of increasing kidney transplant volume are likely to be different across different sizes of programs. ASN wishes to avoid an unintended dynamic in which certain centers find themselves struggling to achieve IOTA's goals. In particular, many larger centers that have grown in recent years have expressed concerns about being able to grow quickly enough to do well in IOTA given their size and recent growth.

Given the diversity of program sizes, and the relative advantages and disadvantages to rapid growth that accompanies each size, ASN recommends that CMMI pursue a stratified national growth rate that compares growth at programs to the national growth at programs of a similar size. Appendix 2 of ASN's original July 2024 comments (included here as **Appendix A**) breaks out program growth rates by program size (11-50, 51-200, and >200) for 2021-2022 and 2022-2023 demonstrates that programs of different sizes grow at substantially different rates. Accordingly, ASN suggests CMMI reconsider three national growth rates: one growth rate for the highest volume centers (>200 transplants per year), one growth rate for medium (51-200 transplants per year) and lowest volume centers (11-50 transplants per year), among centers that meet IOTA participation criteria.

## 6. Revisiting transparency of organ offer declines

In general, ASN strongly supports greater transparency for patients and appreciates IOTA's focus on empowering patients by making waitlist eligibility criteria publicly available. Recognizing it would be a major undertaking requiring systemic investments not currently in place, ASN continues to be supportive of working towards retrospective, asynchronous sharing of offers made on their behalf (such as every six months).

Not every patient will want information about offers made on their behalf and it is important that a pathway exists for them to opt out of receiving it. However, many patients and their families have expressed interest in obtaining and using this information to guide future decisions made on their behalf: ASN supports fulfilling this desire. The vast majority of kidney patients (including those that do not want this information themselves) believe that patients have a right to know this information if they so choose.<sup>vi</sup> This belief is also consistent with CMS regulation, particularly the 2020 CMS Interoperability and Patient Access Final Rule (CMS-9115-F), which affirmed that patients have a right to access their healthcare data and information.<sup>vii</sup>

Making offer history accessible may also benefit clinicians and the broader transplant ecosystem. Retrospective review of offer trends can help identify systemic delays or patterns in organ acceptance behavior that could be optimized to improve organ utilization and patient outcomes.

In its July 16, 2024 comments, ASN provides detailed recommendation about steps HRSA and the OPTN could take to support this goal within IOTA, such as developing an automated mechanism to support transplant centers in sharing this information with patients and their referring nephrologist. Any reports shared with patients should be standardized and include explanatory context—such as the reason an offer was not accepted, the organ's quality, or patient-specific considerations—so the information is meaningful and not misleading or distressing. Clarity and education must accompany transparency.

Crucially, all the relevant information to accomplish this goal already exists in the OPTN database and a twice-annual report could be generated and shared electronically, such as through the transplant center's patient portal. ASN notes that creation of this infrastructure is solidly in line with the OPTN Modernization Initiative, which focuses on greater transparency, increased accountability, and adoption of 21st century technology.

HRSA and the OPTN may wish to consider pilot programs that test retrospective offer-sharing mechanisms at select centers, incorporating patient and provider feedback before full-scale rollout. As offer-sharing infrastructure is developed, special attention must be paid to ensuring it

is usable for all patients—including those with limited digital literacy, language barriers, and individuals without consistent internet access. Mechanisms such as printed reports, telephone-based support, and multilingual access options must be part of the implementation strategy.

## **7. Balancing any potential new metrics or reporting elements with minimizing administrative burden**

As the IOTA Technical Expert Panel initiates its work, particularly exploring options for new health-related quality of life outcomes, ASN reiterates *both* its support for developing better mechanisms to capture the patient experience of care and its apprehension about adding substantial reporting or other administrative burden for IOTA participants.

Notably, any measure development work and related analyses should take into account time after transplantation, as numerous studies show that perceived quality of life changes over time following transplantation.<sup>viii, ix</sup>

As the model is being implemented and any potential measure is being considered or developed in parallel, such as a patient-reported outcomes measure, ASN encourages CMMI to work closely with the community, including patient and health professional organizations, and IOTA participants to assess whether implementation of the measure in the model makes sense at that point in the trajectory of the model's existence. This point is particularly important given the previously-noted evolving perceptions of quality of life over time amongst transplant recipients.

## **8. Advancing efforts to promote interoperability nationwide**

In the proposed and final IOTA rules, CMMI indicated interest in exploring how the model might help to facilitate interoperability, including through TECFA. As CMMI rightly outlined, “Despite the growth of data exchange and investment in kidney and transplant care HIT, an infrastructure for interoperability that supports the exchange of clinical data across different HIT tools, different approaches to exchange, and proprietary systems and tools is still emerging. We understand that barriers to interoperability create silos that limit care coordination between transplant hospitals, as well as with dialysis facilities and nephrology practices.”

ASN has been advocating for federal action to foster interoperability, particularly the creation of a transplant nephrology data dictionary. Developing standard data definitions for transplant nephrology would improve data quality, allowing for better monitoring and faster analysis, keeping the system abreast of clinical advances would pave the way for interoperability – an essential prerequisite to improving clinical care as well as data quality and capture. Interoperability is not just a technical goal—it is a means to reduce clinical delays, avoid redundant testing, and identify high-risk patients sooner, leading to better graft survival and patient outcomes. Fully interoperable systems can reduce administrative burden and allow transplant teams to focus more on patient care.

Today, different standard data definitions across databases and registries make it difficult to link databases to paint a complete picture of kidney transplant care or conduct optimally robust analyses. Lack of data standards/data elements impede interoperability and thus, provision of efficient care, and limits automated data capture.

Recently, ASN has urged HRSA to work collaboratively with professional societies as well as the Assistant Secretary for Technology Policy (ASTP) (particularly USCDI) to develop a consensus-

based data standards and definitions for transplant nephrology (either in lead or participant role). These data standards and definitions should be integrated to EMR standards set by ASTP so they are used consistently across transplant centers as well as dialysis facilities and other stakeholders and both facilitate systematic data capture and interoperability. Examples of similar successful efforts abound: achieving a data dictionary in transplantation is imminently doable with the appropriate commitment from HHS.

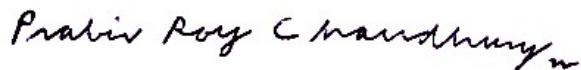
Were ASN to convene a multi-sector working group—including EMR vendors, researchers, patient advocates, and data scientists—to accelerate consensus-building on transplant data standards and ensure real-world applicability across clinical and technological contexts, would CMMI in particular, and HHS more broadly, be willing to participate as a key stakeholder?

This feasible step is foundational to improving data quality, increasing dataset linkages, automating data capture, and enabling interoperability, and—all of which are necessary for an optimally functional U.S. transplant system. Ideally this initiative would also connect to a broader, similar effort for kidney disease in general.

ASN would welcome CMMI efforts to jumpstart, or participate in, a multi-agency initiative together with the kidney and transplant community to develop a data dictionary. Given CMMI's interest data-related opportunities for improvement in the transplant system, ASN's recent recommendations to HRSA, which also have relevance for the broader U.S. Department of Health and Human Services including CMMI, along these lines are included for reference as **Appendix B**.

Again, ASN commends CMMI for its leadership on the IOTA and stands ready to provide additional information or offer access to its expert members as CMMI considers future improvements to the model. Please contact ASN Strategic Policy Advisor Rachel Meyer at [rmeier@asn-online.org](mailto:rmeier@asn-online.org) to discuss this letter or the IOTA model more generally with ASN.

Sincerely,



Prabir Roy-Chaudhury, MD, PhD, FASN  
President

## Appendix A. Program Growth by Program Size (Excerpt from ASN July 2024 IOTA Comments)

### Appendix 2. Program Growth 2021-2022 and 2022-2023 By Program Size

#### Appendix 2A. Program Growth 2021-2022 By Program Size

Center volume = 11-50									
Variable	N Centers	Mean % Change	SD	50 <sup>th</sup> percentile	25 <sup>th</sup> percentile	75 <sup>th</sup> percentile	Min	Max	
Pct_chg_t~22	77	13.6	52.3	8.3	-21.2	33.3	-58.8	235.1	

Center volume = 51-200									
Variable	N Centers	Mean % Change	SD	50 <sup>th</sup> percentile	25 <sup>th</sup> percentile	75 <sup>th</sup> percentile	Min	Max	
Pct_chg_t~22	92	5.5	21.0	3.3	-7.2	14.1	-30.8	106.8	

Center volume = >200									
Variable	N Centers	Mean % Change	SD	50 <sup>th</sup> percentile	25 <sup>th</sup> percentile	75 <sup>th</sup> percentile	Min	Max	
Pct_chg_t~23	43	-0.7	13.1	.3	-11.0	7.7	-24.6	25.2	

Center volume change between 2021 and 2022 broken out by volume (11-50 transplants [76 programs]; 51-200 transplants [92 programs], and >200 transplants [43 programs]). Median volume shift ranged from 2% to 10% growth. Unsurprisingly, there was greater percentage change volatility for smaller programs, but up to nearly 20% fewer at the 25<sup>th</sup> percentile and nearly 30% more at the 75<sup>th</sup> percentile for the smallest volume centers, while the largest centers appeared more stable, with ~5% fewer at the 25<sup>th</sup> percentile and 13% more at the 85<sup>th</sup> percentile.

#### Appendix 2B. Program Growth 2022-2023 By Program Size

Center volume = 11-50									
Variable	N Centers	Mean % Change	SD	50 <sup>th</sup> percentile	25 <sup>th</sup> percentile	75 <sup>th</sup> percentile	Min	Max	
Pct_chg_t~23	76	7.4	38.3	2.0	-19.4	28.6	-95.8	100	

Center volume = 51-200									
Variable	N Centers	Mean % Change	SD	50 <sup>th</sup> percentile	25 <sup>th</sup> percentile	75 <sup>th</sup> percentile	Min	Max	
Pct_chg_t~23	92	11.0	26.5	9.6	-7.3	22.5	-48.0	105.5	

Center volume = >200									
Variable	N Centers	Mean % Change	SD	50 <sup>th</sup> percentile	25 <sup>th</sup> percentile	75 <sup>th</sup> percentile	Min	Max	
Pct_chg_t~23	43	5.2	13.0	3.5	-4.6	13.6	-23.1	36.6	

Center volume change between 2022 and 2023 broken out by volume (11-50 transplants [76 programs]; 51-200 transplants [92 programs], and >200 transplants [43 programs]). Similar volume change trends by program size patterns are seen in this calendar year, with smaller programs experiencing greater shifts in volume and larger programs appearing more stable.

## Appendix B. ASN High-Priority Opportunities to Improve Transplant Data Landscape

Timely, accessible, high-quality data is a foundational necessity for all operational, policymaking, and oversight aspects of the United States transplant system. Through implementation of the Securing the U.S. OPTN Act and the Organ Procurement and Transplantation Network (OPTN) Modernization Initiative, the Health Resources and Services Administration (HRSA) has a unique opportunity to make critical changes to the OPTN information technology infrastructure and related databases as well as update data management practices. These changes, summarized below, are essential to ensuring accountability, transparency, and efficiency the U.S. transplant system.

Opportunity for Improvement	Detailed Recommendation
<b>1. Improve data-sharing among CMS, CDC, and HRSA</b>	<p>Transplant system policy decisions, regulatory penalties, and care choices are informed by SRTR and OPTN data (as well as USRDS data), yet confidence in the accuracy, completeness and timeliness of data within these databases is undermined by inconsistencies among them. At present, because critical information is not readily shared between the databases, key patient outcomes (e.g. graft failure) remain unknown. Improving linkages and increasing kidney health data-sharing from CMS and CDC to HRSA databases would result in a more complete picture of outcomes and disparities, improve risk adjustment, speed allocation, and drive improvements in care. Sharing these data would also eliminate the need for different approaches to determining or validating key outcomes between SRTR and OPTN, duplication of efforts (and costs) another source of variation and uncertainty between the databases.</p> <p>In particular, it is essential that HRSA databases receive timely access to patient death data and graft failure data, data from CMS and CDC, as this information is critical to the organ allocation process and for transplant program performance evaluation.</p> <p>This step may require changes to existing data use agreements among agencies or waivers of existing inter-agency fee structures within HHS, but should be imminently doable given that these data all exist within the same department (particularly recognizing that Medicare is the primary payor for the majority of patients receiving an organ transplant and that transplantation is the most cost-efficient form of therapy for kidney failure, which Medicare also covers for virtually every American).</p>
<b>2. Leverage technology to minimize reporting burdens</b>	Lower the reporting burden for OPTN members by automating reporting and/or adding batch reporting for aspects of OPTN data collection that are not time sensitive.

	<p>Data elements collected across the OPTN should be collected on an automated, efficient basis (e.g. batch reporting) as technology adoption is supported through the OPTN Modernization Initiative. The transplant system at present does not have the optimal IT infrastructure to execute automated or batch reporting but these are highly attainable goals that should be prioritized through Securing the US OPTN Act implementation/modernization. For example, the forthcoming pre-waitlisting referral and evaluation data collection is prime opportunity to work towards technology adoption and data standardization to enable batch reporting.</p> <p>Among other things, a standardized data dictionary/ontology shared by all EMRs will help facilitate streamlined data reporting.</p>
<p><b>3. Redesign the process for adding or revising data points collected from OPTN members to be more nimble</b></p>	<p>The design and implementation of a new, more nimble and responsive process for data is low-hanging fruit that HRSA should pursue.</p> <p>As clinical practice evolves, therapeutic advances emerge (such as novel perfusion technologies), and as novel events (such as COVID-19) transpire affecting transplant outcomes, it is imperative that the data elements collected from OPTN members also evolve to keep pace with the therapeutic innovations and novel clinical paradigms. At present, lengthy approval processes (including the time horizon currently required for OMB approval) for data changes have largely stymied updates or additions to the data collected, hindering our ability to understand the implications of changes that are taking place in the real world.</p>
<p><b>4. Institute routine, proactive data audits to improve data quality and ensure veracity and validity</b></p>	<p>Ensuring comprehensive, accurate reporting from transplant centers is foundational to establishing accountability, transparency, and fairness in the transplant system.</p> <p>At present, audits of OPTN and SRTR data are limited, passive, and with no meaningful consequences for incomplete, inaccurate data reporting coupled with frequent changes leading to concerns about the veracity and validity of the data. Addressing critical gaps in active oversight and validation of data reported by transplant centers and organ procurement organizations must be a priority for HRSA, including instituting proactive data validity checks and the development of a formal data audit and monitoring process coupled with a meaningful data lock.</p>

	<p>Particularly as the number of organs placed out of sequence continues to increase, close, active attention must be paid to reported data concerning organ procurement/organ quality, the allocation match run, and transplant outcomes. Operational data should be considered an integral part of the transplant registry and used to monitor the health of the transplant system.</p> <p>These imperative changes will require a significant resource investment and should be a top priority to implement through increased Congressional appropriations related to the Securing the U.S. OPTN Act.</p>
<p><b>5. Develop, in coordination with the kidney and transplant community and HHS ASTP (including USCDI), a transplant data dictionary of data standards and data elements</b></p>	<p>Developing standard data definitions for transplant nephrology would improve data quality, allowing for better monitoring and faster analysis, keeping the system abreast of clinical advances would pave the way for interoperability – an essential prerequisite to improving data quality and capture. Today, different standard data definitions across databases and registries make it difficult to link databases to paint a complete picture of kidney transplant care or conduct optimally robust analyses. Lack of data standards/data elements impede interoperability and thus, provision of efficient care, and limits automated data capture.</p> <p>HRSA should work collaboratively with professional societies as well as the Assistant Secretary for Technology Policy (ASTP) (particularly USCDI) to develop a consensus-based data standards and definitions for transplant nephrology (either in lead or participant role). These data standards and definitions should be integrated to EMR standards set by ASTP so they are used consistently across transplant centers as well as dialysis facilities and other stakeholders and both facilitate systematic data capture and interoperability. Examples of similar successful efforts abound: achieving a data dictionary in transplantation is imminently doable with the appropriate commitment from HHS.</p> <p>This feasible step is foundational to improving data quality, increasing dataset linkages, automating data capture, and enabling interoperability, and—all of which are necessary for an optimally functional U.S. transplant system. Ideally this initiative would also connect to a broader, similar effort for kidney disease in general.</p>
<p><b>6. Standardize and improve data capture to improve data quality</b></p>	<p>Given the extent to which data inform transplant patient and candidate care, organ allocation, regulatory enforcement, and policymaking, having access to accurate, reliable, reproducible data capture is essential in this field. In support of this goal, data capture</p>

	<p>should be automated the greatest extent possible. The development and implementation of a data dictionary, described above, will help facilitate this goal.</p> <p>As complementary/interim steps to improve data capture and quality, HRSA should prioritize:</p> <ul style="list-style-type: none"> <li>• Holding transplant centers and OPOs accountable for the quality of the data they report with meaningful incentives/penalties (which the current system does not do very effectively) with appropriate and adequate oversight of the reporting/operational registry.</li> <li>• Instituting training for coders and data abstractors to ensure uniformity and consistency (training that is lacking in the current system)</li> <li>• Establishing and enforcing a more rigid data reporting lock-out period (which is important to prevent gaming and ensure accountability)</li> <li>• Reiterate that funding for transplant centers to invest in improved data reporting efforts is available through the Organ Acquisition Cost Center (and thus does not constitute an unfunded mandate)</li> </ul>
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<sup>i</sup> ASN public comment: Proposed Increasing Organ Transplant Access (IOTA) model. July 16, 2024. Available: <https://www.asn-online.org/policy/webdocs/24.7.16FINALASNIOTACComments.pdf>

<sup>ii</sup> Axelrod DA et al. An economic assessment of contemporary kidney transplant practice. *Am J Transplant*. January 2018. DOI: 10.1111/ajt.14702

<sup>iii</sup> Schold J. et al. Healthcare costs among preemptive kidney transplant vs. maintenance dialysis patients: a real-world study of patients with end-stage kidney disease. Abstract presentation, American Transplant Congress. June 1-5, 2024.

<sup>iv</sup> Husain SA et al. Policy Strategies to Reduce Financial Risks for Living Donors. *Kidney360*. 2023 May 22; 4(7):987–989. doi: 10.34067/KID.0000000000000157

<sup>v</sup> Schold J. et al. Association of Candidate Removals From the Kidney Transplant Waiting List and Center Performance Oversight. *American Journal of Transplantation*, Volume 16, Issue 4, 1276 - 1284

<sup>vi</sup> Husain SA et al. Patient and Provider Attitudes Toward Patient-Facing Kidney Organ Offer Reporting. *Kidney International Reports*, Volume 10, Issue 4, 1122 - 1130

<sup>vii</sup> Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services. Interoperability and Patient Access Final Rule (CMS-9115-F). May 20, 2020. *Federal Register* 2020-05050 (85 FR 25510). <https://www.federalregister.gov/documents/2020/05/01/2020-05050/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and>

<sup>viii</sup> Purnajo, I et al. Trajectories of health-related quality of life among renal transplant patients associated with graft failure and symptom distress: Analysis of the BENEFIT and BENEFIT-EXT trials. *Am J Transplant*. 2020 Jun;20(6):1650-1658. doi: 10.1111/ajt.15757. *Epub* 2020 Jan 11.

<sup>ix</sup> Wang Y et al. Understanding Health-Related Quality of Life in Kidney Transplant Recipients: The Role of Symptom Experience and Illness Perceptions. *Transpl Int*. 2023 Apr 13:36:10837. doi: 10.3389/ti.2023.10837. *eCollection* 2023.